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RESOLUTION - RE NO. 2.803, AUGUST 2, 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: Biopharma Plasma LLC
Address: 37 V Bila Tserkva, Kyivska 09100, Kyiv
Country: Ukraine
Manufacturer number: A.001431
Requester: ASP-Farmacêutica Ltda.
CNPJ: 28.942.435/0001-74
File number: 0131787/24-1
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Biological active pharmaceutical ingredients: human immunoglobulin and human albumin (plasma fractionation).

Manufacturer: Sanofi Pasteur
Address: 1541 Avenue Marcel Mérieux, 69280 - Marcy L´Etoile
Country: France
Manufacturer number: A.000549
Requester: Fundação Oswaldo Cruz.
CNPJ: 33.781.055/0001-35
File number: 1317261/23-2
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Biological active pharmaceutical ingredients: poliovirus types 1, 2 and 3 (inactivated), Haemophilus Influenzae type B polysaccharide conjugated with tetanus toxoid, tetanus toxoid, filamentous hemagglutinin, diphtheria toxoid, pertussis toxoid.

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Manufacturer: Sanofi Pasteur

Address: 1541 Avenue Marcel Mérieux, 69280 - Marcy L´Etoile

Country: France

Manufacturer number: A.000549

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 1266188/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: Haemophilus influenzae type b polysaccharide conjugated with tetanus toxoid; inactivated poliovirus types 1, 2 and 3; tetanus toxoid; diphtheria toxoid; toxoid pertussis; filamentous hemagglutinin; capsular polysaccharide of Salmonella typhi VI; inactivated Hepatitis A virus.

Manufacturer: Sanofi Pasteur S.A.

Address: Calle 8, n° 703, Esquina 5, 1629, Parque Industrial Pilar, Província de Buenos Aires

Country: Argentina

Manufacturer number: A.000950

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 1251420/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: hepatitis B surface antigen.

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RESOLUTION - RE NO. 2.804, AUGUST 2, 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 Limited
Address: Plot No. N-198, M.I.D.C., Tarapur, Tal.-Palghar, Dist.: Thane, Maharashtra - 401 506
Country: India
Manufacturer number: B.000175
File number: 4575440/22-1
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Active pharmaceutical ingredient obtained by chemical synthesis: Nimesulide and tinidazole.

Manufacturer: F. I. S. - Fabbrica Italiana Sintetici S.p.A.
Address: Viale Milano 26, Montecchio Maggiore - 36075
Country: Italy
Manufacturer number: B.000029
File number: 0878303/24-3
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Active pharmaceutical ingredient obtained by chemical synthesis: edoxaban tosylate monohydrate.

Manufacturer: Ingredion Brasil Ingredientes Industriais Ltda
CNPJ: 01.730.520/0015-18
Address: Rua Joaquim Lemos, n° 48, Bairro Trindade, São Gonçalo - RJ
Country: Brazil
Manufacturer number: B.001107
File number: 0579161/24-2
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Active pharmaceutical ingredient obtained by chemical synthesis: glucose and mannitol.

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Manufacturer: Pfizer Ireland Pharmaceuticals

Address: Ringaskiddy API Plant, P.O. Box 140, Ringaskiddy, County Cork

Country: Ireland

Manufacturer number: B.000126

File number: 1258511/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: bosutinib monohydrate, nirmatrelvir and tafamidis meglumine.

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RESOLUTION - RE NO. 2.805, AUGUST 2, 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 biological active pharmaceutical ingredient tocilizumab in the certification of the company Merck Serono S. A. (Manufacturer number: A.000409), requested by the company Fresenius Kabi Brasil Ltda, CNPJ No. 49.324.221/0001-04, published by Resolution RE No. 130, of January 13, 2023, published in the Federal Official Gazette No. 11, of January 16, 2023, section 1, page 66, according to files no. 4318835/22-7 and 0869854/24-1.

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

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RESOLUTION - RE NO. 2.792, AUGUST 2, 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 Medicines, or the non-compliance with the procedures of petitions submitted for analysis, recommended in current legislation, resolves:

Art. 1st To reject the Application(s) for Certification of Good Manufacturing Practices for Medicines of the company(ies) contained in the ANNEX.

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

Manufacturer: GENZYME FLANDERS

Address: CIPALSTRAAT 8, GEEL, 2440

Country: Belgium

Manufacturer number: A.000252

File number: 0398661/24-3

Subject: 70855 - BIOLOGICAL PRODUCTS - Renewal of GMP Certification of the International Biological Products Industry except MERCOSUR

REASON FOR REJECTION: The petition under analysis refers to the Renewal of GMP Certification of the International Biological Products Industry, however the company filed two APQRs referring to the manufacturing stage of the active Pharmaceutical Ingredient and does not include the stages referring to the finished product (freeze-drying). In view of this, it is understood that the company failed to comply with the provisions of items IV of article 4 and VI of article 36 of RDC No. 497, of 2021 by not presenting mandatory documentation, provided for in the petition's checklist, and should therefore be rejected.

Manufacturer: PHARMACIA & UPJOHN COMPANY LLC

Address: 7000 PORTAGE ROAD, KALAMAZOO, MICHIGAN (MI) 49001

Country: United States of America

Manufacturer number: A.000504

File number: 0054879/24-8

Subject: 70855 - BIOLOGICAL PRODUCTS - Renewal of GMP Certification of the International Biological Products Industry except MERCOSUR

REASON FOR REJECTION: The requesting company presented the files of the Master File of the Plant and the Periodic Product Review with stripes in the texts, and it was not possible to analyze their content in full. The addition functionality could have been used by third parties in Solicita, if necessary, for reasons of confidentiality, but this did not occur. In view of this, it is understood that the company failed to comply with the provisions of items IV of article 4 and VI of article 36 of RDC No. 497, of 2021 by not presenting mandatory documentation, provided for in the petition's checklist, and should therefore be rejected.