Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number	UK API 44301
2. Name or corporate name of registrant	CURIUM PHARMA UK LIMITED
3. Permanent or legal address of registrant	CURIUM PHARMA UK LIMITED, SUITE G030, REGUS, GROUND FLOOR, BUILDING 1000, LAKESIDE NORTH HARBOUR, WESTERN ROAD, PORTSMOUTH, PO6 3EZ, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	CURIUM PHARMA UK LIMITED, C/O HAMMERSMITH RADIOPHARMACY, BURLINGTON DANES BUILDING, IMPERIAL COLLEGE LONDON, DU CANE ROAD WHITE CITY, LONDON, W12 0NN, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	03/05/2024

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

CURIUM PHARMA UK LIMITED, C/O HAMMERSMITH RADIOPHARMACY, BURLINGTON DANES BUILDING, IMPERIAL COLLEGE LONDON, DU CANE ROAD WHITE CITY, LONDON, W12 0NN, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
18F-DCFPYL
3000022568

A	Manufacture of Active Substance by Chemical Synthesis

	A.1 Manufacture of Active Substance Intermediates **Special Requirements** Radiopharmaceuticals
D	Manufacture of Sterile Active Substance
	D.1 Aseptically prepared **Special Requirements** Radiopharmaceuticals
E	General Finishing Steps
	E.2 Primary Packaging **Special Requirements** Radiopharmaceuticals
	E.3 Secondary Packaging **Special Requirements** Radiopharmaceuticals
F	Quality Control Testing
	F.2 Microbiological testing (excluding sterility testing) **Special Requirements** Radiopharmaceuticals
	F.3 Microbiological testing (including sterility testing) **Special Requirements** Radiopharmaceuticals
	Other Activities The F18 process uses VHP as sanitisation, then filtration as the sterilisation step **Special Requirements** Radiopharmaceuticals