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	14/04/2025
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) 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

[1.2] Non-sterile products

- [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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation