

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 2.415, JUNE 27, 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: Adeste Indústria de Produtos Animais Ltda.

CNPJ: 44.885.291/0055-00

Address: Estrada HT 005 Km 01, S/N, Zona Rural, Jaguapitã - PR

Country: Brazil

File number: 1323581/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: bovine heparin sodium, porcine heparin sodium and chondroitin sulfate.

Manufacturer: AGC Biologics A/S.

Address: Vandtaarsnsvej 83 B, DK 2860 Soeborg Copenhagen

Country: Denmark

Manufacturer number: A.001313

Requester: Medison Pharma Brasil Produtos Farmacêuticos Ltda

CNPJ: 48.682.588/0001-37

File number: 1317488/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: tebentafuspe.

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Manufacturer: Astrazeneca Pharmaceuticals LP.

Address: 633 Research Court, Frederick, Maryland (MD) 21703

Country: USA

Manufacturer number: A.001047

Requester: Horizon Therapeutics Brasil Ltda.

CNPJ: 41.590.794/0001-78

File number: 1480485/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: inebilizumab.

Manufacturer: Bioiberica S.A.U.

Address: Av. Cadí 43 - 49, Polígono Industrial Sant Pere de Molanta - 08734 - Olèrdola (Barcelona)

Country: Spain

Manufacturer number: A.001334

Requester: Aché Laboratórios Farmacêuticos S.A.

CNPJ: 60.659.463/0029-92

File number: 1386645/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: porcine sodium heparin.

Manufacturer: Boiron S.A.

Address: 2 Avenue de l'Ouest Lyonnais, 69510 Messimy

Country: France

Manufacturer number: A.000341

Requester: Boiron Medicamentos Homeopáticos Ltda.

CNPJ: 07.498.711/0001-87

File number: 1466876/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: Anas barbariae hep et Cordis extractum

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Manufacturer: Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd.

Address: Nanjing High & New Technology Development Zone MA 010-1, Nanjing, Jiangsu

Country: China

Manufacturer number: A.000424

Requester: Cristália Produtos Químicos Farmacêuticos Ltda.

CNPJ: 44.734.671/0001-51

File number: 1441672/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: enoxaparin sodium and porcine heparin sodium.

Manufacturer: Novartis Pharmaceutical Manufacturing GmbH.

Address: Biochemiestrasse 10, 6336 Langkampfen

Country: Austria

Manufacturer number: A.000541

Requester: Fundação Oswaldo Cruz.

CNPJ: 33.781.055/0001-35

File number: 1333118/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: rituximab.

Manufacturer: Novartis Pharmaceutical Manufacturing GmbH.

Address: Biochemiestrasse 10, 6336 Langkampfen

Country: Austria

Manufacturer number: A.000541

Requester: Instituto Butantan.

CNPJ: 61.821.344/0001-56

File number: 1392525/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: adalimumab.

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Manufacturer: Prothya Biosolutions Belgium BV.

Address: De Tyraslaan 109, Neder-Over-Heembeek (Brussel), 1120

Country: Belgium

Manufacturer number: A.000148

Requester: Blau Farmacêutica S.A.

CNPJ: 58.430.828/0001-60

File number: 1435238/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients (fractionation): immunoglobulin G paste II and human albumin paste V.

Manufacturer: Samsung Biologics Co. Ltd.

Address: 300, Songdo Bio-Daero, Yeonsu-Gu, Incheon, 21987

Country: South Korea

Manufacturer number: A.001327

Requester: Pfizer Brasil Ltda

CNPJ: 61.072.393/0001-33

File number: 0383574/24-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: bevacizumab.

Manufacturer: Samsung Biologics Co. Ltd.

Address: 300, Songdo Bio-Daero, Yeonsu-Gu, Incheon, 21987

Country: South Korea

Manufacturer number: A.001327

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 1286059/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: rituximab and tocilizumab.

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RESOLUTION - RE NO. 2.416, JUNE 27, 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:

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

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.0000031

File number: 1448520/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

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

Manufacturer: Jiangsu Weiqida Pharmaceutical Co., Ltd

Address: Nº 1 Linjiang Avenue, Linjiang Town, Haimen, Nantong, Jiangsu - 226133

Country: China

Manufacturer number: B.000131

File number: 1153696/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: azithromycin dihydrate (chemical synthesis steps).

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Manufacturer: Jubilant Pharmova Limited

Address: Plot # 18, 56, 57 and 58, KIADB Industrial Area, Nanjangud, Mysore District Karnataka - 571302

Country: India

Manufacturer number: B.000042

File number: 1462581/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: azithromycin dihydrate (chemical synthesis steps).

Manufacturer: Livzon Group Fuzhou Fuxing Pharmaceutical Co. LTD

Address: No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, P. R. China, Post Code: 350309

Country: China

Manufacturer number: B.000483

File number: 1027540/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: tobramycin..

Manufacturer: Livzon Group Fuzhou Fuxing Pharmaceutical Co. LTD

Address: No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, P. R. China, Post Code: 350309

Country: China

Manufacturer number: B.000483

File number: 0373581/24-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by classical fermentation: vancomycin hydrochloride, daptomycin and teicoplanin.

Manufacturer: Micro Labs Limited.

Address: Plot no. 43-45, KIADB, Jigani-Bommasandra Link Road, Anekal Taluk, Bengaluru, 560 105, Karnataka - Bengaluru

Country: India

Manufacturer number: B.000601

File number: 0628852/24-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: lurasidone hydrochloride.

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Manufacturer: Neuland Laboratories Ltd. - Unit I.

Address: Sy. No: 347, 473, 474 & 490/2, Veerabhadra Swamy Temple Road, Bonthapally, Gummadidala Mandal, Sangareddy District, Telangana State - 502313

Country: India

Manufacturer number: B.000051

File number: 1369431/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: donepezil; donepezil hydrochloride; dorzolamide hydrochloride; enalapril maleate; escitalopram oxalate; indacaterol maleate; ipratropium bromide; itraconazole; levetiracetam; levofloxacin hemihydrate; mirtazapine; ofloxacin; paliperidone palmitate; posaconazole; ramipril; ropinirole; ropinirole hydrochloride; rotigotine; salbutamol sulfate; salmeterol xinafoate; Sotalol hydrochloride; vilanterol trifenate.

Manufacturer: SMS Pharmaceuticals Limited

Address: Kandivalasa (Village), Poosapatirega (Mandal), Vizianagaram District - 535 204, Andhra Pradesh

Country: India

Manufacturer number: B.001140

File number: 0666545/24-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: compound (S)-pyrrolidine-2-carboxylic acid with (2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-ethoxybenzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol (1:1 - dapaglifozin intermediate) and compound (S)-pyrrolidine-2-carboxylic acid with (2S,3R, 4R, 5S,6R)-2-(4-chloro-3-(4-((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol (empaglifozin intermediate).

Manufacturer: Synthon Argentina S.A.

Address: Ruta 11 Km 325, San Lorenzo, Provincia de Santa Fe - 2200

Country: Argentina

Manufacturer number: B.001063

File number: 0358004/24-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: glatiramer acetate.

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

Address: Xunqiao, Zhejiang Province - 317024 - Linhai

Country: China

Manufacturer number: B.000082

File number: 4456286/22-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: paroxetine hydrochloride hemihydrate.

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