Medicines and Healthcare Products Regulatory Agency

Report No: ***Insp GMP 31201/349094-0009 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: ***MEDOPHARM PRIVATE LIMITED***
Site address: ***NO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY, CHENGALPET DISTRICT, IN-603202, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-10-16*** , 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**
	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 1.2.1.17 Other: Dry Powder for Oral Suspension(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: Dry Powder for Oral Suspension(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Part 3

1. Nature of non-compliance:

The inspection in October 2019 identified further chronic non-compliance with EU GMP and failure to adequately address deficiencies from previous inspections. In process checks were not performed effectively and an adequate risk based approach to cross contamination control was not demonstrated.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. UK GMP 31201 Insp GMP 31201/349094-0008
Withdrawal of previous GMP Certificate No: UK GMP 31201 Insp GMP 31201/349094-0008 Issue of a statement of non-compliance.

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

Additional comments
This Statement of Non Compliance does not include manufacture of critical products. Such products should be agreed in writing with individual EU Competent Authorities. Although previous GMP certificates have carried the site address, these referred to the original unit 1. There is a second unit on the site that has never been inspected by an EU Member state and thus is not in scope of previous GMP certification or this Statement of Non-Compliance.

2020-02-13

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

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