

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 1.102, MARCH 21, 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.

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Manufacturer: Amgen Singapore Manufacturing Pte. Ltd.

Address: 1 Tuas View Drive, Singapore, 637026

Country: Singapore

Manufacturer number: A.001246

Requester: Amgen Biotecnologia do Brasil Ltda.

CNPJ: 18.774.815/0001-93

File number: 0715476/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: aflibercept, denosumab, eculizumab and rituximab.

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Manufacturer: Cartibras Beneficiadora de Produtos Animais Ltda.

CNPJ: 00.976.728/0001-53

Address: Rua Natal Braghini 975, Centro. Iomerê - SC

Country: Brazil

File number: 1011313/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: chondroitin sulfate.

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Manufacturer: Roche Diagnostics GmbH

Address: Nonnenwald 2, 82377, Penzberg

Country: Germany

Manufacturer number: A.000530

Requester: Innovative Medicines Brasil SP Distribuição de Medicamentos Ltda

CNPJ: 21.810.980/0001-68

File number: 0987497/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: peginterferon alfa 2A.

 [development@tmconsultancy.com.br](mailto:development@tmconsultancy.com.br)

 +55 45 3054 7096

 +55 45 99857 3570

 [www.tmconsultancy.com.br](http://www.tmconsultancy.com.br)



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Manufacturer: Biocon Limited (Site 1)

Address: 20TH KM Hosur Road, Electronics City, Bangalore 560100

Country: India

Manufacturer number: B.000324

File number: 1421935/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by classical fermentation: tacrolimus.

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Manufacturer: Kopran Research Laboratories Limited

Address: K4/4, Additional MIDC, At/Post: Birwadi, Tal: Mahad, Dist: Raigad, Pin 402302, Maharashtra State

Country: India

Manufacturer number: B.000130

File number: 1093062/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: atenolol, azithromycin and pregabalin.

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