Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-00848-1

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 8 to 11 February 2021 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 July 2018.

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.

Issue Date: **25 January 2023** **Expiry Date:** **11 February 2024**

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.

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

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-00848-1

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	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
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

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.

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

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-LI-00848-1

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.