

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 456, FEBRUARY 02<sup>nd</sup>, 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.

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Manufacturer: Farmson Pharmaceutical Gujarat Private Limited - Unit II

Address: Plot No. 14. GIDC Industrial State, Nandesari, District Vadodara, Gujarat - 391340

Country: India

Manufacturer number: B.001002

File number: 0560445/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: paracetamol.

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

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Manufacturer: Guangdong Shuanglin Biological Pharmacy Co., Ltd.

Address: No 1, Xinfeng Est 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.

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Manufacturer: Novartis Singapore Pharmaceutical Manufacturing PTE LTD (Bioproduction Operation Singapore)

Address: 8 Tuas Bay Lane, Singapore 636986

Country: Singapore

Manufacturer number: A.001566

Requester: Novartis Biociências S.A.

CNPJ: 56.994.502/0001-30

File number: 0553248/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: omalizumab.

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Manufacturer: Samsung Biologics CO. Ltd.

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

Country: Korea

Manufacturer number: A.001327

Requester: Astrazeneca do Brasil Ltda.

CNPJ: 60.318.797/0001-00

File number: 0837208/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: cilgavimab, durvalumab and tixagevimab.

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Manufacturer: Carbogen AMCIS AG

Address: Schachenallee 29 Aarau - 5501

Country: Switzerland

Manufacturer number: B.000996

File number: 0576926/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient: 40K PSC (intermediate of alfaturoctocogue pegal and betanonacogue pegal).

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Manufacturer: Carbogen AMCIS AG.

Address: Neulandweg 5, Hunzenschwil - 5502

Country: Switzerland

Manufacturer number: B.001004

File number: 0576153/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient: 40K PSC (intermediate of alfaturoctocogue pegal and betanonacogue pegal).

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Manufacturer: F.I.S. - Fabbrica Italiana Sintetici S.P.A

Address: Via Massimo D'Antona 13 - Termoli, Campobasso - 86039

Country: Italy

Manufacturer number: B.000384

File number: 0662297/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: mycophenolate mofetil.

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Manufacturer: F.I.S. - Fabbrica Italiana Sintetici S.P.A.

Address: Viale Milano 26, Montecchio Maggiore, Vicenza - 36075

Country: Italy

Manufacturer number: B.000029

File number: 0726908/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: tezacaftor.

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Manufacturer: Jubilant Pharmova Ltd.

Address: Plot # 18, 56, 57 and 58, KIADB Industrial Area, Nanjangud, Mysore District Karnataka - 571302

Country: India

Manufacturer number: B.000042

File number: 0576282/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: escitalopram oxalate.

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Manufacturer: Neopharma Japan Co., Ltd. - Fukuroi Plant

Address: 3056, Kuno, Fukuroi, Shizuoka

Country: Japan

Manufacturer number: B.000976

File number: 0630308/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Pharmaceutical ingredient intermediate obtained by classical fermentation: mycophenolic acid (mycophenolate mofetil intermediate).

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Manufacturer: PharmaZell Private Limited (Índia)

Address: Plot no. 115, Ramky Pharma City Ltd, Sez, Parawada, Visakhapatnam, Andhra Pradesh - 531019 - Visakhapatnam

Country: India

Manufacturer number: B.000717

File number: 4782591/22-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: mesalazine.

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Manufacturer: Recordati Industria Chimica Farmaceutica S.p.A.

Address: Via Mediana Cisterna, 4, Campoverde di Aprilia (LT), Aprilia - 04011

Country: Italy

Manufacturer number: A.000059

File number: 0683139/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: acyclovir.

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