Índex 2012

abiquifi

Associação Brasileira da Indústria Farmoquímica e de Insumos Farmacêuticos

MERCOSUL
INSUMOS FARMACÊUTICOS E SEUS PRODUTORES
31ª EDIÇÃO
Português/*English*

Índex

2012

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E SEUS PRODUTORES

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Associação Brasileira da Indústria Farmoquímica
e de Insumos Farmacêuticos

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Editorial

O ano de 2011 encerrou-se com um excelente resultado no esforço dos setores farmoquímico e farmacêutico para o aumento das exportações da cadeia produtiva.

Tivemos um aumento de 17% sobre as exportações de 2010, alcançando a importante cifra de US$ 2 bilhões, o que coloca o Brasil numa boa posição entre os países exportadores de produtos de alta tecnologia no setor farmacêutico.

Fazemos questão de destacar que o setor farmoquímico e de adjuvantes, quando visto separadamente, teve desempenho ainda melhor, crescendo 38% sobre o resultado de 2010, com um total de US$ 820 milhões em exportações.

Também é muito importante notar que o número de produtos fabricados localmente aumentou e o número de empresas nascentes e incubadas de alta tecnologia está proliferando no Brasil.

Isso é resultado do trabalho incansável das entidades representativas da cadeia produtiva, que, juntamente com o Governo, vêm apoiando essas iniciativas.

Temos ainda muito por fazer, e desse esforço faz parte esclarecer a todos os participantes de nosso setor de atividades, muito especialmente aos órgãos governamentais, a enorme importância de que este setor receba atenção especial para o seu desenvolvimento, haja vista sua importância no dia a dia da população brasileira.

É na boa administração de um sistema regulatório eficiente e objetivo, que seja respeitado nacional e internacionalmente, de um sistema tributário justo e adequado a esse segmento e da celeridade do encaminhamento dos processos que objetivem reduzir a dependência brasileira com desenvolvimento tecnológico interno, que repousa nossa convicção de que temos todas as condições e recursos humanos e financeiros para atingir nossos objetivos.

É muito bom estarmos atentos ao aumento dos gastos públicos no setor Saúde como um todo, posicionando o Brasil entre as nações que dedicam parte importante de seus orçamentos ao atendimento das demandas da sociedade.

O aumento da demanda sinaliza para a necessidade premente de revermos nossos investimentos em equipamentos, produtos e processos a fim de atender às expectativas de nossos clientes internos e externos.

Evidentemente, nossos esforços estão totalmente dependentes do esforço interno dos órgãos reguladores para que também possam avaliar as melhores políticas de alocação de recursos, dando celeridade aos pleitos do segmento privado na autorização de produções que venham a utilizar os insumos aqui produzidos.

Essa sinergia de atitudes e competências é a melhor parceria público-privada que poderemos almejar para o ano de 2012!!!

José Correia da Silva
Presidente da **abiquifi**

Editorial

Excellent results were obtained during 2011 from sterling efforts made by our pharmochemical / pharmaceutical sector in increasing exports from its production lines.

We had an increase of 17% over 2010 exports, achieving the important mark of US$ 2 billion, placing Brazil in a good position among the international exporters of hi-tech products in the pharmaceutical sector.

We make a special point in highlighting the fact that the pharmochemical / adjuvant sector, when judged on its own individual merits, performed exceptionally, showing a growth of 38% over the 2010 results, billing a total of US$ 820 million in exports.

It is also important to note that the number products made locally has increased, and a substantial number of companies, 'newly-born and weaned' on hi-tech procedures now proliferate in Brazil.

This is the results of the untiring efforts of production chain representatives that, in unison with government encouragement, provide support to such initiatives.

There is still a lot to do. Our endeavours help to make it clear to all concerned in the sector's activities, especially in the case government departments, that every participant should pay special attention to development of the sector as a whole, given its importance in the daily lives of the Brazilian population.

We are convinced that we have all the necessary conditions and the human and financial resources needed to achieve our objectives. Our sector has excellent administrative and financial capabilities, is respected at home and abroad, and the taxation system is smoothly and justly applied to our segment.

Our sector can be satisfied that it is monitoring public spending on Health in general. Increases in the Health budget have now placed Brazil among the countries that invest more in meeting public demands.

The increase in demand signals an urgent need to review our investments in equipment, products and processes in order to meet with expected needs

of our local and international clients.

We can also assess and select the best policies for allocation of resources, awarding authorization for private segment proposals based on utilization of locally-produced component materials.

This synergy of response and ability is the best private-public sector combination we could hope to achieve in 2012!!!

José Correia da Silva
abiquifi *President*

Associação Brasileira da Indústria Farmoquímica
e de Insumos Farmacêuticos

abiquiflashes (2012)

A força da exportação.

Informações pontuais sobre as exportações de produtos da cadeia produtiva farmacêutica brasileira

■ **FEIRA:** a maior feira mundial dos setores farmoquímico e farmacêutico (**CPhI Worldwide**) será realizada, **em 2012, em Madri – Espanha, de 9 a 11 de outubro.** O Brasil estará presente com um **pavilhão de 345m²** e contará com a presença de **14 empresas** do setor que buscam a sua internacionalização.

■ **PSI:** a presença brasileira nesse megaevento, que contará com a participação de mais de 1.800 empresas de todo o mundo, é uma das importantes ações do **Projeto Setorial Integrado (PSI) de Farmoquímicos e Farmacêuticos**, desenvolvido pela **abiquifi** em colaboração com a **Agência Brasileira de Promoção de Exportações e Investimentos (Apex-Brasil)** e com o apoio das entidades do setor: **Abifina**, **Alanac**, **Interfarma**, **Pró Genéricos** e **Sindusfarma**. Essas ações do **PSI** visam ao aumento das exportações da cadeia produtiva farmacêutica brasileira.

■ **PERSPECTIVAS:** considerando os excelentes resultados das exportações em **2011**, a **meta para 2013** é que as **exportações de farmoquímicos alcancem US$ 1 bilhão** e as de **medicamentos US$ 1,4 bilhão**, totalizando US$ 2,4 bilhões.

Fonte: abiquifi

Visite o nosso Portal: www.abiquifi.org.br

23 anos de História
Índex abiquifi

A 31ª edição do **Índex abiquifi** coincide com apreciáveis índices de crescimento do setor. Esse desempenho está fortemente ligado à fabricação, no Brasil, de novas moléculas de alta tecnicidade, especialmente aquelas denominadas retrovirais destinadas à fabricação de medicamentos no tratamento da AIDS, as oncológicas utilizadas no tratamento do câncer e as antidiabéticas. Essas moléculas, até então largamente importadas pela indústria farmacêutica e pelos laboratórios oficiais, demonstram claro indício do esforço das empresas privadas em produzir localmente fármacos inovadores de amplo espectro.

O crescimento acelerado da economia brasileira em 2010, em boa parte mantido em 2011, foi acompanhado pela evolução do setor de insumos farmacêuticos (princípios ativos e excipientes farmacotécnicos), respaldado na crescente qualificação da produção nacional e de investimentos em inovações que alçou o País para a nona maior cadeia produtiva farmacêutica do mundo. O desempenho externo também vem apresentando resultados relevantes mediante aumento do índice de crescimento das exportações em relação à redução percentual das aquisições externas de princípios ativos e adjuvantes. Esses resultados mostram, inequivocamente, uma reversão importante na série histórica de déficits crescentes do setor na área externa.

Os anos subsequentes revelam-se ainda mais promissores para o setor, principalmente face à aprovação da Lei 12.349/10, resultante da conversão da MP 495, introduzindo o uso do poder de compra do Estado como fator de incentivo à inovação tecnológica e à produção doméstica, ao conferir até 25% de preferência no preço do produto nacional em relação ao importado nas compras públicas. O Ministério da Saúde, por seu turno, vem incentivando a produção local de princípios ativos tradicionalmente fornecidos externamente mediante o incentivo de formar parcerias estratégicas entre laboratórios públicos e empresas privadas, com o duplo objetivo de promover a fabricação local de substâncias estratégicas para o Complexo Industrial da Saúde e reduzir o tradicional déficit do setor na balança comercial do País.

Na área externa, o desempenho setorial também vem apresentando resultados relevantes. Em 2010, as exportações de insumos farmoquímicos e medicamentos alcançaram a inédita cifra de US$ 1,7 bilhão. Na última década, a proporção das vendas externas em relação às importações ascendeu de 17%

para 25%, porque, enquanto as importações cresceram 156%, as exportações aumentaram 261%. Esses índices revelam-se importantes, uma vez que recuperam a tendência ascendente de vendas externas ocorrida na década de 1980, em que o setor farmoquímico, amparado pelas negociações setoriais no âmbito da ALADI, que resultavam na formulação e ampliação dos acordos comerciais vigentes naquele organismo, deu início ao processo de sedimentação exportadora de fármacos brasileiros na América Latina, notadamente dirigida aos mercados argentino e mexicano. Ao mesmo tempo, incentivam a diversificação das vendas externas em áreas do primeiro mundo, especialmente nos EUA e em países da Comunidade Europeia, tais como Alemanha, Itália, França, Espanha e Bélgica, entre outros, inclusive como fruto da presença marcante de empresas do setor na CPhI Worldwide, o maior evento farmoquímico do mundo, para o qual a **abiquifi** vem mantendo, desde 1998, efetiva coordenação e amparo aos programas da FINEP e da Apex-Brasil.

Por tudo isso, a edição do **Índex abiquifi 2012** vem prestar justa homenagem às empresas produtoras que colaboraram nessa empreitada nos últimos 23 anos, relacionadas a seguir, responsáveis pelo notável desempenho do setor nesse período, culminando com a fabricação, em 2011, de 397 substâncias farmoquímicas e adjuvantes farmacêuticos com acentuado grau de aperfeiçoamento tecnológico decorrente do crescente surgimento de novas moléculas no cenário internacional e da necessidade de adotar estratégias produtivas mais verticalizadas como preceito básico para aprimorar a competitividade do setor nos mercados doméstico e internacional.

Mauro Laviola
Consultor de Comércio Exterior

O quadro das páginas 18 a 27 relaciona as empresas do setor farmoquímico e de adjuvantes farmacotécnicos que operaram no Brasil nos últimos 23 anos – que constaram nas edições do Índex abiquifi de 1989 a 2011 –, indicando o Estado de atuação e o número de produtos produzidos a cada ano.

23 Historical years
Índex abiquifi

The 31st edition of the **Índex abiquifi** *coincides with some appreciable growth indices in our sector. This positive performance is closely linked to Brazil's construction of new high-technology molecules, especially those classified as retro-viral, used as AIDS medicines, the oncologics used in cancer treatment and the anti-diabetics. The types of molecule heretofore mostly imported by the pharmaceutical industry by official laboratories provide a clear demonstration of the efforts being made by private enterprise towards local production of high spectrum and innovative pharmacons.*

The accelerated growth of the Brazilian economy in 2010, to a large extent maintained in 2011, motivated by the evolution of the pharmaceutical supply sector (in consumption of active ingredients and pharmacological excipients), backed up by the ever-increasing quality of the local product and investments in innovation that hoisted Brazil to the world's ninth greatest pharmaceutical production chain. Performance abroad is also bringing significant results by increasing the export index related to the percentage reduction in imports of foreign active ingredients and adjutants. These results unequivocally demonstrate an important reversion in the historical series of growing deficits in the sector's overseas trade.

The following years turned out to be even more promising for the sector. The turning point was approval of Law 12.349/10, brought about by conversion of Law MP 495 thereby enabling the State to use its own purchasing power in order to motivate technological innovation and domestic production. It allowed preference of local products quoted at up 25% more than imported goods on public sector purchases. The Ministry of Health, in turn, is encouraging local production of active ingredients traditionally brought in from overseas by a strategic partnership arrangement between public laboratories and private enterprise. This arrangement had the twin objective of promoting local production of strategic substances for the Health Industry Complex and reducing the sector's traditional deficit in the Brazil's balance of payments.

The Sector's performance overseas is also bringing in results of relevance. In 2010, exports of pharmaceutical chemical components and medicines

reached an all-time record of US$ 1.7 billion. Over the last decade the proportion of export sales abroad compared to imports increased from 17% to 25%, while imports increased by 156% and exports grew 261%. These figures have proved to be significant since they indicate an upward export sales trend, as occurred in the 1980's. At this time, the pharmaceutical chemicals sector, propped up by negotiations and its inclusion in the ALADI area, lead to formulation and expansion of the ongoing commercial trade within that organization. This led to firmer establishment of Brazil as a supplier of medicines to Latin American markets – especially those of Mexico and Argentina. Simultaneously, incentives for diversification of overseas sales were obtained from the North America and Europe (Germany, France, Italy Spain and Belgium – among others) including presentations in CPhI Worldwide congresses, the major global event for pharmaceutical chemicals, to which **abiquifi** *has contributed since 1998, and effective coordination and support for the FINEP and Apex-Brasil organizations.*

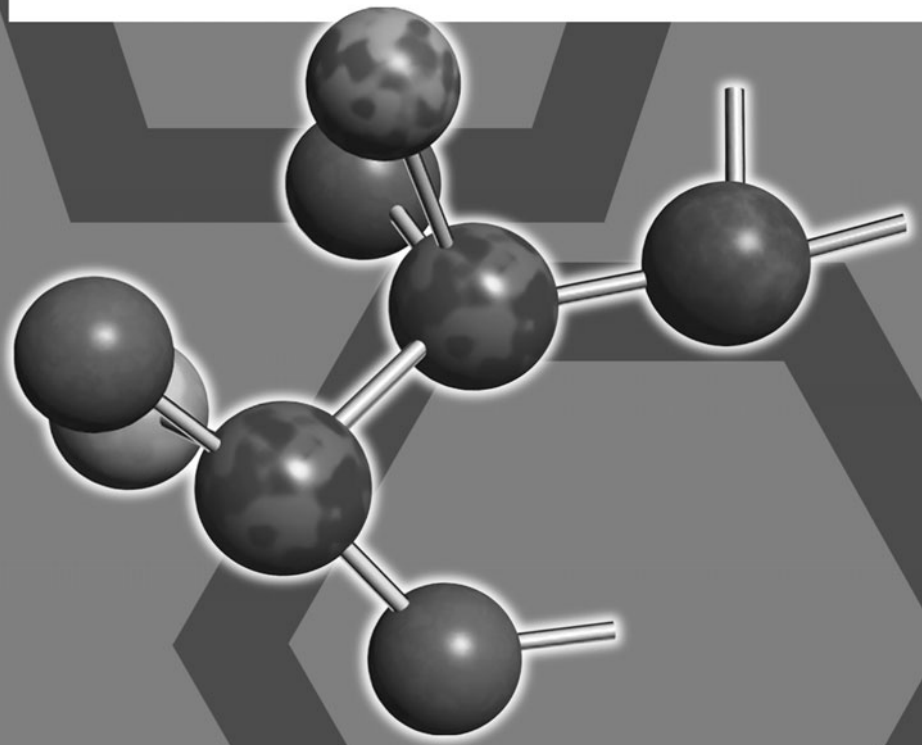
Our **Índex abiquifi** *2012 pays homage to all production organizations that have collaborated in a noble mission over the last 23 years, giving wholehearted support to our sector. In 2011 the pharmochemicals companies in Brazil were responsible for producing 397 types of pharmaceutical chemicals and adjuvants of high quality and technological perfection. Those companies have faced the challenge of a growing need, worldwide, for new molecules and the need to adopt vertically-organized production strategies that will streamline their competitive edge within the local and international markets.*

Mauro Laviola
Consultant

The table on pages 18 to 27 lists the companies in the Pharmaceutical Chemicals and Technological Adjuvant area operating in Brazil over 23 years – as recorded in the* Índex abiquifi *from 1989 to 2011, noting Brazilian regions of operation and the quantities and types of product produced each year.

Dicionário de

Substâncias Farmacêuticas Comerciais



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Vendas: AMA Editora e Treinamento
e-mail: dsfc@abiquifi.org.br
Tel.: (21) 2553-6391
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Associação Brasileira da Indústria Farmoquímica e de Insumos Farmacêuticos

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Edson Luiz da Silva Lima (Cristália)

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Cléa Camargo (Eli Lilly)

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Fausto Spina
Georges Barrenne
Jayme Junqueira Drummond
Renato Libanio
Robert Haller

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1986 – Fausto Spina (Presidente Sindusfarm)
1987 – Edson Vaz Musa (Presidente Rhodia)
1988 – Rolf Loechner (Presidente Bayer)
1989 – Adalmiro Dellape Baptista (Presidente Grupo Aché)
1990 – Ricardo Lins de Barros (Diretor Pan-Americana)
1991 – Kurt Politzer (Presidente Conselho IQT)
1992 – Dárcio Fabra Navarro (Diretor Assuntos Corporativos Empresas Dow)
1993 – Claudio Sonder (Presidente Hoechst do Brasil)
1994 – Bruno Hollnagel (Diretor Divisão Farma-Sandoz)
1995 – Elisaldo L. A. Carlini (Secretário de Vigilância Sanitária do Ministério da Saúde)
1996 – Lourival Carmo Monaco (Presidente da FINEP)
1997 – José Loureiro Cardoso (Diretor Industrial Eli Lilly)
1999 – Gonzalo Vecina Neto (Diretor Presidente ANVS)

Unidos pelo desenvolvimento do
setor farmoquímico brasileiro,
pelo fortalecimento do mercado doméstico
e pela conquista de novos mercados.

Junte-se a nós!

**Associação Brasileira da Indústria Farmoquímica
e de Insumos Farmacêuticos**

Av. Calógeras, 15 / 10º andar • Centro
Rio de Janeiro • CEP 20030-070 • RJ • Brasil
Tel.: +55 21 2220-3005 • Fax: +55 21 2524-6506
E-mail: abiquifi@abiquifi.org.br • Site: www.abiquifi.org.br

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ALPHA Br PRODUTOS QUÍMICOS

BLANVER

CRISTÁLIA PRODUTOS QUÍMICOS FARMACÊUTICOS LTDA.

CRODA

Diosynth Schering-Plough

Lilly

EMS

Eurofarma Brasil, sempre.

EXTRASUL extracting quality

Formil Química

Genix

ITF CHEMICAL

KM KIN MASTER

KLEY HERTZ

NORTEC QUÍMICA

NOVARTIS

Planalquímica DO BRASIL

Phibro ANIMAL HEALTH CORPORATION

QUERCEGEN PHARMACEUTICALS

Relthy

Nº	EMPRESA		89	90	91	92	93	94	95	96
1	ABC	SP	4	2	2					
2	ABL	SP								
3	ACHÉ	SP	7	6	6			3		
4	AGROQUISA	SP	3	1	1	6	7	7	7	6
5	AJINOMOTO	SP								
6	AKZO	SP	14	1	1					
7	ALBA	SP	1	1	1					
8	ALBANO	SP	1	1	1	1	1	1	1	1
9	ÁLCALIS	RJ	1	1		1	1	1	1	1
10	ALCLOR	RJ	3	3	4	4				
11	ALFA	RJ	1	1	1	4	6	1	1	1
12	ALPHA BR	SP								
13	AMONEX	SP	1	1	1	1	1	1	1	1
14	ANASTACIO	SP	6	3						
15	AQUACULTURA	RJ	1	1						
16	AQUALON	SP	1	1		2	2	2	2	2
17	AQUATEC	SP	30	13						
18	ARCOS	MG							1	1
19	AREX	SP			3	6	6	6	6	6
20	ARIPÉ	RS			1		1			
21	ASCA	SP	16	18	4					
22	ASSESSA	RJ	2	3	3	3				
23	ATLAS	RJ	3							
24	BARRA DO PIRAÍ	RJ	2	2						
25	BASF	SP	5	5	4	4	5	5	5	5
26	BAYER	SP	8	8	8	7	6	3		
27	BEECHAM	RJ	7	3	3	1	1			
28	BELA VISTA	SP	1	1	1	1	1	1	1	1
29	BERLIMED	SP	2	2						
30	BICARBON	SP	2	2	1					
31	BILLI	SP	3	3	3	2				
32	BIOBRÁS	MG	8	6	10	10	9	9	8	8
33	BIOCON	RJ	14	14	1					
34	BIOGALÊNICA	RJ	11	11	11	11	11	12	11	11
35	BIOTECFARMA	SP		3	12	10	10	9	9	
36	BLANVER	SP	6	6	6	9	8	7	7	7
37	BOA ESPERANÇA	MG				2				
38	BONONIA	SP	1							
39	BRAÍDO	SP	4	4						
40	BRASFANTA	SP	7	6	6	20	25	25	25	24
41	BRASILAC	PR	4	1	1	1	1	1	1	1
42	BRASKAP	SP	1	1	1	1	1	1	1	1
43	BRASPECTINA	SP	1	1	1	1	1	1	1	1
44	BRASWEY	SP	4	4	4					
45	BRAZINCO	SP								
46	BRESSIANI	SP	4	4	4					
47	BRISTOL	SP	4	4	4					
48	BUSCHLE & LEPPER	PR	4	2	2	4	4	4	4	4
49	BYK	SP	4	4						
50	CAMPINEIRA	SP	6	4	2	3	3	2	2	2
51	CAPSUGEL	RJ	1	1	1	1	1	1	1	1
52	CAQ	SP							42	40
53	CARBOMAFRA	PR	6	5	5	1	1	1	1	1
54	CARBONOR	RJ	4	5	5	4	4	4	5	5
55	CARDINAL	SP								
56	CATAGUASES	MG				1	1			

97	98	99	00	01	02	03	04	05	06	07	08	09	10	11
							3	2	2	2	12	12	12	12
5	5	5												
	2	2	2	2	2	1	1	2	2	2	1	2	2	2
3	3	3	3	3	3	1								
1	1	1	1	1	1	1	1	2	1	1				
2	2	20	20											
													6	6
3	2	2	1	1	1	1	1	1	1	1	1	1	1	
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	1	1	1											
6	6	6	6											
5	4	4												
1	1	1	1	1	1	1	1	1	1	1				
8	8	8	5	2	2	2	2							
11														
6	6	6	5	5	5	5	5	5	5	5	5	5	5	5
4														
1	1	1	1	1	1	1	1	1	1	1	1			
1	1							2	2	2				
1														
		1	1	1	1	1	1	1	1	1	1	1	1	1
4	4	4	4	4	4	6	6	6	6	6	6	5	4	4
2														
1	1	1	1	1	1	1								
44	44	51	52	53	49	49	48	41	43	50	50	50	50	50
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	1	1												
							2	2	2	2				

Nº	EMPRESA		89	90	91	92	93	94	95	96
57	CATALENT	SP								
58	CATARINENSE	SC	2	2						
59	CATEDRAL	MG								
60	CENTROFLORA	SP	5	6	6	5	5	5	5	5
61	CERALIT	SP	14	18	17	22				
62	CHAMPION	GO								
63	CHEMIE	SP	1	1						
64	CHEMS	RS	5	6	7	13	11	11	8	7
65	CIALGAS	SP	3	2	2					
66	CIBRAN	RJ	7	14	14	5	17	16	15	15
67	CILAG	SP						18		
68	CIRUMÉDICA	SP	3							
69	CITRATUS	SP					2			
70	CITRUS	SP								
71	CLOROETIL	SP	4	3	4	3	3	3	3	3
72	COBRASCAL	SP	2	1	1	1	1	1	1	1
73	COCAM	SP		1	1					
74	COELHO	PE	3	2						
75	COLBRÁS	SP								
76	CPKELCO	SP								
77	CRISTÁLIA	SP		5	6	6	6	6	6	15
78	CRODA	SP	4	2	2	3	5	5	10	9
79	CYANAMID	RJ	7	9	10	10	9	9	13	13
80	CYG BIOTECH	SP								
81	DEFENSA	RS	7	3	3	3	3	3	3	3
82	DEGUSSA	SP	1	1	1					
83	DEL MONTE	SP	17	4	4	4	4	2	2	2
84	DELTA	SP	5	7	6	6	4	4	3	2
85	DENVER-COTIA	SP								
86	DIADEMA	SP	9	7						
87	DIERBERGER	SP	4	1	1					
88	DIETRICH	SC	1	1						
89	DIFCO	SP	1	1	1					
90	DIOSYNTH	SP								
91	DOW	SP	1	1	1	1	1	1	1	1
92	ECADIL	SP	13	10	12	16	16	17	18	20
93	EKA	RJ	2	3	2	2	2	2	2	2
94	ELANCO	SP	6	5	5	5	5	3	4	4
95	ELEKEIROZ	PE	5							
96	EMCA	RJ	1	1						
97	ENGECLOR	SP	1							
98	EQP	PR				3				
99	ESSEMBRA	MG	6	4	4	6	6	6	3	3
100	ESSEX	RJ	1	1	1	1				
101	ETOXILADOS	SP	4							
102	EXTRASUL	PR								
103	F. MAIA	SP	21	23	26					
104	FANABRA	SP	3	2	2	2				
105	FAP	RJ								
106	FAPROL	RS	6	6	6					
107	FARMASA	SP	1	1	1					
108	FARMITÁLIA	RJ	5	4	4	4				
109	FARMOCHEM	SP								
110	FARMOS	RJ								
111	FATER	SP				1	1			
112	FAVAB	SP	3	2	2	2	2		2	2

97	98	99	00	01	02	03	04	05	06	07	08	09	10	11
											2	2	2	1
														3
6	6	5	5	5	5	5	5	5	5	6	6	6	6	6
7	7	4	4	4	4	4	4	4	5	5	5	4	4	3
6	6													
16	15	15	15											
	1	1	1											
3	3	3	3											
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
						1	1		1	1				
					1	1	1	1	1	1	1	1	1	1
17	18	16	16	18	20	24	23	22	20	20	20	21	21	21
9	8	8	8	12	12	13	13	13	13	13	13	13	13	18
7	6	3	3	3										
														10
2	2													
	6	6	6	6										
	2	2	1	1	3	1	1	1	1	1				
								11	11	11	11	11	12	12
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
6	15	14												
2	2	2	2	2	2	2	2	2	2	2	2	2		
3	1	1	1	1	1	1								
			3	3	3	2	3	3	3	3	3	5	3	3
2	2	2	2	2	1	1	1	1						
								2	1	2	2	2		
					12	12								
2	2	2	2	2	2	2	2	2	2	2	2	2		

Nº	EMPRESA		89	90	91	92	93	94	95	96
113	FERMENTA	SP	6	5	5	5	5		4	
114	FINA	SP					5			
115	FLORA BRASIL	SP								
116	FLORASYNTH	RJ							1	1
117	FONTOURA-WYETH	SP	11	11	3					
118	FORMIL	SP	8	8	8	11	11	13	32	22
119	FRAMA	RJ	26	19	14	13	13	13	13	12
120	GELITA	SP								
121	GÊNIX	SP								
122	GESSY	SP	1	1						
123	GETEC	RJ	3	3	3	3	3	3	3	3
124	GEYER	RS	3	1	1	1	1	1	1	1
125	GIRARDI	SP	9	7						
126	GIVAUDAN	SP	2	2						
127	GLAXO	RJ		4	4	4	4	4	3	4
128	GLOBE	SP								
129	GRUPO QUÍMICA	RJ	26	22			28	28	28	29
130	HAARMAN REIMER	SP								4
131	HARIMA	SP	3	3	1	1				
132	HERCULES	SP								
133	HERGA	RJ	14	2	2	3				
134	HESTER	RJ								
135	HOECHST	SP	21	14	12	12	8	7	6	
136	IEN	RJ								
137	INCASA	SC	16	11	6		5	6	6	5
138	INDIMPEX	PR							3	1
139	INGÁ	PR	1	1	1	1	1			
140	INPAL	RJ	1	1	1	3	3	3	5	3
141	IPC	SP	4	4	4	4				
142	IPEN	SP								
143	ITACA	RJ								
144	ITATEX	SP	2	1	1					
145	ITF	BA								
146	IVA	SP	7	8	8	8				
147	JOHNSON-JOHNSON	SP	16	16	19	18	18			
148	JUPITER	SP	1	1	1					
149	KIMPLAS	RS	11	9	9	9				
150	KIN-MASTER	RS								10
151	KNOLL	RJ	3	3	2	2	1			
152	KRESS	SC	4	9	8	8	4	4	5	5
153	KROSNOWSKI	PR			1	1	1			
154	LABOGEN	SP								
155	LABORMAX	SP	1	1	1					
156	LAOB	SP	11	21	21	25	25	12	19	19
157	LEINER	SP	1	1	1	1	1			
158	LIBBS	SP							4	14
159	LILLY	SP								
160	LIQUID	RJ	3	2	2	2	2	2	2	2
161	MAGNESITA	RJ	1	2	1	1	1	1	1	1
162	MEDAPI	SP								
163	MEMPHIS	RS	1	1	1	1	1	1	1	1
164	MERCK	RJ		3	3	3	3	3	3	3
165	MERCK MARANHÃO	MA	1	1	1	1	1	1	1	1
166	MERCOCÍTRICO	SP								
167	MERRELL-LEPETIT	SP	10	9	12	12				
168	MICROBIOLÓGICA	RJ	15	3	4	5	5	5	4	4

97	98	99	00	01	02	03	04	05	06	07	08	09	10	11
				5	5	6	7	7	5	5	5	3	3	3
24	21	23	20	20	21	17	20	26	22	18	18	38	34	35
12														
						1	1	1						
										1	1	1	1	1
3	3	3	3	3	3	3	3	3	3	3				
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
4	4													
				19	20	20	27	25	32	34	34	28	28	22
5														
				1										
							1	1	1	1	1	1	1	1
													3	3
6	6	6	6	6	6	7	6	6	6	6	2	4	4	4
1														
2														
													22	22
14	13	7												
				3	4	4	5	6	11	11	12	14	17	22
8	7	8	10	11	11	12	12	15	15	16	17	17	17	17
5	5	5	5	5	4									
11	9	8	8	9	10	10	18	17	17					
			1											
			1	1	1									
9	10	10	9		12	12	12	10	10	10	8	8	10	10
4	4	6	5	5	4	2								
2														
1	1	1	1											
								5	5	5	6	8	8	2
1	1	1	1	1										
3	3	3	9	9			5	5	6	6	6	3		
3	3	3	3											
	4	4	4	8	11	11	11	11	10					
6	6	6	6	8	9	9	10	10	5	5	6	6	6	4

Nº	EMPRESA		89	90	91	92	93	94	95	96
169	MIRACEMA	SP			4	4	4	4	4	4
170	MONSANTO	SP			1	1	1			
171	NACIONAL	MG			1	1	1	2		
172	NEOMED	SP	1	1						
173	NIKKHO	RJ					1	1	1	1
174	NITROCLOR	RJ	3	2	2	2	2	2		
175	NITROFÉRTIL	BA	1	1	1	1				
176	NITROQUÍMICA	SE			5	2	2	1	1	1
177	NORTEC	RJ	6	8	12	16	17	16	17	17
178	NOVAQUÍMICA	SP	9	7	3					
179	NOVARTIS	RJ								
180	NOVO	PR	4	3	5	5	5	5	5	5
181	OURO BRANCO	SP	4	4						
182	PALQUIMA	SP	1	7	2					
183	PAN-AMERICANA	RJ	18	16	18	20	20	21	19	19
184	PARANAENSE	PR	17	12	5					
185	PARAQUÍMICA	SP	10	4	4		4	6	10	11
186	PENN WALT	SP	1	1	1					
187	PERÓXIDOS	SP	1	1	1	3	3		2	2
188	PFIZER	SP	13	16	16	8				
189	PHEBO	BA	1	1	1	1				
190	PHIBRO	SP								
191	PLANALQUÍMICA	SP			1	1	1	3	2	2
192	PLESTIN	RJ	5	5	8	3				
193	POLENGHI	GO	1	1			1			
194	POLYTECHNO	SP	10	16	16					
195	PRO-ANALYSI	RJ	1	1						
196	PROAROMA	SP			1					
197	PRODOME	SP	12	12	12	12	12	10	10	10
198	PRODOTTI	SP								
199	PROQUÍMIO	SP	14	14	11	11	12	13	15	15
200	PROSINT	RJ	1	1						
201	PROTEQUIM	SP	4	4	4	4	4	7	7	7
202	PURAC SINTESES	RJ								5
203	PVP	PI	15	11	14	13	14	14	15	14
204	QEEL	SP	31	29	34	34	34			
205	QGN	BA								
206	QUATIS	RJ	1	1	1	1	1			
207	QUELUZ	SP	12	10						
208	QUERCEGEN	MA								
209	QUIMBARRA	RJ			2	1	2			
210	QUIMIBRAS	RJ	26	28	58	59	33	33	40	85
211	QUÍMICA INDAIATUBA	SP								
212	QUÍMIO	RJ			8	8	3			
213	QUIMISINTESA	RJ	8	4	10	10	13	16		
214	QUIMVALE	RJ			1	1	1	1	1	1
215	QUIRAL	MG							2	2
216	RDM	RJ	4	4	4	5	5	5	5	5
217	REBIERE	SP	3	1	1	1	1	1	1	1
218	REFINAÇÕES	SP	2	4	4	3				
219	RELTHY	SP								
220	RESIPRATES	RS	2	2						
221	RHODIA	SP	72	41	40	13	7	7	7	7
222	RHODIA FARMA	SP	5	5	5	5	3	3	3	3
223	ROCHE	RJ	12	14	15	13	13	12	13	13
224	ROYALPLAS	SP	1	1						

97	98	99	00	01	02	03	04	05	06	07	08	09	10	11
1	1	1	1	1										
1	1	1	1											
20	20	28	29	33	37	40	64	67	67	64	62	63	62	63
	23	23	24	24	24	23	23	21	22	18	20	18	19	20
5	5													
15	13	13	13	10	10	6								
17	15	15	15	15										
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
								1	1	1	1	1	1	1
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
10	8	6	5											
					15	10	10	9	9					
15	15	15	10	10	10	10	5							
7	7	7	7	6	6	6	6							
2	2	2	6	6	6	6	6	2	2	2	2	2		
14	14	14	11	11	11	11	11	11	11	11				
			2	1	1	2	2	2	2	3	3	3	3	3
													3	3
65	85	86	86	87	86	87	87	87	86	86	86	86	86	86
														1
1	1	1	1	1	1	1	1	1	1	1				
2	5	6	7	8	8	4	5	5	5	5	5	5	5	5
5	5													
1	1	1	1	1	1	1	1	1	1	1	1	1		
					1	1	1	1	1	1	2	2	2	1
3	2	1	1	2	2		1	1	1	1	1	1	1	1
13	12	5	4											

Nº	EMPRESA		89	90	91	92	93	94	95	96
225	SABARÁ	SP	1	1						
226	SAIRSA	SP	4	1	1	1	2	2	2	2
227	SANBRA	SP	7	5	2					
228	SANDOZ	RJ	19	27	28	24	21	20	22	10
229	SANOFI	SP	9	13	11	14	14	17	17	18
230	SANOFI-PHARMA	RJ	1	1	1	1	1	1	1	1
231	SANRIG	RS	7	2						
232	SANRISIL	SP	7	5	6	6				
233	SANTA CATARINA	RJ		4	4					
234	SARGEL	SP								
235	SARSA	RJ	2	2	1	1				
236	SCHERER	SP	2	2	2	2	2	2	2	2
237	SCHERING PLOUGH	RJ	1	4	4	4	4	4	4	4
238	SESPO	SP	12	14	14	5	5	3		
239	SHELL	SP	1							
240	SIDNEY ROSS	RJ	2	2	2					
241	SILVESTRE	RJ								
242	SINTEFINA	SP				4	6	6	6	6
243	SINTESES	RJ	1	3	1		2	4	5	
244	SINTOGRAM	SP	4	4			5	6	6	2
245	SIQUEIRA GURGEL	CE	1	1	1	1	1	1	1	1
246	SMITHKLINE	RJ	1	1	1	1	1	1		
247	SMITHKLINE NORDESTE	BA	3	2	2	2	2	4	5	2
248	SOUCERTECH	SP								
249	SQ BRASIL	SP								
250	SQUIBB	SP	4	4	6					
251	STAUFFER	SP	3	2						
252	STEVIAFARMA	PR						1	1	1
253	SULBRA	SP		1	1		2	2	2	2
254	SULFABRÁS	SP	13	13	22	22	21	19		
255	SULFAQUIM	SP	3	3	3	3	3	3	3	
256	SUPRE MAIS	SP	4	4	4	9	10			
257	SYNTHELABÓ	RJ							13	10
258	TANAC	SP	1	1	1					
259	TATELYLE	SP								
260	TAUBATÉ (IQT)	SP	11	12	11	13	7	7	5	4
261	TEOBRASA	ES			1					
262	TETRAQUÍMICA	SP			1					
263	TIRADENTES	MG	2	1	1	1	1	1	1	1
264	TORTUGA	SP	10	10	8	9	9	9	11	11
265	TRÊS BARRAS	SP	3	1						
266	TUMIARU	SP	1	1						
267	UFE	RJ	1	1						
268	ULTRAQUÍMICA	SP		9	8	8	8			
269	UNIÃO	SP	1	1						
270	UNIMANÃ	SP	2	1	1	1	1	8	3	3
271	VALLÉE	MG			1	1				
272	VEGEFLORA	PI								
273	VEGETEX	PI	2	4	4	4	2	2	2	2
274	VERONESE	RS	2	2	2					
275	VETEC	RJ	12	54	54	54	54	8	6	10
276	VICTOR SENCE	RJ	4	2	3	2	2			
277	VICTORIA	SP	9	5	5	5	5	6	5	5
278	VIRBAC	SP	5	2	3	3				
279	WALLERSTEIN	SP	1	1	1	1	1	1	1	1

97	98	99	00	01	02	03	04	05	06	07	08	09	10	11
10														
14	15	15	15	20										
1														
						2	2	4	4	4				
2	2	2	2	2	1	1								
2	2	2	2	2	2	2								
4	4	4	4	4	4	4	4	4						
										1	1	1	1	1
7	6	4	6	9	8	14	18	16	17	23	23			
2	2	2	2											
1	1	1	1	1										
2	2	2	2											
2	2	2	3	3	3	3	3	3	3	3	3	3	3	3
												1	1	1
1	1	1	1	1	1	1	1	1	1	1	2	2	2	2
										10	10			
4	3	3	3	3	3	2	2	8	8	6	6			
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
10	9	9	9	9	10	4	4	4	4	3	3			
3		1	1											
													2	2
2	2	2												
22	15	19	19	19	19	19	19	41	40	40	40	40	13	23
5	5	5	8	9	9	9	9	3						
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Fonte: abiquifi

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Relação de Produtos

Como usar o **Índex abiquifi**:

Para um uso mais eficiente deste Índex, recomendamos ao leitor observar as seguintes referências para os produtos que se encontram relacionados por ordem alfabética, independente do seu nome genérico básico:

1. Denominações Comuns Brasileiras (DCB)
2. Denominação Comum Internacional (DCI, INN ou USAN)
3. Nome(s) químico(s) em inglês
4. Categoria farmacológica e/ou terapêutica (português)
5. Categoria farmacológica e/ou terapêutica (inglês)
6. Referência bibliográfica do produto (inglês)
7. Número CAS do produto
8. Número na Denominação Comum Brasileira (DCB)
9. Classificação na Nomenclatura Comum do Mercosul (NCM)
10. Valor da tarifa modal na TEC do Mercosul
11. Empresa(s) produtora(s) da Argentina
12. Empresa(s) produtora(s) do Brasil **(*)**

Verbete ilustrativo:

1 diclofenaco sódico; **2** *diclofenac sodium*; **3** 2-[(2,6-dichlorophenyl)amino]benzeneacetic acid monosodium salt; **4** anti-inflamatório, antirreumático e analgésico; **5** anti-inflammatory; **6** Merck Index 14, 3081; **7** CAS: 15307-79-6; **8** DCB: 02930; **9** NCM: 2922.49.61; **10** TEC: 14%; **11** **Arg:** Bagó; **12** **Bra:** Nortec Química, Novartis •

Identificação de algumas siglas:

INN – International Nonproprietary Names
USAN – United States Approved Names
CAS – Chemical Abstracts Service
TEC – Tarifa Externa do Mercosul

(*) No caso dos produtos brasileiros, pode haver a indicação (•) que significa que o produto é fabricado pela empresa apenas para uso cativo. Não havendo esta indicação o produto é de livre venda para terceiros. O mesmo não acontece com os produtos argentinos, para os quais devem ser consultados os produtores.

List of Products

How to use the **Índex abiquifi**

For maximum efficiency in utilizing this Index, we recommend that corresponding product references be used for the products listed below in alphabetical order, regardless of basic generic names:

1. *Denominations Common in Brazil (DCB)*
2. *Denominations Common Internationally (DCI, INN or USAN)*
3. *Chemical name in english*
4. *Pharmacological and/or therapeutic category (portuguese)*
5. *Pharmacological and/or therapeutic category (english)*
6. *Bibliographical reference of the product (english)*
7. *CAS Number of the product*
8. *Number of the Denominations Common in Brazil (DCB)*
9. *Classification of Nomenclature Common in the Mercosul countries (NCM)*
10. *TEC modal tariff value in the Mercosul*
11. *Manufacturing companies in Argentina*
12. *Manufacturing companies in Brazil* ***(*)***

Illustrative example:

1 diclofenaco sódico; **2** *diclofenac sodium*; **3** 2-[(2,6-dichlorophenyl)amino]benzeneacetic acid monosodium salt; **4** anti-inflamatório, antirreumático e analgésico; **5** anti-inflammatory; **6** Merck Index 14, 3081; **7** CAS: 15307-79-6; **8** DCB: 02930; **9** NCM: 2922.49.61; **10** TEC: 14%; **11** **Arg:** Bagó; **12** **Bra:** Nortec Química, Novartis •

Identification of some acronyms:

INN – *International Nonproprietary Names*
USAN – *United States Approved Names*
CAS – *Chemical Abstracts Service*
TEC – *Mercosul External Tariff (Tarifa Externa do Mercosul)*

(*) *In the case of Brazilian products, the symbol (•) indicates that the product is manufactured by the company just for in-line use. Without this symbol it means that product can be sold to third parties. This rule does not apply to Argentinian products and the producers in that country must be consulted for further information.*

acetato de alumínio; *aluminum acetate*; acetic acid aluminum salt; adstringente e antisséptico; astringent / antiseptic; Merck Index 14, 324; CAS: 139-12-8; DCB: 00054; NCM: 2915.29.90; TEC: 12%; **Bra:** Vetec

acetato de amônio; *ammonium acetate*; acetic acid ammonium salt; diurético; diuretic; Merck Index 14, 495; CAS: 631-61-8; DCB: 00055; NCM: 2915.29.90; TEC: 12%; **Bra:** Quimibrás

acetato de chumbo; *lead acetate*; neutral lead acetate; adstringente; astringent; Merck Index 14, 5397; CAS: 301-04-2; DCB: 09340; NCM: 2915.29.90; TEC: 12%; **Bra:** Quimibrás, Vetec

acetato de flecainida; *flecainide acetate*; N-(2-piperidinylmethyl)-2,5-bis(2,2-2-trifluoroethoxy)benzamide acetate; antiarrítmico; antiarrhythmic (class IC); Merck Index 14, 4098; CAS: 54143-56-5; DCB: 04069; NCM: 2933.39.19; TEC: 2%; **Arg:** Maprimed

acetato de hidroxocobalamina; *hydroxocobalamin acetate*; alpha-(5,6-dimethylbenzimidazolyl)-hydroxocobamide acetate; vitamínico; vitamin (hematopoietic); Merck Index 14, 4809; CAS: 22465-48-1; DCB: 04720; NCM: 2936.26.30; TEC: 14%; **Arg:** Bagó

acetato de potássio; *potassium acetate*; acetic acid potassium salt; alcalinizante, expectorante e diurético, em veterinária; alkalizer, expectorant, diuretic in vet; Merck Index 14, 7605; CAS: 127-08-2; DCB: 00061; NCM: 2915.29.90; TEC: 12%; **Bra:** Quimibrás, Vetec

acetato de sódio; *sodium acetate*; acetic acid sodium salt; em soluções para diálise; pharmaceutical aid (in dialysis solutions); Merck Index 14, 8571; CAS: 127-09-3; DCB: 00087; NCM: 2915.29.10; TEC: 12%; **Bra:** Caq, Quimibrás

acetato de zinco; *zinc acetate*; adstringente e emético; astringent, emetic; Merck Index 14, 10128; CAS: 557-34-6; DCB: 09345; NCM: 2915.29.90; TEC: 12%; **Bra:** Quimibrás

aciclovir; *aciclovir*; 2-amino-1,9-dihydro-9[(2-hydroxyethoxy)methyl]-6H-purin-6-one; antiviral; antiviral; Merck Index 14, 146; CAS: 59277-89-3; DCB: 00082; NCM: 2933.59.42; TEC: 2%; **Bra:** Nortec Química

ácido alendrônico; *alendronic acid*; (4-amino-1-hydroxybutilidene)bisphosphonic acid; antiosteolítico; supressant (bone resorption); Merck Index 14, 229; CAS: 66376-36-1; DCB: 00096; NCM: 2931.90.39; TEC: 12%; **Arg:** Gador

ácido benzoico; *benzoic acid*; benzenecarboxylic acid; adjuvante farmacotécnico como agente antifúngico; pharmaceutic aid (antifungal); Merck Index 14, 1091; CAS: 65-85-0; DCB: 00115; NCM: 2916.31.10; TEC: 12%; **Bra:** Quimibrás

ácido bórico; *boric acid*; orthoboric acid; adstringente e antisséptico; astringent, antiseptic; Merck Index 14, 1336; CAS: 10043-35-3; DCB: 00116; NCM: 2810.00.10; TEC: 10%; **Bra:** Caq

ácido cítrico anidro; *citric acid anhydrous*; 2-hydroxy-1,2,3-propanetricarboxylic acid anhydrous; adjuvante farmacotécnico; pharmaceutical aid; Merck Index 14, 2326; CAS: 77-92-9; DCB: 00134; NCM: 2918.14.00; TEC: 12%; **Bra:** Quimibrás

ácido cítrico monoidratado; *citric acid monohydrate*; 2-hydroxy-1,2,3-propanetricarboxylic acid monohydrate; adjuvante farmacotécnico; pharmaceutical aid; Merck Index 14, 2326; CAS: 5949-29-1; DCB: n.d.; NCM: 2918.14.00; TEC: 12%; **Bra:** Caq, Quimibrás

ácido cólico; *cholic acid*; (3alfa,5beta,7alfa,12alfa)-3,7,12-trihydroxicholan-24-oic acid; colerético; choleretic; Merck Index 14, 2203; CAS: 81-25-4; DCB: 00152; NCM: 2918.29.90; TEC: 2%; **Arg:** Bagó

ácido deidrocólico; *dehydrocholic acid*; veja ácido desidrocólico; *see dehydrocholic acid*

ácido desidrocólico; *dehydrocholic acid*; (5beta)-3,7,12-trioxocholan-24-oic acid; colerético; choleretic; Merck Index 14, 2868; CAS: 81-23-2; DCB: 00157; NCM: 2918.30.31; TEC: 2%; **Arg:** Bagó

ácido desoxicólico; *deoxycholic acid*; (3alpha-5beta,12alpha)-3,12-dihydroxy-5-cholan-24-oic acid; colerético; choleretic; Merck Index 14, 2899; CAS: 83-44-3; DCB: 00160; NCM: 2918.19.29; TEC: 12%; **Arg:** Bagó

ácido oxálico; *oxalic acid*; ethanedioic acid; hemostático, em veterinária; as hemostatic agent in vet; Merck Index 14, 6911; CAS: 144-62-7; DCB: n.d.; NCM: 2917.11.10; TEC: 12%; **Bra:** Caq

ácido pamidrônico; *pamidronic acid*; (3-amino-1-hydroxypropylidene) bisphosphonic acid; antipagético; antipagetic; Merck Index 14, 7003; CAS: 40391-99-9; DCB: 00314; NCM: 2931.90.39; TEC: 12%; **Arg:** Gador; **Bra:** Libbs

ácido salicílico; *salicylic acid*; 2-hydroxybenzoic acid; queratolítico e intermediário na produção de ácido acetilsalicílico; keratolytic (topical) and in the manufacture of acetylsalicylic acid; Merck Index 14, 8332; CAS: 69-72-7; DCB: 00340; NCM: 2918.21.10; TEC: 12%; **Bra:** Rhodia

ácido tartárico; *L-tartaric acid*; (2R,3R)-2,3-dihydroxybutanedioic acid; adjuvante farmacotécnico como estabilizante; pharmaceutic aid (buffering agent); Merck Index 14, 9070; CAS: 87-69-4; DCB: 00350; NCM: 2918.12.00; TEC: 12%; **Bra:** Quimibrás

ácido zoledrônico; *zoledronic acid*; zoledronic acid; antiosteolítico; antiosteolytic; Merck Index 14, 10187; CAS: 118072-93-8; DCB: 00379; NCM: 2933.29.99; TEC: 2%; **Arg:** Maprimed; **Bra:** ITF, Libbs

albendazol; *albendazole*; [5-(propylthio)-1H-benzimidazol-2-yl]carbamic acid methyl ester; anti-helmíntico, em veterinária; anthelmintic in vet; Merck Index 14, 210; CAS: 54965-21-8; DCB: 00458; NCM: 2933.99.53; TEC: 14%; **Bra:** Formil

albumina humana sérica cromada (51 Cr): SAH 51 Cr; *albumin*, chromated Cr 51 serum; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 45; CAS: n.d.; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

albumina humana sérica iodada (131 I): SAH I 131; *albumin*, iodinated I 131 serum; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 45; CAS: 9048-49-1; DCB: 00462; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

álcool benzílico; *benzyl alcohol*; benzenemethanol; adjuvante farmacotécnico como conservante; pharmaceutic aid (antimicrobial); Merck Index 14, 1124; CAS: 100-51-6; DCB: 00471; NCM: 2906.21.00; TEC: 12%; **Bra:** Caq

álcool oleílico; *oleyl alcohol*; (Z)-9-octadecen-1-ol; adjuvante farmacotécnico como veículo; pharmaceutic aid (carrier); Merck Index 14, 6831; CAS: 143-28-2; DCB: 00480; NCM: 2905.29.90; TEC: 2%; **Bra:** Croda

alendronato de sódio; *alendronate monosodium*; (4-amino-1-hydroxybutylidene)bisphosphonic acid monosodium salt; antiosteolítico; suppressant (bone resorption); Merck Index 14, 229; CAS: 121268-17-5; DCB: 00097; NCM: 2931.90.39; TEC: 12%; **Bra:** Globe, ITF

alfainterferona 2a; *interferon alpha-2a recombinant*; alpha-interferon; antiviral e antineoplásico; antiviral, antineoplastic; Merck Index 14, 4990; CAS: 76543-88-9; DCB: 00515; NCM: 3002.10.29; TEC: 2%; **Arg:** Bio Sidus

alfainterferona 2b; *interferon alpha-2b recombinant*; alpha-interferon; antiviral e antineoplásico; antiviral, antineoplastic; Merck Index 14, 4990; CAS: 99210-65-8; DCB: 00516; NCM: 3002.10.29; TEC: 2%; **Arg:** Bio Sidus

alprazolam; *alprazolam*; 8-chloro-1-methyl-6-phenyl-4H-[1,2,4]triazol [4,3-a][1,4]benzodiazepine; ansiolitico; anxiolitic; Merck Index 14, 312; CAS: 28981-97-7; DCB: 00597; NCM: 2933.91.11; TEC: 12%; **Bra:** Formil

alume de potássio; *potassium alum*; aluminum potassium sulfate; adstringente; astringent; Merck Index 14, 360; CAS: 10043-67-1; DCB: 08161; NCM: 2833.30.00; TEC: 10%; **Bra:** Quimibrás

ambufilina; *ambuphylline*; 3-7-dihydro-1,3-dimethyl-1H-purine-2,6-dione compd. with 2-amino-2-methyl-1-propanol; broncodilatador; bronchodilator; Merck Index 13, 384; CAS: 5634-34-4; DCB: 00636; NCM: 2939.59.90; TEC: 2%; **Bra:** Formil

amitraz; *amitraz*; N-(2,4-dimethyl phenyl)-N-[[(2,4-dimethylphenyl)-imino]methyl]-N-methyl-methanimidamide; ectoparasiticida; ectoparasiticid; Merck Index 14, 486; CAS: 33089-61-1; DCB: 00710; NCM: 2925.29.30; TEC: 12%; **Arg:** Aca

antimoniato de meglumina; *meglumine antimonate*; 3,5-diacetamido-2,4,6-triiodobenzoic acid antimony salt; auxiliar de diagnóstico; diagnostic aid (radiopaque medium); DSFC 2007, pág. 56; CAS: 133-51-7; DCB: 05587; NCM: 2922.19.99; TEC: 2%; **Arg:** Triquim

arginina; *L-arginine*; 2-amino-5-guanidinovaleric acid; auxiliar de diagnóstico, desintoxicante da amônia; diagnostic aid, ammonia detoxicant; Index Merck 14, 780; CAS: 74-79-3; DCB: 00866; NCM: 2925.29.19; TEC: 2%; **Bra:** ABL

aripiprazol; *aripiprazole*; 7-[4-[4-(2,3-dichlorophenyl)-1-piperazinyl] butoxy]-3,4-dibydro-2(1H)-quinolinone; antipsicótico; antipsychotic; Merck Index 14, 785; CAS: 129722-12-9; DCB: 00875; NCM: 2933.79.90; TEC: 2%; **Arg:** Maprimed

atazanavir; *atazanavir*; 1-[4-(pyridin-2-yl)phenyl]-5S-2,5bis[[N-(methoxycarbonyl)-L-tert-leucinyl]amino]-4S-hydroxy-6-phenyl-2-azahexane; antiviral; antiviral; Merck Index 14, 858; CAS: 198904-31-3; DCB:09566; NCM: 2933.39.99; TEC: 2%; Bra: CYG Biotech

azatioprina; *azathioprine*; 6-[(1-methyl-4-nitro-1H-imidazol-5-yl)thio]-1H-purine; imunossupressor e antirreumático; immunosuppressant, antirheumatic; Merck Index 14, 902; CAS: 446-86-6; DCB: 00984; NCM: 2933.59.34; TEC: 14%; **Bra:** Microbiológica

AZT (zidovudina); zidovudine; 3-azido-3-deoxythymidine / azidothymidine; no tratamento da AIDS / antiviral; antiviral; Merck Index 14, 10123; CAS: 30516-87-1; DCB: 09256; NCM: 2934.99.22; TEC: 12%; **Bra:** CYG Biotech, Globe, Microbiológica, Nortec Química

bendamustina; *bendamustine*; 5-[bis(2-chloroethyl)amino]-1-methyl-1H-benzimidazole-2-butanoic acid; antineoplásico; antineoplastic; Merck Index 14, 1034; CAS: 16506-27-7; DCB: 01097; NCM: 2933.99.99; TEC: 2%; **Bra:** ITF

benzoato de amônio; *ammonium benzoate*; benzoic acid ammonium salt; antiinfeccioso urinário; urinary anti-infective; Merck Index 14, 496; CAS: 1863-63-4; DCB: 01154; NCM: 2916.31.22; TEC: 12%; **Bra:** Quimibrás

benzoato de denatônio; *denatonium benzoate*; N-[2-((2,6-dimethylphenyl)amino)-2-oxoethyl]-N,N-diethylbenzenemethanaminium benzoate; adjuvante farmacotécnico; pharmaceutical aid; Merck Index 14, 2891; CAS: 3734-33-6; DCB: 01156; NCM: 2924.29.96; TEC: 2%; **Bra:** Nortec Química

benzoato de sódio; *sodium benzoate*; sodium benzoate; adjuvante farmacotécnico como agente antifúngico; pharmaceutic aid (antifungal); Merck Index 14, 8582; CAS: 532-32-1; DCB: 01157; NCM: 2916.31.21; TEC: 12%; **Bra:** Quimibrás

benzoilmetronidazol; *benzoyl metronidazole*; 2-methyl-5-nitroimidazole-1-ethanol benzoyl; tricomonicida; antiprotozoal (trichomonas); USP Dictionary 2009, pág. 591; CAS: 13182-89-3; DCB: 01166; NCM: 2933.29.12; TEC: 14%; **Bra:** Formil

betainterferona 1a recombinante; *interferon beta 1a recombinant*; interferon beta; antineoplásico, antiviral; Merck Index 14, 4991; CAS: 145258-61-3; DCB: 09361; NCM: 3002.10.29; TEC: 2%; **Arg:** Bio Sidus

bicarbonato de sódio; *sodium bicarbonate*; sodium hydrogen carbonate; antiácido e alcalinizante; antacid, urinary and systemic alkalizer; Merck Index 14, 8583; CAS: 144-55-8; DCB: 01249; NCM: 2836.30.00; TEC: 10%; **Bra:** ABL, Caq, Qgn, Quimibrás

bissulfato de potássio; *potassium bisulfate*; potassium acid sulfate; catártico; cathartic; Merck Index 14, 7613; CAS: 7646-93-7; DCB: n.d.; NCM: 2833.29.90; TEC: 10%; **Bra:** Vetec

bitartarato de di-hidrocodeína; *dihydrocodeine bitartrate*; veja hemitartarato de di-hidrocodeína; *see dihydrocodeine bitartrate*

bitartarato de hidrocodona; *hydrocodone bitartrate*; veja hemitartarato de hidrocodona; *see hydrocodone bitartrate*

bitartarato de zolpidem; *zolpidem bitartrate*; veja hemitartarato de zolpidem; *see zolpidem hemitartrate*

borato de sódio; *sodium borate*; sodium tetraborate / borax; alcalinizante / em veterinária, antisséptico, detergente e adstringente; pharmaceutic aid (alkalizer) / antiseptic, detergent and astringent in vet; Merck Index 14, 8590; CAS: 1330-43-4; DCB: 00117; NCM: 2840.11.00; TEC: 10%; **Bra:** Caq, Quimibrás

bromazepam; *bromazepam*; 7-bromo-1,3-dihydro-5-(2-pyridinyl)-2H-1,4-benzodiazepin-2-one; ansiolítico; anxiolytic; Merck Index 14, 1385; CAS: 1812-30-2; DCB: 01366; NCM: 2933.33.22; TEC: 12%; **Bra:** Formil, Globe, Nortec Química

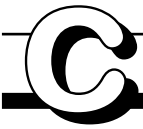
bromidrato de bupropiona; *bupropion hydrobromide*; 1-(3-chlorophenyl)-2-[(1,1-dimethylethyl)amino]-1-propanone hydrobromide; antidepressivo; Merck Index 14, 1499; CAS: 905818-69-1; DCB: n.d.; NCM: 2922.39.90; TEC: 2%; **Bra:** ITF

bromofórmio; *bromoform*; tribromomethane; antitussígeno, sedativo, hipnótico; sedative, hypnotic, antitussive; Merck Index 14, 1420; CAS: 75-25-2; DCB: 01468; NCM: 2903.39.21; TEC: 0%; **Bra:** Quimibrás

bromoprida; *bromopride*; 4-amino-5-bromo-N-[2-(diethylamino)ethyl]-2-methoxybenzamide; antiemético; antiemetic; Merck Index 14, 1432; CAS: 4093-35-0; DCB: 01471; NCM: 2924.29.51; TEC: 14%; **Bra:** Libbs

bromotolil benzonitrila; *bromotolil benzonitril*; 4-bromomethyl-(1,1-biphenyl)-2-carbonitril; intermediário para a produção de anti-hipertensivo; intermediate for antihypertensive production; reference not informed; CAS: 114772-54-2; DCB: n.d.; NCM: 2926.90.99; TEC: 2%; **Bra:** Novartis •

bupivacaína; *bupivacaine*; Dl-1-butyl-2,6-pipecoloxylidide; anestésico local; anesthetic (local); Merck Index 14, 1495; CAS: 2180-92-9; DCB: 01551; NCM: 2933.39.89; TEC: 2%; **Arg:** Triquim; **Bra:** Nortec Química



cápsulas de gelatina dura; *hard gelatin capsules*; hard gelatin capsules; adjuvante farmacotécnico; pharmaceutic aid; USP 22 th Edition; NCM: 9602.00.10; TEC: 14%; **Bra:** Gênix

cápsulas de gelatina elástica; *soft gelatin capsules*; soft gelatin capsules; adjuvante farmacotécnico; pharmaceutic aid; USP 22 th Edition; NCM: 9602.00.10; TEC: 14%; **Bra:** Catalent, Relthy

carbamazepina; *carbamazepine*; 5H-dibenz[b,f]azepine-5-carboxamide; analgésico e anticonvulsivante; analgesic, anticonvulsant; Merck Index 14, 1781; CAS: 298-46-4; DCB: 01710; NCM: 2933.99.32; TEC: 14%; **Bra:** Nortec Química, Novartis •

carbocisteína; *carbocysteine*; S-carboxymethyl-L-cysteine; mucolítico e expectorante; mucolytic, expectorant; Merck Index 14, 1802; CAS: 638-23-3; DCB: 01739; NCM: 2930.90.36; TEC: 12%; **Bra:** Globe

carbonato básico de bismuto; *bismuth subcarbonate*; bismuth carbonate basic; protetor tópico; topical protectant; Merck Index 14, 1282; CAS: 5892-10-4; DCB: 01747; NCM: 2836.99.19; TEC: 10%; **Bra:** Quimibrás

carbonato de cálcio; *calcium carbonate*; carbonic acid calcium salt; antiácido e fonte de cálcio; antacid, calcium supplement; Merck Index 14, 1657; CAS: 471-34-1; DCB: 01748; NCM: 2836.50.00; TEC: 10%; **Bra:** Caq, Quimibrás

carbonato de lítio; *lithium carbonate*; carbonic acid lithium salt; nas doenças maníaco-depressivas; antimaniac; Merck Index 14, 5527; CAS: 554-13-2; DCB: 01749; NCM: 2836.91.00; TEC: 10%; **Bra:** CYG Biotech, Globe

carbonato de lodenafila; *lodenafil carbonate*; bis(2-[4-[4-ethoxy-3-(1-methyl-7-oxo-3-propyl-4,7-dihydro-1H-pyrazolo[4,3-d]pyrimidin-5-yl] phenylsulfonyl]piperazin-1-yl]ethyl)carbonate; vasodilatador; vasodilator; WHO Drug Information, vol. 19, nº 4, 2005; CAS: 398507-55-6; DCB: 09594; NCM: 2934.99.99; TEC: 2%; **Bra:** Cristália

carbonato de magnésio; *magnesium carbonate*; carbonic acid magnesium salt; antiácido e catártico; antacid, cathartic; Merck Index 13, 5682; CAS: 546-93-0; DCB: 01750; NCM: 2836.99.11; TEC: 10%; **Bra:** Buschle Lepper, Caq

carbonato de potássio; *potassium carbonate*; carbonic acid potassium salt; alcalinizante e diurético; alkalizer, diuretic; Merck Index 14, 7619; CAS: 584-08-7; DCB: 01751; NCM: 2836.40.00; TEC: 10%; **Bra:** Quimibrás

carbonato de sevelâmer; *sevelamer carbonate*; 2-propen-1-amine polymer with (chloromethyl) oxirane carbonate; anti-hiperfosfatêmico; antihyperphosphatemic; USP Dictionary 2009, pág. 827; CAS: 845273-93-0; DCB: 09631; NCM: 2922.50.99; TEC: 2%; **Bra:** ITF

carbonato de sódio; *sodium carbonate*; carbonic acid sodium salt; alcalinizante / emético, em veterinária; pharmaceutical aid (alkalizer), emetic in vet; Merck Index 14, 8596; CAS: 497-19-8; DCB: 01752; NCM: 2836.20.10; TEC: 10%; **Bra:** ABL, Quimibrás

carboplatina; *carboplatin*; (SP-4-2)diammine[1,1-cyclobutanedicarboxylate(2)-0,0]platinum; antineoplásico; antineoplastic; Merck Index 14, 1822; CAS: 41575-94-4; DCB: 01754; NCM: 2843.90.90; TEC: 10%; **Bra:** Quiral

carvão ativado; *activated carbon*; carbon black; antídoto e adsorvente; antidote, adsorptive; Merck Index 14, 1808; CAS: 16291-96-6; DCB: 09367; NCM: 3802.10.00; TEC: 12%; **Bra:** Carbomafra

cefalexina sódica; *cephalexin sodium monohydrate*; 7-(D-alpha-aminophenyl-acetamido)desacetoxycephalosporanic acid monohydrate sodium salt; antibiótico; antibacterial; Merck Index 14, 1974; CAS: 39832-40-0; DCB: 01828; NCM: 2941.90.39; TEC: 14%; **Bra:** ABL

cefalotina sódica; *cefalotin sodium*; 7-(2-thienylacetamido)cephalosporanic acid sodium salt; antibiótico; antibacterial; Merck Index 14, 1982; CAS: 58-71-9; DCB: 01836; NCM: 2941.90.33; TEC: 14%; **Bra:** ABL

cefepima; *cefepime*; 1-[[(6R,7R)-[[(2Z)-(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methyl]-1-methylpyrrolidinium inner salt; antibacteriano (antibiótico); antibacterial; Index Merck 14, 1922; CAS: 88040-23-7; DCB: 01855; NCM: 2941.90.39; TEC: 2%; **Bra:** ABL

cefotaxima sódica; *cefotaxime sodium*; (6R,7R)-3-[(acetyloxy)-methyl]-7-[[(2Z)-(2-amino-4-thyazolyl)(methoxyimino)acetyl]amino]-8-oxo-thia-1-azabicyclo [4.2.0] oct-2-ene-2-carboxylic acid sodium salt; antibacteriano (antibiótico); antibacterial; Index Merck 14, 1933; CAS: 64485-93-4; DCB: 01877; NCM: 2941.90.35; TEC: 2%; **Bra:** ABL

cefoxitina sódica; *cefoxitin sodium*; (6R,7S)-3-[[aminocarbonyl)oxy] methyl]-7-methoxy-8-oxo-7-[(2-thienylacetyl)amino]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid sodium salt; antibacteriano (antibiótico); antibacterial; Index Merck 14, 1936; CAS: 33564-30-6; DCB: 01883; NCM: 2941.90.36; TEC: 2%; **Bra:** ABL

ceftazidima; *ceftazidime*; 1-[[(6R,7R)-7-[[(2Z)-(2-amino-4-thiazolyl)[(1-carboxy-1-methylethoxy)imino]acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]pyridinium inner salt; antibacteriano (antibiótico); antibacterial; Index Merck 14, 1946; CAS: 72558-82-8; DCB: 01897; NCM: 2941.90.39; TEC: 2%; **Bra:** ABL

ceftriaxona sódica; *ceftriaxone sodium*; (6R,7R)-7-[[(2Z)-(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-3-[[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo-1,2,4-triazin-3-yl)thio]methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid sodium salt; antibacteriano (antibiótico); antibacterial; Index Merck 14, 1953; CAS: 74578-69-1; DCB: 01910; NCM: 2941.90.31; TEC: 2%; **Bra:** ABL

celulose gel; *cellulose gel*; microcrystalline cellulose and carboxymethylcellulose sodium; adjuvante farmacotécnico; pharmaceutic aid; Merck Index 14, 1965; CAS: 9004-34-6; DCB: n.d.; NCM: 3912.90.40; TEC: 14%; **Bra:** Blanver

celulose microcristalina; *microcrystalline cellulose*; microcrystalline cellulose; adjuvante farmacotécnico; pharmaceutic aid; Merck Index 14, 1965; CAS: 9004-34-6; DCB: 09371; NCM: 3912.90.31; TEC: 14%; **Bra:** Blanver

cetoconazol; *ketoconazole*; cis-1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-yl-methyl]-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine; antifúngico; antifungal; Merck Index 14, 5302; CAS: 65277-42-1; DCB: 01956; NCM: 2934.99.31; TEC: 14%; **Bra:** Globe

cetorolaco; *ketorolac*; 5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid; analgésico e anti-inflamatório; analgesic, anti-inflammatory; Merck Index 14, 5306; CAS: 74103-06-3; DCB: 01963; NCM: 2933.99.49; TEC: 2%; **Arg:** Maprimed

cilostazol; *cilostazol*; 6-[4-(1-cyclohexyl-1H-tetrazol-5-yl)butoxy]-3,4-dihydro-2-1H-quinolinone; antitrombótico; antithrombotic; Merck Index 14, 2277; CAS: 73963-72-1; DCB: 02067; NCM: 2933.79.90; TEC: 2%; **Bra:** Formil, Libbs

ciprofibrato; *ciprofibrate*; 2-[4-(2,2-dichlorocyclopropyl)phenoxy]-2-methylpropanoic acid; anti-hiperlipoproteinêmico; Merck Index 14, 2313; CAS: 52214-84-3; DCB: 02136; NCM: 2918.99.99; TEC: 2%; **Bra:** Formil

cisplatina; *cisplatin*; (SP-4-2)diamminedichloro-platinum; antineoplásico; antineoplastic; Merck Index 14, 2317; CAS: 15663-27-1; DCB: 02156; NCM: 2843.90.90; TEC: 10%; **Bra:** Quiral

citrato de cálcio; *calcium citrate*; 2-hydroxy-1,2,3-propanetricarboxylic acid calcium salt; na produção de ácido cítrico e citratos; in the production of citric acid and other citrates; Merck Index 14, 1661; CAS: 813-94-5; DCB: 02176; NCM: 2918.15.00; TEC: 12%; **Bra:** Quimibrás

citrato de dietilcarbamazina; *diethylcarbamazine citrate*; N,N-diethyl-4-methyl-1-piperazine carboxamide; anti-helmíntico; anthelmintic; Merck Index 14, 3116; CAS: 1642-54-2; DCB: 02959; NCM: 2933.59.19; TEC: 2%; **Bra:** Nortec Química

citrato de fentanila; *fentanyl citrate*; N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]propanamide citrate; analgésico narcótico; analgesic (narcotic); Merck Index 14, 4001; CAS: 990-73-8; DCB: 04005; NCM: 2933.33.69; TEC: 2%; **Arg:** Triquim; **Bra:** Alpha Br, Cristália

citrato de gálio (67 Ga); *gallium (67 Ga) citrate*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 425; CAS: 4183-64-6; DCB: 02179; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

citrato de magnésio; *magnesium citrate*; 2-hydroxy-1,2,3-propanetricarboxylic acid magnesium salt(2:3); catártico; cathartic; Merck Index 14, 5663; CAS: 3344-18-1; DCB: 02180; NCM: 2918.15.00; TEC: 12%; **Bra:** Quimibrás

citrato de orfenadrina; *orphenadrine citrate*; N,N-dimethyl-2-[(2-methylphenyl)phenylmetoxy]ethanamine citrate; relaxante muscular / antihistamínico; muscle relaxant (skeletal) / antihistaminic; Merck Index 14, 6879; CAS: 4682-36-4; DCB: 06630; NCM: 2922.19.21; TEC: 14%; **Bra:** Nortec Química

citrato de potássio; *potassium citrate*; 2-hydroxy-1,2,3-propanetricarboxylic acid potassium salt; alcalinizante e antiácido / diurético em veterinária; antiurolithic, antacid / diuretic in vet; Merck Index 14, 7623; CAS: 866-84-2; DCB: 02181; NCM: 2918.15.00; TEC: 12%; **Bra:** Quimibrás, Vetec

citrato de sildenafila; *sildenafil citrate*; 1-[[3-(4,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl] sulfonyl]-4-methylpiperazine citrate; no tratamento da disfunção erétil masculina; in treatment of male erectile disfunction; Merck Index 14, 8489; CAS: 171599-83-0; DCB: 07991; NCM: 2935.00.19; TEC: 2%; **Arg:** Maprimed

citrato de sódio; *sodium citrate*; alcalinizante sistêmico, diurético, expectorante e anticoagulante in vitro; systemic alkalizer, diuretic, expectorant, anticoagulant; Merck Index 14, 8602; CAS: 68-04-2; DCB: 02182; NCM: 2918.15.00; TEC: 12%; **Bra:** Quimibrás

citrato de sufentanila; *sufentanil citrate*; N-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide citrate; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 8887; CAS: 60561-17-3; DCB: 08085; NCM: 2934.91.70; TEC: 2%; **Bra:** Cristália

citrato de trietila; *triethyl citrate*; ethyl citrate; adjuvante farmacotécnico; pharmaceutic aid; Merck Index 12, 2350; CAS: 77-93-0; DCB: n.d.; NCM: 2918.15.00; TEC: 12%; **Bra:** Quimibrás

citrato férrico amoniacal; *ammonium ferric citrate*; ferric ammonium citrate; hematínico; hematinic; Merck Index 14, 4017; CAS: 1185-57-5; DCB: 02187; NCM: 2918.15.00; TEC: 12%; **Bra:** Quimibrás

citrato ferroso de cálcio; *calcium ferrous citrate*; ferrous calcium citrate; hematínico; hematinic; Merck Index 13, 1668; CAS: 53684-61-0; DCB: 09372; NCM: 2918.15.00; TEC: 12%; **Bra:** Globe, Quimibrás

citrato monossódico; *monosodium citrate*; monosodium citrate anhydrous; alcalinizante sistêmico, diurético e expectorante; systemic alkalizer, diuretic, expectorant; USP 22 th Edition; CAS: 18996-35-5; DCB: n.d.; NCM: 2918.15.00; TEC: 12%; **Bra:** Quimibrás

clonazepam; *clonazepam*; 5-(2-chlorophenyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin-2-one; anticonvulsivante; anticonvulsant; Merck Index 14, 2389; CAS: 1622-61-3; DCB: 02300; NCM: 2933.91.13; TEC: 2%; **Bra:** Alpha Br, Formil, Nortec Química

clonixinato de lisina; *clonixin lysine salt*; 2-[(3-chloro-2-methylphenyl)-amino]-3-pyridinecarboxylic acid lysine salt; analgésico; analgesic; Merck Index 14, 2392; CAS: 55837-30-4; DCB: 05349; NCM: 2922.41.90; TEC: 12%; **Arg:** Maprimed, Triquim

cloreto de alumínio; *aluminum chloride*; aluminum chloride; adstringente tópico; topical astringent; Merck Index 14, 337; CAS: 7446-70-0; DCB: 02360; NCM: 2827.32.00; TEC: 10%; **Bra:** Quimibrás

cloreto de amônio; *ammonium chloride*; ammonium muriate; acidificante sistêmico; systemic acidifier; Merck Index 14, 509; CAS: 12125-02-9; DCB: 02362; NCM: 2827.10.00; TEC: 10%; **Bra:** Quimibrás

cloreto de benzalcônio; *benzalkonium chloride*; alkylbenzyldimethyl (phenylmethyl)ammonium chloride; antisséptico tópico; antiseptic (topical); Merck Index 14, 1059; CAS: 8001-54-5; DCB: 02364; NCM: 3824.90.86; TEC: 14%; **Bra:** Hester

cloreto de cálcio; *calcium chloride*; calcium chloride; diurético, acidificante urinário e antialérgico; diuretic, urinary acidifier, antiallergic; Merck Index 14, 1659; CAS: 10043-52-4; DCB: 02369; NCM: 2827.20.10; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

cloreto de lapírio; *lapirium chloride*; 1-[2-oxo-2-[[2-[(1-oxododecyl) oxy]ethyl]amino]ethyl]pyridinium chloride; adjuvante farmacotécnico (surfactante); pharmaceutic acid (surfactant); Merck Index 14, 5370; CAS: 6272-74-8; DCB: 02397; NCM: 2933.39.99; TEC: 2%; **Arg:** Triquim

cloreto de lítio; *lithium chloride*; lithium chloride, antidepressivo; antidepressant; Merck Index 14, 5528; CAS: 7447-41-8; DCB: n.d.; NCM: 2827.39.60; TEC: 2%; **Bra:** CYG Biotech

cloreto de magnésio; *magnesium chloride*; magnesium chloride; catártico; cathartic; Merck Index 14, 5662; CAS: 7786-30-3; DCB: 02399; NCM: 2827.31.90; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

cloreto de potássio; *potassium chloride*; chloropotassuril; repositor de eletrólitos; electrolyte replenisher; Merck Index 14, 7621; CAS: 7447-40-7; DCB: 02415; NCM: 3104.20.90; TEC: 0%; **Bra:** Caq, Quimibrás, Vetec

cloreto de sódio; *sodium chloride*; common salt; repositor de eletrólitos, emético e anti-inflamatório tópico; electrolyte replenisher, emetic, topical anti-inflammatory; Merck Index 14, 8599; CAS: 7647-14-5; DCB: 02421; NCM: 2501.00.90; TEC: 4%; **Bra:** Caq, Quimibrás, Vetec

cloreto de tálio (201 Tl); *thallous chloride Tl 201*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 903; CAS: 55172-29-7; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

cloreto férrico; *ferric chloride*; flores martis; adstringente; astringent; Merck Index 14, 4019; CAS: 7705-08-0; DCB: 02431; NCM: 2827.39.96; TEC: 10%; **Bra:** Quimibrás

cloridrato de alfentanila monoidratado; *alfentanil hydrochloride monohydrate*; N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidinyl]-N-phenylpropanamide hydrochloride; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 236; CAS: 70879-28-6; DCB: n.d.; NCM: 2933.33.19; TEC: 2%; **Bra:** Cristália

cloridrato de amiodarona; *amiodarone hydrochloride*; (2-butyl-3-benzofuranyl)[4-[2(diethylamino)ethoxy]-3,5-diiodophenyl]methanone hydrochloride; antiarrítmico e antianginoso; antiarrhythmic (class III), antianginal; Merck Index 14, 482; CAS: 19774-82-4; DCB: 00700; NCM: 2932.99.91; TEC: 14%; **Bra:** Globe, Libbs

cloridrato de anfepramona; *diethylpropion hydrochloride*; amfepramone hydrochloride / 2-(diethylamino)-1-phenyl-1-propanone hydrochloride; anorexígeno; anorexic; Merck Index 14, 3127; CAS: 134-80-5; DCB: 00775; NCM: 2922.31.12; TEC: 2%; **Bra:** Formil, Globe

cloridrato de articaína; *articaine hydrochloride*; methyl-3-[[1-oxo-2-(propylamino)-propyl]amino]-2-thiophenecarboxylic acid methyl ester hydrochloride / carticaine hydrochloride; anestésico; anesthetic (local); Merck Index 14, 1869; CAS: 23964-57-0; DCB: 00891; NCM: 2934.99.99; TEC: 2%; **Bra:** Nortec Química

cloridrato de benzetimida; *benzetimide hydrochloride*; 3-phenyl-1-(phenylmethyl)-[3,4-biperidine]-2,6-dione hydrochloride; anticolinérgico; anticholinergic; Merck Index 14, 1075; CAS: 5633-14-7; DCB: 01136; NCM: 2933.39.81; TEC: 14%; **Bra:** Formil

cloridrato de bupivacaína; *bupivacaine hydrochloride*; Dl-1-butyl-2,6-pipecoloxylidide hydrochloride; anestésico local; anesthetic (local); Merck Index 14, 1495; CAS: 18010-40-7; DCB: 01552; NCM: 2933.39.83; TEC: 14%; **Bra:** Nortec Química

cloridrato de bupropiona; *bupropion hydrochloride*; 1-(3-chlorophenyl)-2-[1,1-dimethylethyl)amino]-1-propanone hydrochloride; anoréxico; anorexic; Merck Index 14, 1499; CAS: 31677-93-7; DCB: 01558; NCM: 2922.39.90; TEC: 2%; **Bra:** Globe

cloridrato de cefepima; *cefepime hydrochloride*; 1-[[(6R,7R)-7-[[(2Z)-(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methylpyrrolidinium inner salt hydrochloride; antibacteriano (antibiótico); antibacterial; Index Merck 14, 1922; CAS: 123171-59-5; DCB: 01856; NCM: 2941.90.39; TEC: 2%; **Bra:** ABL

cloridrato de clembuterol; *clembuterol hydrochloride*; 4-amino-3,5-dichloro-alpha-[[(1,1-dimethylethyl)-amino]methyl]benzenemethanol hydrochloride; antiasmático / broncodilatador; bronchodilator; Merck Index 14, 2347; CAS: 21898-19-1; DCB: 02210; NCM: 2922.19.93; TEC: 14%; **Arg:** Sindrofar

cloridrato de cocaína; *cocaine hydrochloride*; 2-beta-carbomethoxy-3 betabenzoxytropane hydrochloride; anestésico local; anesthetic (local); Merck Index 14, 2455; CAS: 53-21-4; DCB: n.d.; NCM: 2939.91.11; TEC: 2%; **Arg:** Verardo

cloridrato de codeína; *codeine hydrochloride*; (5alpha,6alpha)-7,8-didehydro-4,5-epoxy-3-methoxy-17-methylmorphinan-6-ol hydrochloride; analgésico narcótico e antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 2463; CAS: 1422-07-7; DCB: 02554; NCM: 2939.11.22; TEC: 12%; **Arg:** Verardo

cloridrato de dextrobupivacaína; *dextrobupivacaine hydrochloride*; D-1-butyl-2,6-pipecoloxylidide hydrochloride; anestésico local; anesthetic local; Index Merck 14, 1495; CAS: 27262-45-9; DCB: n.d.; NCM: 2933.39.89; TEC: 14%; **Bra:** Cristália

