

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 [2.3] Other Importation Activities [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