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, WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM,

SWADLINCOTE, DE12 7DT, UNITED KINGDOM

4: Legally registered address of authorisation

3: Address(es) of manufacturing site(s)

holder

KENT PHARMACEUTICALS LIMITED, UNIT 200, WESTMINSTER 42, WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM,

SWADLINCOTE, DE12 7DT, 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

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Confidential

8: Authorisation Date 21/10/2024

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

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

[2.2.1.2] Terminally sterilised

Issue Date: 21 Oct 2024

[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

