Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 13101 Insp IMP 13101/21095-0012[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 : FORTREA CLINICAL RESEARCH UNIT LIMITED

Site address : FORTREA CLINICAL RESEARCH UNIT LIMITED, SPRINGFIELD HOUSE, HYDE STREET, LEEDS, LS2 9LH, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 13101 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 20/12/2021 , 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)

[1.1.1.1] Large volume liquids

[1.1.1.4] Small volume liquids

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[1.1.1.6] Other aseptically prepared products

Formulation/Reconstitution of biologicals and peptide hormones with subsequent manufacture of small and large volumes. Reconstitution of lyophilisates and manufacture of radiolabelled small and large volumes

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.17] Other non-sterile medicinal products

Radiolabelled substances e.g. liquids, solid dosage forms and capsules

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Packaging of immunological and biotechnology products. Packaging of human or animal extracted products

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Packaging of immunological and biotechnology products. Packaging of human or animal extracted products

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Radiolabelled substances e.g. e.g. liquid and solid dosage forms./Importation of QP-certified IMPs from a country on the approved country for import list

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.3] Chewing gums

[1.5.1.4] Impregnated matrices

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[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.1.14] Transdermal patches

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.2] Immunological products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Other

Radiolabelled substances e.g. e.g. liquid and solid dosage forms./Importation of QP-certified IMPs from a country on the approved country for import list

Restrictions or Remarks

This was a focused remote inspection following a variation to add oversight process for IMP from listed countries.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
			Testing activities limited to: appearance, visible particles, pH and extractable volume.	

25/10/2023	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential

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