Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-LI-11733-1

Issued to:

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

Primary Manufacturing Site Address:

18 Distribution Place
SEVEN HILLS NSW 2147

Secondary Manufacturing Site Address:

19 Distribution Place
Seven Hills NSW 2147

Secondary Manufacturing Site Address:

14 Distribution Place
Seven Hills NSW 2147

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-02102007-LI-002140-11** 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 22 to 26 October 2018, 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 January 2017.

EXPIRY DATE: 26 October 2021

ISSUE DATE: 29 October 2019

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.

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

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-LI-11733-1

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: 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

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

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

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-LI-11733-1

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

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*:

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.

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

TGA Health Safety Regulation