# RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC Nº 39, DE 8 DE JULHO DE 2014

# (Publicada no DOU nº 130, de 10 de julho de 2014)

Dispõe sobre a alteração da RDC nº. 64/2012, pela inclusão e retificação de Denominações Comuns Brasileiras – DCB, na lista completa das DCB da Anvisa.

**A Diretoria Colegiada da Agência Nacional de Vigilância Sanitária,** no uso da atribuição que lhe conferem os incisos III e IV, do art. 15, da Lei nº 9.782, de 26 de janeiro de 1999, inciso V e §§ 1º e 3º do art. 5º do Regimento Interno aprovado nos termos do Anexo I da Portaria nº 650 da ANVISA, de 29 de maio de 2014, publicada no DOU de 02 de junho de 2014, tendo em vista o disposto nos incisos III, do art. 2º, III e IV, do art. 7º da Lei nº 9.782, de 1999, e o Programa de Melhoria do Processo de Regulamentação da Agência, instituído por Portaria nº 422, de 16 de abril de 2008, em reunião ordinária n° 20/2014 realizada em 02 de julho de 2014, adota a seguinte Resolução da Diretoria Colegiada e eu, Diretor-Presidente Substituto, determino a sua publicação:

Art. 1º Aprovar a inclusão das Denominações Comuns Brasileiras (DCB) relacionadas no Anexo I, na Lista Completa das DCB, divulgada pela Resolução RDC nº. 64, de 28 de dezembro de 2012 (DOU 03/01/2013).

Art. 2º Alterar as DCB relacionadas no Anexo II da lista completa publicada na Resolução RDC nº. 64 de 28 de dezembro de 2012 (DOU 03/01/2013).

Art. 3° Esta Resolução entra em vigor na data da sua publicação.

