Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 45803 Insp IMP 45803/4883575-0018[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 : ROSLINCT INSTITUTE FOR REGENERATION AND REPAIR NORTH

Site address : ROSLINCT INSTITUTE FOR REGENERATION AND REPAIR NORTH, GMP CELLULAR THERAPY FACILITY, SCOTTISH CENTRE FOR REGENERATIVE MEDICINE, EDINBURGH BIOQUARTER, 5 LITTLE FRANCE DRIVE, EDINBURGH, EH16 4UU, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 45803 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 27/07/2021 , 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

MHRA-GMDP MHRA

[1.1.1.6] Other aseptically prepared products
cellular therapy products (ATMPS), Master cell banks

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

[1.3.1.4] Gene therapy products

[1.3.1.6] Human or animal extracted products

[1.3.1.7] Tissue Engineered Products

Special Requirements
Live Cells

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.3.2.7] Tissue Engineered Products

Special Requirements
Live Cells

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.4] Biological

03/12/2024	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

MHRA-GMDP MHRA