

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.051, MARCH 15, 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: Boehringer Ingelheim RCV GmbH & Co KG

Address: Dr. Boehringer-Gasse 5-11, A-1121, Viena

Country: Austria

Manufacturer number: A.000117

Requester: Pfizer Brasil Ltda.

CNPJ: 61.072.393/0001-33

File number: 0953787/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: recombinant lipoprotein from *Neisseria meningitidis* serogroup B (rLP2086) subfamily A and recombinant lipoprotein from *Neisseria meningitidis* serogroup B (rLP2086) subfamily B.

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RESOLUTION - RE NO. 1.052, MARCH 15, 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: Genentech, Inc.

Address: 1 Antibody Way, Oceanside, CA 92056

Country: USA

Manufacturer number: A.000248

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 0832286/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: bevacizumab, rituximab, tiragolumab and tocilizumab.

Manufacturer: GlaxoSmithKline Biologicals S.A.

Address: Parc de La Noire Epine, Rue Fleming 20, 1300, Wavre

Country: Belgium

Manufacturer number: A.000270

Requester: Instituto Butantan

CNPJ: 61.821.344/0001-56

File number: 0756668/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN).

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Manufacturer: GSK Vaccines GMBH

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

Country: Germany

Manufacturer number: A.001390

Requester: Instituto Butantan

CNPJ: 61.821.344/0001-56

File number: 0756535/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: diphtheria toxoid, tetanus toxoid, diphtheria-tetanus adsorbed concentrate (DTCC).

Manufacturer: Human Genome Sciences, Inc

Address: 9911 Belward Campus Drive - Rockville - Maryland 20850

Country: USA

Manufacturer number: A.000790

Requester: Glaxosmithkline Brasil Ltda.

CNPJ: 33.247.743/0001-10

File number: 0677838/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: belimumab and mepolizumab.

Manufacturer: MSD Biotech B.V.

Address: Kloosterstraat 6, 5349 AB Oss

Country: Netherlands

Manufacturer number: A.000423

Requester: Organon Farmacêutica Ltda.

CNPJ: 45.987.013/0001-34

File number: 0769923/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: betafolitropin.

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Manufacturer: Polpharma Biologics S.A.

Address: Ul. Trzy Lipy 3, 80-172 Gdansk

Country: Poland

Manufacturer number: A.001666

Requester: Biom SA

CNPJ: 04.752.991/0001-10

File number: 0208693/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: ranibizumab.

Manufacturer: Richter-Helm Biologics GmbH & Co. KG

Address: Dengelsberg, 24796, Bovenau

Country: Germany

Manufacturer number: A.001040

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ:10.588.595/0010-92

File number: 0636447/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: caplacizumab.

Manufacturer: Samsung Biologics Co. Ltd.

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

Country: Korea

Manufacturer number: A.001327

Requester: Bristol-Myers Squibb Farmacêutica Ltda

CNPJ: 56.998.982/0001-07

File number: 0954506/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: ipilimumab.

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Manufacturer: Shire Human Genetic Therapies, Inc.

Address: 300 Shire Way, Lexington, Massachusetts (MA) 02421

Country: USA

Manufacturer number: A.000793

Requester: Takeda Pharma Ltda

CNPJ: 60.397.775/0001-74

File number: 0882425/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: idursulfase (fermentation).

Manufacturer: Taizhou Mabtech Pharmaceuticals Co., Ltd.

Address: Building G79, West of Koutai Road and East of Lujia Road, Chinese Medicine Center, Taizhou City, Jiangsu Province

Country: China

Manufacturer number: A.001658

Requester: Blau Farmacêutica S.A.

CNPJ: 58.430.828/0001-60

File number: 0053783/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: infliximab.

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RESOLUTION - RE NO. 1.053, MARCH 15, 2024

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Art. 2nd This Certification is valid for 02 (two) years from its publication.

Manufacturer: Apitoria Pharma Private Limited - Unit V

Address: Plot N° 68-70, 73-91, 95, 96, 260 & 261 I.D.A., Chemical Zone, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Telangana State - 502307

Country: India

Manufacturer number: B.000012

File number: 0960989/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

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

Manufacturer: Biocon Limited

Address: Plot No. 2, Road No. 21, J. N. Pharma City, Thadi Village, Ida Paravada, Anakapalli District, Andhra Pradesh - 531 019

Country: India

Manufacturer number: B.001044

File number: 0089092/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semi-synthesis: mycophenolate mofetil; sodium mycophenolate.

Manufacturer: Fleming Laboratories Limited - Unit I

Address: Survey N° 270, Navabpet Village, Shivampet Mandal, Medak District, Telangana - 502 313

Country: India

Manufacturer number: B.000345

File number: 0122599/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: meclizine dihydrochloride monohydrate.

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Manufacturer: Glenmark Life Sciences Limited

Address: Plot N^o. 3109, GIDC Industrial Estate, Ankleshwar, Dist. Bharuch, Gujarat State - 393 002 - Ankleshwar

Country: India

Manufacturer number: B.000207

File number: 4564127/22-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical inputs obtained by chemical synthesis: adapalene, apixabana, tofacitinib citrate, fingolimode hydrochloride, levocetyrizine dichloride, lurasidone hydrochloride, olopatadine hydrochloride, deloratadine, eszopiclone, ezetimiba, zolpidem hemitartrate, lacous MIDA, LINAGLIPTIN, RASAGILINE MESILATE, olmesartan medoxomil, telmisartan, topiramate, vildagliptin.

Manufacturer: Mangalam Drugs and Organics Ltd. - Unit 2

Address: Plant 2A, 2B and 2C, Plot N^o 1203, GIDC, Vapi, Gujarat - 39195

Country: India

Manufacturer number: B.000948

File number: 5034400/22-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: acyclovir, emtricitabine, chloroquine phosphate, bisoprolol fumarate, hydroxychloroquine sulfate, furosemide, nimesulide, dolutegravir sodium, tenofovir disoproxil fumarate, pregabalin.

Manufacturer: MSN Laboratories Pvt. Ltd.

Address: Sy No- 50, 53, 53A, 54, 54A, Kardanur (Village), Patancheru (Mandal), Sangareddy (District), Telangana - 502300

Country: India

Manufacturer number: B.000752

File number: 1441440/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: bortezomib.

Manufacturer: Novacyl

Address: Rue Gaston Monmousseau, Roussillon - F38150

Country: France

Manufacturer number: B.000310

File number: 0140087/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: salicylic acid.

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Manufacturer: Olon S.p.A.

Address: Via Della Vittoria, 89 Cassino D' Alberi, Mulazzano - 26837

Country: Italy

Manufacturer number: B.000032

File number: 0944049/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: acyclovir.

Manufacturer: Xellia Pharmaceuticals ApS

Address: Dalslandsgade 11, 2300 Copenhagen S

Country: Denmark

Manufacturer number: B.000768

File number: 1486088/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: amphotericin B.

Manufacturer: Zhejiang Huahai Pharmaceutical Co., Ltd.

Address: Chuannan, Duqiao, Linhai, Zhejiang Province - 317016

Country: China

Manufacturer number: B.000081

File number: 1435240/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: nebivolol hydrochloride.

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