

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 18565
2: Name of authorisation holder	MEDICINES EVALUATION UNIT LIMITED
3: Address(es) of manufacturing site(s)	MEDICINES EVALUATION UNIT LIMITED, THE Langley BUILDING, SOUTHMOOR ROAD, WYTHENSHAWE, MANCHESTER, M23 9QZ, UNITED KINGDOM
4: Legally registered address of authorisation holder	MEDICINES EVALUATION UNIT LIMITED, 3 FORBURY PLACE, 23 FORBURY ROAD, READING, RG1 3JH, 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	22/01/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

**MEDICINES EVALUATION UNIT LIMITED, THE Langley BUILDING, SOUTHMOOR ROAD, WYTHENSHAWE, MANCHESTER,
M23 9QZ, 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

[1.2] 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
 - [1.2.1.5] Liquids for external use
 - [1.2.1.6] Liquids for internal use
- [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
 - [1.5.1.5] Liquids for external use
 - [1.5.1.6] Liquids for internal use
 - [1.5.1.11] Semi-solids
 - [1.5.1.13] Tablets
- [1.5.2] Secondary packaging

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
 - [2.2.3.4] Gene therapy products
 - [2.2.3.5] Biotechnology 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