

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 101
2: Name of authorisation holder	NOVARTIS PHARMACEUTICALS UK LIMITED
3: Address(es) of manufacturing site(s)	NOVARTIS PHARMACEUTICALS UK LIMITED, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, UNITED KINGDOM
4: Legally registered address of authorisation holder	NOVARTIS PHARMACEUTICALS UK LIMITED, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, 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	09/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

NOVARTIS PHARMACEUTICALS UK LIMITED, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, 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
- [1.3.2.3] Cell therapy products
- [1.3.2.4] Gene therapy products
- [1.3.2.5] Biotechnology products
- [1.3.2.6] Human or animal extracted products
- [1.3.2.8] Other biological medicinal products
Standard fermentation Biological 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
 - [2.2.3.3] Cell therapy products
 - [2.2.3.4] Gene therapy products
 - [2.2.3.5] Biotechnology products
 - [2.2.3.6] Human or animal extracted products
 - [2.2.3.8] Other biological medicinal products
Standard fermentation Biological Products

[2.3] Other Importation Activities

- [2.3.4] Other

1) The Importation of Radiopharmaceuticals/Radionuclide generators. 2) Importation of QP certified IMPs from a country on the approved country for import list.