**RESOLUÇÃO DA DIRETORIA COLEGIADA – RDC Nº 54, DE 10 DE DEZEMBRO DE 2010**

**(Publicada no DOU nº 237, de 13 de dezembro de 2010)**

**(Revogada pela Resolução – RDC nº 63, de 28 de dezembro de 2012)**

|  |  |
| --- | --- |
|  | ~~Dispõe sobre a inclusão, retificação e exclusão de Denominações Comuns Brasileiras - DCB na Lista de DCB.~~ |

~~A~~ **~~Diretoria Colegiada da Agência Nacional de Vigilância Sanitária~~**~~, no uso da atribuição que lhe confere o inciso IV do art. 11 do Regulamento da ANVISA aprovado pelo Decreto nº 3.029, de 16 de abril de 1999, e tendo em vista o disposto no inciso II e nos §§ 1º e 3º do art. 54 do Regimento Interno aprovado nos termos do Anexo I da Portaria nº 354 da ANVISA, de 11 de agosto de 2006, republicada no DOU de 21 de agosto de 2006, em reunião realizada em XX de XXXXXXXX de 2010,~~

~~considerando as recomendações da Organização Mundial da Saúde (OMS), aos seus países membros, sobre a importância das denominações comuns para as substâncias farmacêuticas;~~

~~considerando o inciso XIX, do artigo 7º, da Lei nº 9.782, de 26 de janeiro de 1999;~~

~~considerando o inciso XVIII do artigo 3º, o § 4º do artigo 5º e o parágrafo único do artigo 57 , da Lei nº 6.360, de 23 de setembro de 1976;~~

~~considerando as regras de nomenclatura e de tradução para fármacos ou medicamentos, estabelecidas pela Resolução Anvisa RDC nº 276, de 21 de outubro de 2002 (DOU 12/11/2002) e suas alterações;~~

~~considerando o parecer emitido pelo Comitê Técnico Temático das Denominações Comuns Brasileiras (CTT DCB) da Comissão da Farmacopeia Brasileira (CFB), em cumprimento do seu dever de, periodicamente, revisar e atualizar as Denominações Comuns Brasileiras - DCB para substâncias farmacêuticas;~~

~~adota a seguinte Resolução de Diretoria Colegiada e eu Diretor-Presidente, determino a sua publicação:~~

~~Art. 1º Aprovar, na forma do Anexo I, a inclusão das Denominações Comuns Brasileiras (DCB) na Lista de DCB, divulgada pela Resolução RDC nº 211, de 17 de novembro de 2006, (DOU 20/11/2006), e suas alterações.~~

~~Art. 2º Retificar, na forma do Anexo II, a Resolução RDC nº 211, de 17 de novembro de 2006 (DOU 20/11/2006) e suas alterações.~~

~~Art. 3º Excluir as Denominações Comuns Brasileiras - DCB relacionadas no Anexo III, publicadas pela Resolução RDC nº 211, de 17 de novembro de 2006, e suas alterações.~~

