

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 2.475, JULY 3, 2024

THE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the use of the powers conferred on him by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board - RDC nº 585, of December 10, 2021,

Considering the fulfillment of the requirements set forth in article 39 of the Resolution of the Collegiate Board of Directors - RDC No. 497, of May 20, 2021, resolves:

Art. 1st Grant to the company(ies) listed in the ANNEX, the Certification of Good Manufacturing Practices of Active Pharmaceutical Ingredients through its 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: Zhuhai United Laboratories Co. Ltd.

Address: No 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040 - PR

Country: China

Manufacturer number: B.000140

File number: 0009898/24-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semi-synthesis (penicillin class): sodium ampicillin (chemical synthesis and sterilization steps).

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RESOLUTION - RE NO. 2.476, JULY 3, 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: BioMarin International Limited

Address: Shanbally, Ringaskiddy, Co. Cork

Country: Ireland

Manufacturer number: A.001189

Requester: Biomarin Brasil Farmacêutica Ltda.

CNPJ: 08.002.360/0001-34

File number: 1322843/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alphacerliponase and alphaelosulfase.

Manufacturer: F. Hoffmann - La Roche Ltd

Address: Grenzacherstrasse 124, CH-4070, Basileia

Country: Switzerland

Manufacturer number: A.000217

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 1455720/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: atezolizumab and bevacizumab.

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Manufacturer: Regeneron Ireland Designated Activity Company

Address: Raheen Business Park, Limerick

Country: Ireland

Manufacturer number: A.001399

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 1109467/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: aflibercept, alirocumab, cemiplimab, and dupilumab.

Manufacturer: Shenzhen Hepalink Pharmaceutical Group Co. Ltd.

Address: No. 1 Rongtian South, Kengzi Sub-District, Pingshan New District, Shenzhen 518122

Country: China

Manufacturer number: A.001445

Requester: Biomm S.A.

CNPJ: 04.752.991/0001-10

File number: 1027111/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: porcine sodium heparin.

Manufacturer: Swords Laboratories T/A Bristol-Myers Squibb Cruiserath Biologics

Address: Cruiserath Road, Mulhuddart, Dublin 15, D15 H6EF, Dublin

Country: Ireland

Manufacturer number: A.001427

Requester: Bristol-Myers Squibb Farmacêutica Ltda.

CNPJ: 56.998.982/0001-07

File number: 1441798/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: nivolumab.

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Manufacturer: Valneva Scotland Limited.

Address: Oakbank Park Road, Mid Calder, Livingston, EH53 0TG

Country: UK

Manufacturer number: A.001682

Requester: Instituto Butantan

CNPJ: 61.821.344/0001-56

File number: 0850599/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: monovalent chikungunya vaccine (recombinant and attenuated).

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RESOLUTION - RE NO. 2.477, JULY 3, 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: Cdymax (India) Pharma Private Limited

Address: Plot. No 77D & 116/117, KIADB Industrial Area, Jigani, Bangalore, Karnataka

Country: India

Manufacturer number: B.000582

File number: 0035277/24-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: palbociclib.

Manufacturer: Excella GmbH & Co. KG

Address: Nürnberger Strasse 12, Feucht - 90537

Country: Germany

Manufacturer number: B.000028

File number: 1334233/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

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

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: 0681634/24-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: progesterone.

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Manufacturer: Hy-Gro Chemicals Pharmtek Private Limited

Address: Unit -1, Plot No.174, Progressive Industrial Society, Bollaram Village, Jinnaram Mandal, Sangareddy District, Telangana State, PIN-502 325

Country: India

Manufacturer number: B.001171

File number: 0586985/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: flurbiprofen.

Manufacturer: Livzon Group Fuzhou Fuxing Pharmaceutical Co. LTD

Address: No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, P. R. China, Post Code: 350309

Country: China

Manufacturer number: B.000483

File number: 4411283/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semi-synthesis: tobramycin.

Manufacturer: Micro Labs Limited.

Address: Plot no. 43-45, KIADB, Jigani-Bommasandra Link Road, Anekal Taluk, Bengaluru, 560 105, Karnataka - Bengaluru

Country: India

Manufacturer number: B.000601

File number: 0601303/24-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: brexpiprazole, brivaracetam, lurasidone hydrochloride, timolol maleate and solifenacin succinate.

Manufacturer: Sicor Societa' Italiana Corticosteroidi S.R.L. - Rho Site.

Address: Via Terrazzano 77 - 20017, Rho (MI)

Country: Italy

Manufacturer number: B.000274

File number: 0694949/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by classical fermentation: bleomycin sulfate.

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Manufacturer: SMS Pharmaceuticals Limited (Unit II)

Address: Plot No. 24 & 24B and 36 & 37, S.V. Co-Operative Industrial Estate, Bachupally, Medchal-Malkajgiri District, Hyderabad, Telangana - 500 090

Country: India

Manufacturer number: B.000711

File number: 0622833/24-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ondansetron hydrochloride dihydrate, sumatriptan succinate, sumatriptan and tadalafil.

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RESOLUTION - RE NO. 2.478, JULY 3, 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 ingredients obtained by chemical synthesis tramadol hydrochloride, mepyramine maleate, bisoprolol hemifumarate in the certification of the company Supriya Lifescience Ltd. - Unit I (Manufacturer number: B.000298), published by Resolution RE No. 705, of February 22, 2024, in the Official Gazette No. 38, of February 26, 2024, Section 1, pgs. 149 and 150, according to file no. 0514802/23-5 and 0682121/24-0.

Art. 2nd Include the biological active pharmaceutical ingredient chondroitin sulfate in the certification of the company Yantai Dongcheng Biochemicals Co., Ltd. (Manufacturer number: A.000645), requested by the company Aché Laboratórios Farmacêuticos S.A., CNPJ no. 60.659.463/0029-92, published by Resolution RE No. 1,565, of May 4, 2023, in the Federal Official Gazette No. 86, of May 8, 2023, Section 1, page 84, according to file no. 1109993/22-6 and 0545110/24-6.

Art. 3rd Include the active pharmaceutical ingredients obtained by chemical synthesis empagliflozin and linagliptin, in the certification of the company Zhejiang Huahai Pharmaceutical Co., Ltd. (Duqiao) (Manufacturer number: B.000081), published by Resolution - RE No. 852, of March 1, 2024, in the Official Gazette No. 43, of March 4, 2024, section 1, page 181, according to files No. 0787106/23-2 and 0629545/24-3.

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

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RESOLUTION - RE NO. 2.510, JULY 7, 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,

Art. 1st Repeal Resolution-RE No. 1,536, of April 22, 2024, published in the Official Gazette No. 78, of April 23, 2024, Section 1, pages. 69 and 70, referring to the company listed in the Annex to this Resolution.

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

Manufacturer: EVEREST ORGANICS LIMITED

Manufacturer number: B000701

Product (Batch): ALL ACTIVE PHARMACEUTICAL INGREDIENTS (BATCHES: ALL);

Product Type: Medicine

File number: 0871698/24-6

Subject: 70358 - Revocation of Inspection Actions in Health Surveillance

Inspection actions repealed: Suspension - Commercialization, Distribution, Importation, Handling, Use

Motivation: Considering that analytical data of the imported batches of the ingredient were presented, as well as analytical data of the batches of medicines previously manufactured from the ingredient, which rule out the possibility of deviation. Also considering the actions implemented by the manufacturer to adapt the manufacturing unit to the standards of good manufacturing practices.

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