

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 8794

**2: Name of authorisation holder** MICROPHARM LIMITED

**3: Address(es) of manufacturing site(s)** MICROPHARM LIMITED, STATION ROAD INDUSTRIAL ESTATE, NEWCASTLE EMLYN, SA38 9BY, UNITED KINGDOM  
MICROPHARM LIMITED, UNITS B2, B1 & D1, ANTUR TEIFI BUSINESS PARK, NEWCASTLE EMLYN, SA38 9DB, UNITED KINGDOM  
MICROPHARM LIMITED, CNWCAU, CILGERRAN, CARDIGAN, SA43 2SN, 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** 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** 15/03/2024

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

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

|   |
|---|
| Human Investigational Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 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**

- [ 1.6.3 ] Chemical/Physical
- [ 1.6.4 ] Biological

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

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

|  |
|--|
| Human Investigational Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)   |
| <p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p> <ul style="list-style-type: none"> <li>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) <ul style="list-style-type: none"> <li>[ 1.1.1.4 ] Small volume liquids</li> </ul> </li> </ul> <p><b>[ 1.2 ] Non-sterile investigational medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) <ul style="list-style-type: none"> <li>[ 1.2.1.6 ] Liquids for internal use</li> </ul> </li> </ul> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 1.3.1 ] Biological medicinal products <ul style="list-style-type: none"> <li>[ 1.3.1.2 ] Immunological products</li> <li>[ 1.3.1.6 ] Human or animal extracted products</li> </ul> </li> </ul> <p><b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b></p> <ul style="list-style-type: none"> <li>[ 1.4.2 ] Sterilisation of active substances/excipients/finished products: <ul style="list-style-type: none"> <li>[ 1.4.2.1 ] Filtration</li> </ul> </li> </ul> <p><b>[ 1.5 ] Packaging</b></p> <ul style="list-style-type: none"> <li>[ 1.5.1 ] Primary packaging <ul style="list-style-type: none"> <li>[ 1.5.1.6 ] Liquids for internal use</li> </ul> </li> <li>[ 1.5.2 ] Secondary packaging</li> </ul> <p><b>[ 1.6 ] Quality control testing</b></p> <ul style="list-style-type: none"> <li>[ 1.6.2 ] Microbiological: non-sterility</li> <li>[ 1.6.3 ] Chemical/Physical</li> </ul> |

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

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