

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|                                                                                                                        |                                                                                  |
|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1: Authorisation Number                                                                                                | UK MIA 4543                                                                      |
| 2: Name of authorisation holder                                                                                        | CP PHARMACEUTICALS LIMITED                                                       |
| 3: Address(es) of manufacturing site(s)                                                                                | CP PHARMACEUTICALS LIMITED, ASH ROAD NORTH,<br>WREXHAM, LL13 9UF, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder                                                                  | CP PHARMACEUTICALS LIMITED, ASH ROAD NORTH,<br>WREXHAM, LL13 9UF, 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<br>(SI 2012/1916)          |
| 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Confidential                                                                     |
| 8: Authorisation Date                                                                                                  | 19/08/2025                                                                       |
| 9: Annexes attached                                                                                                    | Annex 1 and/or Annex 2                                                           |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**CP PHARMACEUTICALS LIMITED**, ASH ROAD NORTH, WREXHAM, LL13 9UF, 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>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.2 ] Lyophilisates<br>[ 1.1.1.4 ] Small volume liquids<br>[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)<br>[ 1.1.2.3 ] Small volume liquids<br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) |

[ 1.2.1.17 ] Other non-sterile medicinal products

Nasal Sprays

[ 1.2.2 ] Batch certification

### **[ 1.3 ] Biological medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.6 ] Human or animal extracted products

[ 1.3.1.8 ] Other biological medicinal products

manufacture of products based on botanical extracts and hormones

[ 1.3.2 ] Batch certification

[ 1.3.2.5 ] Biotechnology products

[ 1.3.2.6 ] Human or animal extracted products

[ 1.3.2.8 ] Other biological medicinal products

manufacture of products based on botanical extracts and hormones

### **[ 1.4 ] Other products or manufacturing activity**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.4 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

[ 1.4.2.2 ] Dry heat

[ 1.4.2.3 ] Moist heat

### **[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.17 ] Other non-sterile medicinal products

Nasal spray

[ 1.5.2 ] Secondary packaging

### **[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

## **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

### **[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.1 ] Microbiological: sterility

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

[ 2.1.4 ] Biological

### **[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products

[ 2.2.3.6 ] Human or animal extracted products