## JAIME CÉSAR DE MOURA OLIVEIRA

**ANEXO I**

**Inclusão na Lista Completa das Denominações Comuns Brasileiras – DCB**

**(Retificado no DOU nº 145, de 31 de julho de 2014)**

**~~I. Insumos:~~**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **~~Nº DCB~~** | **~~Denominação Comum Brasileira - DCB~~** | **~~Nº de Registro CAS~~** |
| ~~1~~ | ~~10920~~ | ~~álcool diclorobenzílico~~ | ~~1777-82-8~~ |
| ~~2~~ | ~~10956~~ | ~~citrato dissódico sesqui-hidratado~~ | ~~6132-05-4~~ |
| ~~3~~ | ~~10957~~ | ~~copolímero de ácido metacrílico e metacrilato de metila (1:2)~~ | ~~[Ref. 7]~~ |
| ~~4~~ | ~~10958~~ | ~~copolímero de acrilato de etila e metacrilato de metila (2:1)~~ | ~~9010-88-2~~ |
| ~~5~~ | ~~10959~~ | ~~copolímero de acriloildimetiltaurato de sódio e acrilato de hidroxietila~~ | ~~111286-86-3~~ |
| ~~6~~ | ~~10960~~ | ~~copolímero de ácido metacrílico e metacrilato de metila~~ | ~~25086-15-1~~ |
| ~~7~~ | ~~10961~~ | ~~crospolímero de dimeticona~~ | ~~213629-14-2~~ |
| ~~8~~ | ~~10962~~ | ~~estearato de macrogol 30~~ | ~~[Ref. 9]~~ |
| ~~9~~ | ~~10963~~ | ~~éter de macrogol monoestearílico~~ | ~~9005-00-9~~ |
| ~~10~~ | ~~10964~~ | ~~éter de macrogol monoestearílico 10~~ | ~~13149-86-5~~ |
| ~~11~~ | ~~10965~~ | ~~éter de macrogol monoestearílico 7~~ | ~~66146-84-7~~ |
| ~~12~~ | ~~10966~~ | ~~etilvanilina~~ | ~~121-32-4~~ |
| ~~13~~ | ~~10967~~ | ~~glicirrizinato de amônio~~ | ~~53956-04-0~~ |
| ~~14~~ | ~~10968~~ | ~~glicofurol~~ | ~~31692-85-0~~ |
| ~~15~~ | ~~10969~~ | ~~laurilsulfato de trietanolamina~~ | ~~139-96-8~~ |
| ~~16~~ | ~~10970~~ | ~~maltitol~~ | ~~585-88-6~~ |
| ~~17~~ | ~~10971~~ | ~~parafina~~ | ~~8002-74-2~~ |
| ~~18~~ | ~~10972~~ | ~~trimetilsiloxissilicato~~ | ~~3555-47-3~~ |
| ~~19~~ | ~~10973~~ | ~~cloridrato de lurasidona~~ | ~~367514-88-3~~ |
| ~~20~~ | ~~10974~~ | ~~dapaconazol~~ | ~~1269726-67-1~~ |
| ~~21~~ | ~~10975~~ | ~~dasabuvir~~ | ~~1132935-63-7~~ |
| ~~22~~ | ~~10976~~ | ~~dasabuvir sódico monoidratado~~ | ~~1456607-55-8~~ |
| ~~23~~ | ~~11015~~ | ~~eculizumabe~~ | ~~219685-50-4~~ |
| ~~24~~ | ~~10977~~ | ~~edoxabana~~ | ~~480449-70-5~~ |
| ~~25~~ | ~~10978~~ | ~~evolocumabe~~ | ~~1256937-27-5~~ |
| ~~26~~ | ~~10979~~ | ~~fimasartana~~ | ~~247257-48-3~~ |
| ~~27~~ | ~~10980~~ | ~~hemitartarato de eliglustate~~ | ~~928659-70-5~~ |
| ~~28~~ | ~~10981~~ | ~~ibrutinibe~~ | ~~936563-96-1~~ |
| ~~29~~ | ~~10982~~ | ~~lurasidona~~ | ~~367514-87-2~~ |
| ~~30~~ | ~~10983~~ | ~~macitentana~~ | ~~441798-33-0~~ |
| ~~31~~ | ~~10984~~ | ~~ombitasvir~~ | ~~1258226-87-7~~ |
| ~~32~~ | ~~10985~~ | ~~ombitasvir hidratado~~ | ~~1456607-70-7~~ |
| ~~33~~ | ~~11016~~ | ~~perindopril arginina~~ | ~~612548-45-5~~ |
| ~~34~~ | ~~10986~~ | ~~picossulfato de sódio monoidratado~~ | ~~1307301-38-7~~ |
| ~~35~~ | ~~10987~~ | ~~ramelteona~~ | ~~196597-26-9~~ |
| ~~36~~ | ~~10988~~ | ~~sofosbuvir~~ | ~~1190307-88-0~~ |
| ~~37~~ | ~~10989~~ | ~~sulfato de vorapaxar~~ | ~~705260-08-8~~ |
| ~~38~~ | ~~10990~~ | ~~tafamidis~~ | ~~594839-88-0~~ |
| ~~39~~ | ~~10991~~ | ~~tafamidis meglumina~~ | ~~951395-08-7~~ |
| ~~40~~ | ~~10992~~ | ~~tosilato de dapaconazol~~ | ~~1394826-04-0~~ |
| ~~41~~ | ~~10993~~ | ~~tosilato de edoxabana~~ | ~~480449-71-6~~ |
| ~~42~~ | ~~10994~~ | ~~tosilato de edoxabana monoidratado~~ | ~~1229194-11-9~~ |
| ~~43~~ | ~~10995~~ | ~~veruprevir~~ | ~~1216941-48-8~~ |
| ~~44~~ | ~~10996~~ | ~~veruprevir di-hidratado~~ | ~~1456607-71-9~~ |
| ~~45~~ | ~~10997~~ | ~~vorapaxar~~ | ~~618385-01-6~~ |

**~~II. Biológicos:~~**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~Item~~** | **~~Nº DCB~~** | **~~Denominação Comum Brasileira - DCB~~** | **~~Nº de Registro CAS~~** |  |
| ~~46~~ | ~~11006~~ | ~~betapeginterferona 1a~~ | ~~1211327-92-2~~ |
| ~~47~~ | ~~11007~~ | ~~hemoglobina crosfumarila bovina~~ | ~~1360741-07-6~~ |
| ~~48~~ | ~~11008~~ | ~~siltuximabe~~ | ~~541502-14-1~~ |
| ~~49~~ | ~~11009~~ | ~~vedolizumabe~~ | ~~943609-66-3~~ |

