Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2026-LI-00411-1

Issued to:

Chemika Pty Ltd
ABN: 44 093 373 534

Manufacturing Site Address:

119 Magowar Road
GIRRAWEEN NSW 2145
AUSTRALIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-2012-LI-00095-3** 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.*

This certificate is issued based on a remote inspection of GMP compliance. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 15 to 17 February 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 – 01 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: **23 January 2026** **Expiry Date:** **17 February 2027**

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
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing chemical and physical

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*:

No further conditions are applicable.

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