

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 42551

2: Name of authorisation holder COPEA PHARMA LIMITED

3: Address(es) of manufacturing site(s) COPEA PHARMA LIMITED, 25 COMPASS WEST, SPINDUS ROAD, LIVERPOOL, L24 1YA, UNITED KINGDOM

4: Legally registered address of authorisation holder COPEA PHARMA LIMITED, 25 COMPASS WEST, SPINDUS ROAD, LIVERPOOL, L24 1YA, 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 25/09/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

COPEA PHARMA LIMITED, 25 COMPASS WEST, SPINDUS ROAD, LIVERPOOL, L24 1YA, 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 [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification [1.3] Biological medicinal products [1.3.2] Batch certification [1.3.2.2] Immunological products

[1.3.2.5] Biotechnology products

[1.5] Packaging

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[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

[2.2.3.2] Immunological products

[2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

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

Herbal products