

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.407, APRIL 11, 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 the non-compliance with Good Manufacturing Practices requirements for Pharmaceutical Ingredients, or the non-compliance with procedures for petitions submitted for analysis, as outlined in current legislation, it is resolved:

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

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

Manufacturer: ORGAPHARM

Address: ZONE INDUSTRIELLE RUE DU MOULIN DE LA CANNE, PITHIVIERS – 45300

Country: France

Manufacturer number: B.001109

File number: 5102643/22-3

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

REASON FOR DENIAL: In compliance with Article 4, § 1, item I of RDC No. 497/2021.

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RESOLUTION - RE NO. 1.408, APRIL 11, 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 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: GSK Vaccines GmbH

Address: Emil-von-Behring Str. 76 und 79, 35041, Marburg

Country: Germany

Manufacturer number: A.001390

Requester: GlaxoSmithKline Brasil Ltda.

CNPJ: 33.247.743/0001-10

File number: 0798921/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: live attenuated mumps virus (strain RIT 4385), concentrated diphtheria toxoid, concentrated tetanus toxoid, and adsorbed tetanus-diphtheria concentrate.

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RESOLUTION - RE NO. 1.409, APRIL 11, 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 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: Neuland Laboratories Ltd. - Unit III.

Address: SY No. 10, Plot. 3-72, Gaddapotharam (V), Jinnaram (M), Sangareddy - 502325

Country: India

Manufacturer number: B.000964

File number: 0770280/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ciprofloxacin hydrochloride.

Manufacturer: Qilu Pharmaceutical Co. Ltd.

Address: NO. 23999 Gongyebei Road. Jinan, Shandong Province - 250100

Country: República Popular Da China

Manufacturer number: B.000727

File number: 1016438/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: carboplatin, oxaliplatin, irinotecan hydrochloride, ondansetron hydrochloride, docetaxel, trihydrate docetaxel, bortezomib.

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RESOLUTION - RE NO. 1.410, APRIL 11, 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.

Art. 3rd This Resolution comes into force on the date of its publication.

Manufacturer: Bachem AG

Address: Hauptstrasse 144, CH 4416

Country: Switzerland

Manufacturer number: A.001562

Requester: Novo Nordisk Farmacêutica do Brasil Ltda.

CNPJ: 82.277.955/0001-55

File number: 0739481/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active Pharmaceutical Ingredients: 40K PSC - intermediate of alfatroctocog pegol and betanonacog pegol (lyophilization).

Manufacturer: Janssen Sciences Ireland Unlimited Company

Address: Barnahely, Ringaskiddy, P43 FA46

Country: Ireland

Manufacturer number: A.000939

Requester: Janssen-Cilag Farmacêutica Ltda.

CNPJ: 51.780.468/0001-87

File number: 1093521/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: amivantamab, daratumumab, golimumab, guselcumab, teclistamab, ustekinumab, talquemab.

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Manufacturer: Ukraine PJSC Indar

Address: Zroshuvalna 5, Kyiv

Country: Ukraine

Manufacturer number: A.000620

Requester: União Química Farmacêutica Nacional S/A


CNPJ: 60.665.981/0001-18

File number: 1410868/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: human insulin.

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RESOLUTION - RE NO. 1.411, APRIL 11, 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.

Art. 3rd This Resolution comes into force on the date of its publication.

Manufacturer: Lonza AG.

Address: Lonzastrasse, CH-3930, Visp

Country: Switzerland

Manufacturer number: B.000043

File number 1368823/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: SG3249 (intermediate of loncastuximab tesirine)

Manufacturer: Pharco-B International (2) For Chemicals (PBIC)

Address: New Borg El Arab City, Second Industrial Zone. Part No. 5; Block No. 22, Alexandria

Country: Egypt

Manufacturer number: B.001135

File number: 5054576/22-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ravidasvir dichloride.

Manufacturer: Urquima S.A.

Address: Arnau de Vilanova 22-42, 08105, Sant Fost de Campsentelles - Sant Fost de Campsentelles

Country: Spain

Manufacturer number: B.000926

File number: 4682300/22-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: bilastine.

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Manufacturer: Yuhan Chemical Inc.

Address: 162 Cheongwonsandan 8-Gil, Mado-Myeon, Hwaseong, Gyeonggi - 18543

Country: South Korea

Manufacturer number: B.001104

File number: 4990222/22-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: velpatasvir.

Manufacturer: Zhejiang Charioteer Pharmaceutical Co., Ltd.

Address: Tongyuanxi, Dazhan, Xianju, Zhejiang Province - 317321

Country: China

Manufacturer number: B.000078

File number: 1093421/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: acyclovir.

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