

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 2.353, JUNE 20, 2024

THE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the use of the powers conferred on him by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board - RDC nº 585, of December 10, 2021,

Considering the fulfillment of the requirements set forth in article 39 of the Resolution of the Collegiate Board of Directors - RDC No. 497, of May 20, 2021, resolves:

Art. 1st Grant to the company(ies) listed in the ANNEX, the Certification of Good Manufacturing Practices of Active Pharmaceutical Ingredients through its automatic renewal.

Art. 2nd This Certification is valid for 02 (two) years from its publication.

Art. 3rd This Resolution comes into force on the date of its publication.

Manufacturer: Lupin Limited (Mandideep)

Address: 198-202, New Industrial Area No.2, Mandideep 462 046, Dist. Raisen, Madhya Pradesh

Country: India

Manufacturer number: B.000122

File number: 1227347/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis (cephalosporin class): Cephalexin monohydrate (chemical synthesis steps).

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RESOLUTION - RE NO. 2.354, JUNE 20, 2024

THE GENERAL MANAGER OF INSPECTION AND SANITARY SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred upon her by article 140, in conjunction with article 203, I, § 1 of the Internal Regulations approved by Resolution of the Collegiate Board - RDC No. 585, of December 10, 2021,

Considering compliance with the requirements of Good Manufacturing Practices recommended in current legislation, for the area of Active Pharmaceutical Ingredients, resolves to:

Art. 1st Grant to the company listed hereinafter, the Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients.

Art. 2nd This Certification is valid for 02 (two) years from its publication.

Art. 3rd This Resolution comes into force on the date of its publication.

Manufacturer: Patheon Biologics B.V.

Address: Zuiderweg 72/2, Groningen, 9744AP

Country: Holland

Manufacturer number: A.001281

Requester: Adium S.A.

CNPJ: 55.980.684/0001-27

File number: 1317532/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: naxitamab.

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THE GENERAL MANAGER OF INSPECTION AND SANITARY SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred upon her by article 140, in conjunction with article 203, I, § 1 of the Internal Regulations approved by Resolution of the Collegiate Board - RDC No. 585, of December 10, 2021,

Considering compliance with the requirements of Good Manufacturing Practices recommended in current legislation, for the area of Active Pharmaceutical Ingredients, resolves to:

Art. 1st Grant to the company listed hereinafter, the Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients.

Art. 2nd This Certification is valid for 02 (two) years from its publication.

Art. 3rd This Resolution comes into force on the date of its publication.

Manufacturer: Aarti Drugs Ltd.

Address: Plot G-60, M.I.D.C., Tal. - Palghar, District Thane, Tarapur, Maharashtra - 401506

Country: India

Manufacturer number: B.000001

File number: 1206246/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ciprofloxacin hydrochloride.

Manufacturer: Abbvie S.R.L.

Address: Strada Regionale 148 Pontina Km 52 Snc, Campoverde di Aprilia - 04011

Country: Italy

Manufacturer number: B.000003

File number: 1206735/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ritonavir.

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Manufacturer: Aspen Oss B.V. (Moleneind Site).

Address: Kloosterstraat 6, Oss, - 5349 AB

Country: Holland

Manufacturer number: B.000492

File number: 1377848/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient(s) obtained by chemical synthesis: asenapine, budesonide, desmopressin, estradiol, estradiol acetate, estradiol valerate, estriol, desogestrel, dexamethasone phenylpropionate, etonogestrel, conjugated estrogens, esterified estrogens, ethinyl estradiol, ethinyl diacetate, ganirelix, gonadorelin acetate, hydroxyprogesterone caproate, leuprorelin, linstrenol, mirtazapine, norethindrone, norethindrone acetate oxytocin, progesterone, rocuronium bromide, sugammadex, testosterone, testosterone decanoate, testosterone isocaproate, testosterone phenylpropionate, testosterone propionate, testosterone cypionate, tibolone, testosterone undecanoate.

Manufacturer: Aspen Oss B.V. (DIOSITE)

Address: Veersemeer 4, 5347 JN, Oss

Country: Holland

Manufacturer number: B.000195

File number: 1378013/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient(s) obtained by chemical synthesis (milling and packaging steps): asenapine, budesonide, desogestrel, dexamethasone phenylpropionate, estradiol, estradiol acetate, estradiol valerate, estriol, conjugated estrogens, esterified estrogens, ethinethiodiol diacetate, ethinyl estradiol, etonogestrel, hydroxyprogesterone caproate, linstrenol, mirtazapine, nandrolone decanoate, norethindrone, norethindrone acetate, progesterone, rocuronium bromide, sugammadex, testosterone, testosterone decanoate, testosterone isocaproate, testosterone phenylpropionate, testosterone propionate, tibolone, testosterone cypionate, testosterone undecanoate.