cloridrato de dextrocetamina; *dextrocetamine hydrochoride*; (S)-2-(2-chlorophenyl)-2-(methylamino)-cyclo-hexanone hydrochloride; anestésico geral; anesthetic; APDS vol. 6, 297; CAS: 33795-24-3; DCB: n.d.; NCM: 2922.39.21; TEC: 12%; **Bra:** Cristália

cloridrato de dietilpropiona; *diethylpropione hydrochloride*; veja cloridrato de anfepramona; *see amfepramone hydrochloride*

cloridrato de efedrina; *ephedrine hydrochloride*; (alphaR)-alpha-[(1S)-1-(methylamino)ethyl]benzenemethanol hydrochloride; broncodilatador; bronchodilator; Merck Index 14, 3608; CAS: 50-98-6; DCB: 03310; NCM: 2939.41.00; TEC: 2%; **Bra:** Nortec Química

cloridrato de etafedrina; *etafedrine hydrochloride*; alfa-[1-(ethylmethylamino)ethyl]benzenemethanol hydrochloride; adrenérgico, broncodilatador; adrenergic, bronchodilator; Merck Index 14, 3709; CAS: 5591-29-7; DCB: 03638; NCM: 2939.49.00; TEC: 2%; **Bra:** Nortec Química

cloridrato de etilmorfina di-hidratado; *ethylmorphine hydrochloride dihydrate*; 7,8-didehydro-4,5-epoxy-3-ethoxy-17-methylmorphinan-6-ol hydrochloride dihydrate; analgésico narcótico / antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 3830; CAS: 6746-59-4; DCB: 03690; NCM: 2939.11.31; TEC: 2%; **Arg:** Verardo

cloridrato de femproporex; *fenproporex hydrochloride*; (+/-)-3-[(1-methyl-2-phenylethyl)-amino]propanenitrile hydrochloride; anoréxico; anorexic; Merck Index 14, 3994; CAS: 18305-29-8; DCB: 03849; NCM: 2926.30.12; TEC: 2%; **Bra:** Formil

cloridrato de fenilefrina; *phenylephrine hydrochloride*; L-1-(m-hydroxyphenyl)-2-methylaminoethanol hydrochloride; descongestionante e midriático; decongestant, mydriatic; Merck Index 14, 7286; CAS: 61-76-7; DCB: 03926; NCM: 2922.50.11; TEC: 2%; **Bra:** Nortec Química

cloridrato de glicinato de tianfenicol; *thianphenicol glycinate hydrochloride*; [R-(R-R)-2,2-dichloro-N-2-[hydroxy-1-(hydroxymethyl)-2-[4-(methyl-sulfonyl)phenyl]ethyl]acetamide glycinate hydrochloride; antibiótico; antibacterial; Merck Index 14, 9301; CAS: 2611-61-2; DCB: 08524; NCM: 2941.40.90; TEC: 2%; **Bra:** Globe

cloridrato de hidrocodona; *hydrocodone hydrochloride*; dihydrocodeinone hydrochloride; analgésico narcótico / antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 4785; CAS: 25968-91-6; DCB: 04656; NCM: 2939.11.52; TEC: 2%; **Arg:** Verardo

cloridrato de hidroxocobalamina; *hydroxocobalamin hydrochloride*; alpha-(5,6-dimethylbenzimidazolyl)-hydroxocobamide hydrochloride; vitamínico; vitamin (hematopoietic); Merck Index 14, 4809; CAS: 58288-50-9; DCB: 04721; NCM: 2936.26.30; TEC: 14%; **Arg:** Bagó

cloridrato de isometepteno; *isometheptene hydrochloride*; N,6-dimethyl-5-hepten-2-amine hydrochloride; adrenérgico; adrenergic; Merck Index 14, 5185; CAS: 6168-86-1; DCB: 05090; NCM: 2921.19.99; TEC: 2%; **Bra:** Nortec Química

cloridrato de levobupivacaína; *levobupivacaine hydrochloride*; L-1-butyl-2,6-pipecoloxylidide hydrochloride; anestésico local; anesthetic local; Merck Index 14, 1495; CAS: 27262-48-2; DCB: 02458; NCM: 2933.39.89; TEC: 14%; **Bra:** Cristália

cloridrato de lidocaína; *lidocaine hydrochloride*; 2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride; anestésico local / antiarrítmico; anesthetic (local), antiarrhythmic (class IB); Merck Index 14, 5482; CAS: 73-78-9; DCB: 05314; NCM: 2924.29.14; TEC: 14%; **Bra:** Nortec Química

cloridrato de liotironina; *liothyronine hydrochloride*; 0-(4-hydroxy-3-iodophenyl)-3,5-diiodotyrosine hydrochloride; hormônio da tiróide; thyroid hormone; Merck Index 14, 5510; CAS: 6138-47-2; DCB: 05335; NCM: 2937.90.90; TEC: 2%; **Arg:** Tolbiac

cloridrato de maprotilina; *maprotiline hydrochloride*; 1-(3-methylaminopropyl)-dibenzo(b,e)-bicyclo-(2.2.2)-octadiene hydrochloride; antidepressivo; antidepressant; Merck Index 14, 5748; CAS: 10347-81-6; DCB: 05499; NCM: 2921.49.90; TEC: 2%; **Bra:** Novartis •

cloridrato de mepivacaína; *mepivacaine hydrochloride*; N-(2,6-dimethylphenyl)-1-methyl-2-piperidinecarboxamide hydrochloride; anestésico local; anesthetic (local); Merck Index 14, 5859; CAS: 1722-62-9; DCB: 05657; NCM: 2933.39.82; TEC: 14%; **Bra:** Nortec Química

cloridrato de midazolam; *midazolam hydrochloride*; 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-alfa][1,4]benzodiazepine hydrochloride; anestésico intravenoso; anesthetic intravenous; Merck Index 14, 6182; CAS: 59467-96-8; DCB: 05938; NCM: 2933.91.53; TEC: 2%; **Bra:** Alpha Br, Formil, Nortec Química

cloridrato de morfina; *morphine hydrochloride*; (5alpha,6alpha)-7,8-didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol hydrochloride; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 6276; CAS: 52-26-6; DCB: 06095; NCM: 2939.11.62; TEC: 2%; **Arg:** Verardo; **Bra:** Diosynth

cloridrato de moxifloxacino; *moxifloxacin hydrochloride*; 1-ciclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[(4aS,7aS)-octaoctahydro-6H-pyrrolo [3,4-b]pyridin-6-yl]-4-oxo-3-quinoline carboxylic acid hydrochloride; antibacteriano; antibacterial; Merck Index 14, 6291; CAS: 186826-86-8; DCB: 06140; NCM: 2933.59.19; TEC: 2%; **Bra:** ITF

cloridrato de oxicodona; *oxycodone hydrochloride*; dihydrohydroxycodeinone hydrochloride; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 6959; CAS: 124-90-3; DCB: 06718; NCM: 2939.11.81; TEC: 2%; **Arg:** Verardo

cloridrato de paroxetina; *paroxetine hydrochloride*; (3S trans)-3-[(1,3-benzodioxol-5-yl-oxy)methyl]-4-(4-fluorophenyl)piperidine hydrochloride; antidepressivo; antidepressant; Merck Index 14, 7043; CAS: 110429-35-1; DCB: 06859; NCM: 2934.99.99; TEC: 2%; **Bra:** ITF, Libbs

cloridrato de petidina; *pethidine hydrochloride*; meperidine hydrochloride / 1-methyl-4-phenyl-4-piperidinecarboxylic acid ethyl ester hydrochloride; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 5849; CAS: 50-13-5; DCB: 07008; NCM: 2933.33.84; TEC: 14%; **Bra:** Cristália

cloridrato de pilocarpina; *pilocarpine hydrochloride*; (3S-cis)-3-ethyldihydro-4-[(1-methyl-1H-imidazol-5-yl)methyl]-2-(3H)-furanone hydrochloride; anticolinérgico oftálmico e antiglaucoma; antiglaucoma agent, miotic; Merck Index 14, 7424; CAS: 54-71-7; DCB: 07050; NCM: 2939.99.31; TEC: 14%; **Bra:** Sourcetech, Vegeflora

cloridrato de piperidolato; *piperidolate hydrochloride*; alpha-phenylbenzeneacetic acid 1-ethyl-3-piperidinyl éster hydrochloride; antiespasmódico; antispamodic; Index Merck 14, 7470; CAS: 129-77-1; DCB: 07107; NCM:2933.39.99; TEC: 2%; **Bra:** Nortec Química

cloridrato de pramocaína; *pramocaine hydrochloride*; veja cloridrato de pramoxina; *see pramoxine hydrochloride*

cloridrato de pramoxina; *pramoxine hydrochloride*; 4-[3-(4-butoxyphenoxy)propyl]morfoline hydrochloride / pramocaine hydrochloride; anestésico local; anesthetic (local); Merck Index 14, 7709; CAS: 637-58-1; DCB: 07304; NCM: 2934.99.99; TEC: 2%; **Bra:** Nortec Química

cloridrato de prilocaína; *prilocaine hydrochloride*; N-(2-methylphenyl)-2-(propylamino)-propanamide hydrochloride; anestésico local; anesthetic (local); Merck Index 14, 7743; CAS: 1786-81-8; DCB: 07364; NCM: 2924.29.63; TEC: 14%; **Bra:** Nortec Química

cloridrato de propranolol; *propranolol hydrochloride*; 1-[(1-methylethyl) amino]-3-(1-naphthalenyloxy)-2-propanol hydrochloride; antiarrítmico, antianginoso e anti-hipertensivo; antihypertensive, antianginal, antiarrhythmic (class II); Merck Index 14, 7840; CAS: 318-98-9; DCB: 07482; NCM: 2922.50.50; TEC: 12%; **Bra:** Globe

cloridrato de pseudoefedrina; *pseudoephedrine hydrochloride*; (alphaS)-alpha-[(1S)-1-(methylamino)ethyl]benzene methanol hydrochloride; descongestionante nasal; decongestant (nasal); Merck Index 14, 7916; CAS: 345-78-8; DCB: 07520; NCM: 2939.42.00; TEC: 2%; **Bra:** Nortec Química

cloridrato de ropivacaina; *ropivacaine hydrochloride*; (2S)-N-(2,6-dimethyl-phenyl)-1-propyl-2-piperidine carboxamide; anestésico local; anesthetic (local); Merck Index 14, 8258; CAS: 98717-15-8; DCB: 07805; NCM: 2933.39.89; TEC: 2%; **Bra:** Cristalia

cloridrato de sevelâmer; *sevelamer hydrochloride*; 2-propen-1-amine polymer with (chloromethyl) oxirane hydrochloride; anti-hiperfosfatêmico; antihyperphosphatemic; Merck Index 14, 8474; CAS: 182683-00-7; DCB: 07973; NCM: 2922.50.99; TEC: 2%; **Bra:** ITF

cloridrato de sibutramina; *sibutramine hydrochloride*; 1-(4-chlorophenyl)-N,N-dimethyl-alfa-(2-methyl-propyl)-cyclobutanemethanamine hydrochloride; anoréxico, antidepressivo; anorexic, antidepressant; Merck Index 14, 8485; CAS: 125494-59-9; DCB: 09375; NCM: 2921.19.99; TEC: 2%; **Bra:** Globe

cloridrato de ticlopidina; *ticlopidine hydrochloride*; 5-[(2-chlorophenyl)methyl]-4,5,6,7-tetrahydrothieno-[3,2-c]-pyridine hydrochloride; antiagregante plaquetário (cardiologia); antithrombotic; Merck Index 14, 9429; CAS: 53885-35-1; DCB: 08551; NCM: 2934.99.99; TEC: 2%; **Bra:** Globe

cloridrato de tramadol; *tramadol hydrochloride*; (1R,2R)-rel-2-[(dimethylamino)-methyl]-1-(3-methoxyphenyl)cyclohexanol hydrochloride; analgésico; analgesic; Merck Index 14, 9566; CAS: 22204-88-2; DCB: 08807; NCM: 2922.50.99; TEC: 2%; **Bra:** Globe

cloridrato de venlafaxina; *venlafaxine hydrochloride*; (+)-1-[alpha-[(dimethylamino)-methyl]-p-methoxybenzyl]cyclohexanol hydrochloride; antidepressivo; antidepressant; Merck Index 14, 9946; CAS: 99300-78-4; DCB: 09113; NCM: 2915.90.90; TEC: 2%; **Arg:** Gador

cloroidróxido de alumínio; *aluminum hydroxychloride*; basic aluminum chloride; adstringente e antiperspirante; astringent, antiperspirant; Merck Index 14, 343; CAS: 1327-41-9; DCB: n.d.; NCM: 2827.49.21; TEC: 10%; **Bra:** Quimibrás

closantel; *closantel*; N-[5-chloro-4-[chlorophenyl)cyanomethyl]-2-methylphenyl]-2-hydroxy-3,5-diiodo benzamide; anti-helmíntico, em veterinária; anthelmintic in vet; Merck Index 14, 2411; CAS: 57808-65-8; DCB: 02517; NCM: 2926.90.93; TEC: 14%; **Arg:** Aca

cloxazolam; *cloxazolam*; 10-chloro-11b-(2-chlorophenyl)-2,3,7,11b-tetrahydroxazole[3,2-d][1,4]benzodiazepine-6-(5H)-one; ansiolítico; anxiolytic; Merck Index 14, 2420; CAS: 24166-13-0; DCB: 02535; NCM: 2934.91.22; TEC: 12%; **Arg:** Maprimed; **Bra:** Alpha Br, Formil, Novartis •

clozapina; *clozapine*; 8-chloro-11-(4-methyl-1-piperazinyl)-5H-dibenzo [b,e][1,4]diazepine; antipsicótico; antipsychotic; Merck Index 14, 2423; CAS: 5786-21-0; DCB: 02540; NCM: 2933.99.39; TEC: 2%; **Bra:** CYG Biotech

codeína; *codeine*; (5alpha,6alpha)-7,8-didehydro-4,5-epoxy-3-methoxy-17-methylmorphinan-6-ol; analgésico (narcótico) e antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 2463; CAS: 76-57-3; DCB: 02545; NCM: 2939.11.22; TEC: 12%; **Arg:** Verardo; **Bra:** Diosynth

corantes naturais; *natural dyes*; veja na 2ª parte desta edição (relação de produtores) os corantes naturais produzidos pelas empresas indicadas; *see in the 2nd. part of this book the names of the natural dyes produced by the companies listed*; **Bra:** Centroflora

cromato de sódio (51 Cr); *sodium chromate Cr 51*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 836; CAS: 7775-11-3; DCB: 02634; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

croscarmelose sódica; *croscarmellose sodium*; polymer of sodium carboxymethylcellulose; adjuvante farmacotécnico; pharmaceutic aid; Merck Index 14, 2592; CAS: 74811-65-7; DCB: 02641; NCM: 3912.31.19; TEC: 14%; **Bra:** Blanver

dantroleno sódico hemieptaidratado; *dantrolene sodium hemiheptahydrate*; 1-[[[5-(4-nitrophenyl)-2-furanyl]-methylene]amino]-2,4-imidazolidinedione sodium salt; relaxante muscular; muscle relaxant (skeletal); Merck Index 14, 2816; CAS: 24868-20-0; DCB: n.d.; NCM: 2934.99.99; TEC: 2%; **Bra:** Cristália

dapoxetina; *dapoxetine*; (alfaS)-N,N-dimethyl-alfa-[2-(1-naphthalenyloxy) ethyl]benzenemethanamine; antidepressivo; antidepressive; Merck Index 14, 2821; CAS: 119356-77-3; DCB: 02685; NCM: 2922.19.99; TEC: 2%; **Arg:** Triquim

DDI (didanosina); *DDI (dideoxyinosine)*; didanosine / 2,3-dideoxyinosine; antiviral; antiviral; Merck Index 14, 3098; CAS: 69655-05-6; DCB: 02948; NCM: 2934.99.39; TEC: 2%; **Bra:** CYG Biotech, Globe, Nortec Química

decanoato de flufenazina; *fluphenazine decanoate*; 4-[3-[2-trifluoromethyl)-10H-phenothiazin-10-yl]propyl]-1-1-piperazineethanol decanoate; antipsicótico; antipsychotic; Merck Index 14, 4189; CAS: 5002-47-1; DCB: 04123; NCM: 2934.30.90; TEC: 2%; **Bra:** Cristália

decanoato de haloperidol; *haloperidol decanoate*; 4-[4-chlorophenyl)-4-hydroxy-1-piperidinyl]-1-(4-fluorophenyl)-1-butanone decanoate; antipsicótico; antipsychotic; Merck Index 14, 4598; CAS: 74050-97-8; DCB: 04591; NCM: 2933.39.19; TEC: 2%; **Bra:** Cristália

desogestrel; *desogestrel*; (17alpha)-13-ethyl-11-methylene-18-19-dinorpregn-4-en-20-yn-17-ol; hormônio; hormone; Merck Index 14, 2926; CAS: 54024-22-5; DCB: 02795; NCM: 2937.23.60; TEC: 12%; **Bra:** Diosynth •, Libbs

dextrorrazoxano; *dexrazoxane*; (+)-4,4-(1-methyl-1,2-ethanediyl)bis-2,6-piperazinedione; cardioprotetor; cardioprotectant; Merck Index 14, 8123; CAS: 24584-09-6; DCB: 02860; NCM: 2933.59.99; TEC: 2%; **Arg:** Tolbiac, Triquim

diazepam; *diazepam*; 7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one; ansiolítico e relaxante muscular; anxiolytic, muscle relaxant (skeletal); Merck Index 14, 2994; CAS: 439-14-5; DCB: 02904; NCM: 2933.91.22; TEC: 14%; **Bra:** Globe

diclofenaco; *diclofenac acid*; 2-[(2,6-dichlorophenyl)amino]benzeneacetic acid; anti-inflamatório, antirreumático e analgésico; anti-inflammatory; Merck Index 14, 3081; CAS: 15307-86-5; DCB: 02926; NCM: 2922.49.64; TEC: 14%; **Bra:** Nortec Química, Novartis •

diclofenaco colestiramina; *diclofenac cholestyramin*; 2-[(2,6-dichlorophenyl)amino]benzeneacetate of cholestyrammonium; anti-inflamatório, antirreumático e analgésico; anti-inflammatory; DEF 2005/2006, pág. 105; CAS: 240490-15-7; DCB: 02931; NCM: 2922.49.69; TEC: 2%; **Arg:** Triquim; **Bra:** Nortec Química, Novartis •

diclofenaco colestiramônio; *diclofenac cholestyrammonium*; veja diclofenaco colestiramina; *see diclofenac colestyramine*

diclofenaco dietilamônio; *diclofenac diethylammonium*; 2-[(2,6-dichlorophenyl)amino]benzeneacetate diethylammonium; anti-inflamatório, antirreumático e analgésico; anti-inflammatory; Merck Index 14, 3081; CAS: 78213-16-8; DCB: 02927; NCM: 2922.49.63; TEC: 14%; **Arg:** Triquim; **Bra:** Nortec Química, Novartis •

diclofenaco epolamina; *diclofenac epolamine*; diclofenac hydroxyethylpyrrolidine; anti-inflamatório; anti-inflammatory; Martindale 36ª ed., pág 44; CAS: 119623-66-4; DCB: 02928; NCM: 2933.99.49; TEC: 2%; **Arg:** Triquim

diclofenaco potássico; *diclofenac potassium*; 2-[(2,6-dichlorophenyl) amino]benzeneacetate acid potassium salt; anti-inflamatório, antirreumático e analgésico; anti-inflammatory; Merck Index 14, 3081; CAS: 15307-81-0; DCB: 02929; NCM: 2922.49.62; TEC: 14%; **Bra:** Nortec Química, Novartis •

diclofenaco sódico; *diclofenac sodium*; 2-[(2,6-dichlorophenyl)amino] benzeneacetic acid monosodium salt; anti-inflamatório, antirreumático e analgésico; anti-inflammatory; Merck Index 14, 3081; CAS: 15307-79-6; DCB: 02930; NCM: 2922.49.61; TEC: 14%; **Arg:** Bagó; **Bra:** Nortec Química, Novartis •

dicloridrato de mitoxantrona; *mitoxantrone dihydrochloride*; 1,4-dihydroxy-5,8-bis[[2-[(2-hydroxyethyl)amino]ethyl]amino]-9,10-anthracenedione dihydrochloride; antineoplásico; antineoplastic; Merck Index 14, 6217; CAS: 70476-82-3; DCB: 06023; NCM: 2922.50.99; TEC: 2%; **Bra:** Quiral

didanosina; *didanosine*; DDI, 2.3 – dideoxyiosine; antiviral; antiviral; Merck Index 14, 3098; CAS: 69655-05-6; DCB: 02948; NCM: 2934.99.39; TEC: 2%; **Bra:** CYG Biotech, Globe, Nortec Química

diflubenzurona; *diflubenzuron*; N-[[4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide; larvicida; insecticide; Merck Index 14, 3142; CAS: 35367-38-5; DCB: n.d.; NCM: 2924.29.92; TEC: 2%; **Bra:** Champion

disofenol; *disophenol*; 2,6-diiodo-4-nitrophenol; anti-helmíntico em veterinária; anthelmintic (hookworm) in vet; Merck Index 14, 3359; CAS: 305-85-1; DCB: n.d.; NCM: 2908.99.21; TEC: 14%; **Bra:** Champion

docetaxel; *docetaxel anhydrous*; N-debenzoyl-N-(tert-butoxycarbonyl)-10-deacetyltaxol; antineoplásico; antineoplastic; Merck Index 14, 3397; CAS: 114977-28-5; DCB: 03167; NCM: 2932.99.99; TEC: 2%; **Bra:** Quiral

doxazosina; *doxazosin*; 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-[(2,3-dihydro-1,4-benzodioxin-2-yl)carbonyl]piperazine; anti-hipertensivo, no tratamento da hipertrofia prostática benigna; antihypertensive, in treatment of benign prostatic hypertrophy; Merck Index 14, 3433; CAS: 74191-85-8; DCB: 03209; NCM: 2934.99.39; TEC: 2%; **Bra:** ITF

dronedarona; *dronedarone*; N-[butyl-3-[4-[3-(dibutylamino)propoxy]benzoyl]-5-benzofuranyl]methanesulfonamide; antiarrítmico (classe III); antiarrhythmic (class III); Merck Index 14, 3449; CAS: 141626-36-0; DCB: 09663; NCM: 2935.00.99; TEC: 2%; **Arg:** Maprimed

droperidol; *droperidol*; 1-[1-[4(4-fluorophenyl)-4-oxobutyl]-1,2,3,6-tetrahydro-4-piridinyl]-1,3-dihydro-2H-benzimidazol-2-one; antipsicótico; antipsycotic; Merck Index 14, 3450; CAS: 548-73-2; DCB: 03246; NCM: 2933.39.12; TEC: 12%; **Bra:** Cristália

edetato crômico (51 Cr): *EDTA 51 Cr*; chromium Cr 51 edetate; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 207; CAS: 27849-89-4; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

edetato de potássio; *edetate dipotassium*; ethylenediamine tetracetic acid dipotassium salt; agente quelante; pharmaceutic aid (chelating agent); Merck Index 14, 3517; CAS: 25102-12-9; DCB: 00170; NCM: 2922.49.20; TEC: 12%; **Bra:** Vetec

edotreotida (177 Lu): DOTA octreotato 177 Lu; *edotreotide 177 Lu*; agente radioativo; radioactive agent; Merck Index 14, 3513; CAS: 204318-14-9; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

efavirenz; *efavirenz*; (4S)-6-chloro-4-(cyclopropylethynyl)-1,4-dihydro-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one; antiviral; antiviral; Merck Index 14, 3521; CAS: 154598-52-4; DCB: 03308; NCM: 2933.39.99; TEC: 2%; **Bra:** Cristália, CYG Biotech, Globe, Nortec Química

embonato de imipramina; *imipramine pamoate*; 10,11-dihydro-N-N-dimethyl-5H-dibenz(b,f)azepin-5-propanamine pamoate; antidepressivo; antidepressant; Merck Index 14, 4920; CAS: 10075-24-8; DCB: 04838; NCM: 2933.99.39; TEC: 2%; **Bra:** Novartis •

enantato de flufenazina; *fluphenazine enanthate*; 4-[3-[2(trifluoromethyl)-10H-phenothiazin-10-yl]propyl]-1-1-piperazineethanol enanthate; antipsicótico; antipsychotic; Merck Index 14, 4189; CAS: 2746-81-8; DCB: 04126; NCM: 2934.30.20; TEC: 12%; **Bra:** Cristália

enrofloxacino; *enrofloxacin*; 1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid; antibacteriano; antibacterial; Merck Index 14, 3592; CAS: 93106-60-6; DCB: 03412; NCM: 2933.59.15; TEC: 12%; **Arg:** Aca

eritropoietina humana recombinante; *human erythropoietin recombinant*, hemopoietine; hematínico; hematinic; Merck Index 14, 3688; CAS: 11096-26-7; DCB: 03498; NCM: 3001.20.90; TEC: 6%; **Arg:** Bio Sidus

espironolactona; *spironolactone*; (7alpha,17alpha)-7-(acetylthyo)-17-hydroxy-3-oxopregn-4-ene-21-carboxylic acid gamma lactone; diurético; diuretic; Merck Index 14, 8760; CAS: 52-01-7; DCB: 03561; NCM: 2937.29.50; TEC: 14%; **Bra:** Nortec Química

estavudina; *stavudine*; 2,3-didehydro-3-deoxythimidine / D4T; anti-HIV; antiviral; Merck Index 14, 8803; CAS: 3056-17-5; DCB: 03574; NCM: 2934.99.27; TEC: 12%; **Bra:** Nortec Química

estearato de cálcio; *calcium stearate*; octadecanoic acid calcium salt; adjuvante farmacotécnico na fabricação de comprimidos; pharmaceutic aid; Merck Index 14, 1703; CAS: 1592-23-0; DCB: 03576; NCM: 2915.70.39; TEC: 12%; **Bra:** Quimibrás

estearato de magnésio; *magnesium stearate*; octadecanoic acid magnesium salt; adjuvante farmacotécnico na fabricação de comprimidos; pharmaceutic aid (tablets lubricant); Merck Index 14, 5690; CAS: 557-04-0; DCB: 03577; NCM: 2915.70.39; TEC: 12%; **Bra:** Quimibrás

estearato de sorbitana; *sorbitan monostearate*; sorbitan monostearate; adjuvante farmacotécnico; pharmaceutic aid (surfactant); Merck Index 14, 8724; CAS: 1338-41-6; DCB: 03580; NCM: 3824.90.89; TEC: 14%; **Bra:** Croda

esteviosídeo; *stevioside*; 4alpha-13-[(2-0-beta-D-glucopyranosyl-beta-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid beta-D-glucopyranosyl ester; adoçante natural; non-nutritive sweetener agent; Merck Index 14, 8810; CAS: 57817-89-7; DCB: n.d.; NCM: 2938.90.20; TEC: 14%; **Bra:** Steviafarma

estradiol; *estradiol*; (17beta)-estra-1,3,5(10)-triene-3,17-diol; estrogênio; estrogen; Merck Index 14, 3703; CAS: 50-28-2; DCB: 03595; NCM: 2937.23.49; TEC: 2%; **Bra:** Diosynth ●

estriol; *estriol*; (16alfa,17beta)-estra-1,3,5(10)-triene-3,16,17-triol; estrogênio; estrogen; Merck Index 14, 3707; CAS: 50-27-1; DCB: 09436; NCM: 2937.23.31; TEC: 12%; **Bra:** Diosynth ●

eszopiclona; *eszopiclone*; 1-piperazinecarboxylic acid, 4-methyl-(5S)-6-(5-chloro-2-pyridinyl)-6,7-dihydro-7-oxo-5H-pyrrolo[3,4-b]pyrazin-5-yl ester; no tratamento da insônia; treatment of insonnia; USP Dictionary 2009, pág. 358; CAS: 138729-47-2; DCB: n.d.; NCM: 2933.59.19; TEC: 2%; **Arg:** Maprimed

éter etílico; *sulfuric ether*; ethyl ether; anestésico; anesthetic (inhalation); Merck Index 14, 3806; CAS: 60-29-7; DCB: 03663; NCM: 2909.11.00; TEC: 12%; **Bra:** Quimibrás

etidronato de sódio; *etidronate disodium*; (1-hydroxyethylidene)bisphosphonic acid disodium salt; regulador de cálcio; calcium regulator; Merck Index 14, 3863; CAS: 7414-83-7; DCB: n.d.; NCM: 2931.90.33; TEC: 14%; **Arg:** Gador

etinilestradiol; *ethinyl estradiol*; (17alfa)-19-norpregna-1,3,5(10)-trien-20-yne-3,17-diol; estrogênio, em combinação com progesterona como anticonceptivo; estrogen, in combination with progestogen as oral contraceptive; Merck Index 14, 3734; CAS: 57-63-6; DCB: 03699; NCM: 2937.23.49; TEC: 2%; **Bra:** Libbs

etomidato; *etomidate*; (R)-1-(1-phenylethyl)-1H-imidazole-5-carboxylic acid ethyl ester; hipnótico; hypnotic; Merck Index 14, 3881; CAS: 33125-97-2; DCB: 03731; NCM: 2933.21.90; TEC: 2%; **Bra:** Cristália

extratos opoterápicos; animal extracts; veja produtos opoterápicos; *see animal products*

extratos vegetais; *vegetal extracts*; veja na 2ª parte desta edição (relação de produtores) os extratos vegetais produzidos pelas empresas indicadas; *see in the 2nd. part of this book the names of the vegetal extracts produced by the companies listed*; NCM: 1302.1; TEC: 8%; **Bra:** Catedral, Centroflora

fenitoína (difenilidantoína); *phenytoin*; 5,5-diphenyl-2,4-imidazolidinedione / diphenylhydantoin; anticonvulsivante e antiepiléptico; anticonvulsant, antiepileptic; Merck Index 14, 7322; CAS: 57-41-0; DCB: 03953; NCM: 2933.21.21; TEC: 14%; **Bra:** Nortec Química

fenitoína sódica; *phenytoin sodium*; 5,5-diphenyl-2,4-imidazolidinedione sodium salt / diphenylhydantoin sodium; anticonvulsivante e antiepiléptico; anticonvulsant, antiepileptic; Merck Index 14, 7322; CAS: 630-93-3; DCB: 03954; NCM: 2933.21.21; TEC: 14%; **Bra:** Nortec Química

fenobarbital; *phenobarbital*; 5-ethyl-5-phenyl-2,4,6(1H,3H,5H)-pyrimidinetrione; anticonvulsivante, sedativo e hipnótico; anticonvulsant, sedative, hipnotic; Merck Index 14, 7238; CAS: 50-06-6; DCB: 03960; NCM: 2933.53.40; TEC: 14%; **Bra:** Nortec Química

fenobarbital sódico; *phenobarbital sodium*; 5-ethyl-5-phenyl-2,4,6 (1H,3H,5H)-pyriminetrione sodium; anticonvulsivante, sedativo e hipnótico; anticonvulsant, sedative, hipnotic; Merck Index 14, 7238; CAS: 57-30-7; DCB: 03962; NCM: 2933.53.40; TEC: 14%; **Bra:** Nortec Química

fentanila; *fentanyl*; N-phenyl-N-[1-(2-phenyl-ethyl)-4-piperidinyl]propanamide; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 4001; CAS: 437-38-7; DCB: 04004; NCM: 2933.33.63; TEC: 2%; **Arg:** Triquim; **Bra:** Cristalia

ferrolate; *ferrolat*; ferroprotein succinylate / ferrosuccinyl caseine; hematínico; hematinic; reference not informed; CAS: n.d.; DCB: n.d.; NCM: 3501.90.19; TEC: 14%; **Bra:** ITF

filgrastim; *filgrastin*; granulocyte colonystimulating factor; estimulante hematopoiético e antineutropênico; hematopoietic, stimulant, antineutropenic; Merck Index 14, 4537; CAS: 121181-53-1; DCB: 04052; NCM: 3001.20.90; TEC: 6%; **Arg:** Bio Sidus

fludesoxiglicose (18 F): FDG 18 F; *fludeoxyglucose (18 F)*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 397; CAS: 105851-17-0; DCB: 04114; NCM: 2844.40.90; TEC: 2%; **Bra:** IEN, IPEN

flumazenil; *flumazenil*; 8-fluoro-5,6-dihydro-5-methyl-6-oxo-4H-imidazo[1,5-a][1,4]benzodiazepine-3-carboxylic acid ethyl ester; antagonista benzodiazepínico; benzodiazepine antagonist; Merck Index 14, 4135; CAS: 78755-81-4; DCB: 04134; NCM: 2933.99.20; TEC: 2%; **Bra:** Formil

fluoreto de potássio; *potassium fluoride*; potassium fluoride; fonte de flúor; fluor source; Merck Index 14, 7632; CAS: 7789-23-3; DCB: 09443; NCM: 2826.19.90; TEC: 10%; **Bra:** Quimibras

fluoreto de sódio; *sodium fluoride*; sodium fluoride; na osteoporose e na prevenção das cáries; in treatment of osteoporosis; Merck Index 14, 8618; CAS: 7681-49-4; DCB: 04170; NCM: 2826.19.90; TEC: 10%; **Bra:** Caq, Quimibras

fluoreto de sódio (18 F); *sodium fluoride F 18*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 837; CAS: 22554-99-0; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

flurazepam; *flurazepam*; 7-chloro-1-[2-(diethylamino)ethyl]-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; sedativo e hipnótico; sedative, hypnotic; Merck Index 14, 4198; CAS: 17617-23-1; DCB: 04206; NCM: 2933.91.33; TEC: 2%; **Bra:** Nortec Química

flutamida; *flutamide*; 2-methyl-N-[4-nitro-3-(trifluoromethyl)phenyl] propanamide; antiandrogênico (hormonal) e antineoplásico; antiandrogen, antineoplastic; Merck Index 14, 4208; CAS: 13311-84-7; DCB: 04220; NCM: 2924.29.62; TEC: 14%; **Arg:** Triquim

folcodina; *pholcodine*; beta-morpholinyl ethylmorfine; antitussígeno; antitussive; Merck Index 14, 7329; CAS: 509-67-1; DCB: 04239; NCM: 2939.11.40; TEC: 2%; **Arg:** Verardo

fosfatidilserina; *phosphatidylserine*; phosphatidylserine 50%; em síndromes demenciais; in dementia syndrome; Martindale; CAS: n.d.; DCB: 04276; NCM: 2923.20.00; TEC: 12%; **Bra:** ITF

fosfato de cálcio dibásico; *calcium phosphate dibasic*; calcium dihydrogen phosphate; fonte de cálcio; calcium replenisher; Merck Index 14, 1692; CAS: 7757-93-9; DCB: 00201; NCM: 2835.25.00; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

fosfato de cálcio monobásico; *calcium phosphate monobasic*; calcium monohydrogen phosphate; fonte de cálcio; calcium replenisher; Merck Index 14, 1693; CAS: 7758-23-8; DCB: 00202; NCM: 2835.26.00; TEC: 10%; **Bra:** Caq

fosfato de cálcio tribásico; *calcium phosphate tribasic*; tricalcium orthophosphate; fonte de cálcio; calcium replenisher; Merck Index 14, 1694; CAS: 12167-74-7; DCB: 00203; NCM: 2835.26.00; TEC: 10%; **Bra:** Caq, Quimibrás

fosfato de carvedilol; *carvedilol phosphate*; 1-(9H-Carbazol-4-yloxy)-3-[[(2-methoxyphenoxy)ethyl]amino]-2-propanol phosphate; anti-hipertensivo, no tratamento da insuficiência cardiaca congestiva; antihypertensive and in treatment of congestive heart failure; USP Dictionary 2009, pág. 179; CAS: 610309-89-2; DCB: n.d.; NCM: 2933.99.99; TEC: 2%; **Arg:** Bagó

fosfato de codeína; *codeine phosphate*; (5alpha,6alpha)-7,8-didehydro-4,5-epoxy-3-methoxy-17-methylmorphinan-6-ol phosphate; analgésico narcótico e antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 2464; CAS: 52-28-8; DCB: 02557; NCM: 2939.11.22; TEC: 12%; **Arg:** Verardo; **Bra:** Diosynth

fosfato de magnésio dibásico; *magnesium phosphate dibasic*; magnesium hydrogen phosphate; catártico; cathartic; Merck Index 14, 5681; CAS: 7757-86-0; DCB: 00204; NCM: 2835.29.90; TEC: 10%; **Bra:** Caq, Quimibrás

fosfato de magnésio tribásico; *magnesium phosphate tribasic*; tertiary magnesium phosphate; antiácido; antacid; Merck Index 14, 5683; CAS: 7757-87-1; DCB: n.d.; NCM: 2835.29.90; TEC: 10%; **Bra:** Caq

fosfato de potássio dibásico; *potassium phosphate dibasic*; dipotassium phosphate; catártico; cathartic; Merck Index 14, 7658; CAS: 7758-11-4; DCB: 00205; NCM: 2835.24.00; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

fosfato de potássio monobásico; *potassium phosphate monobasic*; potassium biphosphate; agente estabilizante; pharmaceutic aid (buffering agent); Merck Index 14, 7659; CAS: 7778-77-0; DCB: 00206; NCM: 2835.24.00; TEC: 10%; **Bra:** Caq, Quimibrás

fosfato de sódio (32 P); *sodium phosphate P 32*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 839; CAS: 7635-46-3; DCB: 04282; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

fosfato de sódio dibásico; *sodium phosphate dibasic*; disodium hydrogen phosphate; catártico; cathartic; Merck Index 14, 8659; CAS: 7558-79-4; DCB: 00207; NCM: 2835.22.00; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

fosfato de sódio monobásico; sodium phosphate monobasic; sodium dihydrogen phosphate; acidificante urinário; urinary acidifier; Merck Index 14, 8660; CAS: 7558-80-7; DCB: 00212; NCM: 2835.22.00; TEC: 10%; **Bra:** Caq, Quimibrás

fosfomicina trometamol; *fosfomycin tromethamine*; (2R-cis)-(3-methyloxiranyl)-phosphonic acid compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1); antibacteriano; antibacterial; Merck Index 14, 4254; CAS: 78964-85-9; DCB: 04292; NCM: 2941.90.99; TEC: 2%; **Bra:** ITF

fumarato de cetotifeno; *ketotifen fumarate*; 4,9-dihydro-4-(1-methyl-4-piperidinylidene)-10H-benzo[4,5]cyclo-heptal[1,2-b]thiophen-10-one hydrogen fumarate; antiasmático; antiasthmatic; Merck Index 14, 5307; CAS: 34580-14-8; DCB: 01968; NCM: 2934.99.99; TEC: 2%; **Bra:** Novartis •

fumarato de fesoterodina; *fesoterodine fumarate*; propanoic acid, 2-methyl-2-[(1R)]-3-[bis(1-methylethyl)amino]-1-phenylpropyl]-4-(hydroxymethyl)phenyl ester, (2E)-2-butenedioate (1:1) salt; no tratamento da bexiga superativada; treatment of overactive bladder; USP Dictionary 2009, pág. 389; CAS: 286930-03-8; DCB: n.d.; NCM: 2934.99.99; TEC: 2%; **Bra:** ITF

fumarato de quetiapina; *quetiapine fumarate*; 2-[2-(4-dibenzo][b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]ethanol fumarate; antipsicótico; antipsychotic; Index Merck 14, 8039; CAS: 111974-72-2; DCB: 07539; NCM:2933.99.39; TEC: 2%; **Bra:** Nortec Química

fumarato de tenofovir disoproxila; *tenofovir disoproxyl fumarate*; 5-[[(1R)-2-(6-amino-purin-9-yl)-1-methylethoxy]methyl]-2,4,6-8-tetraoxa-5-phosphanononanedioic acid bis (1-methylethyl) ester-5-oxide fumarate; antiviral;antiviral; CAS: 202138-50-9; DCB: 08389; NCM: 2933.59.49; TEC: 2%; **Bra:** Globe, Nortec Química

fumarato ferroso; *ferrous fumarate*; ferrous fumarate; hematínico; hematinic; Merck Index 14, 4046; CAS: 141-01-5; DCB: 04336; NCM: 2917.19.30; TEC: 12%; **Bra:** Quimibrás

ganciclovir; *ganciclovir*; 2-amino-1,9-[[2-hydroxy-1-(hydroxymethyl) etoxy]-methyl]-6H-purin-6-one; antiviral; antiviral; Merck Index 14, 4363; CAS: 82410-32-0; DCB: 04394; NCM: 2933.59.49; TEC: 2%; **Bra:** CYG Biotech

gestodeno; *gestodene*; (17alpha)-13-ethyl-17-hydroxy-18,19-dinorpregna-4,15-dien-20-yn-3-one; progestogênio; progestogen; Merck Index 14, 4413; CAS: 60282-87-3; DCB: 04430; NCM: 2937.23.92; TEC: 2%; **Bra:** Libbs

glicolato de amido sódico; *sodium starch glycolate*; sodium starch glycolate; adjuvante farmacotécnico; pharmaceutic aid; NF XVIII, 2238; CAS: 9063-38-1; DCB: 00658; NCM: 3505.10.00; TEC: 14%; **Bra:** Blanver

glutamina (L); *glutamine (L)*; (S)-2-aminoglutaramic acid; protetor do trato gastrointestinal e imunoestimulante; gastro-intestinal protector and immune stimulant; Merck Index 14, 4471; CAS: 56-85-9; DCB: 04518; NCM: 2924.19.99; TEC: 2%; **Bra:** Ajinomoto

gonadotrofina coriônica humana; *HCG (human chorionic gonadotropin)*; princípio estimulante das gônadas; gonad-stimulating principle; Merck Index 14, 2216; CAS: 9002-61-3; DCB: 04527; NCM: 2937.19.20; TEC: 14%; **Bra:** Diosynth ●

haloperidol; *haloperidol*; 4-[4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl]-1-(4-fluorophenyl)-1-butanone; antipsicótico; antipsychotic; Merck Index 14, 4598; CAS: 52-86-8; DCB: 04589; NCM: 2933.39.15; TEC: 2%; **Bra:** Nortec Química

hemifumarato de quetiapina; quetiapine hemifumarate; 2-[2-(4-dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]ethanol; antipsicótico; antipsychotic; Merck Index 14, 8039; CAS: 111974-72-2; DCB: 07539; NCM: 2933.99.39; TEC: 2%; **Bra:** Formil

hemitartarato de di-hidrocodeína; *dihydrocodeine bitartrate*; (5alpha, 6alpha)-4,5-epoxy-3-methoxy-17-methyl-morphinan-6-ol bitartrate; analgésico narcótico e antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 3171; CAS: 5965-13-9; DCB: 03014; NCM: 2939.11.23; TEC: 2%; **Arg:** Verardo

hemitartarato de hidrocodona; *hydrocodone bitartrate*; dihydrocodeinone bitartrate; analgésico narcótico / antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 4785; CAS: 143-71-5; DCB: 04654; NCM: 2939.11.52; TEC: 2%; **Arg:** Verardo

hemitartarato de zolpidem; *zolpidem bitartrate*; N,N,6-trimethyl-2-(4-methyl-phenyl)imidazo[1,2-alpha]pyridine-3-acetamide hemitartrate; sedativo e hipnótico; sedative, hypnotic; Merck Index 14, 10190; CAS: 99294-93-6; DCB: 09296; NCM: 2933.99.99; TEC: 2%; **Arg:** Gador; **Bra:** Formil

heparina; *heparin*; heparinic acid; anticoagulante; anticoagulant; Merck Index 14, 4653; CAS: 9005-49-6; DCB: 04607; NCM: 3001.90.10; TEC: 8%; **Bra:** Diosynth ●

heparina BPM; *heparin LMW*; heparinic acid low molecular weight; anticoagulante; anticoagulant; Merck Index 14, 4653; CAS: 9005-49-6; DCB: 04607; NCM: 3001.90.10; TEC: 8%; **Bra:** Kin Master

heparina sódica; *heparin sodium*; heparinic acid sodium salt; anticoagulante; anticoagulant; Merck Index 14, 4653; CAS: 9041-08-1; DCB: 04610; NCM: 3001.90.10; TEC: 8%; **Bra:** Diosynth, Extrasul, Kin Master

heparinoide; *heparinoid*; heparinoid; anti-inflamatório e antiexsudativo; anti-inflammatory; reference not confirmed; CAS: 9010-06-4; DCB: n.d.; NCM: 3001.90.90; TEC: 2%; **Bra:** Diosynth, Extrasul, Kin Master

hidroxiapatita (153 Sm): HA 153 Sm; *samarium Sm 153 hydroxyapatite*; agente radioativo; radioactive agent; Merck Index 14, 3467; CAS: n.d.; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

hidróxido de alumínio; *aluminum hydroxide*; aluminum trihydrate; antiácido; antacid; Merck Index 14, 342; CAS: 21645-51-2; DCB: 04694; NCM: 2818.30.00; TEC: 2%; **Bra:** Buschle Lepper, Caq, Quimibrás

hidróxido de amônio; *ammonium hydroxide*; ammonium water; na extração de alcalóides; extraction of alkaloids; Merck Index 14, 494; CAS: 1336-21-6; DCB: 09458; NCM: 2814.20.00; TEC: 4%; **Bra:** Quimibrás

hidróxido de cálcio; *calcium hydroxide*; calcium hydrate; adstringente; astringent; Merck Index 14, 1673; CAS: 1305-62-0; DCB: 04696; NCM: 2825.90.90; TEC: 10%; **Bra:** Cobrascal, Tiradentes

hidróxido de magnésio; *magnesium hydroxide*; magnesium hydrate; antiácido e catártico; antacid, cathartic; Merck Index 14, 5670; CAS: 1309-42-8; DCB: 04697; NCM: 2816.10.10; TEC: 10%; **Bra:** Buschle Lepper, Quimibrás

hidroximetano sulfonato de sódio; *sodium hydroxymethane sulfonate*; conservante de formulações farmacêuticas; conservator of pharmaceutical formulations; CAS: 870-72-4; DCB: n.d.; NCM: 2904.10.19; TEC: 8%; **Bra:** Nortec Química

hipoclorito de sódio; *sodium hypochlorite*; ClNaO; antisséptico, desinfetante; antiseptic, disinfectant; Merck Index 14, 8628; CAS: 7681-52-9; DCB: 04731; NCM: 2828.90.11; TEC: 10%; **Bra:** Química Indaiatuba

ibandronato de sódio; *ibandronate monosodium*; ibandronic acid monosodium salt; antiosteolítico; antiosteolytic; Merck Index 14, 4873; CAS: 138926-19-9; DCB: n.d.; NCM: 2931.90.39; TEC: 12%; **Arg:** Maprimed

ibuprofenato de lisina; *ibuprofen lysine*; veja lisinato de ibuprofeno; *see ibuprofen lysine*

iobenguano (123 I): MIBG, metaiodobenzilguanidina 123 I; *iobenguane (123 I)*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 482; CAS: 77679-27-7; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IEN, IPEN

iobenguano (131 I): MIBG, metaiodobenzilguanidina 131 I; *iobenguane (131 I)*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 482; CAS: 139755-80-9; DCB: 04932; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

iodeto de potássio; *potassium iodide*; potassium iodide; expectorante, antifúngico e fonte de iodo; antifungal, expectorant, iodine supplement; Merck Index 14, 7643; CAS: 7681-11-0; DCB: 04965; NCM: 2827.60.12; TEC: 10%; **Bra:** Incasa, Quimibrás

iodeto de sódio; *sodium iodide*; sodium iodide; expectorante e fonte de iodo; expectorant, iodine supplement; Merck Index 14, 8631; CAS: 7681-82-5; DCB: 04969; NCM: 2827.60.11; TEC: 10%; **Bra:** Incasa, Quimibrás

iodeto de sódio (123 I); *sodium iodide I 123*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 838; CAS: 41927-88-2; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IEN, IPEN

iodeto de sódio (131 I); *sodium iodide I 131*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 838; CAS: 7790-26-3; DCB: 04972; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

iodoipurato de sódio (131 I): O-iodo-hipurato de sódio 131 I; *iodohippurate sodium I 131*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 485; CAS: 881-17-4; DCB: 04987; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

iodo ressublimado; *iodine*; iodine; antiinfeccioso tópico / anti-hipertiroidiano; anti-infective (topical), antihyperthyroid; Merck Index 14, 5014; CAS: 7553-56-2; DCB: 04983; NCM: 2801.20.10; TEC: 2%; **Bra:** Incasa, Quimibrás

iodofórmio; *iodoform*; triiodomethane; anti-infeccioso tópico; anti-infective (topical); Merck Index 14, 5033; CAS: 75-47-8; DCB: 04985; NCM: 2903.39.32; TEC: 2%; **Bra:** Incasa, Quimibrás

isoleucina (L); *isoleucine (L)*; 2-amino-3-methylvaleric acid; aminoácido essencial para o desenvolvimento humano; Merck Index 14, 5179; CAS: 73-32-5; DCB: 05083; NCM: 2922.49.90; TEC: 2%; **Bra:** Ajinomoto

ivermectina; *ivermectin*; 22,23-dihydroabamectin; anti-helmíntico; anthelmintic (onchocerca); Merck Index 14, 5248; CAS: 70288-86-7; DCB: 05128; NCM: 2932.99.99; TEC: 2%; **Arg:** Aca

lactato de amônio; *ammonium lactate*; DL-lactic acid ammonium salt; na cetose, em veterinária; bovine ketosis in vet; Merck Index 14, 530; CAS: 52003-58-4; DCB: 05138; NCM: 2918.11.00; TEC: 12%; **Bra:** Quimibrás

lactato de biperideno; *biperiden lactate*; alpha-bicyclo[2.2.1]hept-5-en-2-yl-alpha-phenyl-1-piperidinepropanol lactate; anticolinérgico e antiparkinsoniano; anticholinergic, antiparkinsonian; Merck Index 14, 1233; CAS: 7085-45-2; DCB: 01284; NCM: 2933.39.32; TEC: 2%; **Bra:** Cristália

lactato de cálcio; *calcium lactate*; 2-hydroxypropanoic acid calcium salt; fonte de cálcio; calcium replenisher; Merck Index 14, 1678; CAS: 814-80-2; DCB: 00275; NCM: 2918.11.00; TEC: 12%; **Bra:** Quimibrás

lactato de ferro; *ferrous lactate*; 2-hydroxypropanoic acid ferrous salt; hematínico; hematinic; Merck Index 14, 4050; CAS: 5905-52-2; DCB: 05139; NCM: 2918.11.00; TEC: 12%; **Bra:** Quimibrás

lactato de magnésio; *magnesium lactate*; 2-hydroxypropanoic acid magnesium salt; catártico; cathartic; Merck Index 14, 5672; CAS: 18917-93-6; DCB: 00277; NCM: 2918.11.00; TEC: 12%; **Bra:** Quimibrás

lactato de miristila; *myristil lactate*; adjuvante farmacotécnico como emoliente; pharmaceutical aid (emollient); Merck Index 14, 6333; CAS: 1323-03-1; DCB: n.d.; NCM: 2918.11.00; TEC: 12%; **Bra:** Croda

lactato de sódio; *sodium lactate*; 2-hydroxypropanoic acid sodium salt; alcalinizante sistêmico e urinário / repositor eletrolítico; systemic and urinary alkalizer, electrolyte replenisher; Merck Index 14, 8635; CAS: 72-17-3; DCB: 00278; NCM: 2918.11.00; TEC: 12%; **Bra:** Caq, Quimibrás

lactofosfato de cálcio; *calcium lactophosphate*; fonte de cálcio; calcium source; USP Dictionary 2009, pág. 163; CAS: 7546-28-3; DCB: 05142; NCM: 2919.90.50; TEC: 12%; **Bra:** Quimibrás

lamivudina (3TC); *lamivudine*; (2R-cis)-4-amino-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-2(1H)-pyrimidinone; antiviral; antiviral; Merck Index 14, 5352; CAS: 134678-17-4; DCB: 05152; NCM: 2934.99.93; TEC: 12%; **Bra:** CYG Biotech, Globe, Nortec Química

lanolina anidra; *lanolin anhydrous*; lanolin anhydrous; adjuvante farmacotécnico como base para pomadas; pharmaceutic aid (ointment base); Merck Index 14, 5358; CAS: 8006-54-0; DCB: 05161; NCM: 1505.00.10; TEC: 8%; **Bra:** Croda

lanolina, derivados; *lanolin derivatives*; lanolin derivatives; adjuvantes farmacotécnicos como base para pomadas; pharmaceutic aid; Merck Index 14, 5358; NCM: 1505.00.90; TEC: 6%; **Bra:** Croda

lansoprazol; *lansoprazole*; 2-[[[3-methyl-4-(2,2,2-trifluoro-ethoxy)-2-piridinyl]methyl]sulfinyl]-1H-benzimidazole; antiulcerativo; antiulcerative; Merck Index 14, 5362; CAS: 103577-45-3; DCB: 05165; NCM: 2933.39.89; TEC: 2%; **Bra:** ITF

leflunomida; *leflunomide*; 5-methyl-N-[4-(trifluoromethyl)phenyl]-4-isoxazolecarboxamide; antiartrítico / imunomodulador; antiarthritic / immunomodulator; Merck Index 14, 5432; CAS: 75706-12-6; DCB: 05192; NCM: 2934.99.99; TEC: 2%; **Arg:** Triquim

lenograstim; *lenograstim*; granulocyte colonystimulating factor; estimulante hematopoiético e antineutropênico; hematopoietic stimulant, antineutropenic; Merck Index 14, 4537; CAS: 135968-09-1; DCB: 05201; NCM: 3001.20.90; TEC: 6%; **Arg:** Bio Sidus

levobupivacaína; *levobupivacaine*; S-1-butyl-N-(2,6-dimethyl-phenyl)-2-piperidinecarboxamide; analgésico, anestésico (local); analgesic, anesthetic (local); Merck Index 14, 1495; CAS: 27262-48-2; DCB: 05239; NCM: 2933.39.89; TEC: 2%; **Arg:** Triquim

levofloxacino; *levofloxacin*; 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxilyc acid; antibacteriano; antibacterial; Merck Index 14, 6771; CAS: 100986-85-4; DCB: 05257; NCM: 2934.99.19; TEC: 2%; **Bra:** ITF

levotiroxina; *levothyroxine*; 0-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L tyrosine; no tratamento do hipotiroidismo; treatment of hypothyroidism; Merck Index 14, 9415; CAS: 51-48-9; DCB: 05294; NCM: 2937.90.90; TEC: 2%; **Arg:** Tolbiac

levotiroxina sódica; *levothyroxine sodium*; 0-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine monosodium salt; no tratamento do hipotiroidismo; treatment of hypothyroidism; Merck Index 14, 9415; CAS: 55-03-8; DCB: 05295; NCM: 2937.90.30; TEC: 12%; **Arg:** Tolbiac

lexidronam (153 Sm): EDTMP, ácido etilenodiaminotetrametileno fosfônico 153 Sm; *samarium Sm 153 lexidronam*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 815; CAS: 154427-83-5; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

lidocaína; *lidocaine*; 2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide; anestésico local / antiarrítmico; anesthetic (local), antiarrhythmic (class IB); Merck Index 14, 5482; CAS: 137-58-6; DCB: 05313; NCM: 2924.29.14; TEC: 14%; **Bra:** Nortec Química

liotironina; *liothyronine*; 0-(4-hydroxy-3-iodophenyl)-3,5-diiodotyrosine; hormônio da tiróide; thyroid hormone; Merck Index 14, 5510; CAS: 6893-02-3; DCB: 05334; NCM: 2937.90.90; TEC: 2%; **Arg:** Tolbiac

liotironina sódica; *liothyronine sodium*; 0-(4-hydroxy-3-iodophenyl)-3,5-diiodotyrosine sodium salt; hormônio da tiróide; thyroid hormone; Merck Index 14, 5510; CAS: 55-06-1; DCB: 05338; NCM: 2937.90.40; TEC: 12%; **Arg:** Tolbiac

lisinato de ibuprofeno; *ibuprofen lysine*; alpha-methyl-4-(2-methylpropyl)-benzene acetic acid lysine salt; anti-inflamatório; anti-inflammatory; Merck Index 14, 4881; CAS: 141505-32-0; DCB: 04775; NCM: 2916.39.90; TEC: 12%; **Arg:** Triquim

lomifilina; *lomifylline*; 1,3-dimethyl-7-(5-oxohexyl)purine-2,6(1H,3H)-dione; antiarrítmico; antiarrithymic; USP Dictionary 2009, pág. 540; CAS: 10226-54-7; DCB: 05398; NCM: 2939.59.90; TEC: 2%; **Arg:** Triquim

lorazepam; *lorazepam*; 7-chloro-5-(2-chlorophenyl)-1-dihydro-3-hydroxy-2H-1,4-benzodiazepin-2-one; ansiolítico; anxiolytic; Merck Index 14, 5579; CAS: 846-49-1; DCB: 05417; NCM: 2933.91.42; TEC: 2%; **Bra:** Formil

losartana potássica; *losartan potassium*; 2-butyl-4-chloro-1-[[2-1H-tetrazol-5-yl)[1,1-biphenyl]4-yl]methyl]-1H-imidazole-5-methanol potassium salt; anti-hipertensivo; antihypertensive; Merck Index 14, 5583; CAS: 124750-99-8; DCB: 05432; NCM: 2933.29.99; TEC: 2%; **Arg:** Maprimed

malato de cleboprida; *clebopride hydrogen malate*; 4-amino-5-chloro-2-methoxy-N-[1-(phenylmethyl)-4-piperidinyl]benzamide hydrogen malate; antiemético e antiespasmódico; antiemetic, antispasmodic; Merck Index 14, 2344; CAS: 57645-91-7; DCB: 02205; NCM: 2933.39.23; TEC: 14%; **Arg:** Sindrofar

maleato de enalapril; *enalapril maleate*; (S)-1-[N-[1-(ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate; anti-hipertensivo; antihypertensive; Merck Index 14, 3567; CAS: 76095-16-4; DCB: 03370; NCM: 2933.99.46; TEC: 14%; **Arg:** Maprimed

maleato de midazolam; *midazolam maleate*; 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine maleate; anestésico intravenoso; anesthetic intravenous; Merck Index 14, 6182; CAS: 59467-94-6; DCB: 05939; NCM: 2933.91.53; TEC: 2%; **Bra;** Alpha Br, Formil, Nortec Química

maleato de rosiglitazona; *rosiglitazone maleate*; 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]2,4-thiazolidineodione maleate; antidiabético; antidiabetic; Merck Index 14, 8265; CAS: 155141-29-0; DCB: 07813; NCM: 2934.10.90; TEC: 2%; **Bra:** ITF

manteiga de cupuaçu; *cupuaçu butter*; Theobroma grandiflorum seed butter; adjuvante farmacotécnico como emoliente; pharmaceutical aid (emollient); CAS: 394236-97-6; DCB: n.d.; NCM: 1515.90.90; TEC: 10%; **Bra:** Croda

mazindol; *mazindol*; 5-(4-chlorophenyl)-2,5-dihydro-3H-imidazo[2,1-a] isoindol-5-ol; anorexígeno e estimulante do sistema nervoso central; anorexic, CNS stimulant; Merck Index 14, 5762; CAS: 22232-71-9; DCB: 05511; NCM: 2933.91.51; TEC: 14%; **Arg:** Sindrofar; **Bra:** Libbs

mebendazol; *mebendazole*; (5-benzoyl-1H-benzimidazol-2-yl)carbamic acid methyl ester; anti-helmíntico; anthelmintic (nematodes); Merck Index 14, 5768; CAS: 31431-39-7; DCB: 05515; NCM: 2933.99.54; TEC: 14%; **Bra:** Formil

6-mercaptopurina; *6-mercaptopurine*; purine-6-thiol; antineoplásico; antineoplastic, immunossupressant; Merck Index 14, 5871; CAS: 50-44-2; DCB: 05680; NCM: 2933.59.35; TEC: 14%; **Bra:** Microbiológica

mesilato de di-hidroergocristina; *dihydroergocristine mesilate*; dihydroergocristine methanesulfonate; vasorregulador cerebral; alpha adrenergic blocker; Merck Index 14, 3653; CAS: 24730-10-7; DCB: 03019; NCM: 2939.69.52; TEC: 14%; **Bra:** Novartis •

mesilato de di-hidroergotamina; *dihydroergotamine mesilate*; dihydroergotamine methanesulfonate; vasorregulador cerebral; antimigraine; Merck Index 14, 3174; CAS: 6190-39-2; DCB: 03021; NCM: 2939.69.21; TEC: 2%; **Bra:** Novartis •

mesilato de rasagilina; *rasagiline mesilate*; (1R)-2,3-dihydro-N-2-propynyl-1H-inden-1-amine mesilate; antiparkinsoniano; antiparkinsonian; Index Merck 14, 8116; CAS: 161735-79-1; DCB: n.d.; NCM: 2921.49.90; TEC: 2%; **Arg:** Maprimed

metabissulfito de sódio; *sodium metabisulfite*; sodium acid sulfite; adjuvante farmacotécnico como antioxidante; pharmaceutic aid (antioxidant); Merck Index 14, 8638; CAS: 7681-57-4; DCB: 05711; NCM: 2832.10.90; TEC: 10%; **Bra:** Qgn, Quimibrás

metadona; *methadone*; 6-dimethylamino-4,4-diphenyl-3-heptanone; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 5944; CAS: 76-99-3; DCB: 05717; NCM: 2922.31.20; TEC: 2%; **Arg:** Triquim

metilbrometo de homatropina; *homatropine methylbromide*; 1-alfaH,5-alfaH-tropan-3-alfa-ol mandelate; midriático; midriatic; Merck Index 14, 4730; CAS: 80-49-9; DCB: 04747; NCM: 2939.99.90; TEC: 2%; **Arg:** Triquim

metronidazol; *metronidazole*; 2-methyl-5-nitroimidazole-1-ethanol; tricomonicida; antiprotozoal (trichomonas); Merck Index 14, 6157; CAS: 443-48-1; DCB: 05902; NCM: 2933.29.12; TEC: 14%; **Bra:** Formil

midazolam; *midazolam*; 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-alfa][1,4]benzodiazepine; anestésico intravenoso; anesthetic intravenous; Merck Index 14, 6182; CAS: 59467-70-8; DCB: 05937; NCM: 2933.91.53; TEC: 2%; **Bra:** Alpha Br, Formil, Nortec Química

miltefosina; *miltefosine*; 2-[[(hexadecyloxy)hydroxyphosphinyl]oxy]-N,N,N-trimethyl-ethanaminium inner salt; antineoplásico; antineoplastic; Merck Index 14, 6198; CAS: 58066-85-6; DCB: 05965; NCM: 2923.90.90; TEC: 2%; **Arg:** Triquim

miristato de isopropila; *isopropyl myristate*; tetradecanoic acid 1-methyl ethyl ester; adjuvante farmacotécnico na fabricação de cremes; pharmaceutic aid; Merck Index 14, 5215; CAS: 110-27-0; DCB: 05994; NCM: 2915.90.33; TEC: 12%; **Bra:** Croda

mirtazapina; *mirtazapine*; 2-methyl-1,2,3,4,10,14b-hexahydrobenzol-[c]pyrazino[1,2-alfa]pyrido[3,2-f]azepine; antidepressivo; antidepressant; Merck Index 14, 6208; CAS: 61337-67-5; DCB: 06000; NCM: 2933.59.19; TEC: 2%; **Arg:** Triquim

modafinila; *modafinil*; 2-[(diphenylmethyl)sulfinyl]acetamide; estimulante do SNC; CNS stimulant; Merck Index 14, 6228; CAS: 68693-11-8; DCB: 06041; NCM: 2930.90.99; TEC: 2%; **Arg:** Triquim; **Bra:** Formil

monoestearato de dietilenoglicol; *diethylene glycol monostearate*; diethylene glycol monostearate; adjuvante farmacotécnico na fabricação de cremes e loções; pharmaceutic aid; C.T.F.A; CAS: 106-11-6; DCB: 06066; NCM: 2915.70.40; TEC: 12%; **Bra:** Croda

monoestearato de etilenoglicol; *ethylene glycol monostearate*; ethylene glycol monostearate; adjuvante farmacotécnico na fabricação de cremes; pharmaceutic aid; C.T.F.A; CAS: 111-60-4; DCB: 06067; NCM: 2915.70.40; TEC: 12%; **Bra:** Croda

monoestearato de glicerila; *glyceryl monostearate*; octadecanoic acid with 1,2,3-propanetriol; adjuvante farmacotécnico na fabricação de cremes e pomadas; pharmaceutic aid; Merck Index 14, 4489; CAS: 31566-31-1; DCB: 06068; NCM: 2915.70.40; TEC: 12%; **Bra:** Croda

monoestearato de sorbitana; *sorbitan monostearate*; sorbitan fatty acid ester; emulsificante; emulsifier; Merck Index 14, 8724; CAS: 1338-41-6; DCB: n.d.; NCM: 3824.90.89; TEC: 14%; **Bra:** Croda

mucato de isometepteno; *isometheptene mucate*; N,6-dimethyl-5-hepten-2-amine mucate; adrenérgico; adrenergic; Merck Index 14, 5185; CAS: 7492-31-1; DCB: 05091; NCM: 2921.19.93; TEC: 14%; **Bra:** Nortec Química

nafato de cefamandol; *cefamandole nafate*; (6R,7R)-7-[[(2R)-hydroxyphenyl]acetyl]amino]-3-[[(1-methyl-1H-tetrazol-5-yl)thio]-methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid nafate salt; antibacteriano (antibiótico); antibacterial; Index Merck 14, 1914; CAS: 42540-40-9; DCB: 01838; NCM: 2941.90.39; TEC: 2%; **Bra:** ABL

nevirapina; *nevirapine*; 11-cyclopropyl-5,11-dihydro-4-methyl-6H-dipyrido [3,2-b:2,3-e][1,4]diazepin-6-one; antiviral; antiviral; Merck Index 14, 6490; CAS: 129618-40-2; DCB: 06310; NCM: 2934.99.99; TEC: 2%; **Bra:** Nortec Química

nicarbazina; *nicarbazin*; 4,4-dinitrocarbanilide with 4,6-dimethyl-2-pyrimidinol (1:1); coccidiostático, em veterinária; coccidiostat in vet; Merck Index 14, 6494; CAS: 330-95-0; DCB: 06320; NCM: 2933.59.44; TEC: 14%; **Bra:** Planalquímica

nilutamida; *nilutamide*; 5,5-dimethyl-3-[4-nitro-3-(trifluoromethyl) phenyl]-2,4-imidazolidine-dione; antiandrogênico; antiandrogen; Merck Index 14, 6544; CAS: 63612-50-0; DCB: 06388; NCM: 2933.21.90; TEC: 2%; **Arg:** Triquim

nimodipino; *nimodipine*; 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-3,5-pyridinecarboxylic acid 2-methoxyethyl 1-methylethyl ester; vasodilatador cerebral; vasodilator (cerebral); Merck Index 14, 6551; CAS: 66085-59-4; DCB: 06394; NCM: 2933.39.48; TEC: 12%; **Arg:** Triquim

nisoldipino; *nisoldipine*; 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-3,5-pyridinecarboxylic acid methyl 2-methylpropyl ester; anti-hipertensivo e antianginoso; antihypertensive, antianginal; Merck Index 14, 6565; CAS: 63675-72-9; DCB: 06408; NCM: 2933.39.99; TEC: 2%; **Arg:** Triquim

nitrato de amônio; *ammonium nitrate*; ammonium nitrate; expectorante e acidulante, em veterinária; expectorant and urinary acidifier in vet; Merck Index 14, 534; CAS: 6484-52-2; DCB: 06423; NCM: 3102.30.00; TEC: 0%; **Bra:** Caq, Quimibrás

nitrato de bismuto monobásico; *bismuth subnitrate*; bismuth hydroxide nitrate oxide; antiácido; antacid; Merck Index 14, 1284; CAS: 1304-85-4; DCB: 06424; NCM: 2834.29.90; TEC: 10%; **Bra:** Quimibrás

nitrato de isoconazol; *isoconazole nitrate*; 1-[2-(2,4-dichlorophenyl)-2-[(2,6-dichlophenyl)methoxy]-ethyl]-1H-imidazole nitrate; antibacteriano e antifúngico; antibacterial, antifungal; Merck Index 14, 5160; CAS: 24168-96-5; DCB: 05076; NCM: 2933.29.24; TEC: 2%; **Bra:** Formil

nitrato de miconazol; *miconazole nitrate*; 1-[2-(2,4-dichlorophenyl)-2[(2,4-dichlorophenyl)methoxy]ethyl-1H-imidazole nitrate; antifúngico tópico; antifungal (topical); Merck Index 14, 6178; CAS: 22832-87-7; DCB: 05929; NCM: 2933.29.22; TEC: 14%; **Bra:** Formil

nitrato de pilocarpina; *pilocarpine nitrate*; (3S-cis)-3-ethyldihydro-4-[(1-methyl-1H-imidazol-5-yl)methyl-2-(3H)-furanone nitrate; anticolinérgico oftálmico e antiglaucoma; antiglaucoma agent, miotic; Merck Index 14, 7424; CAS: 148-72-1; DCB: 07051; NCM: 2939.99.31; TEC: 14%; **Bra:** Sourcetech, Vegeflora

nitrato de potássio; *potassium nitrate*; saltpeter; diurético; diuretic; Merck Index 14, 7648; CAS: 7757-79-1; DCB: 06426; NCM: 2834.21.90; TEC: 10%; **Bra:** Caq, Quimibrás

nitrendipino; *nitrendipine*; 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-3,5-pyridinecarboxylic acid ethyl methyl ester; anti-hipertensivo; antihypertensive; Merck Index 14, 6576; CAS: 39562-70-4; DCB: 06431; NCM: 2933.39.44; TEC: 14%; **Arg:** Triquim; **Bra:** Libbs

norelgestromina; *norelgestromine*; 18,19-dinorpregn-4-en-20-yn-3-ona-13-ethyl-17-hydroxyoxima-17alpha; progestogênio; progestogen; Merck Index 14, 6694; CAS: 53016-31-2; DCB: 06485; NCM: 2937.29.90; TEC: 2%; **Arg:** Gador

norgestimato; *norgestimate*; (17alpha)-17-(acetyloxy)-13-ethyl-18,19-dinorpregn-4-en-20-yn-3-one-3-oxime; progestogênio / com o estrogênio, usado como contraceptivo oral; progestogen / in combination with estrogen as oral contraceptive; Merck Index 14, 6703; CAS: 35189-28-7; DCB: 06501; NCM: 2937.23.99; TEC: 2%; **Arg:** Gador

noroximorfona; *noroxymorphone*; (5alfa)-4,5-epoxy-3,14-dihydroxy-17-methylmorphinan-6-one; analgésico; analgesic; Merck Index 14, 6969; CAS: 33522-95-1; DCB: n.d.; NCM: 2939.11.82; TEC: 2%; **Bra:** Diosynth ●

O

octacetato de sacarose; *sucrose octaacetate*; desnaturante do álcool; denaturant for alcohol; Merck Index 14, 8882; CAS: 126-14-7; DCB: n.d.; NCM: 2940.00.99; TEC: 2%; Bra: PVP

olanzapina; *olanzapine*; 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno [2,3-b][1,5]benzodiazepine; antipsicótico; antipsychotic; Merck Index 14, 6822; CAS: 132539-06-1; DCB: 06580; NCM: 2933.99.39; TEC: 2%; **Bra:** Alpha Br, CYG Biotech, Globe

óleo de gergelim; *sesame oil*; obtido de sementes de variedades cultivadas de Sesamum indicum L.; adjuvante farmacotécnico como solvente; pharmaceutical aid (solvent); Merck Index 14, 8469; CAS: 8008-74-0; DCB: 09888; NCM: 1515.50.00; TEC: 30%; **Bra:** Croda

óleo de maracujá; *passiflora seed oil*; obtido de sementes da Passiflora incarnata L.; adjuvante farmacotécnico como emoliente; pharmaceutical aid (emollient); Merck Index 14, 7051; CAS: 97676-26-1; DCB: n.d.; NCM: 1515.90.90; TEC: 10%; **Bra:** Croda

óleo etiodado (131 I): lipiodol 131 I; *ethiodized oil (131 I)*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 362; CAS: 8016-07-7; DCB: 06587; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

oxalato de potássio; *potassium oxalate*; potassium oxalate; anticoagulante sanguíneo; in vitro blood anticoagulant; Merck Index 14, 7651; CAS: 583-52-8; DCB: n.d; NCM: 2917.11.10; TEC: 2%; **Bra:** Quimibrás

oxaliplatina; *oxaliplatin*; [SP-4-2-(1R-trans)]-(1,2-cyclohexanediamine-N,N)[ethanedioato(2-)-0,0]platinum; antineoplásico; antineoplastic; Merck Index 14, 6912; CAS: 61825-94-3; DCB: 06669; NCM: 2843.90.90; TEC: 10%; **Bra:** Quiral

oxcarbazepina; *oxcarbazepine*; 10,11-dihydro-10-oxo-5H-dibenz[b,f] azepine-5-carboxamide; anticonvulsivo, antiepiléptico; anticonvulsant, antiepileptic; Merck Index 14, 6929; CAS: 28721-07-5; DCB: 06691; NCM: 2933.99.39; TEC: 2%; **Bra:** Nortec Química

oxfendazol; *oxfendazole*; [5-phenylsulfinyl)-1H-benzimidazol-2-yl]carbamic acid methyl ester; anti-helmíntico, em veterinária; anthelmintic in vet; Merck Index 14, 6935; CAS: 53716-50-0; DCB: 06702; NCM: 2933.99.52; TEC: 14%; **Arg:** Aca

óxido de albendazol; *albendazole oxide*; [5-(propylthio)-1H-benzimidazol-2-yl]carbamic acid methyl ester sulfoxide; anti-helmíntico; anthelmintic in vet; Merck Index 14, 210; CAS: 54029-12-8; DCB: 00459; NCM: 2933.99.53; TEC: 14%; **Arg:** Aca; **Bra:** Formil

óxido de magnésio; *magnesium oxide*; calcined magnesia; antiácido; antacid; Merck Index 14, 5677; CAS: 1309-48-4; DCB: 06728; NCM: 2519.90.90; TEC: 4%; **Bra:** Buschle Lepper

óxido de zinco; *zinc oxide*; flowers of zinc; adstringente e protetor tópico; astringent, protectant (topical); Merck Index 14, 10147; CAS: 1314-13-2; DCB: 06730; NCM: 2817.00.10; TEC: 10%; **Bra:** Brazinco

palmitato de cetila; *cetyl palmitate*; hexadecanoic acid hexadecyl ester; adjuvante farmacotécnico (espessante, solubilizante); pharmaceutical aid; Merck Index 14, 2031; CAS: 540-10-3; DCB: 06797; NCM: 2915.70.19; TEC: 12%; **Bra:** Croda

pancreatina; *pancreatin*; diastase vera; auxiliar como digestivo; digestive aid; Merck Index 14, 7006; CAS: 8049-47-6; DCB: 06811; NCM: 3507.90.19; TEC: 14%; **Bra:** Kin Master

papaína; *papain*; papayotin; enzima proteolítica; enzyme (proteolytic); Merck Index 14, 7016; CAS: 9001-73-4; DCB: 06821; NCM: 3507.90.26; TEC: 14%; **Bra:** Wallerstein

pectina cítrica; *citric pectin*; pectin; antidiarréico; antidiarrheal; Merck Index 14, 7063; CAS: 9000-69-5; DCB: 06874; NCM: 1302.20.10; TEC: 8%; **Bra:** CPKelco

pemetrexede; *pemetrexed*; N-[4-[2-(amino-4,7-dihydro-4-oxo-1H-pyrrolo[2,3-d]pyrimidin-5-yl)ethyl]benzoil]-L-glutamic acid; antineoplásico; antineoplasic; Merck Index 14, 7077; CAS: 137281-23-3; DCB: 06897; NCM: 2933.59.99; TEC: 2%; **Bra:** ITF

pentamidina; *pentamidine*; 4,4-[1,5-pentamedyl-bis(oxy)]bisbenzene carboximidamide; antiprotozoário(tripanossomo e leishmânia); antiprotozoal (trypanosoma, leishmania); Merck Index 14, 7115; CAS: 100-33-4; DCB: 06927; NCM: 2925.29.90; TEC: 2%; **Arg:** Triquim

pentecnetato de sódio (99m Tc): gerador de tecnécio 99m; *technetium 99m Tc pentechnetate*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 838; CAS: 23288-60-0; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

pentetreotida (111 In): DTPA, octreotídeo 111 In; *indium In 111 pentetreotide*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 703; CAS: 139096-04-1; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

pepsina; *pepsin*; pepsin; enzima digestiva; enzyme (digestive); Merck Index 14, 7146; CAS: 9001-75-6; DCB: 06963; NCM: 3507.90.29; TEC: 14%; **Bra:** Kin Master

peptona bacteriológica; *bacteriological peptone*; peptone; na preparação de meios de cultura; in the preparation of culture medium; reference not informed; CAS: n.d.; DCB: n.d.; NCM: 3504.00.11; TEC: 14%; **Bra:** Geyer, Kin Master

peróxido de hidrogênio (água oxigenada); *hydrogen peroxide*; hydrogen dioxide; antisséptico e desinfetante; antiseptic, disinfectant; Merck Index 14, 4798; CAS: 7722-84-1; DCB: 07004; NCM: 2847.00.00; TEC: 10%; **Bra:** Peróxidos

pilocarpina; pilocarpine; (3S-cis)-3-ethyldihydro-4-[(1-methyl-1H-imidazol-5-yl)methyl]-2-(3H)-furanone; anticolinérgico oftálmico e antiglaucoma; antiglaucoma agent, miotic; Merck Index 14, 7424; CAS: 92-13-7; DCB: 07049; NCM: 2939.99.31; TEC: 14%; **Bra:** Sourcetech

pimetixeno; *pimethixene*; 9-(N-methyl-4-piperidilene)thioxantene; ansiolítico; ansiolytic; USP Dictionary 2009, pág. 723; CAS: 314-03-4; DCB: 07060; NCM: 2934.99.99; TEC: 2%; **Bra:** Novartis •

pirofosfato férrico; *ferric pyrophosphate*; ferric pyrophosphate; hematínico; hematinic; Merck Index 14, 4030; CAS: 10058-44-3; DCB: n.d.; NCM: 2835.29.10; TEC: 2%; **Bra:** Caq

piroxicam; *piroxicam*; 4-hydroxy-2-methyl-N-2-pyridinyl-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide; anti-inflamatório; anti-inflammatory; Index Merck 14, 7506; CAS: 36322-90-4; DCB: 07211; NCM: 2935.00.23; TEC: 2%; **Bra:** Globe

pivossulbactam; *pivsulbactam*; veja sulbactam pivoxila; *see sulbactam pivoxil*

plantas medicinais; *medicinal plants*; NCM: 1211; TEC: 8%; **Bra:** Centroflora

polissorbato 20; *polysorbate 20*; sorbitan monooleate; adjuvante farmacotécnico; pharmaceutic aid; Merck Index 14, 7582; CAS: 9005-64-5; DCB: 07272; NCM: 3402.13.00; TEC: 14%; **Bra:** Croda

polissorbato 60; *polysorbate 60*; sorbitan monooleate; adjuvante farmacotécnico; pharmaceutic aid; Merck Index 14, 7582; CAS: 9005-67-8; DCB: 07274; NCM: 3402.13.00; TEC: 14%; **Bra:** Croda

polissorbato 80; *polysorbate 80*; sorbitan monooleate; adjuvante farmacotécnico; pharmaceutic aid; Merck Index 14, 7582; CAS: 9005-65-6; DCB: 07275; NCM: 3402.13.00; TEC: 14%; **Bra:** Croda

prasugrel; *prasugrel*; ethanone, 2-[2-(acetyloxy)-6,7-dihydrothieno[3,2-c] pyridine-5(4H)-yl]-1-cyclopropyl-2-(2-fluorophenyl); inibidor da agregação plaquetária; inhibits platelet aggregation; USP Dictionary 2009, pág. 751; CAS: 150322-43-3; DCB: n.d.; NCM: 2933.39.99; TEC: 2%; **Arg:** Maprimed

prilocaína; *prilocaine*; N-(2-methylphenyl)-2-(propylamino)propanamide; anestésico local; anesthetic (local); Merck Index 14, 7743; CAS: 721-50-6; DCB: 07363; NCM: 2924.29.63; TEC: 14%; **Bra:** Nortec Química

produtos opoterápicos; *animal products*; veja na 2ª parte desta edição (relação de produtores) os produtos opoterápicos produzidos pelas empresas indicadas; *see in the 2nd. part of this book the name of the animal products produced by the companies listed*; **Arg:** Gaveteco; **Bra:** Croda, Kin Master

propilenoglicol; *propylene glycol*; 1,2-propanediol; adjuvante farmacotécnico como humectante e solvente; pharmaceutic aid (humectant, solvent); Merck Index 14, 7855; CAS: 57-55-6; DCB: 07455; NCM: 2905.32.00; TEC: 12%; **Bra:** Dow

