

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 2.615, JULY 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: Aventis Pharma Manufacturing Pte. Ltd

Address: 61 Gul Circle Singapore 629585

Country: Singapore

Manufacturer number: A.000058

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 1161497/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: enoxaparin sodium.

Manufacturer: Kin Master Produtos Químicos Ltda.

CNPJ: 91.806.729/0002-96

Address: Rua Miguel Vargas, 595, Bairro Boqueirão. Passo Fundo - RS

Country: Brazil

File number: 1371382/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: Bovine heparin sodium, porcine heparin sodium, mesoglycan, mucopolysaccharide polysulfate, chondroitin sulfate, and sulodexide.

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Manufacturer: Patheon Biologics LLC

Address: 4766 La Guardia Drive, Saint Louis, Missouri (MO) 63134-3116

Country: United States of America

Manufacturer number: A.000146

Requester: Merck Sharp & Dohme Farmacêutica Ltda.

CNPJ: 03.560.974/0001-18

File number: 0687920/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: vibostolimab.

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RESOLUTION - RE NO. 2.616, JULY 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: 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: 1378958/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ciprofloxacin hydrochloride monohydrate.

Manufacturer: Alembic Pharmaceuticals Limited - Unit I

Address: P.O. Tajpura, Tal. Halol, Panelav, District Panchmahal, Gujarat State, 389 350.

Country: India

Manufacturer number: B.000097

File number: 1221138/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semisynthesis: azithromycin dihydrate, azithromycin monohydrate, clarithromycin (chemical synthesis steps).

Manufacturer: Anqiu Lu'an Pharmaceutical Co., Ltd.

Address: No. 35 Weixu North Road, Anqiu, Shandong Province - 262100

Country: China

Manufacturer number: B.000242

File number: 0644181/24-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: paracetamol.

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Manufacturer: Glaxo Wellcome Manufacturing Pte Ltd.

Address: 1 Pioneer Sector 1, Jurong - 628413

Country: Singapore

Manufacturer number: B.000033

File number: 1169680/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: dolutegravir, lamivudine, fluticasone propionate.

Manufacturer: Jiangsu Hansoh Pharmaceutical Group Co., Ltd.

Address: Kaitai Road, Dapu Industrial Park, Economic And Technical Development Zone, Lianyungang, Jiangsu - 222000

Country: China

Manufacturer number: B.000978

File number: 0264563/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: gemcitabine hydrochloride.

Manufacturer: Natco Pharma Limited (Chemical Division)

Address: Mekaguda Village, Nandigama Mandal, Ranga Reddy District, Telangana-509 223

Country: India

Manufacturer number: B.000220

File number: 0405535/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: anastrozole; imatinib mesylate; ondansetron hydrochloride; apixaban; nilotinib hydrochloride monohydrate; gefitinib; sorafenib tosylate; salmeterol xinafoate; ribociclib succinate; ibandronate sodium monohydrate; regorafenib; ibrutinib; zoledronic acid monohydrate; sugammadex sodium; letrozole; trihexyphenidyl hydrochloride.

Manufacturer: Olon S.P.A.

Address: Via Benvenuto Cellini, 20, Segrate, Milano - 20054

Country: Italy

Manufacturer number: B.000476

File number: 0030393/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: acebrophylline

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Manufacturer: Shandong Xinhua Pharmaceutical Co., LTD.

Address: Hutian Chemical Industrial Zone, Zibo, Shandong - 255075 - Zibo.

Country: China

Manufacturer number: B.000424

File number: 1422557/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: dipyrone monohydrate.

Manufacturer: Shandong Xinhua Pharmaceutical Co., LTD.

Address: Hutian Chemical Industrial Zone, Zibo, Shandong - 255075 - Zibo.

Country: China

Manufacturer number: B.000424

File number: 5034485/22-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: dipyrone monohydrate, acetylsalicylic acid.

Manufacturer: Shandong Xinhua Pharmaceutical Co., LTD.

Address: Hutian Chemical Industrial Zone, Zibo, Shandong - 255075 - Zibo.

Country: China

Manufacturer number: B.000424

File number: 1010544/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: acetylsalicylic acid.

Manufacturer: Synthimed Labs Private Limited

Address: Village Bhagwanpur, Barwala Road, Derabassi, Dist S.A.S. Nagar (Mohali), Punjab - 140507

Country: India

Manufacturer number: B.000100

File number: 4505595/22-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: atorvastatin, clarithromycin, fexofenadine hydrochloride, lisdexamfetamine dimesylate.

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Manufacturer: Wuhan Wuyao Pharmaceutical Co, Ltd.

Address: Nº 18 Wangfen Road, Fuchi Town, Yangxin County, Huangshi City, Hubei Province 1 - Hubei

Country: China

Manufacturer number: B.000739

File number: 0398767/24-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: dipyron monohydrate.

Manufacturer: Wuhan Wuyao Pharmaceutical Co, Ltd.

Address: Nº 18 Wangfen Road, Fuchi Town, Yangxin County, Huangshi City, Hubei Province 1 - Hubei

Country: China

Manufacturer number: B.000739

File number: 0405569/24-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: dipyron monohydrate.

Manufacturer: Zhejiang Hisun Pharmaceutical Co., Ltd.

Address: 56 Binhai Road, Jiaojiang District, Taizhou City, Zhejiang Province - 318000

Country: China

Manufacturer number: B.000152

File number: 0702049/24-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: ivermectin.

Manufacturer: Zhuhai United Laboratories Co. Ltd.

Address: No 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040 - PR

Country: China

Manufacturer number: B.000140

File number: 0029853/24-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis (penicillin class): ampicillin sodium (chemical synthesis and sterilization steps).

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Manufacturer: Zhuhai United Laboratories Co., Ltd.

