



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2022-CE-02175-1

Issued to:

COSMAX NBT INC

Manufacturing Site Address:

127-16 Deokpyeong-ro 663 Beon-gil
Icheon-si Gyeonggi-do 17389
Republic of Korea

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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 6 to 10 February 2023, 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. 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: 17 July 2023

Expiry Date: 10 February 2026

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 - Tablets	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule soft enteric	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Powder	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Gel	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Oral Liquid	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Pastille	Listed Therapeutic Good	Finished Product Manufacture

The following limitations are applicable to these manufacturing operations:

No further limitations are applicable.

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