

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
3: Address(es) of manufacturing site(s)	JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED , UNIT 730, 735, 740, 840, 955, 957, 960 AND 970, KENT SCIENCE PARK, SITTINGBOURNE, ME9 8AG, UNITED KINGDOM
4: Legally registered address of authorisation holder	JAZZ PHARMACEUTICALS OPERATIONS UK LIMITED, BUILDING 730, 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	19/11/2024
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 [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

[2.3.4] Other

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