

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.235, MARCH 28, 2024

GENERAL MANAGER OF INSPECTION AND SANITARY REGULATION AT 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.

Manufacturer: Avid Bioservices, Inc.

Address: 14282 Franklin Ave, Tustin, California (CA) 92780

Country: USA

Manufacturer number: A.000915

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 0981891/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: recombinant human hyaluronidase.

Manufacturer: Avid Bioservices, Inc.

Address: 14191 Myford Road, Tustin, California (CA) 92780

Country: USA

Manufacturer number: A.001614

Requester: Orphandc G Importação e Distribuição De Produtos Farmacêuticos Ltda.

CNPJ: 22.566.515/0001-96

File number: 1026902/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredient: loncastuximab tesirine (intermediate).

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Manufacturer: BSP Pharmaceuticals S.p.A.

Address: Via Appia Km 65,561, (LOC. Latina Scalo) - 04013 Latina (LT)

Country: Italy

Manufacturer number: A.000688

Requester: Orphandc G Importação e Distribuição de Produtos Farmacêuticos Ltda.

CNPJ: 22.566.515/0001-96

File number: 1369055/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: loncastuximab tesirine.

Manufacturer: Lotte Biologics USA, LLC

Address: 6000 Thompson Road, East Syracuse, New York 13057

Country: USA

Manufacturer number: A.000123

Requester: Bristol-Myers Squibb Farmacêutica Ltda.

CNPJ: 56.998.982/0001-07

File number: 0595864/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: elotuzumab, ipilimumab and nivolumab.

Manufacturer: Lupin Limited (Biotech Division)

Address: GAT No. 1156, Village Ghotawade, Taluka-Mulshi, Pune 412115, Maharashtra State

Country: India

Manufacturer number: A.001377

Requester: Biomm S.A

CNPJ: 04.752.991/0001-10

File number: 0998954/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: pegfilgrastim.

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Manufacturer: Patheon Biologics LLC

Address: 4766 LaGuardia Drive, Saint Louis, Missouri (MO) 63134-3116

Country: USA

Manufacturer number: A.000146

Requester: Sanofi Medley Farmacêutica Ltda

CNPJ: 10.588.595/0010-92

File number: 0703646/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alfaoliudase

Manufacturer: Piramal Healthcare UK Limited

Address: Earls Road, Grangemouth, Stirlingshire, FK3 8XG

Country: UK

Manufacturer number: A.000907

Requester: Takeda Pharma Ltda.

CNPJ: 60.397.775/0001-74

File number: 0953938/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: brentuximab vedotin (conjugation).

Manufacturer: Roche Singapore Technical Operations Pte Ltd

Address: 10 Tuas Bay Link, Singapore, 637394

Country: Cingapura

Manufacturer number: A.000953

Requester: Novartis Biociências S.A.

CNPJ: 56.994.502/0001-30

File number: 0793561/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: ranibizumab.

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Manufacturer: TRB Chemedica SA

Address: Chemin St.-Marc 3, 1896 Vouvry

Country: Switzerland

Manufacturer number: A.001096

Requester: TRB Pharma Indústria Química e Farmacêutica Ltda.

CNPJ: 61.455.192/0001-15

File number: 0842830/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: GM1 ganglioside.

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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.

Manufacturer: Fleming Laboratories Limited - Unit I.

Address: Survey Nº 270, Navabpet Village, Shivampet Mandal, Medak District, Telangana - 502 313

Country: India

Manufacturer number: B.000345

File number: 0618419/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: etodolac and flunarizine.

Manufacturer: Glochem Industries Private Limited

Address: Survey No. 174 - 176, IDA Bollaram, Jinnaram Mandal, Sangareddy District, Telangana State - 502 325.

Country: India

Manufacturer number: B.000216

File number: 0943757/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: amlodipine besylate; levanlodipine besylate; cetirizine dihydrochloride and hydroxyzine dihydrochloride.

Manufacturer: Teva API India Private Limited

Address: Plot no.: A-2, A-2/1, A-2/2 UPSIDC Industrial Area, Bijnor Road, Gajraula - 244 235 Distt. Amroha (U.P.)

