French National Agency for Medicines and Health Products Safety

Report No: ***18MPP020NCR***

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: ***Dhanuka Laboratories Ltd.***
Site address: ***7 km, Old Manesar Road, Village Mohammedpur, Gurgaon, Haryana, 122 001, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-03-28*** , 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: active substance(en)

Manufacture of active substance. Names of substances subject to non-compliant :
CEFIXIME(en)

Part 3

1. Nature of non-compliance:
Overall, around 24 deficiencies were observed, out of which one was classified as critical and eight as major // Critical: multiple risks of contamination. // Major 1: deficient management of CAPAs. // Major 2: insufficient maintenance of facilities. // Major 3: failing controls of water quality. // Major 4&5: multiple shortcomings in the management and maintenance of equipment. // Major 6: deficient management of material storage. // Major 7: multiple validation shortcomings. // Major 8: failing change control management system.
Action taken/proposed by the NCA **Recall of batches already released** A recall of products should be considered using QRM principles. **Prohibition of supply** After issuance of the non-compliance report and as long as it remains active, the site should not be named in any new MAs or used in drug compounding activities. **Suspension or voiding of CEP (action to be taken by EDQM)** EDQM to consider the withdrawal of R1-CEP 2003-014 Cefixime and R0-CEP 2011-173 Cefuroxime axetil
Additional comments The existence of MAs or MA variations referencing an active substance manufactured by this site has to be verified. In these circumstances, the removal of the site from the MA should be considered using QRM principles.

2018-06-19

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

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