

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 2.736, JULY 26, 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: Merck Sharp & Dohme Corp.

Address: 2778 South East Side Highway, Elkton, Virginia 22827

Country: United States of America

Manufacturer number: A.000401

Requester: Merck Sharp & Dohme Farmacêutica Ltda.

CNPJ: 03.560.974/0001-18

File number: 1298561/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: virus-like particle of HPV L1 protein types 6, 11, 16, 18, 31, 33, 45, 52 and 58.

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RESOLUTION - RE NO. 2.737, JULY 26, 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: Chugai Pharma Manufacturing Co., LTD
Address: 16-3 Kiyohara Kogyodanchi, Utsunomiya City, Tochigi
Country: Japan

Manufacturer number: A.000155

Requester: Produtos Roche Químicos Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 1274347/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: tocilizumab

Manufacturer: Lonza Biologics PLC
Address: 228 Bath Road, Slough, Berkshire, SL1 4DX
Country: United Kingdom

Manufacturer number: A.001117

Requester: Amgen Biotecnologia do Brasil Ltda.

CNPJ: 18.774.815/0001-93

File number: 1378189/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: blinatumomab.

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RESOLUTION - RE NO. 2.738, JULY 26, 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: Aarti Drugs Limited

Address: Plot No. E - 22, M.I.D.C. Tarapur, Tal: Palghar, Dist: Thane, Maharashtra - 401 506

Country: India

Manufacturer number: B.000634

File number: 4961031/22-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: zolpidem hemitartrate.

Manufacturer: Ampac Fine Chemicals LLC

Address: Highway 50 & Hazel Avenue Rancho Cordova, California (CA) 95670.

Country: United States of America

Manufacturer number: B.000563

File number: 0473087/24-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: etrasimod arginine

Manufacturer: Anlon Healthcare Pvt. Ltd.

Address: Survey No. 36/2 P2, near Bharudi Toll Plaza, Gondal Road, N.H.27, Rajkot, Gujarat -360311

Country: India

Manufacturer number: B.001107

File number: 4861170/22-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: Loxoprofen sodium dihydrate.

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Manufacturer: Corden Pharma Chenôve SAS

Address: 47, Rue de Longvic, Chenôve - 21301

Country: France

Manufacturer number: B.000530

File number: 0728764/24-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: stiripentol.

Manufacturer: Euroapi Germany GmbH

Address: Bruningstraße 50, Frankfurt Am Main - 65926

Country: Germany

Manufacturer number: B.000702

File number: 0481265/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: dipyron monohydrate.

Manufacturer: Industriale Chimica S.R.L.

Address: Via E. H. Grieg, 13, Saronno (Varese) - 21047

Country: Italy

Manufacturer number: B.000187

File number: 0045944/24-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: desogestrel; gestodene; tibolone; ethinyl estradiol; formoterol fumarate dihydrate; latanoprost; levonorgestrel; abiraterone acetate; nomegestrol acetate; fluticasone furoate; budesonide; tafluprost; memantine hydrochloride; salmeterol xinafoate; vilanterol trifenate; dienogest; drospirenone; bimatoprost; fulvestrant; fluticasone propionate; eplerenone.

Manufacturer: Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd

Address: No. 302, Huzhuangtou, Sanhuangmiao, Zhenglu, Tianning, Changzhou - Jiangsu 213111

Country: China

Manufacturer number: B.000576

File number: 0337754/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: progesterone.

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Manufacturer: Newchem S.p.A.

Address: Via Parco Del Ticino, 10, San Martino Siccomario, Pavia - 27028 - Pavia.

Country: Italy

Manufacturer number: B.000724

File number: 0800305/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: methylprednisolone acetate, bimatoprost, deflazacort, prednisolone sodium phosphate, hydrocortisone hemesuccinate, methylprednisolone hemesuccinate, latanoprost, latanoprostene bunod, travoprost, triamcinolone acetonide.

Manufacturer: Malladi Drugs & Pharmaceuticals Limited

Address: 7B & 7C, SIPCOT Industrial Complex, Ranipet, Vellore District, Tamil Nadu- 632 403.

Country: India

Manufacturer number: B.000341

File number: 1435450/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: phenylephrine hydrochloride.

Manufacturer: Shanghai Syntheall Pharmaceutical Co., Ltd

Address: 9 Yuegong Road, Jinshan District, Shanghai Chemical Industry Park, Shanghai - 201507.

Country: China

Manufacturer number: B.000499

File number: 0029808/24-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: tezacaftor and ivacaftor.

Manufacturer: Solara Active Pharma Sciences Limited

Address: RS#: 33 & 34, Mathur Road, Periyakalapet, Puducherry - 605 014

Country: India

Manufacturer number: B.000330

File number: 0136919/24-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ibuprofen.

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Manufacturer: Zhejiang Guobang Pharmaceutical Co., Ltd.

Address: No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic And Technological Development Zone, Shaoxing Zhejiang - 310053

Country: China

Manufacturer number: B.000079

File number: 1274960/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Intermediate used to obtain the active pharmaceutical ingredient azithromycin dihydrate, obtained by semisynthesis: azaerythromycin (chemical synthesis steps).

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RESOLUTION - RE NO. 2.739, JULY 26, 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 biological active pharmaceutical ingredient bevacizumab in the certification of the company Libbs Farmacêutica Ltda., CNPJ No. 61.230.314/0008-41, published by Resolution RE No. 174, of January 19, 2023, in the Federal Official Gazette No. 16, of January 23, 2023, Section 1, page 126, according to files No. 4307402/22-7 and 0559296/24-0.

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

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