Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 49565**

2: Name of authorisation holder RUDIPHARM LIMITED

RUDIPHARM LIMITED, OAK HOUSE, REEDS CRESCENT, 3: Address(es) of manufacturing site(s)

WATFORD, WD24 4QP, UNITED KINGDOM

RUDIPHARM LIMITED, UNIT 6, SALBROOK ROAD INDUSTRIAL 4: Legally registered address of authorisation holder

ESTATE, SALBROOK ROAD, SALFORDS, REDHILL, RH1 5GJ,

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 Confidential

the member state granting the manufacturing authorisation

8: Authorisation Date 01/09/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

RUDIPHARM LIMITED, OAK HOUSE, REEDS CRESCENT, WATFORD, WD24 4QP, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

Issue Date: 01 Sep 2025