Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Mrs Khaleda Jamal
QA Manager
Costar Pharma Laboratory Pty Ltd
171 - 177 Woodpark Road
SMITHFIELD NSW 2164

TGA Reference: 2014/045821

**Subject: Issue of GMP certificate MI-2025-LI-07688-1**

Dear Mrs Jamal,

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

Scott Pearce
Assistant Director
Licensing, Certification and Engagement Section
Manufacturing Quality Branch

13 March 2026

Contact: GMP@health.gov.au, Phone: 1800 020 653

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

# Certificate of GMP Compliance of a Manufacturer

**Certificate Number:**

MI-2025-LI-07688-1

**Issued to:**

Costar Pharma Laboratory Pty Ltd
ABN: 33 132 907 138

**Manufacturing Site Address:**

171 - 177 Woodpark Road
SMITHFIELD NSW 2164
AUSTRALIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a licence with number **MI-2014-LI-01856-1** 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 07 to 11 April 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.

**Issue Date:** **13 March 2026** **Expiry Date:** **11 April 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

# Certificate of GMP Compliance of a Manufacturer

**Certificate Number:**

MI-2025-LI-07688-1

## 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 Testing |
| Medicine manufacture | Non Sterile | Powders and Granules Group | Listed Therapeutic Good | Full Product Manufacture - excluding Testing |
| Medicine manufacture | Non Sterile | Solid Unit Dosage Forms - Tablets | Listed Therapeutic Good | Full Product Manufacture - excluding Testing |
| Medicine manufacture | Non Sterile | Liquid, multipurpose | Listed Therapeutic Good | Full Product Manufacture - excluding Testing |
| Medicine manufacture | Non Sterile | Oral Liquid | Listed Therapeutic Good | Full Product Manufacture - excluding Testing |
| Medicine manufacture | Non Sterile | Oral Liquid, powder for | Listed Therapeutic Good | Full Product Manufacture - excluding Testing |
| Medicine manufacture | Non Sterile | All Dosage Forms | Listed Therapeutic Good | Testing chemical and physical |
| Medicine manufacture | Non Sterile | All Dosage Forms | Listed Therapeutic Good | Storage |
| Medicine manufacture | Non Sterile | Pastille | Listed Therapeutic Good | Full Product Manufacture - excluding Testing |
| Medicine manufacture | Non Sterile | Capsule, hard | Listed Therapeutic Good | Full Product Manufacture - excluding 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.

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Therapeutic Goods Administration

# Certificate of GMP Compliance of a Manufacturer

**Certificate Number:**

MI-2025-LI-07688-1

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 manufacturing step Testing chemical and physical is restricted 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 schedule 2, 3, 4 and 8 of the Poisons Standard.

The manufacturing activities conducted in Building 3 are restricted to storage only.



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