

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 43685

2: Name of authorisation holder WASDELL MANUFACTURING LIMITED

3: Address(es) of manufacturing site(s) WASDELL MANUFACTURING LIMITED, UNIT 3 & 4, GATEWAY WEST, GREENFINCH WAY, NEWBURN, NEWCASTLE UPON TYNE, NE15 8NX, UNITED KINGDOM

4: Legally registered address of authorisation holder WASDELL MANUFACTURING LIMITED, UNITS 1, 2, 3, 5, 6, 7 & 8 EURO WAY INDUSTRIAL ESTATE, BLAGROVE, SWINDON, SN5 8YW, 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 24/07/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

WASDELL MANUFACTURING LIMITED, UNIT 3 & 4, GATEWAY WEST, GREENFINCH WAY, NEWBURN, NEWCASTLE UPON TYNE, NE15 8NX, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [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 [1.2.2] Batch certification [1.5] Packaging [1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical