

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 56952
2: Name of authorisation holder	PNR PHARMA CONSULTING LIMITED
	PNR PHARMA CONSULTING LTD, UNITS 5 AND 6, LIME AVENUE, EBBW VALE, NP23 6GL, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	PNR PHARMA, UPPER GROUND FLOOR ROOM 2, CREUDDYN, PONTFAEN ROAD, LAMPETER, SA48 7BN, UNITED KINGDOM
4: Legally registered address of authorisation holder	PNR PHARMA CONSULTING LIMITED, UNITS 5 AND 6, LIME AVENUE, EBBW VALE, NP23 6GL, 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	17/03/2025
9: Annexes attached	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**PNR PHARMA CONSULTING LTD**, UNITS 5 AND 6, LIME AVENUE, EBBW VALE, NP23 6GL, 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>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.2 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b>

- [ 1.3.2 ] Batch certification
  - [ 1.3.2.1 ] Blood products
  - [ 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

#### [ 1.5 ] Packaging

- [ 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
  - [ 2.2.3.1 ] Blood 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
- [ 2.3.3 ] Biological Active Substance

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**PNR PHARMA**, UPPER GROUND FLOOR ROOM 2, CREUDDYN, PONTFAEN ROAD, LAMPETER, SA48 7BN, 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> [ 2.3.4 ] Other Importation of QP-certified IMPs from a country on the approved country for import list