

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 937, MARCH 7, 2024

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.

Manufacturer: Glenmark Life Sciences Limited.

Address: Plot No. 3109- C, Gidc Industrial Estate, Ankleshwar, Dist. Bharuch, Gujarat State - 393 002

Country: India

Manufacturer number: B.000207

File number: 0953833/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: zolpidem hemitartrate.

Manufacturer: Torrent Pharmaceuticals Limited

Address: Indrad, Taluka: Kadi, District: Mehsana, Gujarat - 382 721 - KADI

Country: India

Manufacturer number: B.000577

File number: 0943610/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: lurasidone hydrochloride, nebivolol hydrochloride, lamotrigine and rasagiline mesylate.

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RESOLUTION - RE NO. 938, MARCH 7, 2024

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: Lonza Biologics Tuas Pte Ltd

Address: 35 Tuas South Avenue 6, 637377

Country: Singapore

Manufacturer number: A.001056

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 0709995/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: trastuzumab and dornase alfa.

Manufacturer: Novo Nordisk US BIO Production Inc.

Address: 9 Technology Drive, West Lebanon, New Hampshire (NH) 03784

Country: USA

Manufacturer number: A.001356

Requester: Novo Nordisk Indústria Farmacêutica do Brasil Ltda.

CNPJ: 82.277.955/0001-55

File number: 0672392/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alfatroctocogue, alfatroctocogue pegal and somapacitan.

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Manufacturer: Samsung Biologics Co. Ltd.

Address: 300, Song-Do Bio-Daero, Yeonsu-GU, Incheon, 21987

Country: South Korea

Manufacturer number: A.001327

Requester: Fundação Oswaldo Cruz

CNPJ: 33.781.055/0001-35

File number: 0934595/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: etanercept and trastuzumab.

Manufacturer: Samsung Biologics Co. Ltd.

Address: 300, Song-do Bio-Daero, Yeonsu-gu, Incheon

Country: South Korea

Manufacturer number: A.001327

Requester: Janssen-Cilag Farmacêutica Ltda

CNPJ: 51.780.468/0001-87

File number: 0756831/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: daratumumab.

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RESOLUTION - RE NO. 939, MARCH 7, 2024

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: Amoli Organics PVT. Ltd.

Address: Plot No. 422 E.C.P. Canal Road - Padra Taluka, Luna Village, Vadodara District, Gujarat State - 391440

Country: India

Manufacturer number: B.000007

File number: 1435693/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: chlorthalidone.

Manufacturer: Cadila Pharmaceuticals Limited

Address: 294, G.I.D.C. Industrial Estate, Ankleshwar, Gujarat - 393002

Country: India

Manufacturer number: B.000227

File number: 0992372/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: Loratadine.

Manufacturer: Carbogen Amcis AG

Address: Hauptstrasse 171, Bubendorf - 4416

Country: Switzerland

Manufacturer number: B.000620

File number: 0537216/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: pemigatinib.

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Manufacturer: Flamma S.p.A.

Address: Via Bedeschi 22, Chignolo D'isola, Bergamo - 24040

Country: Italy

Manufacturer number: B.000938

File number: 1310007/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: melatonin, Minoxidil.

Manufacturer: Glenmark Life Sciences Limited.

Address: Plot No. 3109- C, GIDC Industrial Estate, Ankleshwar, Dist. Bharuch, Gujarat State - 393 002

Country: India

Manufacturer number: B.000207

File number: 0953833/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: zolpidem hemitartrate.

Manufacturer: Mylan Laboratories Limited - Unit II

Address: Survey N°.10&42, Gaddapotharam Village, Kazipally Industrial Area, Jinnaram Mandal, Sanga Reddy District, Telangana - 502319

Country: India

Manufacturer number: B.000010

File number: 0677671/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: Lamivudine.

Manufacturer: Pfizer Asia Manufacturing Pte Ltd.

Address: 31 Tuas South Avenue 6 - 637578

Country: Singapore

Manufacturer number: B.000295

File number: 1352277/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: sertraline hydrochloride.

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Manufacturer: Shangyu Jingxin Pharmaceutical Co., Ltd.

Address: N° 31, Weisan Road, Hangzhou Bay Shangyu Economic And Technological Development Area, Shangyu, Zhejiang Province - 312369

Country: China

Manufacturer number: B.000066

File number: 0943760/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ciprofloxacin hydrochloride.

Manufacturer: Sterling Pharma Ringaskiddy Limited

Address: Ringaskiddy, County Cork

Country: Ireland

Manufacturer number: B.000054

File number: 0837234/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: cyclosporine (purification step).

Manufacturer: Xellia (Taizhou) Pharmaceuticals Co., Ltd.

Address: 108 Binhai Road, Jiaojiang District, Taizhou, 318000, Zhejiang Province

Country: China

Manufacturer number: B.000172

File number: 0641385/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by classical fermentation: zinc bacitracin.

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RESOLUTION - RE NO. 940, MARCH 7, 2024

The General Manager of Inspection and Sanitary Inspection of the National Health Surveillance Agency, in the exercise of the powers conferred upon him by art. 140, combined with art. 203, I, § 1 of the Internal Regulation approved by the Collegiate Board Resolution - RDC No. 585, of December 10, 2021,

Considering the need to include in the good manufacturing practices certification, provided for in art. 11 of Collegiate Board Resolution - RDC No. 497, of May 20, 2021, resolves:

Art. 1st Include the intermediate of the active pharmaceutical ingredient obtained by chemical synthesis tirzepatide in the certification of the company Eli Lilly Kinsale Limited, (Manufacturer number: B.000377), published by Resolution - RE No. 885, of March 16, 2023, published in the Official Gazette of the Union No. 54, of March 20, 2023, Section 1, page 153, as per documents No. 4588649/22-1 and 1455167/23-1.

Art. 2nd Include the active pharmaceutical ingredient obtained by chemical synthesis amitriptyline hydrochloride in the certification of the company Vasudha Pharma Chem Limited - Unit III (Manufacturer number: B.000756), published by Resolution - RE No. 2,332, of June 29, 2023, published in the Official Gazette of the Union No. 124, of July 3, 2023, Section 1, page 184, as per documents No. 4318848/22-1 and 0119490/24-2.

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

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