# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 18024

2: Name of authorisation holder JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED

JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED, UNIT 730, 735,

3: Address(es) of manufacturing site(s) 740, 840, 955, 957, 960 AND 970, KENT SCIENCE PARK,

SITTINGBOURNE, ME9 8AG, UNITED KINGDOM

JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED, BUILDING 730,

4: Legally registered address of authorisation holder KENT SCIENCE PARK, BROAD OAK ROAD, SITTINGBOURNE, ME9

8AG, 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 22/10/2025

9: Annexes attached 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** 

**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

[ 1.2.1 ] 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

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[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

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