Address: No 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040 - PR

Country: China

Manufacturer number: B.000140

File number: 4925902/22-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semisynthesis (chemical synthesis and sterilization steps): amoxicillin sodium, ampicillin sodium, cefotaxime sodium, ceftriaxone sodium, potassium clavulanate, sulbactam sodium.

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RESOLUTION - RE NO. 2.669, JULY 19, 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: AryoGen Pharmed

Address: No. 140, Corner of Tajbakhsh Street, 24th Km Tehran-Karaj Makhsous Road, Alborz

Country: Iran

Manufacturer number: A.001286

Requester: Laboratórios Bagó do Brasil S/A.

CNPJ: 04.748.181/0009-47

File number: 0076416/24-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: activated eptacog alfa, etanercept, rituximab, and trastuzumab.

Manufacturer: Boehringer Ingelheim RCV GmbH & Co KG.

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

Country: Austria

Manufacturer number: A.000117

Requester: Bayer S.A.

CNPJ: 18.459.628/0001-15

File number: 1241900/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: interferon beta-1b.

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Manufacturer: CinnaGen Co.

Address: West Sixth St., 3rd Sq., Simindasht Industrial Area, Karaj, Alborz

Country: Iran

Manufacturer number: A.001285

Requester: Laboratórios Bagó do Brasil S.A.

CNPJ: 04.748.181/0009-47

File number: 0076655/24-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: adalimumab and interferon beta-1a.

Manufacturer: Novartis Pharmaceutical Manufacturing GmbH

Address: Biochemiestrasse 10, 6250 Kundl

Country: Austria

Manufacturer number: A.000540

Requester: Glaxosmithkline Brasil Ltda

CNPJ: 33.247.743/0001-10

File number: 1351713/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: recombinant serogroup B Neisseria meningitidis fusion protein NHBA, recombinant serogroup B Neisseria meningitidis protein Nad A and recombinant serogroup B Neisseria meningitidis fHBP fusion protein.

Manufacturer: Takeda Manufacturing Italia S.P.A.

Address: Via Della Chimica, 5 - 02015 Santa Rufina, Cittaducale, Rieti

Country: Italy

Manufacturer number: A.000079

Requester: Takeda Pharma Ltda.

CNPJ: 60.397.775/0001-74

File number: 1430982/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: prothrombin complex (factors II, VII, IX, and X), coagulation factor VIII, coagulation factor IX, immunoglobulin G, feiba eluate intermediate, plasma-derived C1 esterase inhibitor.

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RESOLUTION - RE NO. 2.670, JULY 19, 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: Abbvie S.R.L.

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

Country: Italy

Manufacturer number: B.000003

File number: 0707784/24-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: pibrentasvir.

Manufacturer: Centrient Pharmaceuticals Spain S/A.

Address: Pol. Ind. Urvasa, c/Ripollès, 2. Sta. Perpétua de Mogoda, Barcelona E- 08130

Country: Spain

Manufacturer number: B.000107

File number: 0266872/24-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis (cephalosporin class): cephalexin monohydrate (enzymatic synthesis step).

Manufacturer: Fersinsa Gb S.A de C.V.

Address: Rincón del Gato, Camino a Guanajuato SN, Ramos Arizpe, Coahuila - 25900

Country: Mexico

Manufacturer number: B.000031

File number: 0076398/24-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis (penicillin class): ampicillin.

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Manufacturer: Hy-Gro Chemicals Pharmtek Private Limited

Address: Unit 1 Plot 174 Progressive Industrial Society, Bollaram Village, Jinnaram Mandal, Sangareddy District, Telangana - PIN-502 325

Country: India

Manufacturer number: B.001171

File number: 0268037/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: flurbiprofen.

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: 0432346/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: abemaciclib, apalutamide, axitinib, belinostat, bicalutamide, bimatoprost, bosutinib monohydrate, capecitabine, cyclophosphamide monohydrate, alectinib hydrochloride, erlotinib hydrochloride, gemcitabine hydrochloride, nilotinib hydrochloride monohydrate, palonosetron hydrochloride, ponatinib hydrochloride, darolutamide, decitabine, dexrazoxane, afatinib dimaleate, trametinib dimethyl sulfoxide, ruxolitinib phosphate, latanoprost, lenalidomide, cabozantinib levomalate, neratinib maleate, lenvatinib mesylate, osimertinib mesylate, olaparib, paclitaxel, palbociclib, pemetrexed disodium heptahydrate, ribociclib succinate, sorafenib tosylate, travoprost, venetoclax.

Manufacturer: Shandong Xinhua Pharmaceutical Co., LTD.

Address: East Chemical Zone of Zibo High & New Technology Zone of Zibo, Zibo, Shandong. P.R. China 220575

Country: China

Manufacturer number: B.000424

File number: 0374559/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ibuprofen.

Manufacturer: Zhuhai United Laboratories Co., Ltd.

Address: No 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040 - PR

Country: China

Manufacturer number: B.000140

File number: 4027325/20-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: ampicillin (chemical synthesis and sterilization steps).

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Manufacturer: Zhuhai United Laboratories Co., Ltd.

Address: No 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040 - PR China

Country: China

Manufacturer number: B.000140

File number: 0384146/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: ampicillin trihydrate (chemical synthesis steps).

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RESOLUTION - RE NO. 2.671, JULY 19, 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 active pharmaceutical ingredients obtained by chemical synthesis allopurinol, sitagliptin phosphate monohydrate and linagliptin in the certification of the company Harman Finochem Limited - Site I (Manufacturer number: B.000754), published by Resolution - RE No. 3,682, of November 4, 2022, in the Official Gazette No. 210, of November 7, 2022, section 1, page 103, according to file no. 1110500/22-0 and 1430566/23-0.

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

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