Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2019-LI-10319-1

Granted to:

Eurofins BioPharma Product Testing Australia Pty Ltd
ABN: 63 114 804 572

Manufacturing Site Address:

6 Monterey Road
DANDENONG SOUTH VIC 3175

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 & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing chemical and physical
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Therapeutic Goods for Clinical Trials	Testing chemical and physical
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing chemical and physical
Medicine manufacture	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing microbial
Medicine manufacture	Non Sterile	All Dosage Forms	Therapeutic Goods for Clinical Trials	Testing microbial
Medicine manufacture	Non Sterile	All Dosage Forms	Not Applicable	Testing microbial
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Endotoxin Testing
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Therapeutic Goods for Clinical Trials	Endotoxin Testing
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Endotoxin 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: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

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Department of Health, Disability and Ageing
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2019-LI-10319-1

This licence is subject to the requirements of the *Therapeutic Goods Act 1989*, and its Regulations.

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: 28 July 2020 **Date Revised:** 12 February 2026

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Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2: Schedule of Conditions

Licence Number:

MI-2019-LI-10319-1

Granted to:

Eurofins BioPharma Product Testing Australia Pty Ltd
ABN: 63 114 804 572

Manufacturing Site Address:

6 Monterey Road
DANDENONG SOUTH VIC 3175

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*:

No further conditions are applicable.

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

Production: Jason Hall

Quality Control: Elizabeth Ooi

Originally Granted: 28 July 2020 **Date Revised: 12 February 2026**

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