

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 4.692, DECEMBER 07th, 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: Amgen, Inc.

Address: One Amgen Center Drive, Thousand Oaks, California (CA) 91320.

Country: USA

Manufacturer number: A.001197

Requester: Astrazeneca do Brasil Ltda.

CNPJ: 60.318.797/0001-00

File number: 0547955/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: Tezepelumab.

Manufacturer: CSL Behring Australia Pty Ltd.

Address: 189-209 Camp Road - Broadmeadows - Victoria 3047.

Country: Australia

Manufacturer number: A.000175

Requester: CSL Behring Comércio de Produtos Farmacêuticos Ltda.

CNPJ: 62.969.589/0001-98

File number: 0323756/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: coagulation factor VIII and von Willebrand factor.

Manufacturer: Novo Nordisk A/S

Address: Hagedornsvej 1, DK-2820, Gentofte

Country: Denmark

Manufacturer number: A.000443

Requester: Novo Nordisk Farmacêutica do Brasil Ltda.

CNPJ: 82.277.955/0001-55

File number: 0554480/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: Somatropin and betanocogue pegol 12631 (purification and pegylation).

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Manufacturer: Zhejiang Hisun Pharmaceutical Co., Ltd.

Address: Nº. 46, Waisha Road, Jiaojiang District, Taizhou City, Zhejiang; Nº 56, Binhai Road Jiaojiang District, Taizhou City, Zhejiang Province, P.R.C.

Country: China

Manufacturer number: A.000905

Requester: EMS Sigma Pharma Ltda.

CNPJ: 00.923.140/0001-31

File number: 0602176/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: acarbose.

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RESOLUTION - RE NO. 4.693, DECEMBER 07th, 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: Euroapi Italy S.R.L.

Address: Via Angelo Titi 22/26, Brindisi - 72100

Country: Italy

Manufacturer number: B.000062

File number: 0292040/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semisynthesis: Rifampin.

Manufacturer: Química Sintética S.A.

Address: Calle Dulcinea s/n, Alcalá de Henares - 28805, Madri.

Country: Spain

Manufacturer number: B.000058

File number: 1197821/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: brexpiprazole, eltrombopague olamine, fluconazole, fosfomicin trometamol, guanfacine hydrochloride, miconazole nitrate, omeprazole, paliperidone palmitate.

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RESOLUTION - RE NO. 4.691, DECEMBER 07th, 2023

Considering compliance with the requirements laid down on article 39 of Board Direction Resolution RDC nº 497 of May 20th, 2021, 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.

Art. 3rd This resolution gets in force on its publication date.

Manufacturer: Biocon Sdn. Bhd.

Address: No.1, Jalan Bioteknologi 1, Kawasan Perindustrian SILC, Nusajaya 79200, Johor

Country: Malaysia

Manufacturer number: A.001269

Requester: Aspen Pharma Indústria Farmacêutica Ltda.

CNPJ: 02.433.631/0001-20

File number: 0581853/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: insulin glargine, human insulin and isophanous insulin.

Manufacturer: BSP Pharmaceuticals S.p.A.

Address: Via Appia Km 65,561 (loc. Latina Scalo) - 04013 - Latina (LT)

Country: Italy

Manufacturer number: A.000688

Requester: Gilead Sciences Farmacêutica do Brasil Ltda.

CNPJ: 15.670.288/0001-89

File number: 0591627/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: sacituzumab govitecana.

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