

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 1.511, APRIL 18, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated December 10, 2021,

Considering compliance with the requirements set out in art. 39, of Resolution RDC No. 497, of May 20, 2021, resolves:

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.

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

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Manufacturer: Abbvie Operations Singapore Pte. Ltd.

Address: 23 Tuas South Avenue 6, 637022.

Country: Singapore

Manufacturer number: A.001405

Requester: Abbvie Farmacêutica Ltda

CNPJ: 15.800.545/0001-50

File number: 0859459/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: adalimumab.

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Manufacturer: GlaxoSmithKline Biologicals

Address: 10 Tuas South Avenue 8, Singapore 637421

Country: Singapore

Manufacturer number: A.000770

Requester: Fundação Oswaldo Cruz

CNPJ: 33.781.055/0001-35

File number: 0828637/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: pneumococcal polysaccharides of serotypes 1, 4, 5, 6B, 7F, 9V, 14 and 23F conjugated to protein D, pneumococcal polysaccharide of serotype 18C conjugated to tetanus toxoid, pneumococcal polysaccharide of serotype 19F conjugated to diphtheria toxoid.

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

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# DIÁRIO OFICIAL DA UNIÃO

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## RESOLUTION - RE NO. 1.512, APRIL 18, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated December 10, 2021,

Considering compliance with the requirements set out in art. 39, of Resolution RDC No. 497, of May 20, 2021, resolves:

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.

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

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Manufacturer: CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, 052106 Hebei Province

Country: China

Manufacturer number: B.000761

File number: 0933021/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active Pharmaceutical Ingredient Obtained by Classical Fermentation (penicillin class): potassium benzylpenicillin, procaine benzylpenicillin (sterilization steps)

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Manufacturer: Inner Mongolia Changsheng Pharmaceutical CO., LTD.

Address: Tuodian Industry Zone, Tuoketuo, Hohhot Inner Mongolia, Hohhot - 010206

Country: China

Manufacturer number: B.000737

File number: 0932806/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Intermediate obtained by classical fermentation (penicillin class): penicillin G potassium.

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# DIÁRIO OFICIAL DA UNIÃO

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## RESOLUTION - RE NO. 1.513, APRIL 18, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated 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 02 (two) years from its publication.

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

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Manufacturer: Kedrion S.p.A.

Address: S.S. 7 BIS KM 19,5, 80029 - Sant'Antimo

Country: Italy

Manufacturer number: A.001588

Requester: Kedrion Brasil Distribuidora de Produtos Hospitalares Ltda.

CNPJ: 09.284.952/0001-59

File number: 1032676/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: Anti-Rho (D) immunoglobulin and human immunoglobulin.

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Manufacturer: Polymun Scientific Immunbiologische Forschung GmbH

Address: Donaustrasse 99, 3400 - Klosterneuburg

Country: Austria

Manufacturer number: A.001414

Requester: Gedeon Richter do Brasil Importadora, Exportadora e Distribuidora S.A.

CNPJ: 12.134.906/0001-88

File number: 0906163/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alfafolitropin.

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Manufacturer: Sanofi Chimie

Address: 9 Quai Jules Guesde 94403 - Vitry-Sur-Seine Cedex

Country: France

Manufacturer number: A.001401

Requester: Sanofi Medley Farmacêutica Ltda.

CNPJ: 10.588.595/0010-92

File number: 0786917/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alirocumab and isatuximab.

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Manufacturer: Shenzhen Techdow Pharmaceutical Co., Ltd

Address: nº 19, Gaoxinhongyi Road, Nanshan District, Shenzhen, Guangdong Province

Country: China

Manufacturer number: A.000581

Requester: Eurofarma Laboratórios S.A.

CNPJ: 61.190.096/0001-92

File number: 1037251/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: enoxaparin sodium.

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Manufacturer: Solabia Biotecnológica Ltda.

CNPJ: 03.402.014/0001-20

Address: Rua Rosa Fernandes da Silva, nº 200, lote 237 C, Gleba Ribeirão Pinguim, Maringá, PR, Brazil.

File number: 1004100/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: chondroitin sulfate.

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## RESOLUTION - RE NO. 1.514, APRIL 18, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated 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 02 (two) years from its publication.

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

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Manufacturer: Centrient Pharmaceuticals Spain S/A.

Address: Pol. Ind. Urvasa, c/Ripollès, 2. Sta. Perpétua de Mogoda, Barcelona E- 08130

Country: Spain

Manufacturer number: B.000107

File number: 0999347/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis (cephalosporin class): cephalexin monohydrate (enzymatic synthesis step)

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Manufacturer: Granules India Limited

Address: H.NO. 6-5 & 6-11, Temple Road, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State - 502 313

Country: India

Manufacturer number: B.000743

File number: 1399793/23-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: guaifenesin; paracetamol.

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Manufacturer: Morepen Laboratories Limited

Address: Malkumajra (Morepen Village), Baddi Nalagarh Road, Baddi , Solan State, Himachal Pradesh 1

Country: India

Manufacturer number: B.000742

File number: 0182574/24-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: atorvastatin calcium, fexofenadine hydrochloride, loratadine.

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Manufacturer: NCPH Hebei Huamin Pharmaceutical Co., Ltd.

Address: N°. 98 Hainan Road, Economic and Technological Development Zone, Shijiazhuang, Hebei.

Country: China

Manufacturer number: B.000137

File number: 1060473/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis (cephalosporin class): ceftriaxone disodium hemieptahydrate (chemical synthesis and sterilization steps).

Intermediate obtained by semisynthesis (cephalosporin class): ceftazidime dihydrochloride.

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Manufacturer: Novartis Pharmaceutical Manufacturing LLC

Address: Kolodvorska cesta 27, SI-1234, Menges

Country: Slovenia

Manufacturer number: B.000327

File number: 0770083/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: iptacopan.

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Manufacturer: Zhejiang Guobang Pharmaceutical Co., Ltd.

Address: No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic And Technological Development Zone, Shaoxing Zhejiang - 312369

Country: China

Manufacturer number: B.000079

File number: 1049502/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Intermediate of the active pharmaceutical ingredient azithromycin dihydrate obtained by semisynthesis: azaerythromycin (chemical synthesis step).

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## RESOLUTION - RE NO. 1.515, APRIL 18, 2024

THE SUBSTITUTE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE exercising the powers conferred upon him by Article 140, combined with Article 203, I, § 1 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 585, dated December 10, 2021,

Considering the need for inclusion in the certification of good manufacturing practices, provided for in Article 11 of RDC nº 497, of May 20, 2021, resolves:

Art. 1 Include the active pharmaceutical ingredient carbegoline by chemical synthesis in the certification of the company Prati Donaduzzi & Cia Ltda, CNPJ: 73.856.593/0001-66, published by Resolution - RE No. 3,497, of October 21, 2022, in the Official Gazette of the Union nº 202, on October 24, 2022, section 1, page 154, according to files nº 1480991/22-8 and 5096432/22-1.

Art. 2 This Resolution comes into force on the date of its publication.

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