**~~III. Radiofármacos:~~**

|  |  |  |  |
| --- | --- | --- | --- |
| **~~Item~~** | **~~Nº DCB~~** | **~~Denominação Comum Brasileira - DCB~~** | **~~Nº de Registro CAS~~** |
| ~~50~~ | ~~11010~~ | ~~cloreto de trofolastate (99m Tc)~~ | ~~1333117-95-5~~ |
| ~~51~~ | ~~11011~~ | ~~flortanidazol (18 F)~~ | ~~1070878-86-2~~ |
| ~~52~~ | ~~11012~~ | ~~flotegatida (18 F)~~ | ~~1010702-75-6~~ |
| ~~53~~ | ~~11013~~ | ~~fluorfenidina (18 F)~~ | ~~917894-12-3~~ |
| ~~54~~ | ~~11014~~ | ~~flutriciclamida (18 F)~~ | ~~1274863-98-7~~ |

**~~IV.Plantas Medicinais:~~**

|  |  |  |  |
| --- | --- | --- | --- |
| **~~Item~~** | **~~Nº DCB~~** | **~~Denominação Comum Brasileira - DCB~~** | **~~Nº de Registro CAS~~** |
| ~~55~~ | ~~10999~~ | *~~Artemisia absinthium~~* ~~L.~~ | ~~[Ref. 6]~~ |
| ~~56~~ | ~~11000~~ | *~~Centaurium erythraea~~* ~~Rafn~~ | ~~[Ref. 6]~~ |
| ~~57~~ | ~~11001~~ | *~~Coffea canephora~~* ~~Pierre ex A. Froehner~~ | ~~[Ref. 6]~~ |
| ~~58~~ | ~~11002~~ | *~~Marsdenia cundurango~~* ~~Rchb. F.~~ | ~~[Ref. 6]~~ |
| ~~59~~ | ~~11003~~ | *~~Maytenus aquifolia~~* ~~Mart.~~ | ~~[Ref. 6]~~ |
| ~~60~~ | ~~11004~~ | *~~Picrasma excelsa~~* ~~(Sw.) Planch.~~ | ~~[Ref. 6]~~ |
| ~~61~~ | ~~11005~~ | *~~Vaccinium macrocarpon~~* ~~Aiton~~ | ~~[Ref. 6]~~ |

**~~V.Padrões analíticos:~~**

|  |  |  |  |
| --- | --- | --- | --- |
| **~~Item~~** | **~~Nº DCB~~** | **~~Denominação Comum Brasileira - DCB~~** | **~~Nº de Registro CAS~~** |
| ~~62~~ | ~~10917~~ | ~~benzoilmorfina~~ | ~~105092-16-8~~ |
| ~~63~~ | ~~10998~~ | ~~racemetanfetamina~~ | ~~7632-10-2~~ |

**I. Insumos e Hemoderivados**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Nº DCB** | **Denominação Comum Brasileira - DCB** | **Nº de Registro CAS** |
| 1 | 11029 | acetilracemetionina | 1115-47-5 |
| 2 | 11081 | alfaefmoroctocogue | 1270012-79-7 |
| 3 | 11080 | alfaeftrenonacogue | 1270012-74-2 |
| 4 | 11030 | asunaprevir | 630420-16-5 |
| 5 | 11031 | bromidrato de dextrometorfano monoidratado | 6700-34-1 |
| 6 | 11032 | carfilzomibe | 868540-17-4 |
| 7 | 11033 | daclatasvir | 1009119-64-5 |
| 8 | 11034 | dasabuvir | 1132935-63-7 |
| 9 | 11035 | dicloridrato de daclatasvir | 1009119-65-6 |
| 10 | 11036 | fimasartana potássica tri-hidratada | 1020110-23-9 |
| 11 | 11037 | gliconato férrico de sódio | 34089-81-1 |
| 12 | 11038 | melatonina | 73-31-4 |

