

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.966, MAY 23, 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: Alvotech HF.

Address: Sæmundargata 15-19, Reykjavík, 102.

Country: Iceland

Manufacturer number: A.001665

Requester: Eolias Health Comércio e Importação Ltda

CNPJ: 15.729.838/0001-98

File number: 1466866/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: ustekinumab.

Manufacturer: FujiFilm Dyosinth Biotechnologies ApS.

Address: Biogen Allé 1, 3400, Hillerod

Country: Denmark

Manufacturer number: A.000788

Requester: Samsung Bioepis BR Pharmaceutical Ltda

CNPJ: 24.563.776/0001-88

File number: 1214354/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologics active pharmaceutical ingredients: adalimumab, bevacizumab, etanercept, infliximab, and trastuzumab.

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Manufacturer: GlaxoSmithKline Biologicals.

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

Country: France

Manufacturer number: A.000731

Requester: GlaxoSmithKline Brasil Ltda.

CNPJ: 33.247.743/0001-10

File number: 1455077/23-2

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: Opocrin S.p.A.

Address: Via Pacinotti, 3, Corlo di Formigine, 41043 Formigine (MO)

Country: Italy

Manufacturer number: A.000465

Requester: EMS S/A

CNPJ: 57.507.378/0003-65

File number: 1285649/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: porcine sodium heparin.

Manufacturer: Ukraine PJSC Indar

Address: Zroshuvalna 5, Kyiv

Country: Ukraine

Manufacturer number: A.000620

Requester: Star Pharma Distribuidora de Medicamentos e Correlatos Ltda.

CNPJ: 41.622.520/0001-13

File number: 1334072/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: human insulin.

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Manufacturer: Wyeth Biopharma Division Of Wyeth Pharmaceuticals LLC.

Address: One Burt Road, Andover, Massachusetts (MA) 01810

Country: USA

Manufacturer number: A.000633

Requester: Pfizer Brasil Ltda.

CNPJ: 61.072.393/0001-33

File number: 1257843/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: adalimumab; alfanonacogue; bevacizumab; elranatamab; gentuzumab ozogamicin; inotuzumab ozogamicin; Marstacimab; tanezumab; pneumococcal polysaccharides 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F; mRNA encoding the Spike protein of the SARS-CoV-2 virus; Bivalent (recombinant) respiratory syncytial virus vaccine.

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RESOLUTION - RE NO. 1.967, MAY 23, 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: Anthem Biosciences Private Limited.

Address: # 49 F1 & F2 Block A5, A3 & A8 (AB4 & 11), Canara Bank Road, Bommasandra Industrial Area Phase I, Bommasandra, Bangalore, Karnataka - 560099.

Country: India

Manufacturer number: B.001119

File number: 0084224/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: rimegapate hemisulfate sesquihydrate.

Manufacturer: Anthem Biosciences Private Limited - Unit II.

Address: No. 276-P & 277-P, Sy. No. 20, Bannikuppe Road, Harohalli Industrial Area, Phase-II, Kanakapura Taluk, Ramanagara District, Ramnagar 562112, Karnataka

Country: India

Manufacturer number: B.001120

File number: 0084178/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: rimegapate hemisulfate sesquihydrate.

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Manufacturer: BGP Healthcare PVT Limited.

Address: 3707, G.I.D.C., Ankleshwar, District Bharuch, Gujarat - 393002

Country: India

Manufacturer number: B.001125

File number: 0906626/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: nicotine.

Manufacturer: BGP Healthcare PVT Limited.

Address: 3707, G.I.D.C., Ankleshwar, District Bharuch, Gujarat - 393002

Country: India

Manufacturer number: B.001125

File number: 5084812/22-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: nicotine.

Manufacturer: Biocon Limited - Site 3.