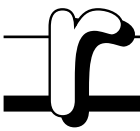
propiltiouracila; *propylthiouracil*; 2,3-dihydro-6-propyl-2-thioxo-4-(1H) pyrimidinone; anti-hipertiroideano; antihyperthyroid; Merck Index 14, 7869; CAS: 51-52-5; DCB: 07462; NCM: 2933.59.31; TEC: 14%; **Bra:** Nortec Química

propinox; *propinox*; 2-dimethylaminoethyl-0-(2-propinyl)benzilate; espasmolítico; spasmolytic; Pharmazeutische Stoffliste 8th Edition; CAS: n.d.; DCB: n.d.; NCM: 2916.39.90; TEC: 2%; **Arg:** Triquim

propiverina; *propiverine*; alfa-phenyl-alfa-propoxybenzeneacetic acid 1-methyl-4-piperidinyl ester; no tratamento da incontinência urinária; in treatment of urinary incontinence; Merck Index 14, 7832; CAS: 60569-19-9; DCB: 07472; NCM: 2933.39.99; TEC: 2%; **Arg:** Triquim

pseudoefedrina; *pseudoephedrine*; (1S,2S)-2-methylamino-1-phenyl-propan-1-ol; descongestionante (nasal); decongestant (nasal); Merck Index 14, 7916; CAS: 90-82-4; DCB: 07519; NCM: 2939.42.00; TEC: 2%; **Bra:** Formil

quercetina; *quercetin*; 2-(3,4-dihydroxyphenyl)-3,5,7-trihydroxy-4H-1-benzopyran-4-one; na fragilidade capilar; capillary protectant; Merck Index 14, 8034; CAS: 117-39-5; DCB: 07537; NCM: 2932.99.12; TEC: 14%; **Bra:** PVP, Quercegen



raloxifeno; *raloxifene*; 6-hydroxy-2-(4-hydroxyphenyl)benzo[b]-thien-3-yl] [4-[2-(1-piperidinyl]ethoxy]phenyl]methanone; antiosteoporose; antiosteoporotic; Merck Index 14, 8098; CAS: 84449-90-1; DCB: 07621; NCM: 2934.99.99; TEC: 2%; **Bra:** Nortec Química

ramnose; *rhamnose*; 6-deoxy-L-mannose; na produção de alcalóides; in the production of alkaloids; Merck Index 14, 8172; CAS: 3615-41-6; DCB: 07631; NCM: 2940.00.13; TEC: 14%; **Bra:** Quercegen

ranolazina; *ranolazine*; N-(2,6-dimethylphenyl)-4-[2-hydroxy-3-(2-methoxyphenoxy)propyl]-1-piperazineacetamide; antianginoso; antianginal; Merck Index 14, 8111; CAS: 95635-55-5; DCB: 07640; NCM: 2933.59.19; TEC: 2%; **Arg:** Triquim

reagentes analíticos; *analytical reagents*; NCM: 3822.00.90; TEC: 14%; **Bra:** Caq, Quimibrás, Vetec

remifentanila; *remifentanil*; 4-(methoxycarbonyl)-4-[(1-oxopropyl)phenylamino]-1-piperidine propanoic acid methyl ester; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 8131; CAS: 132875-61-7; DCB: 07663; NCM: 2933.39.99; TEC: 2%; **Arg:** Triquim

resinato de codeína; *codeine resinate*; (5alpha,6alpha)-7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-morphinan-6-ol resinate; analgésico (narcótico); analgesic (narcotic), antitussive; Merck Index 14, 2463; CAS: n.d.; DCB: n.d.; NCM: 2939.19.00; TEC: 2%; **Arg:** Verardo

resinato de diclofenaco; *diclofenac resinate*; 2-[(2,6-dichlorophenyl) amino]benzeneacetate of cholestyrammonium; anti-inflamatório, antirreumático e analgésico; anti-inflammatory; DEF 2005/2006, pág. 105; CAS: 240490-15-7; DCB: 02931; NCM: 2922.49.69; TEC: 2%; **Bra:** Nortec Química, Novartis •

resinato de feniltoloxamina; *phenyltoloxamine resinate*; N,N-dimethyl-2-[2-(phenyl-methyl)phenoxy]ethanamine; anti-histamínico; antihistaminic; Merck Index 14, 7316; CAS: n.d.; DCB: n.d.; NCM: 2922.19.99; TEC: 2%; **Bra:** Nortec Química

resinato de hidrocodona; *hydrocodone resinate*; dihydrocodeinone resinate; analgésico (narcótico) e antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 4785; CAS: n.d.; DCB: n.d.; NCM: 2939.19.00; TEC: 2%; **Arg:** Verardo

ribavirina; *ribavirine*; 1-beta-D-ribofuranosyl-1H-1,2,4-triazole-3-carboxamide; antiviral; antiviral; Merck Index 14, 8198; CAS: 36791-04-5; DCB: 07700; NCM: 2934.99.99; TEC: 2%; **Bra:** Nortec Química

riluzol; *riluzole*; 6-(trifluoromethoxy)-2-benzothiazolamine; neuroprotetor e no tratamento da esclerose lateral amiotrófica; neuroprotectant; Merck Index 14, 8223; CAS: 1744-22-5; DCB: 07729; NCM: 2934.20.90; TEC: 2%; **Arg:** Triquim; **Bra:** Medapi

risedronato de sódio; *risedronate monosodium*; [1-hydroxy-2-(3-pyridinyl)ethylidene]bisphosphonic acid monosodium salt; antiosteolítico; bone resorption inhibitor; Merck Index 14, 8232; CAS: 115436-72-1; DCB: 00339; NCM: 2933.39.39; TEC: 2%; **Bra:** ITF

ritonavir; *ritonavir*; [5S-(5R,8R,10R,11R)]-10-hydroxy-2-methyl-5-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid 5-thiazol ester; antiviral; antiviral; Merck Index 14, 8238; CAS: 155213-67-5; DCB: 07756; NCM: 2934.99.99; TEC: 2%; **Bra:** Cristália

ropivacaína; *ropivacaine*; (2S)-N-(2,6-dimethyl-phenyl)-1-propyl-2-piperidine carboxamide; anestésico (local); anesthetic (local); Merck Index 14, 8258; CAS: 84057-95-4; DCB: 07804; NCM: 2933.39.89; TEC: 2%; **Arg:** Triquim

rutina (rutosídeo); *rutin*; 3-[[6-0-(6-deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl]oxy]-2-(3,4-dihydroxyphenyl-5,7-dihydroxy-4H-1-benzopyran-4-one; redutor da fragilidade capilar; capillary protectant; Merck Index 14, 8304; CAS: 153-18-4; DCB: 07841; NCM: 2938.10.00; TEC: 12%; **Bra:** PVP, Quercegen

sais biliares totais; *total bile salts*; total bile acid; colerético; choleretic; reference not informed; NCM: 3001.20.90; TEC: 6%; **Bra:** Kin Master

salinomicina sódica miceliana; *salinomycin sodium*; salinomycin sodium micelle form; coccidiostático em veterinária; anticoccidial agent in vet; Merck Index 14, 8336; CAS: 55721-31-8; DCB: n.d.; NCM: 3824.90.11; TEC: 14%; **Bra:** Phibro

saquinavir; *saquinavir*; (2S)-N-[1S,2R)-3-[(3S-4aS-8aS)-3-[[(1,1-dimethylethyl)amino]carbonyl]octahydro-2-(1H)-isoquinolinyl]-2-hydroxy-1-(phenylmethyl)propyl]-2-[(2-quinolinylcarbonyl)amino]butanediene; antiviral; antiviral; Merck Index 14, 8369; CAS: 127779-20-8; DCB: 07892; NCM: 2934.99.99; TEC: 2%; **Bra:** Cristália

senduramicina; *semduramicin*; semi-synthetic polyether ionophore antibiotic; coccidiostático em veterinária; Merck Index 14, 8443; CAS: 113378-31-7; DCB: 07941; NCM: 2941.90.79; TEC: 2%; **Bra:** Phibro

sevoflurano; *sevoflurane*; 1,1,1,3,3,3-hexafluoro-2-(fluoromethoxy)propane; anestésico; anesthetic (inhalation); Merck Index 14, 8475; CAS: 28523-86-6; DCB: 07975; NCM: 2909.19.90; TEC: 2%; **Bra:** Cristália

sinvastatina; *simvastatin*; 2,2-dimethylbutanoic acid (15,3R, 7S, 8S, 8a R)-1,2,3,7,8-8a-hexahydro-3,7-dimethyl-8-[2-[(2R-4R)-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1-naphthalenyl ester; anti-hiperlipidêmico; antihyperlipidemic; Merck Index 14, 8539; CAS: 79902-63-9; DCB: 08016; NCM: 2932.20.00; TEC: 2%; **Bra:** Nortec Química

somatropina; *somatotropin*; adenohypophyseal growth hormone / somatropin; estimulante do crescimento; growth stimulant; Merck Index 14, 8716; CAS: 12629-01-5; DCB: 08047; NCM: 2937.11.00; TEC: 2%; **Arg:** Bio Sidus

soro fetal bovino; *bovine fetal serum*; suplemento para meios de cultura celular "in vitro"; supplement for "in vitro" celular culture medium; CAS: n.d.; DCB: n.d.; NCM: 3002.90.99; TEC: 8%; **Bra:** Biosul

sulbactam pivoxila; *sulbactam pivoxil*; 4-thia-1-azabicyclo[3.2.0]-heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-4,4-dioxide, (2,2 dimethyl-1-oxopropoxy)-methyl ester, (2S-cis); antibacteriano em associação com antibióticos betalactâmicos; in combination with beta-lactam antibiotics as antibacterials; USP Dictionary 2009, pág. 856; CAS: 69388-79-0; DCB: n.d.; NCM: 2941.90.99; TEC: 2%; **Arg:** Bagó

sulbactam sódico; *sulbactam sodium*; (2S-cis)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]-heptane-2-carboxylic acid 4,4-dioxide sodium salt; antibacteriano em associação com antibióticos betalactâmicos; in combination with beta-lactam antibiotics as antibacterials; Merck Index 14, 8889; CAS: 69388-84-7; DCB: 08092; NCM: 2941.90.99; TEC: 2%; **Arg:** Bagó

sulfadiazina de prata; *sulfadiazine silver salt*; 2-amino-N-2-pyrimidinyl-benzene-sulfonamide silver salt; antibacteriano; antibacterial; Merck Index 14, 8903; CAS: 22199-08-2; DCB: 08118; NCM: 2935.00.19; TEC: 2%; **Bra:** Silvestre •

sulfametoxazol; *sulfamethoxazole*; 4-amino-N-(5-methyl-3-isoxazolyl)-benzenesulfonamide; antibacteriano; antibacterial, antipneumocystis; Merck Index 14, 8918; CAS: 723-46-6; DCB: 08134; NCM: 2935.00.25; TEC: 14%; **Bra:** Globe

sulfato amoniacal de alumínio; *aluminum ammonium sulfate*; aluminum ammonium sulfate; adstringente; astringent; Merck Index 14, 327; CAS: 7784-25-0; DCB: 08156; NCM: 2833.30.00; TEC: 10%; **Bra:** Vetec

sulfato cúprico; *cupric sulfate*; sulfuric acid cupric salt; antifúngico tópico; antifungal (topical); Merck Index 14, 2653; CAS: 7758-98-7; DCB: 08158; NCM: 2833.25.20; TEC: 10%; **Bra:** Caq, Quimibrás

sulfato de alumínio; *aluminum sulfate*; aluminum sulfate; anti-infeccioso; anti-infective; Merck Index 14, 366; CAS: 10043-01-3; DCB: 08160; NCM: 2833.22.00; TEC: 10%; **Bra:** Quimibrás

sulfato de alumínio e potássio; *aluminum potassium sulfate*; aluminum potassium sulfate; adstringente; astringent; Merck Index 14, 360; CAS: 10043-67-1; DCB: 08161; NCM: 2833.30.00; TEC: 10%; **Bra:** Quimibrás, Vetec

sulfato de bário; *barium sulfate*; blanc fixe; auxiliar de diagnóstico; diagnostic aid (radiopaque medium); Merck Index 14, 994; CAS: 7727-43-7; DCB: 08162; NCM: 2833.27.10; TEC: 10%; **Bra:** Qgn, Quimibrás

sulfato de cálcio; *calcium sulfate*; calcium sulfate; adjuvante farmacotécnico; pharmaceutical aid (in plaster casts); Merck Index 14, 1706; CAS: 7778-18-9; DCB: 08164; NCM: 2833.29.90; TEC: 10%; **Bra:** Caq, Quimibrás

sulfato de codeína; *codeine sulfate*; (5alpha,6alpha)-7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-morphinan-6-ol sulfate; analgésico (narcótico) e antitussígeno; analgesic (narcotic), antitussive; Merck Index 14, 2463; CAS: 1420-53-7; DCB: 02562; NCM: 2939.11.22; TEC: 12%; **Arg:** Verardo

sulfato de condroitina; *chondroitin sulfate*; chondroitin sulfuric acid sodium salt; anti-hiperlipoproteinêmico; antihyperlipoproteinemic; Merck Index 14, 2214; CAS: 9007-28-7; DCB: 02597; NCM: 3913.90.60; TEC: 14%; **Arg:** Bio-Cow, Inter Farma; **Bra:** Extrasul, Kin Master

sulfato de condroitina BPM; *chondroitin sulfate LWM*; chondroitin sulfuric acid sodium sal LWM; anti-hiperlipoproteinêmico; antihyperlipoproteinemic; Merck Index 14, 2214; CAS: 9007-28-7; DCB: 02597; NCM: 3913.90.60; TEC: 14%; **Bra:** Kin Master

sulfato de efedrina; *ephedrine sulfate*; alpha R-alpha-[(1S)-1-(methylamino)ethyl]benzene methanol sulfate; broncodilatador; bronchodilator; Merck Index 14, 3608; CAS: 134-72-5; DCB: 03311; NCM: 2939.41.00; TEC: 2%; **Bra:** Nortec Química

sulfato de ferro amoniacal; *ammonium ferric sulfate*; ferric ammonium sulfate; adstringente; astringent; Merck Index 14, 518; CAS: 10138-04-2; DCB: n.d.; NCM: 2833.29.90; TEC: 10%; **Bra:** Quimibrás, Vetec

sulfato de hidroxocobalamina; *hydroxocobalamin sulfate*; alpha-(5,6-dimethylbenzimidazolyl)-hydroxocobamide sulfate; vitamínico; vitamin (hematopoietic); Merck Index 14, 4809; CAS: n.d.; DCB: n.d.; NCM: 2936.26.30; TEC: 14%; **Arg:** Bagó

sulfato de indinavir; *indinavir sulfate*; [1(1S,2R),5(S)]-2,3,5-trideoxy-N-(2,3-dihydro-1H-inden-1-yl)-5-[2-[[(1,1-dimethylethyl)-amino] carbonyl]-4-(3-pyridinyl)-1-piperazinyl]-2-(phenylmethyl]-D-erythro-pentonamide sulfate; antiviral; antiviral; Merck Index 14, 4945; CAS: 157810-81-6; DCB: 04883; NCM: 2933.39.99; TEC: 2%; **Bra:** Nortec Química

sulfato de lítio; *lithium sulfate*; lithium sulfate; antidepressivo; antidepressant; Merck Index 14, 5541; CAS: 10377-48-7; DCB: 08166; NCM: 2833.29.20; TEC: 2%; **Bra:** Quimibrás

sulfato de magnésio; *magnesium sulfate*; magnesium sulfate; catártico; cathartic; Merck Index 14, 5691; CAS: 7487-88-9; DCB: 08167; NCM: 2833.21.00; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

sulfato de manganês; *manganese sulfate*; manganese sulfate; nutriente em veterinária; nutritional factor in vet; Merck Index 14, 5739; CAS: 7785-87-7; DCB: 08169; NCM: 2833.29.90; TEC: 10%; **Bra:** Caq

sulfato de morfina; *morphine sulfate*; (5alpha,6alpha)-7,8-didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol sulfate; analgésico (narcótico); analgesic (narcotic); Merck Index 14, 6276; CAS: 64-31-3; DCB: 06114; NCM: 2939.11.62; TEC: 2%; **Arg:** Verardo; **Bra:** Diosynth

sulfato de potássio; *potassium sulfate*; potassium sulfate; catártico; cathartic; Merck Index 14, 7674; CAS: 7778-80-5; DCB: 08171; NCM: 3104.30.90; TEC: 0%; **Bra:** Caq, Quimibrás, Vetec

sulfato de pseudoefedrina; *pseudoephedrine sulfate*; (alphaS)-alpha-[(1S)-1-(methylamino)ethyl]benzene methanol sulfate; descongestionante nasal; decongestant (nasal); Merck Index 14, 7916; CAS: 7460-12-0; DCB: 07522; NCM: 2939.42.00; TEC: 2%; **Bra:** Nortec Química

sulfato de sódio; *sodium sulfate*; sodium sulfate; catártico; cathartic; Merck Index 14, 8680; CAS: 7757-82-6; DCB: 08173; NCM: 2833.11.10; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

sulfato de sódio (35 S); *sodium sulfate S 35*; agente radioativo; radioactive agent; USP Dictionary 2009, pág. 840; CAS: 14262-80-7; DCB: n.d.; NCM: 2844.40.90; TEC: 2%; **Bra:** IPEN

sulfato de tranilcipromina; *tranylcypromine sulfate*; trans-(+/-)-2-phenyl-cyclopropanamine sulfate; antidepressivo; antidepressant; Merck Index 14, 9573; CAS: 13492-01-8; DCB: 08814; NCM: 2921.49.31; TEC: 14%; **Arg:** Sindrofar

sulfato de zinco; *zinc sulfate*; white vitriol; adstringente oftálmico / fonte de zinco; ophthalmic astringent, zinc supplement; Merck Index 14, 10159; CAS: 7733-02-0; DCB: 08174; NCM: 2833.29.70; TEC: 10%; **Bra:** Caq, Quimibrás

sulfato ferroso; *ferrous sulfate*; ferrous sulfate; hematínico; hematinic; Merck Index 14, 4057; CAS: 7720-78-7; DCB: 08176; NCM: 2833.29.90; TEC: 10%; **Bra:** Caq, Quimibrás, Vetec

sulfato ferroso heptaidratado; *ferrous sulfate heptahydrate*; hematínico; hematinic; Merck Index 14, 4057; CAS: 7782-63-0; DCB: 08177; NCM: 2833.29.90; TEC: 10%; **Bra:** SQ Brasil

sulfeto de selênio; *selenium sulfide*; selenium disulfide; antisseborréico tópico; topical antiseborrheic; Merck Index 14, 8436; CAS: 7488-56-4; DCB: 08182; NCM: 2830.90.19; TEC: 2%; **Bra:** Quimibrás

sulfiram; *monosulfiram*; sulfiram / tetraethylthiodicarbonic diamide; ectoparasiticida; ectoparasiticide; Merck Index 14, 8950; CAS: 95-05-6; DCB: 08185; NCM: 2930.30.12; TEC: 12%; **Bra:** Champion

sulfóxido de albendazol; *albendazole sulfoxide*; veja óxido de albendrazol; *see albendazole oxide*

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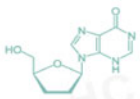
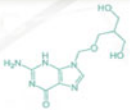
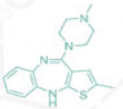
Didanosine
Didanosina

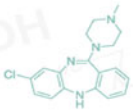




Ganciclovir
Ganciclovir

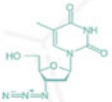
Clozapine
Clozapina

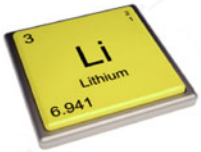




Olanzapine
Olanzapina

Zidovudine
Zidovudina

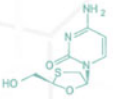




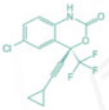
Lithium Chloride
Cloreto de Lítio

Lithium Carbonate
Carbonato de Lítio

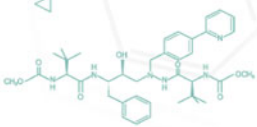
Lamivudine
Lamivudina



Efavirenz
Efavirenz



Atazanavir
Atazanavir



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Anti-Inflamatórios/Analgésicos: Ácido Acetilsalicílico • Diclofenaco • Diclofenaco Colestiramina • Diclofenaco Dietilamônio • Diclofenaco Potássico • Diclofenaco Resinato • Diclofenaco Sódico • Ibuprofeno • Paracetamol.

Benzodiazepínicos: Bromazepam • Clonazepam • Cloridrato de Midazolam • Flurazepam • Maleato de Midazolam • Midazolam.

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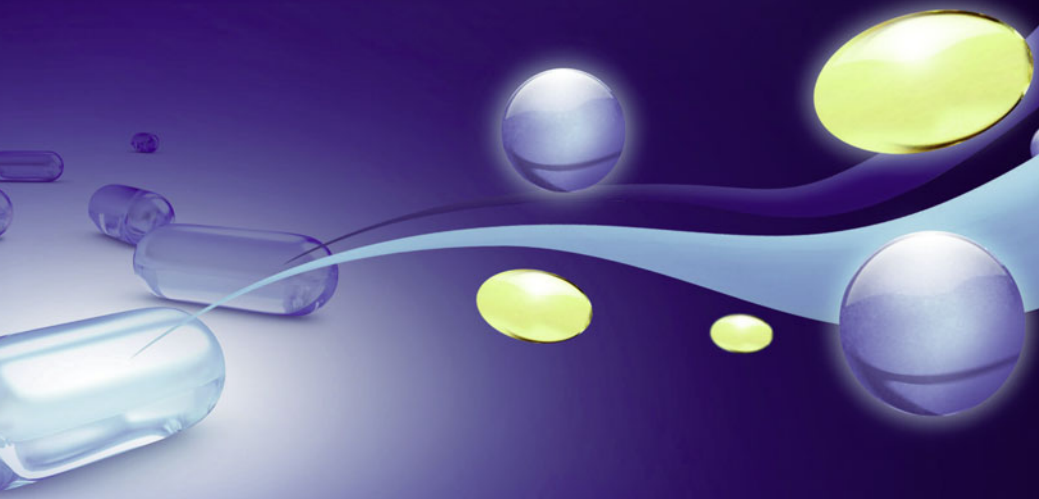

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PRODUCTOS

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Bupivacaína
Clonixinato de Lisina
Cloruro de Lapirio
Dapoxetina
Dexrazoxano
Diclofenac Colestiramina
Diclofenac Dietilamina
Diclofenac Epolamina
Fentanilo Base
Fentanilo Citrato
Flutamida
Homatropina Metilbromuro
Ibuprofenato de Lisina
Leflunomida
Levobupivacaina
Lomifilina
Metadona
Miltefosina
Mirtazapina
Modafinilo
Nilutamida
Nimodipina
Nisoldipina
Nitrendipina
Pentamidina
Propinox
Propiverina
Ranolazina
Remifentanilo
Riluzol
Ropivacaina
Talidomida
Topiramato

PRODUCTS

Meglumine Antimonate
Bupivacaine
Clonixin Lysine Salt
Lapyrium Chloride
Dapoxetine
Dexrazoxane
Diclofenac Cholestyramine
Diclofenac Diethylamine
Diclofenac Epolamine
Fentanyl Base
Fentanyl Citrate
Flutamide
Homatropine Methylbromide
Ibuprofen Lysine Salt
Leflunomide
Levobupivacaine
Lomifyline
Methadone
Miltefosine
Mirtazapine
Modafinil
Nilutamide
Nimodipine
Nisoldipine
Nitrendipine
Pentamidine
Propinox
Propiverine
Ranolazine
Remifentanyl
Riluzole
Ropivacaine
Thalidomide
Topiramate

Av. Veléz Sarsfield 5855 | B1606ARI | Carapachay | Bs. As. | Argentina
tel./fax-phone: (5411) 4762 6405 | triquim@lazar.com.ar

tacrolimo; *tacrolimus*; 15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone,5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26ª-hexadeca-hydro-5,19-dihydroxy-3-[2-(4-hydroxy-3-methoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propenyl)-monohydrate,[3S-[3R,[E(1S,3S,4S)],4S,5R,8S,9E,12R,14R,15S,16R,18S,19S,26Ar]]-(2)(-)-(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-8-allyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26ª-hexadecahydro-5,19-dihydroxy-3[(E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido [2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone)-monohydrate; imunossupressor; immunosuppressant; Index Merck 14, 9025; CAS: 104987-11-3; DCB: 08252; NCM: 2934.99.99; TEC: 2%; **Bra:** Medapi

talidomida; *thalidomide*; 3-(2,6-dioxo-3-piperidinyl)-1H-isoindole-1,3-(2H)-dione; imunomodulador / sedativo; immunomodulator, sedative; Merck Index 14, 9255; CAS: 50-35-1; DCB: 08266; NCM: 2925.19.10; TEC: 14%; **Arg:** Triquim; **Bra:** Microbiológica

tartarato ácido de potássio; *potassium bitartrate*; potassium acid tartrate; catártico; cathartic; Merck Index 14, 7615; CAS: 868-14-4; DCB: 00351; NCM: 2918.13.10; TEC: 12%; **Bra:** Quimibrás, Vetec

tartarato de sódio; *sodium tartrate*; sodium tartrate; catártico; cathartic; Merck Index 14, 8684; CAS: 868-18-8; DCB: 00355; NCM: 2918.13.10; TEC: 12%; **Bra:** Quimibrás, Vetec

tartarato de tolterodina; *tolterodine tartrate*; 2-[(1R)-3-[bis-(1-methylethyl)amino]-1-phenylpropyl]-4-methylphenol tartrate; no tratamento da incontinência urinária; in treatment of urinary incontinence; Merck Index 14, 9525; CAS: 124937-52-6; DCB: 08762; NCM: 2922.29.90; TEC: 2%; **Bra:** ITF

tartarato do ácido G-aminobutírico; *G-aminobutyric acid tartrate*; 4-aminobutanoic acid tartrate; anti-hipertensivo; antihypertensive; Merck Index 14, 430; CAS: n.d.; DCB: n.d.; NCM: 2922.49.90; TEC: 2%; **Bra:** Formil

tartarato de potássio e sódio (sal de Seignette); *potassium sodium tartrate*; Rochelle salt / Seignette salt; catártico; cathartic; Merck Index 14, 7670; CAS: 6381-59-5; DCB: n.d.; NCM: 2918.13.10; TEC: 12%; **Bra:** Quimibrás

temozolomida; *temozolomide;* 3,4-dihydro-3-methyl-4-oxoimidazo[5,1-d]-1,2,3,5-tetrazine-8-carboxamida; antineoplásico; antineoplastic; Merck Index 14, 9139; CAS: 85622-93-1; DCB: 08370; NCM: 2933.99.99; TEC: 2%; **Bra:** ITF

tetrafluoroborato de cobre; *copper tetrafluoroborate*, tetramibi; carreador de 99m Tecnécio; 99m Tc carrier; CAS: 103694-84-4; DCB: n.d.; NCM: 2841.90.90; TEC: 10%; **Bra:** Formil

tiabendazol; *thiabendazole*; 2-(4-thiazolyl)-1H-benzimidazole; antihelmíntico; anthelmintic (nematodes); Merck Index 14, 9289; CAS: 148-79-8; DCB: 08493; NCM: 2934.10.30; TEC: 2%; **Bra:** Nortec Química

tibolona; *tibolone*; (7alfa,17alfa)-17-hydroxy-7-methyl-19-norpregn-5(10)-en-20-yn-3-one; no tratamento da síndrome da menopausa; in treatment of menopausal syndrome; Merck Index 14, 9427; CAS: 5630-53-5; DCB: 08542; NCM: 2937.29.90; TEC: 2%; **Bra:** Libbs

timomodulina; *thymomodulin*; leucotrofin; imunorregulador; immunoregulator; Merck Index 14, 9402; CAS: 90803-92-2; DCB: 08605; NCM: 3001.20.90; TEC: 6%; **Bra:** Kin Master

tinturas de plantas; *medicinal plants tinctures*; NCM: 1302.19.90; TEC: 8%; **Bra:** Catedral, Centroflora

tiossulfato de sódio; *sodium thiosulfate*; sodium hyposulfite; desintoxicante, em veterinária; detoxifier in vet; Merck Index 14, 8694; CAS: 7772-98-7; DCB: 08650; NCM: 2832.30.20; TEC: 10%; **Bra:** Caq, Quimibrás

tiratricol; *tiratricol;* [4-(4-hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid; terapia substitutiva da tiróide / na obesidade; antihypothyroid; Merck Index 14, 9462; CAS: 51-24-1; DCB: 08681; NCM: 2937.90.10; TEC: 14%; **Arg:** Tolbiac

tiratricol sódico; *tiratricol sodium*; [4-(4-hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid sodium salt; na terapia substitutiva da tiróide / na obesidade; antihypothyroid; Merck Index 14, 9462; CAS: 1477-04-9; DCB: 08682; NCM: 2937.90.10; TEC: 14%; **Arg:** Tolbiac

topiramato; *topiramate*; 2,3: 4,5-bis-0-(1-methylethylidene)-beta-D-fructopyranose sulfamate; anticonvulsivo, antienxaqueca; anticonvulsant, antimigraine; Merck Index 14, 9547; CAS: 97240-79-4; DCB: 08776; NCM: 2935.00.99; TEC: 2%; **Arg:** Triquim; **Bra:** Globe

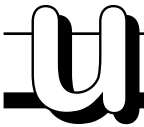
tosilato de valinéster; *valinester tosylate*; 2-amino-3-methyl-butiric acid benzyl ester toluene-4-sulfonate; intermediário para a produção de valsartana; intermediate to valsartan production; CAS: 16652-76-9; DCB: n.d.; NCM: 2922.49.90; TEC: 2%; **Bra:** Novartis •

tosilcloramida sódica; *chloramine-T*; N-chloro-4-methylbenzenesulfonamide sodium salt; antibacteriano; antibacterial; Merck Index 14, 2075; CAS: 127-65-1; DCB: 08797; NCM: 2935.00.91; TEC: 2%; **Bra:** Vetec

triglicérido dos ácidos cáprico e caprílico; *capric and caprylic acids triglycerides*; capric and caprylic acids triglycerides; adjuvante farmacotécnico como dissolvente em preparações farmacêuticas; pharmaceutic aid; Merck Index 14, 1758 and 1765; CAS: n.d.; DCB: n.d.; NCM: 1516.20.00; TEC: 10%; **Bra:** Croda

trimetoprima; *trimethoprim*; 5-[(3,4,5-trimethoxyphenyl)methyl]-2,4-pyrimidinediamine; antibacteriano; antibacterial; Merck Index 14, 9709; CAS: 738-70-5; DCB: 08921; NCM: 2933.59.41; TEC: 14%; **Bra:** Globe

trissilicato de magnésio; *magnesium trisilicate*; magnesium trisilicate; antiácido; antacid; Merck Index 14, 5687; CAS: 14987-04-3; DCB: 08952; NCM: 2839.90.10; TEC: 10%; **Bra:** Quimibrás



undecilenato de zinco; *zinc undecylenate*; 9-undecylenic acid zinc salt; antifúngico (tópico); antifungal (topic); Merck Index 14, 9848; CAS: 557-08-4; DCB: 00368; NCM: 2916.19.23; TEC: 2%; **Bra:** Formil

ureia; *urea*, carbamide; diurético; diuretic; Merck Index 14, 9867; CAS: 57-13-6; DCB: 01711; NCM: 3102.10.10; TEC: 6%; **Bra:** Quimibrás

valesteramida; *valesteramide*; biphenyl valinesteramide; intermediário para a produção de anti-hipertensivo; intermediate for antihypertensive production; reference not informed; CAS: 137864-22-3; DCB: n.d.; NCM: 2922.50.99; TEC: 2%; Bra: Novartis •

valina (L); *valine (L)*; 2-aminoisovaleric acid; aminoácido; aminoacid; Merck Index 14, 9909; CAS: 72-18-4; DCB: n.d.; NCM: 2922.49.90; TEC: 2%; **Bra:** Ajinomoto

vaselina sólida (petrolato); *petrolatum*; petroleum jelly; adjuvante farmacotécnico como base para pomadas; pharmaceutic aid (ointment base); Merck Index 14, 7186; CAS: 8009-03-8; DCB: 09103; NCM: 2712.10.00; TEC: 4%; **Bra:** Caq

virginiamicina; *virginiamycin*; staphylomycin; antibacteriano (antibiótico); antibacterial; Merck Index 14, 10004; CAS: 11006-76-1; DCB: 09176; NCM: 2941.90.83; TEC: 2%; **Bra:** Phibro

zaleplona; *zaleplon*; N-[3-3(cianopirazolo[1,5]pirimidin-7-il)-phenyl]-N-ethylacetamida; sedativo e hipnótico; sedative and hypnotic; Merck Index 14, 10111; CAS: 151319-34-5; DCB: 09231; NCM: 2933.59.19; TEC: 2%; **Arg:** Gador

zidovudina; *zidovudine*; AZT / azidothymidine / 3-azido-3-deoxythymidine; no tratamento da AIDS / antiviral; antiviral; Merck Index 14, 10123; CAS: 30516-87-1; DCB: 09256; NCM: 2934.99.22; TEC: 12%; **Bra:** CYG Biotech, Microbiológica, Nortec Química

Se o seu produto não constou nesta edição do Índex, entre em contato com a **abiquifi** informando:

- Dados completos de sua firma.
- Insumos farmacêuticos que produz.
- Referência de cada produto no Index Merck (ou similar).
- Indicação da capacidade instalada para cada produto.
- Informe se tem projetos para outros insumos e para quando.
- Nome e telefone do responsável pela área técnica.

Associação Brasileira da Indústria Farmoquímica e de Insumos Farmacêuticos

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Tel.: +55 21 2220-3005 • Fax: +55 21 2524-6506
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Anuncie no Índex abiquifi

Sua empresa em destaque em uma publicação tradicional e de grande abrangência.

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O **Índex abiquifi** é enviado para todos os laboratórios farmoquímicos e farmacêuticos brasileiros, para as indústrias farmacêuticas do continente americano (exceto EUA e Canadá) e também para autoridades brasileiras, consulados e embaixadas do Brasil no exterior e de outros países no Brasil, servindo como importante fonte de consulta.

Em sua 31ª edição, o **Índex abiquifi** é uma publicação de alcance crescente e já tradicional nos mercados farmoquímico e farmacêutico.

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2ª PARTE

Relação de Produtores

A relação de produtores está em ordem alfabética, independente do país em que se encontrem.

No caso dos produtos brasileiros o sinal (•) indica que os mesmos são fabricados para uso cativo da empresa – são incluídos aqui, apenas, para fins de registro.

Para produtos argentinos, a disponibilidade para terceiros deve ser consultada junto aos respectivos produtores.

Para alguns associados da **abiquifi** estamos publicando um resumo das suas atividades e um histórico do seu desenvolvimento no País.

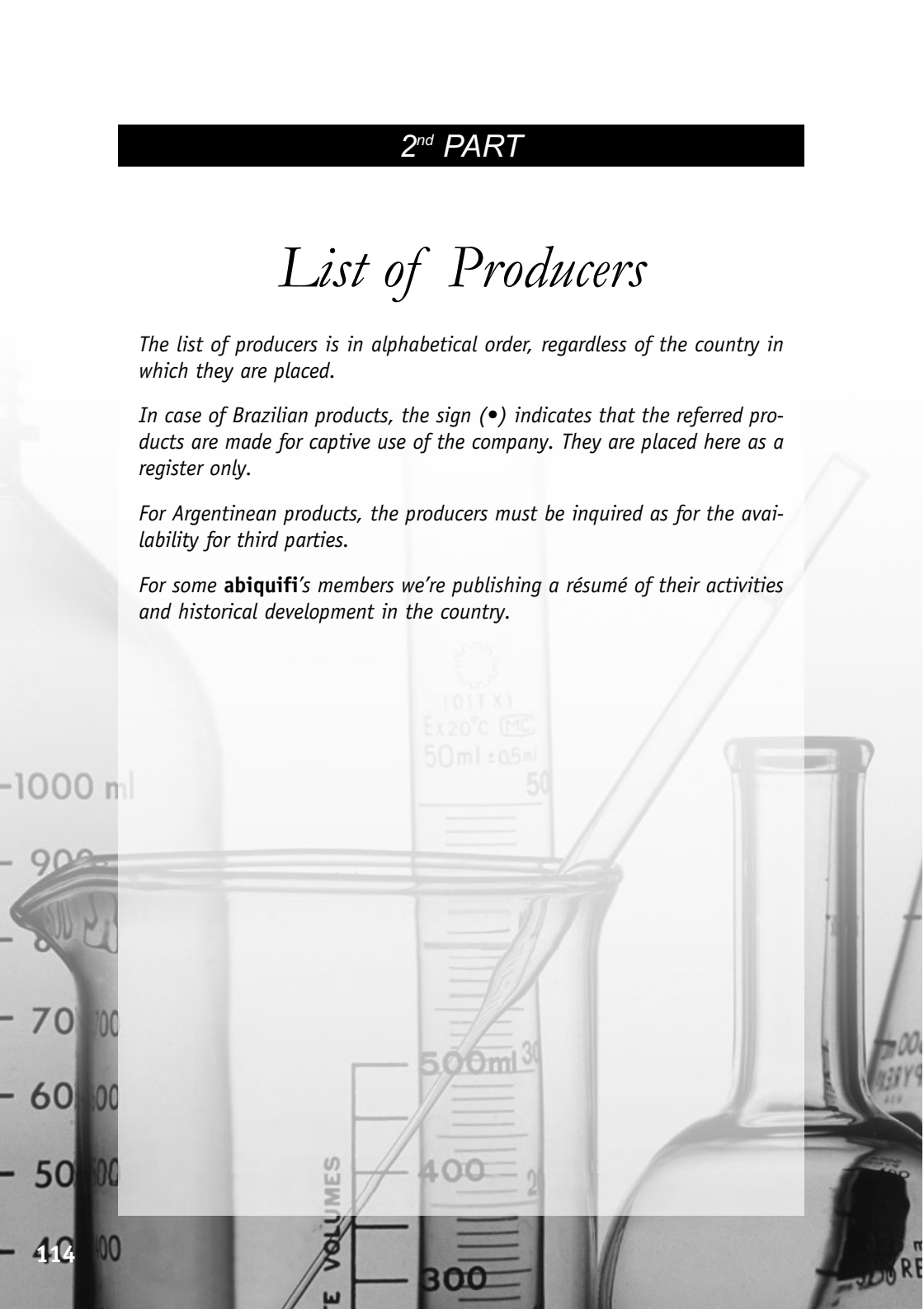
List of Producers

The list of producers is in alphabetical order, regardless of the country in which they are placed.

In case of Brazilian products, the sign (•) indicates that the referred products are made for captive use of the company. They are placed here as a register only.

For Argentinean products, the producers must be inquired as for the availability for third parties.

For some **abiquifi***'s members we're publishing a résumé of their activities and historical development in the country.*



ABL
Antibióticos do Brasil Ltda.
Rodovia Professor Zeferino Vaz – SP-332 – km 135 – Itapavussu
13150-000 – Cosmópolis – SP – Bra.
Tel/Phone: (19) 3872-9325
Fax: (19) 2845-2153
e-mail: mbosoni@ablbrasil.com.br

arginina estéril/*arginine sterile*
bicarbonato de sódio estéril/*sodium bicarbonate sterile*
carbonato de sódio estéril/*sodium carbonate sterile*
cefalexina estéril/*cephalexin sterile*
cefalotina sódica estéril/*cefalotin sodium sterile*
cefepima sódica estéril/*cefepime sodium sterile*
cefotaxima sódica estéril/*cefotaxime sodium sterile*
cefoxitina sódica estéril/*cefoxitin sodium sterile*
ceftazidima tamponada estéril/*ceftazidime sterile*
ceftriaxona sódica estéril/*ceftriaxone sodium sterile*
cloridrato de cefepima estéril/*cefepime hydrochloride sterile*
nafato de cefamandol estéril/*cefamandole nafate sterile*

A Antibióticos do Brasil – ABL, com fábrica localizada em Cosmópolis-SP e escritórios comerciais em São Paulo e no Rio de Janeiro, foi criada em janeiro de 2003 pela Eli Lilly do Brasil após decisão estratégica da Multinacional Americana de deixar o segmento voltado à fabricação e comercialização de antibióticos e concentrar os seus negócios em medicamentos patenteados e inovadores.

Em abril de 2003 a ABL foi vendida ao Grupo Italiano ACS Dobfar, que atua na Itália há quase trinta anos na produção de antibióticos penicilânicos e cefalosporânicos e tinha interesse em atuar no mercado brasileiro.

A ABL, empresa associada à **abiquifi**, conta com aproximadamente 336 colaboradores e produz, além de medicamentos para o segmento hospitalar, farmoquímicos para atender o seu consumo e de outros laboratórios.

Tem como uma de suas prioridades o meio ambiente, possuindo em sua planta um incinerador de alta tecnologia, o maior em capacidade de queima instalado no país, prestando inclusive serviços para outras empresas, para destruição de resíduos perigosos.

Antibiotics do Brasil – ABL, with its production units in Cosmópolis-SP and sales offices in São Paulo and Rio de Janeiro, was established in January 2003, by Eli Lilly do Brasil. This constituted a strategy decision taken by the American Multinational, to leave the segment of sales and manufacture of antibiotics and to concentrate its business on the manufacture and marketing of patent and innovative drugs.

In April 2003, ABL was sold to the Italian group ACS Dobfar, operating for almost 30 years in production of penicillin and cephalosporanic antibiotics in Italy and became interested in operating on the Brazilian market.

ABL, a member company of **abiquifi***, has a staff of about 336 and, in addition to producing medication items for the hospital segment, supplies pharmaceutical chemicals for such institutions and also for consumption by other laboratories.*

With a priority concern for the environment, the company plant has its own advanced technology incinerator – which has biggest incineration capacity of its kind in Brazil, providing services for other companies in completely destroying hazardous wastes.

ACA
Associacion de Cooperativas Argentinas C.L.
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C1106ACW – Buenos Aires – Arg.
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Fax: (11) 4313-7571
e-mail: porta@acacoop.com.ar

amitraz/*amitraz*
closantel/*closantel*
enrofloxacino/*enrofloxacin*
ivermectina/*ivermectin*
oxfendazol/*oxfendazole*
óxido de albendazol/*albendazole sulfoxide*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

AJINOMOTO
Ajinomoto do Brasil Indústria e Comércio de Alimentos Ltda.
Rua Joaquim Távora, 845 – Vila Mariana
04015-001 – São Paulo – SP – Bra.
Tel/*Phone*: (11) 5080-8778
Fax: (11) 5908-8799
e-mail: amino@br.ajinomoto.com
Internet: www.ajinomoto.com.br

glutamina (L)/*glutamine (L)*
isoleucina (L)/*isoleucine (L)*
valina (L)/*valine (L)*

ALPHA BR
Alpha Br Produtos Químicos Ltda.
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05508-090 – São Paulo – SP – Bra.
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Fax: (11) 3039-8356
e-mail: apq@apq.com.br
Internet: www.apq.com.br

citrato de fentanila/*fentanyl citrate*
clonazepam/*clonazepam*
cloridrato de midazolam/*midazolam hydrochloride*
cloxazolam/*cloxazolam*
maleato de midazolam/*midazolam maleate*
midazolam/*midazolam*
olanzapina/*olanzapine*

BAGÓ
Laboratórios Bagó S.A.
Calle 455, 24 a 27 – City Bell
Partido de La Plata – Província de Buenos Aires – Arg.
Tel/*Phone*: (221) 480-0015
Fax: (221) 480-0019
e-mail: jlambrus@bago.com.ar
Internet: www.bago.com.br

acetato de hidroxocobalamina/*hydroxocobalamin acetate*
ácido cólico/*cholic acid*
ácido deidrocólico/*dehydrocholic acid*
ácido desoxicólico/*desoxycholic acid*
cloridrato de hidroxocobalamina/*hydroxocobalamin hydrochloride*
diclofenaco sódico microencapsulado
/diclofenac sodium microencapsulated
fosfato de carvedilol/*carvedilol phosphate*
sulbactam pivoxila/*sulbactam pivoxil*
sulbactam sódico estéril/*sulbactam sodium sterile*
sulfato de hidroxocobalamina/*hydroxocobalamin sulfate*

BIO-COW
Bio-Cow
Otamendi, 1462 – Valentin Alsina
B1822ESJ – Buenos Aires – Arg.
Tel/Phone: (911) 5302-9906
e-mail: achiocconi@bio-cow.com
Internet: www.bio.com

sulfato de condroitina/*chondroitin sulfate*

BIO SIDUS
Bio Sidus S.A.
Constitución, 4.234
1254 – Buenos Aires – Arg.
Tel/*Phone*: (11) 4909-8063
Fax: (11) 4909-8055
e-mail: m.denegri@biosidus.com.ar

eritropoietina humana recombinante
/human erythropoietin recombinant
filgrastim/*filgrastin*
interferona alfa-2a recombinante/*interferon alpha-2a recombinant*
interferona alfa-2b recombinante/*interferon alpha-2b recombinant*
interferona beta-1a recombinante/*interferon beta-1a recombinant*
lenograstim/*lenograstim*
somatropina/*somatropin*

BIOSUL
Biosul Produtos Biológicos Ltda.
Rua da Glória, 60 – Jardim America
79080-250 – Campo Grande – MS – Bra.
Tel/*Phone*: (67) 3028-4443
Fax: (67) 3028-4436
e-mail: martinique.madach@biosulcg.br

Soro fetal bovino/*bovine fetal serum*

BLANVER

Blanver Farmoquímica Ltda.
Rua Dr. José Alexandre Crosgnac, 715
06680-035 – Itapevi – SP – Bra.
Tel/*Phone*: (11) 4144-9400
Fax: (11) 4144-9401
e-mail: blanver@blanver.com.br
Internet: www.blanver.com.br

celulose gel/*cellulose gel*
celulose microcristalina/*microcrystalline cellulose*
croscarmelose sódica/*croscarmellose sodium*
glicolato de amido sódico/*sodium starch glycolate*

A Blanver foi fundada em 1978 e é a única fabricante de seus produtos na América Latina para as indústrias Farmacêutica, Alimentícia e Cosmética, comercializado-os em mais de 100 países. Com mais de 300 funcionários e duas unidades fabris, Taboão da Serra e Itapevi, a Blanver também terceiriza etapas de fabricação farmacêutica para seus clientes.

Blanver founded in 1978 is the only manufacturer in Latin America for the Pharmaceutical, Food and Cosmetic industry of its products used in more tham 100 countries. With more than 300 employees and two manufacturing sites, Taboão da Serra and Itapevi, Blanver also provides pharmaceutical contract-manufacturing services for its customers.

BRAZINCO

Brazinco Indústria de Pigmentos Ltda.
Rua Capitão Ferraiuolo, 648 – Chácara Mafalda
03370-000 – São Paulo – SP – Bra.
Tel/*Phone*: (11) 2671-1133
Fax: (11) 2671-0164
e-mail: brazinco@brazinco.com.br
Internet: www.brazinco.com.br

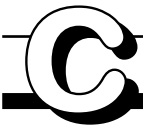
óxido de zinco/*zinc oxide*

BUSCHLE & LEPPER

Buschle & Lepper S.A.
Rodovia BR-116 – km 2,5, nº 14.951 – Xaxim
81690-300 – Curitiba – PR – Bra.
Tel/*Phone*: (41) 3275-7577
Fax: (41) 3275-7887
e-mail: magnesio.ctba@buschle.com.br
Internet: www.buschle.com.br

carbonato de magnésio precipitado/*magnesium carbonate precipitated*
hidróxido de alumínio gel e pó/*aluminum hydroxide gel and powder*
hidróxido de magnésio precipitado gel e pó
/magnesium precipitated gel and powder
óxido de magnésio precipitado/*magnesium oxide precipitated*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*



CAQ
Casa da Química Indústria e Comércio Ltda.
Rua Álvares Cabral, 693 – Vila Conceição
09981-030 – Diadema – SP – Bra.
Tel/*Phone*: (11) 4053-2855
Fax: (11) 4053-2556
e-mail: vendas@caq.com.br
Internet: www.caq.com.br

acetato de sódio/*sodium acetate*
ácido bórico/*boric acid*
ácido cítrico monoidratado/*citric acid monohydrate*
ácido oxálico/*oxalic acid*
borato de sódio (tetraborato de sódio)/*sodium borate*
carbonato de cálcio/*calcium carbonate*
carbonato de magnésio/*magnesium carbonate*
cloreto de cálcio/*calcium chloride*
cloreto de magnésio/*magnesium chloride*
cloreto de potássio/*potassium chloride*
cloreto de sódio/*sodium chloride*
fluoreto de sódio/*sodium fluoride*
fosfato de cálcio dibásico/*calcium phosphate dibasic*
fosfato de cálcio monobásico/*calcium phosphate monobasic*
fosfato de cálcio tribásico/*calcium phosphate tribasic*
fosfato de magnésio dibásico/*magnesium phosphate dibasic*
fosfato de magnésio tribásico/*magnesium phosphate tribasic*
fosfato de potássio dibásico/*potassium phosphate dibasic*
fosfato de potássio monobásico/*potassium phosphate monobasic*
fosfato de sódio dibásico/*sodium phosphate dibasic*
fosfato de sódio monobásico/*sodium phosphate monobasic*
hidróxido de alumínio/*aluminum hydroxide*
lactato de sódio/*sodium lactate*
nitrato de amônio/*ammonium nitrate*
nitrato de potássio/*potassium nitrate*
pirofosfato férrico/*ferric pyrophosphate*
reagentes analíticos/*analytical reagents*

sulfato cúprico/*cupric sulfate*
sulfato de cálcio/*calcium sulfate*
sulfato de magnésio/*magnesium sulfate*
sulfato de manganês/*manganese sulfate*
sulfato de potássio/*potassium sulfate*
sulfato de sódio/*sodium sulfate*
sulfato de zinco/*zinc sulfate*
sulfato ferroso/*ferrous sulfate*
tiossulfato de sódio/*sodium thiosulfate*
vaselina sólida (petrolato)/*petrolatum*

CARBOMAFRA
Indústrias Químicas Carbomafra S.A.
Rua Wiegando Olsen, 2.540 – CIC
81450-100 – Curitiba – PR – Bra.
Tel/*Phone*: (41) 3348-2323
Fax: (41) 3348-1531
e-mail: tecnico@carbomafra.com.br
Internet: www.carbomafra.com.br

carvão ativado/*activated carbon*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

CATALENT
Catalent Brasil Ltda.
Avenida Jerome Case, 1.277 – Eden
18087-220 – Sorocaba – SP – Bra.
Tel/*Phone*: (15) 3235-3513 / 3235-3500
Fax: (15) 3225-2306
Internet: www.catalent.com

cápsulas de gelatina elástica/*soft gelatin capsules*

CATEDRAL
Indústria Faramcêutica Catedral Ltda
Rua Hum, 288 – Nova Pampulha
33200-000 – Vespasiano – MG – Br.
Tel/Phone: (31) 3629-2000
Fax: (31) 3629-2000
e-mail: contato@laboratoriocatedral.com.br
Internet: www.laboratoriocatedral.com.br

extratos fluidos/*fluid vegetal extracts*
extratos secos/*dried vegetal extracts*
tinturas de plantas/*medicinal plants tinctures*

CENTROFLORA
Anidro do Brasil Extrações S.A.
Avenida Eduardo Zuccari – km 21,5 – Caixa Postal 254
18603-970 – Botucatu – SP – Bra.
Tel/*Phone*: (14) 3811-3520
Fax: (14) 3813-3877
e-mail: melissa@centroflora.com.br
Internet: www.centroflora.com.br

GRUPO CENTROFLORA
Parcerias para um mundo melhor.

corantes naturais/*natural dyes*
extratos fluídos/*fluidextracts*
extratos moles/*soft vegetal extracts*
extratos secos/*dried vegetal extracts*
plantas medicinais/*medicinal plants*
tinturas de plantas/*medicinal plants tinctures*

CHAMPION
Champion Farmoquímico Ltda.
Avenida Diomício de Freitas s/n – lote 12 – DAIA
75133-000 – Anápolis – GO – Bra.
Tel/*Phone*: (62) 3310-0728
Fax: (62) 3310-0725
e-mail: flavio@champion.ind.br

diflubenzurona/*diflubenzuron*
disofenol/*disophenol*
sulfiram/*monosulfiram*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

COBRASCAL
Cobrascal Indústria de Cal Ltda.
Estrada Velha de Bragança Paulista – km 44,5 – Terra Preta
07600-000 – Mairiporã – SP – Bra.
Tel/*Phone*: (11) 4486-8600
Fax: (11) 4486-8611
e-mail: cobrascal@cobrascal.com.br

hidróxido de cálcio/*calcium hydroxide*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

CPKELCO
CPKelco Brasil S.A.
Avenida Araras, 799
13485-130 – Limeira – SP – Bra.
Tel/*Phone*: (19) 3404-4600
Fax: (19) 3404-4639
e-mail: joao.c.golfi@cpkelco.com
Internet: www.cpkelko.com

pectina cítrica/*citric pectin*

CRISTÁLIA

Cristália Produtos Químicos Farmacêuticos Ltda.
Rodovia Itapira – Lindoia, Km 14
13970-000 – Itapira – SP – Bra.
Tel/*Phone*: (19) 3843-9500
Fax: (19) 3843-9449
e-mail: gq.sintese@cristalia.com.br
Internet: www.cristalia.com.br

carbonato de lodenafila/*lodenafil carbonate*
citrato de fentanila/*fentanyl citrate*
citrato de sufentanila/*sufentanil citrate*
cloridrato de alfentanila monoidratado
/*alfentanil hydrochloride monohydrate*
cloridrato de dextrobupivacaína/*dextrobupivacaine hydrochloride*
cloridrato de dextrocetamina/*dextrocetamine hydrochloride*
cloridrato de levobupivacaína/*levobupivacaine hydrochloride*
cloridrato de petidina (meperidina)/*pethidine hydrochloride*
cloridrato de ropivacaína/*ropivacaine hydrochloride*
dantroleno sódico hemieptaidratado
/*dantrolene sodium hemiheptahydrate*
decanoato de flufenazina/*fluphenazine decanoate*
decanoato de haloperidol/*haloperidol decanoate*
droperidol/*droperidol*
efavirenz/*efavirenz*
enantato de flufenazina/*fluphenazine enanthate*
etomidato/*etomidate*
fentanila/*fentanyl*
lactato de biperideno/*biperiden lactate*
ritonavir/*ritonavir*
saquinavir/*saquinavir*
sevoflurano/*sevoflurane*

O Cristália é uma indústria farmoquímica e farmacêutica brasileira, focada no desenvolvimento e na produção de insumos ativos e de medicamentos que atendam cada vez melhor as necessidades dos médicos e seus pacientes.

Fundado em 1972, o laboratório possui três unidades fabris, uma sede comercial e outros oito escritórios regionais. Em Itapira (SP), a 180 km da capital, fica a maior unidade, onde estão a Farmoquímica (pesquisa e fabricação de insumos farmacêuticos ativos), os laboratórios de Pesquisa, Desenvolvimento e Inovação (PD&I) e a produção farmacêutica. A administração e

outra unidade fabril também ficam naquela cidade.

Já em São Paulo, no bairro Butantã, localizam-se a fábrica de injetáveis e o escritório comercial, que abriga o Marketing, o Departamento Médico e outros setores de apoio.

Todas as plantas possuem Certificados de Boas Práticas de Fabricação da Anvisa (Agência Nacional de Vigilância Sanitária). Ao todo, são cerca de 2 mil funcionários.

Entre os diferenciais do Cristália pode-se destacar o investimento consistente em PD&I, sempre em busca da síntese de novas moléculas, da produção de novos medicamentos e do aprimoramento de processos. A empresa conta com sete patentes internacionais concedidas e têm mais de 80 pedidos depositados no Brasil e no exterior.

Além do mercado interno, o Cristália exporta regularmente seus insumos farmacêuticos ativos e medicamentos para diversos países da América Latina, África, Ásia e Oceania.

Unidades de negócio:

Hospitalar – Líder brasileira do segmento, a empresa atende especialidades como Anestesiologia, Algologia (tratamento da Dor), Terapia Intensiva e Oncologia.

Farma – Voltada a medicamentos éticos (vendidos sob prescrição médica), tem como foco as especialidades Urologia, Algologia, Psiquiatria, Neurologia, Oncologia, Geriatria e Ortopedia.

Corporis – Produtos de alta complexidade destinados à Dermatologia e à Medicina Estética.

Biológica – Dedica-se a medicamentos essenciais para o aumento da taxa de sobrevida e da qualidade de vida de pacientes imunodeprimidos e doentes crônicos.

Genéricos – Linha diversificada de produtos para as especialidades Cardiologia, Oftalmologia, Pneumologia e Ginecologia, entre outras.

Nossa missão:

"Produzir o maior número possível de medicamentos com qualidade e preço justo, estimular a pesquisa nacional, buscar incessantemente a inovação, para contribuir na solução dos problemas de saúde."

Cristália is a Brazilian pharmaceuticals and pharmochemicals industry focused on the development and production of active pharmaceutical ingredients and medical products that meet with the ever-increasing needs of doctors and their patients.

Established in 1972, the Cristália laboratory has three manufacturing

units, a commercial head office and eight regional offices. The Pharmochemicals facility (research and manufacture of active pharmaceutical ingredients), a Research, Development and Innovation laboratory (PD&I) and Pharmaceuticals Production Facility are all located at the largest Cristália unit in the city of Itapira (SP), 180 km from the State Capital. The company's administration office and another manufacturing are also in Itapira.

The injection component factory and the commercial office, which includes Marketing, the Medical Department and other support sectors, are located in the district of Butantã in the city of São Paulo.

All units are holders of Good business Practice Certificates issued by ANVISA (the Brazilian Sanitation Authority). The undertaking comprises about 2,000 employees.

Cristália has a number of sector differentials, including its well-established and consistent application of investments in PD&I, an ongoing quest for the synthesis of new molecules, the production of new medications and constant upgrading of its processes. The company is the holder of seven international patents and has more than 80 patents applied for in Brazil and abroad.

In addition to its local market, Cristália regularly exports its active pharmaceutical ingredients to various countries in n Latin America, Africa, Asia and Oceania.

Business Units:

Hospital – Brazil's leader in this Segment, Cristália is an active in speciality procedures such as Anaesthesiology, Algology (pain treatment), Intensive Therapy and Oncology.

Farma – Specialises in ethical medicines (sold against a doctor's prescription) with a particular focus on Urology, Algology, Psychiatry, Neurology, Oncology, Geriatrics and Orthopaedics.

Corporis – Highly complex products for Dermatology and Aesthetic Medicine.

Biológica – Dedicated to essential medicines for increase in the Life Expectancy rate and the quality of life of patients suffering from immune system depression and chronic illnesses.

Generics – A diversified product line for specialist areas such asCardiology, Ophthalmology, Pneumology and Gynaecology, among others.

Our mission:

"To produce the largest possible number of medications with quality and fair price, stimulate the national research, continuously seek innovation, in order to contribute solving health problems."

CRODA
Croda do Brasil Ltda.
Rua Croda, 580 – Distrito Industrial
13054-710 – Campinas – SP – Bra.
Tel/*Phone*: (19) 3765-3500
Fax: (19) 3765-3536
e-mail: marketingla@croda.com.br
Internet: www.croda.com.br

álcool oleílico/*oleyl alcohol*
lactato de miristila/*myristil lactate*
lanolina, anidra/*lanolin anhydrous*
lanolina, derivados/*lanolin derivatives*
manteiga de cupuaçu/*cupuaçu butter*
miristato de isopropila/*isopropyl myristate*
monoestearato de dietilenoglicol/*diethylene glycol monostearate*
monoestearato de etilenoglicol/*ethyleneglycol monostearate*
monoestearato de glicerila/*glyceryl monostearate*
monoestearato de sorbitana/*sorbitan monostearate*
óleo de gergelim/*sesame oil*
óleo de maracujá/*passiflora seed oil*
óleo de peixe/*fish oil*
palmitato de cetila/*cetyl palmitate*
polissorbato 20/*polysorbate 20*
polissorbato 60/*polisorbate 60*
polissorbato 80/*polisorbate 80*
triglicérido dos ácidos cáprico e caprílico/
capric and caprylic acids triglycerides

CYG BIOTECH
CYG Biotech Química e Farmacêutica Ltda.
Rua Hermínio de Mello, 311 – Distrito Industrial
13347-330 – Indaiatuba – SP – Bra.
Tel/*Phone*: (19) 3936-5040
e-mail: contato@cygbiotech.com.br

atazanavir/atazanavir
AZT (zidovudina)/*AZT (zidovudine)*
carbonato de lítio/*lithium carbonate*
cloreto de lítio/*lithium chloride*

clozapina/*clozapine*
didanosina (DDI)/*didanosine (DDI)*
efavirenz/*efavirenz*
ganciclovir/*ganciclovir*
lamivudina/*lamivudine*
olanzapina/*olanzapine*

A CYG Biotech é uma empresa brasileira de capital 100% nacional, dedicada à produção de princípios ativos e medicamentos farmacêuticos. Criada em 2010 por sócios com uma vasta experiência no mercado químico farmacêutico, a empresa além de medicamentos, síntese de produtos, laboratórios, planta piloto, presta serviços a outras indústrias do ramo sempre oferecendo soluções farmacêuticas que proporcionem melhoria da qualidade de vida às pessoas.

A CYG Biotech com escritórios em São Paulo tem uma fábrica localizada em Indaiatuba, interior do Estado de São Paulo, próximo aos melhores centros de pesquisa e pólos comerciais do Brasil a 100 km de São Paulo, 30 km de Campinas e a 10 km do aeroporto de Viracopos. Com uma fábrica moderna e investimentos significativos a CYG Biotech entra no mercado brasileiro como uma opção de qualidade e produtos inovadores.

CYG Biotech is a brazilian company dedicated to the production of active pharmaceutical ingredients and pharmaceutical drugs. Established in 2010 by partners with extensive experience in the chemical and pharmaceutical fields. In addition to medications, product synthesis, laboratories, pilot plant, we also provide services to other industries of the branch always offering pharmaceutical solutions that provide improved quality of life.

CYG Biotech with offices in São Paulo and the manufacturing plant located in Indaiatuba, interior of São Paulo, close to the best research centers and commercial hubs of Brazil, 100 km from São Paulo, 30 km from Campinas and 10 km from the Viracopos intenational airport. Modern facilities and significant investments make CYG Biotech an important choice of quality and innovative products for the brazilian market.

DIOSYNTH
Diosynth Produtos Farmo-Químicos Ltda.
Avenida Marginal Esquerda do Rio Tietê, 5.101
06410-240 – Barueri – SP – Bra.
Tel/*Phone*: (11) 2176-8900
Fax: (11) 2176-8998
e-mail: vanessa.batista@spcorp.com

cloridrato de morfina/*morphine hydrocloride*
codeína/*codeine*
desogestrel/*desogestrel* •
estradiol/*estradiol* •
estriol/*estriol* •
fosfato de codeína/*codein phosphate*
gonadotrofina coriônica humana/*HCG (human chorionic gonadotropin)* •
heparina bovina sódica/*heparin sodium*
heparina suína crua/*heparin swine crude* •
heparinoide/*heparinoid*
noroximorfona/*noroxymorphone* •
sulfato de morfina/*morphine sulfate*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

DOW
Dow Brasil S.A.
Avenida das Nações Unidas, 14.171 – Diamond Tower – Santo Amaro
04794-000 – São Paulo – SP – Bra.
Tel/*Phone*: (11) 5188-9297
Fax: (11) 5188-9400
e-mail: jfmaggioni@dow.com
Internet: www.dow.com.br

propilenoglicol/*propylene glycol*

EXTRASUL
Extratos Animais e Vegetais Ltda.
Estrada HT, 005, Km 01 – Zona Rural
86610-000 – Jaguapitã – PR – Bra.
Tel/Phone: (43) 3372-1532
Fax: (43) 3372-1532
e-mail: mmadach@extrasul.com.br
Internet: www.extrasul.com.br

heparina sódica bovina e suína/*heparin sodium bovine and porcine*
heparina sódica crua bovina e suína
/heparin sodium crude bovine and porcine
heparinoide bovino e suíno/*heparinoid bovine and porcine*
sulfato de condroitina/*chondroitin sulfate*

FORMIL

Formil Química Ltda.
Estrada Velha de Itú, 800 – Vila Márcia
06612-250 – Barueri – SP – Bra.
Tel/*Phone*: (11) 4789-8700
Fax: (11) 4707-2167
e-mail: formil@formil.com.br
Internet: www.formil.com.br

albendazol/*albendazole*
alprazolam/*alprazolam*
ambufilina/*ambuphylline*
benzoilmetronidazol/*benzoyl metronidazole*
bromazepam/*bromazepam*
cilostazol/*cilostazol*
ciprofibrato/*ciprofibrate*
clonazepam/*clonazepam*
cloridrato de anfepramona/*diethylpropion hydrochloride*
cloridrato de benzetimida/*benzetimide hydrochloride*
cloridrato de femproporex/*fenproporex hydrochloride*
cloridrato de midazolam/*midazolam hydrochloride*
cloxazolam/*cloxazolam*
flumazenil/*flumazenil*
hemifumarato de quetiapina/*quetiapine hemifumarate*
hemitartarato de zolpidem/*zolpidem bitartrate*
lorazepam/*lorazepam*
maleato de midazolam/*midazolam maleate*
mebendazol/*mebendazole*
metronidazol/*metronidazole*
midazolam/*midazolam*
modafinila/*modafinil*
nitrato de isoconazol/*isoconazole nitrate*
nitrato de miconazol/*miconazole nitrate*
pseudoefedrina/*pseudoephedrine*
sulfóxido de albendazol/*albendazole sulfoxide*
tartarato do ácido G-aminobutírico/*G-aminobutyric acid tartrate*

tetrafluoroborato de cobre/*copper tetrafluoroborate*
undecilenato de zinco/*zinc undecylenate*

Empresa:

A Formil Química Ltda. é uma empresa brasileira fundada em 1973, cuja fábrica localiza-se no Município de Barueri, Estado de São Paulo. Produzimos por síntese química ou extração e comercializamos IFA's (Insumos Farmacêuticos Ativos) no mercado interno e externo para as indústrias farmacêuticas humana, veterinária e cosmética. Nossa expertise está na busca constante de inovações, desenvolvidas por nosso departamento de P&D de forma autônoma, com colaboração de Universidades e Centros de Pesquisa e em parcerias com nossos clientes. Industrialmente, fabricamos produtos sob as mais rígidas normas de BPFc (Boas Práticas de Fabricação e Controle), garantindo a qualidade e confiabilidade de produtos, processos e serviços.

About us:

Formil Química Ltd. is a Brazilian company located in Barueri – SP. We produce through chemical synthesis or extraction and comercialize API (Active Pharmaceutical Ingredient) on local and external markets focused on Pharmaceuticals, Veterinary and Cosmetic companies. Our expertise is based in constant innovation's research, driven through our R&D department that works independently and with cooperation with Universities, Research Centers and also with costumer's partnership. Formil produces under rigorous GMP procedures that can guarantee the quality and reliability of our products, processes and services.

GADOR
Gador S.A.
Darwin, 429
C1414CUI – Buenos Aires – Arg.
Tel/*Phone*: (11) 4858-9000
Fax: (11) 4856-2868
e-mail: dejecutiva@gador.com.ar

ácido alendrônico/*alendronic acid*
ácido pamidrônico/*pamidronic acid*
cloridrato de venlafaxina/*venlafaxine hydrochloride*
etidronato de sódio/*etidronate disodium*
hemitartarato de zolpidem/*zolpidem hemitartrate*
norelgestromina/*norelgestromine*
norgestimato/*norgestimate*
zaleplona/*zaleplon*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

GAVETECO
Gaveteco S.A.I.C.F. e I.
Avenida Belgrano, 1.281
1093 – Buenos Aires – Arg.
Tel/*Phone*: (11) 4381-1053
Fax: (11) 4381-5324
e-mail: ventas@gaveteco.com

cartilagem de tubarão/*shark's cartilage*

GENIX
Genix Indústria Farmacêutica Ltda.
VP 1E Quadra 03 Mód. 01/02 DAIA
75132-040 – Anápolis – GO – Bra.
Tel/Phone: (62) 4014-9000
Fax: (62) 4014-9001
e-mail: genix@genix.ind.br
Internet: www.genix.ind.br

cápsulas de gelatina dura/*hard gelatin capsules*

A Genix Indústria Farmacêutica, fabricante das cápsulas de gelatina dura vazias marca Extracaps, é certificada pela Agência Nacional de Vigilância Sanitária – ANVISA, e considerada por especialistas do mercado como fábrica modelo devido à utilização dos melhores padrões de tecnologia internacional, equipamentos de última geração importados do Canadá, grande capacidade produtiva e uma equipe de profissionais altamente qualificados.

Genix Pharmaceutical Industry manufacturer of Extracaps brand of hard gelatin empty capsules is GMP certified by National Health Surveilance Agency – ANVISA, and considered by specialists of the market as a model plant due to use of the best standards of international technology, imported equipment of last generation from Canada, counting on great productive capacity and a highly qualified professionals team.

GEYER
Geyer Medicamentos S.A.
Rua Pelotas, 320 – Bairro Floresta
90220-110 – Porto Alegre – RS – Bra.
Tel/*Phone*: (51) 3092-7200
Fax: (51) 3092-7200
e-mail: geyer@geyermed.com.br
Internet: www.geyermed.com.br

peptona bacteriológica/*bacteriological peptone*

GLOBE

Globe Química S.A.
Rodovia SP, 332 – km 136 – Portão A (Parte) – Bairro Itapavussu
13150-000 – Cosmópolis – SP – Bra.
Tel/Phone: (19) 3872-8700
Fax: (19) 3872-8701
e-mail: robert@globequimica.com.br
Internet: www.globequimica.com.br

alendronato de sódio/*alendronate monosodium*
AZT (zidovudina)/*zidovudine*
bromazepam/*bromazepam*
carbocisteína (S-carboximetil cisteína)/*carbocysteine*
carbonato de lítio/*lithium carbonate*
cetoconazol/*ketoconazole*
citrato ferroso de cálcio/*calcium ferrous citrate*
cloridrato de amiodarona/*amiodarone hydrochloride*
cloridrato de bupropiona/*bupropione hydrochloride*
cloridrato de dietilpropiona (anfepramona)
/*diethylpropion (anfepramone) hydrochloride*
cloridrato de glicinato de tianfenicol/*tianfenicol glycinate hydrochloride*
cloridrato de propranolol/*propranolol hydrochloride*
cloridrato de sibutramina/*sibutramin hydrochloride*
cloridrato de ticlopidina/*ticlopidina hydrochloride*
cloridrato de tramadol/*tramadol hydrochloride*
diazepam/*diazepam*
didanosina/*didanosine*
efavirenz/*efavirenz*
fumarato de tenofovir disoproxila/*tenofovir disoproxyl fumarate*
lamivudina/*lamivudine*
olanzapina/*olanzapine*
piroxicam/*piroxicam*
sulfametoxazol/*sulfamethoxazole*
topiramato/*topiramate*
trimetoprima/*trimethoprin*

HESTER
Hester Química do Brasil Ltda.
Rua Maria Rodrigues, 26 – Olaria
21031-490 – Rio de Janeiro – RJ – Bra.
Tel/Phone: (21) 2560-0403
Fax: (21) 2560-0062
e-mail: hesterquimica@hesterquimica.com.br
Internet: www.hesterquimica.com.br

cloreto de benzalcônio/*benzalkonium chloride*

IEN
Instituto de Engenharia Nuclear
Rua Hélio de Almeida, 75 - Cidade Universitária
Ilha do Fundão – Rio de Janeiro – RJ – Bra.
Tel/Phone: (21) 2173-3700
Fax: (21) 2590-2692
e-mail: ien@ien.gov.br

fludesoxiglicose (18 F): FDG 18 F/*fludeoxyglucose (18 F)*
iobenguano (123 I): MIBG, metaiodobenzilguanidina 123 I */iobenguane (123 I)*
iodeto de sódio (123 I)/*sodium iodide I 123*

INCASA
Incasa S.A.
Rua Dona Francisca, 11.700
89239-270 – Joinville – SC – Bra.
Tel/*Phone*: (47) 3205-7100
Fax: (47) 3205-7000
e-mail: comercial@incasa.ind.br
Internet: www.incasa.ind.br

iodeto de potássio/*potassium iodide*
iodeto de sódio/*sodium iodide*
iodo/*iodine*
iodoformio/*iodoform*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

INTER FARMA
Inter Farma S.A.
J. B. Albedi, 5771 – Floor 2A
1440 – Buenos Aires – Arg.
Tel/Phone: (11) 4740-7550
e-mail: info@inter-farma.com
Internet: www.inter-farma.com

sulfato de condroitina/*chondroitin sulfate*

IPEN
Instituto de Pesquisas Energéticas e Nucleares
Av. Lineu Prestes, 2242 – Cidade Universitária
05508-000 São Paulo – SP – Bra
Tel/Phone: (11) 3133-9000
Fax: (11) 3812-3546

albumina humana sérica cromada (51 Cr): SAH 51 Cr
/albumin, chromated Cr 51 serum
albumina humana sérica iodada (131 I): SAH I 131
/albumin, iodinated I 131 serum
citrato de gálio (67 Ga)*/gallium (67 Ga) citrate*
cloreto de tálio (201 Tl)*/thallous chloride Tl 201*
cromato de sódio (51 Cr)*/sodium chromate Cr 51*
edetato crômico (51 Cr): EDTA 51 Cr*/chromium Cr 51 edetate*
edotreotida (177 Lu): DOTA octreotato 177 Lu*/edotreotide 177 Lu*
fludesoxiglicose (18 F): FDG 18 F*/fludeoxyglucose (18 F)*
fluoreto de sódio (18 F)*/sodium fluoride F 18*
fosfato de sódio (32 P)*/sodium phosphate P 32*
hidroxiapatita (153 Sm): HA 153 Sm
/samarium Sm 153 hydroxyapatite
iobenguano (123 I): MIBG, metaiodobenzilguanidina 123 I
/iobenguane (123 I)
iobenguano (131 I): MIBG, metaiodobenzilguanidina 131 I
/iobenguane (131 I)
iodeto de sódio (123 I)*/sodium iodide I 123*
iodeto de sódio (131 I)*/sodium iodide I 131*
iodoipurato de sódio (131 I): 0-iodo-hipurato de sódio 131 I
/iodohippurate sodium I 131

lexidronam (153 Sm): EDTMP, ácido etilenodiaminotetrametileno fosfônico 153 Sm/*samarium Sm 153 lexidronam*
óleo etiodado (131 I): lipiodol 131 I/*ethiodized oil (131 I)*
pentetreotida (111 In): DTPA, octreotídeo 111 In */indium In 111 pentetreotide*
pentecnetato de sódio (99m Tc): gerador de tecnécio 99m */technetium 99m Tc pentechnetate*
sulfato de sódio (35 S)/*sodium sulfate S 35*

ITF

ITF Chemical Ltda.
Rua Beta, 574 – Área Industrial Norte
Complexo Petroquímico de Camaçari
42810-300 – Camaçari – BA – Bra
Tel/Phone: (71) 3634-2903
Fax: (71) 3634-2902
e-mail: rr@itfchemical.com.br

ácido zoledrônico/*zoledronic acid*
alendronato de sódio/*alendronate monosodium*
bendamustina/*bendamustine*
bromidrato de bupropiona/*bupropion hydrobromide*
carbonato de sevelâmer/*sevelamer carbonate*
cloridrato de moxifloxacino/*moxifloxacin hydrochloride*
cloridrato de paroxetina/*paroxetine hydrochloride*
cloridrato de sevelâmer/*sevelamer hydrochloride*
doxazosina/*doxazosin*
ferrolate/*ferrolat*
fosfatidilserina/*phosphatidylserine*
fosfomicina trometamol/*fosfomycin tromethamine*
fumarato de fesoterodina/ *esoterodine fumarate*
lansoprazol/*lansoprazole*
levofloxacino/*levofloxacin*
maleato de rosiglitazona/*rosiglitazone maleate*
pemetrexede/*pemetrexed*
risedronato de sódio/*sodium risedronate*
tartarato de tolterodina/*tolterodine tartrate*
temozolomida/*temozolomide*

KIN MASTER
Kin Master Produtos Químicos Ltda.
Rua Manoel Portela, 780
99010-115 – Passo Fundo – RS – Bra.
Tel/*Phone*: (54) 3313-2700
Fax: (54) 3313-2700
e-mail: km@kinmaster.com.br
Internet: www.kinmaster.com.br

ácido mucopolissacarídeo polissulfúrico tópico
/mucopolysacharide polysulfuric acid
bílis bovina/*bovine bile*
extrato de aorta/*Aorta hydrosoluble extract*
extrato de baço/*Spleen hydrosoluble extract*
extrato de colágeno/*collagen hydrosoluble extract*
extrato de fígado com estômago NF XI
/liver with stomach NF XI *hydrosoluble extract*
extrato de fígado concentrado NF XI
/concentrated liver extract NF XI
extrato de fígado dessecado NF XI/*dessicated liver NF XI*
extrato de fígado injetável crú NF XI
/liver injection crude NF XI extract
extrato de fígado NF XI/*liver extract NF XI*
extrato de músculo estriado/*striated muscle extract*
extrato de ovário/*ovary extract*
extrato de placenta/*placenta hydrosoluble extract*
extrato de suprarrenal/*suprarenal hydrosoluble extract*
extrato hepático, fração 1, NF XI/*hepatic extract, fraction 1, NF XI*
extrato hepático, fração 2, NF XI/*hepatic extract, fraction 2, NF XI*
heparina de baixo peso molecular/*heparin LMW*
heparina sódica (injetável e tópica)
/heparin sodium (injectable and topical)
heparinoide/*heparinoid*
mesoglicano sódico/*mesoglycan sodium*
mucosa gástrica em pó/*gastric mucose powder*
pancreatina (4,6,8 e 10 NF)/*pancreatin (4,6,8 and 10 NF)*

pepsina (1:10.000 - 1:40.000)/*pepsin(1:10.000 - 1:40.000)*
peptona de carne/*meat peptone*
peptona de coração/*heart peptone*
peptona de fígado/*liver peptone*
sais biliares totais/*total bile salts*
sulfato de condroitina A (injetável e oral)
/chondroitin A sulfate (injectable and oral)
sulfato de condroitina BPM/*condroitin sulfate LMW*
timomodulina/*thymomodulin*
tireóide em pó/*thyroid*

KIN MASTER, fundada em 1976, é especializada na produção de insumos farmacêuticos ativos (IFAs), por metologias extrativas, tendo grande experiência em processos de extração de fontes naturais, conhecimento técnico, bem como a necessária infraestrutura para a produção de glicosaminoglicanos, enzimas e extratos hidrossolúveis de órgãos. As substâncias são produzidas a partir de glândulas e tecidos de mamíferos aprovados por Certificações das Autoridades Sanitárias do Ministério da Agricultura. A equipe técnica é altamente qualificada e treinada dentro dos padrões regulatórios internacionais e de acordo com as normas de GMP.

A fábrica está certificada pela Agência Nacional de Vigilância Sanitária (ANVISA). Atenção especial é dada aos métodos de validação e a Kin Master está sempre atenta aos problemas ambientais. Os processos de toda a cadeia produtiva são controlados e certificados por meio de rigorosas análises o que não somente garante a identidade dos produtos, mas também a sua atividade.

KIN MASTER, founded in 1976, is specialized in manufacture of bulk active pharmaceuticals ingredients by extractive methodologies having extensive experience in downstream processing derived from natural sources, technological expertise, as well as the necessary infrastructure for manufacture of glicosaminoglycans, enzymes and hydrosoluble organs extracts. The substances are produced from glands and tissues of mammals approved by Certificates of Sanitary Authorities of the Ministery of Agriculture. The staff is highty qualified and trained with worldwide regulatory standards and in full compliance with GMP directives.

The factory is GMP certified by National Health Surveillance Agency – ANVISA. Attention is paid to methods validation, and KIN MASTER gives special attention to the environment. The downstream process is controlled and certified by means of strict analysis that not only can guarantee the identity, but also the activity of the products.

