Medicines and Healthcare Products Regulatory Agency

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

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer [1]

Part 1

Issued following an inspection in accordance with :
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of United Kingdom confirms the following:
The manufacturer: ***EVERTOGEN LIFE SCIENCES LIMITED***
Site address: ***PLOT NO: S-8, S-9, S-13/P & S-14/P TSIIC, PHARMA SEZ, GREEN INDUSTRIAL PARK, POLEPALLY (V), JADCHERLA (M), MAHABUBNAGAR, TELANGANA, IN-509 301, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-08-31*** , 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 Directive 2003/94/EC

[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

Part 2

Human Medicinal Products

1 NON-COMPLIANT MANUFACTURING OPERATIONS	
Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;	
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 1.2.1.2 Capsules, soft shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The scope of this statement of non-compliance is limited to medicinal products considered non-critical to public health. National Competent Authorities should evaluate the criticality of products being supplied by this manufacturing site and enact measures to ensure continued supplies where appropriate. Marketing authorisation holders are requested to contact the European Medicines Agency or relevant National Authority to verify whether their products are considered medically critical to public health in their territory and therefore outside the scope of the non-compliance statement. Where manufacture and/or testing is continued for critical products, this should be supported by a documented risk assessment containing sufficient information to support activity on a risk management basis.

Part 3

1. Nature of non-compliance:
A desktop inspection identified a critical deficiency in regard to the integrity of data, QC laboratory capability, cross contamination, a lack of senior management control and a failure of the quality system. This was confirmed following an on-site inspection. Manufacturing personnel changed the method of manufacture without approval. Rejected in-process material was added to subsequent batches and excess discarded at packaging. Cross contamination events from marketed products include rogue tablets, capsules, package inserts and blisters in cartons. QC personnel used a single sample from one batch in a campaign to provide data for all batches under the direction of QC management. Stability testing was significantly behind schedule and time points were skipped due to inadequate QC laboratory resource. Risk assessments were based on recorded data only. The facility has identified that not all GMP relevant operations are recorded in batch records.
Action taken/proposed by the NCA
Recall of batches already released

Recall of medicines not considered critical to public health is under consideration. The integrity of all GMP records is compromised such that there is no assurance that batches have been manufactured and tested in accordance with their relevant authorisations. In addition, the failure to perform stability testing weakens the assurance that distributed product is safe.

Prohibition of supply
No future batches of non-critical product to be supplied to the EU while this statement of non-compliance remains in force

Additional comments
Withdrawal of current valid GMP Certificate No: UK GMP 43979 Insp GMP 43979/11316477-0003

2017-10-18

Name and signature of the authorised person of the Competent Authority of United Kingdom

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