

DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 1.296, APRIL 4, 2024

GENERAL MANAGER OF INSPECTION AND SANITARY REGULATION AT 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 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.

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: 1073366/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Intermediate used to obtain the active pharmaceutical ingredient azithromycin dihydrate, obtained by semi-synthesis: azaerythromycin (chemical synthesis steps).

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 +55 45 99857 3570

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Manufacturer: Human Bioplazma LLC

Address: Táncsics Mihály út 82/A, Gödöllő, H-2100

Country: Hungary

Manufacturer number: A.000308

Requester: Biotest Farmacêutica Ltda.

CNPJ: 33.348.731/0001-81

File number: 0953621/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: human immunoglobulin fraction III.

Manufacturer: Instituto Butantan

CNPJ: 61.821.344/0001-56

Address: Avenida Vital Brasil Nº 1500, Butantã (prédio 41), São Paulo.

Country: Brazil

File number: 0988903/23-7

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: heterologous immunoglobulins.

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Manufacturer: Janssen Sciences Ireland UC

Address: Barnahely, Ringaskiddy, Co. Cork

Country: Ireland

Manufacturer number: A.000939

Requester: Fundação Oswaldo Cruz

CNPJ: 33.781.055/0001-35

File number: 0987835/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: golimumab.

Manufacturer: Opocrin S.p.A.

Address: Via Pacinotti, 3, Corlo di Formigine, 41043 Formigine (MO)

Country: Italy

Manufacturer number: A.000465

Requester: Chiesi Farmacêutica Ltda.

CNPJ: 61.363.032/0001-46

File number: 3955873/21-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: alfaporactant.

Manufacturer: Wacker Biotech GmbH

Address: Hans-Knöll Strasse 3 07745 Jena

Country: Germany

Manufacturer number: A.001289

Requester: Samsung Bioepis BR Pharmaceutical Ltda

CNPJ: 24.563.776/0001-88

File number: 1003757/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: ranibizumab.

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Manufacturer: Wyeth Pharmaceutical Division of Wyeth Holdings LLC

Address: 4300 Oak Park Rd, Sanford, NC 27330

Country: USA

Manufacturer number: A.000641

Requester: Pfizer Brasil Ltda

CNPJ: 61.072.393/0001-33

File number: 1044184/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: capsular polysaccharides from *Streptococcus pneumoniae* serotypes 3, 4, 6B, 9V, 14, 18C, 19A and 23F (activation/conjugation); serotypes 8, 10A, 11A, 12F, 15B, 22F, 33F (activation, conjugation, fermentation/purification); CRM 197 carrier protein (fermentation/purification); *Clostridium difficile* toxoids A and B (recombinant) (fermentation and purification).

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Manufacturer: Alchem International Private Limited

Address: 25/2, Main Mathura Road, Village Kaili, Ballabgarh, Faridabad, Haryana - 121004

Country: India

Manufacturer number: B.000603

File number: 0435560/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by semisynthesis: homatropine methylbromide, scopolamine butylbromide, hyoscyamine hydrobromide, paclitaxel, thiocolchicoside, vinpocetine.

Manufacturer: Euroapi Italy S.R.L.

Address: Via Angelo Titi 22/26, Brindisi - 72100

Country: Italy

Manufacturer number: B.000062

File number: 0826325/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: rifampicin.

Manufacturer: Zhejiang Charioteer Pharmaceutical Co., Ltd.

Address: Tongyuanxi, Dazhan, Xianju, Zhejiang Province - 317321

Country: China

Manufacturer number: B.000078

File number: 0987439/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: acyclovir.

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