

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA 39   |
| <b>2: Name of authorisation holder</b>  | UCB PHARMA LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | UCB PHARMA LIMITED, 208 BATH ROAD,<br>SLOUGH, SL1 3WE, UNITED KINGDOM   |
| <b>4: Legally registered address of authorisation holder</b>  | UCB PHARMA LIMITED, 208 BATH ROAD,<br>SLOUGH, SL1 3WE, UNITED KINGDOM   |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations<br>2012 (SI 2012/1916) |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential  |
| <b>8: Authorisation Date</b>  | 30/01/2024  |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**UCB PHARMA LIMITED**, 208 BATH ROAD, SLOUGH, SL1 3WE, UNITED KINGDOM

|   |
|---|
| Human Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.2 ] Batch certification<br><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b><br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.1 ] Sterile Products<br>[ 2.2.1.1 ] Aseptically prepared<br>[ 2.2.1.2 ] Terminally sterilised |

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