

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, BARNSELY, S70 2JW, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | OMEGA PHARMA LIMITED, ELMHIRST PARK, MIDDLE FIELD ROAD, SILKSTONE, BARNSELY, S75 4LS, UNITED KINGDOM |
| 5: Scope of authorisation and dosage forms | OMEGA PHARMA LIMITED, WRAFTON, BRAUNTON, EX33 2DL, UNITED KINGDOM |
| 6: Legal Basis of authorisation | ANNEX 1 and/ or ANNEX 2 |
| 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) |
| 8: Authorisation Date | Confidential |
| 9: Annexes attached | 24/06/2024 |
| | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

OMEGA PHARMA LIMITED, DMC02, COUNTY WAY, BARNSELY, 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 |

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 |