

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 51381
2: Name of authorisation holder	ROYLANCE STABILITY STORAGE LIMITED
3: Address(es) of manufacturing site(s)	ROYLANCE STABILITY STORAGE LIMITED, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM  ROYLANCE STABILITY STORAGE LIMITED, ELPHINSTONE SQUARE, DEANS INDUSTRIAL ESTATE, LIVINGSTONE, EH54 8RG, UNITED KINGDOM  ROYLANCE STABILITY STORAGE LIMITED (WISHAW), UNIT 1 EXCELSIOR PARK, NETHERTON INDUSTRIAL ESTATE, WISHAW, ML2 0EG, UNITED KINGDOM
4: Legally registered address of authorisation holder	ROYLANCE STABILITY STORAGE LIMITED, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, 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	28/04/2025
9: Annexes attached	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**ROYLANCE STABILITY STORAGE LIMITED**, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED  
KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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
- [ 2.3 ] 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

#### SCOPE OF AUTHORISATION

##### Annex 2

Name and address of the site:

**ROYLANCE STABILITY STORAGE LIMITED**, ELPHINSTONE SQUARE, DEANS INDUSTRIAL ESTATE, LIVINGSTONE, EH54 8RG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS <b>[ 2.3 ] Other Importation Activities</b> [ 2.3.2 ] Importation of Intermediate which undergoes further processing

#### SCOPE OF AUTHORISATION

##### Annex 2

Name and address of the site:

**ROYLANCE STABILITY STORAGE LIMITED (WISHAW)**, UNIT 1 EXCELSIOR PARK, NETHERTON INDUSTRIAL ESTATE, WISHAW, ML2 0EG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing