

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 4.853, DECEMBER 20th, 2023

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 gets in force on its publication date.

Manufacturer: AGC Biologics A/S.

Address: Vandtaarsnsvej 83 B, DK 2860 Sobog Copenhagen

Country: Denmark

Manufacturer number: A.001313

Requester: Samsung Bioepis BR Pharmaceutical Ltda.

CNPJ: 24.563.776/0001-88

File number: 0642237/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: Ustekinumab.

Manufacturer: Takeda Manufacturing Singapore PTE LTD.

Address: 2A Woodlands Industrial Park D Street 2 Singapore 737779

Country: Singapore

Manufacturer number: A.001085

Requester: Takeda Pharma Ltda.

CNPJ: 60.397.775/0001-74

File number: 0607919/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alfaoctocogue, gamanonacogue and recombinant ADAMTS13 (alphapadantase and alfacinaxadanthase - cell culture, purification, viral inactivation).

Manufacturer: USV Private Limited.

Address: Plot No. D-115, TTC Industrial Area, Shirvane, Navi Mumbai- 400706, Maharashtra

Country: Denmark

Manufacturer number: A.001653

Requester: Aché Laboratórios Farmacêuticos S. A.

CNPJ: 60659463/0029-92

File number: 5060694/22-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: pegfilgrastim.

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Manufacturer: Laurus Labs Limited.

Address: Plot No. 18, Jawaharlal Nehru Pharma City, Parawada, Anakapalli, Andhra Pradesh -531 021

Country: India

Manufacturer number: B.001144

File number: 4505646/22-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: Atazanavir sulfate, emtricitabine, hydroxychloroquine sulfate, imatinib mesylate, lamivudine, pirfenidone, ritonavir, tenofovir disoproxil fumarate.

Active pharmaceutical ingredients obtained by chemical synthesis (cytotoxic): azacitidine, pemetrexed disodium.

Manufacturer: Laurus Labs Limited.

Address: Plot No. 21, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli - 531 021

Country: India

Manufacturer number: B.000194

File number: 4397806/22-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: Hydroxychloroquine sulfate, tenofovir disoproxil fumarate, darunavir, imatinib mesylate, sacubitril sodium, montelukast sodium, tenofovir alafenamide fumarate, erlotinib hydrochloride, efavirenz, enzalutamide.

Active pharmaceutical ingredients obtained by chemical synthesis (Cytotoxic): azacitidine, bortezomib, cabazitaxel, carfilzomib, gemcitabine hydrochloride, irinotecan hydrochloride trihydrate, lenalidomide.

Manufacturer: Ruyuan HEC Pharm Co., Ltd.

Address: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province

Country: China

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Manufacturer number: B.001090

File number: 4624996/22-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: rosuvastatin calcium.

Manufacturer: Zhejiang Hisoar Chuannan Pharmaceutical Co., LTD. (Linhai).

Address: N°. 23, Donghai 5th Avenue, Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejiang Province - 317016

Country: China

Manufacturer number: B.000115

File number: 0624479/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semi synthesis: clindamycin phosphate (chemical synthesis step).

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