

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 4.617, DECEMBER 01st, 2023

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 be in force on the date of its publication.

Manufacturer: Abbvie Bioresearch Center

Address: 100 Research Drive, Worcester, Massachusetts (MA) 01605

Country: USA

Manufacturer number: A.000002

Requester: Takeda Pharma Ltda

CNPJ: 60.397.775/0001-74

File number: 0450146/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: brentuximab vedotin and vedolizumab.

Manufacturer: Boehringer Ingelheim Pharma GmbH & Co. KG

Address: Birkendorfer Strasse 65, 88397 - Biberach an der Riss

Country: Germany

Manufacturer number: A.000116

Requester: Merck Sharp & Dohme Farmacêutica Ltda CNPJ: 03.560.974/0001-18

CNPJ: 03.560.974/0001-18

File number: 0571178/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: pembrolizumab.

Manufacturer: Celltrion, Inc.

Address: 20, Academy-ro 51 Beon-gil, Yeonsu-gu, Incheon 22014

Country: South Korea

Manufacturer number: A.000975

Requester: Celltrion Healthcare Distribuição de Produtos Farmacêuticos do Brasil Ltda.

CNPJ: 05.452.889/0001-61

File number: 0346042/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: adalimumab, bevacizumab, infliximab, omalizumab, rituximab and trastuzumab.

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Manufacturer: Gland Pharma Limited.

Address: Unit I, Block-C, Phase-I, Vsez, Duvvada, Visakhapatnam, 530049, Andhra Pradesh

Country: India

Manufacturer number: A.001338

Requester: Mylan Laboratórios Ltda.

CNPJ: 11.643.096/0001-22

File number: 0415200/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: enoxaparin sodium.

Manufacturer: Novo Nordisk A/S

Address: Brogardsvej 66, DK-2820, Gentofte

Country: Denmark

Manufacturer number: A.000442

Requester: Novo Nordisk Farmacêutica do Brasil Ltda.

CNPJ: 82.277.955/0001-55

File number: 0553446/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: glucagon (purification and pre-formulation).

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RESOLUTION - RE NO. 4.618, DECEMBER 01st, 2023

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Art. 3rd This Resolution be in 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: 0554053/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ciprofloxacin hydrochloride.

Manufacturer: Ajinomoto Omnicem N.V.

Address: Coopallaan 91, Ind. Zone 7, Wetteren - B-9230

Country: Belgium

Manufacturer number: B.000278

File number: 1153011/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: alectinib hydrochloride.

Manufacturer: Anidro do Brasil Extrações S.A.

Address: Rua Pilocarpina, nº1000 - Bairro Igarapu

Country: Brazil

Manufacturer number: 1063311

File number: 0447432/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: pilocarpine hydrochloride and pilocarpine nitrate.

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Manufacturer: F.I.S. - Fabbrica Italiana Sintetici S.P.A.

Address: Viale Milano 26, Alte di Montecchio Maggiore, Vicenza - 36075

Country: Italy

Manufacturer number: B.000029

File number: 1095210/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: vemurafenib.

Manufacturer: Fujimoto Chemicals Co., (Senboku Plant)

Address: 1-24, Rinkai-Cho Izumiotsu, Osaka 595-0075

Country: Japan

Manufacturer number: B.000286

File number: 1153101/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: cloridrato de alectinibe.

Manufacturer: Mylan Laboratories Ltd. - Unit VII.

Address: Plot No. 14, 99 & 100, IDA, Pashamylaram, Phase II, Patancheru, Sangareddy District, Telangana - 502307

Country: India

Manufacturer number: B.000048

File number: 0392470/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: acyclovir.

Manufacturer: Mylan Laboratories Ltd. (UNIT- 8)

Address: G. Chodavaram Village, Poosapatirega Mandal, Andhra Pradesh - 535204

Country: India

Manufacturer number: B.000047

File number: 0532171/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Intermediates of the active pharmaceutical ingredient lamivudine obtained by chemical synthesis: Cytosine Menthyl Ester (CME) and Cyclohexyl Ester (CXE).

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Manufacturer: Rolabo Outsourcing, S.L.

Address: Polígono Industrial Malpica, C/J Nº 3 y 4, Zaragoza - 50016

Country: Spain

Manufacturer number: B.001208

File number: 1153489/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: palonosetron hydrochloride.

Manufacturer: Zhejiang Hisoar Chuannan Pharmaceutical Co., LTD. (Linhai).

Address: N°. 23, Donghai 5th Avenue, Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejiang Province - 317 016.

Country: China

Manufacturer number: B.000115

File number: 0457928/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semisynthesis: clindamycin phosphate, clindamycin hydrochloride (chemical synthesis steps).

Manufacturer: Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd. (Linhai).

Address: N°. 23, Donghai 5th Avenue, Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejiang Province - 317 016.

Country: China

Manufacturer number: B.000115

File number: 0554189/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

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

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RESOLUTION - RE NO. 4.615, DECEMBER 01st, 2023

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 through its automatic renewal.

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

Art. 3rd This Resolution be in force on the date of its publication.

Manufacturer: Biomarin Pharmaceutical Inc.

Address: 46 Galli Drive, Novato, California (CA) 94949.

Country: USA

Manufacturer number: B.000107

Requester: Biomarin Brasil Farmacêutica.

CNPJ: 08.002.360/0001-34

File number: 0409503/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alfaelosulfase, galsulfase, pegvaliase and vosoritide.

Manufacturer: Celltrion, Inc.

Address: 23, Academy-ro 51 Beon-gil, Yeonsu-gu, Incheon 22014.

Country: South Korea

Manufacturer number: B.001697

Requester: Celltrion Healthcare Distribuição de Produtos Farmacêuticos do Brasil Ltda.

CNPJ: 05.452.889/0001-61

File number: 0346507/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: infliximab and rituximab.

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RESOLUTION - RE NO. 4.616, DECEMBER 01st, 2023

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 through its automatic renewal.

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

Art. 3rd This Resolution be in force on the date of its publication.

Manufacturer: Aurobindo Pharma Limited, Unit VIII.

Address: Survey Nº. 10 &13, Gaddapotharam Village, Industrial Development Area, Kazipally, Jinnaram (Mandal), Sangareddy District, Telangana State – 502319.

Country: India

Manufacturer number: B.000013

File number: 0370264/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: zidovudine.

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