Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 13101
2: Name of authorisation holder	FORTREA CLINICAL RESEARCH UNIT LIMITED
3: Address(es) of manufacturing site(s)	FORTREA CLINICAL RESEARCH UNIT LIMITED , DRAPERS YARD, MARSHALL STREET, LEEDS, LS11 9EH, UNITED KINGDOM
4: Legally registered address of authorisation holder	FORTREA CLINICAL RESEARCH UNIT LIMITED, DRAPERS YARD, MARSHALL STREET, LEEDS, LS11 9EH, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	03/07/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

FORTREA CLINICAL RESEARCH UNIT LIMITED , DRAPERS YARD, MARSHALL STREET, LEEDS, LS11 9EH, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 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

[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

[1.2.1.15] 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 biotechnological 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 biotechnological products. Packaging of human or animal extracted products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.3] Other

Radiolabelled substances 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

[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

Part 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

[2.3.2] Importation of Intermediate which undergoes further processing