

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 8794
<b>2: Name of authorisation holder</b>	MICROPHARM LIMITED MICROPHARM LIMITED, STATION ROAD INDUSTRIAL ESTATE, NEWCASTLE EMLYN, SA38 9BY, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	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
<b>4: Legally registered address of authorisation holder</b>	MICROPHARM LIMITED, STATION ROAD INDUSTRIAL ESTATE, NEWCASTLE EMLYN, SA38 9BY, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	15/03/2024
<b>9: Annexes attached</b>	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> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 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:

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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> <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>

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