

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 126, JANUARY 11th, 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: Alvotech hf.

Address: Sæmundargata 15-19, Reykjavík, 101

Country: Iceland

Manufacturer number: A.001665

Requester: Megalabs Farmacêutica S.A.

CNPJ: 33.026.055/0001-20

File number: 0190743/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: adalimumab.

Manufacturer: Bio Sidus S.A.U.

Address: Constitución 4234, Ciudad Autonoma de Buenos Aires.

Country: Argentina

Manufacturer number: A.001054

Requester: Aché Laboratórios Farmacêuticos S.A.

CNPJ: 60.659.463/0029-92

File number: 0401928/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: epoetin alfa, interferon alfa 2b, filgrastim and somatropin.

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The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024011500075

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Manufacturer: Guangdong Shuanglin Biological Pharmacy Co., Ltd

Address: No 1, Xinfeng East Road, Donghai Island, Zhanjiang

Country: China

Manufacturer number: A.001634

Requester: Brainfarma Indústria Química e Farmacêutica S.A

CNPJ: 05.161.069/0001-10

File number: 4954660/22-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: human immunoglobulin.

Manufacturer: Shandong Boan Biotechnology Co., Ltd.

Address: No. 8, Weiyi Road, High-Tech District, Yantai, Shandong

Country: China

Manufacturer number: A.001651

Requester: ASP-Farmacêutica Ltda.

CNPJ: 28.942.435/0001-74

File number: 5062865/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: bevacizumab.

Manufacturer: Virchow Biotech Pvt Ltd.

Address: Sy. No. 172 Part, Gagillapur Village, Ranga Reddy District, Andhra Pradesh

Country: India

Manufacturer number: A.000669

Requester: ON Pharma Importadora, Exportadora e Distribuidora De Medicamentos Ltda.

CNPJ: 18.173.548/0001-07

File number: 4653865/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: human immunoglobulin.

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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(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 02 (two) years from its publication.

Manufacturer: Bayer AG (Wuppertal).

Address: Friedrich-Ebert-Strasse, 217-333, 42117 - Wuppertal

Country: Germany

Manufacturer number: B.000017

File number: 0677845/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

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

Manufacturer: Farmak, A.S.

Address: Na vlcinci 16/3, Klášterní Hradisko, 779 00 Olomouc

Country: Czech Republic

Manufacturer number: B.000408

File number: 1310085/22-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: zolpidem hemitartrate and brimonidine tartrate.

Manufacturer: Macfarlan Smith Limited

Address: Three Trees Road, Newbie, Annan, Dumfriesshire - DG12 5QH

Country: UK

Manufacturer number: B.000965

File number: 0587106/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: codeine phosphate hemihydrate.

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Manufacturer: Pfizer Pharmaceuticals LLC

Address: Road No 2 Km 58.2, Barceloneta, Porto Rico 00617

Country: USA

Manufacturer number: B.000125

File number: 0683127/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: azithromycin dihydrate (purification step).

Manufacturer: Zhejiang Langhua Pharmaceutical Co., Ltd.

Address: No.7, Donghai 3rd Avenue, Zhejiang Provincial Chemical and Medical Material Base Linhai Zone, Linhai City, Zhejiang Province - 317016

Country: China

Manufacturer number: B.000085

File number: 0414783/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ciprofloxacin hydrochloride.

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