LIBBS
Libbs Farmoquímica Ltda.
Avenida Dona Cesária Camargo de Oliveira, 240
06807-320 – Embú – SP – Bra.
Tel/Phone: (11) 4704-2419
Fax: (11) 4704-2419
e-mail: alvaro@libbs.com.br
Internet: www.libbs.com.br

ácido pamidrônico/*pamidronic acid*
ácido zoledrônico monoidratado/*zoledronic acid monohydrate*
bromoprida/*bromopride*
cilostazol/*cilostazol*
cloridrato de amiodarona/*amiodarone hydrochloride*
cloridrato de paroxetina/*paroxetine hydrochloride*
desogestrel/*desogestrel*
etinilestradiol/*ethinyl estradiol*
gestodeno/*gestodene*
mazindol/*mazindol*
nitrendipino/*nitrendipine*
tibolona/*tibolone*

MAPRIMED
Maprimed S.A.
Avenida Directorio, 6.155
C1440ATA – Buenos Aires – Arg.
Tel/*Phone*: (11) 4630-1508
Fax: (11) 4630-1597
e-mail: rpagano@maprimed.com.ar

acetato de flecainida/*flecainide acetate*
ácido zoledrônico/*zoledronic acid*
aripiprazol/*aripiprazole*
cetorolaco/*ketorolac*
citrato de sildenafila/*sildenafil citrate*
clonixinato de lisina/*lysine clonixinate*
cloxazolam/*cloxazolam*
dronedarona/*dronedarone*
eszopiclona/*eszopiclone*
ibandronato de sódio/*ibandronate monosodium*
losartana potássica/*losartan potassium*
maleato de enalapril/*enalapril maleate*
mesilato de rasagilina/*rasagiline mesilate*
prasugrel/*prasugrel*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

MEDAPI
Medapi Farmacêutica Ltda.
Estrada dos Romeiros, 1.792
06417-000 – Barueri – SP – Bra.
Tel/*Phone*: (11) 4706-1000
Fax: (11) 4706-1005
e-mail: medapi@medapi.com.br
Internet: www.medapi.com.br

riluzol/*riluzole*
tacrolimo/*tacrolimus*

MICROBIOLÓGICA

Microbiológica Química e Farmacêutica Ltda.
Rua Dr. Nicanor, 238 – Inhaúma
20765-120 – Rio de Janeiro – RJ – Bra.
Tel/*Phone*: (21) 3296-3200
Fax: (21) 3296-3200
e-mail: microbiologica@microbiologica.ind.br
Internet: www.microbiológica.ind.br

azatioprina/*azathioprine*
6-mercaptopurina/*6-mercaptopurine*
talidomida/*thalidomide*
zidovudina/*zidovudine*

A Microbiologica é uma empresa brasileira de base científica que descobre e desenvolve processos tecnológicos baseados na química dos nucleosídeos. Sua competência essencial tem sido aplicada na produção de nucleosideos anti-virais; agentes imunomoduladores; agentes anti-senescentes e desenvolvimento de novos nucleosideos anti-HBV.

Microbiologica is a science-based Brazilian company that discovers and develops process technologies based on nucleoside chemistry. Its essential competence has been applied in the manufacture of anti HIV nucleosides; immunomodulating agents; antisenescent agents; and new anti HBV nucleosides under development.

NORTEC QUÍMICA

Nortec Química S.A.
Rua Dezessete, 200 – Distrito Industrial de Duque de Caxias – Xerém
25250-612 – Duque de Caxias – RJ – Bra.
Tel/*Phone*: (21) 3651-7300
Fax: (21) 3651-7319
e-mail: nortecquimica@nortecquimica.com.br
Internet: www.nortecquimica.com.br

aciclovir/*acyclovir*
AZT/*AZT*
benzoato de denatônio/*denatonium benzoate*
bromazepam/*bromazepam*
bupivacaína/*bupivacaine*
carbamazepina/*carbamazepine*
citrato de dietilcarbamazina/*diethylcarbamazine citrate*
citrato de orfenadrina/*orphenadrine citrate*
clonazepam/*clonazepam*
cloridrato de articaina/*articaine hydrochloride*
cloridrato de bupivacaína/*bupivacaine hydrochloride*
cloridrato de efedrina/*ephedrine hydrochloride*
cloridrato de etafedrina/*etafedrine hydrochloride*
cloridrato de fenilefrina/*phenylephrine hydrochloride*
cloridrato de isometepteno/*isometheptene hydrochloride*
cloridrato de lidocaína/*lidocaine hydrochloride*
cloridrato de mepivacaína/*mepivacaine hydrochloride*
cloridrato de midazolam/*midazolam hydrochloride*
cloridrato de piperidolato/*piperidolate hydrochloride*
cloridrato de pramoxina/*pramoxine hydrochloride*
cloridrato de prilocaína/*prilocaine hydrochloride*
cloridrato de pseudoefedrina/*pseudoephedrine hydrochloride*
diclofenaco/*diclofenac acid*
diclofenaco colestiramina/*diclofenac colestiramine*
diclofenaco dietilamônio/*diclofenac diethylammonium*
diclofenaco potássico/*diclofenac potassium*
diclofenaco sódico/*diclofenac sodium*

didanosina/*didanosine*
efavirenz/*efavirenz*
espironolactona/*spironolactone*
estavudina/*stavudine*
fenitoína (difenilhidantoína)/*phenytoin (diphenylhydantoine)*
fenitoína sódica/*phenytoin sodium*
fenobarbital/*phenobarbital*
fenobarbital sódico/*phenobarbital sodium*
flurazepam/*flunazepam*
fumarato de quetiapina/*quetiapine fumarate*
fumarato de tenofovir disoproxila/*tenofovir disoproxyl fumarate*
haloperidol/*haloperidol*
hidroximetano sulfonato de sódio/*sodium hydroxymethane sulfonate*
lamivudina/*lamivudine*
lidocaína/*lidocaine*
maleato de midazolam/*midazolam maleate*
midazolam/*midazolam*
mucato de isometepteno/*isometeptene mucate*
nevirapina/*nevirapine*
oxcarbazepina/*oxcarbazepine*
prilocaína/*prilocaine*
propiltiouracila/*propylthiouracil*
raloxifeno/*raloxifene*
resinato de diclofenaco/*diclofenac resinate*
resinato de feniltoloxamina/*phenyltoloxamine resinate*
ribavirina/*ribavirine*
sinvastatina/*simvastatin*
sulfato de efedrina/*ephedrine sulfate*
sulfato de indinavir/*indinavir sulfate*
sulfato de pseudoefedrina/*pseudoephedrine sulfate*
tiabendazol/*thiabendazole*
zidovudina/*zidovudine*

A NORTEC QUÍMICA é um companhia privada, independente, dedicada à pesquisa, desenvolvimento, produção e comercialização de farmoquímicos e outros produtos de química fina e alta qualidade. Criada no início dos anos 80, a NORTEC QUÍMICA tem, desde o início, uma tradição de cooperação com reputadas instituições brasileiras de P&D, especialmente a Fundação Oswaldo Cruz – FIOCRUZ. Este enfoque inovativo em PD foi reconhecido através do Prêmio Liceo de Tecnologia, o mais importante prêmio oficial em trabalhos de PD dirigidos ao mercado no Brasil, entregue pelo Sr. Presidente da República.

Além da sua própria produção, a capacitação técnica e controles adequados levaram a NORTEC QUÍMICA a ser escolhida pelas principais companhias européias para representar seus interesses no mercado brasileiro de química fina. A NORTEC QUÍMICA é, também, um parceiro confiável para a produção para clientes em base confidencial – serviço atualmente usado por diversas companhias da Europa Ocidental e Estados Unidos.

A NORTEC QUÍMICA foi contemplada pelo 9º ano (1999, 2000, 2001, 2002, 2003, 2004, 2006, 2007 e 2008) com o prêmio FEBRAFARMA/SINDUSFARMA de excelência por ter sido o melhor fornecedor de farmoquímicos no Brasil, como resultado de uma pesquisa direta a mais de 300 companhias farmacêuticas.

NORTEC QUÍMICA is a Brazilian independent, privately owned company devoted to research, development, production and marketing of bulk pharmaceutical especially local anesthetics – and other high quality fine chemicals. Created in the early 80's thourgh an agreement with Fundação Oswaldo Cruz – FIOCRUZ (National Institute for Health Studies within the Brazilian Ministry of Health) When the Brazilian Government decided to have bulk pharmaceuticals as "Priority 1" to be produced in Brazil, for strategic reasons.

Besides its own production programme, the technical background and superior service policy prompted NORTEC QUIMICA to be chosen by major European companies to represent their interests in the Brazilian API / fine chemical markets. NORTEC QUÍMICA is also a reliable partner for custom manufacturing on confidential basis – a service currently used by five multinational companies.

Our innovative approach in R&D has been recognised with the Premio Liceo de Tecnologia, the most important prize for market-oriented in our Country. On the other hand, we have been awarded the FEBRAFARMA/SINDUSFARMA' 99, 2000, 2001, 2002, 2003, 2004, 2006, 2007 and 2008 – Prize for the best supplier of Active Pharmaceutical Ingredients for the Pharmaceutical Industry in Brazil, as export bulk pharmaceutical regularly to MERCOSUR and Latin America. Spot Sales to the US, Asia and Europe are also being accomplished.

NOVARTIS

Novartis Biociências S.A.
Avenida Basiléia, 590
27521-210 – Resende – RJ – Bra.
Tel/*Phone*: (24) 3358-5527
Fax: (24) 3354-2993
e-mail: hugo.casarin@novartis.com

bromotolil benzonitrila/*bromotolil benzonitril* •
carbamazepina/*carbamazepine* •
cloridrato de maprotilina/*maprotiline hydrochloride* •
cloxazolam/*cloxazolam* •
diclofenaco/*diclofenac acid* •
diclofenaco colestiramina/*diclofenac colestiramine* •
diclofenaco dietilamônio/*diclofenac diethylammonium* •
diclofenaco potássico/*diclofenac potassium* •
diclofenaco sódico/*diclofenac sodium* •
embonato de imipramina/*imipramine pamoate* •
fumarato de cetotifeno/*ketotifen fumarate* •
mesilato de di-hidroergocristina/*dihydroergocristine mesylate* •
mesilato de di-hidroergotamina/*dihydroergotamine mesylate* •
pimetixeno/*pimetixene* •
resinato de diclofenaco/*diclofenac resinate* •
tosilato de valinester/*valinester tosylate* •
valesteramida/*valesteramide* •

A NOVARTIS surgiu em 1996 através da fusão das empresas suiças Ciba e Sandoz. O nome originou-se do latim *novae artes* – novas habilidades. O nome Novartis reflete o compromisso com a pesquisa e o desenvolvimento que conduz à descoberta de produtos inovadores e serviços que melhoram a saúde e o bem estar das pessoas nas comunidades em que a NOVARTIS atua.

No Brasil há muitos anos sob os nomes Ciba e Sandoz, a NOVARTIS foi uma das pioneiras da produção farmoquímica no Brasil, através de sua fábrica instalada em Resende (RJ), inicialmente sob o nome de Indústrias Químicas Resende. Atualmente a planta de Resende integra a cadeia de Suprimento Global da Novartis, com a exportação de Valestaramida 55% para a Inglaterra, como material de partida para o Diovan (valsartana).

NOVARTIS came into existance in 1996, from the merger of Swiss companies CIBA and SANDOZ. Novartis name was originated from Latin new arts – new abilities. The name Novartis reflects the commitment to research and development, that leads to the discovery of innovative products and services,

improving both health and well-being of people in the communities where NOVARTIS operates.

In Brazil, operating for many years under the names of CIBA and SANDOZ, NOVARTIS was a Brazil pioneer in pharma chemical production with its factory installed in Resende (RJ), at the beginning under the business name of Indústrias Químicas Resende.

Nowadays Resende plant is part of Novartis Global Supply Chain, with the exportation of Valesteramida 55% to UK as a starting material for Diovan (valsartan).

PERÓXIDOS
Peróxidos do Brasil Ltda.
Rua Urussuí, 300 / 4º andar – Itaim Bibi
04542-903 – São Paulo – SP – Bra.
Tel/*Phone*: (11) 3708-5050
Fax: (11) 3708-5080
e-mail: vendas.peroxidos@solvay.com
Internet: www.peroxidos.com.br

peróxido de hidrogênio (água oxigenada)/*hydrogen peroxide*

PHIBRO
Phibro Saúde Animal Internacional Ltda.
Avenida Presidente Tancredo de Almeida Neves, 1.111
07112-070 – Guarulhos – SP – Bra.
Tel/*Phone*: (11) 2185-4422
Fax: (11) 2185-4455
e-mail: marina.cesar@pahc.com
Internet: www.phibroah.com

salinomicina sódica miceliana/*salinomycin sodium mecelle form* •
senduramicina/*semduramicin*
virginiamicina/*virginiamycin*

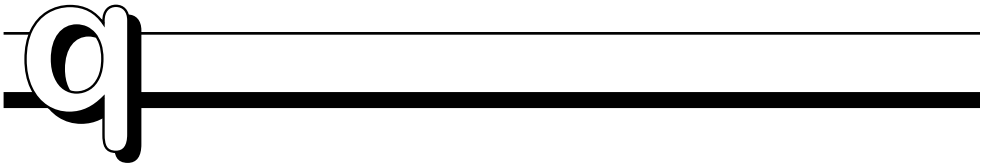
Informação não confirmada pelo produtor / *Information not confirmed by the producer*

PLANALQUÍMICA
Planalquímica Industrial Ltda.
Rua Professor Gilberto Venturini, 555 – Distrito Industrial IV
12922-735 – Bragança Paulista – SP – Bra.
Tel/*Phone*: (11) 4031-2466
Fax: (11) 4031-2535
e-mail: almir@planalquimica.com.br e viviane@planalquimica.com.br

nicarbazina/*nicarbazin*

PVP
PVP Sociedade Anônima
Rua Dr. João Emilio Falcão Costa, 48
64218-290 – Parnaíba – PI – Bra.
Tel/Phone: (86) 3315-8000 / 8005
Fax: (86) 3315-8006
e-mail: pvp@pvp.com.br
Internet: www.pvp.com.br

octacetato de sacarose/*sucrose octaacetate*
quercetina/*quercetin*
rutina/*rutin*



QGN
Química Geral do Nordeste S.A.
Rua do Carmo, 8 – 10º andar – Centro
20011-020 – Rio de Janeiro – RJ – Bra.
Tel/*Phone*: (21) 2534-0081
Fax: (21) 2534-0097
e-mail: kelly.ronchi@churchdwigt.com.br
Internet: www.qgn-carbonor.com.br

bicarbonato de sódio/*sodium bicarbonate*
metabissulfito de sódio/*sodium metabisulfite*
sulfato de bario/*barium sulfate*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

QUERCEGEN
Quercegen Agronegocios I Ltda.
Rua Marly Sarney, 120 – Ivar Saldanha
65.099-110 – São Luis – Maranhão – Bra.
Tel/Phone: (98) 2109-6000 / (21) 8019-8666
Fax: (98) 2109-6085
e-mail: customer.relation@quercegen.com.br
Internet: www.quercegen.com.br

quercetina/*quercetin*
ramnose/*rhamnose*
rutina/*rutin*

QUÍMICA INDAIATUBA
Química Indaiatuba – Indústria e Comércio Ltda.
Avenida José Vieira, 396
Distrito Industrial Domingos Giomi
13347-360 – Indaiatuba – SP – Bra.
Tel/Phone: (19) 3936-9199
Fax: (19) 2936-9198
e-mail: atendimento@quimicaindaiatuba.com.br

hipoclorito de sódio a 1% ou 2,5% (validade 12, 18 ou 24 meses) */sodium hypochlorite*

QUIMIBRÁS
Quimibrás Indústrias Químicas S.A.
Rua General Corrêa e Castro, 445/465 – Jardim América
21240-030 – Rio de Janeiro – RJ – Bra.
Tel/*Phone*: (21) 2471-5080
Fax: (21) 2471-5080
e-mail: quimibras@yahoo.com.br
Internet: www.quimibras.com.br

acetato de amônio/*ammonium acetate*
acetato de chumbo/*lead acetate*
acetato de potássio/*potassium acetate*
acetato de sódio/*sodium acetate*
acetato de zinco/*zinc acetate*
ácido benzoico/*benzoic acid*
ácido cítrico anidro/*citric acid anhydrous*
ácido cítrico monoidratado/*citric acid monohydrate*
ácido tartárico/*tartaric acid*
alúme de potássio/*potassium alum*
benzoato de amônio/*ammonium benzoate*
benzoato de sódio/*sodium benzoate*
bicarbonato de sódio/*sodium bicarbonate*
borato de sódio/*sodium borate*
bromofórmio/*bromoform*
carbonato básico de bismuto/*bismuth subcarbonate*
carbonato de cálcio/*calcium carbonate*
carbonato de potássio/*potassium carbonate*
carbonato de sódio/*sodium carbonate*

citrato de cálcio/*calcium citrate*
citrato de magnésio/*magnesium citrate*
citrato de potássio/*potassium citrate*
citrato de sódio (tri)/*trisodium citrate*
citrato de sódio (mono)/*monosodium citrate*
citrato de trietila/*triethyl citrate*
citrato férrico amoniacal/*ammonium ferric citrate*
citrato ferroso de cálcio/*calcium ferrous citrate*
cloreto de alumínio/*aluminum chloride*
cloreto de amônio/*ammonium chloride*
cloreto de cálcio/*calcium chloride*
cloreto de magnésio/*magnesium chloride*
cloreto de potássio/*potassium chloride*
cloreto de sódio/*sodium chloride*
cloreto férrico/*ferric chloride*
cloroidróxido de alumínio/*aluminum hydroxychloride*
estearato de cálcio/*calcium stearate*
estearato de magnésio/*magnesium stearate*
éter etílico/*sulfuric ether*
fluoreto de potássio/*potassium fluoride*
fluoreto de sódio/*sodium fluoride*
fosfato de cálcio dibásico/*calcium phosphate dibasic*
fosfato de cálcio tribásico/*calcium phosphatetribasic*
fosfato de magnésio dibásico/*magnesium phosphate dibasic*
fosfato de potássio dibásico/*potassium phosphate dibasic*
fosfato de potássio monobásico/*potassium phosphate monobasic*
fosfato de sódio dibásico/*sodium phosphate dibasic*
fosfato de sódio monobásico/*sodium phosphate monobasic*
fumarato ferroso/*ferrous fumarate*
hidróxido de alumínio/*aluminum hydroxide*
hidróxido de amônio/*ammonium hydroxide*
hidróxido de magnésio/*magnesium hydroxide*
iodeto de potássio/*potassium iodide*
iodeto de sódio/*sodium iodide*
iodofórmio/*iodoform*
iodo ressublimado/*sublimated iodine*
lactato de amônio/*ammonium lactate*
lactato de cálcio/*calcium lactate*
lactato de ferro/*ferrous lactate*
lactato de magnésio/*magnesium lactate*
lactato de sódio/*sodium lactate*

lactofosfato de cálcio/*calcium lactophosphate*
metabissulfito de sódio/*sodium metabisulfite*
nitrato básico de bismuto/*bismuth subnitrate*
nitrato de amônio/*ammonium nitrate*
nitrato de potássio/*potassium nitrate*
oxalato de potássio/*potassium oxalate*
reagentes analíticos/*analytical reagents*
sulfato cúprico (anidro e pentaidratado)
/cupric sulfate (anhydrous and pentahydrate)
sulfato de alumínio/*aluminum sulfate*
sulfato de alumínio e potássio/*aluminum potassium sulfate*
sulfato de bário/*barium sulfate*
sulfato de cálcio di-hidratado/*calcium sulfate dihydrate*
sulfato de ferro amoniacal/*ammonium ferric sulfate*
sulfato de lítio/*lithium sulfate*
sulfato de magnésio/*magnesium sulfate*
sulfato de potássio/*potassium sulfate*
sulfato de sódio/*sodium sulfate*
sulfato de zinco/*zinc sulfate*
sulfato ferroso/*ferrous sulfate*
sulfeto de selênio/*selenium sulfide*
tartarato ácido de potássio/*potassium bitartrate*
tartarato de sódio/*sodium tartrate*
tartarato duplo de potássio e sódio/*potassium sodium tartrate*
tiossulfato de sódio/*sodium thiosulfate*
trissilicato de magnésio/*magnesium trisilicate*
ureia/*urea*

QUIRAL

Quiral Química do Brasil S.A.
Rua José Lourenço, 245 – São Pedro
36036-230 – Juiz de Fora – MG – Bra.
Tel/*Phone*: (32) 3691-6600
Fax: (32) 3691-6601
e-mail: farmaceutico@quiral.com.br

carboplatina/*carboplatin*
cisplatina/*cisplatin*
dicloridrato de mitoxantrona/*mitoxantrone dihydrochloride*
docetaxel/*docetaxel*
oxaliplatina/*oxaliplatin*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

RELTHY

Relthy Laboratórios Ltda.
Avenida José Vieira, 446 – Distrito Industrial Domingos Giomi
13347-360 – Indaiatuba – SP – Bra.
Tel/Phone: (19) 3936-9199
Fax: (19) 3936-9198
e-mail: relthy@relthy.com.br
Internet: www.relthy.com.br

cápsulas de gelatina elástica/*soft gelatin capsules*

A RELTHY LABORATÓRIOS LTDA. é uma empresa nacional, fundada em 1998 e está situada na cidade de Indaiatuba, Estado de São Paulo, próxima dos melhores centros de pesquisa do país, tais como CPQBA/UNICAMP, Laboratório de Luz Sincontron. A empresa ocupa uma área de 4.900 m², com 2.653 m² de área construída, dentro dos mais rígidos padrões exigidos para a indústria farmacêutica.

ESPECIALIDADE – A RELTHY é uma empresa especializada na fabricação de Cápsulas Gelatinosas Moles por meio de microemulsão, tendo projetado e concluido suas próprias matrizes rotativas, segundo o processo "Remington's Pharmaceutical Science" 19ª ed., págs. 1662 e 1663. Autorizada a produzir medicamentos e alimentos, a RELTHY se constitui em excelente opção para o mercado farmacêutico nacional, como empresa terceirizadora, para a produção de toda sua linha de produtos em Cápsulas Gelatinosas Moles.

PESQUISA, DESENVOLVIMENTO & INOVAÇÃO – A RELTHY oferece ainda para seus clientes um Departamento de Pesquisa, Desenvolvimento e Inovação (PD&I) de novos produtos, formulações, cores e apresentações, oferecendo ainda controles microbiologicos, assegurando a seus produtos garantia total.

A RELTHY opera segundo as normas de Boas Praticas de Fabricação e Controle da ANVISA.

RELTHY LABORATÓRIOS LTDA. is a Brazilian company, founded in 1998, located in the township of Indaiatuba, in the State of Sâo Paulo, near to the foremost Brazilian research centres, such as CPQBA/UNICAMP and the Laboratório de Luz Sincontron. The company premises occupy a 4.900 m² site, with

a built-on area of 2.653 m², constructed to the rigid standards demanded by the pharmaceutical industry.

SPECIALITY - RELTHY is a company specialised in the manufacture of Soft Gelatinous Capsules, produced by micro-emulsion methods, designed and finished in custom-made die rolls, in accordance with "Remington's Pharmaceutical Science" process described in the 19th edition, pp. 1662 and 1663. Duly authorised for production of medicines and foodstuffs, RELTHY constitutes an excellent option for the pharmaceutical market in the role of an outsource company, for the production of a complete line of Soft Gelatinous Capsules.

RESEARCH, DEVELOPMENT & INNOVATION - RELTHY can also offer its clients the services of its Research, Development & Innovation (RD&I) for new products, formulations, colours and presentation packs, monitored by microbiological controls, ensuring a complete guarantee for its products.

RELTHY operates in compliance with ANVISA Good Manufacturing Practices standards.

RHODIA
Rhodia Poliamida e Especialidades
Avenida Maria Coelho de Aguiar, 215 – bloco B - 1º andar
05804-902 – São Paulo – SP – Bra.
Tel/*Phone*: (11) 3741-7007
Fax: (11) 3741-7074

ácido salicílico/*salicylic acid*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

SILVESTRE
Silvestre Laboratórios Química e Farmacêutica Ltda.
Avenida Carlos Chagas Filho, 791 – Ilha do Fundão – Cidade Universitária
21941-904 – Rio de Janeiro – RJ – Bra.
Tel/Phone: (21) 2142-7777
Fax: (21) 2142-7734
e-mail: silvestrelabs@silvestrelabs.com.br
Internet: www.silvestrelabs.com.br

sulfadiazina de prata/*sulfadiazine silver salt* •

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

SINDROFAR
Sindrofar S.R.L.
Alvarado, 2.575
C 1290 AAM – Buenos Aires – Arg.
Tel/*Phone*: (11) 4303-2990
Fax: (11) 4302-2990
e-mail: sindrofar@yahoo.com.ar

cloridrato de clembuterol/*clembuterol hydrochloride*
malato ácido de cleboprida/*clebopride hydrogen malate*
mazindol/*mazindol*
sulfato de tranilcipromina/*tranylcypromine sulfate*

SOURCETECH
Sourcetech Química Ltda.
Rua Suiça, 3.430 – Água Preta
12403-610 – Pindamonhangaba – SP – Bra.
Tel/*Phone*: (12) 3643-2678
Fax: (12) 3643-2632
e-mail: sourcetech@sourcetech.com.br

cloridrato de pilocarpina/*pilocarpine hydrochloride*
nitrato de pilocarpina/*pilocarpine nitrate*
pilocarpina/*pilocarpine*

SQ BRASIL
Soluções Químicas Brasil Pigmentos e Sais Inorgânicos Ltda-ME
Rua Helena de Moraes Trani, 446
13977-105 – Itapira – SP – Bra.
Tel/*Phone*: (19) 3863-0261
Fax: (19) 3863-0261
e-mail: contato@sqbrasil.com.br

sulfato ferroso heptaidratado/*ferrous sulfate heptahydrate*

STEVIAFARMA
Steviafarma Industrial S.A.
Rua Stevia, 300 – Parque Industril – Bandeirantes III
87070-140 – Maringá – PR – Bra.
Tel/*Phone*: (44) 2101-4335
Fax: (44) 2101-4343
e-mail: stevita@stevita.com.br
Internet: www.stevita.com.br

esteviosídeo/*stevioside*

TIRADENTES
Cal Tiradentes Ltda.
Alto da Serra, s/nº – Caixa Postal 213
36328-000 – Santa Cruz de Minas – MG – Bra.
Tel/*Phone*: (32) 3371-5529
Fax: (32) 3371-5850

hidróxido de cálcio/*calcium hydroxide*

TOLBIAC
Tolbiac S.R.L. – Química Fina y Extractiva
José Enrique Rodó, 4.759
C1407HDW – Buenos Aires – Arg.
Tel/*Phone*: (11) 4635-9265
Fax: (11) 4682-0273
e-mail: info@tolbiac.com.ar
Internet: www.tolbiac.com.ar

cloridrato de liotironina/*liothyronine hydrochloride*
dextrorrazoxano/*dexrazoxane*
levotiroxina/*levothyroxine*
levotiroxina sódica/*levothyroxine sodium*
liotironina/*liothyronine*
liotironina sódica/*liothyronine sodium*
tiratricol/*tiratricol*
tiratricol sódico/*tiratricol sodium*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

TRIQUIM
Triquim S.A.
Avenida Vélez Sársfield, 5.855
BI606ARI – Carapachay – BA – Arg.
Tel/*Phone*: (11) 4762-6405
Fax: (11) 4762-6405
e.mail: triquim@lazar.com.ar

antimoniato de meglumina/*meglumine antimonate*
bupivacaína/*bupivacaine*
citrato de fentanila/*fentanyl citrate*
clonixinato de lisina/*lysine clonixinate*
cloreto de lapírio/*lapyrium chloride*
dapoxetina/*dapoxetine*
dextrorrazoxano/*dexrazoxane*
diclofenaco colestiramina/*diclofenac cholestyramin*
diclofenaco dietilamônio/*diclofenac diethylammonium*
diclofenaco epolamina/*diclofenac epolamine*
fentanila/*fentanyl*
flutamida/*flutamide*
ibuprofenato de lisina (lisinato de ibuprofeno)/*lysine ibuprofenate*
leflunomida/*leflunomide*
levobupivacaína/*levobupivacaine*
lomifilina/*lomiphylline*
metadona/*methadone*
metilbrometo de homatropina/*homatropine methylbromide*
miltefosina/*miltefosine*
mirtazapina/*mirtazapine*
modafinila/*modafinil*
nilutamida/*nilutamide*
nimodipino/*nimodipine*
nisoldipino/*nisoldipine*
nitrendipino/*nitrendipine*
pentamidina/pentamidine
propinox/*propinox*
propiverina/*propiverine*
ranolazina/*ranolazine*
remifentanila/*remifentanyl*
riluzol/*riluzole*
ropivacaína/*ropivacaine*
talidomida/*thalidomide*
topiramato/*topiramate*

VEGEFLORA
Vegeflora Extrações do Nordeste Ltda.
Povoado Rosápolis s/nº
Caixa Postal 139
64218-710 Parnaíba – PI
Tel/*Phone*: (86) 3323-6202
Fax: (86) 3323-6203
e-mail: luciene@vegeflora.com.br
Internet: www.centroflora.com.br

cloridrato de pilocarpina/*pilocarpine hydrochloride*
nitrato de pilocarpina/*pilocarpine nitrate*

VERARDO
Verardo y Cia. S.A.
Ibera, 5.061
1431 – Buenos Aires – Arg.
Tel/*Phone*: (11) 4545-5454
Fax: (11) 4545-1010

bitartarato de di-hidrocodeína (hemitartarato de di-hidrocodeína)
/*dihydrocodeine bitartrate*
bitartarato de hidrocodona (hemitartarato de hidrocodona)
/*hydrocodone bitartrate*
cloridrato de cocaína/*cocaine hydrochloride*
cloridrato de codeína/*codeine hydrochloride*
cloridrato de etilmorfina di-hidratado
/*ethylmorphine hydrochloride dihydrate*
cloridrato de hidrocodona (cloridrato de diidrocodeinona)
/*hydrocodone hydrochloride*
cloridrato de morfina/*morphine hydrochloride*
cloridrato de oxicodona/*oxycodone hydrochloride*
codeína/*codeine*
folcodina (morfolinil etil morfina)/*pholcodine*
fosfato de codeína/*codeine phosphate*

resinato de codeína/*codeine resinate*
resinato de hidrocodona/*hydrocodone resinate*
sulfato de codeína/*codeine sulfate*
sulfato de morfina/*morphine sulfate*

VETEC
Vetec Química Fina Ltda.
Rua Pastor Manoel Avelino de Souza, 1.021 – Xerém
25250-000 – Duque de Caxias – RJ – Bra.
Tel/*Phone*: (21) 3125-1920
Fax: (21) 2679-1307
e-mail: vetec@vetecquimica.com.br
Internet: www.vetecquimica.com.br

acetato de alumínio/*aluminum acetate*
acetato de chumbo/*lead acetate*
acetato de potássio/*potassium acetate*
bissulfato de potássio/*potassium bisulfate*
citrato de potássio/*potassium citrate*
cloreto de cálcio/*calcium chloride*
cloreto de magnésio/*magnesium chloride*
cloreto de potássio/*potassium chloride*
cloreto de sódio/*sodium chloride*
edetato dipotássico/*edetate dipotassium*
fosfato de cálcio dibásico/*calcium phosphate dibasic*
fosfato de potássio dibásico/*potassium phosphate dibasic*
fosfato de sódio dibásico/*sodium phosphate dibasic*
reagentes analíticos/*analytical reagents*
sulfato de alumínio e amônio/*aluminum ammonium sulfate*
sulfato de alumínio e potássio/*potassium ammonium sulfate*
sulfato de ferro amoniacal/*ammonium ferric sulfate*
sulfato de magnésio/*magnesium sulfate*
sulfato de potássio/*potassium sulfate*
sulfato de sódio/*sodium sulfate*
sulfato ferroso/*ferrous sulfate*
tartarato de potássio/*potassium tartrate*
tartarato de sódio/*sodium tartrate*
tosilcloramida sódica/*chloramine-T*

Informação não confirmada pelo produtor / *Information not confirmed by the producer*

WALLERSTEIN
Wallerstein Industrial e Comercial Ltda.
Rua Funchal, 203 - 9º andar – Vila Olímpia
04551-060 – São Paulo – SP – Bra.
Tel/*Phone*: (11) 3848-2900
Fax: (11) 3845-3720
e-mail: wallerstein@wallerstein.com.br

papaína/*papain*

Produtos por ordem de CAS

Products listed by CAS order

CAS	PRODUTO	PRODUCT
50-06-6	fenobarbital	*phenobarbital*
50-13-5	cloridrato de petidina	*pethidine hydrochloride*
50-27-1	estriol	*estriol*
50-28-2	estradiol	*estradiol*
50-35-1	talidomida	*thalidomide*
50-44-2	6-mercaptopurina	*6-mercaptopurine*
50-98-6	cloridrato de efedrina	*ephedrine hydrochloride*
51-24-1	tiratricol	*tiratricol*
51-48-9	levotiroxina	*levothyroxine*
51-52-5	propiltiouracila	*propylthiouracil*
52-01-7	espironolactona	*spironolactone*
52-26-6	cloridrato de morfina	*morphine hydrochloride*
52-28-8	fosfato de codeína	*codeine phosphate*
52-86-8	haloperidol	*haloperidol*
53-21-4	cloridrato de cocaína	*cocaine hydrochloride*
54-71-7	cloridrato de pilocarpina	*pilocarpine hydrochloride*
55-03-8	levotiroxina sódica	*levothyroxine sodium*
55-06-1	liotironina sódica	*liothyronine sodium*
56-85-9	glutamina (L)	*glutamine (L)*
57-13-6	ureia	*urea, carbamide*
57-30-7	fenobarbital sódico	*phenobarbital sodium*
57-41-0	fenitoína (difenilidantoína)	*phenytoin*
57-55-6	propilenoglicol	*propylene glycol*
57-63-6	etinilestradiol	*ethinyl estradiol*
58-71-9	cefalotina sódica	*cefalotin sodium*
60-29-7	éter etílico	*sulfuric ether*
61-76-7	cloridrato de fenilefrina	*phenylephrine hydrochloride*
64-31-3	sulfato de morfina	*morphine sulfate*
65-85-0	ácido benzoico	*benzoic acid*
68-04-2	citrato de sódio	*sodium citrate*
69-72-7	ácido salicílico	*salicylic acid*
72-17-3	lactato de sódio	*sodium lactate*
72-18-4	valina (L)	*valine (L)*
73-32-5	isoleucina (L)	*isoleucine (L)*
73-78-9	cloridrato de lidocaína	*lidocaine hydrochloride*
74-79-3	arginina	*L-arginine*
75-25-2	bromofórmio	*bromoform*
75-47-8	iodofórmio	*iodoform*
76-57-3	codeína	*codeine*
76-99-3	metadona	*methadone*
77-92-9	ácido cítrico anidro	*citric acid anhydrous*
77-93-0	citrato de trietila	*triethyl citrate*
80-49-9	metilbrometo de homatropina	*homatropine methylbromide*
81-23-2	ácido desidrocólico	*dehydrocholic acid*
81-25-4	ácido cólico	*cholic acid*
83-44-3	ácido desoxicólico	*deoxycholic acid*
87-69-4	ácido tartárico	*L-tartaric acid*
90-82-4	pseudoefedrina	*pseudoephedrine*
92-13-7	pilocarpina	*pilocarpine*
95-05-6	sulfiram	*monosulfiram*

CAS	PRODUTO	PRODUCT
100-33-4	pentamidina	*pentamidine*
100-51-6	álcool benzílico	*benzyl alcohol*
106-11-6	monoestearato de dietilenoglicol	*diethylene glycol monostearate*
110-27-0	miristato de isopropila	*isopropyl myristate*
111-60-4	monoestearato de etilenoglicol	*ethylene glycol monostearate*
117-39-5	quercetina	*quercetin*
124-90-3	cloridrato de oxicodona	*oxycodone hydrochloride*
126-14-7	octacetato de sacarose	*sucrose octaacetate*
127-08-2	acetato de potássio	*potassium acetate*
127-09-3	acetato de sódio	*sodium acetate*
127-65-1	tosilcloramida sódica	*chloramine-T*
129-77-1	cloridrato de piperidolato	*piperidolate hydrochloride*
133-51-7	antimoniato de meglumina	*meglumine antimonate*
134-72-5	sulfato de efedrina	*ephedrine sulfate*
134-80-5	cloridrato de anfepramona	*diethylpropion hydrochloride*
137-58-6	lidocaína	*lidocaine*
139-12-8	acetato de alumínio	*aluminum acetate*
141-01-5	fumarato ferroso	*ferrous fumarate*
143-28-2	álcool oleílico	*oleyl alcohol*
143-71-5	hemitartarato de hidrocodona	*hydrocodone bitartrate*
144-55-8	bicarbonato de sódio	*sodium bicarbonate*
144-62-7	ácido oxálico	*oxalic acid*
148-72-1	nitrato de pilocarpina	*pilocarpine nitrate*
148-79-8	tiabendazol	*thiabendazole*
153-18-4	rutina (rutosídeo)	*rutin*
298-46-4	carbamazepina	*carbamazepine*
301-04-2	acetato de chumbo	*lead acetate*
305-85-1	disofenol	*disophenol*
314-03-4	pimetixeno	*pimethixene*
318-98-9	cloridrato de propranolol	*propranolol hydrochloride*
330-95-0	nicarbazina	*nicarbazin*
345-78-8	cloridrato de pseudoefedrina	*pseudoephedrine hydrochloride*
437-38-7	fentanila	*fentanyl*
439-14-5	diazepam	*diazepam*
443-48-1	metronidazol	*metronidazole*
446-86-6	azatioprina	*azathioprine*
471-34-1	carbonato de cálcio	*calcium carbonate*
497-19-8	carbonato de sódio	*sodium carbonate*
509-67-1	folcodina	*pholcodine*
532-32-1	benzoato de sódio	*sodium benzoate*
540-10-3	palmitato de cetila	*cetyl palmitate*
546-93-0	carbonato de magnésio	*magnesium carbonate*
548-73-2	droperidol	*droperidol*
554-13-2	carbonato de lítio	*lithium carbonate*
557-04-0	estearato de magnésio	*magnesium stearate*
557-08-4	undecilenato de zinco	*zinc undecylenate*
557-34-6	acetato de zinco	*zinc acetate*
583-52-8	oxalato de potássio	*potassium oxalate*
584-08-7	carbonato de potássio	*potassium carbonate*
630-93-3	fenitoína sódica	*phenytoin sodium*

CAS	PRODUTO	PRODUCT
631-61-8	acetato de amônio	*ammonium acetate*
637-58-1	cloridrato de pramoxina	*pramoxine hydrochloride*
638-23-3	carbocisteína	*carbocysteine*
721-50-6	prilocaína	*prilocaine*
723-46-6	sulfametoxazol	*sulfamethoxazole*
738-70-5	trimetoprima	*trimethoprim*
813-94-5	citrato de cálcio	*calcium citrate*
814-80-2	lactato de cálcio	*calcium lactate*
846-49-1	lorazepam	*lorazepam*
866-84-2	citrato de potássio	*potassium citrate*
868-14-4	tartarato ácido de potássio	*potassium bitartrate*
868-18-8	tartarato de sódio	*sodium tartrate*
870-72-4	hidroximetano sulfonato de sódio	*sodium hydroxymethane sulfonate*
881-17-4	iodoipurato de sódio (131 I): 0-iodo-hipurato de sódio 131 I	*iodohippurate sodium I 131*
990-73-8	citrato de fentanila	*fentanyl citrate*
1185-57-5	citrato férrico amoniacal	*ammonium ferric citrate*
1304-85-4	nitrato de bismuto monobásico	*bismuth subnitrate*
1305-62-0	hidróxido de cálcio	*calcium hydroxide*
1309-42-8	hidróxido de magnésio	*magnesium hydroxide*
1309-48-4	óxido de magnésio	*magnesium oxide*
1314-13-2	óxido de zinco	*zinc oxide*
1323-03-1	lactato de miristila	*myristil lactate*
1327-41-9	cloroidróxido de alumínio	*aluminum hydroxychloride*
1330-43-4	borato de sódio	*sodium borate*
1336-21-6	hidróxido de amônio	*ammonium hydroxide*
1338-41-6	estearato de sorbitana	*sorbitan monostearate*
1338-41-6	monoestearato de sorbitana	*sorbitan monostearate*
1420-53-7	sulfato de codeína	*codeine sulfate*
1422-07-7	cloridrato de codeína	*codeine hydrochloride*
1477-04-9	tiratricol sódico	*tiratricol sodium*
1592-23-0	estearato de cálcio	*calcium stearate*
1622-61-3	clonazepam	*clonazepam*
1642-54-2	citrato de dietilcarbamazina	*diethylcarbamazine citrate*
1722-62-9	cloridrato de mepivacaína	*mepivacaine hydrochloride*
1744-22-5	riluzol	*riluzole*
1786-81-8	cloridrato de prilocaína	*prilocaine hydrochloride*
1812-30-2	bromazepam	*bromazepam*
1863-63-4	benzoato de amônio	*ammonium benzoate*
2180-92-9	bupivacaína	*bupivacaine*
2611-61-2	cloridrato de glicinato de tianfenicol	*thianphenicol glycinate hydrochloride*
2746-81-8	enantato de flufenazina	*fluphenazine enanthate*
3056-17-5	estavudina	*stavudine*
3344-18-1	citrato de magnésio	*magnesium citrate*
3615-41-6	ramnose	*rhamnose*
3734-33-6	benzoato de denatônio	*denatonium benzoate*
4093-35-0	bromoprida	*bromopride*
4183-64-6	citrato de gálio (67 Ga)	*gallium (67 Ga) citrate*
4682-36-4	citrato de orfenadrina	*orphenadrine citrate*
5002-47-1	decanoato de flufenazina	*fluphenazine decanoate*

CAS	PRODUTO	PRODUCT
5591-29-7	cloridrato de etafedrina	*etafedrine hydrochloride*
5630-53-5	tibolona	*tibolone*
5633-14-7	cloridrato de benzetimida	*benzetimide hydrochloride*
5634-34-4	ambufilina	*ambuphylline*
5786-21-0	clozapina	*clozapine*
5892-10-4	carbonato básico de bismuto	*bismuth subcarbonate*
5905-52-2	lactato de ferro	*ferrous lactate*
5949-29-1	ácido cítrico monoidratado	*citric acid monohydrate*
5965-13-9	hemitartarato de di-hidrocodeína	*dihydrocodeine bitartrate*
6138-47-2	cloridrato de liotironina	*liothyronine hydrochloride*
6168-86-1	cloridrato de isometepteno	*isometheptene hydrochloride*
6190-39-2	mesilato de di-hidroergotamina	*dihydroergotamine mesilate*
6272-74-8	cloreto de lapírio	*lapirium chloride*
6381-59-5	tartarato de potássio e sódio (sal de Seignette)	*potassium sodium tartrate*
6484-52-2	nitrato de amônio	*ammonium nitrate*
6746-59-4	cloridrato de etilmorfina di-hidratado	*ethylmorphine hydrochloride dihydrate*
6893-02-3	liotironina	*liothyronine*
7085-45-2	lactato de biperideno	*biperiden lactate*
7414-83-7	etidronato de sódio	*etidronate disodium*
7446-70-0	cloreto de alumínio	*aluminum chloride*
7447-40-7	cloreto de potássio	*potassium chloride*
7447-41-8	cloreto de lítio	*lithium chloride*
7460-12-0	sulfato de pseudoefedrina	*pseudoephedrine sulfate*
7487-88-9	sulfato de magnésio	*magnesium sulfate*
7488-56-4	sulfeto de selênio	*selenium sulfide*
7492-31-1	mucato de isometepteno	*isometheptene mucate*
7546-28-3	lactofosfato de cálcio	*calcium lactophosphate*
7553-56-2	iodo ressublimado	*iodine*
7558-79-4	fosfato de sódio dibásico	*sodium phosphate dibasic*
7558-80-7	fosfato de sódio monobásico	*sodium phosphate monobasic*
7635-46-3	fosfato de sódio (32 P)	*sodium phosphate P 32*
7646-93-7	bissulfato de potássio	*potassium bisulfate*
7647-14-5	cloreto de sódio	*sodium chloride*
7681-11-0	iodeto de potássio	*potassium iodide*
7681-49-4	fluoreto de sódio	*sodium fluoride*
7681-52-9	hipoclorito de sódio	*sodium hypochlorite*
7681-57-4	metabissulfito de sódio	*sodium metabisulfite*
7681-82-5	iodeto de sódio	*sodium iodide*
7705-08-0	cloreto férrico	*ferric chloride*
7720-78-7	sulfato ferroso	*ferrous sulfate*
7722-84-1	peróxido de hidrogênio (água oxigenada)	*hydrogen peroxide*
7727-43-7	sulfato de bário	*barium sulfate*
7733-02-0	sulfato de zinco	*zinc sulfate*
7757-79-1	nitrato de potássio	*potassium nitrate*
7757-82-6	sulfato de sódio	*sodium sulfate*
7757-86-0	fosfato de magnésio dibásico	*magnesium phosphate dibasic*
7757-87-1	fosfato de magnésio tribásico	*magnesium phosphate tribasic*
7757-93-9	fosfato de cálcio dibásico	*calcium phosphate dibasic*

CAS	PRODUTO	PRODUCT
7758-11-4	fosfato de potássio dibásico	*potassium phosphate dibasic*
7758-23-8	fosfato de cálcio monobásico	*calcium phosphate monobasic*
7758-98-7	sulfato cúprico	*cupric sulfate*
7772-98-7	tiossulfato de sódio	*sodium thiosulfate*
7775-11-3	cromato de sódio (51 Cr)	*sodium chromate Cr 51*
7778-18-9	sulfato de cálcio	*calcium sulfate*
7778-77-0	fosfato de potássio monobásico	*potassium phosphate monobasic*
7778-80-5	sulfato de potássio	*potassium sulfate*
7782-63-0	sulfato ferroso heptaidratado	*ferrous sulfate heptahydrate*
7784-25-0	sulfato amoniacal de alumínio	*aluminum ammonium sulfate*
7785-87-7	sulfato de manganês	*manganese sulfate*
7786-30-3	cloreto de magnésio	*magnesium chloride*
7789-23-3	fluoreto de potássio	*potassium fluoride*
7790-26-3	iodeto de sódio (131 I)	*sodium iodide I 131*
8001-54-5	cloreto de benzalcônio	*benzalkonium chloride*
8006-54-0	lanolina anidra	*lanolin anhydrous*
8008-74-0	óleo de gergelim	*sesame oil*
8009-03-8	vaselina sólida (petrolato)	*petrolatum*
8016-07-7	óleo etiodado (131 I): lipiodol 131 I	*ethiodized oil (131 I)*
8049-47-6	pancreatina	*pancreatin*
9000-69-5	pectina cítrica	*citric pectin*
9001-73-4	papaína	*papain*
9001-75-6	pepsina	*pepsin*
9002-61-3	gonadotrofina coriônica humana	*HCG (human chorionic gonadotropin)*
9004-34-6	celulose gel	*cellulose gel*
9004-34-6	celulose microcristalina	*microcrystalline cellulose*
9005-49-6	heparina	*heparin*
9005-49-6	heparina BPM	*heparin LMW*
9005-64-5	polissorbato 20	*polysorbate 20*
9005-65-6	polissorbato 80	*polysorbate 80*
9005-67-8	polissorbato 60	*polysorbate 60*
9007-28-7	sulfato de condroitina	*chondroitin sulfate*
9007-28-7	sulfato de condroitina BPM	*chondroitin sulfate LWM*
9010-06-4	heparinoide	*heparinoid*
9041-08-1	heparina sódica	*heparin sodium*
9048-49-1	albumina humana sérica iodada (131 I): SAH I 131	*albumin, iodinated I 131 serum*
9063-38-1	glicolato de amido sódico	*sodium starch glycolate*
10043-01-3	sulfato de alumínio	*aluminum sulfate*
10043-35-3	ácido bórico	*boric acid*
10043-52-4	cloreto de cálcio	*calcium chloride*
10043-67-1	alume de potássio	*potassium alum*
10043-67-1	sulfato de alumínio e potássio	*aluminum potassium sulfate*
10058-44-3	pirofosfato férrico	*ferric pyrophosphate*
10075-24-8	embonato de imipramina	*imipramine pamoate*
10138-04-2	sulfato de ferro amoniacal	*ammonium ferric sulfate*
10226-54-7	lomifilina	*lomifylline*
10347-81-6	cloridrato de maprotilina	*maprotiline hydrochloride*
10377-48-7	sulfato de lítio	*lithium sulfate*
11006-76-1	virginiamicina	*virginiamycin*

CAS	PRODUTO	PRODUCT
11096-26-7	eritropoietina humana recombinante	*human erythropoietin recombinant, hemopoietine*
12125-02-9	cloreto de amônio	*ammonium chloride*
12167-74-7	fosfato de cálcio tribásico	*calcium phosphate tribasic*
12629-01-5	somatropina	*somatotropin*
13182-89-3	benzoilmetronidazol	*benzoyl metronidazole*
13311-84-7	flutamida	*flutamide*
13492-01-8	sulfato de tranilcipromina	*tranylcypromine sulfate*
14262-80-7	sulfato de sódio (35 S)	*sodium sulfate S 35*
14987-04-3	trissilicato de magnésio	*magnesium trisilicate*
15307-79-6	diclofenaco sódico	*diclofenac sodium*
15307-81-0	diclofenaco potássico	*diclofenac potassium*
15307-86-5	diclofenaco	*diclofenac acid*
15663-27-1	cisplatina	*cisplatin*
16291-96-6	carvão ativado	*activated carbon*
16506-27-7	bendamustina	*bendamustine*
16652-76-9	tosilato de valinéster	*valinester tosylate*
17617-23-1	flurazepam	*flurazepam*
18010-40-7	cloridrato de bupivacaína	*bupivacaine hydrochloride*
18305-29-8	cloridrato de femproporex	*fenproporex hydrochloride*
18917-93-6	lactato de magnésio	*magnesium lactate*
18996-35-5	citrato monossódico	*monosodium citrate*
19774-82-4	cloridrato de amiodarona	*amiodarone hydrochloride*
21645-51-2	hidróxido de alumínio	*aluminum hydroxide*
21898-19-1	cloridrato de clembuterol	*clembuterol hydrochloride*
22199-08-2	sulfadiazina de prata	*sulfadiazine silver salt*
22204-88-2	cloridrato de tramadol	*tramadol hydrochloride*
22232-71-9	mazindol	*mazindol*
22465-48-1	acetato de hidroxocobalamina	*hydroxocobalamin acetate*
22554-99-0	fluoreto de sódio (18 F)	*sodium fluoride F 18*
22832-87-7	nitrato de miconazol	*miconazole nitrate*
23288-60-0	pentecnetato de sódio (99m Tc): gerador de tecnécio 99m	*technetium 99m Tc pentechnetate*
23964-57-0	cloridrato de articaína	*articaine hydrochloride*
24166-13-0	cloxazolam	*cloxazolam*
24168-96-5	nitrato de isoconazol	*isoconazole nitrate*
24584-09-6	dextrorrazoxano	*dexrazoxane*
24730-10-7	mesilato de di-hidroergocristina	*dihydroergocristine mesilate*
24868-20-0	dantroleno sódico hemieptaidratado	*dantrolene sodium hemiheptahydrate*
25102-12-9	edetato de potássio	*edetate dipotassium*
25968-91-6	cloridrato de hidrocodona	*hydrocodone hydrochloride*
27262-45-9	cloridrato de dextrobupivacaína	*dextrobupivacaine hydrochloride*
27262-48-2	cloridrato de levobupivacaína	*levobupivacaine hydrochloride*
27262-48-2	levobupivacaína	*levobupivacaine*
27849-89-4	edetato crômico (51 Cr): EDTA 51 Cr	*chromium Cr 51 edetate*
28523-86-6	sevoflurano	*sevoflurane*
28721-07-5	oxcarbazepina	*oxcarbazepine*
28981-97-7	alprazolam	*alprazolam*
30516-87-1	AZT (zidovudina)	*zidovudine*
30516-87-1	zidovudina	*zidovudine*

CAS	PRODUTO	PRODUCT
31431-39-7	mebendazol	*mebendazole*
31566-31-1	monoestearato de glicerila	*glyceryl monostearate*
31677-93-7	cloridrato de bupropiona	*bupropion hydrochloride*
33089-61-1	amitraz	*amitraz*
33125-97-2	etomidato	*etomidate*
33522-95-1	noroximorfona	*noroxymorphone*
33564-30-6	cefoxitina sódica	*cefoxitin sodium*
33795-24-3	cloridrato de dextrocetamina	*dextrocetamine hydrochoride*
34580-14-8	fumarato de cetotifeno	*ketotifen fumarate*
35189-28-7	norgestimato	*norgestimate*
35367-38-5	diflubenzurona	*diflubenzuron*
36322-90-4	piroxicam	*piroxicam*
36791-04-5	ribavirina	*ribavirine*
39562-70-4	nitrendipino	*nitrendipine*
39832-40-0	cefalexina sódica	*cephalexin sodium monohydrate*
40391-99-9	ácido pamidrônico	*pamidronic acid*
41575-94-4	carboplatina	*carboplatin*
41927-88-2	iodeto de sódio (123 I)	*sodium iodide I 123*
42540-40-9	nafato de cefamandol	*cefamandole nafate*
52003-58-4	lactato de amônio	*ammonium lactate*
52214-84-3	ciprofibrato	*ciprofibrate*
53016-31-2	norelgestromina	*norelgestromine*
53684-61-0	citrato ferroso de cálcio	*calcium ferrous citrate*
53716-50-0	oxfendazol	*oxfendazole*
53885-35-1	cloridrato de ticlopidina	*ticlopidine hydrochloride*
54024-22-5	desogestrel	*desogestrel*
54029-12-8	óxido de albendazol	*albendazole oxide*
54143-56-5	acetato de flecainida	*flecainide acetate*
54965-21-8	albendazol	*albendazole*
55172-29-7	cloreto de tálio (201 Tl)	*thallous chloride Tl 201*
55721-31-8	salinomicina sódica miceliana	*salinomycin sodium*
55837-30-4	clonixinato de lisina	*clonixin lysine salt*
57645-91-7	malato de cleboprida	*clebopride hydrogen malate*
57808-65-8	closantel	*closantel*
57817-89-7	esteviosídeo	*stevioside*
58066-85-6	miltefosina	*miltefosine*
58288-50-9	cloridrato de hidroxocobalamina	*hydroxocobalamin hydrochloride*
59277-89-3	aciclovir	*aciclovir*
59467-70-8	midazolam	*midazolam*
59467-94-6	maleato de midazolam	*midazolam maleate*
59467-96-8	cloridrato de midazolam	*midazolam hydrochloride*
60282-87-3	gestodeno	*gestodene*
60561-17-3	citrato de sufentanila	*sufentanil citrate*
60569-19-9	propiverina	*propiverine*
61337-67-5	mirtazapina	*mirtazapine*
61825-94-3	oxaliplatina	*oxaliplatin*
63612-50-0	nilutamida	*nilutamide*
63675-72-9	nisoldipino	*nisoldipine*
64485-93-4	cefotaxima sódica	*cefotaxime sodium*
65277-42-1	cetoconazol	*ketoconazole*

CAS	PRODUTO	PRODUCT
66085-59-4	nimodipino	*nimodipine*
66376-36-1	ácido alendrônico	*alendronic acid*
68693-11-8	modafinila	*modafinil*
69388-79-0	sulbactam pivoxila	*sulbactam pivoxil*
69388-84-7	sulbactam sódico	*sulbactam sodium*
69655-05-6	DDI (didanosina)	*DDI (dideoxyinosine)*
69655-05-6	didanosina	*didanosine*
70288-86-7	ivermectina	*ivermectin*
70476-82-3	dicloridrato de mitoxantrona	*mitoxantrone dihydrochloride*
70879-28-6	cloridrato de alfentanila monoidratado	*alfentanil hydrochloride monohydrate*
72558-82-8	ceftazidima	*ceftazidime*
73963-72-1	cilostazol	*cilostazol*
74050-97-8	decanoato de haloperidol	*haloperidol decanoate*
74103-06-3	cetorolaco	*ketorolac*
74191-85-8	doxazosina	*doxazosin*
74578-69-1	ceftriaxona sódica	*ceftriaxone sodium*
74811-65-7	croscarmelose sódica	*croscarmellose sodium*
75706-12-6	leflunomida	*leflunomide*
76095-16-4	maleato de enalapril	*enalapril maleate*
76543-88-9	alfainterferona 2a	*interferon alpha-2a recombinant*
77679-27-7	iobenguano (123 I): MIBG, metaiodobenzilguanidina 123 I	*iobenguane (123 I)*
78213-16-8	diclofenaco dietilamônio	*diclofenac diethylammonium*
78755-81-4	flumazenil	*flumazenil*
78964-85-9	fosfomicina trometamol	*fosfomycin tromethamine*
79902-63-9	sinvastatina	*simvastatin*
82410-32-0	ganciclovir	*ganciclovir*
84057-95-4	ropivacaína	*ropivacaine*
84449-90-1	raloxifeno	*raloxifene*
85622-93-1	temozolomida	*temozolomide*
88040-23-7	cefepima	*cefepime*
90803-92-2	timomodulina	*thymomodulin*
93106-60-6	enrofloxacino	*enrofloxacin*
95635-55-5	ranolazina	*ranolazine*
97240-79-4	topiramato	*topiramate*
97676-26-1	óleo de maracujá	*passiflora seed oil*
98717-15-8	cloridrato de ropivacaina	*ropivacaine hydrochloride*
99210-65-8	alfainterferona 2b	*interferon alpha-2b recombinant*
99294-93-6	hemitartarato de zolpidem	*zolpidem bitartrate*
99300-78-4	cloridrato de venlafaxina	*venlafaxine hydrochloride*
100986-85-4	levofloxacino	*levofloxacin*
103577-45-3	lansoprazol	*lansoprazole*
103694-84-4	tetrafluoroborato de cobre	*copper tetrafluoroborate, tetramibi*
104987-11-3	tacrolimo	*tacrolimus*
105851-17-0	fludesoxiglicose (18 F): FDG 18 F	*fludeoxyglucose (18 F)*
110429-35-1	cloridrato de paroxetina	*paroxetine hydrochloride*
111974-72-2	fumarato de quetiapina	*quetiapine fumarate*
111974-72-2	hemifumarato de quetiapina	*quetiapine hemifumarate*
113378-31-7	senduramicina	*semduramicin*
114772-54-2	bromotolil benzonitrila	*bromotolil benzonitril*

CAS	PRODUTO	PRODUCT
114977-28-5	docetaxel	*docetaxel anhydrous*
115436-72-1	risedronato de sódio	*risedronate monosodium*
118072-93-8	ácido zoledrônico	*zoledronic acid*
119356-77-3	dapoxetina	*dapoxetine*
119623-66-4	diclofenaco epolamina	*diclofenac epolamine*
121181-53-1	filgrastim	*filgrastin*
121268-17-5	alendronato de sódio	*alendronate monosodium*
123171-59-5	cloridrato de cefepima	*cefepime hydrochloride*
124750-99-8	losartana potássica	*losartan potassium*
124937-52-6	tartarato de tolterodina	*tolterodine tartrate*
125494-59-9	cloridrato de sibutramina	*sibutramine hydrochloride*
127779-20-8	saquinavir	*saquinavir*
129618-40-2	nevirapina	*nevirapine*
129722-12-9	aripiprazol	*aripiprazole*
132539-06-1	olanzapina	*olanzapine*
132875-61-7	remifentanila	*remifentanil*
134678-17-4	lamivudina (3TC)	*lamivudine*
135968-09-1	lenograstim	*lenograstim*
137281-23-3	pemetrexede	*pemetrexed*
137864-22-3	valesteramida	*valesteramide*
138729-47-2	eszopiclona	*eszopiclone*
138926-19-9	ibandronato de sódio	*ibandronate monosodium*
139096-04-1	pentetreotida (111 In): DTPA, octreotídeo 111 In	*indium In 111 pentetreotide*
139755-80-9	iobenguano (131 I): MIBG, metaiodobenzilguanidina 131 I	*iobenguane (131 I)*
141505-32-0	lisinato de ibuprofeno	*ibuprofen lysine*
141626-36-0	dronedarona	*dronedarone*
145258-61-3	betainterferona 1a recombinante	*interferon beta 1a recombinant*
150322-43-3	prasugrel	*prasugrel*
151319-34-5	zaleplona	*zaleplon*
154427-83-5	lexidronam (153 Sm): EDTMP, ácido etilenodiaminotetrametileno fosfônico 153 Sm	*samarium Sm 153 lexidronam*
154598-52-4	efavirenz	*efavirenz*
155141-29-0	maleato de rosiglitazona	*rosiglitazone maleate*
155213-67-5	ritonavir	*ritonavir*
157810-81-6	sulfato de indinavir	*indinavir sulfate*
161735-79-1	mesilato de rasagilina	*rasagiline mesilate*
171599-83-0	citrato de sildenafila	*sildenafil citrate*
182683-00-7	cloridrato de sevelâmer	*sevelamer hydrochloride*
186826-86-8	cloridrato de moxifloxacino	*moxifloxacin hydrochloride*
198904-31-3	atazanavir	*atazanavir*
202138-50-9	fumarato de tenofovir disoproxila	*tenofovir disoproxyl fumarate*
204318-14-9	edotreotida (177 Lu): DOTA octreotato 177 Lu	*edotreotide 177 Lu*
240490-15-7	diclofenaco colestiramina	*diclofenac cholestyramin*
240490-15-7	resinato de diclofenaco	*diclofenac resinate*
286930-03-8	fumarato de fesoterodina	*fesoterodine fumarate*
394236-97-6	manteiga de cupuaçu	*cupuaçu butter*

CAS	PRODUTO	PRODUCT
398507-55-6	carbonato de lodenafila	*lodenafil carbonate*
610309-89-2	fosfato de carvedilol	*carvedilol phosphate*
845273-93-0	carbonato de sevelâmer	*sevelamer carbonate*
905818-69-1	bromidrato de bupropiona	*bupropion hydrobromide*
n.d.	albumina humana sérica cromada (51 Cr): SAH 51 Cr	*albumin, chromated Cr 51 serum*
n.d.	ferrolate	*ferrolat*
n.d.	fosfatidilserina	*phosphatidylserine*
n.d.	hidroxiapatita (153 Sm): HA 153 Sm	*samarium Sm 153 hydroxyapatite*
n.d.	peptona bacteriológica	*bacteriological peptone*
n.d.	propinox	*propinox*
n.d.	resinato de codeína	*codeine resinate*
n.d.	resinato de feniltoloxamina	*phenyltoloxamine resinate*
n.d.	resinato de hidrocodona	*hydrocodone resinate*
n.d.	soro fetal bovino	*bovine fetal serum*
n.d.	sulfato de hidroxocobalamina	*hydroxocobalamin sulfate*
n.d.	tartarato do ácido G-aminobutírico	*G-aminobutyric acid tartrate*
n.d.	triglicérido dos ácidos cáprico e caprílico	*capric and caprylic acids triglycerides*

Produtos por ordem de DCB

Products listed by DCB order

DCB	PRODUTO	PRODUCT
00054	acetato de alumínio	*aluminum acetate*
00055	acetato de amônio	*ammonium acetate*
00061	acetato de potássio	*potassium acetate*
00082	aciclovir	*aciclovir*
00087	acetato de sódio	*sodium acetate*
00096	ácido alendrônico	*alendronic acid*
00097	alendronato de sódio	*alendronate monosodium*
00115	ácido benzoico	*benzoic acid*
00116	ácido bórico	*boric acid*
00117	borato de sódio	*sodium borate*
00134	ácido cítrico anidro	*citric acid anhydrous*
00152	ácido cólico	*cholic acid*
00157	ácido desidrocólico	*dehydrocholic acid*
00160	ácido desoxicólico	*deoxycholic acid*
00170	edetato de potássio	*edetate dipotassium*
00201	fosfato de cálcio dibásico	*calcium phosphate dibasic*
00202	fosfato de cálcio monobásico	*calcium phosphate monobasic*
00203	fosfato de cálcio tribásico	*calcium phosphate tribasic*
00204	fosfato de magnésio dibásico	*magnesium phosphate dibasic*
00205	fosfato de potássio dibásico	*potassium phosphate dibasic*
00206	fosfato de potássio monobásico	*potassium phosphate monobasic*
00207	fosfato de sódio dibásico	*sodium phosphate dibasic*
00212	fosfato de sódio monobásico	*sodium phosphate monobasic*
00275	lactato de cálcio	*calcium lactate*
00277	lactato de magnésio	*magnesium lactate*
00278	lactato de sódio	*sodium lactate*
00314	ácido pamidrônico	*pamidronic acid*
00339	risedronato de sódio	*risedronate monosodium*
00340	ácido salicílico	*salicylic acid*
00350	ácido tartárico	*L-tartaric acid*
00351	tartarato ácido de potássio	*potassium bitartrate*
00355	tartarato de sódio	*sodium tartrate*
00368	undecilenato de zinco	*zinc undecylenate*
00379	ácido zoledrônico	*zoledronic acid*
00458	albendazol	*albendazole*
00459	óxido de albendazol	*albendazole oxide*
00462	albumina humana sérica iodada (131 I): SAH I 131	*albumin, iodinated I 131 serum*
00471	álcool benzílico	*benzyl alcohol*
00480	álcool oleílico	*oleyl alcohol*
00515	alfainterferona 2a	*interferon alpha-2a recombinant*
00516	alfainterferona 2b	*interferon alpha-2b recombinant*
00597	alprazolam	*alprazolam*
00636	ambufilina	*ambuphylline*
00658	glicolato de amido sódico	*sodium starch glycolate*
00700	cloridrato de amiodarona	*amiodarone hydrochloride*
00710	amitraz	*amitraz*
00775	cloridrato de anfepramona	*diethylpropion hydrochloride*
00866	arginina	*L-arginine*
00875	aripiprazol	*aripiprazole*

DCB	PRODUTO	PRODUCT
00891	cloridrato de articaína	*articaine hydrochloride*
00984	azatioprina	*azathioprine*
01097	bendamustina	*bendamustine*
01136	cloridrato de benzetimida	*benzetimide hydrochloride*
01154	benzoato de amônio	*ammonium benzoate*
01156	benzoato de denatônio	*denatonium benzoate*
01157	benzoato de sódio	*sodium benzoate*
01166	benzoilmetronidazol	*benzoyl metronidazole*
01249	bicarbonato de sódio	*sodium bicarbonate*
01284	lactato de biperideno	*biperiden lactate*
01366	bromazepam	*bromazepam*
01468	bromofórmio	*bromoform*
01471	bromoprida	*bromopride*
01551	bupivacaína	*bupivacaine*
01552	cloridrato de bupivacaína	*bupivacaine hydrochloride*
01558	cloridrato de bupropiona	*bupropion hydrochloride*
01710	carbamazepina	*carbamazepine*
01711	ureia	*urea, carbamide*
01739	carbocisteína	*carbocysteine*
01747	carbonato básico de bismuto	*bismuth subcarbonate*
01748	carbonato de cálcio	*calcium carbonate*
01749	carbonato de lítio	*lithium carbonate*
01750	carbonato de magnésio	*magnesium carbonate*
01751	carbonato de potássio	*potassium carbonate*
01752	carbonato de sódio	*sodium carbonate*
01754	carboplatina	*carboplatin*
01828	cefalexina sódica	*cephalexin sodium monohydrate*
01836	cefalotina sódica	*cefalotin sodium*
01838	nafato de cefamandol	*cefamandole nafate*
01855	cefepima	*cefepime*
01856	cloridrato de cefepima	*cefepime hydrochloride*
01877	cefotaxima sódica	*cefotaxime sodium*
01883	cefoxitina sódica	*cefoxitin sodium*
01897	ceftazidima	*ceftazidime*
01910	ceftriaxona sódica	*ceftriaxone sodium*
01956	cetoconazol	*ketoconazole*
01963	cetorolaco	*ketorolac*
01968	fumarato de cetotifeno	*ketotifen fumarate*
02067	cilostazol	*cilostazol*
02136	ciprofibrato	*ciprofibrate*
02156	cisplatina	*cisplatin*
02176	citrato de cálcio	*calcium citrate*
02179	citrato de gálio (67 Ga)	*gallium (67 Ga) citrate*
02180	citrato de magnésio	*magnesium citrate*
02181	citrato de potássio	*potassium citrate*
02182	citrato de sódio	*sodium citrate*
02187	citrato férrico amoniacal	*ammonium ferric citrate*
02205	malato de cleboprida	*clebopride hydrogen malate*
02210	cloridrato de clembuterol	*clembuterol hydrochloride*
02300	clonazepam	*clonazepam*

DCB	PRODUTO	PRODUCT
02360	cloreto de alumínio	*aluminum chloride*
02362	cloreto de amônio	*ammonium chloride*
02364	cloreto de benzalcônio	*benzalkonium chloride*
02369	cloreto de cálcio	*calcium chloride*
02397	cloreto de lapírio	*lapirium chloride*
02399	cloreto de magnésio	*magnesium chloride*
02415	cloreto de potássio	*potassium chloride*
02421	cloreto de sódio	*sodium chloride*
02431	cloreto férrico	*ferric chloride*
02458	cloridrato de levobupivacaína	*levobupivacaine hydrochloride*
02517	closantel	*closantel*
02535	cloxazolam	*cloxazolam*
02540	clozapina	*clozapine*
02545	codeína	*codeine*
02554	cloridrato de codeína	*codeine hydrochloride*
02557	fosfato de codeína	*codeine phosphate*
02562	sulfato de codeína	*codeine sulfate*
02597	sulfato de condroitina	*chondroitin sulfate*
02597	sulfato de condroitina BPM	*chondroitin sulfate LWM*
02634	cromato de sódio (51 Cr)	*sodium chromate Cr 51*
02641	croscarmelose sódica	*croscarmellose sodium*
02685	dapoxetina	*dapoxetine*
02795	desogestrel	*desogestrel*
02860	dextrorrazoxano	*dexrazoxane*
02904	diazepam	*diazepam*
02926	diclofenaco	*diclofenac acid*
02927	diclofenaco dietilamônio	*diclofenac diethylammonium*
02928	diclofenaco epolamina	*diclofenac epolamine*
02929	diclofenaco potássico	*diclofenac potassium*
02930	diclofenaco sódico	*diclofenac sodium*
02931	diclofenaco colestiramina	*diclofenac cholestyramin*
02931	resinato de diclofenaco	*diclofenac resinate*
02948	DDI (didanosina)	*DDI (dideoxyinosine)*
02948	didanosina	*didanosine*
02959	citrato de dietilcarbamazina	*diethylcarbamazine citrate*
03014	hemitartarato de di-hidrocodeína	*dihydrocodeine bitartrate*
03019	mesilato de di-hidroergocristina	*dihydroergocristine mesilate*
03021	mesilato de di-hidroergotamina	*dihydroergotamine mesilate*
03167	docetaxel	*docetaxel anhydrous*
03209	doxazosina	*doxazosin*
03246	droperidol	*droperidol*
03308	efavirenz	*efavirenz*
03310	cloridrato de efedrina	*ephedrine hydrochloride*
03311	sulfato de efedrina	*ephedrine sulfate*
03370	maleato de enalapril	*enalapril maleate*
03412	enrofloxacino	*enrofloxacin*
03498	eritropoietina humana recombinante	*human erythropoietin recombinant, hemopoietine*
03561	espironolactona	*spironolactone*
03574	estavudina	*stavudine*

DCB	PRODUTO	PRODUCT
03576	estearato de cálcio	*calcium stearate*
03577	estearato de magnésio	*magnesium stearate*
03580	estearato de sorbitana	*sorbitan monostearate*
03595	estradiol	*estradiol*
03638	cloridrato de etafedrina	*etafedrine hydrochloride*
03663	éter etílico	*sulfuric ether*
03690	cloridrato de etilmorfina di-hidratado	*ethylmorphine hydrochloride dihydrate*
03699	etinilestradiol	*ethinyl estradiol*
03731	etomidato	*etomidate*
03849	cloridrato de femproporex	*fenproporex hydrochloride*
03926	cloridrato de fenilefrina	*phenylephrine hydrochloride*
03953	fenitoína (difenilidantoína)	*phenytoin*
03954	fenitoína sódica	*phenytoin sodium*
03960	fenobarbital	*phenobarbital*
03962	fenobarbital sódico	*phenobarbital sodium*
04004	fentanila	*fentanyl*
04005	citrato de fentanila	*fentanyl citrate*
04052	filgrastim	*filgrastin*
04069	acetato de flecainida	*flecainide acetate*
04114	fludesoxiglicose (18 F): FDG 18 F	*fludeoxyglucose (18 F)*
04123	decanoato de flufenazina	*fluphenazine decanoate*
04126	enantato de flufenazina	*fluphenazine enanthate*
04134	flumazenil	*flumazenil*
04170	fluoreto de sódio	*sodium fluoride*
04206	flurazepam	*flurazepam*
04220	flutamida	*flutamide*
04239	folcodina	*pholcodine*
04276	fosfatidilserina	*phosphatidylserine*
04282	fosfato de sódio (32 P)	*sodium phosphate P 32*
04292	fosfomicina trometamol	*fosfomycin tromethamine*
04336	fumarato ferroso	*ferrous fumarate*
04394	ganciclovir	*ganciclovir*
04430	gestodeno	*gestodene*
04518	glutamina (L)	*glutamine (L)*
04527	gonadotrofina coriônica humana	*HCG (human chorionic gonadotropin)*
04589	haloperidol	*haloperidol*
04591	decanoato de haloperidol	*haloperidol decanoate*
04607	heparina	*heparin*
04607	heparina BPM	*heparin LMW*
04610	heparina sódica	*heparin sodium*
04654	hemitartarato de hidrocodona	*hydrocodone bitartrate*
04656	cloridrato de hidrocodona	*hydrocodone hydrochloride*
04694	hidróxido de alumínio	*aluminum hydroxide*
04696	hidróxido de cálcio	*calcium hydroxide*
04697	hidróxido de magnésio	*magnesium hydroxide*
04720	acetato de hidroxocobalamina	*hydroxocobalamin acetate*
04721	cloridrato de hidroxocobalamina	*hydroxocobalamin hydrochloride*
04731	hipoclorito de sódio	*sodium hypochlorite*
04747	metilbrometo de homatropina	*homatropine methylbromide*
04775	lisinato de ibuprofeno	*ibuprofen lysine*

DCB	PRODUTO	PRODUCT
04838	embonato de imipramina	*imipramine pamoate*
04883	sulfato de indinavir	*indinavir sulfate*
04932	iobenguano (131 I): MIBG, metaiodobenzilguanidina 131 I	*iobenguane (131 I)*
04965	iodeto de potássio	*potassium iodide*
04969	iodeto de sódio	*sodium iodide*
04972	iodeto de sódio (131 I)	*sodium iodide I 131*
04983	iodo ressublimado	*iodine*
04985	iodofórmio	*iodoform*
04987	iodoipurato de sódio (131 I): 0-iodo-hipurato de sódio 131 I	*iodohippurate sodium I 131*
05076	nitrato de isoconazol	*isoconazole nitrate*
05083	isoleucina (L)	*isoleucine (L)*
05090	cloridrato de isometepteno	*isometheptene hydrochloride*
05091	mucato de isometepteno	*isometheptene mucate*
05128	ivermectina	*ivermectin*
05138	lactato de amônio	*ammonium lactate*
05139	lactato de ferro	*ferrous lactate*
05142	lactofosfato de cálcio	*calcium lactophosphate*
05152	lamivudina (3TC)	*lamivudine*
05161	lanolina anidra	*lanolin anhydrous*
05165	lansoprazol	*lansoprazole*
05192	leflunomida	*leflunomide*
05201	lenograstim	*lenograstim*
05239	levobupivacaína	*levobupivacaine*
05257	levofloxacino	*levofloxacin*
05294	levotiroxina	*levothyroxine*
05295	levotiroxina sódica	*levothyroxine sodium*
05313	lidocaína	*lidocaine*
05314	cloridrato de lidocaína	*lidocaine hydrochloride*
05334	liotironina	*liothyronine*
05335	cloridrato de liotironina	*liothyronine hydrochloride*
05338	liotironina sódica	*liothyronine sodium*
05349	clonixinato de lisina	*clonixin lysine salt*
05398	lomifilina	*lomifylline*
05417	lorazepam	*lorazepam*
05432	losartana potássica	*losartan potassium*
05499	cloridrato de maprotilina	*maprotiline hydrochloride*
05511	mazindol	*mazindol*
05515	mebendazol	*mebendazole*
05587	antimoniato de meglumina	*meglumine antimonate*
05657	cloridrato de mepivacaína	*mepivacaine hydrochloride*
05680	6-mercaptopurina	*6-mercaptopurine*
05711	metabissulfito de sódio	*sodium metabisulfite*
05717	metadona	*methadone*
05902	metronidazol	*metronidazole*
05929	nitrato de miconazol	*miconazole nitrate*
05937	midazolam	*midazolam*
05938	cloridrato de midazolam	*midazolam hydrochloride*
05939	maleato de midazolam	*midazolam maleate*

DCB	PRODUTO	PRODUCT
05965	miltefosina	*miltefosine*
05994	miristato de isopropila	*isopropyl myristate*
06000	mirtazapina	*mirtazapine*
06023	dicloridrato de mitoxantrona	*mitoxantrone dihydrochloride*
06041	modafinila	*modafinil*
06066	monoestearato de dietilenoglicol	*diethylene glycol monostearate*
06067	monoestearato de etilenoglicol	*ethylene glycol monostearate*
06068	monoestearato de glicerila	*glyceryl monostearate*
06095	cloridrato de morfina	*morphine hydrochloride*
06114	sulfato de morfina	*morphine sulfate*
06140	cloridrato de moxifloxacino	*moxifloxacin hydrochloride*
06310	nevirapina	*nevirapine*
06320	nicarbazina	*nicarbazin*
06388	nilutamida	*nilutamide*
06394	nimodipino	*nimodipine*
06408	nisoldipino	*nisoldipine*
06423	nitrato de amônio	*ammonium nitrate*
06424	nitrato de bismuto monobásico	*bismuth subnitrate*
06426	nitrato de potássio	*potassium nitrate*
06431	nitrendipino	*nitrendipine*
06485	norelgestromina	*norelgestromine*
06501	norgestimato	*norgestimate*
06580	olanzapina	*olanzapine*
06587	óleo etiodado (131 I): lipiodol 131 I	*ethiodized oil (131 I)*
06630	citrato de orfenadrina	*orphenadrine citrate*
06669	oxaliplatina	*oxaliplatin*
06691	oxcarbazepina	*oxcarbazepine*
06702	oxfendazol	*oxfendazole*
06718	cloridrato de oxicodona	*oxycodone hydrochloride*
06728	óxido de magnésio	*magnesium oxide*
06730	óxido de zinco	*zinc oxide*
06797	palmitato de cetila	*cetyl palmitate*
06811	pancreatina	*pancreatin*
06821	papaína	*papain*
06859	cloridrato de paroxetina	*paroxetine hydrochloride*
06874	pectina cítrica	*citric pectin*
06897	pemetrexede	*pemetrexed*
06927	pentamidina	*pentamidine*
06963	pepsina	*pepsin*
07004	peróxido de hidrogênio (água oxigenada)	*hydrogen peroxide*
07008	cloridrato de petidina	*pethidine hydrochloride*
07049	pilocarpina	*pilocarpine*
07050	cloridrato de pilocarpina	*pilocarpine hydrochloride*
07051	nitrato de pilocarpina	*pilocarpine nitrate*
07060	pimetixeno	*pimethixene*
07107	cloridrato de piperidolato	*piperidolate hydrochloride*
07211	piroxicam	*piroxicam*
07272	polissorbato 20	*polysorbate 20*
07274	polissorbato 60	*polysorbate 60*

DCB	PRODUTO	PRODUCT
07275	polissorbato 80	*polysorbate 80*
07304	cloridrato de pramoxina	*pramoxine hydrochloride*
07363	prilocaína	*prilocaine*
07364	cloridrato de prilocaína	*prilocaine hydrochloride*
07455	propilenoglicol	*propylene glycol*
07462	propiltiouracila	*propylthiouracil*
07472	propiverina	*propiverine*
07482	cloridrato de propranolol	*propranolol hydrochloride*
07519	pseudoefedrina	*pseudoephedrine*
07520	cloridrato de pseudoefedrina	*pseudoephedrine hydrochloride*
07522	sulfato de pseudoefedrina	*pseudoephedrine sulfate*
07537	quercetina	*quercetin*
07539	fumarato de quetiapina	*quetiapine fumarate*
07539	hemifumarato de quetiapina	*quetiapine hemifumarate*
07621	raloxifeno	*raloxifene*
07631	ramnose	*rhamnose*
07640	ranolazina	*ranolazine*
07663	remifentanila	*remifentanil*
07700	ribavirina	*ribavirine*
07729	riluzol	*riluzole*
07756	ritonavir	*ritonavir*
07804	ropivacaína	*ropivacaine*
07805	cloridrato de ropivacaina	*ropivacaine hydrochloride*
07813	maleato de rosiglitazona	*rosiglitazone maleate*
07841	rutina (rutosídeo)	*rutin*
07892	saquinavir	*saquinavir*
07941	senduramicina	*semduramicin*
07973	cloridrato de sevelâmer	*sevelamer hydrochloride*
07975	sevoflurano	*sevoflurane*
07991	citrato de sildenafila	*sildenafil citrate*
08016	sinvastatina	*simvastatin*
08047	somatropina	*somatotropin*
08085	citrato de sufentanila	*sufentanil citrate*
08092	sulbactam sódico	*sulbactam sodium*
08118	sulfadiazina de prata	*sulfadiazine silver salt*
08134	sulfametoxazol	*sulfamethoxazole*
08156	sulfato amoniacal de alumínio	*aluminum ammonium sulfate*
08158	sulfato cúprico	*cupric sulfate*
08160	sulfato de alumínio	*aluminum sulfate*
08161	alume de potássio	*potassium alum*
08161	sulfato de alumínio e potássio	*aluminum potassium sulfate*
08162	sulfato de bário	*barium sulfate*
08164	sulfato de cálcio	*calcium sulfate*
08166	sulfato de lítio	*lithium sulfate*
08167	sulfato de magnésio	*magnesium sulfate*
08169	sulfato de manganês	*manganese sulfate*
08171	sulfato de potássio	*potassium sulfate*
08173	sulfato de sódio	*sodium sulfate*
08174	sulfato de zinco	*zinc sulfate*
08176	sulfato ferroso	*ferrous sulfate*

