

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 282, JANUARY 25<sup>th</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.

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

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Manufacturer: ImClone Systems LLC.

Address: 33 ImClone Drive Branchburg, New Jersey (NJ), 08876

Country: USA

Manufacturer number: A.001091

Requester: Libbs Farmacêutica Ltda.

CNPJ: 61.230.314/0001-75

File number: 1221121/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: galcanezumab.

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Manufacturer: Immunex Rhode Island Corporation

Address: 40 Technology Way, West Greenwich, Rhode Island 02817.

Country: USA

Manufacturer number: A.001022

Requester: Astrazeneca do Brasil Ltda.

CNPJ: 60.318.797/0001-00

File number: 0912628/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: tezepelumab.

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Manufacturer: Lotte Biologics USA, LLC

Address: 6000 Thompson Road, East Syracuse, New York 13057

Country: USA

Manufacturer number: A.000123

Requester: Bristol-Myers Squibb Farmacêutica Ltda.

CNPJ: 56.998.982/0001-07

File number: 0595864/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: elotuzumab, ipilimumab and nivolumab.

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## RESOLUTION - RE NO. 283, JANUARY 25<sup>th</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(ies) listed in the ANNEX, 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: Cipla Ltd.

Address: Plot n° 285,286,287 Bommasandra - Jigani Link Road, Industrial Area, KIADB 4th phase Bengaluru - 560105

Country: India

Manufacturer number: B.000389

File number: 0554183/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: enzalutamide; imatinib mesylate; erlotinib hydrochloride; Pazopanib hydrochloride; sorafenib tosylate; abiraterone acetate; gefitinib.

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Manufacturer: Delta Synthetic Co., Ltd.

Address: 15 Minsheng St. TuCheng District, 23679 New Taipei City, Taiwan

Country: China (Taiwan)

Manufacturer number: B.000407

File number: 0842521/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: guaifenesin.

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Manufacturer: Dr. Reddy's Laboratories Limited - Chemical Technical Operation - Unit III

Address: Plot No. 116, Sri Venkateswara Co-operative Industrial Estate, IDA Bollaram, Jinnaram (Mandal), Sangareddy District - 502 325, Telangana State

Country: India

Manufacturer number: B.000214

File number: 0254072/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: levocetirizine dihydrochloride; ramipril; palonosetron hydrochloride; gatifloxacin.

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