

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.693, MAY 2, 2024

THE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF 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: Pfizer Ireland Pharmaceuticals

Address: Grange Castle Business Park, Clondalkin, Dublin 22, D22 V8F8.

Country: Ireland

Manufacturer number: A.000635

Requester: Laboratórios Pfizer Ltda.

CNPJ: 46.070.868/0036-99

File number: 1186356/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: etanercept, capsular polysaccharides of *N. meningitidis* types A, C, W and Y conjugated to tetanus toxoid (preformulation) and tetanus toxoid (purification).

Manufacturer: Serum Institute of India Pvt. Ltd.

Address: 212/2, Hadapsar, Pune - 411 028

Country: India

Manufacturer number: A.001380

Requester: Zalika Farmacêutica Ltda.

CNPJ: 29.536.205/0001-78

File number: 1193653/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: attenuated rotavirus serotypes G1, G2, G3, G4 and G9; inactivated rabies virus, diphtheria toxoid, tetanus toxoid, Bordetella pertussis (cellular) antigen, hepatitis B surface antigen (HBsAg), and Haemophilus influenzae type B (Hib).

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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: FDC LIMITED.

Address: Plot No.19 & 20/2 - M.I.D.C Industrial Area, Village Dhatav, Roha-402 116, District Raigad, Maharashtra State
Country: India

Manufacturer number: B.000783

File number: 1084458/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: timolol maleate and olopatadine hydrochloride.

Manufacturer: IOL Chemicals and Pharmaceuticals Limited.

Address: Village Fatehgarh Channa, Mansa Road, (Trident Complex), Barnala Punjab 148101

Country: India

Manufacturer number: B.000037

File number: 4397755/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: pantoprazole sodium sesquihydrate.

Manufacturer: IOL Chemicals and Pharmaceuticals Limited.

Address: Village Fatehgarh Channa, Mansa Road, (Trident Complex), Barnala Punjab 148101

Country: India

Manufacturer number: B.000037

File number: 5000330/22-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ibuprofen.

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Manufacturer: Jiangsu Puxin Pharmaceuticals Co., Ltd

Address: 1 Chenli Road, Chemical Park, Binhai Economic Development Zone, Jiangsu - 224555

Country: China

Manufacturer number: B.000039

File number: 0014446/24-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: Zidovudine intermediate (3'-Azido-3'-deoxy-5'-O-(triphenylmethyl)-thymidine) and lamivudine intermediate (lamivudine salicylate).

Manufacturer: MSN Laboratories Pvt. Ltd. - Oncology Division.

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

Country: India

Manufacturer number: B.000752

File number: 1078705/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: abiraterone acetate, bortezomib, carfilzomib, ibrutinib, nintedanib esylate, pazopanib hydrochloride, regorafenib monohydrate, sorafenib tosylate, dasatinib monohydrate.

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: 1191419/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ciprofloxacin hydrochloride, ciprofloxacin.

Manufacturer: Shouguang Fukang Pharmaceutical Co., Ltd

Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province

Country: China

Manufacturer number: B.000522

File number: 0539174/22-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: metformin hydrochloride.

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