Address: Plot no. 213 - 215 and 216/B, Phase-II, IDA, Pashamylaram, Sangareddy District, Telangana State - 502 307

Country: India

Manufacturer number: B.000325

File number: 5063152/22-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: glatiramer acetate, apixaban, brinzolamide, ivabradine hydrochloride, deferasirox, dapagliflozin propanediol, dapagliflozin butan-2,3-diol monohydrate, empagliflozin, linagliptin, dabigatran etexilate mesylate, posaconazole, rivaroxaban, rosuvastatin calcium.

Manufacturer: Curia Italy S.R.L.

Address: Via Volturmo, 41/43, Rozzano (Mi) - 20089

Country: Italy

Manufacturer number: B.000027

File number: 1084084/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by classical fermentation: cyclosporine.

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Manufacturer: Deretil S.A.

Address: Villaricos S/N, Cuevas Del Alzamora, Almeria, Andalusia - 4616.

Country: Spain

Manufacturer number: B.001213

File number: 1462154/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semisynthesis: amoxicillin trihydrate (enzymatic synthesis steps).

Manufacturer: Glaxo Operations UK Limited

Address: Cobden Street, Montrose, Angus - DD10 8EA - Montrose

Country: UK

Manufacturer number: B.001183

File number: 0816375/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: dutasteride.

Manufacturer: Shandong Ruiying Pioneer Pharmaceutical Co., Ltd

Address: No. 166 Taishan Road, Mudan District, Heze City Shandong Province

Country: China

Manufacturer number: B.000136

File number: 0383151/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: piperacillin monohydrate.

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: 0214079/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: Lenalidomide.

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Manufacturer: Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd.

Address: No.23, 5th Donghai Avenue, Zhejiang Chemical Materials Base Linhai zone, Linhai city, Zhejiang Province

Country: China

Manufacturer number: B.000115

File number: 1177502/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: clindamycin phosphate (chemical synthesis step).

Manufacturer: Zhejiang Tiantai Pharmaceutical Co., Ltd.

Address: Fengze Road N° 588, Tiantai County, Taizhou City, Zhejiang Province - 317200

Country: China

Manufacturer number: B.000084

File number: 1227323/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: clindamycin phosphate (chemical synthesis steps).

Manufacturer: Zhejiang Xianju Pharmaceutical Co., LTD.

Address: No. 15 West Fengxi Road, Modern Industrial Park, Xianju, Taizhou, Zhejiang - Taizhou

Country: China

Manufacturer number: B.000991

File number: 0330934/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: norethisterone acetate, dexamethasone, estradiol hemihydrate, ethinyl estradiol, testosterone undecylate, betamethasone valerate.

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RESOLUTION - RE NO. 1.968, MAY 23, 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 Ingredient obtained by chemical synthesis dolutegravir in the certification of the company Glaxo Wellcome Manufacturing Pte Ltd, (Manufacturer number: B.000033), published by Resolution - RE No. 2,260, of July 7, 2022, in the Official Gazette No. 129, of July 11, 2022, Section 1, page 93, according to files No. 0128205/22-9 and 1448358/23-0.

Art. 2nd Include the biological active pharmaceutical ingredient glofitamab in the certification of the company Roche Diagnostics GmbH (Manufacturer number: A.000530), requested by the company Produtos Roche Químicos e Farmacêuticos S.A., CNPJ 33.009.945/0001-23, published by Resolution - RE No. 3,295, of October 5, 2022, published in the Official Gazette No. 193, of October 10, 2022, section 1, page 104, according to files no. 0696071/22-3 and 1397598/23-9.

Art. 3rd Include the active pharmaceutical ingredient obtained by chemical synthesis azacitidine in the certification of the company Cristália Produtos Químicos Farmacêuticos Ltda., CNPJ No. 44.734.671/0001-51, published by Resolution - RE No. 3,993, of December 2, 2022, published in the Official Gazette No. 227, of December 5, 2022, section 1, page 115, according to files No. 2665327/22-8 and 0294417/24-9.

Art. 4 This Resolution comes into force on the date of its publication.

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