Medicines and Healthcare products Regulatory Agency

Report No : UK GMP 43979 Insp GMP 43979/11316477-0004 NCR

STATEMENT OF NON-COMPLIANCE WITH GMP

Part 1

Issued following an inspection in accordance with :

- Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following:
The Manufacturer: EVERTOGEN LIFE SCIENCES LIMITED

Site address:

EVERTOGEN LIFE SCIENCES LIMITED, PLOT NO: S-8, S-9, S-13/P & S-14/P TSIIC, PHARMA SEZ, GREEN INDUSTRIAL PARK, POLEPALLY (V), JADCHERLA (M), , MAHABUBNAGAR, IN-509 301, INDIA

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***03/09/2018*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

Part 2

Human Medicinal Products
1. MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.13] Tablets [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.13] Tablets [1.5.2] Secondary packing

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 3

Nature of non-compliance :
The inspection on 03-08 September 2018 identified continued extensive failures in the GMP controls applied by the manufacturer. A restricted Statement of Non Compliance was previously issued to allow supply of critical products to EU. However, as no further demand is expected from the site to meet critical needs a full Statement of Non Compliance is now issued.

Withdrawal of current valid GMP certificates:
Withdrawal of previous Statement of Non Compliance and GMP Certificate No: UK GMP 43979 Insp GMP 43979/11316477-0004 NCR and UK GMP 43979 Insp GMP 43979/11316477-0004

Prohibition of supply:
No batches to be supplied to EU markets whilst this statement on non compliance remains in force.

Additional comments:
Serious, chronic GMP non compliance

16/04/2019	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential