

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 850, MARCH 1<sup>st</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: Genentech, Inc.

Address: 1000 New Horizons Way, Vacaville, California (CA) 95688

Country: USA

Manufacturer number: A.000247

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 0751622/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: casirivimab, imdevimab, ocrelizumab, pertuzumab, rituximab, tocilizumab and trastuzumab.

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# DIÁRIO OFICIAL DA UNIÃO

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## RESOLUTION - RE NO. 851, MARCH 1<sup>st</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: Baxalta Incorporated

Address: 4501 Colorado Boulevard, Los Angeles, CA 90039

Country: USA

Manufacturer number: A.000075

Requester: Takeda Pharma Ltda.

CNPJ: 60.397.775/0001-74

File number: 0848261/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: C1 esterase inhibitor derived from human plasma, human albumin, human immunoglobulin, immunoglobulin G, and coagulation factor VIII.

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Manufacturer: Biocon Biologics India Limited

Address: 20th K.M. Hosur Road, Electronics City, Bangalore 560100

Country: India

Requester: Aspen Pharma Indústria Farmacêutica Ltda.

CNPJ: 02.433.631/0001-20

File number: 0911692/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

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

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Manufacturer: Fujifilm Diosynth Biotechnologies Denmark ApS

Address: Biotek Allé 1, Hillerod, 3400

Country: Denmark

Manufacturer number: A.000788

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 0832176/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: obinutuzumab.

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Manufacturer: Fundação Ezequiel Dias - FUNED

CNPJ: 17.503.475/0001-01

Address: Rua Conde Pereira Carneiro, N° 80, Belo Horizonte, MG

File number: 4871945/22-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: heterologous immunoglobulins.

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Manufacturer: Laboratório De Extratos Alergênicos Ltda.

CNPJ: 28.614.626 / 0001 - 07

Address: Avenida Rio Branco, 277, Grupo 1101 E 1201, Centro, Rio de Janeiro, RJ

File number: 0859447/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: allergenic extracts.

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# DIÁRIO OFICIAL DA UNIÃO

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## RESOLUTION - RE NO. 852, MARCH 1<sup>st</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: Alcaliber S.A.

Address: Avenida Ventalomar N° 01, Polígono Industrial de Toledo, Toledo - 45007

Country: Spain

Manufacturer number: B.000897

File number: 0843308/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by plant extraction: morphine sulfate pentahydrate.

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Manufacturer: Changzhou Syntheall Pharmaceutical Co., Ltd.

Address: 589, North Yulong Road, Xinbei District, Changzhou, Jiangsu - 213127

Country: China

Manufacturer number: B.000892

File number: 1257700/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: nirmatrelvir.

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Manufacturer: Chifeng Arker Pharmaceutical Technology CO., LTD

Address: N° 8 Mysun Street, Hongshan, Economic Development Zone, Chifeng, Inner Mongolia - 024000

Country: China

Manufacturer number: B.001133

File number: 0866500/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: pseudoephedrine hydrochloride.

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Manufacturer: Concord Biotech Limited

Address: Plot No. 1482-1486, Trasad Road, Dholka, District Ahmedabad, Gujarat - 382 225

Country: India

Manufacturer number: B.000887

File number: 0838213/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by classical fermentation: sirolimus, cyclosporine, mupirocin, tacrolimus.

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Manufacturer: Concord Biotech Limited

Address: Plot No. 1482-1486, Trasad Road, Dholka, District Ahmedabad, Gujarat - 382 225

Country: India

Manufacturer number: B.000887

File number: 4899161/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semisynthesis: midostaurin, everolimus, mycophenolate mofetil, mycophenolate sodium.

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Manufacturer: Glochem Industries Private Limited

Address: Survey No. 174 - 176, IDA Bollaram, Jinnaram Mandal, Sangareddy District, Telangana State - 502 325.

Country: India

Manufacturer number: B.000216

File number: 1474676/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: levanlodipine besylate hemipentahydrate.

