State Institute for Drug Control

Report No: ***sukls206914/2015***

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 Czech Republic confirms the following:
The manufacturer: ***HUBEI HONGYUAN PHARMACEUTICAL CO., LTD.***
Site address: ***No. 428 Yishui North Road, Fengshan Town, Luotian County, Huanggang City, Hubei Province, 438600, China***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-10-30*** , 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 :
METRONIDAZOLE(en) / METRONIDAZOLUM(cs)

Part 3

1. Nature of non-compliance:

The Company's facility at No. 428 Yishui North Road, Fengshan Town, Luotian County, Huanggang City, Hubei Province, China was subject to a spot check, because this site is mentioned as an intermediate manufacturing site in CEP 2001-450 Metronidazole. The Company clearly stated in their introduction that the site does not follow EU GMP. The following observations were made and together categorized as critical: a. The manufacturing site and it's equipment was found in a devastated state. b. Huge layers of dust and product indicated that no cleaning was applied to either the facility or the equipment, leading to an extreme risk of cross-contamination. c. The extremely bad shape of the facility and the equipment showed that no maintenance was in place. d. Almost none of the products seen was labelled. e. No batch manufacturing documentation could be seen. Reference: EU GMP Part II was found not implemented at the facility

Action taken/proposed by the NCA

Requested Variation of the marketing authorisation(s)
Removal from marketing authorizations.

Suspension or voiding of CEP (action to be taken by EDQM)
R1-CEP 2001-450-Rev 04/Metronidazole revised.

2016-01-20

Name and signature of the authorised person of the Competent Authority of Czech Republic

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Confidential
State Institute for Drug Control
Tel: ***Confidential***
Fax: ***Confidential***