

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 50143

2: Name of authorisation holder MOBIUS LABORATORIES LIMITED

3: Address(es) of manufacturing site(s) MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS,
UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ,
UNITED KINGDOM

4: Legally registered address of authorisation holder MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS,
UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ,
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 07/07/2025

9: Annexes attached 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) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.6] Quality control testing [1.6.1] Microbiological: sterility [1.6.2] Microbiological: non-sterility Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products [2.1.1] Microbiological: sterility

[2.1.2] Microbiological: non-sterility

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation