Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-LI-12699-1

Issued to:

Eurofins Chemical Analysis Pty Ltd
ACN: 114 804 572

Manufacturing Site Address:

110 Merrindale Drive
CROYDON SOUTH VIC 3136
Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-2011-LI-03353-3** 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 12 to 13 December 2016, 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.

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: 30 June 2020

ISSUE DATE: 29 November 2019

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

TGA Health Safety Regulation

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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 address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing chemical and physical
Testing Laboratory	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing microbial
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Endotoxin Testing
Testing Laboratory	Sterile	All Dosage Forms	Registered Therapeutic Good	Testing sterility

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*:

No further conditions are applicable.

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.

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