

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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|---|---|
| 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 | 22/03/2024 |
| 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

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| 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

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA