



Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

Arvind Sharma
QA Manager
Raydel Australia Pty Ltd
Level 1 Building 1 9-15 Chilvers Road
THORNLEIGH NSW 2120

TGA Reference: 2016/030958

Subject: Reissue of licence to manufacture therapeutic goods MI-2016-LI-07028-1

Dear Arvind,

Please find enclosed the reissued Licence Part 1 (Authorisations) and Part 2 (Schedule of Conditions) for your manufacturing premises as requested.

Please do not hesitate to contact the Manufacturing Quality Branch if you require any further information.

Yours sincerely,

Signed and authorised by

David Rowbury
Delegate of the Secretary
Manufacturing Quality Branch

16 September 2022

Contact: GMP@health.gov.au, Phone: 1800 020 653



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2016-LI-07028-1

Granted to:

Raydel Australia Pty Ltd
ABN: 45 054 555 903

Manufacturing Site Address:

Level 1 Building 1 9-15 Chilvers Road
THORNLEIGH NSW 2120

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	Non Sterile	All Dosage Forms	Listed Therapeutic Good	Secondary packaging
Medicine manufacture	Non Sterile	All Dosage Forms	Listed Therapeutic Good	Release for supply
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Listed Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	API - Not Defined	Listed Therapeutic Good	Sampling

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: 2 February 2017

Date Revised: 16 September 2022

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 and Aged Care
Therapeutic Goods Administration

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

Licence Number:

MI-2016-LI-07028-1

Granted to:

Raydel Australia Pty Ltd
ABN: 45 054 555 903

Manufacturing Site Address:

Level 1 Building 1 9-15 Chilvers Road
THORNLEIGH NSW 2120

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 primary packaging of Solid Unit Dosage Forms is limited to tablets and capsules.

Sampling of actives is limited listed medicines active ingredients only.

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

Production: Mariana Segovia

Quality Control: Arvind Sharma

Originally Granted: 2 February 2017

Date Revised: 16 September 2022

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