

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, BURLINGTON DANES BUILDING, IMPERIAL COLLEGE LONDON, DU CANE ROAD WHITE CITY, LONDON, W12 0NN, UNITED KINGDOM

5: Scope of authorisation and dosage forms CURIUM PHARMA UK LIMITED, C/O CURIUM RADIOPHARMACY (ORP), BLOCK 4, CHURCHILL HOSPITAL, OLD ROAD, HEADINGTON, OXFORD, OX3 7LE, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

8: Authorisation Date Confidential

9: Annexes attached 11/09/2026

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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CURIUM PHARMA UK LIMITED, BURLINGTON DANES BUILDING, IMPERIAL COLLEGE LONDON, DU CANE ROAD WHITE CITY,
LONDON, W12 0NN, 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

[1.1.1.6] Other aseptically prepared products

PET 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