French National Agency for Medicines and Health Products Safety

Report No: ***16MPP053NCR***

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: ***Nandu Chemicals Industries***
Site address: ***Industrial estate N-12, Hubli, 580030, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-08-20*** , 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 substances(en)

Manufacture of active substance. Names of substances subject to non-compliant :
ZINC SULPHATE MONOHYDRATE(en)
4. Non-Compliant Other Activities - Active Substances :
Other active substances routinely manufactured on the site, (as communicated by the company): Calcium chloride dehydrate, potassium chloride, sodium benzoate, sodium gluconate, magnesium sulphate heptahydrate and manganese sulphate monohydrate. The site declared a manufacturing catalogue in excess of 100 active substances.

Part 3

1. Nature of non-compliance:

Significant deficiencies were observed in the vast majority of inspected areas. In particular falsification practices (critical deficiency number 1.1) and inadequate control systems (critical deficiency number 1.2) were recorded across the site. Major deficiencies were also observed : Risks of contamination. Lacking basic hygiene practices for the packing area / Poor standards for the management of retention samples and stability studies / Failing validation practices, in particular regarding analytical and cleaning validations / Lacking cleaning methods / Poor training practices / Deficient monitoring of the quality of the purified water / For documentation, insufficient recording and archiving practices / Deficiencies in product labelling practices.

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.

Additional comments
The existence of MAs or MA variations referencing an active substance manufactured by Nandu Hubli has to be verified. Where such a MA exists, the removal of the site from the MA should be considered using QRM principles.

2016-10-06

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

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Confidential
French National Agency for Medicines and Health Products Safety
Tel: ***Confidential***
Fax: ***Confidential***