

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.629, APRIL 26, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated 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: Chugai Pharma Manufacturing Co., Ltd
Address: 5-1, Ukima 5-Chome, Kita-ku, Tokyo 115-8543.

Country: Japan

Manufacturer number: A.000156

Requester: Produtos Roche Químicos Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 1049740/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: emicizumab and satralizumab.

Manufacturer: Kedrion S.p.A

Address: Via Provinciale (loc. Bolognana) - 55027 Galliciano (LU)

Country: Italy

Manufacturer number: A.001127

Requester: Kedrion Brasil Distribuidora De Produtos Hospitalares Ltda

CNPJ: 09.284.952/0001-59

File number: 0954193/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: human immunoglobulin, human albumin, coagulation factor VIII and fraction II (intermediate to obtain normal human immunoglobulin and Anti-Rho immunoglobulin (D)), and fraction V (intermediate to obtain normal human albumin).

 development@tmconsultancy.com.br

 +55 45 3054 7096

 +55 45 99857 3570

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RESOLUTION - RE NO. 1.630, APRIL 26, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated 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 through automatic renewal.

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: ACG do Brasil S.A.

CNPJ: 09.625.967/0002-14

Address: Rua Edmond Philip Calouche, 1405, Limeira. Pouso Alegre - MG

Country: Brazil

File number: 1448112/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Pharmaceutical Ingredient: Hard Softgel.

Manufacturer: Cambrex Charles City Inc.

Address: 1205 11th Street, Charles City, Iowa (IA) 50616

Country: USA

Manufacturer number: A.000564

File number: 0370409/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: danicopane.

Manufacturer: Curia Italy S.R.L.

Address: Via Volturno, 41/43, Rozzano (MI) - 20089

Country: Italy

Manufacturer number: B.000027

File number: 0168413/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: rocuronium bromide.

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Manufacturer: Fresenius Kabi Oncology Limited

Address: D-35 Industrial Area, Kalyani, Nadia, West Bengal 741 235

Country: India

Manufacturer number: B.000147

File number: 1067048/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis (cytotoxic class): carboplatin.

Manufacturer: Formil Química Ltda.

CNPJ: 43.994.268/0001-07

Address: Estrada Velha de Itu, 800, Vila Márcia, Jandira – SP

Country: Brazil

File number: 1153453/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: alprazolam, bromazepam, lithium carbonate, cilostazol, midazolam hydrochloride, dapaconazole, flumazenil, zolpidem hemitartrate, midazolam, isoconazole nitrate, miconazole nitrate, gamaminobutyric acid tartrate monohydrate and dapaconazole tosylate (obtained by chemical synthesis) and albendazole (purification step).

Manufacturer: Gentec S.A.

Address: Tramontana 3, Avinyonet Del Penedes, Barcelona - 08793

Country: Spain

Manufacturer number: B.000567

File number: 5102640/22-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: bimatoprost, latanoprost, travoprost.

Manufacturer: IOL Chemicals and Pharmaceuticals Limited

Address: Village Fatehgarh Channa, Mansa Road, (Trident Complex), Barnala Punjab 148101

Country: India

Manufacturer number: B.000037

File number: 0710030/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: clopidogrel bisulfate, metformin hydrochloride, fenofibrate, gabapentin, ibuprofen, ibuprofen sodium, lamotrigine, levetiracetam, ibuprofen levolisinate, losartan potassium, pantoprazole sodium, paracetamol.

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Manufacturer: Pfizer Asia Manufacturing Pte Ltd

Address: 31 Tuas South Avenue 6 - 637578

Country: Singapore

Manufacturer number: B.000295

File number: 1152742/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: Azithromycin dihydrate (purification steps).

Manufacturer: Sun Pharmaceutical Industries Ltd.

Address: Plot N 24 / 2 & 25, PHASE-IV, G.I.D.C. Industrial Zone, At & Post. Panoli, - 394 116, Dist. - Bharuch, Gujarat State

Country: India

Manufacturer number: B.000200

File number: 4332151/22-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: carvedilol, clomipramine hydrochloride, methylphenidate hydrochloride, naltrexone hydrochloride, ondansetron hydrochloride, levocetirizine dihydrochloride, pramipexole dihydrochloride monohydrate, empagliflozin, exemestane, sitagliptin phosphate, sodium esomeprazole, zolpidem hemitartrate, lacosamide, levetiracetam, ondansetron, pentoxifylline, fluticasone propionate, rifaximin, riluzole, topiramate, prucalopride succinate, and sumatriptan succinate.

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RESOLUTION - RE NO. 1.631, APRIL 26, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated December 10, 2021,

Considering the need for inclusion in the certification of good manufacturing practices, provided for in Article 11 of RDC No. 497, of May 20, 2021, resolves:

Art. 1st Include Active Pharmaceutical Ingredients obtained by chemical synthesis busulfan; melphalan hydrochloride; dexmedetomidine hydrochloride; leflunomide; milrinone; teriflunomide; in the certification of the company Emcure Pharmaceuticals LTD (Manufacturer number: B.000915), published by Resolution - RE No. 1,831, of June 3, 2022, in the Official Gazette No. 106, of June 6, 2022, Section 1, page 204, according to files No. 1164166/21-2, 5039465/22-0, 0090459/23-7, 0709681/23-2 and 0252627/24-5.

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

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