Published on: 05/13/2024 | Edition: 91| Section: 1 | Page: 287

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.810, MAY 10, 2024

THE SUBSTITUTE 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 fulfillment of the requirements provided for in article 39 of Collegiate Board Resolution - 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 for Active Pharmaceutical Ingredients through its automatic renewal.

Art. 2nd This Certification is valid for 2 (two) years from its publication.

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

Manufacturer: Medichem S.A.

Address: Pirineus Street 127, Polígon Industrial de Celrà, Celrà, Girona - 17460

Country: Spain

Manufacturer number: B.000852

File number: 1227396/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: chlorhexidine digluconate, mirtazapine, quetiapine hemifumarate, brimonidine tartrate, clozapine, varenicline tartrate.

Published on: 05/13/2024 | Edition: 91| Section: 1 | Page: 287

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.811, MAY 10, 2024

THE SUBSTITUTE 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 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: Octapharma SAS.
Address: 72 Rue du Maréchal Foch, Lingolsheim, 67380
Country: France
Manufacturer number: A.000457
Requester: Octapharma Brasil Ltda.
CNPJ: 02.552.927/0001-60
File number: 0921137/23-1
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Biological active pharmaceutical ingredients: human albumin; human immunoglobulin; coagulation factor VIII; coagulation factor IX; coagulation factor II; coagulation factor VII; coagulation factor IX; factor X (prothrombin complex).

Manufacturer: Serum Institute of India Pvt. Ltd.
Address: S. No 105-110, Manjari BK, Tal-Haveli, Pune 412307
Country: India
Manufacturer number: A.001584
Requester: Uno Healthcare Comércio de Medicamentos Ltda.
CNPJ: 13.109.151/0001-24
File number: 0076486/23-1
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Biological active pharmaceutical ingredients: Bacillus Calmette-Guérin (BCG).

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: Shire Human Genetic Therapies, Inc.

Address: 400 Shire Way, Lexington, Massachusetts (MA) 02421

Country: USA

Manufacturer number: A.000795

Requester: Takeda Pharma Ltda.

CNPJ: 60.397.775/0001-74

File number: 1152856/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alpha-galsidase (purification, viral inactivation and fermentation), alfavelaglycerase. lanadelumab.

Published on: 05/13/2024 | Edition: 91| Section: 1 | Page: 288

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.812, MAY 10, 2024

THE SUBSTITUTE 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 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: Lianhe Chemical Technology (Taizhou) Co., Ltd.
Address: No. 3 Donghai 8th Avenue, Toumengang New District, Taizhou, Zhejiang 317016
Country: China
Manufacturer number: B.001061
File number: 1411833/23-6
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Active pharmaceutical ingredient obtained by chemical synthesis: capmatinib dihydrochloride monohydrate.

Manufacturer: Mylan Laboratories Limited- Unit IX
Address: Plot Nº 5 Road nº 12, J.N. Pharma City, Parawada Mandal, Visakhapatnam (Dist.), Tadi Village, Andhra Pradesh
Country: India
Manufacturer number: B.000158
File number: 0649175/23-9
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Active pharmaceutical ingredient obtained by chemical synthesis: mirtazapine.

Manufacturer: Mylan Laboratories Limited- Unit IX
Address: Plot Nº 5 Road nº 12, J.N. Pharma City, Parawada Mandal, Visakhapatnam (Dist.), Tadi Village, Andhra Pradesh
Country: India
Manufacturer number: B.000158
File number: 0458067/23-7
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Active pharmaceutical ingredients obtained by chemical synthesis: sertraline hydrochloride.

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: Mylan Laboratories Limited- Unit IX

Address: Plot Nº 5 Road nº 12, J.N. Pharma City, Parawada Mandal, Visakhapatnam (Dist.), Tadi Village, Andhra Pradesh

Country: India

Manufacturer number: B.000158

File number: 4519015/22-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: Levofloxacin.

Manufacturer: Novartis Pharma Schweizerhalle AG

Address: Rothausstrasse, 4133 Pratteln

Country: Switzerland

Manufacturer number: B.000367

File number: 0770011/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: iptacopane.

Manufacturer: Otsuka Pharmaceutical Co., Ltd. Second Tokushima Factory

Address: 224-18, Hiraishi Ebisuno, Kawauchi-cho Tokushima-shi, Tokushima 771-0182

Country: Japan

Manufacturer number: B.000808

File number: 1275467/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: brexpiprazole.

Manufacturer: Steroid S.P.A.

Address: Viale Spagna, 156 20093 Cologno Monzese

Country: Italy

Manufacturer number: B.000321

File number: 1410865/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: acetophenide algestone, estradiol enanthate, estradiol cypionate.

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

Manufacturer: Sun Pharmaceutical Industries Ltd.

Address: Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamil Nadu - 603 303

Country: India

Manufacturer number: B.000606

File number: 4675323/22-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: sodium divalproate, mephentermine sulfate, sodium valproate.

Manufacturer: Zhejiang Xianju Pharmaceutical Co., LTD

Address: No. 15 West Fengxi Road, Modern Industrial Park, Xianju, Taizhou, Zhejiang - Taizhou

Country: China

Manufacturer number: B.000991

File number: 1369557/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: dexamethasone acetate.

Published on: 05/13/2024 | Edition: 91| Section: 1 | Page: 288

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.813, MAY 10, 2024

THE SUBSTITUTE 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 RDC No. 497, of May 20, 2021, resolves to:

Art. 1st Include the Active Pharmaceutical Ingredient obtained by chemical synthesis esomeprazole magnesium dihydrate in the certification of the company Cipla Ltd. (Manufacturer number: B.000023), published by Resolution RE No. 3,082, of August 17, 2023, in the Official Gazette No. 159, of August 21, 2023, Section 1, page 160, according to files No. 4426251/22-2 and 0222727/24-1.

Art. 2 Include the Active Pharmaceutical Ingredient obtained by chemical synthesis clarithromycin in the certification of the company Zhejiang Guobang Pharmaceutical Co., Ltd. (Manufacturer number: B.000079), published by Resolution RE No. 2,703, of August 18, 2022, in the Official Gazette No. 159, of August 22, 2022, Section 1, page 270, according to files No. 8548900/21-1 and 0222758/24-4.

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