Medicines and Healthcare products Regulatory Agency

Report No : UK GMP 34063 Insp GMP 34063/627590-0001 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: BIOPLUS LIFE SCIENCES PRIVATE LIMITED

Site address:

BIOPLUS LIFE SCIENCES PRIVATE LIMITED, PHARMED GARDENS, WHITEFIELD ROAD, BANGALORE, IN-560048, INDIA

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***13/12/2019*** , 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 Powder Sachet [1.5] Packaging [1.5.2] Secondary packing [1.6] Quality control testing [1.6.2] Microbiological: non-sterility

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[1.6.3] Chemical/Physical

Part 3

Nature of non-compliance :
The Inspection in December 2019 identified failures in the measures to prevent and detect cross-contamination and presented a risk that cross-contamination between products could occur and would not be detected the vendor approval process did not adequately consider the risk of contamination to existing products when introducing new raw materials; the integrity of reported data could not be relied upon; the site had contravened the restrictions on the 2014 GMP certificate.

Recall of batches:
Member states should contact the site to determine the level of risk associated with specific products released to market. MHRA would recommend determining the criticality of the products on the market and to assess if a precautionary recall is appropriate.

Prohibition of supply:
No batches to be supplied to EU markets whilst this statement of non-compliance remains in force.

Additional comments:
Withdrawal of previous GMP Certificate No: DK H 00111418 (and previous certificate DK H 00049315 and DK H 00011411). Issue of a statement of non-compliance. Due to the nature of the issues identified batches not released to market and included in the scope of the SNC.

21/02/2020	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential

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