Medicines Authority

Report No: ***MT/002NCR/2018***

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 Malta confirms the following:
The manufacturer: ***Mercury Laboratories Ltd.***
Site address: ***Unit No-2 Halol-Baroda Road, Village-Jarod, Taluka:Waghodiya, Dist:Vadodara, 391510, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-08-26*** , 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) 1.2.1.6 Liquids for internal use 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.6 Liquids for internal use 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:

A total of one (1) critical deficiency, six (6) major deficiencies and thirteen (13) other deficiencies were reported during this inspection. The critical deficiency concerned authenticity of records which could not be verified including production records and quality risk assessment records. The major deficiencies were cited for highly deficient production activities, process validation that does not provide assurance that the medicinal product consistently produces a product meeting its specifications and quality attributes, deficient supplier approval systems, quality control and microbiology laboratory deficiencies, inadequate pharmaceutical quality system and documentation management and inadequate cleaning validation to ensure no cross contamination.

Action taken/proposed by the NCA

Others

The Medicines Authority recommends that marketing authorization applications or variation applications to current marketing authorisations to include the above manufacturing site should not be considered.

Additional comments

There are no current EU GMP certificates for this site since this was the first inspection by an EU/EEA authority of the site. The site is currently not supporting any application for and/or marketing Authorisation for human medicinal products on any EU/EEA market. Thus there is no impact on any product on the EU/EEA market,

2018-10-23 Name and signature of the authorised person of the

Competent Authority of Malta

Confidential
Medicines Authority
Tel: ***Confidential***
Fax: ***Confidential***