

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, 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	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	08/05/2026
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) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile 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 [1.3] 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

- [1.5.2] 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

[2.3] Other Importation Activities

- [2.3.1] Site of Physical Importation