

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 51463

2: Name of authorisation holder KENT PHARMA UK LIMITED

3: Address(es) of manufacturing site(s) KENT PHARMA UK LIMITED, UNIT 200, WESTMINSTER 42, WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM, SWADLINCOTE, DE12 7DT, UNITED KINGDOM

4: Legally registered address of authorisation holder KENT PHARMA UK LIMITED, CONNECT 38, 2ND FLOOR, 1 DOVER PLACE, ASHFORD, TN23 1FB, 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 20/05/2026

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KENT PHARMA UK LIMITED, UNIT 200, WESTMINSTER 42, WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM, SWADLINCOTE, DE12 7DT, 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 [1.5] 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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing