

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 1384
2: Name of authorisation holder	UNIVERSITY OF EDINBURGH UNIVERSITY OF EDINBURGH - INVESTIGATIONAL SUPPLIES GROUP, 1 GEORGE SQUARE, EDINBURGH, EH8 9JZ, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	HEALTHCARE TECHNOLOGY ACCELERATOR FACILITY (HTAF) STERILE FILL UNIT (SFU), STERILE FILL UNIT, QUEENS MEDICAL RESEARCH INSTITUTE, 47 LITTLE FRANCE CRESCENT, EDINBURGH, EH16 4TJ, UNITED KINGDOM UNIVERSITY OF EDINBURGH - PET RADIOCHEMISTRY, QUEENS MEDICAL RESEARCH INSTITUTE, 47 LITTLE FRANCE CRESCENT, EDINBURGH, EH16 4TJ, UNITED KINGDOM
4: Legally registered address of authorisation holder	UNIVERSITY OF EDINBURGH, THE UNIVERSITY COURT OF THE UNIVERSITY OF EDINBURGH, OLD COLLEGE, SOUTH BRIDGE, EDINBURGH, EH8 9YL, 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	12/03/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UNIVERSITY OF EDINBURGH - INVESTIGATIONAL SUPPLIES GROUP, 1 GEORGE SQUARE, EDINBURGH, EH8 9JZ, 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

[1.2] 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

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.2] Capsules, soft shell

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Powders

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.1] Blood products

[2.2.3.2] Immunological products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

HEALTHCARE TECHNOLOGY ACCELERATOR FACILITY (HTAF) STERILE FILL UNIT (SFU), STERILE FILL UNIT, QUEENS MEDICAL RESEARCH INSTITUTE, 47 LITTLE FRANCE CRESCENT, EDINBURGH, EH16 4TJ, 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 activity

- [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:

UNIVERSITY OF EDINBURGH - PET RADIOCHEMISTRY, QUEENS MEDICAL RESEARCH INSTITUTE, 47 LITTLE FRANCE CRESCENT, EDINBURGH, EH16 4TJ, 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
- [1.1.2] Terminally Sterilised (processing operations for the following dosage forms)
 - [1.1.2.3] Small volume liquids

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.2] Sterilisation of active substances/excipients/finished products:
 - [1.4.2.3] Moist heat

[1.6] Quality control testing

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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

- [2.2.1] Sterile Products
 - [2.2.1.1] Aseptically prepared
 - [2.2.1.2] Terminally sterilised
- [2.2.2] Non-sterile products