**II. Plantas Medicinais**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Nº DCB** | **Denominação Comum Brasileira - DCB** | **Nº de Registro CAS** |
| 13 | 11040 | Achyrocline satureioides (Lam.) DC. | [Ref. 6] |
| 14 | 11041 | Anadenanthera colubrina (Vell.) Brenan | [Ref. 6] |
| 15 | 11042 | Berberis laurina Thunb. | [Ref. 6] |
| 16 | 11043 | Bixa orellana L. | [Ref. 6] |
| 17 | 11044 | Carum carvi L. | [Ref. 6] |
| 18 | 11045 | Citrus aurantium L. subsp. aurantium | [Ref. 6] |
| 19 | 11046 | Citrus limon (L.) Osbeck | [Ref. 6] |
| 20 | 11047 | Citrus sinensis (L.) Osbeck | [Ref. 6] |
| 21 | 11048 | Corymbia citriodora (Hook.) K.D.Hill & L.A.S.Johnson | [Ref. 6] |
| 22 | 11049 | Cymbopogon martini (Roxb.) W. Watson | [Ref. 6] |
| 23 | 11050 | Foeniculum vulgare Mill. ssp. vulgare var. dulce (Mill.) Thelung | [Ref. 6] |
| 24 | 11051 | Foeniculum vulgare Mill. ssp. vulgare var. vulgare | [Ref. 6] |
| ~~25~~ | ~~11052~~ | ~~Krameria triandra Ruiz & Pav.~~ **(Excluída pela Resolução – RDC nº 104, de 31 de agosto de 2016)** | ~~[Ref. 6]~~ |
| 26 | 11053 | Lavandula angustifolia Mill. | [Ref. 6] |
| 27 | 11054 | Libidibia ferrea (Mart.) L.P. Queiroz | [Ref. 6] |
| 28 | 11055 | Myristica fragrans Houtt. | [Ref. 6] |
| 29 | 11056 | Olea europaea L. | [Ref. 6] |
| 30 | 11057 | Psidium guajava L. | [Ref. 6] |
| ~~31~~ | ~~11058~~ | ~~Styrax benzoin Dryand.~~ **(Excluída pela Resolução – RDC nº 104, de 31 de agosto de 2016)** | ~~[Ref. 6]~~ |
| 32 | 11059 | Thymus vulgaris L. | [Ref. 6] |

**III. Padrões analíticos ou substâncias controladas:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Nº DCB** | **Denominação Comum Brasileira - DCB** | **Nº de Registro CAS** |
| 33 | 11060 | ácido acetilantranílico | 89-52-1 |
| 34 | 11061 | ácido antranílico | 118-92-3 |
| 35 | 11062 | ácido fenilacético | 103-82-2 |
| 36 | 11063 | ácido lisérgico | 82-58-6 |
| 37 | 11064 | ácido sulfúrico | 7664-93-9 |
| 38 | 11065 | anidrido acético | 108-24-7 |
| 39 | 11066 | asenapina | 65576-45-6 |
| 40 | 11067 | benzilpiperazina | 2759-28-6 |
| 41 | 11068 | butanona | 78-93-3 |
| 42 | 11069 | clorazepam | 34985-87-0 |
| 43 | 11070 | cloreto de metileno | 75-09-2 |
| 44 | 11071 | desvenlafaxina | 93413-62-8 |
| 45 | 11072 | di-hidroergometrina | 62841-02-5 |
| 46 | 11073 | fenilpropanona | 103-79-7 |
| 47 | 11074 | isossafrol | 120-58-1 |
| 48 | 11075 | metilclostebol | 5785-58-0 |
| 49 | 11076 | metilnaltrexona | 83387-25-1 |
| 50 | 11039 | monoacetilmorfina | 2784-73-8 |
| 51 | 11077 | oripavina | 467-04-9 |
| 52 | 11078 | piperidina | 110-89-4 |
| 53 | 11079 | tolueno | 108-88-3 |
| **Item** | **Nº DCB** | **Denominação Comum Brasileira - DCB** | **Nº de Registro CAS** |
| 54 | 11017 | ácido succínico | 110-15-6 |
| 55 | 11018 | álcool metílico | 67-56-1 |
| 56 | 11019 | copolímero de dimetacrilato de etilenoglicol e metacrilato de metila | 25777-71-3 |
| 57 | 11020 | copolímero de glicolida e lactida | 26780-50-7 |
| 58 | 11021 | copolímero dos ácidos glicólico e láctico | 34346-01-5 |
| 59 | 11022 | dicaprato de propilenoglicol | 53824-77-4 |
| 60 | 11023 | dicaprilato de propilenoglicol | 7384-98-7 |
| 61 | 11024 | diestearato de polipropilenoglicol 20 metilglicopiranosídeo | 93821-74-0 |
| 62 | 11025 | dioleoato de fosfatidilserina | 70614-14-1 |
| 63 | 11026 | glicerol formal | 99569-11-6 |
| 64 | 11027 | glicopiranosídeo cetoestearílico | 246159-33-1 |
| 65 | 11028 | oleoato palmitato de fosfatidilcolina | 26853-31-6 |

