

Medicines and Healthcare Products Regulatory Agency

Report No: **UK MIA 4077 Insp GMP 4077/15191-0040 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 ¹

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: **M & A PHARMACHEM LIMITED**

Site address: **ALLENBY LABORATORIES, WIGAN ROAD, WESTHOUGHTON, BOLTON, BL5 2AL, United Kingdom**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-10-15** , 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

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

Human Medicinal Products	
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
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets 1.2.1.17 Other
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

Part 3

1. Nature of non-compliance:
The inspection in October 2019 identified failures to introduce measures to prevent microbial and mould contamination, cross contamination and carry out appropriate investigations into contamination incidents. The National Competent Authority therefore believes that it is necessary in the interests of patient safety to immediately suspend manufacture of all products until the issues are satisfactorily resolved.
Action taken/proposed by the NCA
Suspension of the manufacturing authorisation No. UK MIA 4077 in Full The National Competent Authority believes that it is necessary in the interests of patient safety to immediately suspend manufacture of all products until the issues are satisfactorily resolved.
Withdrawal, of current valid GMP certificate No. UK MIA 4077 Insp GMP 4077/15191-0040 Issue of a statement of non-compliance
Additional comments
Member states should contact the site to determine the level of risk associated with specific products released to market.

2019-12-20

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

Confidential
Medicines and Healthcare Products Regulatory Agency
Tel: **Confidential**
Fax: **Confidential**

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