Medicines and Healthcare Products Regulatory Agency

Report No: ***UK GMP 31540 Insp GMP 31540/1075658-0006 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: ***APOTEX RESEARCH PRIVATE LIMITED***
Site address: ***PLOT NO 1 & 2, BOMMASANDRA INDUSTRIAL AREA, 4TH PHASE, JIGANI LINK ROAD, BANGALORE, IN-560 099, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-11-17*** , 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 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packing 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

1. Nature of non-compliance:

The inspection in November 2017 identified failures in the cross-contamination controls applied by the manufacturer resulting in a risk of cross contamination above Permitted Daily Exposure (PDE) from some products.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. UK GMP 31540 Insp GMP 31540/1075658-0005
Withdrawal of previous GMP Certificate No: UK GMP 31540 Insp GMP 31540/1075658-0005. Issue of a statement of non-compliance. Due to the nature of the issues identified batches not released to market are included in the scope of this SNC. A new GMP certificate will be issued restricted to products agreed in writing between the marketing authorisation holder and individual competent authorities based on continuity of product supply being critical for continued patient treatment.

Recall of batches already released
Member states should contact the site to determine the level of risk associated with specific products released to market. MHRA would recommend consideration of recall of any products where success of cleaning is not supported by swab testing at product changeover and where the visual threshold is not equivalent to or lower than swab limits. As this may be difficult for the site to substantiate in the short term, it should be considered if precautionary recall should be applied.

Prohibition of supply
No batches to be supplied to EU markets whilst this statement of non-compliance remains in force with the exception of products agreed in writing between the marketing authorisation holder and individual competent authorities based on continuity of product supply being critical for continued patient treatment.

2017-12-08

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

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