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