Italian Medicines Agency

Report No: ***IT/NCR/API/1/2015***

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: ***JINAN JINDA PHARMACEUTICAL CHEMISTRY CO., LTD.***
Site address: ***No. 6121 Longquan Road, Zhangqiu, Shandong Province, 250 200, China***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-06-26*** , 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 :
NITROFURANTOIN(en)

Part 3

1. Nature of non-compliance:

In total 18 deficiencies were identified by the inspection team, one of them was classified as critical and six as major. The critical observation was related to an unofficial and non-controlled storage area containing mainly raw materials and finished products which had been made inaccessible to inspectors as the door had been removed and replaced with a panel fixed with screws to the wall, which during the inspection the Company was requested to remove. The material stored in this area was to be managed outside of the Quality Assurance system and the investigation carried out by the inspection team concluded there was a serious risk of data falsification. One of the six major deficiencies was related to a very similar issue, as access to a locked garage was given to the inspection team only hours after requesting it. In both cases the explanations provided were not sound and different versions were given during the inspection. The remaining five major deficiencies were related to specific aspects of the Quality Assurance System with regards to training, cleaning validation, breaches of data integrity in the context of HPLC analysis, microbiological laboratory, qualification of contract manufacturer of a key intermediate of Nitrofurantoin production.

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-compliances, assessment should include a complete retest of all imported batches of active substance

Prohibition of supply
Due to the nature of non-compliances, prohibition of supply is recommended.

Suspension or voiding of CEP (action to be taken by EDQM)
CEP suspension is ongoing.

Others
This supplier should not be approved in any new / ongoing applications. Each involved NCA should evaluate if the supplier should be removed from existing MAs.

Additional comments
This inspection was performed in the framework of the CEP dossier for the manufacture of Nitrofurantoin R0-CEP 2011-240-Rev 01.

2015-07-28

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

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