

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 206, JANUARY 18<sup>th</sup>, 2024

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 through automatic renewal.

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

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Manufacturer: Sanofi Pasteur

Address: Parc Industriel d'Incarville, 27100 Val de Reuil

Country: France

Manufacturer number: A.000551

Requester: Instituto Butantan

CNPJ: 61.821.344/0001-56

File number: 0609022/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: influenza type A strain (H1N1), influenza type A strain (H3N2), influenza type B strain and rabies virus.

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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.

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Manufacturer: Abbott Biologicals B.V.

Address: C. J. van Houtenlaan 36, Weesp, 1381 CP

Country: Netherlands

Manufacturer number: A.000591

Requester: Abbott Laboratórios do Brasil Ltda.

CNPJ: 56.998.701/0001-16

File number: 0630611/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: type A (H1N1) inactivated and subunitary influenza strain; type A (H3N2) inactivated and subunitary influenza strain; Inactivated, subunit type B influenza strain.

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Manufacturer: Kamada Ltd.

Address: Kibbutz Beit Kama, M.P. Negev 8532500

Country: Israel

Manufacturer number: A.000336

Requester: Panamerican Medical Supply Suprimentos Médicos Ltda

CNPJ: 01.329.816/0001-26

File number: 0781029/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alpha1antitrypsin and anti-Rho immunoglobulin (D).

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Manufacturer: Sanofi Pasteur NVL.

Address: 31-33 quai Armand Barbès, 69250 Neuville-Sur-Saône

Country: France

Manufacturer number: A.001102

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 0469367/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: yellow fever-dengue chimeric virus serotypes 1, 2,3 and 4.

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Manufacturer: Smithfield Bioscience, Inc.

Address: 12150 Best Place, Cincinnati, Ohio (OH) 45241-1569

Country: USA

Manufacturer number: A.001589

Requester: Biomm SA.

CNPJ: 04.752.991/0001-10

File number: 2520950/22-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: porcine sodium heparin.

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Manufacturer: Zelltek S.A.

Address: Ruta Nacional nº. 168 S/N, Paraje "El Pozo", Parque Tecnológico Litoral Centro, Santa Fé, Provincia de Santa Fé

Country: Argentina

Manufacturer number: A.001071

Requester: Blau Farmacêutica S.A.

CNPJ: 58.430.828/0001-60

File number: 0547437/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: epoetin alfa.

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## RESOLUTION - RE NO. 208, JANUARY 18<sup>st</sup>, 2024

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(ies) listed in the ANNEX, the Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients.

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

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Manufacturer: Carbogen AMCIS (Shanghai) Co., Ltd.

Address: No. 69 Shungong Road Shanghai Chemical Industry Park, Shanghai - 201 507

Country: China

Manufacturer number: B.000927

File number: 2013870/21-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: Migalastat hydrochloride intermediate 1 (1,2,3,6-tetrapivaloyl-a-D-galactofuranoside).

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Manufacturer: CF Pharma Gyógyszergyártó Kft

Address: Kén U.5., Budapest, 1097

Country: Hungary

Manufacturer number: B.0156

File number: 0421841/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: atracurium besylate.

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Manufacturer: MSN Life Sciences Private Limited - Unit II

Address: Sy.No. 454, 455, 457, 458 & 459, Chandampet (Village), Shankarampet-R (Mandal), Medak District, Telangana - Pincode: 502 255

Country: India

Manufacturer number: B.000276

File number: 4778169/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: esomeprazole sodium, bilastine, sacubitril, dolutegravir sodium, empagliflozin, sugammadex sodium, valsartan, riociguat, edoxaban tosylate monohydrate, linaclotide, desvenlafaxine succinate monohydrate, brexpiprazole, apremilast, oxcarbazepine, nitazoxanide, sodium phenylacetate, sodium benzoate.

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Manufacturer: Sandoz GmbH

Address: Biochemiestrasse 10, Kundl, Tyrol - A-6250

Country: Austria

Manufacturer number: B.000060

File number: 0487452/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis (penicillin class): benzathine benzylpenicillin tetrahydrate (sterilization steps).

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Manufacturer: Sourcedtech Química Ltda. CNPJ: 71.717.938/0001-75

Address: Rodovia Vereador Abel Fabricio Dias Nº. 3430, Água Preta

Country: Brasil

Operating License: 103.8015

File number: 0775264/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by plant extraction: pilocarpine nitrate and pilocarpine hydrochloride.

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Manufacturer: SpecGx LLC

Address: 3600 North Second Street, St Louis, Missouri (MO) 63147

Country: USA

Manufacturer number: B.000232

File number: 1043671/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: codeine phosphate.

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Considering the need for inclusion in the Good Manufacturing Practices certification, as provided for in article 11 of Collegiate Board Resolution - RDC No. 497, of May 20, 2021, it is hereby resolved:

Art 1st. Include the active pharmaceutical ingredients obtained by chemical synthesis, deferasirox, nintedanib esylate, and rivaroxaban, in the certification of the company Glenmark Life Sciences Limited (Unique Code: B.000755), published by Resolution RE No. 2,813, of August 25, 2022, published in the Official Gazette No. 165, of August 30, 2022, section 1, page 277, according to processes No. 4228925/21-9 and 1037311/23-0.

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

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