

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 14620
2: Name of authorisation holder	BARTS HEALTH NHS TRUST BARTS HEALTH NHS TRUST (PHARMACY CHEMOTHERAPY UNIT 7TH FLOOR), DEPARTMENT OF PHARMACY- PHARMACY CHEMOTHERAPY UNIT, 7TH FLOOR, KING GEORGE V WING, ST BARTHOLOMEW'S HOSPITAL, WEST SMITHFIELD, LONDON, EC1A 7BE, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	BARTS HEALTH NHS TRUST (NUCLEAR MEDICINE RADIOPHARMACY UNIT BASEMENT), NUCLEAR MEDICINE- RADIOPHARMACY, BASEMENT, KING GEORGE V WING, ST BARTHOLOMEW'S HOSPITAL, WEST SMITHFIELD, LONDON, EC1A 7BE, UNITED KINGDOM BARTS HEALTH NHS TRUST, PHARMACY TECHNICAL SERVICES, 1ST FLOOR PATHOLOGY & PHARMACY BUILDING, ROYAL LONDON HOSPITAL ,80 NEWARK STREET, LONDON, E1 2ES, UNITED KINGDOM
4: Legally registered address of authorisation holder	BARTS HEALTH NHS TRUST, 80 NEWARK STREET, WHITECHAPEL, LONDON, E1 2ES, 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	15/03/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BARTS HEALTH NHS TRUST (PHARMACY CHEMOTHERAPY UNIT 7TH FLOOR), DEPARTMENT OF PHARMACY- PHARMACY
CHEMOTHERAPY UNIT, 7TH FLOOR, KING GEORGE V WING, ST BARTHOLOMEW'S HOSPITAL, WEST SMITHFIELD, LONDON,
EC1A 7BE, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

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
- [1.1.2] Terminally Sterilised (processing operations for the following dosage forms)
 - [1.1.2.1] Large volume liquids

[1.2] Non-sterile investigational medicinal products

- [1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
 - [1.2.1.5] Liquids for external use
 - [1.2.1.6] Liquids for internal use

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products
 - [1.3.1.4] Gene therapy products
 - [1.3.1.8] Other biological medicinal products
 - Monoclonal Antibodies

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.1] Manufacture of:
 - [1.4.1.3] Other
 - Radiopharmaceuticals/radionuclide generators

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.5] Liquids for external use
 - [1.5.1.6] Liquids for internal use
 - [1.5.1.11] Semi-solids
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BARTS HEALTH NHS TRUST (NUCLEAR MEDICINE RADIOPHARMACY UNIT BASEMENT), NUCLEAR MEDICINE-
RADIOPHARMACY, BASEMENT, KING GEORGE V WING, ST BARTHOLOMEW'S HOSPITAL, WEST SMITHFIELD, LONDON, EC1A
7BE, 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

Radiopharmaceuticals / Radionuclide Generators/ IMP product dispensing, large and small volumes diagnostic purposes

[1.1.3] Batch certification

[1.4] Other investigational medicinal products or manufacturing activity

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.10] Radionuclide generators

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BARTS HEALTH NHS TRUST, PHARMACY TECHNICAL SERVICES, 1ST FLOOR PATHOLOGY & PHARMACY BUILDING, ROYAL LONDON HOSPITAL ,80 NEWARK STREET, LONDON, E1 2ES, 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)

[1.1.1.1] Large volume liquids

[1.1.1.4] Small volume liquids

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.11] Semi-solids

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

[1.3.1.8] Other biological medicinal products

Antibodies/antibody conjugates

[1.4] Other investigational medicinal products or manufacturing activity

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical