



Australian Government
Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2021-LI-08995-1

Granted to:

Eurofins ams Laboratories Pty Ltd
ABN: 47 075 467 757

Manufacturing Site Address:

179 Magowar Road
GIRRAWEE NSW 2145

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
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing microbial
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing chemical and physical
Testing Laboratory	Sterile	All Dosage Forms	Not Applicable	Testing sterility
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Endotoxin Testing

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: 6 May 2022

Date Revised: N/A

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/>



Australian Government
Department of Health
Therapeutic Goods Administration

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

Licence Number:

MI-2021-LI-08995-1

Granted to:

Eurofins ams Laboratories Pty Ltd
ABN: 47 075 467 757

Manufacturing Site Address:

179 Magowar Road
GIRRAWEE NSW 2145

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*:

The authorisation for chemical testing is restricted to the testing of Ethylene oxide residues by gas-liquid chromatography.

The authorisation for physical testing is restricted to the testing of sub-visible particles

This licence also authorises the potency testing of antibiotics using bioassay, and disinfectant testing.

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

Production: Minal Patel

Quality Control: Fergus O'Connell

Originally Granted: 6 May 2022

Date Revised: N/A

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