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

MHRA-GMDP MHRA

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA