Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 25224
2: Name of authorisation holder	NHS BLOOD AND TRANSPLANT
3: Address(es) of manufacturing site(s)	FILTON BLOOD CENTRE, NORTH BRISTOL PARK, NORTHWAY, FILTON, BRISTOL, BS34 7QH, UNITED KINGDOM BARNSLEY BLOOD CENTRE, NHSBT BARNSLEY BLOOD CENTRE, UNIT D, CAPITOL WAY, DODWORTH, BARNSLEY, S75 3FG, UNITED KINGDOM NHSBT ADVANCED THERAPIES UNIT, 14 ESTUARY BANKS, SPEKE, LIVERPOOL, L24 8RB, UNITED KINGDOM BIRMINGHAM BLOOD CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2SG, UNITED KINGDOM
4: Legally registered address of authorisation holder	NHS BLOOD AND TRANSPLANT, PLYMOUTH GROVE, MANCHESTER, M13 9LL, 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	20/02/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

FILTON BLOOD CENTRE, NORTH BRISTOL PARK, NORTHWAY, FILTON, BRISTOL, BS34 7QH, 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)

[1.1.1.4] Small volume liquids

[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

[1.3.1.5] Biotechnology products

[1.3.1.7] Tissue Engineered Products

[1.3.1.8] Other biological medicinal products

Recombinant Proteins/Enucleated non-replicating Human cells

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.7] Tissue Engineered 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

[1.5] Packaging

[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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.4] Biological

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.3] Biological medicinal products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.8] Other biological medicinal products

Recombinant Proteins/Enucleated non-replicating Human cells

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BARNSLEY BLOOD CENTRE, NHSBT BARNSLEY BLOOD CENTRE, UNIT D, CAPITOL WAY, DODWORTH, BARNSLEY, S75 3FG, 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

Virally transduced cellular product

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

Special Requirements

Live Cells

[1.3.1.4] Gene therapy products

Special Requirements

Live Cells

[1.3.1.7] Tissue Engineered Products

Special Requirements

Live Cells

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

Special Requirements

Live Cells

[1.3.2.4] Gene therapy products

Special Requirements

Live Cells

[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:

NHSBT ADVANCED THERAPIES UNIT, 14 ESTUARY BANKS, SPEKE, LIVERPOOL, L24 8RB, 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

[1.1.1.5] Solids and implants

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

[1.3.1.7] Tissue Engineered Products

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.7] Tissue Engineered Products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.3] Other

Biologically Active Starting materials

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

[1.4.2.1] Filtration

[1.5] Packaging

[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:

BIRMINGHAM BLOOD CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2SG, 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)

[1.1.1.4] Small volume liquids

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

[1.3.1.7] Tissue Engineered Products

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.7] Tissue Engineered 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

[1.5] Packaging

[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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.3] Biological medicinal products

[2.2.3.3] Cell therapy products

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing