檔　　號：
保存年限：

衛生福利部食品藥物管理署　函

地址：11561 臺北市南港區昆陽街161-2號
聯絡人：蘇子婷
聯絡電話：0227877148
傳真：0227877178
電子信箱：daisyhaha@fda.gov.tw

受文者：中華民國西藥代理商業同業公會

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密等及解密條件或保密期限：
附件：原料藥廠違反GMP警訊乙份(A21020000I105110575301-1.pdf)

主旨：PIC/S警訊平台（PIC/S Rapid Alert System）通報印度原料藥廠「Nandu Chemicals Industries」（廠址：Industrial estate N-12, Hubli, 580030, India）嚴重違反GMP乙案，詳如說明段，請轉知所屬會員知照。

說明：

一、法國衛生主管機關French National Agency for Medicines and Health Products Safety（ANSM）於105年8月20日查核旨揭原料藥廠，判定嚴重違反GMP，並於105年10月6日發布旨揭藥廠「STATEMENT OF NON COMPLIANCE WITH GMP」警訊，受影響之原料藥品項為「ZINC SULPHATE MONO HYDRATE）」等共7項（詳附件）。

二、承上，法國ANSM已啟動相關後續處置，包括：

(一)基於風險管理（Quality Risk Management）原則，使用相關原料藥之製劑產品許可證持有者應評估是否啟動回收。

(二)GMP狀態尚未改善完畢前，原料藥暫停出貨。

(三)使用旨揭原料藥廠原料藥之製劑產品，應考慮變更原料

來源。

三、於旨揭原料藥之製造品質無法符合GMP之要求，可能對藥品製造品質帶來影響與危害，請轉知所屬會員釐清相關輸台製劑產品是否使用旨揭原料藥廠所生產原料藥，並應依說明段二所述辦理。

正本：中華民國西藥商業同業公會全國聯合會、中華民國西藥代理商業同業公會、台北市西藥代理商業同業公會、中華民國開發性製藥研究協會、中華民國藥品行銷暨管理協會

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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)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : ZINC SULPHATE MONOHYDRATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : /
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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***