

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 56952 |
| 2: Name of authorisation holder | PNR PHARMA CONSULTING LIMITED |
| 3: Address(es) of manufacturing site(s) | PNR PHARMA, UPPER GROUND FLOOR ROOM 2, CREUDDYN, PONTFAEN ROAD, LAMPETER, SA48 7BN, UNITED KINGDOM PNR PHARMA CONSULTING LTD, UNITS 5 AND 6, LIME AVENUE, EBBW VALE, NP23 6GL, 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 | 09/05/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

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

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| 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 [2.3.4] 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:

PNR PHARMA CONSULTING LTD, UNITS 5 AND 6, LIME AVENUE, EBBW VALE, NP23 6GL, UNITED KINGDOM

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal products [1.2.2] Batch certification [1.3] Biological investigational medicinal products [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 |