DCB	PRODUTO	PRODUCT
08177	sulfato ferroso heptaidratado	*ferrous sulfate heptahydrate*
08182	sulfeto de selênio	*selenium sulfide*
08185	sulfiram	*monosulfiram*
08252	tacrolimo	*tacrolimus*
08266	talidomida	*thalidomide*
08370	temozolomida	*temozolomide*
08389	fumarato de tenofovir disoproxila	*tenofovir disoproxyl fumarate*
08493	tiabendazol	*thiabendazole*
08524	cloridrato de glicinato de tianfenicol	*thianphenicol glycinate hydrochloride*
08542	tibolona	*tibolone*
08551	cloridrato de ticlopidina	*ticlopidine hydrochloride*
08605	timomodulina	*thymomodulin*
08650	tiossulfato de sódio	*sodium thiosulfate*
08681	tiratricol	*tiratricol*
08682	tiratricol sódico	*tiratricol sodium*
08762	tartarato de tolterodina	*tolterodine tartrate*
08776	topiramato	*topiramate*
08797	tosilcloramida sódica	*chloramine-T*
08807	cloridrato de tramadol	*tramadol hydrochloride*
08814	sulfato de tranilcipromina	*tranylcypromine sulfate*
08921	trimetoprima	*trimethoprim*
08952	trissilicato de magnésio	*magnesium trisilicate*
09103	vaselina sólida (petrolato)	*petrolatum*
09113	cloridrato de venlafaxina	*venlafaxine hydrochloride*
09176	virginiamicina	*virginiamycin*
09231	zaleplona	*zaleplon*
09256	AZT (zidovudina)	*zidovudine*
09256	zidovudina	*zidovudine*
09296	hemitartarato de zolpidem	*zolpidem bitartrate*
09340	acetato de chumbo	*lead acetate*
09345	acetato de zinco	*zinc acetate*
09361	betainterferona 1a recombinante	*interferon beta 1a recombinant*
09367	carvão ativado	*activated carbon*
09371	celulose microcristalina	*microcrystalline cellulose*
09372	citrato ferroso de cálcio	*calcium ferrous citrate*
09375	cloridrato de sibutramina	*sibutramine hydrochloride*
09436	estriol	*estriol*
09443	fluoreto de potássio	*potassium fluoride*
09458	hidróxido de amônio	*ammonium hydroxide*
09566	atazanavir	*atazanavir*
09594	carbonato de lodenafila	*lodenafil carbonate*
09631	carbonato de sevelâmer	*sevelamer carbonate*
09663	dronedarona	*dronedarone*
09888	óleo de gergelim	*sesame oil*
n.d.	ácido cítrico monoidratado	*citric acid monohydrate*
n.d.	ácido oxálico	*oxalic acid*
n.d.	albumina humana sérica cromada (51 Cr): SAH 51 Cr	*albumin, chromated Cr 51 serum*
n.d.	bissulfato de potássio	*potassium bisulfate*
n.d.	bromidrato de bupropiona	*bupropion hydrobromide*

DCB	PRODUTO	PRODUCT
n.d.	bromotolil benzonitrila	*bromotolil benzonitril*
n.d.	celulose gel	*cellulose gel*
n.d.	citrato de trietila	*triethyl citrate*
n.d.	citrato monossódico	*monosodium citrate*
n.d.	cloreto de lítio	*lithium chloride*
n.d.	cloreto de tálio (201 Tl)	*thallous chloride Tl 201*
n.d.	cloridrato de alfentanila monoidratado	*alfentanil hydrochloride monohydrate*
n.d.	cloridrato de cocaína	*cocaine hydrochloride*
n.d.	cloridrato de dextrobupivacaína	*dextrobupivacaine hydrochloride*
n.d.	cloridrato de dextrocetamina	*dextrocetamine hydrochoride*
n.d.	cloroidróxido de alumínio	*aluminum hydroxychloride*
n.d.	dantroleno sódico hemieptaidratado	*dantrolene sodium hemiheptahydrate*
n.d.	diflubenzurona	*diflubenzuron*
n.d.	disofenol	*disophenol*
n.d.	edetato crômico (51 Cr): EDTA 51 Cr	*chromium Cr 51 edetate*
n.d.	edotreotida (177 Lu): DOTA octreotato 177 Lu	*edotreotide 177 Lu*
n.d.	esteviosídeo	*stevioside*
n.d.	eszopiclona	*eszopiclone*
n.d.	etidronato de sódio	*etidronate disodium*
n.d.	ferrolate	*ferrolat*
n.d.	fluoreto de sódio (18 F)	*sodium fluoride F 18*
n.d.	fosfato de carvedilol	*carvedilol phosphate*
n.d.	fosfato de magnésio tribásico	*magnesium phosphate tribasic*
n.d.	fumarato de fesoterodina	*fesoterodine fumarate*
n.d.	heparinoide	*heparinoid*
n.d.	hidroxiapatita (153 Sm): HA 153 Sm	*samarium Sm 153 hydroxyapatite*
n.d.	hidroximetano sulfonato de sódio	*sodium hydroxymethane sulfonate*
n.d.	ibandronato de sódio	*ibandronate monosodium*
n.d.	iobenguano (123 I): MIBG, metaiodobenzilguanidina 123 I	*iobenguane (123 I)*
n.d.	iodeto de sódio (123 I)	*sodium iodide I 123*
n.d.	lactato de miristila	*myristil lactate*
n.d.	lexidronam (153 Sm): EDTMP, ácido etilenodiaminotetrametileno fosfônico 153 Sm	*samarium Sm 153 lexidronam*
n.d.	manteiga de cupuaçu	*cupuaçu butter*
n.d.	mesilato de rasagilina	*rasagiline mesilate*
n.d.	monoestearato de sorbitana	*sorbitan monostearate*
n.d.	noroximorfona	*noroxymorphone*
n.d.	octacetato de sacarose	*sucrose octaacetate*
n.d.	óleo de maracujá	*passiflora seed oil*
n.d.	oxalato de potássio	*potassium oxalate*
n.d.	pentecnetato de sódio (99m Tc): gerador de tecnécio 99m	*technetium 99m Tc pentechnetate*
n.d.	pentetreotida (111 In): DTPA, octreotídeo 111 In	*indium In 111 pentetreotide*
n.d.	peptona bacteriológica	*bacteriological peptone*
n.d.	pirofosfato férrico	*ferric pyrophosphate*
n.d.	prasugrel	*prasugrel*

DCB	PRODUTO	PRODUCT
n.d.	propinox	*propinox*
n.d.	resinato de codeína	*codeine resinate*
n.d.	resinato de feniltoloxamina	*phenyltoloxamine resinate*
n.d.	resinato de hidrocodona	*hydrocodone resinate*
n.d.	salinomicina sódica miceliana	*salinomycin sodium*
n.d.	soro fetal bovino	*bovine fetal serum*
n.d.	sulbactam pivoxila	*sulbactam pivoxil*
n.d.	sulfato de ferro amoniacal	*ammonium ferric sulfate*
n.d.	sulfato de hidroxocobalamina	*hydroxocobalamin sulfate*
n.d.	sulfato de sódio (35 S)	*sodium sulfate S 35*
n.d.	tartarato de potássio e sódio (sal de Seignette)	*potassium sodium tartrate*
n.d.	tartarato do ácido G-aminobutírico	*G-aminobutyric acid tartrate*
n.d.	tetrafluoroborato de cobre	*copper tetrafluoroborate, tetramibi*
n.d.	tosilato de valinéster	*valinester tosylate*
n.d.	triglicérido dos ácidos cáprico e caprílico	*capric and caprylic acids triglycerides*
n.d.	valesteramida	*valesteramide*
n.d.	valina (L)	*valine (L)*

Produtos por ordem de NCM

Products listed by NCM order

NCM	PRODUTO	PRODUCT
1211	plantas medicinais	*medicinal plants*
1302.1	extratos vegetais	*vegetal extracts*
1302.19.90	tinturas de plantas	*medicinal plants tinctures*
1302.20.10	pectina cítrica	*citric pectin*
1505.00.10	lanolina anidra	*lanolin anhydrous*
1505.00.90	lanolina, derivados	*lanolin derivatives*
1515.50.00	óleo de gergelim	*sesame oil*
1515.90.90	manteiga de cupuaçu	*cupuaçu butter*
1515.90.90	óleo de maracujá	*passiflora seed oil*
1516.20.00	triglicérido dos ácidos cáprico e caprílico	*capric and caprylic acids triglycerides*
2501.00.90	cloreto de sódio	*sodium chloride*
2519.90.90	óxido de magnésio	*magnesium oxide*
2712.10.00	vaselina sólida (petrolato)	*petrolatum*
2801.20.10	iodo ressublimado	*iodine*
2810.00.10	ácido bórico	*boric acid*
2814.20.00	hidróxido de amônio	*ammonium hydroxide*
2816.10.10	hidróxido de magnésio	*magnesium hydroxide*
2817.00.10	óxido de zinco	*zinc oxide*
2818.30.00	hidróxido de alumínio	*aluminum hydroxide*
2825.90.90	hidróxido de cálcio	*calcium hydroxide*
2826.19.90	fluoreto de potássio	*potassium fluoride*
2826.19.90	fluoreto de sódio	*sodium fluoride*
2827.10.00	cloreto de amônio	*ammonium chloride*
2827.20.10	cloreto de cálcio	*calcium chloride*
2827.31.90	cloreto de magnésio	*magnesium chloride*
2827.32.00	cloreto de alumínio	*aluminum chloride*
2827.39.60	cloreto de lítio	*lithium chloride*
2827.39.96	cloreto férrico	*ferric chloride*
2827.49.21	cloroidróxido de alumínio	*aluminum hydroxychloride*
2827.60.11	iodeto de sódio	*sodium iodide*
2827.60.12	iodeto de potássio	*potassium iodide*
2828.90.11	hipoclorito de sódio	*sodium hypochlorite*
2830.90.19	sulfeto de selênio	*selenium sulfide*
2832.10.90	metabissulfito de sódio	*sodium metabisulfite*
2832.30.20	tiossulfato de sódio	*sodium thiosulfate*
2833.11.10	sulfato de sódio	*sodium sulfate*
2833.21.00	sulfato de magnésio	*magnesium sulfate*
2833.22.00	sulfato de alumínio	*aluminum sulfate*
2833.25.20	sulfato cúprico	*cupric sulfate*
2833.27.10	sulfato de bário	*barium sulfate*
2833.29.20	sulfato de lítio	*lithium sulfate*
2833.29.70	sulfato de zinco	*zinc sulfate*
2833.29.90	bissulfato de potássio	*potassium bisulfate*
2833.29.90	sulfato de cálcio	*calcium sulfate*
2833.29.90	sulfato de ferro amoniacal	*ammonium ferric sulfate*
2833.29.90	sulfato de manganês	*manganese sulfate*
2833.29.90	sulfato ferroso	*ferrous sulfate*
2833.29.90	sulfato ferroso heptaidratado	*ferrous sulfate heptahydrate*
2833.30.00	alume de potássio	*potassium alum*

NCM	PRODUTO	PRODUCT
2833.30.00	sulfato amoniacal de alumínio	*aluminum ammonium sulfate*
2833.30.00	sulfato de alumínio e potássio	*aluminum potassium sulfate*
2834.21.90	nitrato de potássio	*potassium nitrate*
2834.29.90	nitrato de bismuto monobásico	*bismuth subnitrate*
2835.22.00	fosfato de sódio dibásico	*sodium phosphate dibasic*
2835.22.00	fosfato de sódio monobásico	*sodium phosphate monobasic*
2835.24.00	fosfato de potássio dibásico	*potassium phosphate dibasic*
2835.24.00	fosfato de potássio monobásico	*potassium phosphate monobasic*
2835.25.00	fosfato de cálcio dibásico	*calcium phosphate dibasic*
2835.26.00	fosfato de cálcio monobásico	*calcium phosphate monobasic*
2835.26.00	fosfato de cálcio tribásico	*calcium phosphate tribasic*
2835.29.10	pirofosfato férrico	*ferric pyrophosphate*
2835.29.90	fosfato de magnésio dibásico	*magnesium phosphate dibasic*
2835.29.90	fosfato de magnésio tribásico	*magnesium phosphate tribasic*
2836.20.10	carbonato de sódio	*sodium carbonate*
2836.30.00	bicarbonato de sódio	*sodium bicarbonate*
2836.40.00	carbonato de potássio	*potassium carbonate*
2836.50.00	carbonato de cálcio	*calcium carbonate*
2836.91.00	carbonato de lítio	*lithium carbonate*
2836.99.11	carbonato de magnésio	*magnesium carbonate*
2836.99.19	carbonato básico de bismuto	*bismuth subcarbonate*
2839.90.10	trissilicato de magnésio	*magnesium trisilicate*
2840.11.00	borato de sódio	*sodium borate*
2841.90.90	tetrafluoroborato de cobre	*copper tetrafluoroborate, tetramibi*
2843.90.90	carboplatina	*carboplatin*
2843.90.90	cisplatina	*cisplatin*
2843.90.90	oxaliplatina	*oxaliplatin*
2844.40.90	albumina humana sérica cromada (51 Cr): SAH 51 Cr	*albumin, chromated Cr 51 serum*
2844.40.90	albumina humana sérica iodada (131 I): SAH I 131	*albumin, iodinated I 131 serum*
2844.40.90	citrato de gálio (67 Ga)	*gallium (67 Ga) citrate*
2844.40.90	cloreto de tálio (201 Tl)	*thallous chloride Tl 201*
2844.40.90	cromato de sódio (51 Cr)	*sodium chromate Cr 51*
2844.40.90	edetato crômico (51 Cr): EDTA 51 Cr	*chromium Cr 51 edetate*
2844.40.90	edotreotida (177 Lu): DOTA octreotato 177 Lu	*edotreotide 177 Lu*
2844.40.90	fludesoxiglicose (18 F): FDG 18 F	*fludeoxyglucose (18 F)*
2844.40.90	fluoreto de sódio (18 F)	*sodium fluoride F 18*
2844.40.90	fosfato de sódio (32 P)	*sodium phosphate P 32*
2844.40.90	hidroxiapatita (153 Sm): HA 153 Sm	*samarium Sm 153 hydroxyapatite*
2844.40.90	iobenguano (123 I): MIBG, metaiodobenzilguanidina 123 I	*iobenguane (123 I)*
2844.40.90	iobenguano (131 I): MIBG, metaiodobenzilguanidina 131 I	*iobenguane (131 I)*
2844.40.90	iodeto de sódio (123 I)	*sodium iodide I 123*
2844.40.90	iodeto de sódio (131 I)	*sodium iodide I 131*
2844.40.90	iodoipurato de sódio (131 I): O-iodo-hipurato de sódio 131 I	*iodohippurate sodium I 131*

NCM	PRODUTO	PRODUCT
2844.40.90	lexidronam (153 Sm): EDTMP, ácido etilenodiaminotetrametileno fosfônico 153 Sm	*samarium Sm 153 lexidronam*
2844.40.90	óleo etiodado (131 I): lipiodol 131 I	*ethiodized oil (131 I)*
2844.40.90	pentecnetato de sódio (99m Tc): gerador de tecnécio 99m	*technetium 99m Tc pentechnetate*
2844.40.90	pentetreotida (111 In): DTPA, octreotídeo 111 In	*indium In 111 pentetreotide*
2844.40.90	sulfato de sódio (35 S)	*sodium sulfate S 35*
2847.00.00	peróxido de hidrogênio (água oxigenada)	*hydrogen peroxide*
2903.39.21	bromofórmio	*bromoform*
2903.39.32	iodofórmio	*iodoform*
2904.10.19	hidroximetano sulfonato de sódio	*sodium hydroxymethane sulfonate*
2905.29.90	álcool oleílico	*oleyl alcohol*
2905.32.00	propilenoglicol	*propylene glycol*
2906.21.00	álcool benzílico	*benzyl alcohol*
2908.99.21	disofenol	*disophenol*
2909.11.00	éter etílico	*sulfuric ether*
2909.19.90	sevoflurano	*sevoflurane*
2915.29.10	acetato de sódio	*sodium acetate*
2915.29.90	acetato de alumínio	*aluminum acetate*
2915.29.90	acetato de amônio	*ammonium acetate*
2915.29.90	acetato de chumbo	*lead acetate*
2915.29.90	acetato de potássio	*potassium acetate*
2915.29.90	acetato de zinco	*zinc acetate*
2915.70.19	palmitato de cetila	*cetyl palmitate*
2915.70.39	estearato de cálcio	*calcium stearate*
2915.70.39	estearato de magnésio	*magnesium stearate*
2915.70.40	monoestearato de dietilenoglicol	*diethylene glycol monostearate*
2915.70.40	monoestearato de etilenoglicol	*ethylene glycol monostearate*
2915.70.40	monoestearato de glicerila	*glyceryl monostearate*
2915.90.33	miristato de isopropila	*isopropyl myristate*
2915.90.90	cloridrato de venlafaxina	*venlafaxine hydrochloride*
2916.19.23	undecilenato de zinco	*zinc undecylenate*
2916.31.10	ácido benzoico	*benzoic acid*
2916.31.21	benzoato de sódio	*sodium benzoate*
2916.31.22	benzoato de amônio	*ammonium benzoate*
2916.39.90	lisinato de ibuprofeno	*ibuprofen lysine*
2916.39.90	propinox	*propinox*
2917.11.10	ácido oxálico	*oxalic acid*
2917.11.10	oxalato de potássio	*potassium oxalate*
2917.19.30	fumarato ferroso	*ferrous fumarate*
2918.11.00	lactato de amônio	*ammonium lactate*
2918.11.00	lactato de cálcio	*calcium lactate*
2918.11.00	lactato de ferro	*ferrous lactate*
2918.11.00	lactato de magnésio	*magnesium lactate*
2918.11.00	lactato de miristila	*myristil lactate*
2918.11.00	lactato de sódio	*sodium lactate*
2918.12.00	ácido tartárico	*L-tartaric acid*

NCM	PRODUTO	PRODUCT
2918.13.10	tartarato ácido de potássio	*potassium bitartrate*
2918.13.10	tartarato de potássio e sódio (sal de Seignette)	*potassium sodium tartrate*
2918.13.10	tartarato de sódio	*sodium tartrate*
2918.14.00	ácido cítrico anidro	*citric acid anhydrous*
2918.14.00	ácido cítrico monoidratado	*citric acid monohydrate*
2918.15.00	citrato de cálcio	*calcium citrate*
2918.15.00	citrato de magnésio	*magnesium citrate*
2918.15.00	citrato de potássio	*potassium citrate*
2918.15.00	citrato de sódio	*sodium citrate*
2918.15.00	citrato de trietila	*triethyl citrate*
2918.15.00	citrato férrico amoniacal	*ammonium ferric citrate*
2918.15.00	citrato ferroso de cálcio	*calcium ferrous citrate*
2918.15.00	citrato monossódico	*monosodium citrate*
2918.19.29	ácido desoxicólico	*deoxycholic acid*
2918.21.10	ácido salicílico	*salicylic acid*
2918.29.90	ácido cólico	*cholic acid*
2918.30.31	ácido desidrocólico	*dehydrocholic acid*
2918.99.99	ciprofibrato	*ciprofibrate*
2919.90.50	lactofosfato de cálcio	*calcium lactophosphate*
2921.19.93	mucato de isometepteno	*isometheptene mucate*
2921.19.99	cloridrato de isometepteno	*isometheptene hydrochloride*
2921.19.99	cloridrato de sibutramina	*sibutramine hydrochloride*
2921.49.31	sulfato de tranilcipromina	*tranylcypromine sulfate*
2921.49.90	cloridrato de maprotilina	*maprotiline hydrochloride*
2921.49.90	mesilato de rasagilina	*rasagiline mesilate*
2922.19.21	citrato de orfenadrina	*orphenadrine citrate*
2922.19.93	cloridrato de clembuterol	*clembuterol hydrochloride*
2922.19.99	antimoniato de meglumina	*meglumine antimonate*
2922.19.99	dapoxetina	*dapoxetine*
2922.19.99	resinato de feniltoloxamina	*phenyltoloxamine resinate*
2922.29.90	tartarato de tolterodina	*tolterodine tartrate*
2922.31.12	cloridrato de anfepramona	*diethylpropion hydrochloride*
2922.31.20	metadona	*methadone*
2922.39.21	cloridrato de dextrocetamina	*dextrocetamine hydrochoride*
2922.39.90	bromidrato de bupropiona	*bupropion hydrobromide*
2922.39.90	cloridrato de bupropiona	*bupropion hydrochloride*
2922.41.90	clonixinato de lisina	*clonixin lysine salt*
2922.49.20	edetato de potássio	*edetate dipotassium*
2922.49.61	diclofenaco sódico	*diclofenac sodium*
2922.49.62	diclofenaco potássico	*diclofenac potassium*
2922.49.63	diclofenaco dietilamônio	*diclofenac diethylammonium*
2922.49.64	diclofenaco	*diclofenac acid*
2922.49.69	diclofenaco colestiramina	*diclofenac cholestyramin*
2922.49.69	resinato de diclofenaco	*diclofenac resinate*
2922.49.90	isoleucina (L)	*isoleucine (L)*
2922.49.90	tartarato do ácido G-aminobutírico	*G-aminobutyric acid tartrate*
2922.49.90	tosilato de valinéster	*valinester tosylate*
2922.49.90	valina (L)	*valine (L)*
2922.50.11	cloridrato de fenilefrina	*phenylephrine hydrochloride*

NCM	PRODUTO	PRODUCT
2922.50.50	cloridrato de propranolol	*propranolol hydrochloride*
2922.50.99	carbonato de sevelâmer	*sevelamer carbonate*
2922.50.99	cloridrato de sevelâmer	*sevelamer hydrochloride*
2922.50.99	cloridrato de tramadol	*tramadol hydrochloride*
2922.50.99	dicloridrato de mitoxantrona	*mitoxantrone dihydrochloride*
2922.50.99	valesteramida	*valesteramide*
2923.20.00	fosfatidilserina	*phosphatidylserine*
2923.90.90	miltefosina	*miltefosine*
2924.19.99	glutamina (L)	*glutamine (L)*
2924.29.14	cloridrato de lidocaína	*lidocaine hydrochloride*
2924.29.14	lidocaína	*lidocaine*
2924.29.51	bromoprida	*bromopride*
2924.29.62	flutamida	*flutamide*
2924.29.63	cloridrato de prilocaína	*prilocaine hydrochloride*
2924.29.63	prilocaína	*prilocaine*
2924.29.92	diflubenzurona	*diflubenzuron*
2924.29.96	benzoato de denatônio	*denatonium benzoate*
2925.19.10	talidomida	*thalidomide*
2925.29.19	arginina	*L-arginine*
2925.29.30	amitraz	*amitraz*
2925.29.90	pentamidina	*pentamidine*
2926.30.12	cloridrato de femproporex	*fenproporex hydrochloride*
2926.90.93	closantel	*closantel*
2926.90.99	bromotolil benzonitrila	*bromotolil benzonitril*
2930.30.12	sulfiram	*monosulfiram*
2930.90.36	carbocisteína	*carbocysteine*
2930.90.99	modafinila	*modafinil*
2931.90.33	etidronato de sódio	*etidronate disodium*
2931.90.39	ácido alendrônico	*alendronic acid*
2931.90.39	ácido pamidrônico	*pamidronic acid*
2931.90.39	alendronato de sódio	*alendronate monosodium*
2931.90.39	ibandronato de sódio	*ibandronate monosodium*
2932.20.00	sinvastatina	*simvastatin*
2932.99.12	quercetina	*quercetin*
2932.99.91	cloridrato de amiodarona	*amiodarone hydrochloride*
2932.99.99	docetaxel	*docetaxel anhydrous*
2932.99.99	ivermectina	*ivermectin*
2933.21.21	fenitoína (difenilidantoína)	*phenytoin*
2933.21.21	fenitoína sódica	*phenytoin sodium*
2933.21.90	etomidato	*etomidate*
2933.21.90	nilutamida	*nilutamide*
2933.29.12	benzoilmetronidazol	*benzoyl metronidazole*
2933.29.12	metronidazol	*metronidazole*
2933.29.22	nitrato de miconazol	*miconazole nitrate*
2933.29.24	nitrato de isoconazol	*isoconazole nitrate*
2933.29.99	ácido zoledrônico	*zoledronic acid*
2933.29.99	losartana potássica	*losartan potassium*
2933.33.19	cloridrato de alfentanila monoidratado	*alfentanil hydrochloride monohydrate*
2933.33.22	bromazepam	*bromazepam*
2933.33.63	fentanila	*fentanyl*

NCM	PRODUTO	PRODUCT
2933.33.69	citrato de fentanila	*fentanyl citrate*
2933.33.84	cloridrato de petidina	*pethidine hydrochloride*
2933.39.12	droperidol	*droperidol*
2933.39.15	haloperidol	*haloperidol*
2933.39.19	acetato de flecainida	*flecainide acetate*
2933.39.19	decanoato de haloperidol	*haloperidol decanoate*
2933.39.23	malato de cleboprida	*clebopride hydrogen malate*
2933.39.32	lactato de biperideno	*biperiden lactate*
2933.39.39	risedronato de sódio	*risedronate monosodium*
2933.39.44	nitrendipino	*nitrendipine*
2933.39.48	nimodipino	*nimodipine*
2933.39.81	cloridrato de benzetimida	*benzetimide hydrochloride*
2933.39.82	cloridrato de mepivacaína	*mepivacaine hydrochloride*
2933.39.83	cloridrato de bupivacaína	*bupivacaine hydrochloride*
2933.39.89	bupivacaína	*bupivacaine*
2933.39.89	cloridrato de dextrobupivacaína	*dextrobupivacaine hydrochloride*
2933.39.89	cloridrato de levobupivacaína	*levobupivacaine hydrochloride*
2933.39.89	cloridrato de ropivacaina	*ropivacaine hydrochloride*
2933.39.89	lansoprazol	*lansoprazole*
2933.39.89	levobupivacaína	*levobupivacaine*
2933.39.89	ropivacaína	*ropivacaine*
2933.39.99	atazanavir	*atazanavir*
2933.39.99	cloreto de lapírio	*lapirium chloride*
2933.39.99	cloridrato de piperidolato	*piperidolate hydrochloride*
2933.39.99	efavirenz	*efavirenz*
2933.39.99	nisoldipino	*nisoldipine*
2933.39.99	prasugrel	*prasugrel*
2933.39.99	propiverina	*propiverine*
2933.39.99	remifentanila	*remifentanil*
2933.39.99	sulfato de indinavir	*indinavir sulfate*
2933.53.40	fenobarbital	*phenobarbital*
2933.53.40	fenobarbital sódico	*phenobarbital sodium*
2933.59.15	enrofloxacino	*enrofloxacin*
2933.59.19	citrato de dietilcarbamazina	*diethylcarbamazine citrate*
2933.59.19	cloridrato de moxifloxacino	*moxifloxacin hydrochloride*
2933.59.19	eszopiclona	*eszopiclone*
2933.59.19	mirtazapina	*mirtazapine*
2933.59.19	ranolazina	*ranolazine*
2933.59.19	zaleplona	*zaleplon*
2933.59.31	propiltiouracila	*propylthiouracil*
2933.59.34	azatioprina	*azathioprine*
2933.59.35	6-mercaptopurina	*6-mercaptopurine*
2933.59.41	trimetoprima	*trimethoprim*
2933.59.42	aciclovir	*aciclovir*
2933.59.44	nicarbazina	*nicarbazin*
2933.59.49	fumarato de tenofovir disoproxila	*tenofovir disoproxyl fumarate*
2933.59.49	ganciclovir	*ganciclovir*
2933.59.99	dextrorrazoxano	*dexrazoxane*
2933.59.99	pemetrexede	*pemetrexed*
2933.79.90	aripiprazol	*aripiprazole*

NCM	PRODUTO	PRODUCT
2933.79.90	cilostazol	*cilostazol*
2933.91.11	alprazolam	*alprazolam*
2933.91.13	clonazepam	*clonazepam*
2933.91.22	diazepam	*diazepam*
2933.91.33	flurazepam	*flurazepam*
2933.91.42	lorazepam	*lorazepam*
2933.91.51	mazindol	*mazindol*
2933.91.53	cloridrato de midazolam	*midazolam hydrochloride*
2933.91.53	maleato de midazolam	*midazolam maleate*
2933.91.53	midazolam	*midazolam*
2933.99.20	flumazenil	*flumazenil*
2933.99.32	carbamazepina	*carbamazepine*
2933.99.39	clozapina	*clozapine*
2933.99.39	embonato de imipramina	*imipramine pamoate*
2933.99.39	fumarato de quetiapina	*quetiapine fumarate*
2933.99.39	hemifumarato de quetiapina	*quetiapine hemifumarate*
2933.99.39	olanzapina	*olanzapine*
2933.99.39	oxcarbazepina	*oxcarbazepine*
2933.99.46	maleato de enalapril	*enalapril maleate*
2933.99.49	cetorolaco	*ketorolac*
2933.99.49	diclofenaco epolamina	*diclofenac epolamine*
2933.99.52	oxfendazol	*oxfendazole*
2933.99.53	albendazol	*albendazole*
2933.99.53	óxido de albendazol	*albendazole oxide*
2933.99.54	mebendazol	*mebendazole*
2933.99.99	bendamustina	*bendamustine*
2933.99.99	fosfato de carvedilol	*carvedilol phosphate*
2933.99.99	hemitartarato de zolpidem	*zolpidem bitartrate*
2933.99.99	temozolomida	*temozolomide*
2934.10.30	tiabendazol	*thiabendazole*
2934.10.90	maleato de rosiglitazona	*rosiglitazone maleate*
2934.20.90	riluzol	*riluzole*
2934.30.20	enantato de flufenazina	*fluphenazine enanthate*
2934.30.90	decanoato de flufenazina	*fluphenazine decanoate*
2934.91.22	cloxazolam	*cloxazolam*
2934.91.70	citrato de sufentanila	*sufentanil citrate*
2934.99.19	levofloxacino	*levofloxacin*
2934.99.22	AZT (zidovudina)	*zidovudine*
2934.99.22	zidovudina	*zidovudine*
2934.99.27	estavudina	*stavudine*
2934.99.31	cetoconazol	*ketoconazole*
2934.99.39	DDI (didanosina)	*DDI (dideoxyinosine)*
2934.99.39	didanosina	*didanosine*
2934.99.39	doxazosina	*doxazosin*
2934.99.93	lamivudina (3TC)	*lamivudine*
2934.99.99	carbonato de lodenafila	*lodenafil carbonate*
2934.99.99	cloridrato de articaína	*articaine hydrochloride*
2934.99.99	cloridrato de paroxetina	*paroxetine hydrochloride*
2934.99.99	cloridrato de pramoxina	*pramoxine hydrochloride*
2934.99.99	cloridrato de ticlopidina	*ticlopidine hydrochloride*

NCM	PRODUTO	PRODUCT
2934.99.99	dantroleno sódico hemieptaidratado	*dantrolene sodium hemiheptahydrate*
2934.99.99	fumarato de cetotifeno	*ketotifen fumarate*
2934.99.99	fumarato de fesoterodina	*fesoterodine fumarate*
2934.99.99	leflunomida	*leflunomide*
2934.99.99	nevirapina	*nevirapine*
2934.99.99	pimetixeno	*pimethixene*
2934.99.99	raloxifeno	*raloxifene*
2934.99.99	ribavirina	*ribavirine*
2934.99.99	ritonavir	*ritonavir*
2934.99.99	saquinavir	*saquinavir*
2934.99.99	tacrolimo	*tacrolimus*
2935.00.19	citrato de sildenafila	*sildenafil citrate*
2935.00.19	sulfadiazina de prata	*sulfadiazine silver salt*
2935.00.23	piroxicam	*piroxicam*
2935.00.25	sulfametoxazol	*sulfamethoxazole*
2935.00.91	tosilcloramida sódica	*chloramine-T*
2935.00.99	dronedarona	*dronedarone*
2935.00.99	topiramato	*topiramate*
2936.26.30	acetato de hidroxocobalamina	*hydroxocobalamin acetate*
2936.26.30	cloridrato de hidroxocobalamina	*hydroxocobalamin hydrochloride*
2936.26.30	sulfato de hidroxocobalamina	*hydroxocobalamin sulfate*
2937.11.00	somatropina	*somatotropin*
2937.19.20	gonadotrofina coriônica humana	*HCG (human chorionic gonadotropin)*
2937.23.31	estriol	*estriol*
2937.23.49	estradiol	*estradiol*
2937.23.49	etinilestradiol	*ethinyl estradiol*
2937.23.60	desogestrel	*desogestrel*
2937.23.92	gestodeno	*gestodene*
2937.23.99	norgestimato	*norgestimate*
2937.29.50	espironolactona	*spironolactone*
2937.29.90	norelgestromina	*norelgestromine*
2937.29.90	tibolona	*tibolone*
2937.90.10	tiratricol	*tiratricol*
2937.90.10	tiratricol sódico	*tiratricol sodium*
2937.90.30	levotiroxina sódica	*levothyroxine sodium*
2937.90.40	liotironina sódica	*liothyronine sodium*
2937.90.90	cloridrato de liotironina	*liothyronine hydrochloride*
2937.90.90	levotiroxina	*levothyroxine*
2937.90.90	liotironina	*liothyronine*
2938.10.00	rutina (rutosídeo)	*rutin*
2938.90.20	esteviosídeo	*stevioside*
2939.11.22	cloridrato de codeína	*codeine hydrochloride*
2939.11.22	codeína	*codeine*
2939.11.22	fosfato de codeína	*codeine phosphate*
2939.11.22	sulfato de codeína	*codeine sulfate*
2939.11.23	hemitartarato de di-hidrocodeína	*dihydrocodeine bitartrate*
2939.11.31	cloridrato de etilmorfina di-hidratado	*ethylmorphine hydrochloride dihydrate*
2939.11.40	folcodina	*pholcodine*
2939.11.52	cloridrato de hidrocodona	*hydrocodone hydrochloride*
2939.11.52	hemitartarato de hidrocodona	*hydrocodone bitartrate*

NCM	PRODUTO	PRODUCT
2939.11.62	cloridrato de morfina	*morphine hydrochloride*
2939.11.62	sulfato de morfina	*morphine sulfate*
2939.11.81	cloridrato de oxicodona	*oxycodone hydrochloride*
2939.11.82	noroximorfona	*noroxymorphone*
2939.19.00	resinato de codeína	*codeine resinate*
2939.19.00	resinato de hidrocodona	*hydrocodone resinate*
2939.41.00	cloridrato de efedrina	*ephedrine hydrochloride*
2939.41.00	sulfato de efedrina	*ephedrine sulfate*
2939.42.00	cloridrato de pseudoefedrina	*pseudoephedrine hydrochloride*
2939.42.00	pseudoefedrina	*pseudoephedrine*
2939.42.00	sulfato de pseudoefedrina	*pseudoephedrine sulfate*
2939.49.00	cloridrato de etafedrina	*etafedrine hydrochloride*
2939.59.90	ambufilina	*ambuphylline*
2939.59.90	lomifilina	*lomifylline*
2939.69.21	mesilato de di-hidroergotamina	*dihydroergotamine mesilate*
2939.69.52	mesilato de di-hidroergocristina	*dihydroergocristine mesilate*
2939.91.11	cloridrato de cocaína	*cocaine hydrochloride*
2939.99.31	cloridrato de pilocarpina	*pilocarpine hydrochloride*
2939.99.31	nitrato de pilocarpina	*pilocarpine nitrate*
2939.99.31	pilocarpina	*pilocarpine*
2939.99.90	metilbrometo de homatropina	*homatropine methylbromide*
2940.00.13	ramnose	*rhamnose*
2940.00.99	octacetato de sacarose	*sucrose octaacetate*
2941.40.90	cloridrato de glicinato de tianfenicol	*thianphenicol glycinate hydrochloride*
2941.90.31	ceftriaxona sódica	*ceftriaxone sodium*
2941.90.33	cefalotina sódica	*cefalotin sodium*
2941.90.35	cefotaxima sódica	*cefotaxime sodium*
2941.90.36	cefoxitina sódica	*cefoxitin sodium*
2941.90.39	cefalexina sódica	*cephalexin sodium monohydrate*
2941.90.39	cefepima	*cefepime*
2941.90.39	ceftazidima	*ceftazidime*
2941.90.39	cloridrato de cefepima	*cefepime hydrochloride*
2941.90.39	nafato de cefamandol	*cefamandole nafate*
2941.90.79	senduramicina	*semduramicin*
2941.90.83	virginiamicina	*virginiamycin*
2941.90.99	fosfomicina trometamol	*fosfomycin tromethamine*
2941.90.99	sulbactam pivoxila	*sulbactam pivoxil*
2941.90.99	sulbactam sódico	*sulbactam sodium*
3001.20.90	eritropoietina humana recombinante	*human erythropoietin recombinant, hemopoietine*
3001.20.90	filgrastim	*filgrastin*
3001.20.90	lenograstim	*lenograstim*
3001.20.90	sais biliares totais	*total bile salts*
3001.20.90	timomodulina	*thymomodulin*
3001.90.10	heparina	*heparin*
3001.90.10	heparina BPM	*heparin LMW*
3001.90.10	heparina sódica	*heparin sodium*
3001.90.90	heparinoide	*heparinoid*
3002.10.29	alfainterferona 2a	*interferon alpha-2a recombinant*
3002.10.29	alfainterferona 2b	*interferon alpha-2b recombinant*

NCM	PRODUTO	PRODUCT
3002.10.29	betainterferona 1a recombinante	*interferon beta 1a recombinant*
3002.90.99	soro fetal bovino	*bovine fetal serum*
3102.10.10	ureia	*urea, carbamide*
3102.30.00	nitrato de amônio	*ammonium nitrate*
3104.20.90	cloreto de potássio	*potassium chloride*
3104.30.90	sulfato de potássio	*potassium sulfate*
3402.13.00	polissorbato 20	*polysorbate 20*
3402.13.00	polissorbato 60	*polysorbate 60*
3402.13.00	polissorbato 80	*polysorbate 80*
3501.90.19	ferrolate	*ferrolat*
3504.00.11	peptona bacteriológica	*bacteriological peptone*
3505.10.00	glicolato de amido sódico	*sodium starch glycolate*
3507.90.19	pancreatina	*pancreatin*
3507.90.26	papaína	*papain*
3507.90.29	pepsina	*pepsin*
3802.10.00	carvão ativado	*activated carbon*
3822.00.90	reagentes analíticos	*analytical reagents*
3824.90.11	salinomicina sódica miceliana	*salinomycin sodium*
3824.90.86	cloreto de benzalcônio	*benzalkonium chloride*
3824.90.89	estearato de sorbitana	*sorbitan monostearate*
3824.90.89	monoestearato de sorbitana	*sorbitan monostearate*
3912.31.19	croscarmelose sódica	*croscarmellose sodium*
3912.90.31	celulose microcristalina	*microcrystalline cellulose*
3912.90.40	celulose gel	*cellulose gel*
3913.90.60	sulfato de condroitina	*chondroitin sulfate*
3913.90.60	sulfato de condroitina BPM	*chondroitin sulfate LWM*
9602.00.10	cápsulas de gelatina dura	*hard gelatin capsules*
9602.00.10	cápsulas de gelatina elástica	*soft gelatin capsules*

Technical Regulation of Good Manufacturing Pratices of Intermediate Products and Active Pharmaceutical Ingredients

ANVISA Resolution – RDC n. 249, of September 13th, 2005

ANVISA RESOLUTION – RDC N. 249, OF SEPTEMBER 13TH, 2005

The Collegiate Board of Directors of the Brazilian Sanitary Surveillance Agency, in the use of the attribution vested in it by article 11, clause IV, of the Regulation of ANVISA approved by Decree n. 3.029, of April 16, 1999, combined with Article 111, clause I, item "b", of the Bylaws approved by Administrative Order n. 593, of August 25, 2000, republished in the Federal Official Journal of December 22, 2000, in meeting held on September 5, 2005, whereas the Law n. 6.360, of September 23, 1976; the Decree n. 79.094, of January 5, 1977; the Law n. 9.782, of January 26, 1999; the need to bring up-to-date the Good Manufacturing Practices for Intermediate Products and Pharmaceutical Ingredient; the necessity to standardize the sanitary surveillance actions, adopts the following Resolution of the Collegiate Board of Directors and I, the Chairman, determine its publication:

Article 1 – *To determine to all manufacturers of intermediate products and active pharmaceutical ingredients, the fulfillment of the directives established in the Technical Regulation of Good Manufacturing Practices of Intermediate Products and Active Pharmaceutical Ingredients, according annex I of the present Resolution.*

Article 2 – *For effect of this regulation, the definitions included in the glossary of the Annex I is being valid.*

Article 3 – *The Portaria n° 15, of April 4, 1995 is hereby revoked.*

Article 4 – *The non-observance or disobedience to what is described in the present Resolution configures a sanitary nature infraction, in the form of the Law n° 6437, of August 20, 1977, and the infractor is subjecting to the penalties foreseen in this statute.*

Article 5 – *This Resolution enters into force on the date of its publication.*

DIRCEU RAPOSO DE MELLO

ANNEX I – TECHNICAL REGULATION OF GOOD MANUFACTURING PRACTICES OF INTERMEDIATE PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENTS.

1. SCOPE

1.1. *The manufacturer of intermediate product and active pharmaceutical ingredient must detain the establishment authorization and the sanitary license. Its activities should be regularly inspected by the Competent Sanitary Authorities.*

1.2. *This regulation provides guidance and procedures that the manufacturer must apply to assure that the facilities, methods, processes, systems and controls been used to the intermediate products and active pharmaceutical ingredient produced, are adjusted to it, in order to ensure quality, allowing its use in the preparation of pharmaceuticals. It contains recommendations that must suit several manufacturing processes of intermediate products and active pharmaceutical ingredient, which mean that chemical, physical and/or biological processes like, chemical synthesis, extraction, fermentation, would be updated with the purpose to follow the technological advances.*

1.3. *The manufacturer of intermediate products and active pharmaceutical ingredient must guarantee that their products are the proper ones for the intended use and that they follow the requirements of identity, purity and safety based on established quality policies.*

1.4. *The Quality Assurance and Quality Control policies and the concepts of Good Manufacturing Practices are linked. They are described with the purpose to emphasize its fundamental importance for the production and control of the intermediate products and active pharmaceutical ingredient*

1.5. *The manufacturer is the responsible for the quality of the intermediate product and the active pharmaceutical ingredient produced.*

1.6. *It must have a complete evidence of the fulfillment of the Good Manufacturing Practices, starting at the stage where used process, raw material or intermediate product could have a critical impact in the quality of the final pharmaceutical ingredient.*

1.7. *This regulation is applicable for the manufacturing processes from the steps highlighted in the table below, however it does not exclude the necessity of specific controls for other steps described.*

(TABLE 1)

2. QUALITY MANAGEMENT

Quality Management is the aspect of the management function that defines and implements the "Quality Policy", or either, the global intentions and relative directions to the quality, expressed and formally authorized for the superior administration of the company.

2.1. Principles

2.1.1. *Quality should be the responsibility of all personnel of the company.*

2.1.2. *Each manufacturer should establish, document, implement and maintain an effective system for managing quality that involves the active participation of management and appropriate manufacturing personnel.*

2.1.3. *The system for the management of the quality should encompass the organizational structure, procedures, processes and resources, as well as activities necessary to ensure the compliance of the intermediate product and the pharmaceutical ingredient to its intended specifications for quality and purity. All quality related activities should be defined and documented.*

2.1.4. *The quality unit is responsible for assuring that*

TABLE 1:

Chemical Synthesis	*Production of the Intermediate or Pharmaceutical Ingredient Starting Material*	*Introduction of the API Starting Material into process*	*Production of Intermediate(s)*	*Isolation and purification*	*Physical processing, and packaging*
Intermediate or Pharmaceutical Ingredient derivate from animal sources	*Collection of organ, fluid or tissue*	*Cutting, mixing, and/or initial processing*	*Introduction of the Starting Material into process*	*Isolation and purification*	*Physical processing and packaging*
Intermediate or Pharmaceutical Ingredient extracted from plant sources	*Collection of plants and cutting*	*Initial Extraction(s)*	*Introduction of the Starting Material into process*	*Isolation and purification*	*Physical processing and packaging*
Herbal Extracts used as Intermediate or Active Pharmaceutical Ingredient	*Collection of plants and cutting*	*Initial Extraction*	*Introduction of the Starting Material into process*	*Further Extractions*	*Physical processing and packaging*
Intermediate or Active Pharmaceutical Ingredient consisting of comminuted or powdered herbs	*Collection of plants and/or cultivation, harvesting and cutting*	*Comminuting*			*Physical processing and packaging*
Biotechnological: fermentation / cell culture	*Establishment of the master cell bank and working cell bank*	*Maintenance of working cell bank*	*Cell culture and/or fermentation*	*Isolation and purification*	*Physical processing and packaging*
"Classical" fermentation process to produce Intermediate or Active Pharmaceutical Ingredient	*Establishment of the cell bank*	*Maintenance of the cell bank*	*Introduction of the cells into fermentation process*	*Isolation and purification*	*Physical processing and packaging*
Increasing GMP requirements					

intermediate products and active pharmaceutical ingredients comply demanded quality standards and that they can be used to the considered purpose.

2.1.5. *The Quality Unit should be independent of production and should understand the responsibilities of both Quality Assurance (QA) and Quality Control (QC) that makes the production fulfills its responsibilities. A single individual, a group or department, depending upon the size and structure of the organization, can represent the Quality Unit.*

2.1.6. *The personnel authorized to release intermediates and APIs should be specified.*

2.1.7. *All quality related activities should be recorded at the time they are performed.*

2.1.8. *Any deviation from established procedures should be documented and explained. Critical deviations should be investigated, and the investigation and its conclusions should be documented.*

2.1.9. *No materials should be released or used before the satisfactory completion of the evaluation by the Quality Unit unless there are appropriate systems in place to allow for such use, excepting intermediate products for sale and APIs.*

2.1.10. *Procedures should exist to notify the Quality Unit every time that quality deviation occurs, including the related actions.*

2.2. Responsibilities

2.2.1. Introduction

2.2.1.1. *The main positions in the Production and Quality Unit must be filled by people that work full time in the company. It can have necessity to delegate some functions, however, the responsibility can-*

not be delegated.

2.2.1.2. *The responsible for the Production, Quality Control and Quality Unit of the intermediate products and active pharmaceutical ingredients, must be qualified according to the current law of the respective professional council and qualified trough appropriate degree, experience and/or training.*

2.2.1.3. *The responsible for the Production and Quality Unit should practice together quality activities as follows:*

(a) *preparation and review of the procedures and documents, including their update*

(b) *monitoring and control of the production environment*

(c) *hygiene;*

(d) *process validation;*

(e) *training, including the application of GMP principles;*

(f) *supplier qualification;*

(g) *approval and monitoring of contracted suppliers;*

(h) *storage condition specifications for products and materials;*

(i) *archive and filling documents and records;*

(j) *monitoring to the GMP compliance;*

(k) *inspection and research of the factors that can affect quality of the intermediate product and pharmaceutical ingredient.*

2.2.2 Responsibilities of the Quality Unit

2.2.2.1. *The Quality Unit should manage all quality-related activities.*

2.2.2.2. *The main responsibilities of the Quality Unit should not be delegated. These responsibilities should be defined and documented in writing and should include the following activities, at least:*

(a) *releasing or rejecting all intermediate products and active pharmaceutical ingredient;*

(b) *establishing and monitoring a system to release or reject raw materials, intermediate products, packaging and labelling material been used in the production;*

(c) *reviewing completed batch production and Quality Control records of the produced batch before release it for distribution;*

(d) *to certify that quality deviations are investigated and corrective actions are implemented;*

(e) *to manage the activities for the guard, storage and documentation of the retention samples;*

(f) *to approve all procedures, specifications and instructions that can cause impact in the quality of the intermediate product and pharmaceutical ingredient;*

(g) *to approve self-inspection program and make sure that they are performed;*

(h) *to approve technical specifications contract manufacturer related with production and Quality Control of the intermediate products and active pharmaceutical ingredient;*

(i) *to approve changes that affect or potentially could affect the quality of the intermediate product and pharmaceutical ingredient;*

(j) *to approve validation master plan, protocols and reports and ensure the performance of the necessary validations;*

(k) *make sure that quality related complaints and recalls are recorded, investigated and, if necessary, corrective actions are implemented;*

(l) *make sure that effective systems are used for maintaining and calibrating equipments;*

(m) *make sure that stability studies are conducted to ensure that data supports expiry dates, storage conditions and transportation defined for intermediate products or active pharmaceutical ingredient;*

(n) *to execute quality of products reviews;*

(o) *to evaluate environmental monitoring program of the production areas;*

(p) *to approve the training program and make sure that initial training and continuous training are conducted;*

(q) *to evaluate the necessity of product recall for intermediate product and pharmaceutical ingredient;*

(r) *to approve the preventive maintenance and calibration program and make sure that they are correctly performed.*

2.2.3. Responsibilities of the Quality Control

2.2.3.1. *The main responsibilities of the Quality Control cannot be delegated. These responsibilities should be defined and documented in writing describing clearly, at least, the following activities:*

(a) *to elaborate, update and review:*

I – *specifications and analytical methods for raw materials, intermediate products, active pharmaceutical ingredients, in process control and packaging material;*

II – *sampling procedures;*

III – *environmental monitoring procedures of the production areas;*

IV – *evaluating and storing procedures for the reference standards.*

(b) *to approve or reject raw materials, intermediate products, active pharmaceutical ingredients and packaging material;*

(c) *provide certificate of analysis for each analyzed batch of material;*

(d) *conduct stability study of the intermediate products and active pharmaceutical ingredient;*

(e) *participate in the investigation of the complaints and recalls of intermediate products and active pharmaceutical ingredients;*

(f) *to ensure the correct identification of the reagents, materials, laboratory instruments and equipments;*

(g) *to validate the analytical methodologies;*

(h) *to investigate out of specification results, according with procedures;*

(i) *to execute all the necessary assays;*

(j) *to verify the maintenance of the installations and equipments;*

(k) *to ensure the execution of the laboratory equip-*

ments calibration;
(l) *to promote initial and continuous training of the Quality Control staff;*
(m) *to execute the environmental monitoring analysis.*

2.2.4. Responsibilities of the Production

2.2.4.1. *The responsibilities of the Production should be defined and documented in writing describing, at least, the following activities:*
(a) *to participate in the preparation and revision of the production standard/master formula of the intermediate products or active pharmaceutical ingredient in accordance with written procedures;*
(b) *to distribute the production batch orders of the intermediate products or active pharmaceutical ingredients in accordance with written procedures;*
(c) *to produce active pharmaceutical ingredients and, when appropriate, intermediate products in accordance with pre-approved instructions;*
(d) *to review all batch records to ensure that they are completed and signed;*
(e) *to ensure that all production deviations are recorded, evaluated and that the critical deviations are investigated, as well the conclusions are recorded;*
(f) *to ensure that the installations and equipments are clean, and when necessary, they are sanitized, and fully identified;*
(g) *to ensure that the necessary calibrations are executed and the records are kept;*
(h) *to ensure that the protocols and validation reports are revised and approved;*
(i) *to suggest changes for process or equipment;*
(j) *to evaluate proposed changes for the product, process or equipments;*
(k) *to ensure that installations and equipment (when new or modified) are qualified, when necessary;*
(l) *to ensure that maintenance of the installations and equipment has been carried out and the records are kept.*

2.3. Product Quality Review

2.3.1. *Regular quality reviews of intermediate products or active pharmaceutical ingredients should be conducted with the objective of verifying the consistency of the process. Such reviews should normally be conducted and documented annually and should include at least:*
(a) *A review of critical in-process control and critical intermediate products or active pharmaceutical ingredients test results;*
(b) *A review of all batches that failed to meet the established specification(s);*
(c) *A review of all critical deviations or no conformities and related investigations;*
(d) *A review of any changes carried out in the processes or analytical methods validated;*
(e) *A review of the stability monitoring program results;*
(f) *A review of all quality-related returns, complaints and recalls; and*
(g) *A review of the adequacy of corrective actions.*
2.3.2. *The results of this review should be evaluated and, if necessary, corrective action should be undertaken, recorded, followed and completed.*

2.4. Quality Internal Audits (Self Inspections)

2.4.1. *Its purpose is to verify the manufacturer of intermediate products and active pharmaceutical ingredients compliance with the GMP principles, from the acquisition of materials to the dispatch of the intermediate product or pharmaceutical ingredient. The self-inspections must be carried out, at the very least, annually.*
2.4.2. *It should be prepared a self-inspection written procedure. The internal audit should comprise:*
(a) *personnel;*
(b) *utilities;*
(c) *maintenance of buildings and equipment;*
(d) *storage of raw material, packaging material and final product;*
(e) *equipments;*
(f) *production and in process controls;*
(g) *quality control;*
(h) *documentation;*
(i) *sanitation and hygiene;*
(j) *validation and revalidation programmes;*
(k) *calibration of instruments or measurement systems;*
(l) *intermediate product or pharmaceutical ingredient market recall;*
(m) *complaints;*
(n) *label controls;*
(o) *waste management;*
(p) *results of previous self-inspections and any corrective steps taken.*
2.4.3. *The self-inspection team should be consisted by qualified professionals, experts in their respective fields and are familiar with GMP requirements. The members of the team may be appointed from inside or outside the company.*
2.4.4. *The self inspection should be recorded and have at least:*
(a) *self-inspection results;*
(b) *evaluations and conclusions;*
(c) *detected no compliances;*
(d) *recommended corrective actions and established period of time to completion.*
2.4.5. *Corrective actions for no compliances described in the self-inspection report should be implemented and completed in a timely manner.*

3. PERSONNEL

3.1. General Remarks

3.1.1. *The establishment and maintenance of the quality and production of intermediate product and active pharmaceutical ingredient, rely upon employees who carry out them. There must have sufficient qualified personnel, by their education, training and/or experience to execute, supervise and manage the pro-*

duction activities of intermediate products and active pharmaceutical ingredients for which the manufacturer is responsible. Individual responsibilities and authorities should be clearly defined and understood by the persons concerned and be recorded as written descriptions.

3.1.2. *The company must have an organizational chart. The employees should not accumulate responsibilities in order to prevent that the quality of intermediate products and active pharmaceutical ingredient would be placed in risk. Their attributions can be delegated to the substitutes assigned, considering that they possess satisfactory level of qualification. It cannot have absence or responsibility accumulation of the staff when it relates to the application of the GMP.*

3.1.3. *The company staff must be aware about the GMP principles and receive initial and continuous training. Training should be regularly conducted by qualified individuals and should cover, at the very least, the particular operations that the employee performs and GMP as it relates to the employee's functions. Records of training should be maintained. Training should be periodically assessed. The employees should be motivated to support the company in the maintenance of the quality standards.*

3.2. Training

3.2.1. *The manufacturer should provide training in accordance with a written program, for all personnel whose duties can affect the quality of the intermediate product and active pharmaceutical ingredient.*

3.2.2. *Besides basic training on the theory and practise of GMP, newly recruited personnel must participate in the integration program and remain in appropriate training to their tasks, also to be trained and evaluated continuously.*

3.2.3. *The training programs must include all personnel. These programs should be approved by the responsible for production, unit of quality and Quality Control, and their records should be kept.*

3.2.4. *To the personnel working in areas where contamination is a hazard, i.e. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.*

3.3. Consultants

3.3.1. *The consultants that work in the production and in the control of intermediate products and active pharmaceutical ingredients must possess academic degree, training and experience or the combination of these, compatible with the activities for which they had been contracted.*

3.3.2. *Records with name, address, qualification and type of service given for the consultants must be kept.*

3.4. Health, Hygiene, Clothing and Attitude

3.4.1. *All employees must be submitted to health tests for admission and periodical health tests necessary to their activities, in accordance with specific legislation in term.*

3.4.2. *People must be trained the Practices of personal hygiene and safety. All personnel must fulfill with the rules of hygiene and safety. The training must include situations of behaviour in case of contagious diseases or open lesions.*

3.4.3. *Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should not engage in activities that could result in compromising the quality of intermediate products and active pharmaceutical ingredients. They must be excluded from activities where the health condition does not represent risk to the intermediate products and active pharmaceutical ingredients quality and safety.*

3.4.4. *Employees must be instructed and stimulated to tell to its immediate supervisor any condition which is not in the established procedures, that can affect the manufacture of the intermediate products and active pharmaceutical ingredients.*

3.4.5. *Personnel should avoid direct contact with intermediate products and active pharmaceutical ingredients.*

3.4.6. *In order to ensure the protection of the product against contamination, Personnel should wear clean clothes suitable for the manufacturing activity in which they are involved and their clothes should be changed when appropriate. In case of uniform reuse they must be kept in adequate and closed environments, until they are washed and, if necessary disinfected or sterilized. The discard of the uniforms must follow operational procedures.*

3.4.7. *The company should supply the uniforms. The uniform laundry is a company responsibility.*

3.4.8. *In order to ensure the individual protection of the employees, the company must provide Collective Protection Equipment and Individual Protection Equipment according with activities performed.*

3.4.9. *Smoking, eating, drinking, chewing and storage of plants, food, drinks, cigarettes and personal medicines should be restricted to certain designated areas separate from the manufacturing areas.*

3.4.10. *Visitors and not trained people should be prohibited to entry in the manufacturing areas. If it will be inevitable, these people must be oriented and followed by a company designated professional.*

3.4.11. *Some steps must be taken to prevent the entrance of not authorized people in the Production, Storage and Quality Control areas. The people who do not work in these areas should not pass there.*

4. BUILDINGS AND FACILITIES

4.1. General

4.1.1. *Buildings and facilities should be located, designed, constructed, adapted and maintained to be adequate to the operations to be performed. The layout and design of premises must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of intermediate products and active*

pharmaceutical ingredient, the environment preservation and employees safety.

4.1.2. *Premises should be situated in an environment that, when considered together with measures to protect the manufacturing process, presents minimum risk of causing any contamination of materials or products.*

4.1.3. *Buildings and facilities should have adequate space for the orderly placement of equipment and materials to prevent contamination and facilitate cleaning.*

4.1.4. *The installations must be kept in good condition of conservation, hygiene and cleanness. It must be assured that the operations of maintenance and repair do not represent any risk to the intermediate product and active pharmaceutical ingredient quality.*

4.1.5. *Electrical supply, lighting, air conditioning (temperature, humidity) and ventilation should be appropriate and such that they do not adversely affect, directly or indirectly, either the intermediate products or active pharmaceutical ingredients during their manufacture and storage, or the accurate functioning of equipment.*

4.1.6. *Laboratory should normally be separated from production areas. Some laboratory areas, in particular those used for in-process controls, can be located in production areas, provided the operations of the production process do not adversely affect the accuracy of the laboratory measurements, and the laboratory and its operations do not adversely affect the production process of intermediate products and active pharmaceutical ingredients*

4.1.7. *The installations should be designed and equipped to provide the maximum protection against the entrance of insects and other animals.*

4.2. Storage Areas

4.2.1. *Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of materials and products, namely: raw materials; packaging materials; intermediate products and active pharmaceutical ingredients, products in quarantine, and released, rejected, returned and recalled products.*

4.2.2. *Storage areas should be designed to ensure good storage conditions. They should be clean, dry and kept in temperature and humidity compatible with stored materials, not allowing cross and environmental contamination. When required, these conditions should be provided, checked, monitored and recorded.*

4.2.3. *When required, in the receiving and expedition areas, materials must be protected to the climatic and ambient variations. Receiving areas should be designed and equipped to allow containers of incoming materials to be cleaned if necessary before storage.*

4.2.4. *The products in quarantine should be stored in restricted and separate area of the warehouse. This area must be clearly marked and the access must be restricted to authorized people. Any other system replacing the physical quarantine should give equivalent security, ensuring that products are not released for use or commercialization. The products must be identified, individually indicating its status in order to avoid accidental exchanges.*

4.2.5. *When applicable, sampling area for raw materials should exist. If the sampling will be made in the storage area, this must be carried out in specific environment for this purpose with sample collection equipment that does not affect the quality of the sample or the sampled product (i.e.: sampling of truck tank, tank of solvents). When sampling is performed out of the storage area, it should be conducted in such way as to prevent microbiological contamination and/or cross contamination.*

4.2.6. *Segregated and identified area should be provided for the storage of rejected, recalled, or returned materials or products.*

4.2.7. *Highly active materials, narcotics, other dangerous drugs, and substances presenting special risks of abuse, fire or explosion should be stored in safe and secure areas, properly segregated and identified, in accordance with current legislation.*

4.2.8. *GMP printed materials should be stored in safe area, with restricted access, preventing mixtures and deviations; having to be handled by assigned staff and defined written procedures must be followed.*

4.3. Weighing Room

4.3.1. *The rooms or areas destined to weigh raw materials can be located in the warehouse or production area. The rooms should be designed exclusively for this reason, having an independent and adjusted exhaustion system, when applicable, that prevents the occurrence of cross contamination.*

4.4. Production Area

4.4.1. *In order to minimize the probability of cross contamination occurrence, dedicated facilities must be available for the production of particular intermediate products and active pharmaceutical ingredients, such as biological preparations (live microorganisms), hormones, cytotoxic substances, immunosupressors. For highly sensitizing substance production (penicillin, cephalosporin and its derivatives) dedicated and self-contained facilities must be available. The installations must have completely independent air flow systems designed specifically for it.*

4.4.2. *Facilities should preferably be laid out, according to an operational flow, in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the required cleaning levels.*

4.4.3. *The adequacy of the production areas should permit the orderly and logical positioning of equipment and materials so as to minimize the risk of confusion between different intermediate products and active pharmaceutical ingredients or their components, to avoid cross contamination, and to minimize the risk of omission, negligence or wrong application of any of the manufacturing or control steps.*

4.4.4. *Pipework, light fittings, ventilation points and other services should be designed and sited to facilitate cleaning. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas.*

4.4.5. *Drains should be of adequate size and designed and equipped to prevent back-flow of liquids or gas and be closed when it will not affect security.*

4.4.6. *Production areas, when applicable, should be effectively ventilated, with air controlled facilities, including control of temperature and, when necessary, humidity and filtration appropriate to the products handled. These areas should be regularly monitored during both production and non-production periods to ensure compliance with their design specifications*

4.4.7. *Facility for the packaging of intermediate products and active pharmaceutical ingredients should be designed and laid out so as to avoid mix-ups or cross contamination.*

4.4.8. *Production areas should be well lit, particularly where visual on-line controls are carried out.*

4.5. Quality Control Area

4.5.1. *Quality control laboratories should be designed to suit the operations to be carried out in them. Sufficient space should be given to avoid mix-ups and cross-contamination.*

4.5.2. *The design of the laboratories should take into account the suitability of construction materials and should have devices that ensure environmental conditions to the execution of the analysis and personnel health protection.*

4.5.3. *A separate room may be needed for instruments to protect them against electrical interference, vibration, contact with excessive moisture and other external factors.*

4.6. Ancillary areas

4.6.1. *Rest and refreshment rooms should be separate from other areas.*

4.6.2. *Facilities for changing and storing clothes and for washing and toilet purposes should be easily accessible and appropriate for the number of users. Toilets should not communicate directly with production or storage areas. They should always be cleaned and sanitized.*

4.6.3. *Maintenance workshops should be located in separated places from production, quality control and other areas. Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved and identified for that use.*

4.7. Dedicated Areas

4.7.1. *Manufacturers of highly sanitizing ingredients, such as penicillin or cephalosporin must have dedicated and self-contained facilities with completely independent air flow system and be specifically designed to it.*

4.7.2. *Manufacturers of infectious nature ingredients with live microorganisms or highly active products such as cytotoxic, hormones and immunosupressors should have dedicated and self-contained facilities, with completely independent air flow system and be specifically designed to it.*

4.7.3. *The existence of a self-contained area does not necessarily imply in the existence of a dedicated productive building; however, it must guarantee the existence of rooms totally independent and segregated from the synthesis of the active pharmaceutical ingredient mentioned in items 4.7.1 and 4.7.2. The operational flow must be continuous and rational.*

4.7.4. *The drying of an intermediate product and pharmaceutical ingredient must be made in closed systems or in separated rooms, specially when these materials are powder, because it increases the risk of the environment contamination. These rooms must be provided with adjusted extraction systems, with neutralization and collection of the extraction product, not allowing that the dust contaminates external air. The separate rooms interior surfaces (walls, floors and ceilings) should be smooth, impermeable, washable and resistant and be free from cracks and open joints, should permit easy and effective cleaning and disinfection and should not shed particulate matter.*

4.7.5. *Adequate measures must be established and executed to prevent cross contamination originated from the circulation of people and materials.*

4.7.6. *The production activities of any material non-pharmaceutical highly toxic, such as herbicides and pesticides cannot be executed in the same facility and use the same equipment for the production of intermediate product and pharmaceutical ingredient.*

4.8. Utilities

4.8.1. *All the utilities that interact with the product quality (steam, gases, compressed air and warm air, ventilation and cooling) must be identified, qualified, and properly monitored, and corrective actions should be adopted when they are off of the specified limits.*

4.8.2. *The utility plants must be up to date and be available when requested.*

4.8.3. *It should exist systems and equipment of ventilation, air filtration and extraction, when appropriate. These systems must be designed and constructed to minimize risks of contamination and cross contamination, particularly, in areas where the intermediate products and active pharmaceutical ingredients are exposed to the environment.*

4.8.4. When the air would be re-circulated in the production areas, adequate measures must be taken to minimize the risk of contamination and cross contamination.

4.8.5. *Fixed pipework should be correctly labelled. This can be made by the identification of the individual lines, by documentation, computerized control system or alternative measures. The pipes must be placed to prevent risks of contamination of the intermediate products or active pharmaceutical ingredients.*

4.9. Water

4.9.1. *The minimum quality standard acceptable for the water in the manufacture of intermediate pro-*

ducts and active pharmaceutical ingredient should be potable.

4.9.2. *The water used in the manufacture of the intermediate products and active pharmaceutical ingredient must be monitored and adjusted for its intended use, in accordance with the current law.*

4.9.3. *When the manufacturer would treat the water used in the process, the treatment system must be validated and monitored.*

4.9.4. *When the manufacturer of a non-sterile active pharmaceutical ingredient intends to commercialize it for the manufacture of a sterile medicine, the water used in the final stages of the isolation and purification must be monitored and controlled regarding microbiological counting and endotoxine.*

4.9.5. *When the results of the analytical tests of drinking water would be above of the established limits under the current law, the causes must be refined and corrective actions should be identified and recorded.*

4.10. Sanitation

4.10.1. *The manufacture buildings of intermediate products and active pharmaceutical ingredient must be kept clean and in adequate sanitized conditions.*

4.10.2. *There should be written procedures assigning responsibility for cleaning and sanitation and describing in sufficient detail the cleaning schedules, methods, equipment and materials to be used and facilities and equipment to be cleaned.*

4.10.3. *The use of rodenticides, insecticides, fumigating agents, sanitizing and cleaning materials must be established by written procedures to prevent the contamination of equipment, raw materials, packaging and labelling material, intermediate products and active pharmaceutical ingredients.*

4.11. Waste Management

4.11.1. *Written procedures for the destination of the solid effluents, liquids or gaseous must exist, and be in accordance with the norms or regulations that regulate the pollution control in the environment, which all the employees that work with effluents should have prior knowledge about it.*

4.11.2. *The solids, liquids or gaseous effluents resultant from the manufacturing, buildings and surrounding areas must be placed in safe and sanitary way until its destination. The containers and the pipes for the discarding material must be identified.*

4.11.3. *Effluent and residues must be identified and classified according its nature. The destination, controls and the place of withdrawing of the treated effluent and residues must be established. The executed control and its frequency must be recorded.*

5. EQUIPMENTS

5.1. General

5.1.1. *The equipments used in the production of intermediate products and active pharmaceutical ingredients must be designed, have adequate size and be located to suit the their use, cleaning, sanitation and maintenance.*

5.1.2. *Equipments should be constructed in such way that their surfaces that will be in contact with raw materials and intermediate products do not affect the quality of the active pharmaceutical ingredient.*

5.1.3. *There should be established equipment qualifications.*

5.1.4. *The production unit equipments should be identified.*

5.1.5. *Substances involved with the operation of the equipment that can affect the quality of intermediate products and active pharmaceutical ingredient should not have any contact with them. Any deviation of this practise must be evaluated and ensured that it does not harm the manufacture and the quality of intermediate products and active pharmaceutical ingredient. active the intermediate pharmaceutical ingredients and product quality.*

5.1.6. *Equipments and containers must be used closed, as much as possible. When they are opened, procedures to prevent the risk of contamination must be adopted.*

5.1.7. *Not in use and/or defective equipments must be immediately identified, and removed from the Production and Quality Control areas and as soon as they disposal are proved.*

5.2. Equipment Maintenance and Cleaning

5.2.1. *Programs and procedures for preventive and corrective maintenance of the equipment must be established, including the responsibility assignment for the maintenance. The maintenance must be recorded.*

5.2.2. *There should be established cleaning and sanitation written procedures of equipment and its subsequent release for the use in the production. The procedures must contain instructions that allow cleaning to be efficient and reproductive. At least it should include:*

(a) *responsibility assignment for the equipment cleaning and sanitation;*

(b) *programming the cleaning, including, sanitation when appropriate;*

(c) *describe complete methods and materials, including the cleaning agents dilution used;*

(d) *when appropriate, instructions to disassemble and to reassemble each part of the equipment to ensure its cleanness and sanitation;*

(e) *instructions for equipment cleanness release after each batch production;*

(f) *instructions for the equipment protection after cleaning;*

(g) *equipment evaluation and release before its use;*

(h) *to establish the maximum lead time between the process conclusion and the equipment cleaning since this rate could be significant for the cleaning procedure;*

(i) *to establish the maximum lead-time between the equipment cleaning and its next use as well as which*

parameters should be re-evaluated.

5.2.3. *The utensils must be clean, stored and, when appropriate, sanitized or sterilized to prevent the contamination.*

5.2.4. *Equipment cleaning should be proceeded in appropriate intervals, when continuous productions of different batches of the same product occur.*

5.2.5. *Non-dedicated equipment must be clean between productions of different products to avoid cross contamination.*

5.2.6. *There should be established criteria of acceptance for residues limits and election of cleaning agents.*

5.2.7. *The equipment must be labelled in accordance with its cleaning condition.*

5.3. Calibration

5.3.1. *Equipments used in Quality Control, Weighing, Measuring and Monitoring must be calibrated according with written procedures and an established program.*

5.3.2. *The calibrations of the equipment must be executed using certified standards or traceable standards to the certified standards.*

5.3.3. *The calibration records must be kept.*

5.3.4. *The current condition of the calibration must be known and its evaluation be allowed.*

5.3.5. *Weighing and measurement instruments should be used only when calibrated.*

5.3.6. *The deviations originated for calibration standards of approved instruments must be investigated, to find out if these deviations can affect the quality of intermediate product and pharmaceutical ingredient.*

5.4. Computerized System

5.4.1. *Computerized systems related with Good Manufacturing Practices should be validated, considering the parameters of diversity, complexity and criticality of its application.*

5.4.2. *There should be kept installations and appropriate operational qualifications in accordance with the hardware and software of the computer used.*

5.4.3. *Computerized systems must be sufficiently controlled to avoid not authorized access or changes to the database. These controls must avoid omissions in the data and should record all changes made including new data entered, responsible for it and when it was made.*

5.4.4. *Written procedures for the operation and the maintenance of computerized systems must be available to their responsible.*

5.4.5. *The data entered manually must be checked by a second responsible.*

5.4.6. *The incidents related to the computerized systems, that can affect the quality of intermediate products and active pharmaceutical ingredients and the trustworthiness of the records or the results of test, must be recorded and investigated.*

5.4.7. *The changes in the computerized systems must be executed according to a change procedure and must be formally authorized, recorded and tested. The records of all changes must be kept, including the modifications and the improvements carried out in the system. These registers must demonstrate that the system is validated.*

5.4.8. *When failures in the system occur and result in loss of the records, an alternative system must be supplied. There should be established measures that will ensure the protection of the data for all the existing computerized systems.*

6. DOCUMENTATION AND RECORDS

6.1. General

6.1.1. *Documentation is an essential part of the Quality system and, as such, should exist for all aspects of GMP. Its aims are to define the specifications for all materials and methods of manufacturing and control, to ensure that all personnel concerned with manufacture know their attribution and have access to the involved information. On top of that, it has the purpose to ensure that authorized persons have all the information necessary to decide whether or not to release a batch of intermediate product or pharmaceutical ingredient for sale, as well to permit the traceability and investigation of any batch which is under suspect of quality deviation. The documents can be united in just one binder, or remain separated, easily available, comprising the production batch record.*

6.1.2. *Data may be recorded by electronic data-processing systems or by photographic or other reliable means. Master formula and detailed standard operating procedures relating to the system in use should be available as well as the accuracy of the records should be checked. If documentation is handled by electronic data-processing methods, only authorized persons can modify data filed in the computer. There should be a record of executed changes. The computer access should be restricted by passwords or other means. Another authorized person different should check the entry of critical data that the one who made the entry. Back-up transfer on magnetic tape, microfilm, paper printouts or other means should protect batch records stored electronically.*

6.2. Documentation and Specification Systems

6.2.1. *Documents related with the manufacturing of intermediate products and/or active pharmaceutical ingredients should be prepared, reviewed, approved and distributed according written procedures. Original documents can be in printout form, electronic means or other adequate document archiving system.*

6.2.2. *Documents should not have cross outs. They should be available and signed by their respective responsible. Altered records should allow the prior data identification, should be signed and dated by the responsible person.*

6.2.3. *Records should be made/fulfilled in their respective blank spaces, right after the execution of the activity and should identify the responsible person for*

the execution. Corrections should be dated, signed and the original information should remain legible.

