Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 2855

2: Name of authorisation holder OMEGA PHARMA LIMITED

OMEGA PHARMA LIMITED, DMC02, COUNTY WAY,

BARNSLEY, S70 2JW, UNITED KINGDOM

OMEGA PHARMA LIMITED, ELMHIRST PARK, MIDDLE FIELD ROAD, SILKSTONE, BARNSLEY, S75 4LS, UNITED KINGDOM

OMEGA PHARMA LIMITED, WRAFTON, BRAUNTON, EX33

4: Legally registered address of authorisation holder

2DL, UNITED KINGDOM

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

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

04/00/0004

8: Authorisation Date 24/06/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

6: Legal Basis of authorisation

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

Annex 1

Name and address of the site:

OMEGA PHARMA LIMITED, DMC02, COUNTY WAY, BARNSLEY, S70 2JW, 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

Issue Date: 24 Jun 2024

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

OMEGA PHARMA LIMITED, ELMHIRST PARK, MIDDLE FIELD ROAD, SILKSTONE, BARNSLEY, S75 4LS, 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



Manufacturer's Authorisation: UK MIA 2855

Page 2 of 2

Issue Date: 24 Jun 2024