

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 01/11/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.3] Biological 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 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