Medicines and Healthcare products Regulatory Agency

Report No : UK GMP 31201 Insp GMP 31201/349094-0009 NCR

STATEMENT OF NON-COMPLIANCE WITH GMP

Part 1

Issued following an inspection in accordance with :

- Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following:
The Manufacturer: MEDOPHARM PRIVATE LIMITED

Site address:

MEDOPHARM PRIVATE LIMITED, 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 ***16/10/2019*** , 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 Regulation B17 of the Human Medicines Regulations 2012 (as amended)

Part 2

Human Medicinal Products

1. 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

[1.2.1.17] Other non-sterile medicinal products
Dry Powder for Oral Suspension

[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

[1.5.2] Secondary packing

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 3

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.

Withdrawal of current valid GMP certificates:
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.

13/02/2020	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential