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

Registration Number UK API 44301

2. Name or corporate name of registrant CURIUM PHARMA UK LIMITED

CURIUM PHARMA UK LIMITED, SUITE G030, REGUS, GROUND FLOOR, BUILDING

3. Permanent or legal address of registrant 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,

Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)

BURLINGTON DANES BUILDING, IMPERIAL COLLEGE LONDON, DU CANE ROAD

WHITE CITY, LONDON, W12 0NN, UNITED KINGDOM

5. National legal basis of registration

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 ONN, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance 18F-DCFPYL 3000022568

A Manufacture of Active Substance by Chemical Synthesis

Issue Date: 03 May 2024

	A.1 Manufacture of Active Substance Intermediates
	Special Requirements
	Radiopharmaceuticals
D	Manufacture of Sterile Active Substance
	D.1 Aseptically prepared
	Special Requirements
	Radiopharmaceuticals
Е	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

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