

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 2.157, JUNE 6, 2024

THE GENERAL MANAGER OF INSPECTION AND SANITARY SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred upon her by article 140, in conjunction with article 203, I, § 1 of the Internal Regulations approved by Resolution of the Collegiate Board - RDC No. 585, of December 10, 2021,

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 2 (two) years from its publication.

Art. 3rd This Resolution shall enter into force on the date of its publication.

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Manufacturer: Eli Lilly and Company.

Address: Lilly Corporate Center, Indianapolis, Indiana (IN) 46285.

Country: USA

Manufacturer number: A.000204

Requester: Eli Lilly do Brasil Ltda

CNPJ: 43.940.618/0001-44

File number: 1378219/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: insulin glargine, insulin lispro and human insulin

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Manufacturer: Lonza AG.

Address: Lonzastrasse, 3930 Visp

Country: Switzerland

Manufacturer number: A.000934

Requester: Laboratórios Servier do Brasil Ltda

CNPJ: 42.374.207/0001-76

File number: 1161431/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: asparaginase.

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Manufacturer: Regeneron Ireland Designated Activity Company.

Address: Raheen Business Park, Limerick

Country: Ireland

Manufacturer number: A.0001399

Requester: Adium S.A.

CNPJ: 55.980.684/0001-27

File number: 0259228/24-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: cemiplimab.

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Manufacturer: Roche Singapore Technical Operations Pte Ltd.

Address: 10 Tuas Bay Link, Singapore 637394

Country: Singapore

Manufacturer number: A.000953

Requester: Produtos Roche Químicos e Farmacêuticos S.A.

CNPJ: 33.009.945/0001-23

File number: 1078810/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biologic active pharmaceutical ingredients: bevacizumab, orelizumab, ranibizumab and trastuzumab.

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Manufacturer: Shenzhen Hepalink Pharmaceutical Group Co., Ltd.

Address: 21, Langshan Road, Songpingshan, Nanshan District, Shenzhen

Country: China

Manufacturer number: A.000582

Requester: Eurofarma Laboratórios S.A.

CNPJ: 61.190.096/0001-92

File number: 0339178/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: porcine sodium heparin.

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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 comes into force on the date of its publication.

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Manufacturer: Bal Pharma Limited - Unit 2.

Address: 61 - B, Bommasandra Industrial Area, Bangalore, 560 099.

Country: India

Manufacturer number: B.000836

File number: 4998958/22-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: benzidamine hydrochloride.

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Manufacturer: Curia France S.A.S.

Address: Avenue du Docteur Nicole Bru, Tonneins, 47400

Country: France

Manufacturer number: B.001227

File number: 1323007/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: aztreonam.

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Manufacturer: Emcure Pharmaceuticals Ltd.

Address: Plot No. D-24 & D-24/1, M.I.D.C. Kurkumbh, Tal.: Daund, Dist.: Pune. PIN -413802. Maharashtra State

Country: India

Manufacturer number: B.000915

File number: 1405941/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: busulfan, dexmedetomidine hydrochloride, melphalan hydrochloride, mycophenolate mofetil, leflunomide, milrinone, teriflunomide.

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Manufacturer: Saurav Chemicals Limited - Unit 3.

Address: Derabassi-Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab - - 140507

Country: India

Manufacturer number: B.000944

File number: 1198649/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ketorolac trometamol.

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Manufacturer: SIMS Societa' Italiana Medicinali Scandicci S.r.L.

Address: Filarone, Reggello, Firenze - 50066

Country: Italy

Manufacturer number: B.000726

File number: 1021477/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: ketoprofen.

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Manufacturer: Vistin Pharma AS.

Address: Stuttlidalen 4, Fikkjebakke, Sannidal, 3766

Country: Norway

Manufacturer number: B.000930

File number: 0458573/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: metformin hydrochloride.

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Manufacturer: Yichang Sanxia Pharmaceutical Co., Ltd.

Address: No. 8, Ziyang Road, Dianjun District, Yichang, 443002.

Country: China

Manufacturer number: B.000320

File number: 0539437/24-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by classical fermentation: neomycin sulfate.

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## RESOLUTION - RE NO. 2.159, JUNE 6, 2024

THE GENERAL MANAGER OF INSPECTION AND SANITARY SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred upon her by article 140, in conjunction with article 203, I, § 1 of the Internal Regulations approved by Resolution of the Collegiate Board - RDC No. 585, of December 10, 2021,

Considering the need for inclusion in the certification of good manufacturing practices, provided for in article 11 of the Resolution of the Collegiate Board - RDC No. 497, of May 20, 2021, resolves:

Art. 1st Include the biological active pharmaceutical ingredient bevacizumab in the certification of the company Shanghai Henlius Biopharmaceuticals Co., Ltd (Manufacturer number: A.001635), requested by the company Eurofarma Laboratórios S.A., CNPJ 61.190.096/0001-92, published by Resolution - RE No. 3,905, of October 11, 2023, in the Official Gazette No. 196, of October 16, 2023, Section 1, page 152; according to files no. 4898622/22-4 and 0229318/24-0.

Art. 2nd Include the biological active pharmaceutical ingredients denosumab and ustekinumab in the certification of the company Celltrion, Inc. (Manufacturer number: A.000975), requested by the company Celltrion Healthcare Distribuição de Produtos Farmacêuticos Brasil Ltda, CNPJ: 05.452.889/0001-61, published by Resolution - RE No. 4,617, of December 1, 2023, in the Official Gazette No. 229, of December 4, 2023, Section 1, page 166; According to files No. 0346042/23-2 and 0168737/24-8.

Art. 3rd This Resolution comes into force on the date of its publication.

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