Medicines and Healthcare products Regulatory Agency

Report No : Insp GMP 17907/13988-0036

STATEMENT OF NON-COMPLIANCE WITH GMP

Part 1

Issued following an inspection in accordance with :

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

The competent authority of United Kingdom confirms the following:
The Manufacturer: Bristol Laboratories Limited

Site address:

Bristol Laboratories Limited, Laporte Way, Luton, LU4 8WL, UNITED KINGDOM

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***08/04/2024*** , 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(3) and C17 of The Human Medicines Regulations 2012 (SI 2012/1916)

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 [1.2.1.8] Other solid dosage forms Powder for sachets [1.2.1.13] Tablets [1.2.1.17] Other non-sterile medicinal products Powder for sachets [1.2.2] Batch certification [1.5] Packaging

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[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms
Powder for sachets

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products
Powder for sachets

[1.5.2] Secondary packing

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

Part 3

Nature of non-compliance :
Following inspections on 25 July 2023 and 8 April 2024, critical deficiencies were identified in relation to data integrity, good distribution practice, lack of protection from microbial and other contamination, and inadequate control of packaging changes. This Statement of Non Compliance does not include the manufacture of critical products. Such products should be agreed in writing with individual National Competent Authorities.

Withdrawal of current valid GMP certificates:
UK MIA 17907 INSP GMP 17907/13988-0035[H]

Recall of batches:
No recalls necessary at the time of issuance of this SONC.

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

23/05/2024 Name and signature of the authorised person of the Competent Authority of United Kingdom

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