~~Esta resolução entra em vigor na data da sua publicação.~~

~~DIRCEU RAPOSO DE MELLO~~

**~~ANEXOS~~**

**~~ANEXO I~~**

~~Inclusão na Lista de Denominações Comuns Brasileiras – DCB~~

|  |  |  |
| --- | --- | --- |
| **~~Nº DCB~~** | **~~Denominação Comum Brasileira - DCB~~** | **~~Nº de Registro CAS~~** |
| ~~09876~~ | ~~ácido acetilsalicilsalicílico~~ | ~~530-75-6~~ |
| ~~09891~~ | *~~Aconitum napellus~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09892~~ | *~~Aesculus hippocastanum~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09879~~ | ~~água purificada~~ | ~~7732-18-5~~ |
| ~~09880~~ | ~~água ultrapurificada~~ | ~~7732-18-5~~ |
| ~~09931~~ | ~~álcool feniletílico~~ | ~~60-12-8~~ |
| ~~09939~~ | ~~Alfaconestate~~ | ~~80295-38-1~~ |
| ~~09943~~ | ~~alfataliglicerase~~ | ~~37228-64-1~~ |
| ~~09893~~ | *~~Aloe vera~~* ~~(L.) Burm. f~~ | ~~[Ref. 14]~~ |
| ~~09894~~ | *~~Arnica montana~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09895~~ | *~~Atropa belladonna~~* ~~L~~ | ~~[Ref. 14]~~ |
| ~~09896~~ | *~~Baccharis trimera~~* ~~(Less.) DC.~~ | ~~[Ref. 14]~~ |
| ~~09938~~ | ~~belimumabe~~ | ~~356547-88-1~~ |
| ~~09930~~ | ~~benzaldeído~~ | ~~100-52-7~~ |
| ~~09940~~ | ~~besilato de levanlodipino~~ | ~~150566-71-5~~ |
| ~~09932~~ | ~~butanoato de etila~~ | ~~105-54-4~~ |
| ~~09897~~ | *~~Calendula officinalis~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09881~~ | ~~carbômer 2020~~ | ~~176429-87-1~~ |
| ~~09941~~ | ~~carbômer 980~~ | ~~139637-85-7~~ |
| ~~09898~~ | *~~Centella asiatica~~* ~~(L.) Urb.~~ | ~~[Ref. 14]~~ |
| ~~09864~~ | ~~cilazapril monoidratado~~ | ~~92077-78-6~~ |
| ~~09899~~ | *~~Cinchona calisaya~~* ~~Wedd.~~ | ~~[Ref. 14]~~ |
| ~~09900~~ | *~~Cinnamomum cassia~~* ~~(L.) D. Don~~ | ~~[Ref. 14]~~ |
| ~~09901~~ | *~~Cinnamomum verum~~* ~~J. Presl~~ | ~~[Ref. 14]~~ |
| ~~09885~~ | ~~citrato de trietila~~ | ~~77-93-0~~ |
| ~~09902~~ | *~~Cola nitida~~* ~~(Vent.) Schott & Endl.~~ | ~~[Ref. 14]~~ |
| ~~09884~~ | ~~copovidona~~ | ~~25086-89-9~~ |
| ~~09903~~ | *~~Crataegus monogyna~~* ~~Jacq.~~ | ~~[Ref. 14]~~ |
| ~~09904~~ | *~~Cynara scolymus~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09878~~ | ~~dicloridrato de sapropterina~~ | ~~69056-38-8~~ |
| ~~09905~~ | *~~Echinodorus grandiflorus~~* ~~(Cham. & Schltdl.) Micheli~~ | ~~[Ref. 14]~~ |
| ~~09890~~ | ~~estearato de macrogol 40~~ | ~~[Ref. 4]~~ |
| ~~09871~~ | ~~etidronato dissódico~~ | ~~7414-83-7~~ |
| ~~09935~~ | ~~fração insaponificável do óleo de abacate~~ | ~~[Ref. 11]~~ |
| ~~09936~~ | ~~fração insaponificável do óleo de soja~~ | ~~[Ref. 11]~~ |
| ~~09906~~ | *~~Gentiana lutea~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09934~~ | ~~geraniol~~ | ~~106-24-1~~ |
| ~~09907~~ | *~~Glycyrrhiza glabra~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09908~~ | *~~Hamamelis virginiana~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09886~~ | ~~hexafluoreto de enxofre~~ | ~~2551-62-4~~ |
