Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2022-LI-10070-1

Issued to:

Baxter Laboratories Pty Ltd
ABN: 42 093 625 435

Primary Manufacturing Site Address:

1019 Mountain Highway
BORONIA VIC 3155
AUSTRALIA

Secondary Manufacturing Site Address:

12 Isa Way
BORONIA VIC 3155
AUSTRALIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-25112004-LI-000211-1** 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 15 to 17 August 2022, 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: 5 September 2022 **Expiry Date: 17 August 2025**

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

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MANUFACTURING OPERATIONS

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.

Primary Site: 1019 Mountain Highway, BORONIA VIC 3155

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full product manufacture - excluding microbiological testing
Medicine manufacture	Non Sterile	Semi solids	Registered Therapeutic Good	Full product manufacture - excluding microbiological testing
Medicine manufacture	Non Sterile	Powder, dusting	Registered Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Cream	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Gel	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Lotion	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Ointment	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Spray	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Spray, solution	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Medicine manufacture	Non Sterile	Inhalation	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Lotion	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

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Secondary Site: 12 Isa Way, BORONIA VIC 3155

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Storage

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 licence does not authorise the manufacture of preparations containing biological medicines, penicillines, cephalosporins, hormones, steroids or antineoplastic drugs.

The manufacture of inhalations is restricted to the manufacture of nasal sticks only.

The manufacture of liquid is restricted to preparations for topical use and for use in a vaporiser.

The manufacture of semi solid and powder is restricted to preparations for topical use only.

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