

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 4543
<b>2: Name of authorisation holder</b>	CP PHARMACEUTICALS LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	CP PHARMACEUTICALS LIMITED, ASH ROAD NORTH, WREXHAM, LL13 9UF, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	CP PHARMACEUTICALS LIMITED, ASH ROAD NORTH, WREXHAM, LL13 9UF, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<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>	17/05/2021
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**CP PHARMACEUTICALS LIMITED, ASH ROAD NORTH, WREXHAM, LL13 9UF, UNITED KINGDOM**

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.2 ] Lyophilisates [ 1.1.1.4 ] Small volume liquids [ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms) [ 1.1.2.3 ] Small volume liquids [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.2 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

- [ 1.3.1 ] Biological medicinal 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 investigational medicinal products or manufacturing activity**

- [ 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

**[ 1.6 ] 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

**[ 2.3 ] Other Importation Activities**

- [ 2.3.1 ] Site of Physical Importation