Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 17780
2: Name of authorisation holder	ZENTIVA PHARMA UK LIMITED
3: Address(es) of manufacturing site(s)	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-ASHFIELD, NG17 1BX, UNITED KINGDOM ZENTIVA PHARMA UK LIMITED, FIRST FLOOR, ANDREWS HOUSE, COLLEGE ROAD, GUILDFORD, GU1 4QB, UNITED KINGDOM
4: Legally registered address of authorisation holder	ZENTIVA PHARMA UK LIMITED, 12 NEW FETTER LANE, LONDON, EC4A 1JP, 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	07/10/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

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