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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(A2102000I105110444100-1.pdf)

主旨：歐洲理事會European Directorate for the Quality of Medicines & HealthCare（EDQM）通報中國原料藥廠「JI NAN JINDA PHARMACEUTICAL CHEMISTRY CO., LTD.」（廠址：No. 6121 Longquan Road China-250 200 Zhangqiu, Shandong Province）嚴重違反GMP乙案，詳如說明段，請轉知所屬會員知照。

說明：

一、EDQM查核旨揭原料藥廠，判定嚴重違反GMP，EDQM於105年7月22日正式發布「WITHDRAWAL OF CERTIFICATES OF SUITABILITY」，註銷（WITHDRAW）「Nitrofurantoin」之CERTIFICATE OF SUITABILITY（CEP）品質證明文件。

二、西班牙衛生主管機關Spanish Agency of Medicines and Medical Devices（AEMPS）亦於105年7月29日發布「STATEMENT OF NON-COMPLIANCE WITH GMP」（詳如附件），受影響原料藥品項為「Nitrofurantoin, Macrocrystalline」；另，西班牙AEMPS已啟動相關後續處置，包括旨揭藥廠原料藥應暫停出貨。

三、鑒於旨揭原料藥廠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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Spanish Agency of Medicines and Medical Devices

Report No: *INSP 2015-026-0869333*

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 Spain confirms the following:
The manufacturer: ***JINAN JINDA PHARMACEUTICAL CHEMI. CO LTD***
Site address: ***No. 6121 Longquan Road, Zhangqiu, Shandong, 250200, China***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-06-01*** , 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 :
NITROFURANTOIN, MACROCRYSTALLINE(en)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : NITROFURANTOIN, MACROCRYSTALLINE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : drying, milling, sieving 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 3.6.2 Microbiological testing excluding sterility testing

Part 3

1. Nature of non-compliance:
The site was inspected by EDQM in June 2015 and found non-compliant; as a result, the site's CEP was suspended. Despite the 2015 non-compliance, sales to EU customers continued (list available by EDQM on authorities' request). The Company has been found to be not GMP compliant; a total of 30 deficiencies were identified in total, two of them classified as critical and eight as major. The CAPA for the previous EDQM inspection (June 2015, CEP suspension) report were found as not having been implemented in a satisfactory way. Critical deficiencies were found on raw data safety, control and OOS review. Moreover, several major deficiencies were found in training, change control, quality assessment, process and cleaning validations.
Action taken/proposed by the NCA **Prohibition of supply** Prohibition of supply

Suspension or voiding of CEP (action to be taken by EDQM)
CEP 2011-240

Additional comments
This inspection was performed in the frame of the Spanish collaboration on EDQM inspection programme

2016-07-29

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

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