**IV. Excipientes**

**ANEXO II**

**Retificação de DCB ou número de CAS, na RDC nº. 64 de 28 de dezembro de 2012.**

**(Retificado pelo DOU nº 145, de 31 de julho de 2014)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **~~De~~** | | | | **~~Para~~** | | | **~~Justificativa~~** |
| **~~Item~~** | **~~Nº. DCB~~** | **~~DCB~~** | **~~CAS~~** | **~~Nº. DCB~~** | **~~DCB~~** | **~~CAS~~** |  |
| ~~1~~ | ~~06930~~ | ~~pentamido~~ | ~~[Ref. 4]~~ | ~~06930~~ | ~~hidroxietilamido~~ | ~~[Ref. 4]~~ | ~~Adequação ao uso consagrado da substância no mercado~~ |
| ~~2~~ | ~~10625~~ | ~~semuloparina sódica~~ | ~~[Ref. 2]~~ | ~~10625~~ | ~~semuloparina sódica~~ | ~~9041-08-1~~ | ~~Atualização do CAS~~ |
| ~~3~~ | ~~10930~~ | ~~semuloparina sódica~~ | ~~[Ref. 1]~~ | ~~10930~~ | ~~semuloparina~~ | ~~[Ref. 2]~~ | ~~Correção da DCB~~ |
| ~~4~~ | ~~10816~~ | ~~sulfato de condroitina dissódico~~ | ~~9082-07-9~~ | ~~10816~~ | ~~sulfato dissódico de condroitina~~ | ~~9082-07-9~~ | ~~Harmonização da nomenclatura~~ |
| ~~5~~ | ~~08373~~ | ~~tenanfetamina~~ | ~~51497-09-7~~ | ~~08373~~ | ~~tenanfetamina~~ | ~~4764-17-4~~ | ~~Atualização do CAS~~ |
| ~~6~~ | ~~10954~~ | ~~tetraidrocanabinol~~ | ~~519-09-5~~ | ~~10954~~ | ~~benzoilecgonina~~ | ~~519-09-5~~ | ~~Correção da DCB~~ |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **De** | | | | **Para** | | | **Justificativa** |
| **Item** | **Nº. DCB** | **DCB** | **CAS** | **Nº. DCB** | **DCB** | **CAS** |  |
| 1 | 09638 | cloridrato de alfentanila monoidratada | 70879-28-6 | 09638 | cloridrato de alfentanila monoidratado | 70879-28-6 | Adequação da nomenclatura |
| 2 | 02868 | dextriferrona | 8063-26-1 | 02868 | dextriferrona | 9004-51-7 | Atualização do CAS |
| 3 | 05182 | dicloridrato de lauroguadina monoidratada | [Ref. 3] | 05182 | dicloridrato de lauroguadina monoidratado | [Ref. 3] | Adequação da nomenclatura |
| 4 | 10891 | dicloridrato de meclozina monoidratada | 31884-77-2 | 10891 | dicloridrato de meclozina monoidratado | 31884-77-2 | Adequação da nomenclatura |
| 5 | 08373 | tenanfetamina | 51497-09-7 | 08373 | tenanfetamina | 4764-17-4 | Atualização do CAS |
| 6 | 10954 | tetraidrocanabinol | 519-09-5 | 10954 | benzoilecgonina | 519-09-5 | Correção da DCB |