

# 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, 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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.3 ] Biological investigational medicinal products</b> [ 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