6.2.4. *Document launching, reviewing, replacement, recalling and distribution must be controlled. Original documents should be regularly reviewed and kept up to date; its revision history should be kept as well. A system should exist to prevent inadvertent use of the superseded version.*

6.2.5. *Documents and records should be retained and the period of retention should be established in procedures.*

6.2.6. *All production, control and distribution records should be retained for a minimum period of 1 (one) year after the batch expiration date.*

6.2.7. *During the retention period, original documents and records should be retained or their copies, in case of third party documents.*

6.2.8. *Specifications, analytical methods and acceptance criteria should be established and documented for raw materials, packaging and labelling materials and other materials used during the production of intermediate products and active pharmaceutical ingredients.*

6.2.9. *When electronic signatures will be used in documents, these must be notarized and safe.*

6.3. Records of Cleaning, Sanitation, Sterilization, Maintenance and Use of Equipments

6.3.1. *Records of use, cleaning, sanitation and/or sterilization and maintenance of the equipment must contain the date, the hour, the previous product, current product (when applicable) and the batch number of each intermediate product and pharmaceutical ingredient processed, as well as the identification of the person who executed the cleaning and maintenance. The records must be tracked and promptly available.*

6.3.2. *Cleaning, sanitation and/or sterilization and maintenance records must be available in the equipment during the process and transcribed and/or attached to the batch production record as soon as the production is finished.*

6.4. Specifications of Raw Materials, Intermediate Products, Active Pharmaceutical Ingredients, Packaging and Labelling Materials

6.4.1. *The specification of the primary packaging materials and printed materials, should bear a description, including at least:*

(a) *name and internal reference code;*

(b) *quantitative and qualitative requirements with the respective limits of acceptance;*

(c) *model of printed material;*

(d) *storage conditions.*

6.4.2. *The specification of raw materials, intermediate products and active pharmaceutical ingredients must bear the following descriptions:*

(a) *name of the raw material or pharmaceutical ingredient in accordance with the DCB (Brazilian Denomination), DCI (International Denomination) or CAS (obligatory in this order), when applicable and its respective code of identification;*

(b) *pharmacopoeia monograph reference. If the material does not have reference in official compendia, provide developed and validated specifications and methodologies;*

(c) *quantitative and qualitative requirements with the respective limits of acceptance;*

(d) *storage conditions;*

(e) *chemical structure and molecular formula, when applicable;*

(f) *name of the intermediate product, when applicable;*

(g) *physical form.*

6.4.3. *Packaging materials must attend the specifications emphasizing their compatibility with the intermediate product and pharmaceutical ingredients, which contain.*

6.4.4. *Procedures of control assay should indicate the frequency with that each raw material assay should be executed in its expiration period.*

6.4.5. *The specifications of the intermediate products must be always available when these materials are acquired or shipped, or if when the intermediate products data have to be used in the final product evaluation.*

6.5. Route of Synthesis

6.5.1. *It is necessary to define the route of synthesis.*

6.5.2. *It is necessary to know the stereo chemical behaviour of the route of synthesis molecules, when applicable.*

6.5.3. *It is necessary identify the chiral centre of the molecule and the pharmacological difference between its isomers, when applicable.*

6.5.4. *In case of chiral molecules, having an isomer with pharmacological adverse effect, it should be provided a validated methodology of analysis capable to detect that this isomer attends the specified limits.*

6.5.5. *It is necessary to define in process controls.*

6.5.6. *There should be technical information regarding to intermediate products and active pharmaceutical ingredients:*

(a) *route of synthesis;*

(b) *description of the intermediate molecules and purification;*

(c) *catalyst used;*

(d) *quantification and limit of the principal contaminants;*

(e) *list of organic and inorganic solvents used;*

(f) *limit of the solvent residue in the pharmaceutical ingredient;*

(g) *description of the critical steps;*

(h) *parameters of the synthesis control;*

(i) *analytic methods used;*

(j) *isomer assays data;*

(k) *used forms of detention for isomers*

(l) *probable polymorph and used methods of detention;*

(m) *yield;*

(n) *parameters of control of the raw material;*

(o) *type of water used;*
(p) *physical form of the final product;*
(q) *compliance with current sanitary regulation related with animal spongiform encephalopathy, when applicable;*
(r) *compliance with current sanitary regulation related with other contaminants whose maleficent risks or effect will be proved, when applicable.*

6.6. Standard/Master Formula

6.6.1. *A formally authorized standard/master formula should exist for each batch size to be produced.*

6.6.2. *The standard/master formula of each intermediate product or active pharmaceutical ingredient should be elaborated, dated, signed by a responsible person and be approved and dated by the Quality Unit.*

6.6.3. *The standard/master formula should include:*
(a) *the name of the intermediate product or pharmaceutical ingredient manufactured and an internal reference code;*
(b) *batch size;*
(c) *complete list of raw materials, intermediate products and packaging materials designated by names or specific codes;*
(d) *exact indication of the quantity or relation of each raw material or intermediate product to be used, including its measurement unit. The over quantity variations should be justified;*
(e) *place and production equipments to be used;*
(f) *production detailed instructions, inclusive:*
- *sequences to be followed;*
- *operational parameters;*
- *sampling instructions and in process controls with their respective acceptance criteria;*
- *time limits to the conclusion of the individual steps of the individual process and/or of the total process;*
- *expected yields in appropriate steps of the process;*
- *special observations and precautions to be followed, or respective references related to them;*
- *instructions for the intermediate product or pharmaceutical ingredient storage to ensure its appropriate use, including packaging material, labelling and special storage condition with definition of the lead-time to the operation.*

6.6.4. *Obsolete standard/master formula should be recalled from its use as a current document, but they should be archived as reference, second established criteria.*

6.7. Batch Production Records

6.7.1. *Each batch of intermediate product and pharmaceutical ingredient should have its production record. The batch production order should be checked before being issued to ensure that it is the correct version of the standard/master formula. The batch record of the pharmaceutical ingredient should permit its traceability*

6.7.2. *The batch production records should be codified with only one batch number or identification number, dated and signed when issued. In the continuous production, the product code together with the date and time can be used as an identifier until the final number has been allocated.*

6.7.3. *The documentation of each step in the batch production records should include:*
(a) *dates and times of the beginning and end of each step, when applicable;*
(b) *identification of the used equipments;*
(c) *quantity, analytic control and batch number of the raw material, intermediate products or any reprocessed material used during the production;*
(d) *recorded results for critical process parameters;*
(e) *any sampling executed;*
(f) *any recuperated material and applicable procedures;*
(g) *signature of the persons that execute each step and in the critical steps as well the signature of the supervisors or reviewers;*
(h) *results of in process controls and laboratory tests;*
(i) *expected and real yield in stages or appropriate periods;*
(j) *record of the packaging executed in accordance with the batch manufacturing instruction;*
(k) *representative label of the pharmaceutical ingredient or intermediate product when produced to sale;*
(l) *the manufacturing and control records should be reviewed and any deviation should be analyzed and investigated. Critical deviations should be carefully investigated. The investigation should be extended to other batches of the same product and other products that could be associated to the deviation, when necessary the result of the investigation should be recorded and it should include the conclusions and actions taken;*
(m) *releasing test results;*
(n) *the batch number and the quantity of any material required but not used;*
(o) *any important occurrence observed in the production.*

6.7.4. *Written procedures should be established and followed to investigate deviations of one batch of intermediate product or pharmaceutical ingredient out of specification. The investigation should be extended to the other batches, which could be affected by the deviation.*

6.8. Quality Control Records

6.8.1. *The Quality Control records should include complete data obtained in all tests, inclusive:*
(a) *description of the received samples for test, including name, batch number or other code, the date of collection, quantity, date of the test, manufacturer and origin, supplier and precedence (if it has);*
(b) *indication or reference of each method or test used;*
(c) *complete record of all data generated during each test, including calculations, graphics, printed statements and spectres of the instrumentation, with identification of the material and batch analyzed;*
(d) *test results and established acceptance limits;*

(e) *identification of the person whom executed each analysis and date of the execution.*
(f) *date and identification of the responsible for the record reviews.*
6.8.2. *The records should be kept for:*
(a) *change of an established analytical method;*
(b) *calibration periodic of the instruments and equipments;*
(c) *stability test of intermediate products and active pharmaceutical ingredient;*
(d) *investigation of the results out of specification.*
6.9. Batch Record Review
6.9.1. *The evaluation of the intermediate products and active pharmaceutical ingredients should embrace all important factors, including the production conditions, in process control results, production documents, specification compliance and final packaging exam.*
6.9.2. *The records of the critical steps and control of the laboratory should be reviewed and approved by the Quality Unit before the release or expedition of one batch of pharmaceutical ingredient.*
6.9.3. *The investigation report of the results out of specification and quality deviation should be evaluated as part of the batch production record review.*
6.9.4. *The batch record review should contemplate the investigation of the quality deviations.*

7. CONTROL OF THE MATERIALS

7.1. General Controls
7.1.1. *The raw materials should be received, identified, stored, put in quarantine, sampled, analyzed according established specifications and identified according with they situation (released or rejected), according with written procedures.*
7.1.2. *Raw materials should only be acquired from qualified supplier and their names should be noted in the specification chart.*
7.1.3. *There should have written procedures for receiving, identification, quarantine, storage, sampling, handling, tests and approvals or rejections of the materials.*
7.1.4. *Manufacturers of intermediate products and/or active pharmaceutical ingredient should have a qualification program to the material suppliers.*
7.1.5. *The Quality Unit should acquire the materials according with defined specifications and from qualified suppliers.*
7.1.6. *The identification of the received materials should have at least:*
(a) *name, C.N.P.J. (when applicable), address and telephone number of the manufacturer;*
(b) *name, C.N.P.J. (when applicable), address and telephone number of the supplier (when there is one);*
(c) *name of the material (DCB, DCI or CAS), obligatory in this pattern, when possible;*
(d) *producer batch number;*
(e) *supplier batch number, when applicable;*
(f) *manufacturing date;*
(g) *expiration date;*
(h) *quantity and its respective unit of measurement;*
(i) *storage conditions;*
(j) *security alerts, when applicable.*
7.2. Receiving and Quarantine
7.2.1. *All received materials should be verified to ensure that they are in conformity with the order. After the review and before the entry in the stock, each container or group of container of the materials should be visually inspected regarding its correct identification and its correlation between the name used internally and by the manufacturer (or supplier, if there is one), the container condition, broken seals and other evidences of adulteration or contamination.*
7.2.2. *All materials should be kept in quarantine, immediately after being received, until its approval by the Quality Control.*
7.2.3. *When one raw material delivered has different manufacturer batches (or supplier, if there is one) each batch should be considered separately for sampling, analysis and release.*
7.2.4. *The damages in the containers or any other problem that occur which can affect the quality of the material should be recorded and investigated.*
7.2.5. *Materials to be mixed to pre-existent stocks should be identified, sampled, analyzed and can just be mixed in the stock after approval.*
7.2.6. *If the delivery is made in not dedicated containers, there should be a guarantee that there is no cross contamination, trough:*
(a) *cleaning and/or sanitation certificate;*
(b) *impurity tests.*
7.2.7. *Big storage containers and unload place should be properly identified.*
7.2.8. *The containers of the materials should be identified, individually, or according other company adopted system and should ensure traceability. The following information should be available, at least:*
(a) *name of the material and its respective internal reference code, in case the company had been established the system;*
(b) *batch number given by the manufacturer/supplier when it exists and the number given by the company when receives it;*
(c) *status, each batch condition (quarantine, approved or rejected).*
7.3. Sampling and Analysis of the Material before Production
7.3.1. *There should be executed a test to check the identity of each batch of the received material. The raw materials that cannot be analyzed because of their dangerously should have the manufacturer Certificate of Analysis which will be archived in the Quality Control records.*
7.3.2. *Samples should be representative of the material batch size received.*
7.3.3. *The quantity of sampled containers and the size*

of the sample should be based in a sampling plan.
7.3.4. *Only raw materials released by the Quality Unit can be used to manufacture intermediate product or pharmaceutical ingredient.*
7.3.5. *The sampling should be conducted in defined places to avoid cross contamination, under adequate environmental conditions and following approved procedures.*
7.3.6. *All equipments used in the sampling process that have contact with materials should be clean and, if necessary, sanitized and sterilized and stored in appropriated places.*
7.3.7. *Each sample container should be identified with the following information:*
(a) *name of the sampled material;*
(b) *batch number;*
(c) *number of the container sampled;*
(d) *signature of the person who collected the sample;*
(e) *date when the sample was collected;*
7.3.8. *The container sampled should be identified.*
7.4. Storage
7.4.1. *Intermediate products and active pharmaceutical ingredients should be stored in conditions established by the producer, based on stability studies data.*
7.4.2. *The materials should be handled and stored in a way to prevent their degradation and contamination.*
7.4.3. *The materials should be stored far away from floor and walls, with appropriated space to permit cleaning and inspection.*
7.4.4. *The materials should be stored under appropriated conditions and periods in order to preserve their integrity and identity. The stock should be controlled so rotationally follows the rule: first expired, first out (PEPS in portuguese).*
7.4.5. *The highly active materials, substances that present addiction risk, fire or explosion and other dangerous substances should be stored in safe and protected areas, separated and identified according with specific regulation.*
7.4.6. *Rejected materials should be identified, separated and controlled in a way to avoid their use.*

8. PRODUCTION AND IN PROCESS CONTROLS

Production operations must follow clearly defined procedures. Before the production begins, it should be verified and documented if equipments and workstation are clear of previous manufactured products and if documents and materials required for the planned process are available. As well, it should be checked if equipments are clean and suitable for use.
8.1. Production Procedures
8.1.1. *The production should be conducted according with the Standard/Master Formula.*
8.1.2. *Critical steps for intermediate products and pharmaceutical ingredients quality should be defined and validated.*
8.1.3. *Production should be conducted by qualified and trained personnel.*
8.1.4. *At all times during the production, containers, materials, equipments, and area (when applicable) should be labelled with product name, batch number and the stage of the production.*
8.1.5. *All handle of material and product should be executed in accordance with written procedures and should be recorded.*
8.1.6. *Any problem occurred that could affect the quality of the materials should be recorded and informed to the production responsible for relevant measures.*
8.1.7. *The material reconciliation should be performed and recorded. Any deviation must be investigated and recorded.*
8.1.8. *Access to the production areas should be restricted to the authorized persons.*
8.1.9. *Real yields should be compared with expected yields in defined stages of the production process. The expected yields and the acceptance limits should be established based on product development, pilot scale, process validation and production history.*
8.1.10. *Deviations must be documented and investigated. All critical deviations must be investigated and corrective actions should be implemented and recorded.*
8.1.11. *Process stages should be indicated in the individual equipments, by documentation and/or computerized systems.*
8.1.12. *The materials to be reprocessed or reworked must be adequately labelled with product name, quantity, situation, operation to be executed, operator identification, date and should be stored in defined place. There should be a system or procedure of security that avoid non authorized use.*
8.2. Raw Materials
8.2.1. *Raw materials should be weigh or measured under defined conditions in written procedures. The scale and measurement devices should be adequate for the intended use.*
8.2.2. *When one material is subdivided to be used later in the production, it should be stored in compatible container, labelled with the following information:*
(a) *name of the material and/or identification code;*
(b) *control or receiving number, when applicable;*
(c) *quantity of the material in the container;*
(d) *maximum period for use;*
(e) *container number/ total containers number;*
(f) *identification of the original batch;*
(g) *storage condition and care.*
8.2.3. *Weighings, measurements or operation of critical subdivisions should be confirmed or sent to an equivalent control. Before their use, the production personnel must check the materials specified in the order of production for intermediate products or active pharmaceutical ingredient.*
8.2.4. *There should be written procedure to solvent*

mixes during the manufacturing. These solvents should be analyzed and released prior to the mix. The mixed material must be retested in intervals of period already established.

8.3. Intermediate Products and Active Pharmaceutical Ingredients

8.3.1. *Intermediate products should be analyzed identified and stored according with established specifications.*

8.3.2. *Each batch of intermediate product and active pharmaceutical ingredient should comply with established specifications for quality, purity, identity, assay or potency, including specifications for the tests and limits for solvent residues and impurities.*

8.3.3. *Active pharmaceutical ingredient should follow specifications established in official compendia accepted by the Brazilian federal sanitary body. If there is no reference in official compendia the in house analytical methodology can be used since it is validated.*

8.3.4. *Intermediate Product and Active Pharmaceutical Ingredient maintained in quarantine should stay under manufacturer defined conditions until its final released. Active Pharmaceutical Ingredient sterile should be manufactured according with current regulation.*

8.4. Lead Time

8.4.1. *Lead-time to the production stages should be specified in the standard/master formula and should be controlled to ensure the quality of intermediate product and active pharmaceutical ingredient. Deviations must be documented and analyzed. They are not applicable when the reaction conclusion or the production stages are determined with sampling and in process controls.*

8.4.2. *Intermediate products to be used in future processes should be stored in conditions that ensure their integrity.*

8.5. Sampling and In Process Control

8.5.1. *There should be executed the monitoring and control of process stage performance that cause variability in the characteristics of the quality of intermediate products and active pharmaceutical ingredients. In process controls and limits of acceptance should be defined, based on the information acquired during the stage of development or from historical data.*

8.5.2. *Limits of acceptance and in process control executed analysis depend of the nature of the intermediate product or the pharmaceutical ingredient, reaction or stage of the process that is been conducted and its impact in the quality of the product.*

8.5.3. *Critical in process controls and the critical points monitoring, including control points and methods, should be indicated trough written procedures approved by the Quality Unit.*

8.5.4. *In process controls must be executed by qualified personnel of the production or Quality Control. The in process adjustments can be realized without prior approval since they are performed in pre-established limits and approved by the Quality Unit. All analysis and results must be completely documented as part of the batch production record.*

8.5.5. *Sampling plan and the procedures for in process control should be in written and referenced in scientific methodologies.*

8.5.6. *The sampling in process should be performed to avoid the contamination of the sampled material and ensure the integrity of the samples after their collection.*

8.5.7. *Investigations for the out of specification parameters are not necessary to in process analysis that are executed with the intention of monitoring and/or adjust the production process.*

8.6. Batches Joint Processing

The batches joint processing is considered the process of mixture of fractions from only one batch or the combination of some batches with the same specification, for posterior processing.

8.6.1. *All joint processing of batches operation must be foreseen and approved for the Quality Unit.*

8.6.2. *Each batch incorporated in the joint processing must be manufactured using an established productive process and must be tested individually to verify if it follows the specifications before the joint processing.*

8.6.3. *The joint processing of batches must obligatorily pass for one or more stages of process, characterizing it as a batch and later be analyzed by the Quality Control.*

8.6.4. *The joint processing must be controlled, documented and the final batch must be analyzed to confirm the established specifications.*

8.6.5. *The order of manufacture of the joint processing must allow the traceability of the individual batches.*

8.6.6. *The operations of joint processing must be validated.*

8.7. Mixing Batches

8.7.1. *Mixture is considered the homogenization of distinct intermediate products and active pharmaceutical ingredients with same specifications, characterizing it as a batch. The batch must be analyzed by the Quality Control and the records of the mixture must be kept.*

8.7.2. *All operation of batch mixtures must be foreseen and approved by the Quality Unit.*

8.7.3. *Where physical attributes of intermediate products and active pharmaceutical ingredients are critical, the operations of mixture must be validated to demonstrate the homogeneity. The validation must include test of critical attributes that can be affected by the mixture process.*

8.7.4. *Batches out of specification should not be mixed with other batches with the purpose to reach the adequate specifications.*

8.7.5. *Each lot incorporated in the mixture must be manufactured using an established productive process and must be analyzed individually to verify if it follows the specifications before the mixture.*

8.7.6. *Expiration period of the batch resultant lot of the mixture must be based on the date of the oldest batch manufactured.*

8.8. Contamination Control

8.8.1. *When will be manufactured batches of the same product in continuous system or in campaign, control criteria must be established to determine the regularity of the cleaning of the equipments so the residual materials that possibly can be loaded for successive batches do not modify the product quality. This process must be validated.*

8.8.2. *The operations of the production must be lead in a way that prevents the contamination of the intermediate products or pharmaceutical ingredient.*

9. PACKAGING AND LABELLING OF INTERMEDIATE PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENTS

9.1. General Remarks

9.1.1. *Written procedures must exist that describe the act of receiving, identification, storage, quarantine, sampling, tests, release and handle of packaging materials and labelling, and that avoid the inadvertent use of rejected material.*

9.1.2. *The packaging and labelling materials should comply established specifications.*

9.1.3. *The records must be kept for each packaging and labelling material batch that prove that was received, inspected, analyzed and approved or rejected.*

9.2. Packaging and Labelling Materials

9.2.1. *The packaging materials should not affect in the quality of intermediate product or pharmaceutical ingredient and must ensure adequate protection against external influences and eventual contaminations. Written specifications should be available.*

9.2.2. *A system for the control and check of labels must exist to prevent mix-ups/substitution. When the check is carried out electronically, it should be also checked the perfect functioning of the electronic readers of codes, the labels counting and other instruments.*

9.2.3. *The packaging must be clearly identified with the following information:*

(a) *name of the product [DCB (Brazilian denomination), DCI (International denomination) and CAS], obligatorily in this order, when possible;*

(b) *assay and/or potency, if applicable;*

(c) *batch number;*

(d) *expiration period and date of manufacture;*

(e) *quantity and its respective unit of measurement;*

(f) *warnings, if necessary;*

(g) *storage conditions;*

(h) *name, identification and address of the manufacturer;*

(i) *name of the supplier, if applicable;*

(j) *name of the technical responsible and its number in the professional council; (k) other requirements in agreement with the category of products in accordance with the current regulation.*

9.2.4. *The containers must be clean and if necessary, sanitized to ensure the intended use.*

9.2.5. *In case of containers reuse, they must be cleaned in accordance with documented procedures and all previous labels must be removed and destroyed. The destruction process must be documented.*

9.2.6. *Primary or secondary packaging materials out of use must be identified, taken off from the stock and their destination must be documented.*

9.3. Issue and Control of Labels

9.3.1. *The access to the storage areas of labels must be limited to the authorized staff.*

9.3.2. *Printed materials must be stored in safe conditions and the access not authorized must be prevented.*

9.3.3. *Obsolete labels must be destroyed.*

9.3.4. *Labels printing devices used in the operations of packaging must be controlled to ensure that all printing is in compliance with the standard copy present in the batch production record.*

9.3.5. *Labels emitted for one batch must have their identity and conformity checked. This checking must be recorded.*

9.4. Packaging and Labelling Operations

9.4.1. *Written procedures must be adopted to promote the correct use of the packaging and labelling materials.*

9.4.2. *Labelling operations should be executed in order to avoid mix-ups. It must have a physical or spatial segregation of the operations that involve packaging of different products.*

9.4.3. *Procedures should exist for the reconciliation between the amounts of labels sent, used and returned. Deviations must be documented, investigated and corrective and preventive actions be implemented by the Quality Unit.*

9.4.4. *Labelling and packaging locations should be inspected before their use to ensure that all not necessary packaging and labelling materials for this operation have been removed. This inspection must be recorded.*

9.4.5. *Intermediate products or active pharmaceutical ingredients packaged and labelled should be checked to ensure that the batch containers and packaging are correct. The results must be recorded.*

9.4.6. *Products involved in abnormal occurrences during the packaging operation can just be returned to the process, after to be submitted to an inspection, enquiry and release by a responsible person. Records must be kept.*

9.4.7. *Excesses of codified packaging and labelling materials with batch numbers that were not used must be destroyed; the destruction process must be documented. For the return of not codified printed materials to the stock, written procedures must be followed.*

9.4.8. *The manufacturer must seal intermediate products or active pharmaceutical ingredients packages up before being dispatched.*
9.4.9. *A representative printed label should be included in the batch production record.*

10. DISPATCH

10.1. *Materials at the dispatch areas must be kept under the specified storage conditions in the label.*
10.2. *The intermediate products and active pharmaceutical ingredients should only be forwarded after released by the Quality Unit.*
10.3. *The transportation of active pharmaceutical ingredients and intermediate products should not affect their quality.*
10.4. *In the case of third party transportation, document that establishes the conditions for the transport of active pharmaceutical ingredients and intermediate products must be assigned.*
10.5. *Procedure to check and evaluate if the vehicle conditions are in compliance with the established specifications for the transport of intermediate products and active pharmaceutical ingredients. Records must be kept.*
10.6. *The companies that transport active pharmaceutical ingredients and intermediate products must have functioning authorization for this activity.*
10.7. *Traceability system should be implemented that allows promptly identification and localization of each intermediate product and pharmaceutical ingredient forwarded, to ensure its fast recall, if necessary.*
10.8. *It should exist a procedure to check dispatch data with the identification of the intermediate products and active pharmaceutical ingredients to be forwarded.*

11. QUALITY CONTROL LABORATORY

11.1. General Remarks
11.1.1. *The assay procedures should be approved by the Quality Unit and should be available in the units responsible for their execution.*
11.1.2. *Specifications must be reviewed periodically according with reference literature up dates.*
11.1.3. *Pharmacopoeias, literatures, equipment manuals, reference standards of and other necessary materials must be available to the Quality Control laboratory.*
11.1.4. *The company should have its own Quality Control laboratory and should be independent of the production and should integrate the Quality Unit.*
11.1.5. *The minimum requirements for the Quality Control of the Quality are following:*
(a) *the tests must be executed according written procedures and validated methodologies;*
(b) *the instruments must be calibrated in defined intervals;*
(c) *have the necessary equipments for the accomplishment of the tests;*
(d) *qualified and trained personnel;*
(e) *have procedures for the execution of the developed activities available in the areas;*
(f) *records that demonstrate that all the procedures have been really executed and that any deviations have been totally investigated and documented.*
11.1.6. *Retention samples for future reference must:*
(a) *have label with the identification of its content, batch number and date of the sampling and also the analysis number;*
(b) *have enough quantity to allow, at least, two complete analysis;*
(c) *the samples of intermediate products and active pharmaceutical ingredients must be kept in a packaging material equivalent to the material in which the product will be commercialized and be stored in the same specified conditions.*
11.1.7. *Storage time for the future reference retention samples:*
(a) *raw materials samples: to the end of its supply and/or to the conformity verification of the intermediate product or pharmaceutical ingredient batch (except solvent, gases, unstable raw materials and water);*
(b) *samples of intermediate products and active pharmaceutical ingredient: should be retained until 1 (one) year after the stated expiration period.*
11.1.8. *Quality Control should have easily available in the area:*
(a) *specifications;*
(b) *sampling procedures;*
(c) *methods of analysis and records (including analytical sheets and/or notebook);*
(d) *bulletins and/or certificates of analysis;*
(e) *environmental monitoring records, where specified;*
(f) *methodology validation documentation;*
(g) *procedures and records of the instruments calibration and equipment maintenance.*
11.1.9. *Adequate specifications for intermediate products and active pharmaceutical ingredients should be established in accordance with acceptability standards and be consistent with the manufacturing process. The specifications must include impurity controls. In case that the intermediate product or active pharmaceutical ingredient have a specification for microbiological purity, the limit of actions for total counting of microorganisms and undesirable microorganisms (possibly to rejection) must be established. When intermediate products or active pharmaceutical ingredients have specifications for endotoxins, the limit of actions should be specified.*
11.1.10. *Reagents and Standard solutions should be prepared and labelled according with written procedures and their expiration period for use must be defined.*
11.1.11. *The primary reference standards must be appropriate for the accomplishment of the intermedi-*

ate products and active pharmaceutical ingredient analysis, their origin should be documented and kept in the storage conditions recommended by the manufacturer.

11.1.12. *When a primary reference standard from an officially recognized source is available, an internal standard must be established. Identity and purity tests of this internal standard should be carried out. The documentation of the tests must be kept.*

11.1.13. *The secondary reference standards should be correctly prepared, identified, analyzed, approved and stored. Each batch of secondary reference standard should be adequate in comparison with the primary reference standard. Each batch of the secondary reference standard should be periodically re-analyzed against the primary reference standard according with a written procedure.*

11.2. Intermediate Products and Active Pharmaceutical Ingredients

11.2.1. *Quality Control analysis must be conducted to determine the conformity with the specifications of each batch of intermediate product and active pharmaceutical ingredient.*

11.2.2. *For each intermediate product and pharmaceutical ingredient obtained from a controlled specific process, it should be established an impurity profile that describes the identified and not identifying ones. The impurity profile must include some qualitative analytical identity or assignment, the variation of each observed impurity and the classification of each identified impurity.*

11.2.3. *The impurity profile data of intermediate product and pharmaceutical ingredient should be compared, at defined intervals in relation with the impurity profile history, to detect resultant changes of modifications in the raw material, in the equipment operation parameters or in the manufacturing process.*

11.2.4. *Microbiological tests should be conducted in each batch of the intermediate product and pharmaceutical ingredient, when specified.*

11.3. Certificate of Analysis

11.3.1. *Certificate of analysis must be emitted for each dispatched batch of intermediate product or pharmaceutical ingredient.*

11.3.2. *The certificate of analysis at least should contain:*

(a) *name of the intermediate product or pharmaceutical ingredient [DCB (Brazilian denomination), DCI (International denomination) or CAS], obligatorily in this order, when applicable);*

(b) *batch number;*

(c) *manufacture date;*

(d) *expiration date;*

(e) *each executed test, including the acceptance limits and obtained results, and the reference of the analytical methodology used;*

(f) *emission of the certificate date, identification and signed by an authorized person of the Quality Unit;*

(g) *manufacturer identification.*

12. VALIDATION

12.1 General Remarks

The fulfilment of the BPF requires the production process validations, as well, validations of the support activities (utilities, analytical methods, computerized systems and cleaning operations). Validation is a documented evidence of that the process, operated through established parameters, can effectively and reproductively produce a intermediate product or pharmaceutical ingredient gathering pre-defined specifications and quality attributions together. There are three types of validation: prospective, concurrent or simultaneous and retrospective. The prospective validation must be carried out during the stage period of product development, through the analysis of the risks of the manufacturing process. The concurrent/simultaneous validation must be carried out during the routine production. The retrospective validation must be based on the review and analysis of historical records of the functional specifications.

12.2. Validation Policy

12.2.1. *The validation policy must define the validation target contemplating the analytical stages of the manufacturing processes, methodologies, utilities, cleaning operations and computerized systems. The validation policy of the company must include responsible people for the planning, revision, approval and documentation.*

12.2.2. *Critical parameters must be identified during the stage of the development or from industrial scale historical data, the necessary limits for an operation must be defined. The parameters must include the identification of the process critical stages and establish their limits.*

12.2.3. *The critical operations for the intermediate product and pharmaceutical ingredient quality and purity must be validated.*

12.3. Documentation

12.3.1. Validation Master Plan

12.3.1.1. *There should be a validation master plan that includes at least the following topics:*

(a) *objective (and its previous requirements);*

(b) *process presentation by a flow chart, square diagram or described highlighting the critical steps;*

(c) *organizational structure of the validation activities, highlighting the responsibilities;*

(d) *reason for inclusion or exclusion of specific validation;*

(e) *traceability system for references and revisions;*

(f) *indication of necessary trainings for the validation program;*

(g) *planning and schedule of the activities to be conducted;*

(h) *cross reference with other documents;*

(i) *revalidation periodicity and criteria;*

(j) *presentation of the equipments list and utilities/premises that should be validated;*

(k) *prevision of the validation report elaboration.*

12.3.1.2. *The Validation Master Plan should include:*
(a) *Analytical methods.*
(b) *Cleaning.*
(c) *Manufacturing Processes.*
(d) *Utilities.*
(e) *Computerized systems.*

12.3.2. Validation Protocols

12.3.2.1. *There should be established validation protocol that specifies how the validation process will be conducted. The Quality Unit should approve the validation protocol.*

12.3.2.2. *The validation protocol should specify:*
(a) *process description;*
(b) *equipment and facility descriptions;*
(c) *variables to be monitored;*
(d) *samples to be taken (place, frequency, quantity and sampling procedure);*
(e) *characteristics/attributes and performance to be monitored, specifying the analytical methods;*
(f) *acceptable limits;*
(g) *responsibility definitions;*
(h) *description of the used methods for the record and evaluation of the results, including statistic analysis;*
(i) *process critical steps;*
(j) *acceptance criteria;*
(k) *validation type to be conducted;*
(l) *validation program necessary trainings.*

12.3.2.3. *Critical points must be identified, establishing probability, extension, origin, priorities and final evaluation.*

12.3.2.4. *The validation must be prospective when it is carried out in the product development stage of the intermediate product or pharmaceutical ingredient. Each stage of the process must be detailed, based on previous experiences to determine critical situations.*

12.3.2.5. *The concurrent validation should include the analysis of the trend and stability studies during the life of the product, at least in three industrial manufacturing batches.*

12.3.2.6. *In the retrospective validation it should be proved that manufacturing processes, systems, procedures and equipments had remained unchanged, at least in the last ten produced batches; the results of the in process and final control tests must be evaluated. The difficulties and deviations documented during the production must be analyzed to define the parameter limits of the process. A trend analysis must be carried out to define the extension of the acceptable band.*

12.3.2.7. *Batch selections for the retrospective validation should be representative of all produced batches during the period of the review, including the ones that had not comply the specifications, the number must be sufficient to demonstrate the consistency of the process. The retained samples can be tested to confirm data for the retrospective validation of the process.*

12.3.3. Validation Report

12.3.3.1. *The validation report must reference the protocol and be elaborated contemplating the obtained results, deviations, conclusions, changes and recommendations.*

12.3.3.2. *Any deviation of the validation protocol must be documented, investigated and justified.*

12.3.3.3. *The validation process is satisfactory when the results are acceptable. Otherwise, the deviation origin must be analyzed and the necessary changes are defined, until it presents acceptable results.*

12.4. Qualification

12.4.1. *Before starting the validation process activities, the qualification of the critical equipment, systems and utilities must be finalized and documented. The qualification must be carried out conducting the activities of:*
(a) *Project Qualification (PQ): evaluation of the project of installations, equipment or systems proposal in accordance with the intended purpose.*
(b) *Installation Qualification (IQ): evaluation of the conformity of equipment, systems and utilities, installed or modified, with the approved project, and the manufacturer recommendations and/or requirements.*
(c) *Operation Qualification (OQ): set of operations that establish that equipment, systems and utilities present foreseen performance as in all the considered operational bands. All the used equipments in the execution of the tests must be identified and be calibrated before being used.*
(d) *Performance Qualification (PQ) [also known as Process Validation (PV)]: to verify that the equipments, systems and utilities, when jointly operating are capable to execute with effectiveness the reproducibility, methods and specifications defined in the protocol.*

12.5. Analytical Method Validation

12.5.1. *Analytical methods, different of that already exist in recognized official compendiums by the Brazilian federal surveillance agency could be used, duly only if they have been validated.*

12.5.2. *Analytical methods that are not published in recognized official compendiums must be validated. All used methods must be appropriate and verified under real use circumstances and documented. The analytical methods validation must follow the lines of direction of the current regulation.*

12.5.3. *The analytical validation must enclose all the manufacturing stages analysis of the intermediate product, or pharmaceutical ingredient.*

12.5.4. *The qualification of the equipment and instruments must be considered before starting the analytical methods validation.*

12.5.5. *Any performed changes in an already validated analytical methodology must duly be registered, justified and evaluated in order to prove that such change will not affect the accuracy and reliability of the results.*

12.6. Cleaning and Sanitation Validation

12.6.1. *Cleaning process must be validated. The*

cleaning validation should be directed for situations or steps of the process where the contamination or the exposition of materials means a risk to the intermediate product or pharmaceutical ingredient quality.

12.6.2. *The election of the pharmaceutical ingredient or intermediate product, defined as worse case, should be based on the solubility, cleaning difficulty, and the calculation of the limits of the residue based on the potency, toxicity and stability.*

12.6.3. *The cleaning processes for the product changes must be validated.*

12.6.4. *In case of batch production of one same product in dedicated equipment or production for campaign, in the validation it should be defined the criteria to establish intervals and the cleaning methods.*

12.6.5. *The cleaning validation protocol must describe, at least:*

(a) *the equipments to be cleaned;*

(b) *cleaning procedures, materials and agents;*

(c) *choice criteria and accepted residual limit for the cleaning agents, when applicable;*

(d) *acceptance criteria;*

(e) *monitored and controlled parameters;*

(f) *analytical methods, including the limits of detention and quantification;*

(g) *sampling procedures, including the sample types to be obtained and how they should be collected and labelled;*

(h) *studies of recovery data, when applicable;*

(i) *minimum number of three cleaning cycles to be performed consecutively;*

(j) *microbiological criteria when applicable;*

(k) *definition of the interval between the end of the production and the beginning of the cleaning procedure;*

(l) *definition of the cleaning expiration.*

12.6.6. *The sampling method should be defined to detect insoluble and soluble residues. The sampling method should be adequate to obtain a representative sample of the residues found in the equipment surfaces after the cleaning.*

12.6.7. *The validated analytical methods to be used should have sensitivity to detect residues or contaminants. The limit of quantification for each analytical method must be enough sensible to detect the established acceptable level of the residue or contaminant. The reached method recovery level must be established. The limits of residues must be practical, acceptable, checkable, and based on the most deleterious residue. The limits can be established based on the pharmacological, toxicological, or physiological activity known of the pharmaceutical ingredient or its more deleterious component.*

12.6.8. *The cleaning and sanitation process validation of the equipment must include the reduction of the microbiological contamination or endotoxins according with established limits, in the processes where such contamination can affect the specification of the intermediate product or active pharmaceutical ingredient. The existence of favourable conditions to the microorganisms reproduction and the storage time should be considered.*

12.6.9. *It should not be allowed water formation deposited inside of the equipment, after the cleaning/sanitation operations had been performed.*

12.6.10. *The cleaning processes must be monitored in appropriate intervals after the validation ensuring its effectiveness. The equipment cleaning must be monitored by analytical tests.*

12.7. Process Validation

12.7.1. *For prospective and concurrent/simultaneous validation, three successful consecutive production batches should be used as reference, however there are have situations where batches from the additional processes are required to prove the consistency of the process. For the retrospective validation, at least 10 consecutive batches must be used to evaluate the consistency of the process.*

12.7.2. *The critical parameters of the process must be controlled and monitored during the studies of the validation process.*

12.7.3. *The validation of the process should confirm that the profile of the impurity for each intermediate product and active pharmaceutical ingredient complies the specified limits.*

12.8. Computerized System Validation

12.8.1. *The introduction of computerized systems in the manufacturing processes of intermediate products and active pharmaceutical ingredients, including storage, distribution and quality control does not modify the necessity to observe the principles cited in this regulation. When a computerized system substitutes a manual operation, it should not decrease the quality of intermediate products and active pharmaceutical ingredients.*

12.8.2. *It should have cooperation between key people (users) and those involved with the computerized systems (technical area). Responsible people should receive appropriate training for the management and use of the systems.*

12.8.3. *The computerized system validation depends on several factors including the use for which is destined and the incorporation of new elements. The validation must be considered part of the complete life cycle of a computerized system. This cycle includes the planning steps, specification, programming, test, acceptance, documentation, operation, monitoring and changes.*

12.8.4. *Equipments should be installed in adequate conditions, where external factors do not affect the system.*

12.8.5. *The validation protocol must contain a detailed and up dated description of the system (including diagrams, if necessary). The document will have to describe the principles, objectives, security measures and the system target, as well as the main characteristics in which the system will be used and how*

it will have to interact with other systems and procedures.

12.8.6. *Used software must follow all the steps praised by the Quality Unit.*

12.8.7. *The system will have to include, when appropriate, an internal and automatic form of verifying the correct data entry and its processing.*

12.8.8. *Before a computerized system being placed in use, it will have to be exhaustively tested so that it is confirmed that it is capable to reach the expected results. If a manual system is being substituted, it is part of the tests and the validation that two systems work in parallel during a period of time.*

12.8.9. *The data will need to be inserted or edited only by authorized people. Adequate methods that avoid not authorized manipulation of data include: use of keys, passwords, personal codes and restricted access to the computer terminals. It must exist defined procedures for this issue, for the cancellation and for the authorization change for the insertion or edition of data, including the alteration of the personal passwords. There should be considered the use of systems that register attempts of not authorized people access.*

12.8.10. *When critical data are inserted manually, it should have an additional verification that proves the accuracy of the register. This check must be performed by a second person or validated electronic via.*

12.8.11. *The system must register the identity of the operators who insert or confirm critical data. The authority to edit data must be restricted to the authorized people. Any data change must be authorized and documented, specifying the reason of the change. It should be considered the inclusion in the system of a component that creates a complete record of all the data entries and editions.*

12.8.12. *For quality auditing issues, it should be possible to get physical and clear copies of the electronic stored data.*

12.8.13. *The security of the data against intentional or accidental damages must be guaranteed by physic or electronic ways.*

12.8.14. *The way used for the data storage must be evaluated considering its accessibility, durability and security.*

12.8.15. *The data must be protected by regular procedures of security. The security copies must be kept for a period previously determined and in a safe place.*

12.8.16. *It should exist adequate alternatives for the systems that need to be operated in cases failure (contingency). The time necessary to place the alternative system must be in accordance with the possibility of its urgent use.*

12.8.17. *The procedures to be followed in system failure cases or lack of energy must be defined and validated. Any failure as well as any attitude taken for correction of the problem must be documented.*

12.8.18. *Procedure should be established to record analyze errors and allow that corrective measures can be taken.*

12.8.19. *When external consultants are contracted to supply a computerized system, it must have a contract that clearly defines the responsibilities.*

12.8.20. *When the release of a batch for sale is made through a computerized system, it should permit that only qualified and authorized people make it; the system must clearly identify and register the responsible person for the action.*

12.9. Revalidation

12.9.1. General Remarks

12.9.1.1. *Revalidation is necessary to ensure that the intentional changes or not, in the manufacturing process, systems and equipments, adversely do not affect the characteristics of the process and the quality of the product.*

12.9.1.2. *The extension of the revalidation depends on the nature of the changes and how they affect the different aspects of the production, previously validated. It cannot be necessary to re-validate the process due just a punctual change.*

12.9.1.3. *The revalidation must be performed by the introduction of any changes that affect the manufacture and/or the standard procedure, including those detected in the self-inspection, with influence on the established characteristics of product performance.*

12.9.1.4. *Each change of raw material, packaging material, manufacturing process, equipment, systems, analytical methods and utilities (water, steam, etc.), should be evaluated by the company validation group, that decides if it is significant enough to justify the revalidation and, its broadness.*

12.9.1.5. *The revalidation after the changes can be established in the performance of the same tests and activities carried out during the original validation, including the in process tests and those which referring to the equipment.*

12.9.2. Periodic Revalidation

12.9.2.1. *The revalidation in programmed intervals should be performed in cases where there had no changes, considering the equipment consuming and possible human errors.*

12.9.2.2. *The periodic revalidation must be based mainly on the revision of historical data, generated during the in process tests and of the finished product, after the last validation, having for objective to verify if the process is consistent with the last validation. During the revision of the related historical data, the trend analysis of the collected data must be evaluated.*

12.9.2.3. *The interval of the periodic revalidation should be defined and recorded.*

12.9.2.4. *In the productive processes, the following points should be verified by the periodic revalidation:*

(a) *execution of the calibrations according with established programme;*

(b) *execution of the preventive maintenance according with established programme;*

(c) *SOP update and implementation;*

(a) *execution of cleaning and hygiene program.*

13. CHANGE CONTROL

13.1. *A system for change control must be established to evaluate all the changes that could affect the production and the control of the intermediate products or active pharmaceutical ingredients.*

13.2. *The written procedures should supply the identification, documentation, the appropriate revision and the approval of the changes in raw materials, specifications, analytical methods, installations, utilities, equipment (including computers), processing stages, packaging and labelling materials and computer software.*

13.3. *The written procedures must contemplate the actions to be adopted in case it is proposed change of raw material, specifications, analytical methods, utilities, process equipments, productive process or any other change that can affect the quality of the product.*

13.4. *Any change proposed should be approved by the Quality Unit.*

13.5. *The change control system should ensure that all changes are formally proposed and the impact in the product quality evaluated, justified, documented and approved/authorized.*

13.6. *The changes can be classified by its criticality degree, depending on the nature and extension and the effects that can cause in the process. The Quality Unit must evaluate if the intended change requires revalidation.*

13.7. *When executing approved changes it should be sure that all the original procedures are reviewed and substituted.*

13.8. *The first manufactured batches after the change cannot be released for sale without an accurate evaluation by the Quality Unit.*

13.9. *Depending on the criticality degree of the change, a new stability study should be performed to evaluate the impact of the change in the product quality.*

13.10. *Significant changes in the manufacturing process that cause change in the product specification should be notified to the clients.*

13.11. *Change in a system or in a computer program should be made according with a defined procedure that includes actions regarding to the validation, tests, approvals and change implementation. The change should just be implemented with the approval of the responsible person for the part of the system affected by the change. The change must be documented and any significant modification will have to be validated.*

14. MATERIAL REJECTION AND REUSE

14.1. Rejection

14.1.1. *Materials that are not in compliance with the established specifications must be identified as such, stored in a way to prevent its use while they wait for the destruction, reprocess or devolution to the suppliers.*

14.1.2. *Written procedures related to the handling of rejected materials must be kept, are them raw materials, intermediate products, packaging material or active pharmaceutical ingredients.*

14.2. Reuse

14.2.1. Reprocess

14.2.1.1. *When an intermediate product or pharmaceutical ingredient are not in compliance with their defined specification they can be reprocessed by the repetition of one or more steps of the productive process.*

14.2.1.2. *The reprocess of intermediate product or pharmaceutical ingredient should be preceded of the evaluation and authorization of the Quality Unit to ensure that the quality of the product will not be adversely affected by the formation of sub-products or materials partially reacted.*

14.2.2. Rework

14.2.2.1. *Before starting the rework it should be performed a careful investigation to identify what is the reason of the non-conformity to the standards and established specifications.*

14.2.2.2. *It should be established a rework protocol of the batch that does not comply the established specifications, describing responsibilities, steps to be reworked, tests and results expected. The reworked batch should be evaluated to ensure that it attends the established specification.*

14.2.2.3. *The impurity profile of the reworked batch should take in consideration the reactionary measure used.*

14.2.2.4. *When analytical methods in use are inadequate to characterize the reworked batch, additional analytical methods should be validated before its use.*

14.2.2.5. *The reworked batch can only be commercialized after the stability study been performed and identified as such.*

14.2.3. Materials and Solvents Recovery

14.2.3.1. *Pharmaceutical procedures for the recovery of solvent, water-mother, raw materials, intermediate and active ingredients must exist. The recovered material must comply with the established specifications for its use. In the continuous processes the quality of these recovered materials can be guaranteed by in process controls.*

14.2.3.2. *Solvents, water-mothers, raw materials, intermediate and active ingredients can be recovered and reused in the same process or different processes, just if the recovery procedures are controlled and monitored to ensure that they have appropriate standards of quality.*

14.2.3.3. *New and recovered solvents or raw materials can be mixed if they comply with the defined specifications.*

15. STABILITY

15.1. *Intermediate Products and Active Pharmaceuti-*

cal Ingredients Stability Study

15.1.1. *A documented program must be implemented to monitor the characteristics of the stability of intermediate products and active pharmaceutical ingredients, with indication of the analytical methods to be employed. The results must be used to confirm the adequate storage conditions and the expiration periods proposed.*

15.1.2. *The analytical methods used in the stability study must be validated, according with current regulations.*

15.1.3. *The samples destined to the stability study of intermediate products and active pharmaceutical ingredients must be packaged in the same conditions of packaging, with proportional dimensions, the same chemical composition and physical characteristic of the commercial packaging conserving the dead volume ratio.*

15.1.4. *The stability study must be conducted with three batches of intermediate products and active pharmaceutical ingredients produced to define the expiration period.*

15.1.5. *For the intermediate products and active pharmaceutical ingredient with unstable molecules it should be foreseen the test execution in intervals of each three months.*

15.1.6. *The accelerated stability studies can be part of a program that allows projecting a provisory period of a maximum 24 months of lifetime. Expired this defined provisory period; the expiration period must be confirmed trough the presentation of a long duration stability study.*

15.1.7. *Being about stored intermediate products, studies must be presented that guarantee the maintenance of the proposed specifications for the product in this condition. Thus, the period and the conditions of storage of these products to the stage of primary packaging, among others parameters that could be necessary, must be established.*

15.1.8. *The protocol of the stability study should contemplate physical, chemical, physic-chemical and, microbiological evaluations when it will be the case. Also, it must be evaluated, the presence or qualitative and quantitative formation of by-products and/or products of degradation, using the adequate and validated methodology.*

15.1.9. *When out of specification results occur during the accelerate stability study, the later will be considered invalid.*

15.1.10. *For the accelerate studies, the samples must be analyzed at least in 0, 1, 2, 3 and 6 months of storage. The specific tests for evaluation of the stability described in the stability protocol must be all executed.*

15.1.11. *For long duration studies the samples must be analyzed at least in 0, 3, 6, 9, 12, 18 and 24 months, and annually after the second year until the declared expiration period. The specific tests for evaluation of the described stability in the Quality Unit approved protocol of stability must be carried out.*

15.1.12. *The stability report must present the results obtained during the study and its conclusion. Graphics and tables can be used for the presentation of the results.*

15.1.13. *The stability report should have:*

(a) *intermediate product or pharmaceutical ingredient name;*

(b) *Batch number(s);*

(c) *Batch size(s);*

(d) *Batch manufacturing date;*

(e) *Primary packaging material specification;*

(f) *Number of the samples tested per batch;*

(g) *Number of samples tested per period;*

(h) *Storage conditions;*

(i) *Tests to be performed;*

(j) *Test frequency and specification limits;*

(k) *Test results;*

(l) *Conclusion.*

15.1.14. *After concluded the stability study of the product, the storage recommendations must be shown in the intermediate product and pharmaceutical ingredient packaging.*

15.1.15. *Additional information as: protect from the light, keep in dry place and others must be included when necessary;*

15.1.16. *The Brazilian climatic conditions must be considered in the stability study.*

15.2. Expiration

15.2.1. *The expiration period of the intermediate product and pharmaceutical ingredient should be based on the evaluation of the stability study data.*

15.2.2. *The expiration period of the intermediate product and pharmaceutical ingredient can be based on the stability study of the pilot scale batches, when they use the method and manufacturing procedure that simulate the final process used in the manufacturing industrial scale.*

16. COMPLAINTS, RECALL AND RETURNS

16.1. *All complaints related with the quality, received verbally or written regarding the intermediate products and active pharmaceutical ingredients, should be documented, evaluated, and the causes of possible quality deviations should be investigated and documented, according with written procedures.*

16.2. *The complaints records should include at least:*

(a) *name and address of the complaint person;*

(b) *batch number;*

(c) *name and phone number of the person who submit the complaint;*

(d) *nature of the complaint;*

(e) *complaint receiving date;*

(f) *initial action to investigate, including date and identity of the person who initiated the action;*

(g) *first answer given to the complaint person (including the date of the answer emission);*

(h) *complete investigation, with actions taken repor-*

ted, signed and dated;
***(i)** final decision for the destiny of the intermediate product or pharmaceutical ingredient batch;*
***(j)** final answer to the complaint person.*
***16.3.** The complaint records should be retained to evaluate the trends, report frequency per product and a critical analysis for the corrective action to be taken.*
***16.4.** There should be a written procedure that defines the situations where the pharmaceutical ingredient and intermediate product should be recalled.*
***16.5.** It should be designated a responsible person for the measures to be adopted and for the market recall coordination.*
***16.6.** It should be a system available capable to proceed the recall of suspected products with quality deviation, promptly and efficiently, from the market, if necessary.*
***16.7.** Intermediate products and/or active pharmaceutical ingredients recalled should be identified and stored in separate and safe areas, while wait for the decision of their destiny.*
***16.8.** All competent sanitary authorities (local, national, and/or international) should be immediately informed about the suspect of the quality deviation or about any recall intention of them.*
***16.9.** All decisions and measures taken resulting of a quality deviation originated from one complaint, should be documented, signed and referenced to the corresponding batch records.*
***16.10.** Records about batch distribution that present or is under quality deviation suspect should be promptly available to the recall responsible person. The documents should have sufficient information about distributors and about buyers that the products had been directly supplied, including cases where the product had been exported information about buyers that had received samples for assays, to the questioned product has been effectively out of the market.*
***16.11.** There should be Standard Operational Procedures to the receiving, storing and investigating the reasons for the active pharmaceutical ingredient return.*
***16.12.** Intermediate products and active pharmaceutical ingredients returned should be identified in segregated or restrict area to its storage and a designated person for its receiving.*
***16.13.** Intermediate products and active pharmaceutical ingredients returned by the market can only be considered to resale, after had been analyzed and released by the Quality Unit, according with written procedures.*
***16.14.** When there will be any suspect about the quality of the returned product, this should not be considered adequate to be incorporated or reused.*
***16.15.** Records of Intermediate products and active pharmaceutical ingredients returned should be kept.*
***16.16.** All decisions made and measures taken as a result of a quality deviation originated from a return, should be documented, signed, dated and referenced to the corresponding batch records.*
***16.17.** For each return the documentation should include:*
***(a)** name and address of the client;*
***(b)** batch number and returned quantity of the intermediate products and pharmaceutical ingredients returned;*
***(c)** reason for the return;*
***(d)** new certificate of analysis dated and signed;*
***(e)** destiny for intermediate product or pharmaceutical ingredient returned.*

17. CONTRACT PRODUCTION AND/OR QUALITY CONTROL

***17.1.** The manufacturing and/or analysis contract should be mutually agreed between the parties, in order to avoid misunderstandings that could result in unsatisfactory process, product or quality analysis. It should be signed a written contract between the contractor and the contracted that detailed defines the GMP/GLP responsibilities and that clearly establish the tasks of each party, including quality measurements with respect to batch product releases for sale or issuing the Certificate of Analysis.*
***17.2.** Everybody involved in the contract should comply with the GMP/GLP. Special consideration should be given to the cross contamination prevention and the traceability.*
***17.3.** Changes: in the process, equipments, analytical methods, specifications, or other contractual requirements should not be made, unless both parties have been informed and the changes are approved.*
***17.4.** The signed written contract should establish the manufacturing procedures and/or product analysis of the intermediate product or pharmaceutical ingredient with all technical activities related.*
***17.5.** The contract should establish that the contractor could audit the facilities of the contracted, to verify conformities with GMP/GLP.*
***17.6.** In the case of analysis contract, foreseen by the current regulation, the final approval for release of the intermediate product and pharmaceutical ingredient for sale, should be given by the contractor authorized person.*
***17.7.** The contractor should provide to the contracted with all necessary information to carry out the contracted operations correctly in accordance with the specification of the intermediate product or pharmaceutical ingredient, as well as any other legal requirements. The contractor should ensure that the contracted is fully aware of any problems associate with intermediate product or pharmaceutical ingredient, work or tests that might pose a hazard to premises, equipments, personnel other materials and other intermediate product or active pharmaceutical ingredient.*
***17.8.** The contractor should ensure that any intermediate product or active pharmaceutical ingredient*

delivered by the contracted, comply with their specification and that the product has been released by the authorized person.

17.9. *The contracted must have adequate premises, equipment, and knowledge, as well experience and competent personnel to carry out satisfactorily the work ordered by the contractor. Contract manufacture may be undertaken only by a manufacturer who holds a manufacturing authorization (Autorização de Funcionamento e Licença Sanitária) to the activity of intermediate product and/or active pharmaceutical ingredient manufacturing.*

17.10. *The contracted cannot pass to a third party any of the work entrusted to it under the contract, without the contractor prior evaluation and approval these contract changes. Arrangements made between the contracted and any third party should ensure that the manufacturing and analytical information is made available in the same way as the arrangement signed between the original contractor and contracted.*

17.11. *The contracted should refrain from any activity that that may adversely affect the quality of the product manufactured and/or analyzed for the contractor.*

17.12. *The signed agreement between contractor and contracted should specify the responsibilities of each party with respect to production and product control. Technical aspects of the contract should be drawn up by qualified persons suitable knowledgeable in production technology, quality control analysis and GMP and should be agreed by both parties.*

17.13. *The contract should clearly describe the responsibilities for the purchasing, testing and releasing materials, undertaking production and quality controls, including in process controls, as well as the responsibility for sampling and analysis.*

17.14. *The contract should establish that manufacturing, analytical and reference samples should be kept by, or be available to, the contractor. The manufacturing and analytical records in original or copies should be available where the activity happens.*

17.15. *The contract should establish that the forwarding of the intermediate product and/or pharmaceutical ingredient is been carried out by the contractor and records are kept.*

17.16. *The contract should define the actions to be taken in case of rejection of raw materials, intermediate product and active pharmaceutical ingredient.*

Cadastre of Active Pharmaceutical Ingredients

ANVISA Resolution – RDC n. 30, of May 15th, 2008

ANVISA RESOLUTION – RDC N. 30, OF MAY 15TH, 2008

The Collegiate Board of Directors of the Brazilian Sanitary Surveillance Agency, in the use of the attribution vested in it by article 11, clause IV, of the Regulation of ANVISA approved by Decree n. 3.029, of April 16, 1999, and in view of what is determined by the proposition II and paragraphs 1st and 3rd of the article 54, of the Internal Regulation approved by the terms of the Annex I of the ANVISA's Bylaw n. 354, of August 11th, 2006, republished in the Federal Official Journal of August 21, 2006, in meeting held on April 15th , 2008, and

- *whereas the Resolution – RDC 250, of September 13th, 2005, that creates the Pharmaceutical Active Ingredients Program and its article 6th that establishes the registry for the active pharmaceutical ingredients used in the country as one of its technical-administrative activities;*
- *whereas the need of a sanitary control of the production, import, export, fractionate, store, transport and distribute pharmaceutical ingredients;*
- *whereas the need to standardize the referring sanitary actions of monitoring pharmaceutical ingredients;*
- *whereas the need to ensure rastreability and to support inspection actions for pharmaceutical ingredients, adopts the following Resolution of the Collegiate Board of Directors and I, the Chairman, determine its publication:*

Article 1 – *To determine, by means of this resolution, the obligation of all established companies in this country that exercise the activities of manufacturing, import, export, fractionate, store, transport and distribute active pharmaceutical ingredients, to register in the ANVISA'S cadastre all active pharmaceutical ingredients with which they work.*

Paragraph 1 – *Compounding pharmacies and companies which the activity is only to transport are excluded of this obligation.*

Paragraph 2 – *Manufacturers of pharmaceutical products that use active pharmaceutical ingredients for their own production, will have to register only the ingredients which are imported.*

Article 2 – *The ingredients must be registered using the electronic petition system available on www.anvisa.gov.br, in which aditional instructions and definitions can be found for the correct fulfilling of the forms.*

Article 3 – *In the case of active pharmaceutical ingredient not purchased directly from the manufacturer, the data supplied must contain all information about manufacturers, retailers and distributors of any kind.*

Paragraph 1 – *The supplied information must be sufficient for the correct identification of the manufacturer and retailers. Abbreviations are not allowed.*

Article 4 – *The information supplied to the ANVISA's cadastre in the occasion of the pharmaceutical active ingredient registration is of entire responsibility of the involved companies.*

Article 5 – *At any time, the company will have the option to cancel any of its registered pharmaceutical active ingredients, to change the information already provided or to register new ingredients in its cadastre, in a way that its information in the ANVISA's cadastre is always up to date, and it contains only the ingredients with which the company effectively works.*

Article 6 – *At the end of 180 (one hundred and eighty days) period, starting at the date of the publication of this resolution, the companies will only be able to commercialize active pharmaceutical ingredients registered in its ANVISA's cadastre.*

Article 7 – *The non-observance or disobedience to what is described in the present Resolution configures a sanitary nature infraction, and the infractors are subject to the penalties foreseen in law.*

Article 8 – *This Resolution enters into force on the date of its publication.*

DIRCEU RAPOSO DE MELLO

Technical Regulation of Good Manufacturing Practices of Drugs

ANVISA Resolution – RDC n. 17, of April 16th, 2010 (replaces RDC n. 210)

RESOLUTION – RDC Nº 17, of APRIL 16, 2010
Provides the Good Manufacturing Practice for Medicinal Products.

The National Sanitary Surveillance Agency Board of Directors, in exercise of its power conferred by the item IV of article 11 of the regulation approved by the Decree No. 3029 of April 16, 1999 and in view of the provisions of section II and in §§ 1º and 3º of the article 54 of the Bylaws approved in accordance with Annex I of Ordinance No. 354 of ANVISA, in August 11, 2006, republished in the Gazette (DOU) of August 21, 2006, at a meeting held on April 12, 2010, adopts the following Board of Directors Resolution and I, the Director-Deputy Chairman, determine its publication:

TITLE I – INITIAL DISPOSITIONS

CHAPTER I – OBJECTIVE
Article 1. *This resolution has the objective of establishing the minimum requirements to be followed in the manufacture of drugs to standardize the verification of compliance with Good Manufacturing Practices (GMPs) for human use during a sanitary ispection.*
§ 1 *It is internalized the Resolution GMC Nº 15/09 – "Good Manufacturing Practices for Pharmaceuticals and implementation mechanisms within MERCOSUR", which established the adoption of Report Nº 37 of the WHO (WHO Technical Report Series 908), published in 2003.*
§ 2 *Alternative actions, than the ones described in this resolution, can be taken to keep up with technological advances or to meet specific needs of a particular drug, provided that they are validated by the manufacturer and the quality of the product is ensured.*

CHAPTER II – SCOPE
Article 2. *Drug manufacturers must comply with the guidelines of this resolution in all operations involved in the manufacture of drugs, including drugs in development for clinical trials.*
Sole Paragraph. *The activities related to substances subject to special control, or medications that contain them, shall comply with the provisions of specific legislation, in addition to the requirements contained in this resolution.*
Article 3. *Registered medicines should only be produced by companies duly licensed and authorized for this activity, which should be regularly inspected by the competent national authorities.*
Article 4. *This resolution does not cover all aspects of occupational safety or environmental protection, which are regulated by specific legislation.*
Sole Paragraph. *The manufacturer must ensure the safety of its workers and take the necessary measures to protect the environment.*

CHAPTER III – DEFINITIONS
Article 5. *For purposes of this resolution, the following definitions are adopted:*
I – *Corrective action: action taken to eliminate the cause of a detected nonconformity or other undesirable situation;*
II – *Preventive action: action taken to eliminate the cause of a potential nonconformity or other potential undesirable situation;*
III – *Adjustment: operation designed to make a measuring instrument have a performance compatible to its use;*
IV – *Reference sample: samples of raw materials and finished products kept by the manufacturer, duly identified, for a determined period of time after the finished product expiration date. The amount of sample must have, at least, the double of the units required to perform all the analyses foreseen by official compendia;*
V – *Representative sample: sample size statistically calculated, which represents the entire batch that is taken for analysis purposes to release the batch of material or product;*
VI – *Antechamber: closed space with two or more doors, placed between two or more areas of distinct cleanliness classes, with the purpose of controlling the air flow between them, when they need to be entered. The antechamber is so designed to be used for people, materials or equipment;*
VII – *Area: delimited physical space where the operations are performed under specific environmental conditions;*
VIII – *Clean area: area with environmental control defined in terms of contamination by viable and nonviable particles, designed, built and used in a way to decrease the introduction, generation and retention of contaminants in its interior;*
IX – *Segregated area: facilities that offer complete and total separation of the entire operation, including movement of personnel and equipment, with procedures, controls and monitoring well established. It can include physical barriers and also separate air systems, but does not necessarily imply separate buildings;*
X – *Calibration: set of operations establishing, under specific conditions, the relation between the values shown by an instrument or measuring system or values represented by a materialized measurement or a reference material and the corresponding values established by standards;*
XI – *Contamination: the undesired introduction of impurities of chemical or microbiological nature, or of a foreign material, at a raw material, intermediate product and/or finished product during the steps of sampling, production, packaging or repackaging, storage or transportation;*
XII – *Cross-contamination: contamination of a given raw material, intermediary product, bulk product or finished product with another raw material, intermediary product, bulk product or finished product during*

the manufacturing process;

XIII – *In-process control: checks performed during production in order to monitor and, if necessary, adjust the process to ensure that the product is maintained according to its specification. The control of the environment and equipments may also be considered as part of in-process control;*

XIV – *Acceptance criteria: criteria that stablishes the limits of acceptance for raw materials, products or processes/systems specifications;*

XV – *Expiry date: date stated on the packaging of drugs (usually on labels) to which the product is expected to remain within specification if stored properly. This date is established for each lot, adding the expiration period to the date of manufacture;*

XVI – *Retest date: date set by the manufacturer of the ingredient, based on stability studies, after which the material must be re-analised to ensure that it is still suitable for its immediate use, according to indicative tests of stability defined by the manufacturer of the ingredient and stored in its predetermined conditions. The retest date is only applicable when the expiration date is not determined by the manufacturer of the ingredient;*

XVII – *Plant derived drugs: product of the extraction of a plant: extract, tincture, oil, wax, exudate and others;*

XVIII – *Quality deviation: farness of the quality parameters established for a product or process;*

XIX – *Batch documentation: all documents associated with the manufacture of a batch of bulk product or finished product. Provide a history of each batch of product and all circumstances relevant to the quality of the final product;*

XX – *Herbal drug: medicinal herb, or parts thereof, which contain the substances or classes of substances responsible for the therapeutic action after collection, stabilization and/or drying processes. It can be full, scratched, crushed or pulverized;*

XXI – *Packaging: all operations, including filling and labeling, by which the bulk product must pass in order to become a finished product. Typically, the filling of sterile products is not considered part of the packaging process, since in their primary packaging (vials) they are considered bulk products;*

XXII – *Specification: a document that describes in detail the requirements that the materials used during the production, intermediary or finished products must meet. The specifications serve as basis for quality assessment;*

XXIII – *Manufacturing: all operations involved in the preparation of certain medication, including the acquisition of materials, production, quality control, release, storage, shipment of finished products and the related controls;*

XXIV – *Manufacturer: holder of the Operating Permit for the production of medicines, issued by the agency of the Ministry of Health as provided by the current health law;*

XXV – *Master formula/standard formula: document or group of documents that specify raw materials and packaging materials with their respective quantities, together with a description of the procedures and precautions required to produce a given quantity of finished product. It also provides instructions on processing, including those about in-process controls;*

XXVI – *Active pharmaceutical ingredient: any substance introduced into the formulation of a dosage form that, when administered to a patient, acts as an active ingredient. These substances may exert pharmacological activity or other direct effect in the diagnosis, cure, treatment or prevention of a disease and can also affect the structure and function of the human body;*

XXVII – *Installation: physical bounded space plus machines, apparatus, equipment and auxiliary systems used to fulfil the processes;*

XXVIII – *Lot/batch: a specified quantity of raw material, packaging material or processed product in one or more processes, whose essential characteristic is the homogeneity. Sometimes it may be necessary to divide a batch into sub-lots, which are then grouped together to form a final homogeneous batch. In continuous production, the batch must correspond to a defined fraction of the production, characterized by homogeneity;*

XXIX – *Markers: compound or class of chemical compounds (eg: alkaloids, flavonoids, fatty acids, etc.) present in the vegetable raw material, preferably having correlation with the therapeutic effect, which is used as a reference in the quality control of vegetal raw materials and herbal medicines;*

XXX – *Packaging material: any material, including printed material, used to pack a drug product. Excluded from this definition other container used for transporting or shipping. Packaging materials are classified as primary or secondary, according to their degree of contact with the product;*

XXXI – *Raw material: any substance, whether active or inactive, with defined specification, used to produce medicines. Packaging materials are excluded from this definition;*

XXXII – *Vegetable raw material: fresh medicinal herb, vegetable drug or drugs derived from plant:*

XXXIII – *Medicine: pharmaceutical product, technically obtained or prepared, with prophylactic, curative, palliative or diagnostic purposes;*

XXXIV – *Herbal medicine: medicinal product obtained from the exclusive use of vegetal active raw material. It is characterized by the knowledge of the efficacy and the risk of its use, as well as the reproducibility and consistency of its quality. Its efficacy and safety are validated through ethnopharmacological assessment, of utilization, technoscientific documentations or clinical evidences. It is not considered herbal medicine the one that includes in its composition isolated active substances of any origin or its association with vegetal extracts;*

XXXV – *Botanical nomenclature: genus and species;*
XXXVI – *Full official botanical nomenclature: genus, species, variety, author of the binomial and family;*
XXXVIII – *Critical operation: operation in the manufacturing process that can affect the quality of the product;*
XXXIX – *Production order: document or set of documents that serve as the basis for the batch documentation. They must be completed with the data obtained during the production and include the information of the master formula/standard formula;*
XL – *Designated person: qualified professional designated by the company to perform a certain activity;*
XLI – *Worst case: one or more conditions that have the greatest chances to default the product or process, when compared with ideal conditions. Such conditions do not necessarily imply deviation in product or process;*
XLII – *Validation Master Plan (VMP): general document that sets out the strategies and validation guidelines adopted by the manufacturer. It provides information on the work program validation, define details, responsibilities and timelines for the work to be done;*
XLIII – *Reference standard: they are copies of drugs, impurities, degradation products, reagents, among others, highly characterized and higher purity, whose value is accepted without reference to other standards;*
XLIV – *Secondary standard (working standard) standard used in the laboratory routine, whose value is established by comparison to a reference standard;*
XLV – *Standard Operating Procedure (SOP): written and authorized procedure that provides instructions for performing the operations not necessarily specific to a given product or material, but of a general nature (eg: operation, maintenance and equipament cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain procedures can be used to supplement the master batch production documentation of a specific product;*
XLVI – *Production: all operations involved in the preparation of a given drug, from the receipt of materials at the warehouse, through processing and packaging, to obtain the finished product;*
XLVII – *Bulk product: any product that has passed through all the production steps, without including the packaging process. Sterile products in their primary packaging are considered bulk product;*
XLVIII – *Returned product, finished product, shipped and sold, returned to the manufacturer;*
XLIX – *Intermediate product: partially processed product that must be submitted to subsequent manufacturing steps before becoming a bulk product;*
L – *Finished product: a product that has passed through all production stages, including labeling and final packaging;*
LI – *Validation Protocol (VP Plan): document that describes the activities to be performed in the validation of a specific project, including the schedule, responsibilities and acceptance criteria for the approval of a production process, the cleaning procedure analytical method, computer system or part thereof for routine use;*
LII – *Qualification: a set of actions taken to demonstrate and document that premises, systems and equipments are properly installed and/or work correctly and lead to the expected results. The qualification is often a part of the validation, but the individual qualification steps themselves do not constitute a process validation;*
LIII – *Performance Qualification (PQ): documented verification that the equipment or system has a consistent and reproducible performance, according to parameters and specifications laid down for prolonged periods. In some cases, the term "process validation" may also be used;*
LIV – *Installation Qualification (IQ): set of operations to ensure that the facilities (such as equipment, infrastructure, measurement tools, utilities and manufacturing areas) used in production processes and or computer systems are properly selected and properly installed according to established specifications;*
LV – *Operation Qualification (OQ): set of operations that establishes, under specified conditions, that the system or subsystem operates as expected, in all considered operating ranges. All equipment used to perform the tests should be identified and calibrated before being used;*
LVI – *Design Qualification (DQ): documented evidence that the facilities, support systems, utilities, equipment and processes are designed in accordance with the GMP requirements;*
LVII – *Quarantine: temporary retention of raw materials, packaging materials, intermediate, bulk or finished products. Quarentine materials/products should be kept physically or by other effective means isolated while awaiting for a decision on their release, rejection or reprocessing;*
LVIII – *Re-analysis: analysis of raw materials, previously analysed and approved, to confirm the maintenance of the specifications established by the manufacturer within the period of its validity;*
LIX – *Reconciliation: a comparison between the theoretical and actual amounts in different stages of the production of a product lot/batch;*
LX – *Recovery: total or partial inclusion of previous batches of proven quality to another batch in a defined stage of production;*
LXI – *Validation Report (VR): document in which the records, results and evaluation of a validation program are consolidated and summarized. It may also contain proposals for improvements;*
LXII – *Shipment or delivery: a certain amount of material provided in response to a purchase order. A single shipment may include one or more volumes and materials belonging to more than one lot;*
LXIII – *Reprocessing: repetition of one or more steps that are already part of the manufacturing process*

established in a lot that does not meet specifications;
LXIV – *Technical responsible: the person recognized by the regulatory authority as having the responsibility of ensuring that each batch of finished product has been manufactured, tested and approved for release in accordance with the country laws and regulations in force;*
LXV – *Revalidation: partial repetition or complete process validation, cleaning or analytical method to ensure that they still comply with the established requirements;*
LXVI – *Computerized systems: wide range of systems including but not limited to automated manufacturing equipments, automated laboratory equipments, process control, analytical process, manufacturing execution, laboratory information management, manufacturing resource planning and document management system and monitoring. A computerized system consists of hardware, software and network components, added to the controlled functions and related documentation;*
LXVII – *Large Volume Parenteral Solutions (LVPS): sterile and pyrogen-free solution, intended for parenteral application in a single dose, whose volume is 100 mL or higher. Irrigation solutions and solutions for peritoneal dialysis are included in this definition;*
LXVIII – *Validation: documented act stating that any procedure, process, equipment, material, activity or system actually and consistently leads to expected results;*
LXIX – *Concurrent validation: validation performed during routine production of products intended for sale;*
LXX – *Cleaning validation: documented evidence that demonstrates that the cleaning procedures to remove residuals to a pre-determined level of acceptance, taking into account factors such as lot size, dose, toxicological data, solubility and contact area of the equipment with the product;*
LXXI – *Process validation (PV): documented evidence that attests to a high degree of assurance that a specific process will consistently produce a product that meets predetermined specifications and quality characteristics;*
LXXII – *Computer system validation: documented evidence that attests to a high degree of safety that one analysis of a computerized system, controls and records are performed correctly and that data processing complies with predetermined specifications;*
LXXIII – *Prospective validation: validation performed during the product development stage, based on a risk analysis of the production process, which is detailed in individual steps and these in turn, are evaluated based on experiments to determine whether they can lead to critical situations and*
XXIV – *Retrospective validation: it involves the evaluation of the past production experience under the condition that the composition, procedures and equipment remain unchanged.*

TITLE II – QUALITY MANAGEMENT IN THE DRUG INDUSTRY: PHILOSOPHY AND ESSENTIAL ELEMENTS

Article 6. *The quality management determines the implementation of the "Policy of Quality", ie, intentions and global guidelines on quality, formally expressed and authorized by the company's senior management.*
Article 7. *The basic elements of quality management should be:*
I – *Appropriate infrastructure or "quality system" encompassing facilities, procedures, processes and organizational resources and*
II – *Systematic actions necessary to ensure adequate confidence that a product (or service) meets its quality requirements. The totality of these actions is called "quality assurance".*
Article 8. *Within an organization, quality assurance is used as a management tool. In contractual situations, quality assurance also serves to generate confidence in their suppliers.*
Article 9. *The concepts of quality assurance, GMP and quality control are inter-related and included in quality management. They are described in this resolution so that their relationship are emphasized and their importance for the production of medicines.*

CHAPTER I – QUALITY ASSURANCE
Article 10. *"Quality Assurance" is a very broad concept and should cover all aspects that influence individual and collectively the quality of a product.*
§ 1 *It covers all the measures adopted in order to ensure that medicines are within the required quality standards, so they can be used for the proposed purposes.*
§ 2 *The Quality Assurance incorporates GMP and other factors, including the design and development of a product, which are not contemplated in the purpose of this resolution.*
Article 11. *A proper quality assurance system for the manufacture of medicinal products must ensure that:*
I – *The drugs are planned and developed in ways that the requirements of GMP and other requirements are considered, such as good laboratory practices (GLP) and good clinical practices (GCP);*
II – *The operations of production and control are clearly specified in a document formally approved and in compliance with the requirements of GMP;*
III – *Management responsibilities are clearly specified in their job descriptions;*
IV – *Arrangements are made for the manufacture, distribution and correct use of raw materials and packaging materials;*
V – *All the necessary controls on raw materials, intermediate products and bulk products are made, as well as other in-process controls, calibrations and validations;*
VI – *The finished product is correctly processed and checked in accordance with defined procedures;*

VII – *Medicinal products are not marketed or distributed before the responsible personnel have been certified that each production batch has been produced and controlled according to the requirements of registration and any other relevant standards for the production, control and drug delivery;*
VIII – *Instructions are provided and the necessary steps are taken to ensure that medicines are stored by the manufacturer, distributed and subsequently handled so that quality is maintained by the whole period of validity;*
IX – *There is a procedure for self-inspection and/or internal quality audit to assess regularly the effectiveness and applicability of the quality assurance system;*
X – *Deviations are reported, investigated and recorded;*
XI – *There is a change control system and*
XII – *Assessments of the quality of the medicines are conducted regularly, in order to check the consistency of the process and ensure its continuous improvement.*
Article 12. *The manufacturer is responsible for the quality of drugs manufactured by him, ensuring that they are suitable for their intended purpose, comply with the registration requirements and do not put patients at risk for presenting inadequate safety, quality or efficacy.*
§ 1 *The achievement of this objective is the responsibility of senior management of the company and requires the participation and commitment of employees at all organization levels, suppliers and distributors.*
§ 2 *To reliably achieve the objective, there must be a system of Quality Assurance fully structured and properly implemented, which incorporates the GMPs.*
§ 3 *The Quality Assurance System should be fully documented and have its effectiveness monitored.*
§ 4 *All parts of the system of quality assurance should have competent and qualified personnel, as well as space, equipment and sufficient and appropriate facilities.*

CHAPTER II – GOOD MANUFACTURING PRACTICES FOR MEDICINES (GMP)
Article 13. *Good Manufacturing Practices is part of quality assurance which ensures that products are consistently produced and controlled with appropriate quality standards for the intended use and required for product registration.*
§ 1 *The execution of the GMP is oriented primarily to reduce the inherent risk in any pharmaceutical production that cannot be detected only by testing finished products.*
§ 2 *The risks consist mainly of cross-contamination, particulate contamination, exchange or product mix.*
§ 3 *The GMP determine that:*
I – *All manufacturing processes must be clearly defined and systematically reviewed in the light of experience. Furthermore, they should be able to manufacture medicinal products within the required quality standards and in compliance with the specifications;*
II – *To deliver the necessary qualifications and validations;*
III – *All necessary resources are provided, including:*
a) *qualified and properly trained personnel,*
b) *adequate and identified facilities and space,*
c) *equipment, computer systems and appropriate services,*
d) *materials, containers and appropriate labels,*
e) *procedures and instructions approved and valid,*
f) *suitable storage and transportation and*
g) *facilities, equipment and qualified staff for process control;*
IV – *The instructions and procedures must be written in clear and unambiguous language and be applicable to facilities that are been used;*
V – *Employees should be trained to correctly perform the procedures;*
VI – *Records should be made (manually and/or by recording instruments) during the production to show that all the steps in the procedures and instructions were followed and that the quantity and quality of the product are in line with the expectations. Any significant deviations should be recorded and investigated;*
VII – *Records relating to the manufacture and distribution, that enable a complete tracking of a lot, should be filed in an organized and be easily accessible;*
VIII – *Appropriate storage and distribution of products that minimizes any quality risk;*
IX – *It should have implemented a system that is capable to recall any batch, after its sale or distribution and*
X – *The complaints about marketed products should be examined, recorded and the causes of quality deviations, investigated and documented. Measures should be taken with respect to products with quality deviation and it should be taken steps to prevent recurrence.*

CHAPTER III – SANITATION AND HYGIENE
Article 14. *The drug manufacturing requires a high level of sanitation and hygiene that should be observed at all stages.*
§ 1 *The activities of sanitation and hygiene should include personnel, facilities, equipment and utensils, production materials and containers, cleaning, disinfection and any other aspect that may constitute a source of contamination to the product.*
§ 2 *The potential sources of contamination must be eliminated through a broad sanitation and hygiene program.*

CHAPTER IV – QUALIFICATION AND VALIDATION
Article 15. *In line with the GMP, the company should identify what qualification and validation studies are needed to confirm that all critical aspects of operation are under control.*

Article 16. *The key elements of a company qualification and validation program should be clearly defined and documented in a validation master plan.*
Article 17. *Qualification and validation should establish and provide documented evidence that:*
I – *The facilities, utilities, computer systems, equipment and processes are designed in accordance with the requirements of GMP (Design Qualification or DQ);*
II – *The facilities, utilities, computer systems and equipment were constructed and installed in accordance with their design specifications (Installation Qualification or IQ);*
III – *The facilities, utilities, computer systems and equipment operate in accordance with their planned specifications (Operation Qualification or OQ) and*
IV – *A specific process will consistently produce a product that meets its specifications and quality attributes (Process Validation or PV, also called in some cases Performance Qualification or PQ).*
Article 18. *Any aspect of the operation, including significant changes in facilities, location, computer systems, equipment or processes that directly or indirectly may affect product quality, must be qualified and/or validated.*
Article 19. *Qualification and validation should not be considered only exercises. After the adoption of the qualification and/or validation report, it there should have a continuous monitoring program, which must be based on periodic review.*
Article 20. *The commitment to maintain the qualification/validation status should be described in relevant company documents, as the manual of quality or validation master plan.*
Article 21. *The responsibility for conducting the validation should be clearly defined.*
Article 22. *Validation studies are essential part of the GMP and should be conducted in accordance with predefined and approved protocols.*
Article 23. *Qualification and validation reports containing findings and conclusions should be prepared and filed.*
Article 24. *The processes and procedures should be established based on the results of the validation performed.*
Article 25. *Cleaning procedures, analytical methods and computer systems must also be validated.*

CHAPTER V – COMPLAINTS
Article 26. *All complaints and other information regarding products with possible quality deviations must be thoroughly investigated and recorded in accordance with written procedures.*
Sole Paragraph. *Preventive and corrective actions must be adopted when the quality deviation is proved.*
Article 27. *It should be designated a responsible person for receiving complaints and for the measures to be adopted.*
§ 1 *This person must have sufficient support staff to assist it in its function.*
§ 2 *If the person named is not the technical responsible, he/she should be aware of any complaint, investigation or recall.*
Article 28. *There should be written procedures describing the actions to be taken in response to complaints related to possible quality deviations of a product, including the need of a recall.*
Article 29. *It should be given special attention to complaints related to possible counterfeits or stolen cargo.*
Sole Paragraph. *There should be written procedures describing the actions to be taken, including how to report to the relevant health authorities.*
Article 30. *Any claim relating to quality deviation must be registered and must include the original details provided by the consumer and be fully investigated.*
Sole Paragraph. *The person designated by the Quality Assurance should be involved in the investigation of the deviation in question.*
Article 31. *If a quality deviation is detected in any product batch, or if there would be a suspicious deviation on a determined lot, it should be taken into account the possibility that other lots have the same problem and therefore these should be checked.*
Sole Paragraph. *If other batches contain incorporated product from batches with deviation, they must be specially investigated.*
Article 32. *All decisions and actions taken as a result of a specific complaint should be recorded and referenced in the corresponding batch records.*
Article 33. *Records of complaints should be regularly reviewed in order to detect any evidence of specific or recurring problems that require attention and might justify the recall of marketed products.*
Article 34. *The relevant health authorities should be informed by the manufacturer or the registration owner when detected any significant difference in the quality during the manufacturing process, product deterioration, cargo theft or when any other problem is being investigated which has an impact on product quality.*

CHAPTER VI – PRODUCT RECALL
Article 35. *A system that withdraw immediately and effectively products that have quality deviations or that are under suspicion from the market, according to specific health legislation in force.*
Article 36. *It should be designated a person responsible for the actions to be taken and for coordinating the collection of product from the market.*
§ 1 *This person must have sufficient support staff to assist it in all aspects of the recall and with the urgency required.*
§ 2 *Typically, this person should not belong to the sales department and, if it is not the technical responsible, he/she should be informed of any action taken.*
Article 37. *Procedures should be established for the organization of any recall activity.*

Sole Paragraph. *The company should be able to start any recall immediately throughout the distribution chain.*

Article 38. *There must be a written procedure that describes the storage of recalled products collected in a separate and secure area, while deciding on their destination.*

Article 39. *All relevant health authorities in countries to which the product has been sent, shall be promptly informed of any intention of collecting product that bears or is suspected of quality deviation.*

Article 40. *The records of batch distribution should be readily available and should contain sufficient information on distributors and direct customers, including products exported, samples for clinical trials and medical samples, in order to allow an effective recall.*

Article 41. *The progress of the recall process must be monitored and recorded.*

§ 1 *The records shall include the product disposal.*

§ 2 *A final report must be issued including a reconciliation between the product amounts collected and distributed, according to the current health regulation.*

Article 42. *The effectiveness of the recall measures must be tested and evaluated periodically.*

CHAPTER VII – PRODUCTION AND/OR ANALYSIS CONTRACT

Article 43. *The production contracts and/or analysis must be clearly defined, agreed and controlled in order to avoid misunderstandings that could result in an unsatisfactory product, process or quality analysis.*

Section I – General

Article 44. *All conditions established on the contract of production and/or analysis, including any proposed change in the technical conditions or of other nature, must comply with product registration.*

Article 45. *The contract should allow the contractor to audit the contracted's facilities.*

Article 46. *In the case of contract of analysis, the final approval to release the product for marketing should be done by the Quality Assurance designated person of the contractor.*

Article 47. *The guidelines relating to outsource stages of production and quality control analysis contained in this resolution does not preclude compliance with provisions set forth in specific legislation in force.*

Section II – Contractor

Article 48. *The contractor is responsible for: assessing the contracted's competence to properly perform the procedures or tests contracted; to approve of the contracted activities – as well as to ensure in contract that the principles of GMP described in this resolution are followed.*

Article 49. *The contractor shall provide the contracted with all necessary information to carry out the contracted operations correctly in accordance with the product registration and any other legal requirements.*

Sole Paragraph. *The contractor shall ensure that the contracted is informed of any problems associated with the product, process or test which may endanger the premises, equipment, personnel, materials or other products.*

Article 50. *The contractor shall ensure that all processed products and materials delivered by the contracted comply with their specifications and that these are released by a designated Quality Assurance person.*

Section III – Contracted

Article 51. *The contracted shall have facilities, equipment and appropriate knowledge and experience and qualified personnel to satisfactorily perform the service requested by the contractor.*

§ 1 *The manufacturing contract can only be made by manufacturers who hold Operating Permit and Sanitary Licence for manufacturing activity.*

§ 2 *The parties shall comply with the rules determined by specific legislation.*

Article 52. *Contracted manufactuers are prohibited to subcontract any part of the work entrusted to him by the contract.*

Article 53. *The contractor shall refrain from any activity that could negatively affect the quality of the product manufactured and/or analyzed for the contractor.*

Section IV – Contract

Article 54. *There must be a written contract between the contractor and the contracted that clearly establishes the responsibilities of each party.*

Article 55. *The contract should clearly state how the designated Quality Assurance person, in releasing each batch of product for sale or issue the certificate of analysis, has full responsibility and ensures that each batch has been manufactured and checked according to the registration requirements.*

Article 56. *The technical aspects of the contract shall be established by competent people with appropriate knowledge in pharmaceutical technology, quality control and GMP.*

Article 57. *All production procedures and quality control shall be in accordance with the registration of the product involved and be agreed by both parties.*

Article 58. *The contract should clearly describe the responsibilities for the acquisition, control and release testing of materials for production and implementation of quality controls, including in process controls, as well as the responsibility for sampling.*

Article 59. *The production, analysis and distribution records as well as the reference samples must be kept by the contractor or be available.*

Sole Paragraph. *Any records relevant to assessing the quality of a product that is subject of complaints or has suspected deviation must be accessible and specified in the procedures about deviation/contractor's recall.*

Article 60. *The contract should describe the manage-*

ment of raw materials, intermediate products, bulk and finished products that are rejected.

