

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 Regulation 17 of The Human Medicines Regulations 2012 (SI
2012/1916)

**7: Name of responsible officer of the competent authority
of the member state granting the manufacturing
authorisation** Confidential

8: Authorisation Date 14/11/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use [1.2.1.17] Other non-sterile medicinal products Manufacture of cytotoxic agents - Methotrexate disodium [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