Australian Government
Department of Health
Therapeutic Goods Administration

Mr Eugene Ng
Ferngrove Pharmaceuticals Australia Pty Ltd
5 Ferngrove Place
SOUTH GRANVILLE NSW 2142

Our Reference: 2014/013427

Dear Mr. Ng,

Subject: Issue of GMP certificate MI-2020-LI-06927-1

Please find enclosed the GMP certificate 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

Dr Katherine Clark
Director, Licensing & Certification Section
Manufacturing Quality Branch

03 July 2020

Contact: gmp@tga.gov.au, phone 1800 020 653 or fax 02 6203 1605

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2020-LI-06927-1

Issued to:

Ferngrove Pharmaceuticals Australia Pty Ltd
ABN: 80 154 645 762

Manufacturing Site Address:

5 Ferngrove Place
SOUTH GRANVILLE NSW 2142
Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-19092007-LI-002109-11** to manufacture therapeutic goods under section 38 of the *Therapeutic Goods Act 1989* and is included in the national inspection program following section 40(4)(b) of the *Therapeutic Goods Act 1989.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21 to 24 January 2020, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 January 2017.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status after the expiry date. This certificate should also not be relied upon where the status of the Licence to manufacture therapeutic goods is not current. Where required, the Therapeutic Goods Administration as the issuing authority should be consulted.

EXPIRY DATE: 24 January 2023

ISSUE DATE: 03 July 2020

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.

The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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

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MANUFACTURING OPERATIONS

The manufacturer above is 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 - Hard Capsules	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	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
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

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In addition to the statutory conditions that apply to all Licences granted under section 38 of the *Therapeutic Goods Act 1989,* the following specific conditions have been imposed on the Licence under sections 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

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The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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