

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 705, FEBRUARY 22<sup>nd</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: Archimica S.P.A.

Address: Viale Milano 86, San Grato, Lodi LO - 26900

Country: Italy

Manufacturer number: B.000866

File number: 1257299/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: cytarabine.

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Manufacturer: Biogen MA Inc.

Address: 5000 Davis Drive, Research Triangle Park, North Carolina 27709

Country: USA

Manufacturer number: B.001257

File number: 1084233/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: tofersen.

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Manufacturer: Biophore India Pharmaceuticals Pvt.. Ltd.

Address: Plot No. 80/A, Road No 5, J. N. Pharma City, E. Bonangi (V), Parawada (M), Visakhapatnam District - 531021, Andhra Pradesh

Country: India

Manufacturer number: B.001156

File number: 0475266/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: cannabidiol, chlorpromazine hydrochloride, naphazoline hydrochloride, ramelteone.

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Manufacturer: Eskay Iodine Pvt. Ltd.

Address: Plot No - 907/2, GIDC Estate, Jhagadia, Dist: Bharuch, Gujarat - 393 110

Country: India

Manufacturer number: B.001200

File number: 1220759/23-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: clioquinol.

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Manufacturer: Moehs BCN, S.L.

Address: Zenc 12 Castellbisbal, Barcelona -08755

Country: Spain

Manufacturer number: B.001217

File number: 1227363/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: sitagliptin phosphate monohydrate, vildagliptin, lidocaine.

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Manufacturer: SCI Pharmtech, Inc.

Address: N°. 61, Ln. 309, Haihu N. Rd, Luzhu District, Taoyuan City, 33856, Taiwan

Country: Taiwan

Manufacturer number: B.000941

File number: 1205941/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: duloxetine hydrochloride, divalproex sodium, hydroxychloroquine sulfate, methylphenidate hydrochloride, sodium valproate, propafenone hydrochloride, brinzolamide, loxoprofen sodium dihydrate, valproic acid.

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Manufacturer: Shandong Anhong Pharmaceutical Co., Ltd.

Address: N°. 29 Huayuan Street Linyi County, Dezhou, Shandong - 251500

Country: China

Manufacturer number: B.000721

File number: 4873925/22-3

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: abiraterone acetate, terbinafine hydrochloride, ertapenem sodium, exemestane, gefitinib, pemetrexed disodium, meropenem, sorafenib tosylate.

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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: 3812592/21-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semi-synthesis: potassium clavulanate (chemical synthesis and sterilization steps).

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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: 4158946/20-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semi-synthesis: orlistat.

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Manufacturer: Shanghai Syntheall Pharmaceutical Co., Ltd

Address: 9 Yuegong Road, Jinshan District, Shanghai - 201507

Country: China

Manufacturer number: B.000499

File number: 1461764/23-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: vorasidenib.

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Manufacturer: SMS Pharmaceuticals Limited

Address: Unit-VII, Kandivalasa (Village), Poosapatirega (Mandal), Vizianagaram District - 535 204, Andhra Pradesh

Country: India

Manufacturer number: B.001140

File number: 1357479/23-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: levetiracetam, pantoprazole sodium sesquihydrate, ibuprofen, lamotrigine, aripiprazole.

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Manufacturer: Supriya Lifescience Ltd. - Unit I

Address: A-5/2, LOTE Parshuram Industrial Area, M.I.D.C Taluka - Khed, DISTRICT - Ratnagiri, Maharashtra

Country: India

Manufacturer number: B.000298

File number: 0514802/23-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ketamine hydrochloride, diphenhydramine hydrochloride, esketamine hydrochloride, brompheniramine maleate, chlorpheniramine maleate, dexchlorpheniramine maleate, pheniramine maleate.

Manufacturer: Teva Pharmaceutical Works Private Ltd. Company

Address: Pallagi Út 13, Debrecen, 4042

Country: Hungary

Manufacturer number: B.000072

File number: 4644262/22-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Intermediate used to obtain the active pharmaceutical ingredient caspofungin, obtained by classical fermentation: caspofungin intermediate (fermentation stages).

Manufacturer: Zhejiang Hisun Pharmaceutical Co., Ltd.

Address: 56 Binhai Road, Jiaojiang District, Taizhou City, Zhejiang Province - 318000

Country: China

Manufacturer number: B.000152

File number: 0581687/22-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: tigecycline.

Manufacturer: Zhejiang Hisun Pharmaceutical Co., Ltd.

Address: 56 Binhai Road, Jiaojiang District, Taizhou City, Zhejiang Province - 318000

Country: China

Manufacturer number: B.000152

File number: 4971000/22-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: adenosine.

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Manufacturer: Zhejiang Huahai Pharmaceutical Co., Ltd.

Address: Chuannan, Duqiao, Linhai, Zhejiang Province – 317016

Country: China

Manufacturer number: B.000081

File number: 1357663/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: empagliflozin.

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Manufacturer: Zhejiang Tianyu Pharmaceutical Co., Ltd

Address: No 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical, Raw Materials Base Linhai Zone, Taizhou City, Zhejiang - 317016

Country: China

Manufacturer number: B.000182

File number: 4938527/21-9

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: sitagliptin phosphate monohydrate, olmesartan medoxomil, vildagliptin.

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Manufacturer: Zhejiang Tianyu Pharmaceutical Co., Ltd

Address: No 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical, Raw Materials Base Linhai Zone, Taizhou City, Zhejiang - 317016

Country: China

Manufacturer number: B.000182

File number: 0172876/23-1

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: olmesartan medoxomil.

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Manufacturer: Zhejiang Tianyu Pharmaceutical Co., Ltd

Address: No 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical, Raw Materials Base Linhai Zone, Taizhou City, Zhejiang - 317016

Country: China

Manufacturer number: B.000182

File number: 4695669/22-6 and 4696212/22-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: ezetimibe and vildagliptin.

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Manufacturer: Zhejiang Tianyu Pharmaceutical Co., Ltd

Address: No 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical, Raw Materials Base Linhai Zone, Taizhou City, Zhejiang - 317016

Country: China

Manufacturer number: B.000182

File number: 0084359/23-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: rivaroxaban.

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## RESOLUTION - RE NO. 706, FEBRUARY 22<sup>nd</sup>, 2024

The General Manager of Inspection and Sanitary Inspection of the National Health Surveillance Agency, in the exercise of the powers conferred upon him by art. 140, combined with art. 203, I, § 1 of the Internal Regulation approved by the Collegiate Board Resolution - RDC No. 585, of December 10, 2021,

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

Art. 1 Include the active pharmaceutical ingredient obtained by chemical synthesis, olopatadine hydrochloride, in the certification of the company FDC Limited (Manufacturer number: B.000783), published by Resolution - RE No. 1,374, of April 28, 2022, published in the Official Gazette of the Union No. 81, of May 2, 2022, section 1, page 203, according to documents No. 1014152/22-4 and 1300010/23-1.

Art. 2 Include the active pharmaceutical ingredient obtained by chemical synthesis, nirmatrelvir, in the certification of the company Pfizer Ireland Pharmaceuticals (Manufacturer number: B.000126), published by Resolution RE No. 2,469, of July 29, 2022, published in the Official Gazette of the Union No. 144, of August 1, 2022, section 1, pages 147 and 148, according to documents No. 4293748/22-9 and 1258088/23-1.

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

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