Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2022-CE-11243-1

Issued to:

USPL Nutritionals LLC

Primary Manufacturing Site Address:

1300 Airport Road
North Brunswick New Jersey 08902
United States Of America

Secondary Manufacturing Site Address:

1200 Jersey Avenue
North Brunswick New Jersey 08902
United States Of America

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 31 October to 7 November 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 May 2021.

This certificate reflects the status of the manufacturing sites 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.

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

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MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site addresses as specified above.

Primary Site: 1300 Airport Road, North Brunswick, New Jersey 08902 USA

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Capsule, hard	Listed Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Tablet, uncoated	Listed Therapeutic Good	Full Product Manufacture - excluding Testing

Secondary Site: 1200 Jersey Avenue, North Brunswick, New Jersey 08902 USA

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Capsule, hard	Listed Therapeutic Good	Storage
Medicine manufacture	Non Sterile	Powder	Listed Therapeutic Good	Storage
Medicine manufacture	Non Sterile	Tablet, film coated	Listed Therapeutic Good	Storage
Medicine manufacture	Non Sterile	Tablet, enteric coated	Listed Therapeutic Good	Storage
Medicine manufacture	Non Sterile	Tablet, uncoated	Listed Therapeutic Good	Storage

The following limitations are applicable to these manufacturing operations:

Manufacturing is limited to the manufacture of the dosage forms in the Specialty Probiotic Area only.

Issue Date: **17 June 2024** **Expiry Date:** **7 November 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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