

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 48980
2: Name of authorisation holder	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST
3: Address(es) of manufacturing site(s)	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST, RADIOPHARMACY UNIT, NUCLEAR MEDICINE CENTRE, OXFORD ROAD, MANCHESTER, M13 9WL, UNITED KINGDOM
4: Legally registered address of authorisation holder	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST, COBBETT HOUSE, OXFORD ROAD, MANCHESTER, M13 9WL, 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	05/11/2018
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MANCHESTER UNIVERSITY NHS FOUNDATION TRUST, RADIOPHARMACY UNIT, NUCLEAR MEDICINE CENTRE, OXFORD ROAD, MANCHESTER, M13 9WL, 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
Radiomedicinal products; Radiopharmaceuticals
[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
- [1.2.1.8] Other solid dosage forms
- [1.2.1.11] Semi-solids
- [1.2.1.13] Tablets
- [1.2.1.15] Other non-sterile medicinal products
Radiomedicinal; Radiopharmaceuticals

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products
 - [1.3.1.1] Blood products
 - [1.3.1.2] Immunological products
 - [1.3.1.6] Human or animal extracted products
 - [1.3.1.8] Other biological medicinal products
New Chemical Entities (NCE)

[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
 - [1.5.1.5] Liquids for external use
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.3] Chemical/Physical