Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 11149
2: Name of authorisation holder	ROYAL FREE LONDON NHS FOUNDATION TRUST
3: Address(es) of manufacturing site(s)	ROYAL FREE LONDON NHS FOUNDATION TRUST, RADIOPHARMACY NUCLEAR MEDICINE, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM ROYAL FREE LONDON NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM ROYAL FREE LONDON NHS FOUNDATION TRUST, CENTRE FOR CELL, GENE & TISSUE THERAPEUTICS, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM
4: Legally registered address of authorisation holder	ROYAL FREE LONDON NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, 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	29/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ROYAL FREE LONDON NHS FOUNDATION TRUST, RADIOPHARMACY NUCLEAR MEDICINE, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.1.1.6] Other aseptically prepared products

Radio Pharmaceuticals

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.3] Cell therapy products

[1.3.1.4] Gene therapy products

[1.3.1.6] Human or animal extracted products

[1.3.1.8] Other biological medicinal products

Proteins, Peptides

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.3.2.6] Human or animal extracted products

[1.3.2.8] Other biological medicinal products

Proteins, Peptides

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ROYAL FREE LONDON NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, THE ROYAL FREE HOSPITAL, POND STREET, LONDON, NW3 2QG, 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

[1.1.1.3] Semi-solids

[1.1.1.4] Small volume liquids

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[1.1.2.2] Semi-solids

[1.1.2.3] Small volume liquids

[1.1.2.5] Other terminally sterilised prepared products

Ampoules, Creams, Powders, Medicated Dressings, (sent away for sterilisation by irradiation), and Bone Wax.

[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

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.1] Blood products

[1.3.1.2] Immunological products

[1.3.1.6] Human or animal extracted products

[1.3.1.8] Other biological medicinal products

Proteins, Peptides

[1.3.2] Batch certification

[1.3.2.1] Blood products

[1.3.2.2] Immunological products

[1.3.2.6] Human or animal extracted products

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.4.2.2] Dry heat

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.1.4] Biological

[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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ROYAL FREE LONDON NHS FOUNDATION TRUST, CENTRE FOR CELL, GENE & TISSUE THERAPEUTICS, POND STREET, LONDON, NW3 2QG, 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)

[1.1.1.5] Solids and implants

[1.1.1.6] Other aseptically prepared products

ATMPs

[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

[1.3.1.7] Tissue Engineered Products

[1.3.1.8] Other biological medicinal products

INTERMEDIATE MATERIALS: TISSUE CULTURE SUPERNATANTS

[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

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.4] Biological

[2.2] Batch certification of imported medicinal products

[2.2.3] Biological medicinal products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list