Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 17780**

ZENTIVA PHARMA UK LIMITED 2: Name of authorisation holder

ALLOGA UK LIMITED, AMBER PARK 7A, UNIT CW72,

FARMWELL LANE, SUTTON-IN-ASHFIELD, NG17 1BX, UNITED

KINGDOM

ALLOGA UK LIMITED, UNIT 5, FARMWELL LANE, SUTTON-IN-3: Address(es) of manufacturing site(s)

ASHFIELD, NG17 1BX, UNITED KINGDOM

ZENTIVA PHARMA UK LIMITED, FIRST FLOOR, ANDREWS HOUSE, COLLEGE ROAD, GUILDFORD, GU1 4QB, UNITED

KINGDOM

ZENTIVA PHARMA UK LIMITED, 12 NEW FETTER LANE, 4: Legally registered address of authorisation holder

LONDON, EC4A 1JP, 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)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

8: Authorisation Date 07/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

6: Legal Basis of authorisation

ALLOGA UK LIMITED, AMBER PARK 7A, UNIT CW72, FARMWELL LANE, SUTTON-IN-ASHFIELD, NG17 1BX, UNITED KINGDOM

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Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

Issue Date: 07 Oct 2024

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ALLOGA UK LIMITED, UNIT 5, FARMWELL LANE, SUTTON-IN-ASHFIELD, NG17 1BX, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ZENTIVA PHARMA UK LIMITED, FIRST FLOOR, ANDREWS HOUSE, COLLEGE ROAD, GUILDFORD, GU1 4QB, 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

[1.2] Non-sterile products

[1.2.2] Batch certification

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

[2.2.2] Non-sterile products

Issue Date: 07 Oct 2024