

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.914, MAY 16, 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 2 (two) years from its publication.

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

Manufacturer: Abbott Laboratories GmbH.

Address: Justus-von-Liebig-Str. 33, 31535 Neustadt A. Rbge.

Country: Germany

Requester: Abbott Laboratórios do Brasil Ltda.

CNPJ: 56.998.701/0001-16

File number: 1116555/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: pancreatin.

Manufacturer: Boehringer Ingelheim RCV GmbH & Co. KG.

Address: Dr. Boehringer Gasse 5-11, 1121, Viena

Country: Austria

Manufacturer number: A.000117

Requester: Biomarin Brasil Farmacêutica Ltda

CNPJ: 08.002.360/0001-34

File number: 1285645/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: pegvaliase.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000182

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: Fidia Farmaceutici S.p.A.

Address: Via Ponte Della Fabbrica 3/A, 35031 Abano Terme, Padova

Country: Italy

Manufacturer number: A.000230

Requester: TRB Pharma Indústria Química e Farmacêutica Ltda.

CNPJ: 61.455.192/0001-15

File number: 1109526/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: sodium hyaluronate.

Manufacturer: GlaxoSmithKline Biologicals

Address: 637 Rue des Aulnois, 59230 Saint-Amand-Les-Eaux

Country: France

Manufacturer number: A.000731

Requester: Instituto Butantan

CNPJ: 61.821.344/0001-56

File number: 1465194/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients (preformulation): adsorbed tetanus-diphtheria concentrate (DTcc) and adsorbed tetanus toxoid concentrate (ADTT).

Manufacturer: Pfizer Ireland Pharmaceuticals

Address: Grange Castle Business Park, Clondalkin, Dublin 22, D22 V8F8

Country: Ireland

Manufacturer number: A.000635

Requester: Pfizer Brasil Ltda.

CNPJ: 61.072.393/0001-33

File number: 1214427/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alpha moroctocogue, pegvisomant (pegylation), rituximab, somatrogon, trastuzumab, capsular polysaccharides of Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 19A, 18C, 19F, 23F (conjugation), tetanus toxoid (purification), mRNA encoding the Spike protein of the SARS-CoV-2 virus.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000182

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: Shenzhen Hepalink Pharmaceutical Group Co. Ltd.

Address: No. 1 Rongtian South, Kengzi Sub-District, Pingshan New District, Shenzhen 518122

Country: China

Manufacturer number: A.001445

Requester: Biommm S.A.

CNPJ: 04.752.991/0001-10

File number: 1027111/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: porcine sodium heparin.

Manufacturer: Wacker Biotech GmbH

Address: Hans-Knöll Strasse 3 07745 Jena

Country: Germany

Manufacturer number: A.001289

Requester: Laboratórios Bagó do Brasil S.A

CNPJ: 04.748.181/0009-47

File number: 1274384/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: asparaginase.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000182

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.915, MAY 16, 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: Avik Pharmaceutical Ltd.

Address: Plot No. A-1/7 & A-1/8, 1st Phase, GIDC, VAPI - 396195, Dist: Valsad, Gujarat.

Country: India

Manufacturer number: B.000689

File number: 0252962/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: methylprednisolone acetate, prednisolone acetate, triamcinolone acetonide, budesonide, beclomethasone dipropionate; betamethasone dipropionate, prednisolone sodium phosphate, mometasone furoate, mometasone furoate monohydrate, clobetasol propionate, halobetasol propionate, betamethasone valerate.

Manufacturer: Chromo Laboratories India Private Limited.

Address: Plot N°43 & 44, Phase-II, Ida, Pashamylaram, Patancheru (Mandal), Sangareddy District, Telangana - 502307 - Patancheru

Country: India

Manufacturer number: B.001018

File number: 0351423/24-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: candesartan cilexetil.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000183

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: CF Pharma Gyógyszergyártó Kft.

Address: Kén U.5., Budapest, 1097

Country: Hungary

Manufacturer number: B.000156

File number: 0331483/24-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: biperidene hydrochloride.

Manufacturer: Lee Pharma Limited.

Address: Survey No: 10/G-1; Gaddapotharam (Village); Jinnaram (Mandal); Sangareddy (District); Telangana (state); PIN : 502319

Country: India

Manufacturer number: B.000240

File number: 4605635/22-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: bilastine, moxifloxacin hydrochloride, tamsulosin hydroridate, empagliflozin, esomeprazole magnesium trihydrate, sitagliptin phosphate monohydrate, linagliptin, dabigatran etexilate mesylate, omeprazole, rosuvastatin calcium.

Manufacturer: Micro Labs Limited.

Address: Plot no. 43-45, K.I.A.B.D., Jigani-Bommasandra Link Road, Anekal Taluk, Bengaluru, 560 105, Karnataka – Bengaluru

Country: India

Manufacturer number: B.000601

File number: 4807411/22-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: apixaban; celecoxib; tofacitinib citrate; dorzolamide hydrochloride; naphazoline hydrochloride; etoricoxib; ezetimibe; sitagliptin phosphate monohydrate; mirabegrona; sodium nitroprusside dihydrate; escitalopram oxalate; rivaroxaban; brimonidine tartrate.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000183

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: MSN Laboratories Pvt. Ltd. - Oncology Division

Address: Unit-II, Sy. No. 50, 53, 53/A, 54, 54/A, Kardanur (Village), Patancheru (Mandal), Sangareddy (District), Telangana – 502300

Country: India

Manufacturer number: B.000752

File number: 0223149/24-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: abiraterone acetate; bortezomib; carfilzomib; pazopanib hydrochloride; dasatinib monohydrate; enzalutamide; nintedanib esylate; gefitinib; ibrutinib; regorafenib monohydrate; sorafenib tosylate.

