Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Mr Ramamuni Reddy
General Manager- QA
Evertogen Life Sciences Limited
Plot No: S-8 S-9 S-13 (Partly) & S-14 (Partly) Pharma SEZ TSIIC, Green Industrial Park
Polepally Village Jadcherla Mandal
Mahboobnagar Telangana State 509301
India

TGA Reference: E22-614587

Subject: Issue of GMP certificate MI-2020-CE-10927-1

Dear Mr Ramamuni Reddy,

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

Maurice Makdessi
Senior GMP Inspector
Manufacturing Quality Branch

26 September 2022

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

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2020-CE-10927-1

Issued to:

Evertogen Life Sciences Limited

Manufacturing Site Address:

Plot No: S-8 S-9 S-13 (Partly) & S-14 (Partly) Pharma SEZ TSIIC, Green Industrial Park Polepally Village Jadcherla Mandal
Mahboobnagar Telangana State India

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 inspection of GMP compliance during COVID-19 travel restrictions. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 07 March 2022 to 10 March 2022, 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 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.

EXPIRY DATE: 10 May 2024

ISSUE DATE: 26 September 2022

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-2020-CE-10927-1

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	Solid Unit Dosage Forms - Hard Capsules	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Suspension, powder for	Registered Therapeutic Good	Finished Product Manufacture

The following limitations are applicable to these manufacturing operations:

No further limitations are applicable

This Certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
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