Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 427
2: Name of authorisation holder	ROSEMONT PHARMACEUTICALS LIMITED
3: Address(es) of manufacturing site(s)	ROSEMONT PHARMACEUTICALS LIMITED, ROSEMONT HOUSE, YORKDALE INDUSTRIAL PARK, BRAITHWAITE STREET, LEEDS, LS11 9XE, UNITED KINGDOM
4: Legally registered address of authorisation holder	ROSEMONT PHARMACEUTICALS LIMITED, ROSEMONT HOUSE, YORKDALE INDUSTRIAL PARK, BRAITHWAITE STREET, LEEDS, LS11 9XE, 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	17/06/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ROSEMONT PHARMACEUTICALS LIMITED, ROSEMONT HOUSE, YORKDALE INDUSTRIAL PARK, BRAITHWAITE STREET, LEEDS, LS11 9XE, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.13] Tablets

MHRA-GMDP MHRA

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

MHRA-GMDP MHRA MHRA-GMDP MHRA