Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 11387
2: Name of authorisation holder	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST
3: Address(es) of manufacturing site(s)	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, PHARMACY PRODUCTION UNIT, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, THE FMT LABORATORY, CENTRE FOR CLINICAL INFECTION AND DIAGNOSTIC RESEARCH, NORTH WING, FLOOR 5, ST THOMAS'S HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, UNITED KINGDOM CLINICAL PET CENTRE, ST THOMAS HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, UNITED KINGDOM GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, CLINICAL RESEARCH FACILITY, 15TH FLOOR, TOWER WING, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM RADIOPHARMACY UNIT, RADIOPHARMACY UNIT, NUCLEAR MEDICINE, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM
4: Legally registered address of authorisation holder	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, PHARMACY MANUFACTURING UNIT, 13TH FLOOR, GUY'S TOWER, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, 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	18/04/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, PHARMACY PRODUCTION UNIT, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, 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

[1.1.2] 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

[1.2] 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

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Solid non-sterile including powders and granules

[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:

GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, THE FMT LABORATORY, CENTRE FOR CLINICAL INFECTION AND DIAGNOSTIC RESEARCH, NORTH WING, FLOOR 5, ST THOMAS'S HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[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

[1.2.1.6] Liquids for internal use

[1.2.1.15] Other non-sterile medicinal products

Faecal Microbiota for transplantation (FMT)

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.6] Human or animal extracted products

[1.3.1.8] Other biological medicinal products

Faecal Microbiota for transplantation (FMT)

[1.3.2] Batch certification

[1.3.2.6] Human or animal extracted products

[1.3.2.8] Other biological medicinal products

Faecal Microbiota for transplantation (FMT)

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.6] Liquids for internal use

[1.5.1.15] Other non-sterile medicinal products

Faecal Microbiota for transplantation (FMT)

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CLINICAL PET CENTRE, ST THOMAS HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, 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

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, CLINICAL RESEARCH FACILITY, 15TH FLOOR, TOWER WING, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, 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

[1.1.1.4] Small volume liquids

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

Special Requirements

ATMPs

[1.3.1.4] Gene therapy products

Special Requirements

ATMPs

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products

Autologous or allogeneic cell therapies for intravenous or solid tissue

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.6] Quality control testing

[1.6.1] Microbiological: 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

[2.2.3.4] Gene therapy products

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

RADIOPHARMACY UNIT, RADIOPHARMACY UNIT, NUCLEAR MEDICINE, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, 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

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Radiopharmaceuticals; Nano-antibodies

[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

[1.5.1.15] Other non-sterile medicinal products

Solid non-sterile including powders and granules

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical