Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-19092007-LI-002109-11

Issued to:

Ferngrove Pharmaceuticals Australia Pty Ltd
ABN: 80 154 645 762

Manufacturing Site Address:

5 Ferngrove Place
SOUTH GRANVILLE NSW 2142

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	Capsule, soft	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Hard Capsules	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Liquids Group	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Powders Group	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Granules Group	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

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

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-19092007-LI-002109-11

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liniment	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Gel	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Cream	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* 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: **08 February 2008** Date Revised: **20 May 2020**

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

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-19092007-LI-002109-11

Issued to:

Ferngrove Pharmaceuticals Australia Pty Ltd
ABN: 80 154 645 762

Manufacturing Site Address:

5 Ferngrove Place
SOUTH GRANVILLE NSW 2142

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 manufacture of Registered liniments excludes therapeutic products to which any part of the Poisons Standard applies, except for the active ingredients: camphor, turpentine oil and methyl salicylate.

The manufacture of gels and creams is restricted to antibacterial hand hygiene products (hand sanitiser) only.

This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within Schedules 2, 3, 4 & 8 of the Poisons Standard, except liniments containing the active ingredients: camphor, turpentine oil and/or methyl salicylate

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

Production: William Psarakis

Quality Control: Yueting Lu

Originally imposed: **08 February 2008** Date Revised: **20 May 2020**

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