

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 14620
<b>2: Name of authorisation holder</b>	BARTS HEALTH NHS TRUST  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
<b>3: Address(es) of manufacturing site(s)</b>	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, PHARMACY TECHNICAL SERVICES, 1ST FLOOR PATHOLOGY & PHARMACY BUILDING, ROYAL LONDON HOSPITAL ,80 NEWARK STREET, LONDON, E1 2ES, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	BARTS HEALTH NHS TRUST, 80 NEWARK STREET, WHITECHAPEL, LONDON, E1 2ES, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	01/07/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### 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 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

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

[ 1.1.2 ] 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**, 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