

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 19124
2: Name of authorisation holder	CURIA (SCOTLAND) LIMITED
3: Address(es) of manufacturing site(s)	CURIA (SCOTLAND) LIMITED, BLOCK K, TODD CAMPUS, WEST OF SCOTLAND SCIENCE PARK, ACRE ROAD, GLASGOW, G20 0XA, UNITED KINGDOM
4: Legally registered address of authorisation holder	CURIA (SCOTLAND) LIMITED, TODD CAMPUS, WEST OF SCOTLAND SCIENCE PARK, GLASGOW, G20 0XA, 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	12/09/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CURIA (SCOTLAND) LIMITED, BLOCK K, TODD CAMPUS, WEST OF SCOTLAND SCIENCE PARK, ACRE ROAD, GLASGOW, G20 0XA, 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) [1.1.1.2] Lyophilisates [1.1.1.4] Small volume liquids [1.1.2] Terminally Sterilised (processing operations for the following dosage forms) [1.1.2.1] Large volume liquids [1.1.2.3] Small volume liquids

[1.1.2.5] Other terminally sterilised prepared products

Implant for Injection using Glide Technologies Solid Dose Injector System;; Drug loaded, lyophilised polymer beads for intra-arterial injection

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.3.1.6] Human or animal extracted products

[1.3.1.8] Other biological medicinal products

Proteins and Biologics derived from cell lines

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Hormones, Cytotoxics/Cytostatics, Non-Cytotoxic Organic/Inorganic Chemically active.

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

[1.4.2.1] Filtration

[1.4.2.2] Dry heat

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological