

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 13101 |
| 2: Name of authorisation holder | FORTREA CLINICAL RESEARCH UNIT LIMITED FORTREA CLINICAL RESEARCH UNIT LIMITED, SPRINGFIELD HOUSE, HYDE STREET, LEEDS, LS2 9LH, UNITED KINGDOM |
| 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, SPRINGFIELD HOUSE, HYDE STREET, LEEDS, LS2 9LH, 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 | 14/08/2024 |
| 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, SPRINGFIELD HOUSE, HYDE STREET, LEEDS, LS2 9LH, UNITED KINGDOM

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| 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 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 investigational medicinal 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

[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

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| <ul style="list-style-type: none"> [2.2.1] Sterile Products <ul style="list-style-type: none"> [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products [2.2.3] Biological medicinal products <ul style="list-style-type: none"> [2.2.3.2] Immunological products [2.2.3.5] Biotechnology products [2.2.3.6] Human or animal extracted products |
| <p>[2.3] Other Importation Activities</p> <ul style="list-style-type: none"> [2.3.1] Site of Physical Importation [2.3.4] Other <ul style="list-style-type: none"> 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 |

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

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| Human Investigational Medicinal Products |
| Authorised Operations |
| <p>MANUFACTURING OPERATIONS (according to part 1)</p> <p>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)</p> |

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 activity

[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