Country: India

Manufacturer number: B.000390

File number: 1310063/22-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semi-synthesis: caspofungin acetate

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Manufacturer: Virupaksha Organics Limited.

Address: Survey N^o 10, Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana - 502319

Country: India

Manufacturer number: B.000312

File number: 0703586/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: fexofenadine hydrochloride.

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GENERAL MANAGER OF INSPECTION AND SANITARY REGULATION AT 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 good manufacturing practices certification, provided for in Article 11 of Collegiate Board Resolution - RDC No. 497, dated May 20, 2021, resolves:

Art 1st. Include the biological active pharmaceutical ingredient datopotamab deruxtecan in the certification of the company Daiichi Sankyo Chemical Pharma Co., Ltd. Onahama Plant (Manufacturer number: A.001442), requested by the company Daiichi Sankyo Brasil Farmacêutica Ltda, CNPJ 60.874.187/0001-84, published by Resolution - RE No. 129, dated January 13, 2023, in the Official Gazette of the Union No. 11, dated January 16, 2023, section 1, page 66, as per file number No. 4449946/22-7 and 1186008/23-7.

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

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RESOLUTION - RE NO. 1.245, MARCH 28, 2024

THE GENERAL MANAGER OF INSPECTION AND SANITARY REGULATION AT 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 non-compliance with the requirements of Good Manufacturing Practices for Pharmaceutical Ingredients, or the non-compliance with the procedures of petitions submitted for analysis, as recommended in current legislation, resolves:

Art 1st. To deny the Certification Request(s) for Good Manufacturing Practices for Pharmaceutical Ingredients of the company(ies) listed in the ANNEX.

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

MANUFACTURER: AMBIOPHARM, INC -B000971

ADDRESS: 1024 DITTMAN COURT, NORTH AUGUSTA, SC 29842 1

COUNTRY: USA

MANUFACTURER NUMBER: B.000971

FILE NUMBER: 1144490/23-5

SUBJECT: 70158 - PHARMACEUTICAL INGREDIENTS - Good Manufacturing Practices Certification for International Industry, except Mercosur - chemical synthesis

REASON FOR DENIAL: In accordance with Article 4, § 1, item IV of RDC No. 497/2021: Non-submission of mandatory documentation, as outlined in the petition checklist, due to the absence of the Product Periodic Review (PPR) or documentation of production process validation, not submitted by the manufacturing company through third-party amendment.

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MANUFACTURER: WUHAN WUYAO PHARMACEUTICAL CO., LTD - B0739

ADDRESS: NO.18 WANGFEN ROAD, FUCHI TOWN, YANGXIN COUNTY, HUANGSHI CITY, HUBEI PROVINCE

COUNTRY: CHINA

MANUFACTURER NUMBER: B.000739

FILE NUMBER: 4819839/22-5

SUBJECT: 70158 - PHARMACEUTICAL INGREDIENTS - Good Manufacturing Practices Certification for International Industry, except Mercosur - chemical synthesis

REASON FOR DENIAL: In compliance with Article 4, § 1, item I of RDC No. 497/2021: due to non-compliance with articles 13, 38, 44, 46, 89, 186 sole paragraphs, 187, and 228 of RDC No. 654/2022.

MANUFACTURER: WUHAN WUYAO PHARMACEUTICAL CO., LTD - B0739

ADDRESS: NO.18 WANGFEN ROAD, FUCHI TOWN, YANGXIN COUNTY, HUANGSHI CITY, HUBEI PROVINCE

COUNTRY: CHINA

MANUFACTURER NUMBER: B.000739

FILE NUMBER: 0571438/23-7

SUBJECT: 70158 - PHARMACEUTICAL INGREDIENTS - Good Manufacturing Practices Certification for International Industry, except Mercosur - chemical synthesis

REASON FOR DENIAL: In compliance with Article 4, § 1, item I of RDC No. 497/2021: due to non-compliance with articles 13, 38, 44, 46, 89, 186 sole paragraphs, 187, and 228 of RDC No. 654/2022.

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