Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 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

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004

[SI 2004/1031]

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 2

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 Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.1] Capsules, hard shell

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[1.2.1.6] Liquids for internal use [1.2.1.15] 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 [1.5.1.2] Capsules, soft shell [1.5.1.6] Liquids for internal use [1.5.1.13] Tablets [1.5.1.15] Other non-sterile medicinal products Oro-mucosal spray [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.3] Other Importation Activities [2.3.1] Site of Physical Importation [2.3.2] Importation of Intermediate which undergoes further processing

Importation of QP certified IMPs from a country on the approved country for import list



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[2.3.4] Other