Australian Government
Department of Health
Therapeutic Goods Administration

Mr Alan Doughty
Managing Director
Chemika Pty Ltd
119 Magowar Road
GIRRAWEEN NSW 2145

Our Reference: 2014/012419

Dear Mr Doughty,

Subject: Issue of GMP certificate MI-2021-LI-00962-1

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

David Rowbury
Senior GMP Inspector
Manufacturing Quality Branch

1 February 2021

Contact: gmp@health.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-2021-LI-00962-1

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.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 14 to 15 October 2019, 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.

EXPIRY DATE: 15 October 2022

ISSUE DATE: 1 February 2021

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: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2021-LI-00962-1

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
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 additional conditions have been imposed on the Licence.

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/

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