Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2015-LI-04123-1

Issued to:

GD Pharma Pty Ltd
ABN: 49 611 947 712

Manufacturing Site Address:

46a Beulah Road
NORWOOD SA 5067 AUSTRALIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-2012-LI-00154-3** 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 15 to 18 May 2017, 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 – 15 January 2009.

This certificate reflects the status of the manufacturing site 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.

EXPIRY DATE: 18 May 2020

ISSUE DATE: 6 March 2018

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 address specified above.

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.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

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Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile	Eye Drops	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Sterile	Injections	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Oral Liquid, solution	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Sterile	Eye Drops	Registered Therapeutic Good	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Sterile	Injections	Registered Therapeutic Good	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Nasal Drops	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Nasal Drops	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full Product Manufacture - excluding Testing

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*:

Sterile products are limited to terminally sterilised products only.

Quality Control testing is excluded from this licence.

The licence is limited to the manufacture of liquid dosage forms including nasal sprays. The licence excludes the manufacture of Penicillins and Cytotoxic drugs.

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