

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)
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