Sole Paragraph. *The contract should also describe the procedure to be followed in case the contracted analysis demonstrates that the product should be rejected.*

CHAPTER VIII – SELF INSPECTION AND QUALITY AUDITS

Article 61. *The self-inspection must evaluate GMP compliance by the manufacturer in all its aspects.*

§ 1 *The self-inspection program should be designed to detect any deviation in the implementation of GMP and to recommend necessary corrective actions.*

§ 2 *The self-inspections should be performed routinely and, moreover, can be performed on special occasions, such as in the case of recalls, repeated product rejections or before an inspection to be performed by a health authority.*

§ 3 *The staff responsible for self-inspection should be able to assess the implementation of GMP objectively.*

§ 4 *All recommendations for corrective actions must be implemented.*

§ 5 *The self-inspection procedure must be documented and there should be an effective monitoring program.*

Section I – Self Inspection Items

Article 62. *Written procedure should be established for self-inspection.*

Sole Paragraph. *The procedure may include questionnaires on GMP requirements covering at least the following aspects:*

I – *Personnel;*

II – *Facilities, including locker rooms;*

III – *Maintenance of buildings and equipment;*

IV – *Storage of raw materials, packaging materials, intermediate products and finished products;*

V – *Equipments;*

VI – *Production and in process controls;*

VII – *Quality control;*

VIII – *Documentation;*

IX – *Sanitation and hygiene;*

X – *Software validation and revalidation;*

XI – *Calibration of instruments or measurement systems;*

XII – *Recall procedures;*

XIII – *Claims management;*

XIV – *Control labels;*

XV – *Results of previous self-inspections and any corrective actions taken;*

XVI – *Computer systems relevant to Good Manufacturing Practices;*

XVII – *Transportation of drugs and intermediates and*

XVIII – *Waste management.*

Section II – Self Inspection Team

Article 63. *Quality Assurance shall appoint a team to conduct self-inspection, consisting of qualified professionals, experts in their own areas and familiar with GMP.*

Sole Paragraph. *Team members can be professionals from within the company or contracted outside experts.*

Section III – Self Inspection Frequency

Article 64. *The frequency with which self-inspections are conducted must be established in a procedure.*

Sole Paragraph. *The frequency may depend on the characteristics of the company and should be preferably annually.*

Section IV – Self Inspection Report

Article 65. *A report should be prepared after the completion of a self-inspection, which should include:*

I – *The self-inspection results;*

II – *Evaluation and conclusions and*

III – *Recommended corrective actions.*

Section V – Follow-up Actions

Article 66. *There should be an effective program to monitor the activities of self-inspection by the Quality Assurance.*

Sole Paragraph. *The company management should evaluate both the self-inspection reports and the recommended corrective actions, if necessary.*

Section VI – Quality Audit

Article 67. *The complementation of a self-inspection with quality audits may be required.*

§ 1 *The quality audit is the examination and assessment of all or part of a quality system, with the specific aim of improving it.*

§ 2 *It is usually performed by external experts, independent, or by a team designated by the management for that purpose.*

§ 3 *The audits can be extended to suppliers and contractors.*

Section VII – Supplier Qualification Audits

Article 68. *The person designated by the Quality Assurance should have joint responsibility with other relevant departments to adopt reliable suppliers of raw materials and packaging materials that meet established specifications.*

Article 69. *Before suppliers are included in the list of qualified suppliers, these should be evaluated following previously defined procedure or program.*

§ 1 *The assessment should include meeting legal requirements, as well as consider the history and nature of the supplier of materials to be supplied.*

§ 2 *When necessary to carry out audits, they must demonstrate the ability of the supplier to meet the standards of GMP.*

CHAPTER IX – PERSONNEL

Article 70. *The establishment and the maintenance of a quality assurance system and manufacturing of drugs depend on people who perform them.*

§ 1 *There must be sufficient qualified personnel to perform all activities for which the manufacturer is responsible.*

§ 2 *All individual responsibilities must be established in documents formally approved and must be clearly understood by all involved.*

Section I – General

Article 71. *The manufacturer must have an adequate number of staff with the necessary qualifications and experience.*

Sole Paragraph. *The responsibilities assigned to any employee should not be so extensive as to present risks to product quality.*

Article 72. *The company must have an organization chart.*

§ 1 *All employees in positions of responsibility must have their specific and written authority to perform them.*

§ 2 *The functions can be delegated to designated substitutes, which have satisfactory level of qualification.*

§ 3 *There should be no justifiable absences or overlaps in the responsibilities of staff in relation to GMP.*

Article 73. *All staff should know the principles of GMP and receive initial and ongoing training, including hygiene instructions, according to the needs.*

Sole Paragraph. *All staff should be motivated to support the company in maintaining quality standards.*

Article 74. *Measures should be taken to prevent unauthorized persons from entering the areas of production, storage and quality control.*

Sole Paragraph. *The personnel that do not work on these areas should not use them as a gateway to other areas.*

Section II – Key Personnel

Article 75. *Key personnel include those responsible for production, quality assurance, quality control and technical responsible.*

§ 1 *The key positions must be occupied by people who work full time.*

§ 2 *Those responsible for production and quality control should be independent of each other.*

§ 3 *In some companies you may need to delegate certain functions, however, the responsibility cannot be delegated.*

Article 76. *The key personnel responsible for production, quality assurance and quality control of medicinal products must have practical experience and qualifications required by law.*

Sole Paragraph. *Their level of education should include the study of a combination of the following fields of knowledge:*

I – *Chemistry (analytical or organic) or biochemistry;*
II – *Microbiology;*
III – *Technology and pharmaceutical sciences;*
IV – *Pharmacology and toxicology;*
V – *Physiology and*
VI – *Other related sciences.*

Article 77. *Those responsible for Production, Quality Control and Quality Assurance must exercise together, certain activities related to quality, such as:*

I – *Authorization procedures and documents, including its updates;*
II – *Monitoring and controlling the manufacturing environment;*
III – *Establishment and monitoring of hygiene;*
IV – *Process validation and calibration of analytical instruments;*
V – *Training, including the principles of quality assurance;*
VI – *Approval and monitoring of suppliers of materials;*
VII – *Approval and monitoring of contract manufacturers;*
VIII – *Specifications and monitoring of storage conditions of materials and products;*
IX – *Controls;*
X – *File documents/records;*
XI – *Monitoring compliance with GMP and*
XII – *Inspection, investigation and sampling in order to monitor factors that may affect product quality.*

Article 78. *The person responsible for the production has the following responsibilities:*

I – *Ensure that goods are produced and stored according to appropriate procedures, in order to achieve the required quality;*
II – *To approve the instructions relating to production operations, including in-process controls and ensure their strict implementation;*
III – *That the production records are evaluated and signed by a designated person;*
IV – *Check the maintenance of facilities and equipment;*
V – *Ensuring that the processes of validation, calibration and control equipment to be executed and recorded and that the reports are available and*
VI – *Ensure it is carried out initial and ongoing training tailored to the needs of the staff of the production area.*

Article 79. *The person responsible for Quality Control has the following responsibilities:*

I – *To approve or reject raw materials, packaging materials and intermediate products, bulk and finished products in relation to its specification;*
II – *Evaluate the analytical records of the lots;*
III – *Ensure that all necessary tests performed;*
IV – *Participate in the development of sampling instructions, specifications, test methods and procedures for quality control;*
V – *Approve and monitor the analysis carried out under contract;*
VI – *Check maintenance of facilities and quality control equipaments;*
VII – *Ensure that the necessary validations are made, including the validation of analytical methods and calibration of control equipment and*
VIII – *Ensure that initial and ongoing trainings for staff of the Quality Control area, are according to area needs.*

Article 80. *The person responsible for Quality Assurance has the following responsibilities:*

I – *To review the documentation of the produced batches;*
II – *To approve or reject the finished products to market;*

III – *To approve in final form all documents related to Good Manufacturing Practices;*
IV – *To ensure the proper performance of the validation activities;*
V – *To coordinate activities related to the investigation of variances and adoption of preventive and corrective measures;*
VI – *To properly investigate the complaints received;*
VII – *To coordinate the change control system;*
VIII – *To coordinate and participate in the self-inspections program and audits;*
IX – *To ensure the implementation of a comprehensive training program and*
X – *To coordinate the actions of recall.*
Article 81. *The release of a finished product batch can be delegated to a person with appropriate qualifications and experience, which will release the product in accordance with procedures approved by the review of the batch documentation.*
Article 82. *The designated person for approval and release of a lot must ensure that the following requirements are met:*
I – *The lot was manufactured in accordance with product registration;*
II – *The principles and guidelines of Good Manufacturing Practices were followed;*
III – *Manufacturing processes and control were validated;*
IV – *All the necessary checks and tests were performed, considering the conditions and manufacturing records;*
V – *Any planned changes, deviations in manufacturing or quality control have been reported and investigated before release. Such changes may require notification and approval by the regulatory authority.*
VI – *Any additional sampling, inspection, tests and checks have been undertaken or initiated to meet the planned changes to or deviations found;*
VII – *All necessary documentation of production and quality control has been completed and approved by the responsible;*
VIII – *Audits, self-inspections and spot checks were carried out by suitable trained and experienced staff;*
IX – *The quality control attested full compliance with specifications and*
X – *All relevant factors were considered, including any others not specifically associated with the production lot under review.*
Article 83. *If a determined batch does not meet specifications or present differences, this should be investigated.*
§ 1 *If necessary, research should be extended to other batches of the same product or other products that may be linked to the deviation observed.*
§ 2 *It should be a record of research, which should contain the completion and follow-up actions required.*
Article 84. *The Technical Responsible must ensure compliance with the technical and regulatory requirements concerning the quality of the finished products.*
Article 85. *The Technical Responsible must also ensure the implementation of other activities including the following:*
I – *Implementation and establishment of quality system;*
II – *Development of the company's quality manual;*
III – *Self-inspections;*
IV – *External audits (audits of suppliers) and*
V – *Validation programs.*

CHAPTER X – TRAINING
Article 86. *The manufacturer shall train the people involved with the activities of quality assurance, production, quality control, as well as all personnel whose activities can affect the quality of the product through a program written and defined.*
Article 87. *The newly hired personnel must receive specific training to its working position, in addition to basic training on the theory and practice of GMP.*
§ 1 *It must also be given ongoing training and its practical effectiveness should be evaluated periodically.*
§ 2 *Aproved training programs should be available and their records should be kept.*
Article 88. *Personnel working in clean areas, in areas where there is risk of contamination and further areas of material handling highly active, toxic, infectious or sensitizing, should receive specific training.*
Article 89. *The concept of quality assurance and all measures that help the understanding and implementation should be fully discussed during training sessions.*
Article 90. *Visitors or untrained personnel should preferably not go into the areas of production and quality control.*
Sole Paragraph. *If the entrance is inevitable, visitors or untrained personnel should receive relevant information in advance, particularly about personal hygiene, as well as on the use of appropriate protective clothing and should be accompanied by a designated professional.*
Article 91. *The teams of consultants and contracted must be eligible for training services they provide. Evidence should be included in the qualification training records.*

CHAPTER XI – PERSONAL HYGIENE
Article 92. *All staff must undergo periodic health examinations, including admission and laid off.*
Sole Paragraph. *Employees who conduct visual inspections should also undergo to periodic tests of visual acuity.*
Article 93. *All staff should be trained in personal hygiene.*
§ 1 *All people involved in manufacturing processes must comply with hygiene standards and, particularly, should be instructed to wash their hands properly before entering the production.*

§ 2 *It should be posted and observed instructional signs for hand washing.*

Article 94. *People with suspected or confirmed exposure to illness or injury can adversely affect product quality should not handle raw materials, packaging materials, intermediate products, bulk or finished products until their health condition do not pose a risk to the product.*

Article 95. *All employees should be instructed and encouraged to report to their immediate supervisor any conditions relating to production, equipment or personnel, that they believe may adversely affect the products.*

Article 96. *It should be avoided direct contact between the operator's hands and raw materials, primary packaging materials, intermediates and bulk.*

Article 97. *Employees must wear clean and appropriate clothing for each production area to assure the protection of the product from contamination.*

Sole Paragraph. *The uniforms, if reusable, should be kept inside until they are washed and when necessary, disinfected or sterilized.*

Article 98. *The uniforms must be supplied by the manufacturer according to written procedures.*

Sole Paragraph. *The washing of the uniforms is the responsibility of the company.*

Article 99. *In order to ensure the protection of its employees, the manufacturer must provide Collective Protection Equipment (CPE) and Personal Protective Equipment (PPE) according to the activities.*

Article 100. *It is prohibited smoking, eating, drinking, chewing or keeping plants, food, beverages, tobacco and personal medicines in the laboratory of quality control, production and storage areas, or in any other areas where such activities may adversely affect the quality of product.*

Article 101. *Personal hygiene procedures including the use of appropriate clothing should be applied to everybody who enter production areas.*

CHAPTER XII – FACILITIES

Article 102. *The facility should be located, designed, built, adapted and maintained in ways that are appropriate to the operations to be performed.*

Section I – General

Article 103. *The design should minimize the risk of errors and allow for cleaning and maintenance, to avoid cross-contamination, the accumulation of dust and dirt or any adverse effects that may affect product quality.*

Article 104. *Measures should be taken to avoid cross-contamination and facilitate cleaning when dispersion of powders, such as during sampling, weighing, mixing, processing and packaging of powders.*

Article 105. *The premises must be located in a place that, when considered together with measures to protect the manufacturing process, presents minimal risk of causing any contamination of materials or products.*

Article 106. *The facilities used in the manufacture of drugs should be designed and built to permit adequate cleaning.*

Article 107. *The premises must be kept in good repair, cleaning and hygiene.*

Sole Paragraph. *It should be ensured that the maintenance and repair does not represent any risk to the product quality.*

Article 108. *The premises must be cleaned and, where applicable, disinfected according to detailed written procedures.*

Sole Paragraph. *Records of cleanning must be kept.*

Article 109. *The electricity, lighting, temperature, humidity and ventilation supply of the premises must be appropriate so as to not directly or indirectly affect the quality of products during the manufacturing process or the proper functioning of the equipments.*

Article 110. *The facilities must be designed and equipped to offer maximum protection against the entry of insects, birds or other animals.*

Sole Paragraph. *There should be a procedure to control pests and rodents.*

Article 111. *The facility should be planned to ensure the logical flow of materials and personnel.*

Section II – Auxiliary Areas

Article 112. *Rest rooms and dining areas must be separated from areas of manufacturing and control.*

Article 113. *The facilities of changing rooms and toilets should be easily accessible and appropriate for the number of users.*

Sole Paragraph. *Toilets should not have direct communication with the production or storage areas.*

Article 114. *The maintenance areas must be located in separate areas of production.*

Sole Paragraph. *If the tools and spare parts are kept in production, these must be in rooms or lockers reserved for this purpose.*

Article 115. *The laboratory must be isolated from other areas, have separate entrance and unique ventilation system.*

Section III – Storage Areas

Article 116. *Storage areas shall have sufficient capacity to allow orderly storage of materials and products: raw materials, packaging materials, intermediate, bulk and finished products, in their quarentine, approved, rejected, returned or recalled capacities, with the proper separation and identification.*

Article 117. *Storage areas should be designed or adapted to ensure optimal conditions of storage and must be clean, dry, organized and maintained within the temperature limits compatible with the materials stored.*

Sole Paragraph. *When special storage conditions such as temperature and humidity, would be necessary, these should be provided, controlled, monitored and recorded.*

Article 118. *The shipping and receiving areas should be separate and should protect materials and products of climatic variations.*

§ 1 *In the impossibility of separation, appropriate procedures should be adopted to prevent mixtures.*

§ 2 *The receiving areas must be designed and equipped to allow containers to be cleaned, if necessary, before storage.*

Article 119. *The products in quarentine should be stored in a restricted and separate area.*

§ 1 *The area should be clearly marked and the access to it can only be done by authorized persons.*

§ 2 *Any other system that replaces the physical quarantine should have equivalent level of security.*

Article 120. *The storage of materials or products returned, rejected or recalled shall be made in identified and physically isolated areas.*

Article 121. *Highly active and radioactive materials, narcotics, dangerous drugs and other substances that present special risks of abuse, fire or explosion, should be stored in safe and protected, properly identified and segregated as appropriate, in accordance with specific legislation in force.*

Article 122. *It should be given special attention to sampling and safe storage of printed packaging materials because they are considered critical to the quality of drugs.*

Article 123. *There should be a specific area for sampling of raw materials.*

Sole Paragraph. *Sampling shall be conducted so as to prevent contamination or cross contamination.*

Section IV – Weighing Area

Article 124. *The areas designated for weighing raw materials may be located in the warehouse or production area and must be specific and designed for this purpose, the exhaust system should be independent and adequate to prevent the occurrence of cross contamination.*

Section V – Production Areas

Article 125. *The production of certain drugs, such as certain biological preparations (eg: live microorganisms) and the highly sensitizing materials (eg: penicillins, cephalosporins, carbapenems and other betalactam derivatives) should be segregated and have dedicated facilities in order to minimize the risk of serious damage to health due to contamination.*

§ 1 *In some cases, such as highly sensitizing materials, segregation should also occur between them.*

§ 2 *The production of certain highly active ingredients, such as some antibiotics, certain hormones, cytotoxic substances, should be held in segregated areas.*

§ 3 *In exceptional cases, such as accidents (fire, flood etc.) or emergency situations (war etc.), the principle of campaign work on the same premises can be accepted, provided that they take specific precautions and that necessary validations (including cleaning validation) are performed.*

Article 126. *When producing highly active or highly sensitizing drugs, appropriated systems should be used for treatment of exhaust air.*

Article 127. *The facilities shall be arranged according to the continuous operational flow in order to allow the manufacture to correspond to the sequence of production operations and its required cleanliness levels.*

Article 128. *The production areas, including storage of in process materials, should allow logical and orderly placement of equipment and materials, to minimize the risk of mixture between different drugs or their components, to avoid the occurrence of cross-contamination and reduce the risk of omission or misapplication on any stage of manufacture or control.*

Article 129. *In areas where the raw materials, primary packaging materials, intermediate products in bulk are exposed to the environment, interior surfaces (walls, floor and ceiling) shall be lined with smooth waterproof, washable and durable materials, free of joints and cracks, easily cleaned, that allows disinfection and does not release particles.*

Article 130. *The pipes, fixtures, ventilation points and other facilities should be designed and installed to facilitate cleaning.*

Sole Paragraph. *Whenever possible, access for maintenance must be located outside the areas of production.*

Article 131. *The drains must be properly sized, installed to prevent the backflow of liquids or gases and should kept closed when not in use.*

Sole Paragraph. *Installation of open channels should be avoided, but if they are necessary, they should be shallow to facilitate cleaning and disinfection.*

Article 132. *Production areas must have air treatment system suitable for products handled, operations performed and for the external environment.*

§ 1 *The treatment system must include adequate air filtration to avoid contamination and cross contamination, temperature control and, when necessary, humidity and pressure differentials.*

§ 2 *The production areas should be regularly monitored to ensure compliance with the specifications.*

Article 133. *Installations for the drug packaging should be specifically designed and built to avoid mixtures or cross contamination.*

Article 134. *Production areas should be well lit, particularly where they perform visual controls.*

Section VI – Quality Control Areas

Article 135. *The quality control laboratories should be separated from production areas.*

Sole Paragraph. *The areas where biological, microbiological or radioisotope assays are performed should be separated from each other.*

Article 136. *The quality control laboratories should be appropriate to the operations intended.*

§ 1 *It should have enough space to avoid mixing and cross contamination.*

§ 2 *There must be adequate storage space for samples, reference standards (if necessary, with cooling), solvents, reagents and records.*

Article 137. *The areas where microbiological, biological or radioactive isotopes tests are performed must*

be independent and have separate and independent utilities, especially the air system.

Article 138. *It may be necessary to use separate rooms to protect certain instruments from electrical interference, vibration, excessive contact with moisture and other external factors.*

CHAPTER XIII – EQUIPMENTS

Article 139. *The equipment must be designed, constructed, adapted, installed, located and maintained so that they are compatible with the operations to be performed.*

Sole Paragraph. *The design and location of equipment should minimize the risk of errors, allow adequate cleaning and maintenance, in order to avoid cross-contamination, accumulation of dust, dirt and avoid negative effect on product quality.*

Article 140. *The equipment must be installed to minimize any risk of error or contamination.*

Article 141. *The fixed piping must be clearly identified according to the current legislation, to indicate the content and, where applicable, the direction of flow.*

Article 142. *All pipes and devices must be properly identified and it should be given preference to the use of connections or non-interchangeable adapters for gases and hazardous liquids.*

Article 143. *The scales and measuring instruments in the areas of production and quality control must have a working range and accuracy required and must be periodically calibrated.*

Article 144. *The production equipment must be cleaned according to approved and validated cleaning procedures, when appropriate.*

Article 145. *The equipment and analytical instruments must be appropriate to the methodology performed.*

Article 146. *The equipment for washing, cleaning and drying must be selected and used so as not to be a source of contamination.*

Article 147. *The equipment used in production should not present any risk to the products.*

Sole Paragraph. *The share of equipment in direct contact with the product should not be reactive, additive or absorptive so as to not interfere with the quality of the product.*

Article 148. *All unused or defective equipment should be removed from areas of production and quality control.*

Sole Paragraph. *When removal is not possible, the equipments into disuse or defective must be properly identified to prevent their use.*

Article 149. *Enclosed equipment should be used where appropriate.*

Sole Paragraph. *When using open facilities, or when they are opened during any operation, precautions must be taken to minimize contamination.*

Article 150. *The non-dedicated equipment should be cleaned according to validated cleaning procedures to avoid cross contamination.*

Article 151. *In the case of dedicated equipment, cleaning procedures used should be validated, considering residues of cleaning agents, microbiological contamination and degradation products, when applicable.*

Article 152. *The drawings of equipments and supportive critical systems must be kept up to date.*

CHAPTER XIV – MATERIALS

Article 153. *The concept of materials includes: raw materials, packaging materials, gases, solvents, auxiliary materials to the process, the reagents and labeling materials.*

Section I – General

Article 154. *No material used in operations such as cleaning, lubrication equipment and pest control must be in direct contact with the product.*

Sole Paragraph. *Materials must be of suitable quality to minimize health risks.*

Article 155. *All incoming materials and finished products should be quarantined immediately after receipt or produced until they are released for use or sale.*

Article 156. *All materials and products should be stored in appropriate conditions established by the manufacturer, in an orderly fashion to permit batch segregation and stock rotation, following the rule that first expires, first out.*

Article 157. *The water used in the manufacture of pharmaceutical products must be suitable for the purpose for which is intended.*

Section II – Raw Materials

Article 158. *The acquisition of raw materials must be performed by a qualified and trained team.*

Article 159. *Raw materials should be purchased only from suppliers approved by the company, preferably directly from the producer.*

§ 1 *The specifications established by the manufacturer for raw materials should be discussed with suppliers.*

§ 2 *All aspects of production and control of raw materials, the process of acquiring, handling, labeling and requirements relating to packaging, as well as complaints and rejection, should be discussed between the manufacturer and suppliers.*

Article 160. *For each delivery, the containers should be checked at least for the integrity of the packaging and sealing, as well as the correspondence between the order, delivery note and the suppliers' labels.*

Article 161. *All received materials should be checked so that it is assured that the delivery complies with the request.*

§ 1 *The containers must be clean and labeled with the required information.*

§ 2 *When labels are used for internal identification, these should be attached to the containers so that the original information is kept.*

Article 162. *The damage to the vessels or any other*

problems that may affect the quality of the raw material should be recorded, reported to the quality control department and investigated.

Article 163. *If a delivery of material contains different batches, each batch must be individually sampled, analyzed and released.*

Article 164. *Raw materials placed in the storage area must be properly identified.*

§ 1 *The labels must contain at least the following information:*

I – *Name of the raw material and its internal code reference, where applicable;*

II – *Manufacturer's name and its lot number;*

III – *Where applicable, lot number allocated by the supplier and the batch number given by the company at the time of receipt;*

IV – *Situation of raw material in storage (in quarantine, under review, approved, rejected, returned) and*

V – *Date of manufacture, date of retest period or expiration and, where applicable, the date of review.*

§ 2 *It is permitted identification by validated electronic system. In this case, all the information described above do not need to appear on the label.*

Article 165. *There should be procedures or measures to ensure the identity of the contents of each container of raw material.*

Sole Paragraph. *Containers from which samples have been removed must be identified.*

Article 166. *Only released materials by the department of quality control and that are during its validity period should be used.*

Article 167. *The raw materials must be handled only by designated staff in accordance with written procedures.*

Sole Paragraph. *The raw materials must be: carefully weighed or measured, in clean containers and properly identified.*

Article 168. *The raw materials weighed or measured, as well as their respective weights or volumes should be checked by another employee or automated conference. The records must be kept.*

Article 169. *The weighed or measured raw materials for each batch must be kept together and clearly identified as such.*

Section III – Packaging Material

Article 170. *The acquisition, handling and quality control of packaging materials, primary, secondary and printed materials must be conducted in the same way as for raw materials.*

Article 171. *The printed packaging materials should be stored in secure conditions so as to exclude the possibility of unauthorized access.*

§ 1 *Labels on reels should be used whenever possible.*

§ 2 *Fractional labels and other loose printed materials should be stored and transported in separate closed containers so as to avoid mixture.*

§ 3 *The packing materials should be sent to production only by designated personnel following approved and documented procedure.*

Article 172. *Each batch of packaging material, including printed material, must receive a specific reference number or identification mark.*

Article 173. *Printed materials, primary or secondary packaging outdated and obsolete should be destroyed and this must be recorded.*

Article 174. *All products and packaging materials to be used should be checked upon delivery to the packaging department for quantity, identity and compliance with the packing instructions.*

Section IV – Intermediate and Bulk Products

Article 175. *The intermediate and bulk products should be kept under certain specific conditions for each product.*

Article 176. *The intermediate and bulk products purchased should be handled at the receiving area as if they were raw materials.*

Section V – Finished Products

Article 177. *The finished products should be kept in quarantine until their final release.*

Sole Paragraph. *After release, finished products should be stored as stock is available, according to the conditions set by the manufacturer.*

Section VI – Rejected, Recalled and Reprocessed Materials

Article 178. *The rejected materials and products should be identified as such and stored separately in restricted areas.*

Sole Paragraph. *These materials and products can be returned to suppliers or, when appropriate, reprocessed or destroyed within a justified and action taken must be approved by a designated person.*

Article 179. *The reprocessing or recovery of rejected products must be exceptional.*

§ 1 *The reprocess or recovery of rejected material is allowed only if the quality of final product is not affected and its specifications are met and if is still carried out in accordance with a defined and authorized procedure after evaluation of the risks involved.*

§ 2 *Record of reprocessing or recovery should be kept.*

§ 3 *A reprocessed or recovered lot should receive a new batch number.*

Article 180. *The introduction of previous lots or portion thereof in accordance with the required quality, in a lot of the same product in a defined stage of manufacture should be authorized in advance.*

§ 1 *This recovery should be made according to a defined procedure after evaluation of the risks involved, including any possible effect on the expiration date.*

§ 2 *The recovery should be recorded.*

Article 181. *The need of additional testing of any finished product that has been reprocessed, or that has been incorporated, should be considered by the Quality Control.*

Section VII – Recalled Products

Article 182. *Recalled products should be identified and stored separately in a secure area until a decision on their destiny.*

Sole Paragraph. *The decision must be made as soon*

as possible and compliant with specific drug recall legislation.

Section VIII – Returned Products

Article 183. *Returned products must be destroyed, unless it is possible to ensure that their quality remains satisfactory and in these cases may be considered for resale, relabelling, or alternative measures only after critical evaluation conducted by the area of quality, according to written procedure.*

§ 1 *It should be considered when evaluating the nature of the product, any special storage conditions, its condition and history, as well as the time elapsed since their expedition.*

§ 2 *In case of doubt about the quality, the returned products should not be considered suitable for reuse or new expedition.*

§ 3 *Any action taken should be recorded.*

Section IX – Reagents and Media Culture

Article 184. *There should be records for the receipt and preparation of reagents and media culture.*

Article 185. *The reagent preparations should be made in accordance with written procedures, properly labeled and records of the preparation should be kept.*

§ 1 *The label must indicate the concentration, the date of preparation, standardization factor, the expiration date, the date of the next standardization and storage conditions.*

§ 2 *The label must be signed and dated by the person who prepared the reagent.*

Article 186. *Positive controls should be made, as well as negative, to be examined the suitability of media culture.*

Sole Paragraph. *The size of the inoculum used in positive controls should be appropriate to the sensitivity required.*

Section X – Reference Standards

Article 187. *Official reference standards must be used whenever they exist.*

Sole Paragraph. *In their absence, reference standards properly characterized should be used.*

Article 188. *A reference standard not purchased from a recognized pharmacopeia, must be of the highest possible purity to be obtained and be carefully characterized to ensure its identity, content, quality, purity and potency.*

§ 1 *The qualitative and quantitative analytical procedures used to characterize a reference standard must be more extensive than those used to control identity, content, quality, purity and potency of the drug or medicine.*

§ 2 *The analytical procedures used to characterize a reference standard should not be based only on comparison tests to a reference standard previously characterized.*

§ 3 *The documentation of characterization should be available and maintained under the responsibility of a designated person.*

Article 189. *The official reference standards should be used only for the purpose described in the monograph.*

Article 190. *Reference standards should be stored according to manufacturer's recommendations.*

Sole Paragraph. *The manufacturer's recommendations should be followed regarding the proper use, including pre-treatment (drying, correction of content etc.) of these substances.*

Article 191. *All secondary or working standards should be standardized against a reference standard.*

Article 192. *If necessary, appropriate checks should be performed at regular intervals in order to ensure standardization of secondary standards.*

Article 193. *All reference standards should be stored and used so as not to adversely affect their quality.*

Section XI – Residual Materials

Article 194. *Provision must be made as to the proper and safe custody of the waste material for disposal.*

Sole Paragraph. *Toxic substances and flammable materials should be stored in restricted access locations, as required by law.*

Article 195. *The waste material should be collected in suitable containers, kept in a specific and disposed of safely in regular and frequent intervals, according to health standards.*

Sole Paragraph. *The waste material must not be accumulated.*

Section XII – Diverse Materials

Article 196. *It should not be allowed that rodenticides, insecticides products; fumigant agents and sanitizing mateirals, contaminate equipment, raw materials, packaging materials, in process materials or finished products.*

CHAPTER XV – DOCUMENTATION

Article 197. *The documentation is an essential part of the Quality Assurance system and must be related to all aspects of GMP.*

§ 1 *The documentation is intended to define the specifications of all materials and manufacturing and control methods in order to ensure that all personnel involved in manufacturing know how to decide what to do and when.*

§ 2 *The documentation is intended to ensure that the designated person has all the information necessary to decide on the release of a particular batch of product for sale, enabling a trace that allows research the history of any lot under suspicion of misuse of the quality and ensure the availability of data necessary for validation, review and statistical analysis.*

§ 3 *All documents must be readily available, gathered in a single folder or separately.*

Section I – General

Article 198. *The documents must be written, reviewed, approved and distributed only by designated persons.*

Sole Paragraph. *They must meet all manufacturing steps authorized by the record.*

Article 199. *Documents should be approved, signed and dated by the designated person.*

Sole Paragraph. *No document should be changed without authorization and prior approval.*

Article 200. *The contents of the documents can not be ambiguous.*

§ 1 *The title, nature and its purpose must be clearly presented, accurate and correct.*

§ 2 *shall be arranged in an orderly fashion and be easy to check.*

§ 3 *The reproduced documents must be legible and have their fidelity to the original guaranteed.*

Article 201. *Documents should be regularly reviewed and updated.*

§ 1 *When a document is revised, there should be a system that prevents the inadvertent use of obsolete version.*

§ 2 *The obsolete documents should be kept for a specific period of time defined in the procedure.*

Article 202. *When documents require data entry, they must be clear, legible and indelible.*

Sole Paragraph. *Space must be sufficient for each data entry.*

Article 203. *Every change made to any document must be signed, dated and enable the reading of the original information.*

Sole Paragraph. *Where applicable, must be registered the reason for change.*

Article 204. *It should be kept track of all actions taken so that all significant activities concerning the manufacture of medicines can be tracked.*

Sole Paragraph. *All records must be retained for at least one year after the expiration of validity of the finished product.*

Article 205. *Data can be collected through electronic processing system, by photographic or other reliable means.*

§ 1 *The master formula/standard formula and Standard Operating Procedures relating to the system in use should be available and the accuracy of the recorded data must be verified.*

§ 2 *If data logging is done through electronic processing, only designated persons can modify the data in computers.*

§ 3 *should be a record of changes made.*

§ 4 *Access to computers should be restricted by passwords or other means.*

§ 5 *The input data are critical, when inserted manually into a system must be checked by another designated person.*

§ 6 *The electronic records of lots of data must be protected by means of copies on magnetic tape, microfilm, printout or other means.*

§ 7 *During the retention period, the data should be readily available.*

Section II – Labels

Article 206. *The identification affixed to containers, equipment, premises and products should be clear, unambiguous and in a form approved by the company, containing the necessary data.*

Sole Paragraph. *Can be used beyond the text, different colors to indicate their status (quarantined, approved, disapproved, clean and others).*

Article 207. *All finished products should be identified as law.*

Article 208. *Labels of benchmarks and accompanying documents must indicate the concentration, the date of manufacture, the date on which the seal was opened, storage conditions and, where applicable, the expiration date and tracking number.*

Section III – Specifications and Quality Control Tests

Article 209. *The methods of quality control must be validated before they are adopted into routine, taking into account the facilities and equipment available.*

Sole Paragraph. *Compendial analytical methods do not require validation, but before its implementation, there must be documented evidence of their suitability in the laboratory operating conditions.*

Article 210. *All specifications for raw materials, packaging materials and finished products must be duly authorized, signed and dated and maintained by Quality Control or Quality Assurance.*

Article 211. *Tests must be performed in intermediate products and bulk products, when appropriate.*

Sole Paragraph. *Specifications should also be related to water, solvents and reagents (acids and bases) used in production.*

Article 212. *Should be carried out periodic reviews of the specifications to be updated as new editions of the national pharmacopoeia or other official compendia.*

Article 213. *Pharmacopoeias, reference standards, references spectrometry and other reference materials needed should be available in the laboratory quality control.*

Section IV – Specifications for Raw Materials and Packaging Materials

Article 214. *The specifications of raw materials, primary packaging materials and printed materials must have a description, including at least:*

I – *Internal code name as a reference and DCB, if any;*

II – *The reference pharmacopoeia monograph, if any and*

III – *Quantitative and qualitative requirements with the respective limits of acceptance.*

§ 1 *Depending on the practice adopted by the company, other data can be added to the specifications, such as:*

I – *Vendor ID and the original producer of the materials;*

II – *Sample of printed material;*

III – *Guidelines on sampling, testing and quality references used in control procedures;*

IV – *Storage conditions and precautions and*

V – *Maximum storage period before it is carried out further analysis.*

§ 2 *The packaging material must meet specifications with emphasis on its compatibility with the drugs.*

§ 3 *The material should be examined for the presence of defects and correct identification marks.*

Article 215. *The documents describing the test pro-*

cedures of control must indicate the frequency of execution of tests of each raw material, as determined by its stability.

Section V – Specifications for Intermediate and Bulk Products

Article 216. *The specifications of the intermediates and bulk should be available whenever these materials are purchased or dispatched, or if data on intermediate products are used when evaluating the final product.*

Sole Paragraph. *These specifications must be compatible with the specifications for the raw materials or finished products.*

Section VI – Specifications for Finished Products

Article 217. *Specifications for finished products should include:*

I – *Generic name of the product and brand or trade name, if applicable;*

II – *The name(s) principle(s) active(s) with their DCB*

III – *Formula or reference to it;*

IV – *Pharmaceutical form and details of packaging;*

V – *References used for sampling and testing of control;*

VI – *Qualitative and quantitative requirements, with their acceptance limits;*

VII – *Conditions and precautions to be taken in storage, if applicable and*

VIII – *Expiration date.*

Section VII – Master/Standard Formula

Article 218. *There must be a master formula/standard allowed for each product and batch size to be manufactured.*

Article 219. *The master formula/standard should include:*

I – *The name of the product with the reference code relating to its specification;*

II – *Description of the dosage form, concentration of the product and batch size;*

III – *List of all raw materials to be used (with their DCB), with the amount used of each one, using the generic name and reference that are unique to each material. Mention should be made to any substance that may disappear in the process;*

IV – *Declaration of the expected final yield with acceptable limits and intermediate yields, if applicable;*

V – *Indicates the processing site and equipment to be used;*

VI – *The methods (or reference to them) to be used in the preparation of major equipment such as cleaning (especially after product change), installation, calibration and sterilization;*

VII – *Detailed instructions on the steps to be followed in the production (control of materials, pretreatments, the sequence of adding materials, mixing times, temperatures, etc.);*

VIII – *Instructions for any in-process controls with their acceptance limits;*

IX – *Requirements for the packaging, including on the container, labeling and any special storage conditions and*

X – *Any special precautions to be observed.*

Section VIII – Packaging Instructions

Article 220. *There must be authorized instructions regarding the method of packaging for each product and the size and type of packaging.*

§ 1 *The instructions must contain the following data:*

I – *Product name;*

II – *Description of its pharmaceutical form, concentration and route of administration, if applicable;*

III – *Pack size expressed in number, weight or volume of product contained in the final container;*

IV – *Complete listing of all packaging material required for a standard lot size, including quantities, sizes and types, with the code or reference number relating to the specifications of each material;*

V – *Sample or reproduction of materials used in the packaging process, indicating where the batch number of the product and its expiration date must be printed or saved;*

VI – *Special precautions such as checking the equipment and the area where hold the package in order to ensure the absence of printed products in the previous packaging lines;*

VII – *Description of the packaging operations and equipment to be used and*

VIII – *Details of ongoing controls, along with the instructions for sampling and acceptance criteria.*

Section IX – Batch Production Records

Article 221. *Records must be kept of each batch of production.*

Sole Paragraph. *Records shall be based on the master formula/standard approved and in use, avoiding transcription errors.*

Article 222. *Before starting a production process, should be checked if the equipment and the workplace are free from products previously produced, as well as documents and materials required for the planned process are available.*

§ 1 *Must be verified if the equipment is clean and suitable for use.*

§ 2 *Such checks should be recorded.*

Article 223. *During the production process, all steps undertaken should be recorded, looking at the initial time and final implementation of each operation.*

§ 1 *The record of implementation of these steps must be properly dated by the executors, clearly identified by signature or electronic password and ratified by the area supervisor.*

§ 2 *The records of production batches must contain at least the following information:*

I – *Product name;*

II – *Number of the batch being manufactured;*

III – *Dates and times of beginning and end of the main intermediate production stages;*

IV – *Name of the person responsible for each stage of production;*

V – *ID(s) operator(s) at different(s) stages of pro-*

duction and, where appropriate, of person(s) that verifies each of these operations;
VI – *The number of lots and/or the number of analytical control and quantity of each raw material used, including batch number and amount of any recovered or reprocessed material that has been added;*
VII – *Any operation or relevant event observed in the production and major equipment used;*
VIII – *In process controls made, the identification(s) of person(s) that has run and the results obtained;*
IX – *Product quantities obtained in the different stages of production (income), together with comments or explanations of any significant departure from the expected income and*
X – *Observations on special problems including details such as the signed authorization for each change of the formula of manufacture or production instructions.*
Section X – Batch Packaging Records
Article 224. *Records must be kept of each batch of container or part of the lot, according to package instructions.*
Sole Paragraph. *Records should be prepared to avoid transcription errors.*
Article 225. *Before beginning any packaging operation should be checked if the equipment and the workstation are free of previous products, documents or materials not required for the planned packaging operations and that equipment is clean and suitable for use.*
Sole Paragraph. *Such checks should be recorded.*
Article 226. *During the packaging process, all steps undertaken should be recorded, looking at the initial time and final implementation of each operation.*
§ 1 *The records of the execution of each step must be dated by the executors, clearly identified by signature or electronic password and ratified by the area supervisor.*
§ 2 *The records of production batches must contain at least the following information:*
I – *The product name, batch number and quantity of bulk product to be packed and the batch number and the planned quantity of finished product that will be obtained, the quantity actually obtained and reconciliation;*
II – *The date(s) and time(s) of the packaging operations;*
III – *The name of the person responsible for carrying out the packaging operation;*
IV – *Identification of the major operators in steps;*
V – *Checks made on the identification and compliance with the instructions for packaging, including the results of controls;*
VI – *Details of the packaging operations carried out, including references to equipment, packaging lines used to and, when necessary, instructions and records relating to the storage of non-packaged products;*
VII – *Samples of printed packaging materials used, including samples containing the approval for the printing and regular check (where appropriate), containing the batch number, date of manufacture, expiry date and any additional print;*
VIII – *Observations on any special problems, including details of any deviation from the packing instructions, with written authorization of the person designated;*
IX – *The quantities of all packaging materials printed with the reference number or identification and products delivered in bulk to be packaged and*
X – *The quantities of all materials used, destroyed or returned to stock and the amount obtained from the product, so that a reconciliation can be done right.*
Section XI – Standard Operational Procedures (SOPs) and Records
Article 227. *The Standard Operating Procedures and the records associated to possible action taken related to the results obtained, when appropriate, should be available as:*
I – *Assembly and qualification of equipment;*
II – *Analytical apparatus and calibration;*
III – *Maintenance, cleaning and sanitizing;*
IV – *Personnel, including qualification, training, uniforms and hygiene;*
V – *Environmental monitoring;*
VI – *Pest control;*
VII – *Claims;*
VIII – *Recalls and*
IX – *Returns.*
Article 228. *There should be SOPs and records for the receipt of raw materials and primary packaging materials and printed material.*
Article 229. *The records of the receipts should include at least:*
I – *Name of the material described in the delivery note and the containers;*
II – *The name and/or internal code of the material;*
III – *The date of receipt;*
IV – *The name of the supplier and manufacturer's name;*
V – *The batch or reference number of the manufacturer;*
VI – *The amount and number of containers received;*
VII – *The batch number assigned to the receipt, and*
VIII – *Any relevant comments (eg: the state of containers).*
Article 230. *There should be Standard Operating Procedure for internal identification of products stored in quarantine and released (raw materials, packaging materials and other materials).*
Article 231. *The Standard Operating Procedures should be available for each instrument and equipment (eg: use, calibration, cleaning, maintenance) and placed near the equipment.*
Article 232. *There should be standard operating procedure for sampling and the area be defined and designated persons responsible for collecting samples.*
Article 233. *The sampling instructions should include:*

I – *The method and sampling plan;*
II – *The equipment to be used;*
III – *Any precautions to be observed to avoid contamination of the material or any commitment to quality;*
IV – *Amount(s) of sample(s) that is(are) collected;*
V – *Instructions for any required subdivision of the sample;*
VI – *Type of container to be used in sample preparation, labeling and whether the sampling procedure must be performed under aseptic conditions or not and*
VII – *Any precautions to be observed, especially regarding the sampling of sterile or noxious material.*
Article 234. *There should be a Standard Operating Procedure describing the details of the numbering system of lots, in order to ensure that each batch of intermediate, bulk or finished is identified with a specific lot number.*
Article 235. *The Standard Operating Procedure which deals with the batch numbering should ensure traceability at all stages of production, including packaging.*
Article 236. *The standard operating procedure for batch numbering should ensure that batch numbers will not be used repeatedly, which applies also to reprocessing.*
Sole Paragraph. *The allocation of a lot number should be recorded immediately.*
Article 237. *There should be written procedures for the control tests carried out in materials and products in different stages of manufacture, describing the methods and equipment to be used.*
Sole Paragraph. *The tests should be recorded.*
Article 238. *Records of tests must include at least the following data:*
I – *The name of the material or product and, where applicable, the dosage form;*
II – *The batch number and, where appropriate, the manufacturer and/or supplier;*
III – *References the relevant specifications and testing procedures;*
IV – *Test results, including observations and calculations, as well as reference to any specifications (limits);*
V – *Date(s) and number(s) of reference(s) test(s);*
VI – *Identification of persons who have carried out the tests;*
VII – *Identification of persons who have given the tests and calculations and*
VIII – *Statement of approval or disapproval (or other decision), dated and signed by a designated person.*
Article 239. *Should be available written procedures regarding the approval or rejection of materials and products and particularly on the release for sale of the finished product by a designated person.*
Article 240. *Records shall be maintained in the distribution of each batch of a product so, for example, facilitate the gathering of the lot, if necessary.*
Article 241. *Records must be kept for major and critical equipment, such as qualification, calibration, maintenance, cleaning or repair, including date and identification of people who performed these operations.*
Article 242. *The records of the use of equipment and areas where the products are being processed must be made in chronological order.*
Article 243. *There should be written procedures assigning responsibility for cleaning and sanitizing and describing in detail frequency, methods, equipment and cleaning materials to be used, as well as facilities and equipment to be cleaned.*
Article 244. *Procedures should be available to computer systems by defining security rules (user/password), maintenance of systems and IT infrastructure, management of deviations in information technology, data recovery and backup.*

CHAPTER XVI – GOOD MANUFACTURING PRACTICES
Article 245. *Production operations must follow written standard operating procedures, clearly defined and approved in accordance with the approved registration, in order to obtain products that are within the required quality standards.*
Section I – General
Article 246. *All handling of materials and products, such as receipt and cleaning, quarantine, sampling, storage, labeling, dispensing, processing, packaging and distribution, must be in accordance with written procedures or instructions and, where necessary, recorded.*
Article 247. *Any deviation from instructions or procedures should be avoided.*
Sole Paragraph. *In the event, the deviations must be authorized and approved in writing by a person appointed by the Quality Assurance, with the participation of Quality Control, where applicable.*
Article 248. *Checks should be performed on yields and reconciliation of amounts to ensure that there are no discrepancies outside acceptable limits.*
Article 249. *Operations with different products should not be performed simultaneously or consecutively in the same room or area unless there is no risk of mixing or cross contamination.*
Article 250. *During processing, all materials, bulk containers, equipment and the rooms and packaging lines used must be identified with an indication of product or raw material, its concentration (when applicable) and batch number.*
§ 1 *The statement must indicate the production stage.*
§ 2 *Where applicable, must be registered also the name of the processed product before.*
Article 251. *Access to production facilities shall be restricted to authorized personnel.*
Article 252. *The non-pharmaceutical products and not subject to health surveillance should not be produced in areas or with equipment for the production of medicines.*

Article 253. *The in-process controls should not pose any risk to product quality and risks of cross contamination or mixing.*

Section II – Prevention of cross contamination and bacterial contamination during production

Article 254. *When materials and products are used in powder production, special precautions must be taken to prevent the generation and dissemination of post.*

Sole Paragraph. *Should be taken to the appropriate control of air (eg: insufflation of air and exhaust within the specifications previously established).*

Article 255. *The contamination of a raw material or of a product by another material or product should be avoided.*

§ 1 *The risk of accidental cross-contamination arises from the uncontrolled release of dust, gases, vapors, aerosols, or organisms from materials and products in process, waste equipment, the introduction of insects, the clothes of the operators, their skin etc.*

§ 2 *The significance of the risk varies with the type of contaminant and the product was contaminated.*

§ 3 *Among the most hazardous contaminants are highly sensitizing materials (eg: penicillins, cephalosporins, carbapenems and other beta-lactam derivatives), the biological preparations with live organisms, certain hormones, cytotoxic substances and other highly active materials.*

§ 4 *Special attention should also be given to products which contamination can cause major damage to users, such as those administered intravenously or applied to open wounds, products administered in large doses and/or for long periods of time.*

Article 256. *The occurrence of cross-contamination must be avoided by appropriate technical or organizational measures, such as:*

I – *Production in exclusive and closed areas (eg: penicillins, cephalosporins, carbapenems, the other beta-lactam derivatives, preparations with biological organisms, certain hormones, cytotoxic substances and other highly active materials);*

II – *Campaign production (separation time) followed by appropriate cleaning in accordance with a validated procedure. For products listed in paragraph (a), the principle of campaign work is only applicable in exceptional cases such as accidents or emergency situations;*

III – *Use of antechambers, differential pressure and supply air and exhaust systems;*

IV – *Reducing the risk of contamination caused by recirculation or re-air of untreated or insufficiently treated;*

V – *Use of protective clothing where products or materials are handled;*

VI – *Use of validated procedures for cleaning and decontamination;*

VII – *Using "closed system" of production;*

VIII – *Testing of waste and*

IX – *The use of labels on equipment to indicate the state of cleanliness.*

Article 257. *Should be checked periodically the effectiveness of measures taken to prevent cross contamination.*

Sole Paragraph. *This check should be made in accordance with Standard Operating Procedures.*

Article 258. *The production areas which are being processed products susceptible to contamination by micro-organisms should be monitored periodically, for example, microbiological monitoring and particulate matter, as appropriate.*

Section III – Production Operations

Article 259. *Before the commencement of any manufacturing operation must be taken the necessary steps to work position that areas and equipment are clean and free of any raw material, products, waste products, labels or documents that are not needed for the new operation be initiated.*

Article 260. *All in-process controls and environmental controls should be performed and recorded.*

Article 261. *Means should be established to indicate equipment failure or utilities.*

Sole Paragraph. *The defective equipment must be removed from use until they are repaired.*

Article 262. *After use, the production equipment must be cleaned within the specified period, in accordance with detailed procedures.*

Sole Paragraph. *The clean equipment should be stored in clean, dry place to avoid contamination.*

Article 263. *Should define the limits of time that the equipment and/or container may remain dirty before realizadoo procedure for cleaning and after cleaning before reuse.*

Sole Paragraph. *Time limits should be based on validation data.*

Article 264. *The containers used for filling should be cleaned before the operation.*

Sole Paragraph. *One should be careful to avoid and to remove any contaminants such as glass fragments and metal particles.*

Article 265. *Any significant deviation from the expected return should be investigated and recorded.*

Article 266. *It should be ensured that the pipe or other equipment used to transport products from one area to another are connected correctly.*

Article 267. *The pipes used for transporting water or purified water for injection and, when appropriate, other types of piping, must be sanitized and maintained in accordance with written procedures to determine the limits of microbial contamination and the measures to be adopted in case of contamination.*

Article 268. *Equipment and instruments used in procedures of measurements, weights, records and controls should be submitted to the maintenance and calibration at predetermined intervals and records of such operations must be maintained.*

§ 1 *In order to ensure satisfactory operation, the instruments must be checked daily or before being used for analytical tests.*

§ 2 *The date of calibration, maintenance and future*

calibrations must be clearly established and recorded, preferably on a label attached to the instrument or equipment.

Article 269. *The repair and maintenance operations should not present any risk to product quality.*

Section IV – Packaging Operations

Article 270. *In the programming of the packaging operations must exist which minimize the occurrence of cross-contamination from mixtures or substitutions.*

Sole Paragraph. *Different products should not be packed next to each other, unless there is physical segregation or an alternative system that provides equivalent security.*

Article 271. *Before you start packing operations should be taken to ensure that the work area, packaging lines, printing machines and other equipment are clean and free of any products, materials or documents used previously and which are not necessary for the current operation.*

§ 1 *The release of the line must be performed according to procedures and checklist.*

§ 2 *The verification shall be recorded.*

Article 272. *The name and batch number of the product in process must be displayed at each stage of packaging or packaging line.*

Article 273. *The steps of filling and closing must be immediately followed by the labeling step.*

Sole Paragraph. *If the provisions of the caption is not possible, procedures should be appropriate to ensure that there are no mixes or labeling errors.*

Article 274. *Should be checked and recorded the correct performance of the printing operations performed separately or during the packaging process.*

Sole Paragraph. *Should be given greater attention to print manuals, which should be checked at regular intervals.*

Article 275. *In order to avoid mixing/exchange must take special care when loose labels are used or when large quantities are made that is outside of the packaging line and when adopted container operations manual.*

§ 1 *Should be given preference to labels feed rollers loose labels, to avoid mixtures.*

§ 2 *The on-line check of all labels by electronic means may be useful to avoid mixing, but checks should be made to ensure that any electronic code readers, label counters or similar devices are functioning properly.*

§ 3 *When the labels are attached by hand, should be performed in-process controls with greater frequency.*

Article 276. *The information printed and embossed on the packaging material must be clear and resistant to wear and tampering.*

Article 277. *The on-line inspection of the product during packaging should regularly include at least the following checks:*

I – *General appearance of the packaging;*

II – *If the packages are complete;*

III – *If the products are being used and the correct packaging materials;*

IV – *Is the impressions made are correct and*

V – *Monitors the correct functioning of the packaging line.*

Sole Paragraph. *The samples in the packaging line to on-line inspection should not return to the packaging process without proper evaluation.*

Article 278. *The products involved in abnormal occurrences during the packing procedure should only be reintroduced after being subjected to inspection, investigation and approval by a designated person.*

Sole Paragraph. *Detailed records of such transactions should be kept.*

Article 279. *Any discrepancy, significant or unusual, observed during reconciliation of the amount of bulk, of printed packaging materials and the number of packaged units, should be investigated and satisfactorily justified before the batch is released.*

Article 280. *Upon completion of each operation, all packaging materials encoded with the lot number used must not be destroyed and the destruction process to be registered.*

Sole Paragraph. *For uncoded printed materials are returned to stock, written procedures must be followed.*

CHAPTER XVII – GOOD QUALITY CONTROL PRACTICES

Article 281. *Quality Control is responsible for activities related to sampling, specifications and testing as well as organization, documentation and release procedures which ensure that the tests are performed and the materials and finished products are not approved until their quality has been judged satisfactory.*

Sole Paragraph. *Quality Control should not be summarized to laboratory operations, must participate and be involved in all decisions that may relate to product quality.*

Article 282. *The independence of quality control in relation to production is key.*

Article 283. *Each manufacturer (the holder of a manufacturing authorization) should have a Quality Control department.*

§ 1 *The Quality Control Department must be under the responsibility of a person with appropriate qualifications and experience, which has one or several control laboratories at his disposal.*

§ 2 *Should be available adequate resources to ensure that all quality control activities are carried out with efficiency and reliability.*

§ 3 *The basic requirements for quality control are as follows:*

I – *Adequate facilities, trained personnel and approved procedures should be available for sampling, inspection and analysis of raw materials, packaging materials, intermediate products, bulk and finished products. When necessary, procedures should be approved for environmental monitoring;*

II – *Samples of raw materials, packaging materials, intermediate products, bulk and finished products*

should be collected by procedures approved by qualified personnel by Quality Control;
III – *Should be performed and qualifications required validations related to quality control;*
IV – *Must be made records (manual or electronic) showing that all sampling procedures, inspection and tests were actually performed and that any deviations have been properly recorded and investigated;*
V – *Finished products should possess the quantitative and qualitative composition as described in the record, the components must have the required purity, must be in appropriate containers and properly labeled;*
VI – *Should be recorded the results of analysis carried out in materials and intermediate products, bulk and finished;*
VII – *No batch of product must be approved prior to the assessment of conformity with the specifications contained in the record person(s) designated(s) and*
VIII – *Should be retained sufficient samples of raw materials and products to allow a future analysis, the product retained must be kept in its final packaging, unless the package is exceptionally large.*
Article 284. *Quality control has other duties as establish, validate and implement all quality control procedures, evaluate, maintain and store the reference standards, ensure proper labeling of reagents, standards and other materials for its use, ensure that the stability of the active ingredients and medicines should be monitored, participate in the investigation of complaints regarding the quality of the product and participate in environmental monitoring.*
Sole Paragraph. *All these operations must be conducted in accordance with written procedures and, where necessary, recorded.*
Article 285. *The quality control personnel must have access to production areas for sampling and research.*
Section I – Raw Materials and Intermediate, Bulk and Finished Products Control
Article 286. *All tests should follow written procedures and approved.*
Sole Paragraph. *The results should be verified by the head before materials or products are released or rejected.*
Article 287. *Samples should be representative of the batch of material which have been removed, according to written procedures and approved.*
Article 288. *Sampling should be done to prevent the occurrence of contamination or other adverse effects on the quality of the product sampled.*
Sole Paragraph. *The containers must be identified and sampled carefully closed after sampling.*
Article 289. *During sampling care must be taken to prevent contamination or mix the material being sampled.*
§ 1 *All equipment used in sampling and coming into contact with the materials must be clean.*
§ 2 *Some particularly hazardous or potent materials require special precautions.*
Article 290. *The equipment used in the sample must be clean and, if necessary, sterilized and stored separadamentedos other laboratory equipment.*
Article 291. *Each sample container should be identified and contain the following information:*
I – *The name of the sampled material;*
II – *The batch number;*
III – *the number of the container from which the sample was taken;*
IV – *The number of the sample;*
V – *The signature of the person responsible for the collection and*
VI – *The date of sampling.*
Article 292. *The out of specification results obtained during testing of materials or products should be investigated in accordance with an approved procedure.*
Sole Paragraph. *Investigations should be completed, corrective and preventive measures taken and records kept.*
Section II – Tests Required Raw Materials and Packaging Materials
Article 293. *Before the raw materials and packaging materials are released for use, responsible for quality control should ensure that these have been tested for compliance with specifications.*
Article 294. *Tests must be performed to identify the samples from all containers of raw materials.*
Article 295. *It is permissible to sample only a portion of the volumes when a supplier qualification procedure has been established to ensure that no amount of raw material has been incorrectly labeled.*
§ 1 *The qualification should consider at least the following aspects:*
I – *The nature and classification of the manufacturer and the supplier and its degree of compliance with the requirements of Good Manufacturing Practices;*
II – *The system of quality assurance of the manufacturer of raw materials;*
III – *The conditions under which raw materials are produced and controlled and*
IV – *The type of raw material and in what drug product is used.*
§ 2 *With this qualification, it is possible exemption from identification test on samples taken from each container of raw material in the following cases:*
I – *Raw materials from a single production facility, or*
II – *Raw materials sourced directly from the manufacturer or in manufacturer's sealed containers, in which there would be a credible history and also regular audits performed in the quality assurance system at the manufacturer's quality.*
§ 3 *The exemption provided in the preceding paragraph does not apply to the following cases:*
I – *The raw materials supplied by intermediaries such as importers and distributors, when the manufacturer is unknown or not audited by the manufacturer of the drug;*
II – *The raw materials fractionated and*

III – *The raw materials used for parenteral products. Article 296. Each batch of printed packaging material should be inspected before use.*

Article 297. *In lieu of quality control tests, the manufacturer may accept the certificate of analysis issued by the supplier, provided that its reliability is established by means of periodic evaluation of the results presented and audits on its facilities, which does not exclude the need to carry out the identification test.*

§ 1 *Certificates issued by the supplier must be original and have their authenticity assured.*

§ 2 *The certificates must contain the following information:*

I – *Vendor identification, signature of authorized officer;*

II – *The name and batch number of the tested material;*

III – *Description of the specifications and methods used and*

IV – *Description of test results and the date that has been made.*

Section III – Process Control

Article 298. *Process control records must be kept, which should be part of the batch documentation.*

Section IV – Finished Products

Article 299. *For batch release, compliance with the specifications established by laboratory tests should be ensured.*

Article 300. *Products that do not meet established specifications should be rejected.*

Section V – Reference Samples

Article 301. *The retained samples from each batch of finished product should be kept for at least 12 (twelve) months after the due date, except for Large Volume Parenteral Solutions (LVPS), which must be preserved for at least thirty (30) days after the due date.*

§ 1 *The finished products should be kept in their final packaging and stored under recommended conditions.*

§ 2 *If the product is packed in large, exceptionally samples can be stored in recipientesmenores with the same characteristics and stored under recommended conditions.*

§ 3 *The samples of active substances must be retained for at least one year after the expiration of the term of validity of the final products which have given rise.*

§ 4 *Samples of other raw materials (excipients), except solvents, gases and water must be retained for at least two years after the expiration date, if you allow their stability studies performed by the manufacturer of the raw material.*

§ 5 *The quantities of samples of materials and products should be retained sufficient to permit to be made at least two full scans.*

Section VI – Stability Studies

Article 302. *Quality control should evaluate the quality and stability of finished products and, where necessary, of raw materials, intermediate products and bulk.*

Article 303. *Should be established expiration dates and specifications on the basis of stability tests related to storage conditions.*

Article 304. *Should be developed and implemented a written program of study of stability, including the following:*

I – *Complete description of the product involved in the study;*

II – *All parameters of the methods and tests, which should describe the testing procedures of power, purity, physical, microbiological testing (where applicable), as well as documented evidence that the tests are indicators of the stability of the product;*

III – *Prediction regarding the inclusion of a sufficient number of lots;*

IV – *Test schedule for each product;*

V – *Instructions for special storage conditions*

VI – *Instructions regarding the proper retention of samples and*

VII – *A summary of all data obtained, including the assessment and the conclusions of the study.*

Article 305. *The stability of a product shall be determined prior to marketing and should be repeated after any significant changes in production processes, equipment, packaging and other materials that may influence the stability of the product.*

TITLE III – STERILE PRODUCTS

Article 306. *The guidelines presented here do not replace any previous section, but they reinforce specific points on the manufacture of sterile preparations in order to minimize the risk of contamination by pyrogenic, non-viable or viable particles.*

CHAPTER I – GENERAL CONSIDERATIONS

Article 307. *The production of sterile preparations should be carried out in clean areas, the entry of personnel and materials must be made through the antechambers.*

Sole Paragraph. *The areas must be kept within appropriate standards of cleanliness and ventilation systems should contain filters using proven.*

Article 308. *The various operations involved in the preparation of materials (eg: Containers and closures), the preparation of the product, packaging and sterilization should be carried out in separate areas within the area clean.*

Article 309. *Manufacturing operations are divided into two categories: first, where the products are sterilized terminalmentee the second, where part or all process steps are conducted aseptically.*

CHAPTER II – QUALITY CONTROL

Article 310. *The collected samples for sterility testing should be representative of the entire lot and/or sub-lot should be given special attention to parts of*

the plot representing higher risk of contamination, such as:

I – *Products that have gone through the process aseptic filling – samples should include containers from the beginning and end of the batch and also after any significant interruption of work and*

II – *Products that have been sterilized by heat in their final packaging – samples should include containers of areas potentially cooler at load.*

Article 311. *The sterility test carried out in the final product should only be considered as one of the last control measures used to ensure the sterility of the product.*

Article 312. *The sterility of the finished products is ensured by validation of the sterilization cycle, in the case of terminally sterilized products and through simulation with culture media for aseptically manufactured products.*

§ 1 *The batch documentation and records of environmental monitoring should be considered together with the results of sterility tests.*

§ 2 *The sterility test procedure should be validated for each product.*

§ 3 *The pharmacopoeial methods should be used for the validation and performance of the sterility test.*

Article 313. *For injectable products, water for injection, intermediate products and finished products should be monitored for endotoxins, using an pharmacopeial method that has been validated for each product.*

§ 1 *For large volume parenteral solutions, such monitoring of water or intermediates should also be done in addition to the tests required by the approved monograph of the finished product.*

§ 2 *When a sample is failing a test, the cause of failure should be investigated and corrective actions taken when necessary.*

Article 314. *The lots that were not approved in the initial test of sterility can not be approved based on a second test, unless an investigation is conducted and the results clearly demonstrate that the initial test was not valid.*

Sole Paragraph. *The investigation should include, inter alia, the type of microorganism found, the records on the environmental conditions and the processing of lots, as well as records and laboratory procedures used in the initial test.*

CHAPTER III – SANITATION

Article 315. *The sanitation of clean areas is particularly important in the manufacture of sterile products.*

§ 1 *These areas should be cleaned and sanitized frequently, according to a specific program approved by Quality Assurance.*

§ 2 *The areas should be monitored regularly to detect the emergence of resistant microorganisms.*

§ 3 *In view of the limited efficacy of ultraviolet radiation, this should not be used as a substitute for chemical disinfection operations.*

Article 316. *Disinfectants and detergents should be monitored for possible contamination, its effectiveness must be proven, the dilutions should be kept in previously cleaned containers and should not be stored for long periods of time, unless they are sterilized.*

§ 1 *The partially emptied containers should not be completed.*

§ 2 *Disinfectants and detergents used in grade A and B areas should be sterilized before use or have proven their barrenness.*

Article 317. *There must be a microbiological control of the various classes of clean areas during operation.*

§ 1 *When aseptic operations are performed, monitoring should be frequent and methods such as sedimentation plates, volumetric air sampling and surface (eg: swabs and contact plates) should be used.*

§ 2 *The areas should not be contaminated by the sampling methods used.*

§ 3 *The results of monitoring should be reviewed for release of the finished product.*

§ 4 *Surfaces and personnel should be monitored after the completion of critical operations.*

Article 318. *Limits should be set alert and action for the detection of microbiological contamination and for monitoring trends of air quality in the facility.*

Sole Paragraph. *Limits expressed in colony-forming units (CFU) for the microbiological monitoring of clean areas in operation are described in Table 1 at ANNEX.*

CHAPTER IV – MANUFACTURE OF STERILE PREPARATIONS

Article 319. *The clean areas for the manufacture of sterile products are classified according to their environmental conditions.*

§ 1 *Each manufacturing step requires an appropriate environmental condition "in operation" to minimize the risk of microbiological contamination and particles from the product or the materials used.*

§ 2 *To achieve the conditions "in operation", the areas must be designed to achieve certain specified levels of air purity in the condition "at rest". The condition "at rest" is defined as one where the installation is finished, the production equipment installed and running, but there are no people present. The condition "in operation" is defined as one in which the area has been in operation for a transaction set and a specified number of people present.*

§ 3 *The clean areas used in the manufacture of sterile products are classified into four different levels, namely:*

I – *Grade A: operating high-risk area, for example, filling and aseptic connections. Usually these operations must be performed under unidirectional flow. The unidirectional flow systems should provide a homogeneous air speed of approximately 0.45m/s ± 20% in the working position;*

II – *Grade B: in areas surrounding the grade A for aseptic preparation and filling and*

III – *Grade C and D: Clean areas where they are carried out less critical stages in the manufacture of sterile products.*

§ 4 *The classification of air to the four grades is given in Table 2 at Annex.*

§ 5 *To reach grades B, C and D, the number of air changes should be appropriate to the size of the room, the equipment in that area and the number of people working for it.*

§ 6 *The number of exchanges total air area must be at least 20 changes/hour in a room with a standard of adequate air flow and high efficiency filters for particle retention parameters (HEPA – High Efficiency Particulate Air).*

§ 7 *The different classification systems for clean rooms particles are shown in Table 3 at Annex.*

Article 320. *The condition "at rest" described in Table 2 should be achieved after completion of operations, in the absence of staff and after a short recovery period.*

§ 1 *The condition "in operation" for the grade should be kept within the immediate vicinity of the product when it is exposed to the environment.*

§ 2 *There may be difficulty in demonstrating compliance with air classification at the point of filling during this operation due to the formation of particles/droplets from the product itself.*

Article 321. *Limits should be set alert and action for microbiological monitoring and particulate matter.*

Sole Paragraph. *If the limits are exceeded, corrective actions must be taken in accordance with the operating procedures described.*

Article 322. *The degrees of each production area are specified in the following items and should be selected by the manufacturer based on the nature of the process and the corresponding validation.*

Section I – Products Terminally Sterilized

Article 323. *The materials and most products should be prepared in at least a grade D environment to be achieved low microbial and particulate counts, suitable for filtration and sterilization.*

Sole Paragraph. *When the product is subject to a high risk of microbial contamination (eg: by being highly susceptible to microbial growth, needs to be maintained for a long period before sterilization, or is not processed in closed containers), the preparation should be made environment in degree C.*

Article 324. *The packaging of terminally sterilized products must be done in an environment at least grade C.*

Sole Paragraph. *When the product is subject to a risk of contamination by the environment (eg: slow process of filling containers with a large aperture or exposure of more than a few seconds before closing), the filling should be performed in the Grade A, surrounded by an area at least grade C.*

Article 325. *The preparation of sterile products, that is, ointments, creams, suspensions and emulsions, as well as the fillings of their containers must be transported, in general, grade C environment before terminal sterilization.*

Section II – Aseptic Preparation

Article 326. *The materials should be handled in an environment at least grade D after washing.*

Article 327. *The handling of raw materials and sterile, unless subjected to sterilization or sterilizing filtration, should be performed in an environment surrounded by a Grade A Grade B environment*

Article 328. *The preparation of solutions that are sterilized by filtration through the process should be conducted in an area at least grade C.*

Sole Paragraph. *If the solutions were not sterilized by filtration, the preparation of materials and products should be in an environment surrounded by a Grade A Grade B environment.*

Article 329. *The handling and filling of aseptically prepared products, as well as handling equipment previously sterilized must be done in a grade A environment, surrounded by an environment grade B.*

Article 330. *The transfer of partially closed containers, such as those used in freeze drying should be performed in the environment surrounded by Grade A Grade B until completely closed, or the transfer is to occur in closed trays in a grade B environment.*

Article 331. *The preparation and filling of ointments, creams, suspensions and emulsions should be sterile environment in Grade A, Grade B surrounded by the environment when the product is exposed and is not subsequently filtered.*

Section III – Production

Article 332. *Precautions should be taken to minimize contamination during all stages of production, including the steps prior to sterilization.*

Article 333. *Preparations containing live microorganisms can not be produced or bottled in the areas used for the production of other drugs.*

Sole Paragraph. *Vaccines made with inactivated organisms or bacterial extracts can be filled, after inactivation, the same facilities of other drugs, since the inactivation and cleaning procedures are validated.*

Article 334. *Validation of aseptic processing should include the simulation of using culture media.*

§ 1 *The shape of the culture medium used should generally be equivalent to the pharmaceutical form of the product.*

§ 2 *The process simulation should imitate as faithfully as possible the routine operations, including all subsequent critical stages.*

§ 3 *The worst-case conditions should be considered in the simulation.*

§ 4 *The simulation should be repeated at regular intervals and whenever significant changes in equipment and processes.*

§ 5 *The number of containers used in a simulation with culture medium must be sufficient to ensure the reliability of the assessment.*

§ 6 *For small batches, the number of containers used*

in the simulation must be at least equal to the size of the batch of product.

Article 335. *Care must be taken so that the validation process does not negatively influence the production processes.*

Article 336. *The sources of water supply, the water treatment equipment and treated water should be monitored regularly for the presence of chemical and biological contaminants, when appropriate, should also be done to control endotoxins, in order that water meet specifications suitable for their use.*

Sole Paragraph. *Records must be kept of monitoring results and the measures in case of deviation.*

Article 337. *The activities carried out in clean areas should be kept to a minimum, especially when aseptic operations are being performed.*

§ 1 *The movement of people should be methodical and controlled in order to avoid an excessive shedding of particles and microorganisms.*

§ 2 *The temperature and humidity of the environment should not be uncomfortably high because of the nature of the uniforms used.*

Article 338. *The presence of containers and materials that generate particles in clean areas should be minimized and avoided completely when aseptic process being carried out.*

Article 339. *After the final process of cleaning or sterilization, handling of components, bulk product containers and equipment should be made so that these are not contaminated again.*

Sole Paragraph. *Each step in the processing of components, bulk product containers and equipment should be properly identified.*

Article 340. *The interval between washing, drying and sterilization of components, containers of bulk goods and equipment, as well as the interval between sterilization and use, should be as small as possible and be subject to a time limit appropriate storage conditions validated.*

Article 341. *The time between the start of preparation of a particular solution and its sterilization should be minimized.*

Sole Paragraph. *There shall be a maximum time allowed for each product that takes into account its composition and method of storage recommended.*

Article 342. *All gas that comes into direct contact with product, as designed to assist in the process of filtration or filling solutions, should be submitted to sterilizing filtration.*

Sole Paragraph. *The integrity of critical gas filters and air must be confirmed after use.*

Article 343. *The bioburden of products should be monitored before sterilization.*

Sole Paragraph. *Should be established a maximum contamination prior to sterilization, which is related to the efficiency of the method used and the risk of contamination by pyrogenic substances.*

Article 344. *All solutions, especially the large volume parenteral solutions should be subjected to filtration to reduce bioburden, if possible immediately before the filling process.*

Article 345. *When aqueous solutions are placed in sealed containers, pressure compensating the holes must be protected, for example, with hydrophobic filters that prevent the passage of microorganisms.*

Article 346. *Components, bulk product containers, equipment and/or any other items needed in the clean area where aseptic activities are being developed should be sterilized and, wherever possible, transferred to the cleaned areas through a double-door sterilizers built into the wall.*

Sole Paragraph. *Other procedures used in order not to introduce contaminants into the clean area may be acceptable in some circumstances (eg: triple wrapping).*

Article 347. *Any new manufacturing procedure must be validated to prove its effectiveness.*

Sole Paragraph. *Validation should be repeated at regular intervals or when significant changes are made in the process or equipment.*

CHAPTER V – STERILISATION

Article 348. *When possible, products should preferably be sterilized by heat in their final container.*

Sole Paragraph. *When using the method of heat sterilization is not possible due to the instability of the formulation, an alternative method must be used preceded by filtration and/or aseptic process.*

Article 349. *Sterilization can be done by applying dry or moist heat, by irradiation with ionizing radiation, other gaseous sterilizing agents or by sterilizing filtration with subsequent aseptic filling of sterile final containers.*

Sole Paragraph. *Each method has its limitations and special applications. When possible and practicable, the choice of method must be the heat sterilization.*

Article 350. *Microbiological contamination of raw materials should be minimal and their bioburden should be monitored when the need for this has been indicated.*

Article 351. *All sterilization processes must be validated considering different loads.*

§ 1 *The sterilization process must match the declared in the technical report of the Product Registration.*

§ 2 *Should be given special attention when used sterilization methods are inconsistent with those described in pharmacopoeias or other official compendia and when used for the sterilization of products other than simple aqueous or oily.*

Article 352. *Before the adoption of any sterilization process, its effectiveness and suitability must be demonstrated by means of physical tests (including tests of distribution and heat penetration) and the use of biological indicators, in the sense that the conditions are met sterilization desired at all points of each type of load to be processed.*

§ 1 *The process should be subject to periodic revalidation, at least annually and whenever significant*

changes have been made in the load to be sterilized or equipment.

***§ 2** The results should be recorded.*

***Article 353.** For effective sterilization, all material must be submitted to the treatment required and the process should be planned to ensure effective sterilization.*

***Article 354.** The biological indicators should be considered only as an additional method for monitoring sterilization processes. They should be stored and used in accordance with the instructions of the manufacturer and their quality checked by positive controls. If used, strict precautions must be taken to avoid microbial contamination from them.*

***Article 355.** Should be set clear ways to differentiate the products and materials that have been sterilized from those who were not.*

***§ 1** Each container, tray or other carrier of products or materials shall be clearly labeled with the name of the material or product, its batch number and indicate whether or not sterilized.*

***§ 2** Where appropriate, can be used indicators such as autoclave tape to indicate whether a batch (or batches) was or was not subjected to the sterilization process, however, these indicators do not provide reliable information showing that the lot was in fact sterile.*

***Article 356.** Records shall be maintained for each sterilization cycle.*

***Sole Paragraph.** Records shall be approved as part of the batch release procedure.*

Section I – Terminal Sterilisation

SubSection I – Heat Sterilization

***Article 357.** Each heat sterilization cycle must be registered with the appropriate equipment with suitable accuracy and precision (eg: a graph of time/temperature with a large enough scale).*

***§ 1** The temperature should be recorded from a probe installed at the coldest point of the sterilization chamber, a point determined during the qualification process.*

***§ 2** The temperature should be checked, preferably against a second independent temperature sensor located in the same position.*

***§ 3** The records of the sterilization cycle should be part of the batch documentation. § 4 may also be used chemical and biological indicators, these should not replace the physical controls.*

***Article 358.** There should be enough time for the entire load reaches the required temperature, before measurements are started from the time of sterilization.*

***Sole Paragraph.** The time must be determined for each type of load to be processed.*

***Article 359.** After the phase of maximum temperature of the heat sterilization cycle, precautions should be taken to prevent the contamination of sterilized load during the cooling phase.*

***Sole Paragraph.** Any fluid or gas used in the cooling phase that comes into direct contact with the product or material should not be a source of contamination.*

SubSection II – Humid Heat Sterilization

***Article 360.** Sterilization by humid heat is indicated only in the case of material permeable to vapor and aqueous solutions.*

***§ 1** The temperature and pressure must be used to monitor the process.*

***§ 2** The probe temperature recorder must be independent of the probe used by the controller of the autoclave and there should be a temperature indicator, which read during the sterilization process should be routinely checked by comparison with the values obtained in the graph.*

***§ 3** In the case of autoclaves that have a drain at the bottom of the sterilization chamber, you must also record the temperature in this position throughout the sterilization process.*

***§ 4** When a vacuum phase is part of the sterilization cycle should be made airtight periodic controls of the camera.*

***Article 361.** The materials to be sterilized (if products are not in sealed containers) should be wrapped in materials that allow air removal and steam penetration, but to avoid recontamination after sterilization.*

***Sole Paragraph.** All parts of the load of the autoclave must be in contact with saturated steam or water, the temperaturaexigida and throughout the stipulated time.*

***Article 362.** It should be ensured that the steam used for sterilization is of suitable quality to the process and not containing additives in amounts which may cause contamination of the product or equipment.*

SubSection III – Dry Heat Sterilisation

***Article 363.** Sterilization by dry heat may be appropriate for non-aqueous liquids or powders.*

***§ 1** The process of dry heat sterilization should include forced air circulation inside the sterilization chamber and maintaining positive pressure in order to prevent the entry of non-sterile air.*

***§ 2** If air is inserted into the chamber, it must be filtered through filter microbial retention.*

***§ 3** When the process of sterilization by dry heat is also used to remove pyrogens, tests must be conducted using endotoxin as part of validation.*

SubSection IV – Radiation Sterilisation

***Article 364.** The radiation sterilization is used mainly in materials and heat-sensitive products. On the other hand, many drugs and some packaging materials are sensitive to radiation.*

***§ 1** This method should only be applied when there are no harmful effects to the product, proven experimentally.*

***§ 2** The ultraviolet radiation is not an acceptable method of sterilization.*

***Article 365.** If radiation sterilization is performed by*

contract with third parties, the manufacturer has the responsibility to ensure that the requirements of the preceding Article are met and that the sterilization process is validated.

