

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 TECHNICAL SERVICES, 1ST FLOOR PATHOLOGY & PHARMACY BUILDING, ROYAL LONDON HOSPITAL ,80 NEWARK STREET, LONDON, E1 2ES, UNITED KINGDOM 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 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
3: Address(es) of manufacturing site(s)	
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	31/03/2025
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 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)
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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

[1.4] 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

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
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
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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

[1.4] 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)
<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.1] Sterile Investigational Medicinal Products</p> <ul style="list-style-type: none"> [1.1.1] Aseptically prepared (processing operations for the following dosage forms) <ul style="list-style-type: none"> [1.1.1.4] Small volume liquids [1.1.1.6] Other aseptically prepared products <ul style="list-style-type: none"> Radiopharmaceuticals / Radionuclide Generators/ IMP product dispensing, large and small volumes diagnostic purposes [1.1.3] Batch certification <p>[1.4] Other investigational medicinal products or manufacturing activity</p> <ul style="list-style-type: none"> [1.4.2] Sterilisation of active substances/excipients/finished products: <ul style="list-style-type: none"> [1.4.2.1] Filtration <p>[1.5] Packaging</p> <ul style="list-style-type: none"> [1.5.1] Primary packaging <ul style="list-style-type: none"> [1.5.1.10] Radionuclide generators <p>[1.6] Quality control testing</p> <ul style="list-style-type: none"> [1.6.1] Microbiological: sterility