

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 2855

2: Name of authorisation holder OMEGA PHARMA LIMITED

3: Address(es) of manufacturing site(s) OMEGA PHARMA LIMITED, DMC02, COUNTY WAY, BARNLEY, S70 2AG, UNITED KINGDOM

4: Legally registered address of authorisation holder OMEGA PHARMA LIMITED, ELMHIRST PARK, MIDDLE FIELD ROAD, SILKSTONE, BARNLEY, S75 4LS, 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 09/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

OMEGA PHARMA LIMITED, DMC02, COUNTY WAY, BARNLEY, S70 2AG, 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 [1.2] Non-sterile products [1.2.2] Batch certification Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products [2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

SCOPE OF AUTHORISATION

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