Sole Paragraph. *The responsibilities of the radiation plant operator (eg: use the correct dose) should be specified.*

Article 366. *During the process of sterilizing doses of radiation used must be measured.*

§ 1 *Should be used dosimeters that are independent of the applied dose and indicating the actual amount of radiation doses received by the product.*

§ 2 *The dosimeters should be included in the load in sufficient number and so close to each other to ensure that there is always a dosimeter in the radiation chamber.*

§ 3 *Where plastic dosimeters are used, these should also be used within the allotted time for their calibrations.*

§ 4 *The values of the absorption readings of dosimeters should be done soon after exposure to radiation.*

§ 5 *The biological indicators can only be used as a means of additional control.*

§ 6 *Coloured discs sensitive to radiation can be used to identify packages that have been subjected to radiation from those that were not, these can not be considered as indicators of sterility assurance.*

§ 7 *All information obtained during the process must be recorded in the batch documentation.*

Article 367. *The effects of variations in the density of the material to be sterilized must be considered in the validation of the sterilization process.*

Article 368. *The procedures for handling the materials should ensure that there is no possibility of mixing between the products irradiated and non irradiated.*

Sole Paragraph. *Each package must have a radiation sensitive indicator to identify those that were irradiated.*

Article 369. *The total radiation dose should be applied for a period of pre-established time.*

SubSection V – Sterilization by Gases and Fumigants

Article 370. *The methods of sterilization gases or fumigants should be used only when no other method available.*

Article 371. *Various gases and fumigants may be used for sterilization (eg: ethylene oxide, hydrogen peroxide vapor).*

Sole Paragraph. *Ethylene oxide should be used only when no other method is applicable.*

Article 372. *During the validation process must be established that no adverse effects on the product and that the ventilation time is enough for the waste gas and the reactive products are below the limit set as acceptable for this product. These limits should be incorporated into specifications.*

Article 373. *It must be ensured direct contact between gas and microorganisms.*

§ 1 *Precautions should be taken to avoid the presence of organisms that may be contained in materials such as crystals or dried protein.*

§ 2 *The nature and quantity of packaging materials can significantly affect the process.*

Article 374. *Before being submitted to the action of the gas, the material shall achieve and maintain a balance with the temperature and humidity required by the process.*

Sole Paragraph. *The time used in this process should be considered in order to minimize the time before the sterilization.*

Article 375. *Each sterilization cycle should be monitored with suitable biological indicators, appropriate in number, spread over the whole load.*

Sole Paragraph. *The records should be part of the batch documentation.*

Article 376. *The biological indicators should be stored and used according to manufacturer's instructions and its performance should be checked by positive controls.*

Article 377. *For each sterilization cycle, records should be kept the duration of the sterilization cycle, pressure, temperature and humidity inside the chamber during the process and the concentration of gas used.*

§ 1 *The pressure and temperature must be recorded in the chart throughout the cycle.*

§ 2 *The records should be part of the batch documentation.*

Article 378. *After sterilization, the load should be stored in a controlled manner under ventilated conditions, so that the residual gas and the reactive products present to decay to acceptable levels.*

Sole Paragraph. *This process must be validated.*

Section II – Sterilization and Aseptic Process Filtration

Article 379. *The aseptic process must maintain the sterility of a product which is prepared from components, which were sterilized by one of the methods mentioned above.*

Sole Paragraph. *The operating conditions should prevent microbial contamination.*

Article 380. *During the aseptic process must be given special attention to the following items in order to maintain the sterility of the components and products:*

I – *The environment;*

II – *Staff;*

III – *Areas critical;*

IV – *Sterilization procedures and the transfer of containers/lids;*

V – *The maximum period of storage of the product before filling and*

VI – *The sterilizing filter.*

Article 381. *Certain solutions and liquids, which can not be sterilized in their final containers, can be filtered into previously sterilized containers, previously sterilized through filters (according to manufactu-*

rer's recommendations), with specific pore size of 0.2 milimicra (or less), it is essential that the documentation that has been properly subjected to bacterial challenge.

Sole Paragraph. *The filters can remove bacteria and fungi, but may allow the passage of certain minute organisms (eg: mycoplasma). The filter must be validated to prove that effectively sterilizes the product in real process conditions, without causing harmful changes in its composition.*

Article 382. *Due to the potential risk of additional filtration method as compared with other sterilization processes, we recommend use of redundant sterilizing filters (two filters in series) or an additional sterilizing filter immediately before filling.*

Sole Paragraph. *The sterilizing filters can be single or double layer.*

Article 383. *The final sterilizing filtration should be performed as close to the filling point.*

Article 384. *Should not be used to filter fibers.*

Sole Paragraph. *The use of asbestos filters should be absolutely excluded.*

Article 385. *The integrity of the filter should be checked by an appropriate method, such as the bubble point test, diffusive flux or retention test/decline of pressure immediately after use. It is also recommended testing the integrity of the filter prior to use.*

§ 1 *The parameters for the integrity test (wetting liquid, gas test, pressure test, temperature test, criterion deaprovação etc..) Sterilizing filter for each specific procedure must be described. These parameters must be correlated with the bacterial challenge test performed previously and this correlation must be documented.*

§ 2 *If the product itself is used as a wetting liquid, the study of development of the test parameters of integrity must be documented.*

Article 386. *The integrity of critical filters should be confirmed after use. Filters are considered critical for everyone to filter fluid that come into direct contact with the product (eg: gas filters, air filters, breather tanks). It is also recommended testing the integrity of these filters before use.*

§ 1 *The integrity of other sterilizing filters should be confirmed at appropriate intervals.*

§ 2 *Should be considered a more rigorous monitoring of filter integrity in processes involving drastic conditions, such as the circulation of air at high temperature.*

Article 387. *The time of filtration as well as all other operating conditions such as temperature, differential pressure, volume, batch, physico-chemical etc. should have been considered in the validation of sterilizing filtration.*

§ 1 *Any significant differences in relation to the process parameters considered in the validation should be recorded and investigated.*

§ 2 *The results of these checks should be recorded in the batch documentation.*

Article 388. *The same filter should not be used for more than a day's work, unless such use has been validated.*

Article 389. *The filter should not affect the product, its ingredients by removing or adding other substances.*

Section III – Personnel

Article 390. *Only the required minimum number of people must be present in clean areas, this is particularly important during aseptic processes. If possible, inspections and controls should be conducted outside these areas.*

Article 391. *All staff (including cleaning and maintenance) to develop activities in these areas should receive initial and regular training in disciplines relevant to the production of sterile products, including reference to issues of personal hygiene, basic concepts of microbiology and the correct procedures to scrub areas clean.*

Sole Paragraph. *If you need a ticket in those areas of people who have not received training, tomados-cuidados must be specific as to the supervision of the same.*

Article 392. *Employees who are participating in activities related to production of substrate in animal tissue or cultures of microorganisms other than those used in the manufacturing process under way, should not enter the production areas of sterile products, unless they are applied procedures previously established decontamination.*

Article 393. *The adoption of high standards of personal hygiene and cleanliness is essential. People involved in the manufacture of drugs should be instructed to report to his superior any change in his health condition, which can contribute to the spread of contaminants.*

§ 1 *It is recommended to carry out periodic health examinations.*

§ 2 *The actions to be taken with respect to people who might be introducing undue microbiological hazards should be taken by a competent person designated to do so.*

Article 394. *The clothes for personal use should not be brought into clean areas.*

§ 1 *Those who enter the locker room these areas may already be uniform with the factory default.*

§ 2 *The process of changing clothes and washing should follow written procedures designed to minimize contamination of the area cleared of scrub or the introduction of contaminants into clean areas.*

Article 395. *The watches and jewelry should not be used in clean areas, as well as cosmetics that can shed particles.*

Article 396. *The clothes used must be appropriate to the classification process and clean the area where staff are working and should be observed:*

I – *Grade D: hair, beard and mustache should be covered. It should use protective clothing and shoes suitable for the area or protective footwear. Appropriate*

measures should be taken to avoid contamination from external areas;

II – *Grade C: hair, beard and mustache should be covered. Appropriate clothing should be worn, tied on the wrist and turtleneck. The clothing can not release fibers or particles. In addition, closed shoes should be used to own the area or protective footwear and*

III – *Grades A/B: should be used hood that completely covers the hair, beard and mustache; its lower edge should be placed into the garment. Should be used face mask in order to prevent them from being scattered drops of sweat. Sterile gloves should be worn rubber, dust and boots disinfected or sterilized. The bars must be placed the pants into the boots and put the sleeves into the gloves. Protective clothing should not hold any fiber or particle and should retain particles released by the body of whom are using.*

Article 397. *The clothes for personal use should not be brought to the areas of scrub which give access to the areas of grades B and C.*

Article 398. *All employees who are working in rooms A and B grade should be given clean clothes and sterilized each work session.*

Article 399. *Gloves should be regularly disinfected during operations, as well as masks and gloves changed every work session.*

Article 400. *The clothes used in clean areas should be washed or cleaned, to avoid the release of contaminants in areas where they will be used.*

§ 1 *It is recommended to have a laundry room dedicated exclusively to this type of clothing.*

§ 2 *Clothing damaged by use can increase the risk of particle release.*

§ 3 *The cleaning and sterilization of clothes should follow the Standard Operating Procedures – SOPs.*

§ 4 *The use of disposable clothing may be necessary.*

Section IV – Facilities

Article 401. *All facilities, whenever possible, should be designed to avoid unnecessary entry of supervisory personnel and control.*

Sole Paragraph. *Grade B areas should be designed such that all operations can be observed from outside.*

Article 402. *In clean areas, all exposed surfaces shall be smooth, impervious, to minimize the accumulation or release of particles or microorganisms, allowing the repeated application of cleaning agents and disinfectants, where appropriate.*

Article 403. *To reduce dust accumulation and facilitate cleaning in clean areas should not exist surfaces that can not be cleaned.*

§ 1 *The facility should have minimal ledges, shelves, cabinets and equipment.*

§ 2 *The gates must be designed to avoid the existence of surfaces that cannot be cleaned; sliding doors should not be used.*

Article 404. *The liners must be sealed so that contamination is avoided from the space above them.*

Article 405. *Pipes, ducts and other utilities must be installed so as not to create spaces that are difficult to clean.*

Article 406. *The sinks and drains, where possible, should be avoided and should not exist in areas A/B where aseptic operations are being performed.*

§ 1 *When you need to be installed must be designed, located and maintained to minimize the risk of microbial contamination, must contain traps efficient, easy to clean and are adequate to prevent reflux of air and liquids.*

§ 2 *The channels in the soil, if present, must be open, easily cleanable and be connected to drains outside, so that the introduction of microbial contaminants is avoided.*

Article 407. *Changing rooms clean areas should be designed in the form of closed vestibules and used to allow the separation of different stages of change of clothes, thus minimizing microbial contamination and particles arising from protective clothing.*

§ 1 *The dressing rooms must be inflated effectively with filtered air.*

§ 2 *The use of separate changing rooms and out of clean areas may be necessary on some occasions.*

§ 3 *The facilities for hand hygiene should be located only in the dressing room, never in the places where aseptic operations are carried out.*

Article 408. *The two antechambers doors can not be simultaneously open and there should be a system that prevents it does occur.*

Sole Paragraph. *There should be an alarm system, audible and/or visual alert to the situation indicated.*

Article 409. *The clean areas should have a ventilation system that blows air filtered and maintains a positive pressure areas in relation to the surrounding areas.*

§ 1 *The ventilation should be efficient and responsive to conditions.*

§ 2 *The adjacent rooms of different grades should have a pressure differential of approximately 10 – 15 pascals (reference value).*

§ 3 *Special attention should be given to areas of highest risk, where the filtered air comes in contact with the products and components clean.*

§ 4 *May be necessary for the various recommendations regarding air supplies and pressure differentials are to be modified if necessary containment pathogenic, highly toxic, radioactive material or live virus or bacterial.*

§ 5 *In some operations may require the use of facilities for decontamination and treatment of the air exiting the area clean.*

Article 410. *It must be demonstrated that the air system poses no risk of contamination.*

Sole Paragraph. *It should be ensured that the air system does not allow the spread of particles originated from people, equipment or operations for the production areas of greatest risk.*

Article 411. *An alarm system should be installed to indicate the occurrence of failures in the ventilation system.*

§ 1 *Should be placed an indicator of the pressure differential between the areas where this difference is important.*

§ 2 *The pressure differences should be recorded regularly.*

Article 412. *Should be avoided unnecessary access of materials and people to critical areas.*

Sole Paragraph. *When necessary, the access must be achieved through physical barriers.*

Section V – Equipments

Article 413. *Should not be used conveyor belts that interlock areas clean grade A or B grade to areas with lower air classification, unless the conveyor belt itself is continuously sterilized (eg: a tunnel sterilizer).*

Article 414. *Where possible, equipment used in the production of sterile products should be chosen so that they can be sterilized by steam, dry heat or by another method.*

Article 415. *Whenever possible, the provision of equipment and utilities must be designed and installed so that maintenance and repair can be made from outside the clean areas.*

Sole Paragraph. *The equipment required to be removed for maintenance should be re-sterilized after being reassembled where possible.*

Article 416. *When maintenance equipment is made within cleared areas shall be used for instruments and tools also cleaned/disinfected.*

Sole Paragraph. *If the required standards of cleanliness and/or aseptic areas have not been maintained during the maintenance service, the areas must be cleaned and disinfected so that production is resumed.*

Article 417. *All equipment, including sterilizers, filtration systems for air and water production systems, must undergo a periodic maintenance plan, validation and monitoring.*

Sole Paragraph. *Shall be documented for approval to use the equipment after maintenance.*

Article 418. *The treatment facilities and water distribution should be designed, constructed and maintained to ensure the reliable production of water of appropriate quality.*

§ 1 *The system should not be operated beyond their capacity.*

§ 2 *Should be considered a forecast of program monitoring and maintenance of the water system.*

§ 3 *The water for injection should be produced, stored and distributed in order to prevent the growth of microorganisms.*

Section VI – Completion of Manufacturing Steps

Article 419. *Containers should be sealed through appropriate procedures, properly validated.*

§ 1 *Samples must be checked for its integrity according to established procedures.*

§ 2 *In the case of closed containers under vacuum, the samples must be checked to verify the maintenance of the vacuum period of time as predetermined.*

Article 420. *The final containers containing parenteral products should be inspected individually.*

§ 1 *If the inspection is visual, should be done under suitable and controlled conditions of light and contrast.*

§ 2 *The operators for this work should be subjected to periodic tests of visual acuity, considering corrective lenses, if any and take frequent rest breaks during working hours.*

§ 3 *If you use other methods of inspection, the process must be validated and the performance of the equipment shall serverificado periodically. The results should be recorded.*

Section VII – Isolator Technology

Article 421. *The use of isolator technology to minimize human intervention in the areas of production can result in a significant decrease in the risk of microbiological contamination from the environment in aseptically prepared products.*

Sole Paragraph. *To achieve this goal, the isolator should be designed, engineered and installed so that the air inside has the quality required for the process.*

Article 422. *The entry and removal of insulation materials are the primary sources of contamination. Therefore, there must be procedures for conducting these operations.*

Article 423. *The air classification required for the environment surrounding the isolator depends on its design and its implementation.*

Sole Paragraph. *The environment must be controlled and for aseptic processes must be rated for at least a grade D.*

Article 424. *The insulators should only be used after validation. The validation should consider all the critical factors of isolator technology, for example, the internal and external quality of the insulator, sanitation, transfer process and integrity of the insulator material.*

Article 425. *The monitoring should be routinely performed and should include leak testing of the isolator and glove/sleeve.*

Section VIII – Blow/Fill/Seal Technology

Article 426. *The blower/filling/sealing equipment is designed to, in continuous operation, containers formed from thermoplastic pellets, bottle and seal.*

§ 1 *Equipment blowing/filling/sealing used for aseptic operations, which are provided with a supply air system Grade A, can be installed in at least grade C environment, provided they are used for clothing grade A/B.*

§ 2 *The environment should comply with the limits of viable and nonviable particles.*

§ 3 *The equipment blowing/filling/sealing used in the production of terminally sterilized products must be installed in an environment in the least degree D.*

Article 427. *The following minimum requirements must be met:*

I – *Design and equipment qualification;*

II – *Validation and reproducibility of spot cleaning and sterilizing them in place;*

III – *Classification of cleaning the area where the equipment is installed;*
IV – *Training and clothing of operators and*
V – *The areas most critical equipment including any aseptic assembly prior to the start of the filling.*

TITLE IV – BIOLOGIC PRODUCTS

CHAPTER I – SCOPE
Article 428. *The purpose of this title is to supplement the "Good Manufacturing Practices of Drugs", reinforcing specific points on the manufacture of biological products.*
Article 429. *The regulatory procedures necessary to control biological products are largely determined by the origin of the products and the manufacturing technologies used.*
Sole Paragraph. *The fabrication procedures contained in this resolution include medications whose assets were obtained through:*
I – *Growth of strains of microorganisms and eukaryotic cells;*
II – *Extraction of substances from biological fluids or tissues of human origin, animal or plant (allergen);*
III – *Recombinant DNA techniques (rDNA);*
IV – *Hybridoma technique and*
V – *Multiplication of microorganisms in embryos or animals.*
Article 430. *Organic products manufactured using these technologies include allergens, antigens, vaccines, hormones, cytokines, enzymes, derived from human plasma, hyperimmune sera (heterologous), immunoglobulins (including monoclonal antibodies), fermentation products (including products derived from rDNA).*

CHAPTER II – GENERAL CONSIDERATIONS
Article 431. *The manufacture of biological products must be in accordance with the basic principles of Good Manufacturing Practices (GMP). As a result, the points covered in this title are considered complementary to the general rules set forth in "Practice for the Manufacture of Drugs" and relate specifically to the production and quality control of biological products.*
Article 432. *The way organic products are produced, controlled and administered make certain precautions necessary. Unlike conventional pharmaceuticals, which are usually manufactured and controlled reproducible chemical and physical techniques, biological products are manufactured with technologies and processes involving biological materials subject to variability.*
Article 433. *The production of biological processes have an intrinsic variability and therefore the nature of the products is not constant. For this reason, the manufacture of biological products is even more critical compliance with the recommendations established by GMP during all stages of production.*
Article 434. *The quality control of biological products nearly always involves the use of biological techniques that have a greater variability than physicochemical determinations. The control during the process of great importance in the production of biological products because certain quality deviations can not be detected in quality control tests performed in the finished product.*

CHAPTER III – PERSONNEL
Article 435. *During working hours, staff should not move from areas where microorganisms or manipulate live animals for installations where you work with other products or organizations, unless they apply clearly defined decontamination measures, including the exchange of uniforms and footwear.*
Article 436. *The personnel assigned to the production must be distinguished from personnel responsible for animal care.*
Article 437. *All personnel involved directly or indirectly in the production, maintenance, control and animal rooms should be immunized with specific vaccines and, when necessary, subjected to periodic tests for signs of infectious diseases.*
Article 438. *When you make BCG vaccines, access to production areas should be restricted to personnel carefully monitored by periodic medical examinations.*
Article 439. *In the case of the manufacture of blood products or plasma, should staff be immunized with the vaccine against hepatitis B.*

CHAPTER IV – FACILITIES AND EQUIPMENTS
Article 440. *You should avoid the spread of airborne pathogens manipulated microorganisms in production.*
Article 441. *The areas used for processing animal tissues and microorganisms not used in the production process, as well as for the tests with animals or microorganisms must be separated from premises used for the production of sterile biological products, with separate ventilation systems and separate staff.*
Article 442. *In areas used for the production of campaigning, the design and layout of facilities and equipment should permit effective cleaning and sanitizing after the production and, where necessary, decontamination through sterilization and/or fumigation. All processes used must be validated.*
Article 443. *The live microorganisms should be handled in equipment and procedures that ensure the maintenance of the purity of cultures, as well as protect the operator from contamination with the microorganism.*
Article 444. *Organic products such as vaccines with dead microorganisms, toxoids, extracts of bacteria, including those prepared by recombinant DNA techniques may, once inactivated, be filled in the same facilities used for other products, provided they take appropriate measures for decontamination after filling including cleaning and sterilization.*
Article 445. *Organic products from spoilage micro-*

organisms should be handled in facilities unique to this product group until they finish the process of inactivation.

***§ 1** When in an installation or group of facilities in preparations of spoilage microorganisms, should be produced only one product at a time.*

***§ 2** In the case of Bacillus anthracis, Clostridium botulinum and Clostridium tetani, at all stages should be segregated and dedicated facilities used exclusively for each of these products.*

***Art 446.** The viral inactivation steps up to the manufacture of products derived from human blood or plasma should be performed in facilities and equipment used exclusively for that purpose.*

***§ 1** After the viral inactivation, can be filled in the same facilities used for other sterile products, provided they take appropriate measures for decontamination after filling, including cleaning and sterilization.*

***§ 2** All processes used must be validated and the risk must be assessed.*

***Article 447.** Cross-contamination should be avoided by adopting the following measures, if applicable:*

***I –** Carry out production and filling in segregated areas;*

***II –** Prevent the production of different products at the same time, unless they are physically segregated areas;*

***III –** Transferring biological materials safely;*

***IV –** Change of clothing when in the different productive;*

***V –** Thoroughly clean and decontaminate equipment;*

***VI –** Take precautions against the risks of contamination caused by recirculation of air in the clean environment for the return or accidental air removed;*

***VII –** Using "closed systems" in production;*

***VIII –** To take precautions to prevent aerosol formation (especially by centrifugation and mixtures);*

***IX –** Prohibit the entry of samples of pathological specimens not used in the production process in the areas used for the production of biological substances and*

***X –** Use sterile containers and, where appropriate, microbial load containers with downloaded documents.*

***Article 448.** The preparation of sterile products should be performed in a clean area with positive pressure air.*

***Sole Paragraph.** All organisms considered pathogens should be handled with negative air pressure, especially in places reserved for this purpose, according to the standards of insulation for the product in question.*

***Article 449.** The areas where pathogenic microorganisms are handled must be unique system of air circulation and this should not be recirculated.*

***§ 1** The air must be eliminated through sterilizing filters whose operation and efficiency must be checked periodically.*

***§ 2** The filters used should be incinerated after disposal.*

***Article 450.** When pathogenic microorganisms are used in production, there must be specific systems for the decontamination of effluents.*

***Article 451.** The pipes, valves and vent filters and equipment must be designed so as to facilitate cleaning and sterilization.*

CHAPTER V – FACILITIES FOR ANIMALS

***Article 452.** The animals used in the production and quality control should be housed in facilities separate from other company areas that have independent ventilation systems.*

***Article 453.** The design of facilities and construction materials used should permit the maintenance of areas in hygienic conditions and have protection against entry of insects and other animals.*

***Article 454.** The people who work with animals should use clothing for the exclusive use of the area.*

***Article 455.** Facilities for animal care shall include isolation area for animals entering quarantine and area suitable for storing food.*

***Article 456.** There must be adequate facilities for inoculation of animals.*

***Sole Paragraph.** This activity should be done in an area separate from those where there are dead animals.*

***Article 457.** There should be facility for disinfection of cages, if possible, with steam sterilization.*

***Article 458.** It is necessary to monitor and record the health status of animals used.*

***Article 459.** Special precautions are required when using monkeys in the production or quality control.*

***Article 460.** The handling, storage, transport, treatment and disposal of waste generated by animals, including waste and carcasses must be done safely and follow specific regulations.*

TITLE V – VALIDATION

CHAPTER I – INTRODUCTION

***Art 461.** Validation is an essential part of Good Manufacturing Practices (GMP) and an element of quality assurance associated with a product or process in particular.*

***§ 1** The basic principles of quality assurance have as their objective the production of products suitable for their intended use. These principles are:*

***I –** The quality, safety and efficacy must be designed and defined for the product;*

***II –** The quality can not be inspected or tested the product and*

***III –** Each critical step of the manufacturing process must be validated. Other stages of the process must be controlled so that products are consistently produced and that meet all the specifications and quality requirements.*

***§ 2** The validation of processes and systems is fundamental to achieving the goals. It is through the design and validation that a manufacturer can esta-*

blish confidence that the manufactured products will consistently meet their specifications.
§ 3 *The documentation associated with validation includes:*
I – *Standard Operating Procedures (SOP);*
II – *Specifications;*
III – *Validation Master Plan (PMV);*
IV – *Protocols and reports for qualification and*
V – *Protocols and validation reports.*

CHAPTER II – RELATION BETWEEN VALIDATION AND QUALIFICATION
Art 462. *Validation and qualification are essentially components of the same concept.*
§ 1 *The term qualification is normally used for equipment, utilities and systems, as applied to the validation process.*
§ 2 *The qualification constitutes a part of the validation.*

CHAPTER III – VALIDATION
Section I – Approaches to Validation
Article 463. *There are two basic approaches to validation – one based on evidence obtained through testing (prospective and concurrent validation) and one based on analysis of historical data (retrospective validation).*
§ 1 *Where possible, prospective validation is preferred.*
§ 2 *The retrospective validation is no longer encouraged and is not applicable to the manufacture of sterile products.*
Article 464. *The concurrent validation and prospective validation may include:*
I – *Extensive testing of the product, which may involve extensive sampling (with the estimated confidence limits for individual results) and the homogeneity within and between batches;*
II – *Simulating the conditions of case;*
III – *Testing challenge/worst case, which determine the robustness of the process and*
IV – *Control of process parameters monitored during normal production runs to obtain additional information about the reliability of the process.*
Section II – Scope of Validation
Article 465. *There should be an efficient and appropriate, including organizational structure and documentation suficientee personal financial resources for carrying out validation on time.*
Sole Paragraph. *The Management and persons responsible for Quality Assurance should be involved.*
Article 466. *Those responsible for carrying out validation must have appropriate experience and qualifications and represent different departments depending on the validation work to be performed.*
Article 467. *There should be a specific program for the validation activities.*
Article 468. *The validation shall be performed in a structured manner, in accordance with documented procedures and protocols.*
Article 469. *The validation should be performed:*
I – *For facilities, equipment, utilities (eg: water, air, compressed air, steam), systems, processes and procedures;*
II – *At periodic intervals and*
III – *When major changes are introduced.*
Sole Paragraph. *Requalification may be revalidated or replaced, where appropriate, regular assessment of data and information.*
Article 470. *The validation shall be performed according to written protocols.*
Sole Paragraph. *In the end, should be a report of the validation.*
Article 471. *The validation shall be conducted during a period of time, for example, until they are evaluated at least three consecutive batches (industrial scale) to demonstrate process consistency. Situations of "worst case" should be considered.*
Article 472. *There should be a clear distinction between process control and validation.*
Sole Paragraph. *The control process includes tests performed during production of each lot in accordance with specifications and procedures in the development phase, in order to monitor the process continuously.*
Article 473. *When a new manufacturing formula or method is adopted, should be taken to demonstrate its suitability to the routine process.*
Sole Paragraph. *The defined process, using materials and equipment specified, should result in consistent performance of a quality product required.*
Article 474. *Manufacturers should identify what is necessary to validate to prove that the critical aspects of their operations are under control.*
§ 1 *Significant changes in facilities, equipment, systems and processes that may affect product quality should be validated.*
§ 2 *A risk assessment should be used to determine the scope and extent of validation.*

CHAPTER IV – QUALIFICATION
Article 475. *The qualification must be complete before the validation to be conducted.*
Sole Paragraph. *The qualification process must constituirse in systematic and logical as well as be initiated by the design phases of plant, equipment and utilities.*
Article 476. *Depending on the function and operation of equipment, utility or system, in certain situations, only if required to do the installation qualification (IQ) and operational qualification (OQ) and the correct operation of equipment, utilities or systems can be considered a sufficient indicator of its performance (DR).*
Sole Paragraph. *The equipment, utilities and systems should be periodically monitored and calibrated and is undergoing preventive maintenance.*
Article 477. *Major equipment and critical utilities and systems, require the installation qualification (IQ), operation (OQ) and performance (DR).*

CHAPTER V – CALIBRATION AND VERIFICATION

Article 478. *The calibration and verification of equipment, instruments and other devices used in the production and quality control should be performed at regular intervals.*

Article 479. *The staff responsible for carrying out the calibration and preventive maintenance should have appropriate training and qualification.*

Article 480. *A calibration program must be available and should provide information such as calibration standards and limits, designated persons, calibration intervals, records and actions to be taken when problems are identified.*

Article 481. *The standards used in calibration must be traceable to the Brazilian Calibration Network.*

Article 482. *The equipment, instruments and other devices calibrated should be labeled, coded or otherwise identified to indicate calibration status and date of the next recalibration.*

Article 483. *When the equipment, instrument or other device is not used for a certain period of time, its state of operation and calibration should be checked prior to use in order to demonstrate satisfactoriness.*

CHAPTER VI – MASTER VALIDATION PLAN

Article 484. *The MVP should contain the key elements of the validation program. It should be concise and clear and contain at least:*

I – *A validation policy;*

II – *Organizational structure of validation activities;*

III – *Summary/list of facilities, systems, equipment and processes that are validated and still should be validated (current situation and programming);*

IV – *Model documents (eg: protocol model and report) or reference to them;*

V – *Planning and scheduling;*

VI – *Change control and*

VII – *References to other existing documents.*

CHAPTER VII – QUALIFICATION E VALIDATION PROTOCOLS

Article 485. *There should be qualification and validation protocols describing the studies to be conducted.*

Article 486. *The protocols shall include at least the following information:*

I – *Study objectives;*

II – *Local/plant where the study will be conducted;*

III – *Responsibilities;*

IV – *Description of procedures to be followed;*

V – *Equipment to be used, standards and criteria for relevant products and processes;*

VI – *Validation Type;*

VII – *Processes and/or parameters;*

VIII – *Sampling, testing and monitoring requirements and*

IX – *Acceptance criteria.*

Article 487. *There should be a description of how the results of the qualification and validation studies will be analyzed.*

Article 488. *The protocol must be approved before the actual validation. Any change in the protocol must be approved before being adopted.*

CHAPTER VIII – QUALIFICATION E VALIDATION REPORTS

Article 489. *Reports should be drafted qualifications and validations performed.*

Article 490. *The reports should reflect the protocols followed and include at least the title, the objective of the study, as well HOWTO reference to the Protocol, details of materials, equipment, programs and cycles used and also the procedures and methods that were used.*

Article 491. *The results should be evaluated, analyzed and compared with previously established acceptance criteria.*

§ 1 *The results must meet the acceptance criteria.*

§ 2 *Deviations and results outside the limits should be investigated by the company.*

§ 3 *If deviations are accepted, must be justified.*

§ 4 *Where necessary, additional studies should be conducted.*

Article 492. *Departments responsible for the qualification and validation work should approve the full report.*

Article 493. *The conclusion of the report should clearly stating that the qualification and/or validation was considered successful.*

Article 494. *Quality Assurance must approve the report after the final revision. The criterion for approval shall be in accordance with the system of quality assurance of the company.*

Article 495. *Any deviations found during the validation process should be investigated and documented. Can sernecessárias corrective actions.*

CHAPTER IX – QUALIFICATION STEPS

Article 496. *There are four stages of qualification:*

I – *Design Qualification (DQ);*

II – *Installation Qualification (IQ);*

III – *Operation Qualification (OQ) and*

IV – *Performance Qualification (PR).*

Article 497. *All procedures for operation, maintenance and calibration should be prepared during the qualification.*

Article 498. *Training should be performed by operators and records must be maintained.*

Section I – Design Qualification

Article 499. *The design qualification should provide documented evidence that the design specifications were met according to the user's requirements and Good Manufacturing Practices.*

Section II – Installation Qualification

Article 500. *Installation qualification should provide documented evidence that the installation was completed satisfactorily.*

Article 501. *Purchase specifications, drawings, manuals, parts lists for equipment and vendor details should be verified during installation qualification.*

Article 502. *Control and measurement instruments should be calibrated.*

Section III – Operation Qualification

Article 503. *The operational qualification should provide documented evidence that utilities, systems or equipment and all its components operate in accordance with the operational specifications.*

Article 504. *The tests should be designed to demonstrate satisfactory operation in the normal range of operation, as well as the limits of their operating conditions (including worst-case conditions).*

Article 505. *The operating controls, alarms, switches, panels and other operational components must be tested.*

Article 506. *The measures carried out according to a statistical approach should be thoroughly described.*

Section IV – Performance Qualification

Article 507. *The performance qualification should provide documented evidence that utilities, systems or equipment and all its components show consistent performance in accordance with the specifications for routine use.*

Article 508. *The test results must be collected over a period of time to demonstrate consistency.*

Section V – Requalification

Article 509. *Requalification must be performed according to a set schedule.*

Sole Paragraph. *The frequency of requalification may be determined based on factors such as analysis of results relacionadoscom calibration, verification and maintenance.*

Article 510. *There should be periodic requalification, as well as requalification after changes (such as changes in utilities, systems, equipment, maintenance and displacements).*

Sole Paragraph. *There may be a periodic review program for equipment that provides support for evaluating the frequency of regeneration.*

Article 511. *The need for requalification after changes should be considered by the change control procedure.*

Section VI – Revalidation

Article 512. *Processes and procedures should undergo revalidation to ensure that they remain able to achieve the expected results.*

Article 513. *The need for revalidation after changes should be considered by the change control procedure.*

Article 514. *Revalidation should be done according to a set schedule.*

Article 515. *The frequency and extent of periodic revalidation should be determined based on a risk assessment and review of historical data (program of periodic review).*

Section VII – Periodic Revalidation

Article 516. *Must be revalidated performed to verify the process changes that may occur gradually over a period of time, or wear of equipment.*

Article 517. *When a periodic revalidation is performed, the following should be considered:*

I – *Master formula and specifications;*

II – *Operational procedures;*

III – *Records (eg: calibration records, maintenance and cleaning) and*

IV – *analytical methods.*

Section VIII – Revalidation after Changes

Article 518. *Revalidation after change should be performed when the change may affect the process, procedure, product quality and/or product characteristics.*

Sole Paragraph. *Revalidation should be considered as particle of the change control procedure.*

Article 519. *The extent of revalidation depends on the nature and significance of the change.*

Article 520. *The changes should not adversely affect product quality or process characteristics.*

Article 521. *Changes requiring revalidation should be defined in the validation plan and may include:*

I – *Change of starting materials (including physical properties such as density, viscosity or particle size distribution, which affect the process or product);*

II – *Change in manufacturer of raw materials;*

III – *Transfer to another process plant (including change of facilities that influence the process);*

IV – *Changes to the primary packaging material (eg: substituting plastic for glass);*

V – *Changes in the manufacturing process (eg: mixing times, drying temperatures);*

VI – *Changes in equipment (eg: addition of automatic detection systems, installation of new equipment, major revisions of machinery or apparatus and breakdowns);*

VII – *Changes in the production and support systems (eg: rearrangement of areas, new water treatment method);*

VIII – *Appearance of negative quality trends;*

IX – *Appearance of new findings based on current knowledge (eg: new technologies) and*

X – *Changes to support systems.*

Sole Paragraph. *Changes of equipment which involve the replacement of equipment with an equivalent usually do not require revalidation. For example, a new centrifugal pump that is replacing an older model does not necessarily imply in revalidation.*

CHAPTER X – CHANGE CONTROL

Article 522. *The company should establish a management system changes in order to keep under control the changes that will impact on qualified equipment and systems, as well as processes and procedures already validated, may or may not influence the quality of manufactured products.*

Article 523. *The procedure should describe the actions to be taken, including the need and extent of qualification or validation to be performed.*

Article 524. *The changes must be formally requested, documented and approved before implementation. Records must be maintained.*

CHAPTER XI – PERSONNEL

Article 525. *It must be demonstrated that personnel are appropriately qualified, where relevant.*

Article 526. *Personnel requiring qualification include, for example:*

I – *Laboratory analysts;*

II – *Personnel responsible for execution of critical procedures;*

III – *Personnel responsible for performing data entry into computer systems and*

IV – *Risk assessors.*

TITLE VI – WATER FOR PHARMACEUTICAL USE

CHAPTER I – GENERAL REQUIREMENTS FOR WATER SYSTEM FOR PHARMACEUTICAL USE

Article 527. *Systems of production, storage and distribution of water for pharmaceutical use should be planned, installed, validated and maintained to ensure the production of water of appropriate quality.*

§ 1 *The patches should not be operated beyond its planned capacity.*

§ 2 *The water must be produced, stored and distributed in order to prevent microbiological contamination, chemical or physical.*

Article 528. *Any unplanned maintenance or modification must be approved by Quality Assurance.*

Article 529. *Water sources and treated water should be monitored regularly for chemical and microbiological quality.*

§ 1 *The performance purification systems, storage and distribution should be monitored.*

§ 2 *The records of monitoring results and actions taken should be maintained for a defined period of time.*

Article 530. *The degree of water treatment must consider the nature and intended use of intermediate or finished product, as well as step in the production process in which water is used.*

Article 531. *When chemical sanitization of the water systems is particle of biofouling control program, a procedure must be used to ensure that the sanitizing agent was removed effectively.*

CHAPTER II – SPECIFICATIONS OF WATER QUALITY

Section I – Potable Water

Article 532. *Drinking water should be supplied under continuous positive pressure in a plumbing system free of defects that can lead to contamination of any product.*

Article 533. *Tests should be performed periodically to confirm that the water meets the required standards for drinking water.*

Section II – Purified Water

Article 534. *Purified water must meet the specifications of pharmacopoeias accepted by ANVISA.*

Article 535. *The water purification system must be designed to prevent microbiological contamination and proliferation.*

Section III – Water for Injectables

Article 536. *Water for injection must comply with the specifications of pharmacopoeias accepted by ANVISA.*

Article 537. *Water for Injection should be used in preparation of sterile products.*

Sole Paragraph. *Water for injection should also be used in the final rinse after cleaning of equipment and components that come into contact with sterile products.*

Article 538. *The steam, when contacting a sterile product in its final container or equipment for the preparation of sterile products, must meet the requirements for water for injection, when condensed.*

CHAPTER III – METHODS OF WATER PURIFICATION

Section I – Genral Considerations

Article 539. *The chosen method of purifying water, or sequence of purification steps should be appropriate to the application in question.*

Sole Paragraph. *The following items should be considered when selecting the method of water treatment:*

I – *The specification of water quality;*

II – *Performance or efficiency of the purification system;*

III – *The quality of water supply and seasonal changes and*

IV – *The reliability and robustness of water treatment equipment in operation.*

Article 540. *The specifications for the equipment for water purification, storage and distribution systems should consider the following:*

I – *Risk of contamination from contact materials bleaches;*

II – *Adverse impact of absorbable material contact;*

III – *A project that allows sanitize the system, when required;*

IV – *Corrosion resistance;*

V – *Be free of leaks;*

VI – *Configuration to avoid microbial proliferation;*

VII – *Tolerance to cleaning and sanitizing agents (thermal and/or chemical);*

VIII – *Capacity system and production requirements and*

IX – *Installation of all instruments, sampling points needed to allow all critical parameters are monitored dosistema.*

Article 541. *The design, layout and design of water purification equipment and systems for storage and distribution should also consider the following physical variables:*

I – *Available space for installation;*

II – *Structural loads on buildings;*

III – *Access appropriate maintenance and*

IV – *The ability to handle regeneration chemicals and sanitizing chemical safely.*

Section II – Production of Potable Water

Article 542. *The quality of drinking water should be monitored routinely.*

§ 1 *Additional tests should be performed if there is any change in source of raw water in treatment techniques or system configuration.*

§ 2 *If the quality of drinking water significantly change, the direct use of water in pharmaceutical processes, or as feed water for the later stages of treatment should be reviewed and the outcome of the review should be documented.*

Article 543. *Where drinking water is derived from a proprietary system for the treatment of raw water, the water treatment steps used and system configuration should be documented.*

Sole Paragraph. *The changes in the system or its operation should not be made until the review is complete and the change is approved by Quality Assurance.*

Article 544. *Where drinking water is stored and distributed storage systems should allow for maintenance of water quality prior to use.*

§ 1 *After any storage, testing should be performed according to a defined methodology.*

§ 2 *When the water is stored, its use should ensure a renewal enough to prevent stagnation.*

Article 545. *The equipment and systems used to produce drinking water should allow for drainage and sanitation.*

Sole Paragraph. *Storage tanks should be closed properly protected with respirators and should allow for visual inspection, drainage and sanitation.*

Section III – Production of Purified Water

Article 546. *The following items should be considered when setting up a water purification system:*

I – *The quality of feed water and its seasonal;*

II – *The required specification of water quality;*

III – *The sequence of steps required for purification;*

IV – *The extent of pretreatment required to protect the final steps of purification;*

V – *Performance optimization, including yield and efficiency of the treatment unit;*

VI – *The proper location of sampling points in order to avoid contamination and*

VII – *The adoption of instruments to measure some parameters of the system, eg flow, pressure, temperature, conductivity, pH and total organic carbon.*

Article 547. *Should be assessed regularly for possible microbiological contamination of sand filters, multimedia filters, activated carbon beds and softeners in the case of their existence.*

§ 1 *Should be taken to control contamination, such as backwash, chemical or thermal sanitization and frequent regeneration in order to avoid contamination of the system and biofilm formation.*

§ 2 *One should consider all components of water treatment are maintained with continuous flow to inhibit microbial growth.*

Article 548. *Mechanisms must be adopted for microbiological control and sanitization systems for purified water maintained at room temperature, because these are particularly susceptible to microbial contamination, especially when the equipment remain static during periods of little or no demand for water.*

Section IV – Production of Water for Injectables

Article 549. *The following items should be considered when planning a system to produce water for injection:*

I – *The quality of water supply;*

II – *The required specification of water quality;*

III – *Optimizing the size of the water generator in order to avoid frequent starts/stops the system and*

IV – *The functions of discharge and emptying.*

CHAPTER IV – PURIFICATION SYSTEMS, STORAGE AND DISTRIBUTION OF WATER

Section I – General

Article 550. *The storage and distribution system must be configured to prevent recontamination of the water after treatment and should be subjected to a combination of online and offline monitoring to ensure that the appropriate specification of water is maintained.*

Section II – Materials that come in Contact with Water Systems for Pharmaceutical Use

Article 551. *Materials that come in contact with water for pharmaceutical use, including piping, valves and fittings, seals, diaphragms and instruments should be selected to meet the following objectives:*

I – *Compatibility: All materials used must be compatible with temperature and chemicals used by the system or within it;*

II – *Leak Prevention: All materials coming into contact with water for pharmaceutical use can not have leaks within the range of working temperature;*

III – *Resistance to corrosion: the purified water and water for injection are highly corrosive. To avoid system failure and water contamination, the materials selected should be appropriate, the welding process must be carefully controlled and all seals and components must be compatible with the piping used. The system must be submitted to passivation after the initial installation or after modification. When passivation is performed, the system must be thoroughly cleaned before use and the passivation process should be performed in accordance with a documented procedure clearly defined;*

IV – *Smooth internal finish, should be used smooth internal surfaces that help prevent roughness and cracking in the water system for pharmaceutical use;*

V – *Welding, the materials selected system should be easily welded in a controlled manner;*

VI – *Design of flanges or joints, flanges or when used together, they must have sanitary or hygienic design. Should be checked to ensure that the correct seals are used and are correctly fitted and adjusted*

VII – *Documentation: All system components must be fully documented and*

VIII – *Materials: suitable materials should be used that may be considered as elements health system.*

Section III – Sanitation System and Control of Microbial Load

Article 552. *The water treatment equipment and storage and distribution systems used for purified water and water for injection should be designed to prevent microbiological contamination during use and provide the use of means of sanitization or sterilization of the system after maintenance interventions or modification.*

Sole Paragraph. *The techniques used for sanitizing or sterilization should be considered during project planning system and its performance shall be demonstrated during qualification activities.*

Article 553. *Systems that work and are maintained at elevated temperatures in the range of 70-80 ° C, in general, are less susceptible to microbial contamination than systems maintained at lower temperatures.*

Sole Paragraph. *When you require lower temperatures due to water treatment processes employed or the temperature requirements for water use, special precautions must be taken to prevent the entry and proliferation of microbiological contaminants.*

Section IV – Capacity of Storage Containers

Article 554. *The capacity of the storage container should be determined based on the following criteria:*

I – *It is necessary to establish an intermediate capacity between generation capacity of the water system and consumption at different points of use;*

II – *Water treatment equipment should work continuously for significant periods of time to avoid inefficiency and wear, which occurs when the machine is turned on and off frequently and*

III – *The capacity must be sufficient to provide short-term reserve in case of equipment failure or water treatment production of disability due to sanitization or regeneration cycle.*

Section V – Contamination Control for Storage Containers

Article 555. *The following items should be considered for the efficient control of pollution:*

I – *The space between the surface and the tank cover is a risk area in which drops of water and air can come into contact at temperatures that encourage the proliferation of microorganisms;*

II – *The tanks must be configured to avoid dead zones where there may be microbiological contamination;*

III – *Ventilation filters are placed in tanks to allow the internal fluid to float. Filters should retain bacteria, must be hydrophobic and should ideally be configured to permit integrity testing on site. Offline tests are also acceptable and*

IV – *Are used as pressure relief valves and rupture discs in reservoirs to protect them against pressurizaçãoexcessiva, such parts must be of sanitary design.*

Section VI – Requirements for Water Distribution Pipes

Article 556. *The distribution of purified water and water for injection should be performed preferably using a ring of continuous movement.*

Sole Paragraph. *The proliferation of contaminants within the storage tank and distribution of the ring should be controlled.*

Article 557. *The filter should not be used in rings or distribution points use to control biofouling. Such filters can mask contamination of the system.*

Article 558. *When heat exchangers are used to heat or cool water for pharmaceutical use within a system, precautions must be taken to prevent the heating or cooling equipment contaminate water.*

Article 559. *The circulation pumps must have sanitary design to avoid system contamination.*

Article 560. *The use of biofouling control techniques should be considered in isolation or together, to avoid the use of water outside of the established specifications.*

CHAPTER V – OPERATIONAL CONSIDERATIONS

Section I – Qualification

Article 561. *All water systems for pharmaceutical use are considered critical systems and quality of direct impact, so they must be qualified.*

Article 562. *The qualification process must follow procedures previously written and approved. The data must be properly recorded and reviewed for approval.*

Article 563. *Should be considered in the qualification process possible seasonal variations that may affect the quality of water for pharmaceutical use.*

Section II – Continuous System of Monitoring

Article 564. *Upon completion of the qualification of the water system should be conducted review of data, corrective actions taken and adequacy of operational procedures, if necessary. After review, a plan must be established for routine monitoring.*

Article 565. *Monitoring should include a combination of online monitoring of process parameters, as well as offline testing to verify compliance with microbiological and chemical specifications.*

§ 1 *The samples should be collected from offline points of use and specific sampling points.*

§ 2 *The samples of the points of use should be collected in a manner similar to that adopted when the water is being used.*

Article 566. *Tests should be performed to ensure compliance with pharmacopoeial specification.*

Article 567. *Should be performed trend analysis of monitoring data.*

CHAPTER VI – MAINTENANCE OF WATER SYSTEMS

Article 568. *There shall be a maintenance program of water system, which consider the following:*

I – *Defined frequency for system equipment and instruments;*

II – *Calibration program;*

III – *Procedures for specific tasks;*

IV – *Control of parts to be used;*

V – *Schedule and maintenance instructions;*

VI – *Registration, review and approval of the service performed and*

VII – *Record and review of problems and faults during maintenance.*

CHAPTER VII – SYSTEM REVIEWS

Article 569. *The systems of water (purified water and water for injection) should be reviewed at regular intervals appropriate.*

§ 1 *The review team should include representatives from engineering, quality assurance, operations and maintenance.*

§ 2 *The review should consider topics such as:*

I – *Changes made since the last revision;*

II – *System Performance;*

III – *Reliability;*

IV – *Quality trends;*

V – *Failure;*

VI – *Investigations;*

VII – *Results out of specification obtained during monitoring;*

VIII – *Changes at the facility;*

IX – *Documentation update installation;*

X – *Books, records and*

XI – *A situation the current list of operational procedures.*

TITLE VII – COMPUTERIZED INFORMATION SYSTEM

Article 570. *The introduction of a computerized information system in the production chain, including storage, distribution and quality control does not relieve the need for other items to meet the standard.*

§ 1 *When computer systems replace manual operations, there can be no impact on product quality.*

§ 2 *Should consider the risk of losing quality aspects of the previous system by reducing the involvement of operators.*

Article 571. *There must be cooperation between key staff and the people responsible for computer system.*

§ 1 *The people in positions of responsibility must have training for the management and use of systems that are under their responsibility.*

§ 2 *It must be ensured that people with necessary knowledge is available to advise on aspects of design, development, validation and operation of the computer system.*

Article 572. *The extent of validation depends on a number of factors, including the intended use of the system, the type of validation to perform (retrospective, concurrent and prospective) and insertion of new elements.*

Article 573. *The validation shall be considered particle of the life cycle of a computer system, comprising the steps of planning, specification, programming, testing, documentation, operation, monitoring, maintenance and change.*

Article 574. *Computerized systems should be installed in locations where external factors do not interfere with its operation.*

Article 575. *There should be a detailed documentation of the system and this should be kept updated. This description could include diagrams of the system and its technological infrastructure (hardware, software, etc.).*

Sole Paragraph. *Should be described in the principles, objectives, safety items, range of the system and its main characteristics of use, interface with other systems and procedures.*

Article 576. *The software is a critical component of the computerized system. The user of the computer system must ensure that all steps of software construction were performed according to the system of quality assurance.*

Article 577. *The system should include, where applicable, verification of data entry and processing.*

Article 578. *Before you start using a computerized system, you should test and confirm the system's ability to store the desired data, providing the technological infrastructure necessary for their full operation.*

Sole Paragraph. *When there is a replacement manual for a computerized system, the two must work in paralelocomo of the testing and validation.*

Article 579. *The inputs and data modifications can be made only by authorized persons.*

§ 1 *must be taken not to allow unauthorized persons to include, exclude or modify data in the system and can be used safety measures such as use of passwords, personal code, access profiles, keys, or restricted access to the system terminals.*

§ 2 *Should be established a procedure for access management, setting to issue, cancel and change the passwords of people who are no longer allowed to enter or change data in the system, including changing the password.*

§ 3 *Should be preferred systems to record the attempted access by unauthorized persons.*

Article 580. *When critical data are entered manually (eg: weighing value, lot number of a heavy input) should be a further conference to ensure the accuracy of data entered.*

Sole Paragraph. *The conference may be held by a second operator or by validated electronic means.*

Article 581. *The system must record the identification of operators entering or confirming critical data. Permission to change the data must be restricted.*

§ 1 *Any alteration of critical data should be documented, describing the reason for the change.*

§ 2 *When there is a change of data, the records must be kept of all entries, changes, users and dates.*

Article 582. Changes to systems or programs should be conducted in accordance with procedures and methodologies of systems development.

§ 1 *The procedures should define the validation, verification, approval and implementation of change.*

§ 2 *Any amendment must be recorded and implemented only with the consent of the person responsible for part of the system involved.*

§ 3 *Any significant changes must be validated.*

Art 583. *In the case of quality audits should be possible to obtain printed copies of electronically stored data.*

Art 584. *The data must be stored securely by physi-*

cal or electronic means against accidental or intentional damage.
§ 1 *The stored data should be checked for accessibility, durability and accuracy.*
§ 2 *If proposed change in equipment or software mentioned checks should be performed at a frequency appropriate to the storage medium in use.*
Art 585. *Data should be protected by performing backups (backup) at regular intervals.*
§ 1 *The backup data must be stored for a set time and place separate and safe.*
§ 2 *There must be procedures to ensure the process of restoration and maintenance of data backup.*
§ 3 *Missing data should be treated as deviations.*
Article 586. *There must be alternatives to the systems that are in operation, in case of incidents on their operation.*
§ 1 *The time required to implement the use of these alternatives should be related to the possible urgency of the need to use them.*
§ 2 *The information necessary to effect a recall must be available in a short time.*
Article 587. *The procedures to be followed in case of failure or disruption of system operation must be defined and validated.*
Sole Paragraph. *Any failures and corrective measures taken should be recorded.*
Article 588. *Procedures should be established to record and analyze system errors and allow corrective measures are adopted.*
Article 589. *In the case of contracting for development and maintenance of computer systems should be a formal contract including the responsibilities of the contractor.*
Article 590. *When the release of lots for sale is carried out using the computerized system, the system must recognize that only the person(s) designated(s) can release the batches and it is registered is responsible for performing this operation.*

TITLE VIII – GOOD MANUFACTRIG PRACTICES FOR HERBAL MEDICINES

Article 591. *This title complements the Good Manufacturing Practice for Medicinal Products, considering the need for specific targeting of control of herbal medicines.*
Sole Paragraph. *This title deals exclusively with herbal medicines and does not cover the combination of plant materials with the animal and mineral sources, isolated active substances, among others.*

CHAPTER I – GENERAL CONSIDERATIONS
Article 592. *Due to the inherent complexity of medicinal plants, production and processing directly influence the quality of herbal medicines.*
Sole Paragraph. *The application of Good Manufacturing Practices for Herbal Medicines is an essential tool to ensure product quality.*

CHAPTER II – QUALITY ASSURANCE
Article 593. *Besides the use of appropriate analytical techniques for characterizing the herbal medicines, quality assurance also requires the control of herbal raw materials and analytical processes and methodologies validated.*
Sole Paragraph. *An appropriate system of quality assurance should be applied in the manufacture of herbal medicines.*

CHAPTER III – SANITATION AND HYGIENE
Article 594. *Due to its origin, the herbal materials may contain microbiological contaminants.*
Sole Paragraph. *To avoid changes and reduce any kind of contamination, it is necessary to an adequate level of sanitation and hygiene at all stages of the manufacturing process.*

CHAPTER IV – VALIDATION
Article 595. *The company must provide technical justification for the determination of the tests to be used during the cleaning and validation process.*

CHAPTER V – SELF INSPECTION
Article 596. *At least one self-inspection team member should have experience and/or technical qualifications in the area of herbal medicines.*

CHAPTER VI – PERSONNEL
Article 597. *The release of herbal medicines to the market must be authorized by a person who has experience and technical expertise in specific aspects of processing and quality control of herbal medicine.*

CHAPTER VII – TRAINING
Article 598. *All personnel involved in the manufacture must have adequate and regular training on Good Manufacturing Practices and in areas of expertise, appropriated to herbal and medicinal plants.*

CHAPTER VIII – PERSONAL HYGIENE
Article 599. *All personnel involved in manufacturing must be trained in good personal hygiene practices and be protected from contact with raw vegetables potentially allergenic through clothing and appropriate personal protective equipment.*

CHAPTER IX – EQUIPMENTS
Article 600. *The equipments should be sanitized by specific and properly validated cleaning procedures adequated to the process, to avoid contamination.*

CHAPTER X – SAMPLES AND REFERENCE STANDARDS
Section I – Reference Standards for Herbal Drug Identification
Article 601. *In the absence of a monograph containing description of the plant drug in pharmacopoeias recognized by ANVISA, can be used as a reference, the award of identification issued by a qualified profes-*

sional or a description of technical and scientific publication indexed and chromatographic profile or phytochemical prospecting.

Section II – Reference Standard for Quality Control of Active Raw Materials and Herbal Medicines

Article 602. *The benchmark can be a chemically defined substance (eg: a known active component or a marker substance or a class of chemical compounds present in raw plant) or a standard extract.*

§ 1 *Should be used benchmarks officially recognized by the Brazilian Pharmacopoeia or other codes authorized by law, or properly characterized reference standards.*

§ 2 *The standard must be of a quality suitable for this purpose.*

§ 3 *All reference standards should be stored in appropriate conditions to prevent degradation.*

§ 4 *For the benchmark characterized must present report for full analysis, including nuclear magnetic resonance, mass spectrometry (high resolution), infrared, melting point and/or HPLC (purity based on the relative area of peak).*

§ 5 *The extract standard should be referenced against a primary standard for proof of identity and content of the marker.*

CHAPTER XI – DOCUMENTATION

Section I – Specificactions

Article 603. *The specifications for raw materials plants and herbal medicines are intended to define quality and ensure the safety and efficacy. The specifications must include at least the following information when applicable:*

I – *Vegetable raw materials:*

a) *official botanical nomenclature;*

b) *plant particle used;*

c) *identification tests for known active ingredients or markers. A sample of standard should be provided for identification purposes;*

d) *a description based on visual examination (macroscopic) and/or microscopic;*

e) *tests of purity and integrity, including: total ash and/or hydrochloric acid insoluble ash, moisture, loss on drying, search of foreign substances and heavy metals;*

f) *tests for the determination of microbiological contamination, fumigant and pesticide residues, mycotoxins radioactivity and, if applicable;*

g) *other appropriate tests, including residual solvents used in the extraction of the derivative and*

h) *qualitative and quantitative analysis on the active ingredients and/or markers where known, or classes of chemical compounds characteristic of the species.*

II – *Herbal medicines:*

a) *tests for determination of microbiological contamination;*

b) *uniformity of weight, disintegration time, hardness and friability, viscosity, consistency and time of dissolution, where applicable;*

c) *physical appearance such as color, odor, shape, size and texture;*

d) *loss on drying or water content;*

e) *identification tests, qualitative determination of relevant substances from plants (eg: fingerprint chromatograms);*

f) *quantification of markers and analytical methods available and*

g) *limit tests for residual solvents.*

Article 604. *The raw materials derived from plants containing genetically modified organisms must meet specific regulations in force.*

Article 605. *The quality control tests and specifications for herbal medicines should include qualitative and quantitative determination of major active components.*

§ 1 *If the therapeutic activity of constituents is known, this information should be documented.*

§ 2 *Where the therapeutic activity of constituents can not be determined quantitatively, specifications should be based on the determination of markers.*

§ 3 *In both cases the specification of content must be defined.*

Article 606. *When the herbal medicine has associations of plant species in the quantitative determination of a marker by species is not possible, can be displayed chromatographic profile that includes the presence of at least one substance characteristic of each species in medicine, complemented by determination of the least one marker, where it is duly justified.*

CHAPTER XII – QUALITY CONTROL

Article 607. *All quality control personnel must have the knowledge, experience, technical skills and be trained to conduct drug tests on plant, plant-derived drugs and herbal medicines.*

TITLE IX – FINAL AND TRANSITORY DISPOSITIONS

Article 608. *Is granted a period of one year for preparing all protocols and other documents necessary for the validation of computerized systems that are already installed and the completion of the validation studies done within maximum 3 (three) years from the date publication of this resolution.*

Sole Paragraph. *For systems acquired from the date of this resolution, the validation should be performed antesdo its routine use it is applied.*

Article 609. *The Board will publish updates on this resolution, with a view to monitoring the development of new technologies in the pharmaceutical industry.*

Article 610. *Failure to comply with the provisions of this resolution infraction of sanitary nature, in accordance with Law Nº 6437 of August 20, 1977, subjecting the violator to the penalties provided in this statute.*

Article 611. *Are hereby revoked SVS/MS Nº 500 of*

October 9, 1997 and Resolution RDC Nº 210 of August 4, 2003.
Article 612. *This resolution comes into force on the date of its publication.*

DIRCEU BRÁS APARECIDO BARBANO

Registration of Active Pharmaceutical Ingredients

ANVISA Normative Instruction n. 15 and Resolution – RDC n. 57, of November 17th, 2009

NORMATIVE INSTRUCTION N.15, OF NOVEMBER 17TH, 2009

The Collegiate Board of Directors of the Brazilian Sanitary Surveillance Agency, in the use of the attribution vested in it by the Article 11, clause IV, of the Regulation of ANVISA approved by Decree n. 3.029, of April 16, 1999, and in view of what is determined by the proposition II and paragraphs 1st and 3rd of the article 54, and the proposition II of the Article 55 of the Internal Regulation approved by the terms of the Annex I of the ANVISA's Bylaw n. 354, of August 11th, 2006, republished in the Federal Official Journal of August 21, 2006, in meeting held on April 14th, 2009,

• whereas that the health is the people's right and a government commitment, ensuring througout of social and economic policies, the reduction of the illness' risk and other related problems and also the equal and universal access to health actions and services for its promotion, protection and recovery, on the terms of the article 196 of the Federative Republic of Brazil Constitution, of October 5th, 1988;

• whereas that the health actions and services are of the public relevance, in the terms of the article 197 of the Constitution, being the Public Power responsible to make use, in the terms of the law, on its regulamentation, fiscalization and control;

• whereas the dispositions contained in the Law n. 6,360, of September 23rd, 1976, and its Decree n. 79,094, of January 5th,1977, concerning to the sanitary surveilance system which regulates drug products, pharmaceutical ingredients, medical devices and other products;

• whereas the Law n. 6.437, of August 20th, 1977, which defines the violations to the federal sanitary legislation and establishes the respective penalties;

• whereas the Anvisa's institucional purpose to promote the protection of the health for the population and its duty to co-ordinate the National Sanitary Surveilance System, established by the Law n. 9,782 of January 26th, 1999, article n.6 and items I, III and XXII of article n.7;

• whereas the lines of direction, priorities and responsibilities established by the National Drug Policies, enforced by the Bylaw n. 3.916/MS/GM, of October 30th, 1998, that ensures the conditions of safety and quality for the medicines used in the country, promoting the rational use and facilitating the access of the population to those drugs considered essential;

• whereas the dispositions included in the Resolution n. 338, of May 6th, 2004, of the National Council of Health, that approved the National Policies of the Pharmaceutical Assistance, defining the principles and strategies, including the existing pharmaceutical assistance services qualification and the construction of a Sanitary Surveilance Policy that enables the access of the population to services and products, safe, efficient and with quality;

• whereas the Active Pharmaceutical Ingredients Program established by the Resolution – RDC n. 250, of September 13th, 2005;

• whereas the Resolution – RDC n. 30, of May 15th, 2008, that establishes the obligation to register active pharmaceutical ingredients on the Anvisa's cadastre;

• whereas the Bylaw n. 978, of May 16th, 2008, that established the list of strategical products, in the scope of the Unique System of Health, with the purpose of – collaborating with the development of Health Industrial Complex and – the creation of a Commission for Revision and Update of this related list;

• whereas the need to regulate the registration of active pharmaceutical ingredients in Brazil, to improve the quality control of these products in the country and the sanitary requirements to ensure efficacy and safety of the medicines, considering the existence of a specific regulation Resolution RDC n. 57, of November 17th, 2009, that enforces the registration of active pharmaceutical ingredients (IFA – initials in portuguese) and provide other steps,

DECIDE:

Article 1. *It is approved the schedule and priorities for the first stage of the implementation of the active pharmaceutical ingredients (IFA – initials in portuguese), in the terms of the Resolution n. 57, of November 17th, 2009 of the Anvisa Collegiate Board of Directors.*

CHAPTER I – DEFINITION OF THE ACTIVE PHARMACEUTICAL INGREDIENTS (IFA) TO BE SUBMITTED IN THE FIRST STAGE OF THE IMPLEMENTATION OF THE SANITARY REGISTRATION

Article 2. *The following active pharmaceutical ingredients (IFA) will be subject to the first stage of the implementation of the sanitary registration in Anvisa, according to the criteria of priority and other dispositions defined in the Resolution of Collegiate Board of Directors n. 57, of November 17th, 2009:*

I. *Cyclosporin*
II. *Clozapine*
III. *Clindamycin Hydrochloride*
IV. *Cyclophosphamide*
V. *Ciprofloxacin*
VI. *Methotrexate*
VII. *Carbamazepine*
VIII. *Lithium Carbonate*
IX. *Phenytoin*
X. *Phenytoin Sodium*
XI. *Lamivudine*
XII. *Penicilamine*
XIII. *Thiabendazole*
XIV. *Efavirenz*
XV. *Nevirapine*
XVI. *Rifampicin*
XVII. *Ritonavir*
XVIII. *Zidovudine*
XIX. *Acyclovir*
XX. *Ampicillin*

CHAPTER II – TIMELINES FOR COMPLIANCE TO THE FIRST STAGE OF THE IMPLEMENTATION OF THE ACTIVE PHARMACEUTICAL INGREDIENTS (IFA) REGISTRATION

Article 3. *For the active pharmaceutical ingredients (IFA) defined in the Article 2 of the present Normative Instruction, is established that the following periods for the respective adequacy to what is referred in the RDC n. 57 of November 17th, 2009:*

Paragraph 1. *Starting on February 1st, 2010, the companies established in the country which exercise the activities of active pharmaceutical ingredients manufacturing or import will have to submit the request for sanitary inspection to Anvisa for the issuance of the Good Manufacturing Practices of Intermediate Products and Active Pharmaceutical Ingredients Certificate.*

Paragraph 2. *Starting on July 1st, 2010, the companies established in the country which exercise the activities of active pharmaceutical ingredients manufacturing or import included in the scope of this Article, will have to submit the respective request for such ingredients registration to Anvisa.*

Paragraph 3. *It is established that December 30th, 2010 is the last date for the active pharmaceutical ingredients referred by this Normative Instruction, to have its sanitary registration submitted to ANVISA.*

Article 4. *This Resolution enters into force on the date of its publication.*

DIRCEU RAPOSO DE MELLO

ANVISA RESOLUTION – RDC N. 57, OF NOVEMBER 17TH, 2008

The Collegiate Board of Directors of the Brazilian Sanitary Surveillance Agency, in the use of the attribution vested in it by article 11, clause IV, of the Regulation of ANVISA approved by Decree n. 3.029, of April 16, 1999, and in view of what is determined by the proposition II and paragraphs 1st and 3rd of the article 54, of the Internal Regulation approved by the terms of the Annex I of the ANVISA's Bylaw n. 354, of August 11th, 2006, republished in the Federal Official Journal of August 21, 2006, in meeting held on April 14th, 2009,

• whereas that the health is the people's right and a government commitment, ensuring throughout of social and economic policies, the reduction of the illness' risk and other related problems and also the equal and universal access to health actions and services for its promotion, protection and recovery, on the terms of the article 196 of the Federative Republic of Brazil Constitution, of October 5th, 1988;

• whereas that the health actions and services are of the public relevance, in the terms of the article 197 of the Constitution, being the Public Power responsible to make use, in the terms of the law, on its regulamentation, fiscalization and control;

• whereas the dispositions contained in the Law n. 6,360, of September 23rd, 1976, and its Decree n. 79,094, of January 5th,1977, concerning to the sanitary surveilance system which regulates drug products, pharmaceutical ingredients, medical devices and other products;

• whereas the Law n. 6.437, of August 20th, 1977, which defines the violations to the federal sanitary legislation and establishes the respective penalties;

• whereas that the health is a fundamental right for the human being and having the State the responsibility to provide the indispensable condition to its full exercise, as foreseen in the article n. 2 of the Health Organic Law (LOS – initials in portuguese), Law n. 8,080, of September 19th, 1990;

• whereas the Anvisa's institucional purpose to promote the protection of the health for the population and its duty to co-ordinate the National Sanitary Surveilance System, established by the Law n. 9,782 of January 26th, 1999, article n. 6 and items I, III and XXII of article n. 7;

• whereas the lines of direction, priorities and responsibilities established by the National Drug Policies, enforced by the Bylaw n. 3.916/MS/GM, of October 30th, 1998, that ensures the conditions of safety and quality for the medicines used in the country, promoting the rational use and facilitating the access of the population to those drugs considered essential;

• whereas the Resolution n. 338, of May 6th, 2004, of the National Council of Health dispositions, that approved the National Policies of the Pharmaceutical Assistance, defining the principles and strategies, including the existing pharmaceutical assistance ser-

vices qualification and the construction of a Sanitary Surveilance Policy that enables the access of the population to services and products, safe, efficient and with quality;

• *whereas the Resolution – RDC n. 249, of September 13th, 2005, that establishes the Good Manufacturing Practices for Intermediate Products and Pharmaceutical Ingredients;*

• *whereas the Active Pharmaceutical Ingredients Program established by the Resolution – RDC n. 250, of September 13th, 2005;*

• *whereas the Resolution – RDC n. 30, of May 15th, 2008, that establishes the obligation to register active pharmaceutical ingredients on the Anvisa's cadastre;*

• *whereas the Bylaw n. 978, of May 16th, 2008, that established the list of strategical products, in the scope of the Unique System of Health, with the purpose of – collaborating with the development of Health Industrial Complex and – the creation of a Commission for Revision and Update of this related list;*

• *whereas the need to regulate the registration of active pharmaceutical ingredients in Brazil, to improve the quality control of these products in the country and the sanitary requirements to ensure efficacy and safety of the medicines,*

adopts the following Resolution of the Collegiate Board of Directors and I, the Chairman, determine its publication:

Article 1. *Aprove the Technical Regulation for Active Pharmaceutical Ingredients (API) Registration in Brazil, in the terms of the ANNEX of this Resolution.*

Article 2. *The Active Pharmaceutical Ingredients, including the imported ones, after the period of adequacy that article 3 of this resolution, cannot be industrialized, displayed for sale or commercialized in the country, before being registered by Anvisa, with the exception of active pharmaceutical ingredient which would be used for scientific or technological research, as well as for the research and development of formulations.*

Paragraph 1. *The registration of active pharmaceutical ingredients destined exclusively for export will be optional.*

Paragraph 2. *The registration that the caption of this article is related will be valid for 5 (five) years and can be renewed by equal and successive periods as long as the number of the initial registration is kept.*

Paragraph 3. *The registration renewal must be submitted on the first semester of the last (5th) year of validity, counted from the date of publication of such registration, considering itself automatically renewed, independently of decision, if such renewal has not been pronounced until the date of the first registration expiration.*

Paragraph 4. *The register of the product whose revalidation has not been requested in the stated period defined in Paragraph 2 of this article, will be declared extinct.*

Paragraph 5. *The register of the active pharmaceutical ingredients that this resolution deals with, will not be granted when conditions, requirements and procedures foreseen in this regulation are not complied.*

Paragraph 6. *Anvisa is entitled, in emergencial or temporary situation, to exempt from registration active pharmaceutical ingredients destinated to the exclusive use in the production of drug products to be used in public health programs for the Ministry of Health and its entailed entities.*

I – *The dismissal of active pharmaceutical ingredients registration referred in paragraph 5th, will be under exclusive approval of the ANVISA's Collegiate Board of Directors, by a formal and public act signed by its President.*

Article 3. *The companies established in the country which exercise the activities of manufacturing or import active pharmaceutical ingredients, must adjust its activities to what is defined in this Resolution, according to a schedule approved by the Collegiate Board of Directors, that also contains the list of substances in order and classification according to the following criteria of adequacy priority:*

I – *Drug substances with low Therapeutical Index.*

II – *Drug substances produced in the country.*

III – *Drug substances included in the list of strategical ingredients defined by the Ministry of Health.*

IV – *Drug substances used for the production of medicines included in the Ministry of Health Strategical Programs.*

V – *Drug substances used for the production of medicines included in the National List of Essential Medicines (Rename – initials in portuguese).*

VI – *Drug substances used for the production of medicines dispensed in exceptional situations.*

VII – *Drug substances used for the public production of medicines for neglected illnesses, according to the Ministry of Health definition.*

VIII – *Drug substances used for the production of medicines that belongs to the therapeutical categories of antineoplasics, antibiotics and immunosuppressants.*

IX – *Drug substances used for the production of generics.*

X – *Drug substances used for the production of medicines destinated to the basic health attention.*

Only Paragraph. *The publication of the referred schedule in this article will be made by a proper normative act from ANVISA's Collegiate Board of Directors and it will establish the period for companies adequacy.*

Article 4. *The active pharmaceutical ingredients present in the composition of imported medicines, either under half-elaborated form or finished product, must be registered according to the scope of this resolution.*

Article 5. *The disobedience to what is described in the present Resolution and in its approved Regulation, constitutes a sanitary infraction in the terms of the Law n. 6437, of August 20th, 1977, subjecting to civil, administrative and criminal liabilities.*

Article 6. *This Resolution enters into force on the date of its publication.*

DIRCEU RAPOSO DE MELLO

ANNEX – TECHNICAL REGULATIONS FOR THE REGISTRATION OF ACTIVE PHARMACEUTICAL INGREDIENTS (IFA)

1. PURPOSE

To set forth the requirements for registration of active pharmaceutical ingredients with the purpose of ensuring the quality and allowing their use in the elaboration of pharmaceutical products in the country.

2. COMPREHENSIVENESS

These regulations apply to the companies established in the country exercising activities of manufacturing or importing active pharmaceutical ingredients and refer to all active pharmaceutical ingredients, national or imported.
2.1 *The resolution applies to synthetic pharmaceutical ingredients used in the manufacture of medicines.*
I- *The registration of the API used in phytotherapic medicines, dynamized and biological products, including serums and vaccines shall be discussed in separate specific regulations.*

3. DEFINITIONS

For effect of these Technical Regulations, the following definitions are adopted:
3.1 *Common Brazilian Name (DCB – initials in portuguese) – Name of the medicine or pharmacologically active ingredient approved by the Federal Agency responsible for Sanitary Surveillance.*
3.2 *Common International Name (DCI – initials in portuguese) – Name of the medicine or pharmacologically active ingredient recommended by the World Health Organization.*
3.3 *Specification – Is the detailed description of the requisites the products or materials used or obtained during the manufacturing shall fulfill. Serves as basis for quality assessment.*
3.4 *Manufacture – All operations including the purchase of materials, production, quality control, release, storage, finished products issuance and related controls.*
3.5 *Impurity – Any undesired compound present in the intermediate or in the active pharmaceutical ingredient.*
3.6 *Active Pharmaceutical Ingredient (API) – Also called drug or simply active ingredient, is the pharmacologically active compound destined to be used in medicine.*
3.7 *Batch – Specific quantity of product obtained by a process or a series of process, in a manner that it is homogeneous, within the limits set forth. In case of continuous production, a batch can correspond to a defined fraction of the production, determined by a pre-fixed amount of mass or by the produced amount in a fixed time interval.*
3.8 *Raw-material – Active or inactive substances used for the manufacture of ingredients, even though they remain unchanged, experience modifications or are eliminated during the manufacturing process.*
3.9 *Material – Term used generically, including raw-material, auxiliary and intermediate materials, active pharmaceutical ingredients, packaging and labeling materials.*
3.10 *Packaging material – Any form of packaging destined to protect and maintain the intermediates and active pharmaceutical ingredients, including labeling material.*
3.11 *Starting Material – Material of chemical and/or biological origin which shall originate an intermediate product or pharmaceutical ingredient.*
3.12 *Starting Material – Chemical used in the production of an active pharmaceutical ingredient, incorporated thereto as an important structural element. The starting material has the denomination, chemical structure, properties and physical chemical characteristics and impurities profile well defined.*
3.13 *Batch Number – Any combination of numbers or letters through which one can track the complete history of the manufacture of the batch and its operation in the market.*
3.14 *Primary reference standard – Substance which high degree of purity and authenticity have been demonstrated by analytic tests.*
3.15 *Secondary reference standard – Substance of established quality and purity, after comparison with a primary reference standard.*
3.16 *Polymorphism – Is the property of certain substances of presenting more than one crystalline form.*
3.17 *Validity Term – Time during which the product can be used, characterized as useful life period and grounded on the specific stability studies.*
3.19 *Process – Set of unit operations, compliant with techniques, standards and specifications.*
3.20 *Production of Active Pharmaceutical Ingredient – Set of operations involved in the preparation of an intermediate product or active pharmaceutical ingredient, since the receipt of the materials of the storage room, through processing and packaging.*
3.21 *Finished product – Product which has gone through all stages of production, packaging and labeling.*
3.22 *Chiral – Molecules of identical chemical composition, but which mirrored images cannot be superimposed.*
3.23 *Label – Identification printed, lithographed, painted, fireengraved, pressure or self-adhesive, applied directly on vials, packages, enclosures or any inner or outer package protector, and cannot be removed or changed during the use of the product and its transportation or storage.*
3.24 *Solvent – Organic or inorganic liquid used as a vehicle for the preparation of solutions or suspensions in the manufacture of pharmaceutical ingredients.*
3.25 *Validation – Documented act attesting that any*

procedure, process, equipment, material, operation or system really should lead to the expected results.
3.26 *CAS Number – The number of registration with the Chemical Abstract Service (CAS). It is a numerical identifier containing a maximum of 9 digits, divided in 3 parts. Each CAS registration number is unique, assigns only one substance, it has no chemical meaning and is one link to a rich source of information on a specific chemical substance.*
3.27 *Intermediate – Product partially processed that should go through more manufacturing stages prior to the obtention of the active pharmaceutical ingredient.*
3.28 *Auxiliary Materials – Materials used as auxiliaries in the production of an intermediate or active pharmaceutical ingredient, which do not participate in the chemical or biological reaction itself.*
3.29 *Enantiomeric purity – A measure of the excess, normally expressed in percentage terms, of the enantiomer of interest on the total mixture of enantiomers.*
3.30 *Technical Report – Conclusive document presented by the company, containing the information characterizing the product and fulfilling the demands of the sanitary authority which may issue a decision on the registration.*

4. REGISTRATION DOCUMENTATION

In the act of filing the active pharmaceutical ingredient, the company shall file one unique process, instructed with the following documentation:
4.1. *Petition forms duly completed.*
4.2. *Original copy of the proof of collection of the sanitary surveillance inspection fee or proof of exemption, when applicable.*
4.3. *Copy of the Working Permit of the company up to date (Health Permit).*
4.4. *Copy of the Working Permit of the company and Special Working Permit, when applicable, published in the Union's Official Gazette.*
4.5. *Copy of the Certificate of Good Manufacturing Practices and Control of Pharmaceutical ingredients, up-to-date, issued by Anvisa or proof of the Technical-Operational Conditions issued by the local sanitary authority or a protocol requesting the inspection of the local sanitary authority, provided that it presents a satisfactory status according to the last inspection.*
4.6. *For imported API, present a copy of the Certificate of Good Manufacturing Practices and Control of Pharmaceutical ingredients, up-to-date, issued by Anvisa or a protocol requesting the inspection of Anvisa, provided that it presents a satisfactory status according to the last inspection.*
4.7. *Copy of the Technical Responsibility Certificate in effect, of the company requesting the registration, issued by the Regional Chemistry or Pharmacy Council.*
4.8. *Proof of cadastre made of the API in ANVISA.*
4.9 *Documents required in the laws in effect on the control of Transmissible Spongiform Encephalopathies (TSEs).*
4.10 *Technical report containing the information described in item 5, below. All documents of item 5 shall be presented in a paper with the letterhead of the company manufacturing the active pharmaceutical ingredient in Portuguese Language (see Resolution approved by DICOL). It is an option of the manufacturer(s) of the drug(s) to submit, directly to ANVISA, the documents explicated herein, duly identified with the process number they are related to.*

5. TECHNICAL INFORMATION OF THE ACTIVE PHARMACEUTICAL INGREDIENT

The documents for registration shall also contain the following information:
5.1. *General information:*
a) *Nomenclature: Common Brazilian Nomenclature, or, in the lack thereof, Common International Nomenclature.*
b) *CAS No.*
c) *Chemical name.*
d) *Synonyms with complete reference.*
e) *Molecular and structural formula.*
f) *Molecular weight.*
g) *Physical form.*
h) *Melting or boiling point.*
i) *Solubility.*
j) *Loss on drying.*
k) *Physical characteristics (crystalline, amorphous, particle size, solvatation, etc.).*
l) *pka and pH.*
m) *Storage conditions.*
n) *Organoleptic properties.*
5.2. *API manufacturing process:*
a) *Manufacturer(s): Name, full address, company responsible for each step of the manufacture process and quality control (including contractors, third parties).*
b) *Description of the productive process, including materials, equipment and operation conditions (for instance, temperature, pressure, pH, time, speed, agitation ranges, etc.); and the controls in process.*
c) *Identification in the critical stages including the respective acceptance tests and criteria.*
d) *Flowchart of the productive process with indication of the formation of intermediates and possible impurities, including the elucidation of the respective chemical structures.*
e) *Indication of the raw-materials, solvents, catalyzers, etc...*
f) *Indicate the production scale and yield.*
g) *Specifications of raw-materials and packaging materials.*
5.2.1 *Characterization:*
Physical-chemical trials allowing the due characterization of the API structure:
a) *Analyses of one industrial batch proving the functional groups, the chemical structure and molecular form expected for the API.*
b) *Possible Isomers.*

c) *Polymorphism, discriminating the characteristics of the polymorph used and of others related to the active pharmaceutical ingredient.*
5.2.2 *Impurity profile:*
a) *Description of the potential impurities, resulting of the synthesis, with brief description and indication of origin.*
b) *Organic Impurities (of the process and related substances): Raw-materials (starting), related products, intermediate products, degradation products, reagents and catalyzers.*
c) *Inorganic Impurities: Reagents and catalyzers, heavy metals, inorganic salts.*
d) *Residual solvents.*
5.3. *Quality control of the API:*
5.3.1 *Specifications*
b) *Aspect.*
c) *Identification.*
d) *Assay.*
e) *Impurities (organic, inorganic and residual solvents).*
f) *Physical-chemical properties (pH, melting point, etc).*
g) *Granulometric distribution.*
h) *Polymorphism, including the analytic methodology adopted and results of the tests for determination of the probable polymorphs of the ingredient.*
i) *In the ingredients presenting chirality, data on the content of the stereoisomers.*
j) *Moisture.*
k) *Microbiologic limits: Sterility, endotoxins (if applicable).*
l) *Specific optic rotation (if applicable).*
5.3.2 *Copy of a quality control report of three batches produced, with API identification, batch number, reference values and results of the tests carried out.*
5.3.3 *Description of the analytic methodology:*
Validation of analytic methodology according to the specific technical regulations in effect for the validation of analytic and bioanalytic methods, when a pharmacopeic methodology is not used.
In case of pharmacopeic methodology, the company shall present the covalidation of the method.
5.4 *Packaging Material: Description and specification of the material in the primary packaging.*
5.5 *Stability and Photo-stability Report:*
The stability and photo-stability studies shall be conducted according to the specific technical regulations in effect in Brazil.

6. REGISTRATION RENEWAL DOCUMENTATION

For the renewal of the registration of active pharmaceutical ingredients, the company shall present the following documents:
6.1. *Petition forms duly completed.*
6.2. *Original copy of the proof of collection of the sanitary surveillance inspection fee or proof of exemption, when applicable.*
6.3. *Copy of the Certificate of Good Manufacturing Practices and Control (CBPFC) issued by ANVISA for the active pharmaceutical ingredient, object of registration renewal, or copy of the protocol of request of inspection for purposes of issuance of the CBPFC, provided that it was satisfactory in the last inspection.*
6.4. *In case of ingredients registered exclusively for purposes of exporting, according to these regulations, a proof of export shall be presented.*
6.5. *List of all changes and/or inclusions post-registration occurred during the last validity term of the registration of the product.*
6.6. *Conclusive results of long-duration stability studies, according to a specific guide defined by Anvisa.*

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Sede social: Av. Calógeras, 15 / 10º andar - 20030-070 - Rio de Janeiro, Brasil
Portal: www.abiquifi.org.br E-mail: abiquifi@abiquifi.org.br