Medicines and Healthcare Products Regulatory Agency

Report No : ***UK GMP 44338 Insp GMP 44338/11868716-0001 SNC***

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 : ***THE ACME LABORATORIES LIMITED***

Site address : ***DHULIVITA, DHAMRAI, DHAKA, 1350, Bangladesh***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-11-08*** , 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

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
1.5 Packaging
1.5.2 Secondary packing
1.6 Quality control testing
1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users) :

This was the first inspection of the site does not currently have a GMP certificate and has not supplied any product to the EU

Part 3

Nature of non-compliance : There was evidence of data integrity issues with GMP documents bringing into question data used to support GMP decisions such as product release
Action taken/proposed by the NCA : **Prohibition of supply** The site has been issued with a statement of non-compliance and should not be named on any marketing authorisations or clinical trial applications whilst this statement remains in place. **Others** The site does not currently have a GMP certificate as this was the first inspection, a full scope Statement of Non Compliance will be issued
Additional comments : Any request for further information via teleconference should be made to the MHRA by email to IAGSecretariat@mhra.gov.uk No products have been imported into the EU due to this being the first inspection of the site.

Teleconference Date :	**Teleconference Time (CET) :**	**Dial in no. :**

Products manufactured at site, if known	Products	Dosage Form	Reference Member State, National or EMA
Human Medicinal Products	PL 17509/0073 Metronidazole	Tablet	National

2017-12-11

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

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Medicines and Healthcare Products Regulatory Agency

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