

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 8794

2: Name of authorisation holder MICROPHARM LIMITED

3: Address(es) of manufacturing site(s) MICROPHARM LIMITED, UNITS B2, B1 & D1, ANTUR TEIFI BUSINESS PARK, NEWCASTLE EMLYN, SA38 9DB, UNITED KINGDOM

4: Legally registered address of authorisation holder MICROPHARM LIMITED, STATION ROAD INDUSTRIAL ESTATE, NEWCASTLE EMLYN, SA38 9BY, 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 15/03/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MICROPHARM LIMITED, UNITS B2, B1 & D1, ANTUR TEIFI BUSINESS PARK, NEWCASTLE EMLYN, SA38 9DB, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.4] Small volume liquids

- [1.1.1.6] Other aseptically prepared products
- Viper Vet manufactured for trials in accordance with ATC

[1.2] Non-sterile products

- [1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
- [1.2.1.6] Liquids for internal use

[1.3] Biological medicinal products

- [1.3.1] Biological medicinal products
- [1.3.1.2] Immunological products
- [1.3.1.6] Human or animal extracted products

[1.4] Other products or manufacturing activity

- [1.4.2] Sterilisation of active substances/excipients/finished products:
- [1.4.2.1] Filtration

[1.5] Packaging

- [1.5.1] Primary packaging
- [1.5.1.6] Liquids for internal use
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MICROPHARM LIMITED, STATION ROAD INDUSTRIAL ESTATE, NEWCASTLE EMLYN, SA38 9BY, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products <ul style="list-style-type: none"> [1.1.3] Batch certification [1.3] Biological medicinal products <ul style="list-style-type: none"> [1.3.2] Batch certification [1.3.2.2] Immunological products [1.3.2.6] Human or animal extracted products [1.6] Quality control testing <ul style="list-style-type: none"> [1.6.3] Chemical/Physical [1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MICROPHARM LIMITED, CNWCAU, CILGERRAN, CARDIGAN, SA43 2SN, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.3] Biological medicinal products [1.3.1] Biological medicinal products [1.3.1.2] Immunological products Special Requirements Immunoglobulin F(ab') ₂ [1.3.1.6] Human or animal extracted products [1.6] Quality control testing [1.6.2] Microbiological: non-sterility [1.6.3] Chemical/Physical [1.6.4] Biological