Manufacturer: Newchem S.p.A.

Address: Via Roveggia 47, Verona - 37100

Country: Italy

Manufacturer number: B.000186

File number: 1027628/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: dienogest.

Manufacturer: Newchem S.p.A.

Address: Via Roveggia 47, Verona - 37100

Country: Italy

Manufacturer number: B.000186

File number: 0279934/24-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: drospirenone (Final steps of chemical synthesis, purification and micronization).

Manufacturer: Nosch Labs Pvt. Ltd. - Unit II

Address: Survey No. 14, Gaddapotharam Village, IDA, Kazipally, Jinnaram Mandal, Sangareddy District-502 319, Telangana

Country: India

Manufacturer number: B.000758

File number: 4448003/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ketorolac trometamol; moxifloxacin hydrochloride; naratriptan hydrochloride; duloxetine hydrochloride; dexlansoprazole sesqui-hydrate; donepezil hydrochloride; doxazosin mesylate; linezolid; olanzapine; pantoprazole sodium sesquihydrate; pantoprazole magnesium dihydrate; pitavastatin calcium; pramipexole dihydrochloride monohydrate; rabeprazole sodium; tamsulosin hydrochloride.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000183

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: Seripharm (Société D'étude et de Recherche en Ingenierie Pharmaceutique)

Address: 1 rue Démocrite, 72000 - Le Mans

Country: France

Manufacturer number: B.001252

File number: 1369729/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: SG3249 (loncastuximab tesirine intermediate).

Manufacturer: ST Pharm Co. Ltd.

Address: Sihwa Industrial Complex, 231, Hyeomnyeok-ro, Siheung- si, Gyeonggi-do

Country: South Korea

Manufacturer number: B.000070

File number: 0715698/22-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: evogliptin tartrate.

Manufacturer: Sun Pharmaceutical Industries Ltd.

Address: Plot No. 4708, GIDC Industrial Estate, Ankleshwar - 393 002, Dist. Bharuch, Gujarat State

Country: India

Manufacturer number: B.001089

File number: 4582071/22-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: dobutamine hydrochloride, oxcarbazepine.

Manufacturer: Symbiotec Pharmalab Private Limited.

Address: Plot No. 5, 6, 7 & 8, Special Economic Zone Phase-II, Pharma Zone, Pithampur, Dist. Dhar, (M.P) - 454774

Country: India

Manufacturer number: B.000355

File number: 0293839/24-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: drospirenone; testosterone; Estradiol; testosterone cypionate; testosterone undecylate; progesterone, estradiol hemihydrate.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000183

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.916, MAY 16, 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 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 Active Pharmaceutical Ingredients obtained by chemical synthesis empagliflozin, losartan potassium and valsartan in the certification of the company Zhejiang Huahai Pharmaceutical Co., Ltd. (Manufacturer number: B.000081), published by Resolution RE No. 2,840, of August 3, 2023, in the Official Gazette No. 149, of August 7, 2023, Section 1, page 124, according to files no. 0596118/23-6 and 1421717/23-9.

Art. 2nd This Resolution comes into force on the date of its publication.

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.918, MAY 16, 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 the non-compliance with the requirements of Good Manufacturing Practices for Pharmaceutical Ingredients, or the non-compliance with the procedures of petitions submitted for analysis, recommended in current legislation, resolves:

Art. 1st Reject the Application(s) for Certification of Good Manufacturing Practices of Pharmaceutical Ingredients of the company(ies) listed in the ANNEX.

Art. 2nd This Resolution comes into force on the date of its publication.

Manufacturer: SHANGHAI AMBIOPHARM, INC. - B001266

Address: NO. 399 YINGONG ROAD, FENGXIAN SUB-ROAD, FENGXIAN SUB-ZONE, SHANGHAI CHEMICAL INDUSTRY PARK, SHANGHAI

Country: CHINA

Manufacturer number: B.001266

File number: 0293670/24-2

Subject: 70158 - PHARMACEUTICAL INGREDIENTS - Certification of Good Manufacturing Practices for International Industry, except Mercosur - chemical synthesis

REASON FOR REJECTION: In compliance with article 4, § 1, item IV of RDC No. 497/2021: Failure to submit mandatory documentation, provided in the petition checklist, due to the absence of the last complete product quality review report (RQP) generated or, when the RQP is not available, the validation of the manufacturing process for the active pharmaceutical ingredients requested, as well as the absence of a certificate or document proving compliance with the Good Manufacturing Practices in force, issued by the health authority of the country where the producing establishment is located; according to items 2 and 4 of the subject code checklist: 70158 - PHARMACEUTICAL INGREDIENTS - Certification of Good Manufacturing Practices for International Industry except Mercosur - chemical synthesis.

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

 www.tmconsultancy.com.br



The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024052000184