

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 42415 |
| 2: Name of authorisation holder | AB BIOTECHNOLOGY LIMITED |
| 3: Address(es) of manufacturing site(s) | AB BIOTECHNOLOGY LIMITED, PENTLANDS SCIENCE PARK, BUSH LOAN, PENICUIK, EH26 0PZ, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | AB BIOTECHNOLOGY LIMITED, PENTLANDS SCIENCE PARK, BUSH LOAN, PENICUIK, EH26 0PZ, 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 | 22/03/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

AB BIOTECHNOLOGY LIMITED, PENTLANDS SCIENCE PARK, BUSH LOAN, PENICUIK, EH26 0PZ, UNITED KINGDOM

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.8] Other biological medicinal products Drug Substance - Manufacture of biological actives (purified viral inactivated, rabbit polyclonal antisera) for use in oral medicinal products [1.3.2] Batch certification [1.3.2.8] Other biological medicinal products Drug Substance - Manufacture of biological actives (purified viral inactivated, rabbit polyclonal antisera) for use in oral medicinal products [1.4] Other investigational medicinal products or manufacturing activity [1.4.1] Manufacture of: |

[1.4.1.3] Other

Drug Substance - Manufacture of biological actives (purified viral inactivated, rabbit polyclonal antisera) for use in oral medicinal products

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological