Australian Government
Department of Health
Therapeutic Goods Administration

J. Scott Murrin
Director of Quality Services
Capstone Nutrition LLC
900 South Depot Drive
Ogden Utah 84404
United States Of America

Our Reference: 2014/030171

Dear Mr Murrin

Subject: Issue of GMP certificate MI-2018-CE-14235-1

Please find enclosed the GMP certificate for your manufacturing premises.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely,

Signed and authorised by

Robert Prestridge
Senior GMP Inspector
Manufacturing Quality Branch

09 October 2019

Contact: gmp@tga.gov.au, phone +61 2 6221 6881 or fax +61 2 6232 8426

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2018-CE-14235-1

Issued to:

Capstone Nutrition LLC

Manufacturing Site Address:

900 South Depot Drive
Ogden Utah 84404
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 17 to 20 June 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 January 2017.

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.

EXPIRY DATE: 20 June 2022

ISSUE DATE: 09 October 2019

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: 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-2018-CE-14235-1

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	Powders Group	Listed Therapeutic Good	Finished Product Manufacture
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	Capsule, soft	Listed Therapeutic Good	Packaging, Labelling and Release for Supply
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Testing

The following limitations are applicable to these manufacturing operations

No further limitations are applicable

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