Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 43685

2: Name of authorisation holder WASDELL MANUFACTURING LIMITED

WASDELL MANUFACTURING LIMITED, UNIT 3 & 4, GATEWAY

WEST, GREENFINCH WAY, NEWBURN, NEWCASTLE UPON TYNE,

NE15 8NX, UNITED KINGDOM

WASDELL MANUFACTURING LIMITED, UNIT 3-4, GATEWAY WEST,

4: Legally registered address of authorisation holder GREENFINCH WAY, NEWCASTLE UPON TYNE, NE15 8NX, 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 24/10/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

3: Address(es) of manufacturing site(s)

Annex 2

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 Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

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[1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.2] Capsules, soft shell [1.5.1.3] Chewing gums [1.5.1.5] Liquids for external use [1.5.1.6] Liquids for internal use [1.5.1.8] Other solid dosage forms [1.5.1.12] Suppositories [1.5.1.13] Tablets [1.5.1.15] Other non-sterile medicinal products [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.2] Microbiological: non-sterility [1.6.3] Chemical/Physical Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products [2.1.2] Microbiological: non-sterility [2.1.3] Chemical/Physical [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.GMDY MHRA

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[2.3.2] Importation of Intermediate which undergoes further processing

Importation of QP certified IMPs from a country on the 'approved country for import list'

[2.3.4] Other