Italian Medicines Agency

Report No: ***IT/NCR/API/1/2016***

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 Italy confirms the following:
The manufacturer: ***J P LABORATORIES PRIVATE LIMITED Block A-76***
Site address: ***M.I.D.C. Chemical Zone Kurkumbh, Pune District, Daund, Maharashtra, 413801, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-03-16*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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

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;

1.4	Other products or manufacturing activity
	1.4.1 Manufacture of
	1.4.1.4 Other: Active substances(en)

Manufacture of active substance. Names of substances subject to non-compliant :
ISOSORBIDE MONONITRATE, DILUTED (80% IN LACTOSE)(en)

Part 3

1. Nature of non-compliance:

28 deficiencies were raised by the inspectors, 9 of them classified as “Major” in the following areas: - Quality management - integrity and security of data in the quality system (1); - Personnel (2) - Building and facilities (1) - Materials management (1) - Production and In-Process control (1) - Laboratory control - integrity and security of analytical data (1); - Validation: equipment qualification (1) - Change control (1) The extent and severity of the findings, in combination with the repeated negative inspection outcome, demonstrates the inability of the company to sustain an acceptable GMP compliance level, and constitutes a critical risk for public health.

Action taken/proposed by the NCA

Recall of batches already released
Each involved NCA should evaluate, following assessment conducted in conjunction with MAHs, if a recall of medicinal product is needed. Evaluation should take into account if there are alternative suppliers and potential risk of shortage. Given the nature of non-compliance, assessment should include a complete retest of all imported batches of active substance.

Prohibition of supply
Prohibition of supply is recommended, unless there are not alternative suppliers and there is a risk of shortage.

Suspension or voiding of CEP (action to be taken by EDQM)
CEP was withdrawn.

Others
The observed deficiencies are considered to apply to all other active substances manufactured at the same site (Isosorbide Mononitrate Pure, Isosorbide Mononitrate Diluted 90%, Isosorbide Mononitrate Diluted 70% , Isosorbide Mononitrate Diluted 60%, Isosorbide Mononitrate Diluted 50%, Isosorbide Mononitrate Diluted 40% , Isosorbide Mononitrate Diluted 20%, Isosorbide Mononitrate Diluted 25%, Isosorbide Dinitrate Diluted 40% ,Isosorbide Dinitrate Diluted 25%).

2016-04-14

Name and signature of the authorised person of the Competent Authority of Italy

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