Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 59573 Insp IMP 59573/35110486-0002[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 : CELL AND GENE THERAPY CATAPULT MANUFACTURING AND INNOVATION CENTRE

Site address : CELL AND GENE THERAPY CATAPULT MANUFACTURING AND INNOVATION CENTRE, 4 WARNER DRIVE, SPRINGWOOD INDUSTRIAL ESTATE, BRAINTREE, CM7 2YW, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 59573 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 06/12/2023 , 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)

[1.1.1.1] Large volume liquids

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.1.1.4] Small volume liquids

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.1.1.6] Other aseptically prepared products

Cell and viral vector based Advanced Therapeutic Medicinal Products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.1.4] Gene therapy products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.1.5] Biotechnology products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.1.6] Human or animal extracted products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.1.8] Other biological medicinal products

Viral vectors

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.2.4] Gene therapy products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.2.5] Biotechnology products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.2.6] Human or animal extracted products

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[1.3.2.8] Other biological medicinal products

Viral vectors

Special Requirements

Live Cells

Advanced Therapy Medicinal Products

[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

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.1.17] Other non-sterile medicinal products

Cell based Advanced Therapeutic Medicinal Products

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

09/07/2024	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential