Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-02102007-LI-002140-11

Granted to:

ABS (AUS) Pty Ltd
ABN: 62 633 680 065

Primary Manufacturing Site Address:

18 Distribution Place Seven Hills NSW 2147

Secondary Manufacturing Site Addresses:

19 Distribution Place Seven Hills NSW 2147
14 Distribution Place Seven Hills NSW 2147

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 addresses specified above.

Primary site: 18 Distribution Place, SEVEN HILLS NSW 2147

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Hard Capsules	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Oral Chewable Blocks	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Pills	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Capsule, soft	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Lozenges Group	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Pastille	Registered Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Secondary packaging
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Release for supply

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: 1800 020 653 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-02102007-LI-002140-11

Secondary site 1: 19 Distribution Place, SEVEN HILLS NSW 2147

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Storage

Secondary site: 14 Distribution Place Seven Hills NSW 2147

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Storage
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Packaging and labelling

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations. For the secondary manufacturing site/s, refer to Section 38A of the *Therapeutic Goods Act 1989.*

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 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: **11 January 2008** Date Revised: **24 March 2020**

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: 1800 020 653 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 2:

Schedule of Conditions

Licence Number:

MI-02102007-LI-002140-11

Granted to:

ABS (AUS) Pty Ltd
ABN: 62 633 680 065

Manufacturing Site Address:

18 Distribution Place
SEVEN HILLS NSW 2147

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*:

This licence does not authorise the primary packaging of therapeutic goods containing penicillins, cephalosporins, hormones, steroids and antineoplastic drugs.

This licence authorises only the release for supply of sterile medicines from the secondary packaging step where evidence of release from all previous steps of manufacture is held by the licensee.

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

Production: Greg Morozoff

Quality Control: Dr. Chivukula Sekar Subrahmanyam

Originally imposed: **11 January 2008** Date Revised: **24 March 2020**

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: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation