Medicines and Healthcare Products Regulatory Agency

Report No : ***UK GMP 22481 Insp GMP 22481/117371-0004 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 : ***MICRO LABS LIMITED***

Site address : ***92 SIPCOT INDUSTRIAL COMPLEX, HOSUR, IN-635 126, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-11-15*** , 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

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.1 Capsules, hard shell
1.2.1.13 Tablets

1.5 Packaging

1.5.1 Primary Packing
1.5.1.1 Capsules, hard shell
1.5.1.13 Tablets
1.5.2 Secondary packing

1.6 Quality control testing

1.6.2 Microbiological: non-sterility
1.6.3 Chemical/Physical

Any restrictions related to the scope of this statement :

Building	Room	Line/equipment	QC testing	Products
Building ML03	***N/A***	***N/A***	***N/A***	***confidential***

Part 3

Nature of non-compliance : The inspection in November 2018 identified failures in the cross-contamination controls applied by the manufacturer resulting in a risk of cross contamination above Permitted Daily Exposure (PDE) from some products.

Action taken/proposed by the NCA :

Withdrawal, of current valid GMP certificate No. UK GMP 22481 Insp GMP 22481/117371-0003
Withdrawal of previous GMP Certificate No: UK GMP 22481 Insp GMP 22481/117371-0003. Issue of a statement of non-compliance restricted to allow manufacture of products critical to patient supply. Due to the nature of the issues identified batches not released to market are included in the scope of this SNC.

Recall of batches already released
Member states should contact the site to determine the level of risk associated with specific products released to market. MHRA would recommend consideration of recall of any products where manufacture followed low PDE products in equipment used for granulation, blending, compression

Prohibition of supply
Only products critical to maintain patient supply to be supplied to EU markets whilst this statement of non-compliance remains in force.

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

2019-01-24 Name and signature of the authorised person of the Competent Authority of United Kingdom

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