

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 18024
<b>2: Name of authorisation holder</b>	JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED , UNIT 730, 735, 740, 840, 955, 957, 960 AND 970, KENT SCIENCE PARK, SITTINGBOURNE, ME9 8AG, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED, BUILDING 730, KENT SCIENCE PARK, BROAD OAK ROAD, SITTINGBOURNE, ME9 8AG, 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>	13/11/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED** , UNIT 730, 735, 740, 840, 955, 957, 960 AND 970, KENT SCIENCE PARK, SITTINGBOURNE, ME9 8AG, UNITED KINGDOM

Human Medicinal Products
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Authorised Operations
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MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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#### Part 1 - MANUFACTURING OPERATIONS

##### [ 1.2 ] Non-sterile products

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.1 ] Capsules, hard shell

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.17 ] Other non-sterile medicinal products

Oro-mucosal Sprays

[ 1.2.2 ] Batch certification

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.17 ] Other non-sterile medicinal products

Oral - mucosal sprays

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.3 ] Chemical/Physical

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation