

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |  |
|---|--|
| <b>1: Authorisation Number</b>  | UK MIA 50143   |
| <b>2: Name of authorisation holder</b>  | MOBIUS LABORATORIES LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS,<br>UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ,<br>UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS,<br>UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ,<br>UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2  |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI<br>2012/1916)  |
| <b>7: Name of responsible officer of the competent<br/>authority of the member state granting the<br/>manufacturing authorisation</b> | Confidential   |
| <b>8: Authorisation Date</b>  | 18/09/2024   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**MOBIUS LABORATORIES LIMITED**, UNIT 7, BOURNE END MILLS, UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ,  
UNITED KINGDOM

|   |
|---|
| Human Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.6 ] Quality control testing</b><br>[ 1.6.1 ] Microbiological: sterility<br>[ 1.6.2 ] Microbiological: non-sterility<br>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br><b>[ 2.1 ] Quality control testing of imported medicinal products</b><br>[ 2.1.1 ] Microbiological: sterility |

[ 2.1.2 ] Microbiological: non-sterility

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.2 ] Non-sterile products

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA