Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2025-LI-10293-1

Issued to:

Bio Health Pharmaceuticals Pty Ltd
ABN: 63 142 070 344

Manufacturing Site Address:

12 Giffard Street
SILVERWATER NSW 2128
AUSTRALIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-2010-LI-05408-3** 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 11 to 13 March 2025, 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 – 01 February 2022.

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.

BIO HEALTH PHARMACEUTICALS
ABN: 63 142 070 344

Issue Date: **05 November 2025** **Expiry Date:** **13 March 2029**

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

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	Finished Product Manufacturer - Excluding Release for Supply
Medicine manufacture	Non Sterile	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply
Medicine manufacture	Non Sterile	Tablet, uncoated	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply
Medicine manufacture	Non Sterile	Liquids Group	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply
Medicine manufacture	Non Sterile	Semi Solids - Creams, Gels and Ointments	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply
Sunscreen manufacture	Non Sterile	Topical Sunscreen Forms	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply
Medicine manufacture	Non Sterile	Powder	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply
Medicine manufacture	Non Sterile	Powder, oral	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply
Medicine manufacture	Non Sterile	Tablet, effervescent	Listed Therapeutic Good	Finished Product Manufacturer - Excluding Release for Supply

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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*:

Testing is limited to Physical Testing only.

The 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.

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