

**Medicines and Healthcare Products Regulatory Agency**

Report No: **UK GMP 8913 INSP GMP 8913/18322-0005 - NCR**

**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 <sup>1</sup>**

**Part 1**

Issued following an inspection in accordance with :  
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of United Kingdom confirms the following:

The manufacturer: **WOCKHARDT LIMITED**

Site address: **L-1, MIDC, JALGAON ROAD, CHIKALTHANA, MAHARASHTRA STATE, AURANGABAD, IN 431 210, India**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2013-07-26** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

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<sup>1</sup> 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

Human Medicinal Products
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### 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;

<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets 1.2.1.17 Other: Granule(en)
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: Granule(en)
	<i>1.5.2 Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

## Part 3

<b>1. Nature of non-compliance:</b>
<p>1. A critical deficiency was cited with regards to testing of finished product and stability testing in the QC analytical laboratory. The deficiency related to data integrity, deleted electronic files with no explanation, the running of “trial testing” prior to performing system suitability and the formal testing and a loss of control of reconciliation of samples such as those used for additional testing could not be traced. 2. 4 major deficiencies were cited, relating to storage, general manufacturing practices, the performance of tablet coating and qualification and validation of equipment and products. • Issues seen, included temporary storage areas that had been created immediately prior to the inspection and were not visible on the site map. Storage areas did not have adequate temperature control or monitoring and did not protect stored items from contamination from the area or the environment. • Production practices included non contemporaneous record keeping, using equipment, such as balances, that had not been correctly set up, failure to record all critical data, failure to raise deviations for incidents that may impact product quality. • Qualifications were not robust and failed to ensure that all critical elements of equipment and processes were appropriately qualified. • The major deficiency for qualification and validation was cited as a separate deficiency as a number of issues were seen that indicated validation may not be performed consistently and therefore could relate to some of the product testing issues such as dissolution identified as part of the critical deficiency.</p>
<b>Action taken/proposed by the NCA</b>
<b>Withdrawal, of current valid GMP certificate No. UK GMP 8913 Insp GMP 8913/18322-0004</b> UK GMP 8913/18322-0004
<b>Requested Variation of the marketing authorisation(s)</b>

Marketing Authorisation Holder will be instructed to remove the site from the Marketing Authorisations

**Recall of batches already released**

National Competent Authorities should consider recall of all product considered non critical

**Prohibition of supply**

The site has been issued a statement of non compliance and should not be named on any marketing authorisations whilst this statement remains in place.

**Additional comments**

The scope of this statement of non-compliance is limited to medicinal products considered non-critical to public health. In order to avoid market shortage of medically essential products, a GMP certificate will be conditioned to permit continued manufacture and QC testing of 'critical' products in situations where it has been agreed by the national competent authority or EMA (as appropriate) that there is no feasible alternative in the market concerned. UPDATE - The site was re-inspected on 20-24 January 2014. The company's remediation plan remains in progress, and compliance has not yet reached a satisfactory level. No change in product risk was identified as a result of the re-inspection, and no changes to existing regulatory action are proposed. The company remains under close regulatory supervision. Further information may be requested by email to IAGSecretariat@mhra.gsi.gov.uk

2013-10-11

Name and signature of the authorised person of the  
Competent Authority of United Kingdom

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