

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 639, FEBRUARY 16th, 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 through automatic renewal.

Art. 2nd This Certification is valid for 02 (two) years from its publication.

Manufacturer: CSL Behring GmbH

Address: Emil-von-Behring-Strasse 76, 35041 Marburg

Country: Germany

Manufacturer number: A.000170

Requester: Mandala Brasil Importação Distribuição De Produto Médico Hospitalar Ltda

CNPJ: 09.117.476/0001-81

File number: 0822661/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: thrombin and fibrinogen.

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The original publication can be verified at:
<http://www.in.gov.br/autenticidade.html>
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RESOLUTION - RE NO. 640, FEBRUARY 16th, 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: Bionovis S.A. - Companhia Brasileira de Biotecnologia Farmacêutica

CNPJ: 12.320.079/0001-17

Address: Alameda Itajubá, 388. Joapiranga, Valinhos - SP

Country: Brazil

Operation Authorization: 1145316

File number: 0352181/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: infliximab.

Manufacturer: Genzyme Corporation

Address: 8, 45, 51, 74, 76 New York Avenue, Framingham, Massachusetts (MA) 01701

Country: USA

Manufacturer number: A.000250

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 0564797/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alfathytrotropin, beta-agalsidase and imiglucerase.

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Manufacturer: ID Biomedical Corporation Of Quebec

Address: 2323 Parc Technologique Blvd, Quebec, Quebec, G1P 4R8

Country: Canada

Manufacturer number: A.000313

Requester: Glaxosmithkline Brasil Ltda.

CNPJ: 33.247.743/0001-10

File number: 0636930/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: influenza type A strain (H1N1), influenza type A strain (H3N2) and influenza type B strain.

Manufacturer: ImClone Systems LLC

Address: 33 ImClone Drive Branchburg, New Jersey, 08876

Country: USA

Manufacturer number: A.001091

Requester: Eli Lilly do Brasil Ltda

CNPJ: 43.940.618/0001-44

File number: 0688646/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: galcanezumab and ramucirumab.

Manufacturer: Instituto Grifols, S.A.

Address: Polígon Industrial Llevant, Can Guasch 2, 08150 Parets del Vallès, Barcelona

Country: Spain

Manufacturer number: A.000317

Requester: United Medical Ltda.

CNPJ: 68.949.239/0001-46

File number: 0613865/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: human albumin.

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Manufacturer: Kyowa Kirin Co., Ltd.

Address: 100-1 Hagiwara-machi, Takasaki, Gunma 370-0013

Country: Japan

Manufacturer number: A.001337

Requester: Equilíbrio Comércio De Produtos Farmacêuticos Ltda.

CNPJ: 05.215.461/0001-03

File number: 0893263/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: adalimumab.

Manufacturer: PCAS

Address: 35 Avenue Jean-Jaurès, 92390 Villeneuve-la-Garenne

Country: France

Manufacturer number: A.000628

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 0570937/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: enoxaparin sodium.

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RESOLUTION - RE NO. 641, FEBRUARY 16th, 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: M/S Rajasthan Antibiotics Limited

Address: A-619 & 630 RIICO, Phase I, Industrial Area, Bhiwadi, Alwar District, - Rajasthan- 301 019

Country: India

Manufacturer number: B.000118

File number: 0672037/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: acyclovir sodium (sterilization step).

Manufacturer: M/S Rajasthan Antibiotics Limited

Address: A-619 & 630 RIICO, Industrial Area, Bhiwadi, Alwar District, - Rajasthan- 301 019

Country: India

Manufacturer number: B.000118

File number: 0815668/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis (sterilization step): acyclovir sodium and ketoprofen.

Manufacturer: Zhejiang Charioteer Pharmaceutical Co., Ltd.

Address: Tongyuanxi, Dazhan, Xianju, Zhejiang Province - 317321

Country: China

Manufacturer number: B.000078

File number: 0703552/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: acyclovir.

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Manufacturer: Zhejiang Jiuzhou Pharmaceutical Co., Ltd. (Jiaojiang).

Address: Waisha Road 99#, Jiaojiang District, Taizhou City, Zhejiang Province - 317016.

Country: China

Manufacturer number: B.000083

File number: 0702913/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: carbamazepine and gliclazide.

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