

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 17780
<b>2: Name of authorisation holder</b>	ZENTIVA PHARMA UK LIMITED  ZENTIVA PHARMA UK LIMITED, FIRST FLOOR, ANDREWS HOUSE, COLLEGE ROAD, GUILDFORD, GU1 4QB, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	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
<b>4: Legally registered address of authorisation holder</b>	ZENTIVA PHARMA UK LIMITED, 12 NEW FETTER LANE, LONDON, EC4A 1JP, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	09/05/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.2 ] Non-sterile products

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

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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

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

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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