

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 4543

2: Name of authorisation holder CP PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s) CP PHARMACEUTICALS LIMITED, ASH ROAD NORTH, WREXHAM, LL13 9UF, UNITED KINGDOM

4: Legally registered address of authorisation holder CP PHARMACEUTICALS LIMITED, ASH ROAD NORTH, WREXHAM, LL13 9UF, UNITED KINGDOM

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

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 17/05/2021

9: Annexes attached 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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [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 [1.2] Non-sterile investigational medicinal products [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