Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2024-LI-01095-1

Issued to:

Lipa Pharmaceuticals Ltd
ABN: 21 070 106 526

Primary Manufacturing Site Address:

21 Reaghs Farm Road
MINTO NSW 2566
Australia

Secondary Manufacturing Site Address:

3 Reaghs Farm Road
Minto NSW 2566
Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-10052005-LI-000542-1** to manufacture therapeutic goods under Section 38 of the *Therapeutic Goods Act 1989* and is included in the national inspection program following Section 40(4)(b) of the *Therapeutic Goods Act 1989.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 11 to 12 September 2023, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 May 2021.

This certificate reflects the status of the manufacturing sites at the time of the inspection noted above and should not be relied upon to reflect the compliance status after the expiry date. This certificate should also not be relied upon where the status of the licence to manufacture therapeutic goods is not current. Where required, the Therapeutic Goods Administration as the issuing authority should be consulted.

Issue Date: **07 February 2024** **Expiry Date:** **12 September 2026**

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

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MANUFACTURING OPERATIONS

The manufacturer above is authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site addresses specified above.

Primary Site: 21 Reaghs Farm Road MINTO NSW 2566

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liquids Group	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Semi Solids	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Powders and Granules Group	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, soft	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Liquids Group	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Semi Solids	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Powders and Granules Group	Listed Therapeutic Good	Finished Product Manufacture

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Secondary Site: 3 Reaghs Farm Road Minto NSW 2566

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Capsule, soft	Registered Therapeutic Good	Packaging, Labelling and Release for Supply

In addition to the statutory conditions that apply to all licences granted under Section 38 of the *Therapeutic Goods Act 1989,* the following specific conditions have been imposed on the licence under Sections 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

The manufacturer is not authorised to manufacture preparations containing penicillins, cephalosporins, hormones, steroids and antineoplastic drugs.

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