| ~~09909~~ | *~~Hydrastis canadensis~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09910~~ | *~~Hyoscyamus niger~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09889~~ | ~~isotiocianato de alila~~ | ~~57-06-7~~ |
| ~~09937~~ | ~~levomefolato de cálcio~~ | ~~151533-22-1~~ |
| ~~09868~~ | ~~maltol~~ | ~~118-71-8~~ |
| ~~09911~~ | *~~Malva sylvestris~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09912~~ | *~~Maytenus ilicifolia~~* ~~Mart. ex Reiss.~~ | ~~[Ref. 14]~~ |
| ~~09913~~ | *~~Melissa officinalis~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09914~~ | *~~Mentha x piperita~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09933~~ | ~~metilbutirato de etila~~ | ~~7452-79-1~~ |
| ~~09915~~ | *~~Myroxylon balsamum~~* ~~(L.) Harms~~ | ~~[Ref. 14]~~ |
| ~~09883~~ | ~~nitroprusseto de sódio di-hidratado~~ | ~~13755-38-9~~ |
| ~~09942~~ | ~~oleato de trietanolamina~~ | ~~2717-15-9~~ |
| ~~09887~~ | ~~óleo de amendoim~~ | ~~8002-03-7~~ |
| ~~09888~~ | ~~óleo de gergelim~~ | ~~8008-74-0~~ |
| ~~09872~~ | ~~óleo de rícino hidrogenado~~ | ~~8001-78-3~~ |
| ~~09873~~ | ~~óleo de rícino hidrogenado etoxilado~~ | ~~61788-85-0~~ |
| ~~09867~~ | ~~palmitato de sacarose~~ | ~~26446-38-8~~ |
| ~~09916~~ | *~~Passiflora alata~~* ~~Curtis~~ | ~~[Ref. 14]~~ |
| ~~09917~~ | *~~Paullinia cupana~~* ~~Kunth~~ | ~~[Ref. 14]~~ |
| ~~09918~~ | *~~Peumus boldus~~* ~~Molina~~ | ~~[Ref. 14]~~ |
| ~~09882~~ | ~~picolinato de cromo~~ | ~~14639-25-9~~ |
| ~~09919~~ | *~~Pimpinella anisum~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09869~~ | ~~pirofosfato dicálcico~~ | ~~7790-76-3~~ |
| ~~09870~~ | ~~pirofosfato tetrassódico~~ | ~~7722-88-5~~ |
| ~~09920~~ | *~~Polygala senega~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09921~~ | *~~Ptychopetalum olacoides~~* ~~Benth.~~ | ~~[Ref. 14]~~ |
| ~~09922~~ | *~~Rheum officinale~~* ~~Baill.~~ | ~~[Ref. 14]~~ |
| ~~09923~~ | *~~Rheum palmatum~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09874~~ | ~~ricinoleato de glicerila~~ | ~~1323-38-2~~ |
| ~~09875~~ | ~~ricinoleato de poliglicerila~~ | ~~51142-51-9~~ |
| ~~09924~~ | *~~Rosmarinus officinalis~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09925~~ | *~~Salix alba~~* ~~L.~~ | ~~[Ref. 14]~~ |
| ~~09926~~ | *~~Senna alexandrina~~* ~~Mill.~~ | ~~[Ref. 14]~~ |
| ~~09927~~ | *~~Stryphnodendron adstringens~~* ~~(Mart.) Coville~~ | ~~[Ref. 14]~~ |
| ~~09865~~ | ~~tiocianato de potássio~~ | ~~333-20-0~~ |
| ~~09866~~ | ~~trioleína~~ | ~~122-32-7~~ |
| ~~09877~~ | ~~vacina fator de crescimento epidérmico (conjugada)~~ | ~~[Ref. 11]~~ |
| ~~09928~~ | *~~Valeriana officinalis~~* ~~L~~ | ~~[Ref. 14]~~ |
| ~~09929~~ | *~~Zingiber officinale~~* ~~Roscoe~~ | ~~[Ref. 14]~~ |

