Medicines and Healthcare products Regulatory Agency

Report No : Insp GMP 51747/18953344-0001 NCR

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: Genovior Biotech Corporation

Site address:

Genovior Biotech Corporation, Floors 4 & 5 (5F:50-9, 5F:50-8, 4F:50-3), No.50 Keyan Rd, Zhunan Township, Miaoli County, 35053, TAIWAN

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***27/03/2023*** , 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) of the Human Medicines Regulations 2012 (as amended)

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.2] Lyophilisates

[1.1.1.4] Small volume liquids

[1.4] Other products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

Restrictions or remarks: The scope of this statement of non-compliance is limited to Sterile medicinal Oncology products manufactured on the 5th Floor of the No.50 Kenyan Road facility.

Part 3

Nature of non-compliance :
The inspection identified a critical finding regarding sterility assurance of product. The controls in place were such that there was a significant risk that product may not be sterile and that this would not be detected due to lack of robust and repeatable aseptic and sterilisation processes. A second critical finding was identified related to contamination and degradation controls.

Withdrawal of current valid GMP certificates:
N/a – none issued for EU GMP.

Marketing authorisation action :
The UK MAA has been withdrawn by the applicant.

Recall of batches:
No batches have been supplied to the UK or EU

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

30/08/2023 Name and signature of the authorised person of the Competent Authority of United Kingdom

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