

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**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, BRODIES, BARTHOLOMEW CLOSE, LONDON, EC1A 7BN, 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** 21/08/2026

**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)                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 1.3.1 ] Biological medicinal products<br>[ 1.3.1.2 ] Immunological products<br>[ 1.3.1.5 ] Biotechnology products<br>[ 1.3.1.6 ] Human or animal extracted products<br>[ 1.3.1.8 ] Other biological medicinal products<br>Drug Substance - Manufacture of biological actives (purified viral inactivated, rabbit polyclonal antisera) for use in oral medicinal products<br>[ 1.3.2 ] Batch certification |

[ 1.3.2.2 ] Immunological products

[ 1.3.2.5 ] Biotechnology products

[ 1.3.2.6 ] Human or animal extracted products

[ 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