

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 41690

2: Name of authorisation holder MYLAN PHARMA UK LIMITED

3: Address(es) of manufacturing site(s) MYLAN PHARMA UK LIMITED, IPC 008, DISCOVERY PARK HOUSE, FLOOR 3, RAMSGATE ROAD, SANDWICH, CT13 9ND, UNITED KINGDOM

4: Legally registered address of authorisation holder MYLAN PHARMA UK LIMITED, IPC 008, DISCOVERY PARK HOUSE, FLOOR 3, RAMSGATE ROAD, SANDWICH, CT13 9ND, 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 04/10/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MYLAN PHARMA UK LIMITED, IPC 008, DISCOVERY PARK HOUSE, FLOOR 3, RAMSGATE ROAD, SANDWICH, CT13 9ND, 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 [1.2.2] Batch certification [1.3] Biological investigational medicinal products [1.3.2] Batch certification

- [1.3.2.2] Immunological products
- [1.3.2.5] Biotechnology products
- [1.3.2.6] Human or animal extracted products

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

- [2.2.1] Sterile Products
 - [2.2.1.1] Aseptically prepared
 - [2.2.1.2] Terminally sterilised
- [2.2.2] Non-sterile products
- [2.2.3] Biological medicinal products
 - [2.2.3.2] Immunological products
 - [2.2.3.5] Biotechnology products
 - [2.2.3.6] Human or animal extracted products