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

Manufacturer's Authorisation: UK MIA(IMP) 13101

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