

# 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

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| Human Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 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

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| Human Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.3 ] Biological medicinal products</b><br>[ 1.3.2 ] Batch certification<br>[ 1.3.2.2 ] Immunological products<br>[ 1.3.2.6 ] Human or animal extracted products<br><b>[ 1.6 ] Quality control testing</b><br>[ 1.6.3 ] Chemical/Physical<br>[ 1.6.4 ] Biological |

## SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

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

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