

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 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, UNIT 3-4, GATEWAY WEST, 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 | 01/08/2022 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

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

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| 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 [1.2.2] Batch certification |

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.6] Liquids for internal use

[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

[2.3.2] Importation of Intermediate which undergoes further processing