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Manufacturer: Hetero Labs Limited - Unit IX

Address: Plot No. 2, Hetero Infrastructure SEZ Ltd., N. Narasapuram (Village), Nakkapalli (Mandal), Anakapalli (dist.)- 531 081, Andhra Pradesh

Country: India

Manufacturer number: B.000155

File number: 4456635/22-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: quetiapine hemifumarate; atazanavir sulfate; atorvastatin calcium trihydrate; zidovudine; emtricitabine; tenofovir disoproxil fumarate; lamivudine.

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Manufacturer: Olon S.p.A.

Address: Via Della Vittoria, 89 Cassino D' Alberi, Mulazzano - 26837

Country: Italy

Manufacturer number: B.000032

File number: 1351737/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: raloxifene hydrochloride.

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Manufacturer: Olon S.p.A.

Address: Strada Rivoltana km 6/7 - 20053 Rodano (MI)

Country: Italy

Manufacturer number: B.000129

File number: 1352152/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: raloxifene hydrochloride.

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Manufacturer: Patheon Austria GmbH & Co KG

Address: St.Peter-Strasse 25, Linz - 4020

Country: Austria

Manufacturer number: B.000485

File number: 1334699/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: Fostamatinib disodium hexahydrate.

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Manufacturer: Pliva Hrvatska D.O.O

Address: Prigorje Brdovecko, Prudnicka cesta 54 - 10291

Country: Croatia

Manufacturer number: B.000114

File number: 0948608/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: memantine hydrochloride, desatinib monohydrate, sugammadex sodium.

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Manufacturer: Shandong New Time Pharmaceutical Co., Ltd.  
Address: Nº 1, North Outer Ring Road, Feixian County, Shandong Province - 273400  
Country: China  
Manufacturer number: B.000854  
File number: 4526213/22-5  
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:  
Active pharmaceutical ingredient obtained by semisynthesis: potassium clavulanate.

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Manufacturer: Zhejiang Huahai Pharmaceutical Co., Ltd. (Duqiao)  
Address: Chuannan No. 1 Branch Factory Coastal Industrial Zone, Duqiao, Zhejiang Province - 317016  
Country: China  
Manufacturer number: B.000081  
File number: 0787106/23-2  
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:  
Active pharmaceutical ingredients obtained by chemical synthesis: valsartan.

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Manufacturer: Zhejiang Tianyu Pharmaceutical Co., Ltd  
Address: Jiangkou Development Zone, Huangyan, Taizhou City  
Country: China  
Manufacturer number: B.001212  
File number: 0446130/23-1  
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:  
Active pharmaceutical ingredients obtained by chemical synthesis: Losartan potassium.

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## RESOLUTION - RE NO. 853, MARCH 1<sup>st</sup>, 2024

Considering the non-compliance with the requirements of Good Manufacturing Practices for Pharmaceutical Ingredients, or the non-compliance with the procedures for petitions submitted for analysis, recommended in current legislation, resolves:

Art. 1st Reject the Request(s) for Certification of Good Manufacturing Practices for Pharmaceutical Ingredients from the company(ies) listed in the ANNEX.

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MANUFACTURER COMPANY: SHENZHEN HEPALINK PHARMACEUTICAL GROUP CO. LTD.

ADDRESS: 21 LANGSHAN ROAD, SONGPINGSHAN, NANSHAN DISTRICT, SHENZHEN

COUNTRY: CHINA

MANUFACTURER NUMBER: A.000582

REQUESTING COMPANY: EUROFARMA LABORATÓRIOS S.A.

CNPJ: 61.190.096/0001-92

FILE NUMBER: 1031888/23-3

SUBJECT: 70422 - BIOLOGICAL ACTIVE PHARMACEUTICAL INGREDIENTS - Renewal of GMP Certification for INTERNATIONAL INDUSTRY excluding MERCOSUR

REASON FOR DENIAL: In compliance with Article 4, § 1, item IV of RDC No. 497/2021: Failure to submit mandatory documentation, as specified in the petition checklist, due to the absence of the Periodic Product Review (PPR), which was not provided by the manufacturing company through a third-party amendment.

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