

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 4.792, DECEMBER 14<sup>th</sup>, 2023

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 gets in force on its publication date.

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Manufacturer: Changzhou Qianhong Bio-Pharma Co., Ltd.

Address: 192, Huanghe West Road, Xinbei District - Changzhou, Jiangsu

Country: China

Manufacturer number: A.000151

Requester: Mylan Laboratórios Ltda.

CNPJ: 11.643.096/0001-22

File number: 0636518/23-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: sodium heparin (purification).

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verification code: 05152023121800197

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Manufacturer: Hebei Jiheng Pharmaceutical Co. Ltd.

Address: No. 1 Weiwu Street Hengshui Industrial Park Hebei Province - 053000 - Hengshui

Country: China

Manufacturer number: B.000304

File number: 1589065/21-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by synthesis: Paracetamol.

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Manufacturer: Shanghai Desano Chemical Pharmaceutical Co. Ltd.

Address: Nº 417, Binhai Road, Laogang Town, Pudong New Area, 201302- Shanghai

Country: China

Manufacturer number: B.000065

File number: 0614447/23-2

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredients obtained by chemical synthesis: Lamivudine, zidovudine and ritonavir.

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