Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 8215**

2: Name of authorisation holder KENT PHARMACEUTICALS LIMITED

KENT PHARMACEUTICALS LIMITED, UNIT 200, WESTMINSTER 42, 3: Address(es) of manufacturing site(s)

WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM,

SWADLINCOTE, DE12 7DT, UNITED KINGDOM

KENT PHARMACEUTICALS LIMITED, UNIT 200, WESTMINSTER 42,

4: Legally registered address of authorisation holder WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM,

SWADLINCOTE, DE12 7DT, UNITED KINGDOM

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

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) 6: Legal Basis of authorisation

7: Name of responsible officer of the competent

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 31/03/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KENT PHARMACEUTICALS LIMITED, UNIT 200, WESTMINSTER 42, WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM, SWADLINCOTE, DE12 7DT, UNITED KINGDOM

Page 1 of 2

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[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

Issue Date: 31 Mar 2025

[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

