Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 25224 Insp GMP/IMP 25224/89442-0013[I]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : CLINICAL BIOTECHNOLOGY CENTRE, BRISTOL INST FOR TRANSFUSION SCIENCES

Site address : CLINICAL BIOTECHNOLOGY CENTRE, BRISTOL INST FOR TRANSFUSION SCIENCES, UNIVERSITY OF BRISTOL, LANGFORD HOUSE, LOWER LANGFORD, BRISTOL, BS40 5DU, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 25224 in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 13/06/2022 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

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

[1.1.1.4] Small volume liquids

[1.3] Biological investigational medicinal products

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[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products
Recombinant Proteins

[1.4] Other products or manufacturing activity

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.4] Biological

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.4] Biological

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.3] Biological medicinal products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.8] Other biological medicinal products
Recombinant Proteins

28/07/2022	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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