Agence nationale de sécurité du médicament et des produits de santé

Report No: ***13MPP049***

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 France confirms the following:
The manufacturer: ***North China Pharmaceutical Co., Ltd***
Site address: ***388 Heping East Road, Shjiazhuang, Hebei, CN-050015, China***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2013-09-19*** , 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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.17 Other: Other(en)

Manufacture of active substance. Names of substances subject to non-compliant :
PHENOXYMETHYLPENICILLIN POTASSIUM(en) / PHENOXYMETHYLPENICILLINE POTASSIQUE(fr)

Part 3

1. Nature of non-compliance:

Overall, 31 deficiencies were observed, including 2 Critical and 9 Major deficiencies. [Critical1] 4 deficiencies (out of them 2 critical) related to the previous inspections not satisfactory corrected; [Critical 2] Repeated critical deficiency related to the cross-contamination of the facility with beta-lactam. [Major 1] Inadequate cleaning and maintenance of the production equipment; [Major 2] Incomplete Annual Product Quality Reviews; [Major 3] Inadequate control and storage of quality documents; [Major 4] Risk of contamination by reusable plastic containers of raw materials; [Major 5] Cross contamination issues between Phenoxymethylpenicillin potassium and Penicillin G Potassium; [Major 6] Repeated major deficiency related to the cleaning and maintenance of the utensils used for the solvents; [Major 7] Risk of contamination in the filtration and washing area for inadequate cleaning of the production equipment and tools; [Major 8] Risk of microbial, particle and chemical contamination of starting materials; [Major 9] Inadequate review and control of computerized laboratory results and systems.

Action taken/proposed by the NCA

Suspension or voiding of CEP (action to be taken by EDQM)
On the 30 Sep 2013, the EDQM Ad Hoc committee decided to withdraw the CEP 2006-019 for Phenoxymethylpenicillin Potassium.

Additional comments
- This inspection was performed in the frame of the EDQM inspection programme (Inspection number INSP 2007-020 P03). The scope of this inspection was the manufacturing of Phenoxymethylpenicillin Potassium. The site was already GMP non compliant following the previous EDQM inspection conducted on 14-16 October 2010 and the proposed actions were described in the NCS # Insp GMP 36204/1375445-0001. - This site is not suitable for supply of any other materials for EU products due to the risk of contamination with Phenoxymethylpenicillin Potassium.

2013-11-07

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

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