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DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 2.087, MAY 28, 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 2 (two) years from its publication.

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

Manufacturer: Biocon Biologics India Limited.

Address: Block Nº M1, M2 and M6, Q1 (Q3 and QC10) and W3, 20th Km, Hosur Road, Electronics City, Bangalore - 560 100.

Country: India

Manufacturer number: A.000105

Requester: EMS S/A

CNPJ: 57.507.378/0003-65

File number: 1352394/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: human insulin.

Manufacturer: Grifols Biologicals LLC.

Address: 5555 Valley Boulevard, Los Angeles, California (CA) 90032

Country: USA

Manufacturer number: A.000289

Requester: Grifols Brasil Ltda

CNPJ: 02.513.899/0001-71

File number: 1323351/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: human albumin, coagulation factor VIII, coagulation factor IX and von Willebrand factor.

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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: 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.

Manufacturer: Shilpa Pharma Lifesciences Limited - UNIT II
Address: Plot Nº 33, 33a, 40-47, Raichur Industrial Growth Centre, Chicksugur, 584134, Raichur District - Karnataka
Country: India
Manufacturer number: B.000950
File number: 4500203/22-2
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:
Active pharmaceutical ingredients obtained by chemical synthesis: axitinib, azacitidine, bendamustine hydrochloride monohydrate, bicalutamide, bortezomib, busulfan, cabazitaxel, capecitabine, clofarabine, decitabine, dimethyl fumarate, erlotinib hydrochloride, fingolimod hydrochloride, glycopyrronium bromide, ibrutinib, imatinib mesylate, lenalidomide, lenvatinib mesylate, melphalan hydrochloride, hemipentahydrate disodium pemetrexed, prucalopride succinate, sorafenib tosylate, sunitinib malate, tenofovir hemifumarate alfenamide, teriflunomide, tranexamic acid, ursodeoxycholic acid, varenicline tartrate, zoledronic acid monohydrate.
