

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 18565
<b>2: Name of authorisation holder</b>	MEDICINES EVALUATION UNIT LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	MEDICINES EVALUATION UNIT LIMITED, THE LANGLEY BUILDING, SOUTHMOOR ROAD, WYTHENSHAW, MANCHESTER, M23 9QZ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	MEDICINES EVALUATION UNIT LIMITED, THE LANGLEY BUILDING, SOUTHMOOR ROAD, WYTHENSHAW, MANCHESTER, M23 9QZ, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	20/12/2023
<b>9: Annexes attached</b>	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, WYTHENSHAW, 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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