



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2024-CE-11126-1

Issued to:

DXN Pharmaceutical Sdn Bhd

Manufacturing Site Address:

Lot 1109 Mukim Malau, Daerah Kubang Pasu
KEDAH DARUL AMAN 06000
MALAYSIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following section/s 25(1)(g), 26(1)(g) and/or 26A(3) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing manufacturers located outside Australia.

This certificate is issued based on a remote Surveillance Inspection of GMP compliance. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 07 October 2025 to 08 October 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 – August 2023.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

Issue Date: 18 December 2025

Expiry Date: 08 October 2028

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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MANUFACTURING OPERATIONS

This certificate covers 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 | Solid Unit Dosage Forms - Hard Capsules | Listed Therapeutic Good | Finished Product Manufacture |
| Medicine manufacture | Non Sterile | Solid Unit Dosage Forms - Tablets | Listed Therapeutic Good | Finished Product Manufacture |
| Medicine manufacture | Non Sterile | Powders Group | Listed Therapeutic Good | Finished Product Manufacture |

The following limitations are applicable to these manufacturing operations:

Chemical/microbiological testing conducted by third party testing laboratories are under the control of the primary manufacturer DXN Pharmaceutical Sdn Bhd.

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The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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TGA Health Safety
Regulation