



Australian Government
Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods - Part 1

Licence Number:

MI-2017-LI-14233-1

Granted to:

Antaria Pty Ltd
ABN: 54079845855

Primary Manufacturing Site Address:

112 Radium Street
Welshpool WA 6106
Australia

Secondary Manufacturing Site Addresses:

7 Charles Street
Bentley WA 6102
Australia

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: 112 Radium Street, Welshpool WA 6106

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Not Applicable	Active material manufacture

Secondary site: 7 Charles Street, Bentley WA 6102

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Active Pharmaceutical Ingredient manufacture	Non Sterile	Not Applicable	Raw material	Storage

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.rbs.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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Licence to Manufacture Therapeutic Goods - Part 1

Licence Number:
MI-2017-LI-14233-1

This licence is subject to the requirements of the *Therapeutic Goods Act 1989*, 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: **29 March 2018**

Date Revised: **20 April 2020**

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Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-2017-LI-14233-1

Granted to:

Antaria Pty Ltd
ABN: 54079845855

Primary Manufacturing Site Address:

112 Radium Street
Welshpool WA 6106

Secondary Manufacturing Site Address:

7 Charles Street
Bentley WA 6102

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 is limited to the manufacture of non-sterile APIs in the form of zinc oxide and Proprietary Ingredients containing zinc oxide

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

Production:	Glen Piesse
Quality Control:	Marissa Melvin

Originally imposed: **29 March 2018**

Date Revised: **20 April 2020**

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