Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 427**

2: Name of authorisation holder ROSEMONT PHARMACEUTICALS LIMITED

ROSEMONT PHARMACEUTICALS LIMITED, ROSEMONT HOUSE, 3: Address(es) of manufacturing site(s)

YORKDALE INDUSTRIAL PARK, BRAITHWAITE STREET, LEEDS,

LS11 9XE, UNITED KINGDOM

ROSEMONT PHARMACEUTICALS LIMITED, ROSEMONT HOUSE,

4: Legally registered address of authorisation holder YORKDALE INDUSTRIAL PARK, BRAITHWAITE STREET, LEEDS,

LS11 9XE, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

7: Name of responsible officer of the competent authority

of the member state granting the manufacturing Confidential

authorisation

8: Authorisation Date 03/10/2024

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

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

Issue Date: 03 Oct 2024

[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

