

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 47, JANUARY 4th, 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: Lonza AG.

Address: Lonzastrasse, CH-3930 Visp.

Country: Switzerland

Manufacturer number: B.000043

File number: 0649413/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: rosuvastatin calcium.

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The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
verification code: 05152024010800976

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RESOLUTION - RE NO. 48, JANUARY 4th, 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: Biological E. Limited.

Address: Plot no.4, Survey no. 542/P, Biotech Park, Phase-II, Kolthur Village - 500 078, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana State

Country: india

Manufacturer number: A.001424

Requester: Farma Vision Importação e Exportação de Medicamentos Ltda.

CNPJ: 09.058.502/0001-48

File number: 0688766/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: enoxaparin sodium.

Manufacturer: Samsung Biologics Co. Ltd.

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

Country: Korea

Manufacturer number: A.001327

Requester: Gilead Sciences Farmacêutica do Brasil Ltda

CNPJ: 15.670.288/0001-89

File number: 0503993/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients

Biological Active Pharmaceutical Ingredients: sacituzumab.

Manufacturer: Scientific Protein Laboratories LLC

Address: 700 East Main Street, Waunakee, Wisconsin 53597-015

Country: USA

Manufacturer number: A.000574

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 0402391/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological Active Pharmaceutical Ingredients: porcine sodium heparin.

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RESOLUTION - RE NO. 49, JANUARY 4th, 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: Ajinomoto do Brasil Indústria e Comércio de Alimentos Ltda

CNPJ: 46.344.354/0005-88

Address: Rodovia Anhanguera-SP.330, km 131 - Acesso para Estrada Municipal Hans Georg Krauss (LIM-285), Bairro Jaguari.

Country: Brazil

File number: 0683354/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by classical fermentation: L-glutamine and L-isoleucine.

Manufacturer: Aurisco Pharmaceutical Co., Limited.

Address: Badu Industrial Park Zone, Tiantai, Zhejiang Province 317200.

Country: China

Manufacturer number: B.000184

File number: 0669732/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis (cytotoxic class): abiraterone acetate.

Manufacturer: Hebei Jiheng (Group) Pharmaceutical Co. Ltd.

Address: No. 1 Weiwu Street Hengshui Industrial Park Hebei Province - 53000 - Hengshui

Country: China

Manufacturer number: B.000304

File number: 4711481/21-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: paracetamol.

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Manufacturer: Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd.

Address: No.35-1, Yixi Road, Daixi, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105

Country: China

Manufacturer number: B.000153

File number: 0601980/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: valacyclovir hydrochloride.

Manufacturer: Sumitomo Chemical Co., Ltd.

Address: 6-4-1, Kojimatanokuchi, Kurashiki, Okayama 711-0903

Country: Japan

Manufacturer number: B.000825

File number: 1161455/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: Alectinib hydrochloride intermediate.

Manufacturer: Zhejiang Guobang Pharmaceutical Co., Ltd.

Address: No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Shaoxing, Zhejiang

Country: China

Manufacturer number: B.000079

File number: 0601937/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: azithromycin dihydrate.

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