

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA 20072

2: Name of authorisation holder

AMDIPHARM UK LIMITED

3: Address(es) of manufacturing site(s)

AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, UNITED KINGDOM

4: Legally registered address of authorisation holder

AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, 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

22/12/2025

9: Annexes attached

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products [2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

MHRA-GMDP

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