Manufacturer: Curia Italy S.R.L.

Address: Via Volturmo, 41/43, Rozzano (MI) - 20089

Country: Italy

Manufacturer number: B.000027

File number: 1357664/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by classical fermentation: cyclosporine.

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Manufacturer: F.I.S. - Fabbrica Italiana Sintetici S.P.A.

Address: Viale Milano 26, Montecchio Maggiore, Vicenza - 36075

Country: Italy

Manufacturer number: B.000029

File number: 0622187/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: pazopanib hydrochloride.

Manufacturer: MSN Laboratories Private Limited

Address: Survey Number: 317, 320, 321, 322, 323, 604 & 605, Rudraram (Village), Patancheru (Mandal), Sangareddy District, Telangana - 502 329

Country: India

Manufacturer number: B.000224

File number: 0578980/24-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: apixaban, azilsartan medoxomil potassium, alogliptin benzoate, clopidogrel bisulfate, tofacitinib citrate, cariprazine hydrochloride, duloxetine hydrochloride, olopatadine hydrochloride, dapagliflozin, deferasirox, dutasteride, eltrombopague olamine, ezetimibe, finasteride, dabigatran etexilate mesylate, mirabegron, olmesartan medoxomil, pantoprazole sodium sesquihydrate, pitavastatin calcium, posaconazole, dapagliflozin monohydrate propylene glycolate, rameletone, rifaximin, rivaroxaban, rosuvastatin calcium, vilanterol trifenate, ketorolac trometamol, vigabatrin, voriconazole.

Manufacturer: Novacyl Limited

Address: 321 Bangpoo Industrial Estate, Moo 4, Sukhumvit Road, Praeksa, Muang, Samutprakarn - 10280

Country: Thailand

Manufacturer number: B.000555

File number: 0593430/24-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: acetylsalicylic acid.

Manufacturer: Zhejiang Huahai Pharmaceutical Co., Ltd. (Xunqiao)

Address: Xunqiao, Zhejiang Province - 317024 - Linhai

Country: China

Manufacturer number: B.000082

File number: 4512347/22-4 and 0286380/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: enalapril maleate and rivaroxaban.

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Manufacturer: Zhejiang Huahai Pharmaceutical Co., Ltd. (Xunqiao)

Address: Xunqiao, Zhejiang Province - 317024 - Linhai

Country: China

Manufacturer number: B.000082

File number: 0337842/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: carvedilol, escitalopram oxalate and ramipril.

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Considering the need for inclusion in the certification of good manufacturing practices, provided for in article 11 of the Resolution of the Collegiate Board - RDC No. 497, of May 20, 2021, resolves:

Art. 1st Include the biological active pharmaceutical ingredient adalimumab, in the certification of the company Samsung Biologics Co., Ltd (Manufacturer number: A.001327), requested by the company Samsung Bioepis BR Pharmaceutical Ltda, CNPJ: 24.563.776/0001-88, published by Resolution - RE No. 2,291, of June 14, 2024, in the Official Gazette No. 116, of June 19, 2024, section 1, page 143, According to files No. 0039312/24-1 and 0622065/24-6.

Art. 2nd Include the active pharmaceutical ingredient obtained by chemical synthesis dapaglifozin propanediol monohydrate in the certification of the company Sun Pharmaceutical Industries Limited, (Manufacturer number: B.000217), published by Resolution - RE No. 3,774, of November 11, 2022, in the Official Gazette No. 215, of November 16, 2022, Section 1, page 120, according to files No. 0581550/22-6 and 0601142/24-1.

Art. 3rd Include the active pharmaceutical ingredients obtained by chemical synthesis tofacitinib citrate, bendamustine hydrochloride, ribociclib succinate and ticagrelor in the certification of the manufacturing company Intas Pharmaceuticals Limited, (Manufacturer number: B.000332), published by Resolution - RE No. 1,902, of May 26, 2023, in the Official Gazette No. 101, of May 29, 2023, Section 1, page 151; According to files No. 2738814/22-1 and 0315973/24-2.

Art. 4 This Resolution comes into force on the date of its publication.

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