

# 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