Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2012-LI-00154-3

Granted to:

GD Pharma Pty Ltd
ABN: 49 611 947 712

Manufacturing Site Address:

46a Beulah Road
NORWOOD SA 5067

The manufacturer above is hereby 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.

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

This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
This Licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.
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

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2012-LI-00154-3

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and regulations 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

Originally Granted: **19 March 2013** Date Revised: **6 March 2018**

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TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-2012-LI-00154-3

Issued to:

GD Pharma Pty Ltd
ABN: 49 611 947 712

Manufacturing Site Address:

46a Beulah Road
NORWOOD SA 5067

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under section 40(4) of the *Therapeutic Goods Act 1989* and regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 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.

Persons currently nominated under section 37(1)(e) of the Act as having control:

Production: Andrew Gia-Phong Vuong

Quality Control: Maria Fernanda Bolivar

Originally imposed: **19 March 2013** Date Revised: **6 March 2018**

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