**~~ANEXO II~~**

~~Retificação de denominação ou número de CAS, na RDC nº. 211, de 17 de novembro de 2006, e suas alterações~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **~~De~~** | | | **~~Para~~** | | |
| **~~Nº DCB~~** | **~~Nome publicado~~** | **~~Número de Registro CAS~~** | **~~Nº. DCB~~** | **~~Denominação Comum Brasileira - DCB~~** | **~~CAS~~** |
| ~~09340~~ | ~~acetato de chumbo~~ | ~~1335-32-6~~ | ~~09340~~ | ~~acetato de chumbo~~ | ~~301-04-2~~ |
| ~~09320~~ | ~~água para injeção~~ | ~~7732-18-5~~ | ~~09320~~ | ~~água para injetáveis~~ | ~~7732-18-5~~ |
| ~~09630~~ | ~~alfalgasidase~~ | ~~104138-64-9~~ | ~~09630~~ | ~~alfagalsidase~~ | ~~104138-64-9~~ |
| ~~00655~~ | ~~amidefrina~~ | ~~3554-67-4~~ | ~~00655~~ | ~~amidefrina~~ | ~~37571-84-9~~ |
| ~~01199~~ | ~~betagalsidase~~ | ~~104138-64-9~~ | ~~01199~~ | ~~betagalsidase~~ | ~~[Ref. 3]~~ |
| ~~01943~~ | ~~cetete~~ | ~~68439-49-6~~ | ~~01943~~ | ~~cetete~~ | ~~9004-95-9~~ |
| ~~01959~~ | ~~cetomacrogol 1000~~ | ~~9004-95-9~~ | ~~01959~~ | ~~cetomacrogol 1000~~ | ~~68439-49-6~~ |
| ~~02642~~ | ~~crospovidona~~ | ~~9003-39-8~~ | ~~02642~~ | ~~Crospovidona~~ | ~~[Ref. 3]~~ |
| ~~09782~~ | ~~edotreotida (177 Lu)~~ | ~~204318-14-9~~ | ~~09782~~ | ~~edotreotida (177 Lu)~~ | ~~[Ref. 2]~~ |
| ~~09783~~ | ~~enxofre coloidal (99m Tc)~~ | ~~7704-34-9~~ | ~~09783~~ | ~~enxofre coloidal (99m Tc)~~ | ~~[Ref. 2]~~ |
| ~~09330~~ | ~~éster de macrogol 2.000~~ | ~~9004-99-3~~ | ~~09330~~ | ~~estearato de macrogol 2000~~ | ~~[Ref. 4]~~ |
| ~~05475~~ | ~~éster de macrogol 400~~ | ~~9004-99-3~~ | ~~05475~~ | ~~estearato de macrogol 400~~ | ~~68439-49-6~~ |
| ~~09737~~ | ~~exametazima (99m Tc)~~ | ~~105613-48-7~~ | ~~09737~~ | ~~exametazima (99m Tc)~~ | ~~[Ref. 2]~~ |
| ~~04623~~ | ~~hetamido~~ | ~~9004-62-0~~ | ~~04623~~ | ~~hetamido~~ | ~~9005-27-0~~ |
| ~~04923~~ | ~~insulina zíncica amorfa~~ | ~~8049-62-5~~ | ~~04923~~ | ~~insulina zíncica~~ | ~~8049-62-5~~ |
| ~~09497~~ | ~~metilsulfato de prali-doxima~~ | ~~873-69-8~~ | ~~09497~~ | ~~metilsulfato de pralidoxima~~ | ~~1200-55-1~~ |
| ~~06609~~ | ~~ondansetrona~~ | ~~116002-70-1~~ | ~~06609~~ | ~~ondansetrona~~ | ~~99614-02-5~~ |
| ~~06654~~ | ~~ostreogricina~~ | ~~11006-76-1~~ | ~~06654~~ | ~~ostreogricina~~ | ~~21411-53-0~~ |
| ~~06930~~ | ~~pentamido~~ | ~~9005-27-0~~ | ~~06930~~ | ~~pentamido~~ | ~~[Ref. 4]~~ |
| ~~07289~~ | ~~povidona~~ | ~~25086-89-9~~ | ~~07289~~ | ~~povidona~~ | ~~9003-39-8~~ |
| ~~07376~~ | ~~pristinamicina~~ | ~~11006-76-1~~ | ~~07376~~ | ~~pristinamicina~~ | ~~270076-60-3~~ |
| ~~07457~~ | ~~propilexedrina~~ | ~~3595-11-07~~ | ~~07457~~ | ~~propilexedrina~~ | ~~101-40-6~~ |
| ~~07931~~ | ~~selenometionina~~ | ~~1187-56-0~~ | ~~07931~~ | ~~selenometionina~~ | ~~1464-42-2~~ |
| ~~09804~~ | ~~tacatuzumabe (90 Y)~~ | ~~476413-07-7~~ | ~~09804~~ | ~~tacatuzumabe (90 Y)~~ | ~~[Ref. 2]~~ |
| ~~08472~~ | ~~tetrafluorborato tetramibi de cobre~~ | ~~07406-02-9~~ | ~~08472~~ | ~~tetrafluorborato tetramibi cuproso~~ | ~~Ref. 2~~ |
| ~~09176~~ | ~~virginiamicina~~ | ~~11006-76-1~~ | ~~09176~~ | ~~virginiamicina~~ | ~~98455-68-6~~ |

**~~ANEXO III~~**

~~Exclusão de DCB da relação publicada na Resolução RDC nº. 211, de 17 de novembro de 2006 e suas alterações~~

|  |  |  |
| --- | --- | --- |
| **~~Nº DCB~~** | **~~DENOMINAÇÃO COMUM BRASILEIRA~~** | **~~Nº CAS~~** |
| ~~01923~~ | ~~celosídeo~~ | ~~17226-75-4~~ |
| ~~04924~~ | ~~insulina zíncica composta~~ | ~~8049-62-5~~ |
| ~~04925~~ | ~~insulina zíncica cristalina~~ | ~~8049-62-5~~ |
| ~~05418~~ | ~~mesilato de lorazepam~~ | ~~xx~~ |
| ~~05926~~ | ~~micamicina~~ | ~~11006-76-1~~ |
| ~~09586~~ | ~~octoxinol 9~~ | ~~9002-93-1~~ |
| ~~9588~~ | ~~tetrafluoroborato de cobre (1) tetracis (2-metoxi-isobutil- isonitrila)~~ | ~~103694-84-3~~ |