

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 20363

2: Name of authorisation holder UNIVERSITY COLLEGE LONDON

3: Address(es) of manufacturing site(s) UCL GMP FACILITY, UCL RADIOCHEMISTRY, KATHLEEN LONSDALE BUILDING, 5 GOWER PLACE, LONDON, WC1E 6BS, UNITED KINGDOM

4: Legally registered address of authorisation holder UNIVERSITY COLLEGE LONDON, UCL RADIOCHEMISTRY, KATHLEEN LONSDALE BUILDING, 5 GOWER PLACE, LONDON, WC1E 6BS, 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 07/06/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UCL GMP FACILITY, UCL RADIOCHEMISTRY, KATHLEEN LONSDALE BUILDING, 5 GOWER PLACE, LONDON, WC1E 6BS, 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 Special Requirements Radiopharmaceuticals

[1.1.1.6] Other aseptically prepared products

Radiopharmaceuticals for injection (Short lived radio-isotopes). Hyperpolarised Products for injection (Research use only)

Special Requirements

Radiopharmaceuticals

[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

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical