

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 44301

2: Name of authorisation holder CURIUM PHARMA UK LIMITED

3: Address(es) of manufacturing site(s) CURIUM PHARMA UK LIMITED, C/O CURIUM RADIOPHARMACY (ORP), BLOCK 4, CHURCHILL HOSPITAL, OLD ROAD, HEADINGTON, OXFORD, OX3 7LE, UNITED KINGDOM

4: Legally registered address of authorisation holder CURIUM PHARMA UK LIMITED, C/O CURIUM RADIOPHARMACY (ORP), BLOCK 4, CHURCHILL HOSPITAL, OLD ROAD, HEADINGTON, OXFORD, OX3 7LE, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 30/04/2026

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CURIUM PHARMA UK LIMITED, C/O CURIUM RADIOPHARMACY (ORP), BLOCK 4, CHURCHILL HOSPITAL, OLD ROAD, HEADINGTON, OXFORD, OX3 7LE, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.4] Small volume liquids Special Requirements Radiopharmaceuticals [1.1.3] Batch certification [1.4] Other products or manufacturing activity

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical