

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 13485

2: Name of authorisation holder MW ENCAP LIMITED

3: Address(es) of manufacturing site(s) MW ENCAP LIMITED, UNITS 1-8, OAKBANK PARK WAY,
OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON,
EH53 0TH, UNITED KINGDOM

4: Legally registered address of authorisation holder MW ENCAP LIMITED, UNITS 1-8, OAKBANK PARK WAY,
OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON,
EH53 0TH, 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 27/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MW ENCAP LIMITED, UNITS 1-8, OAKBANK PARK WAY, OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON, EH53
0TH, UNITED KINGDOM

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| Human 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 products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.17] Other non-sterile medicinal products Larger scale manufacture of Cytotoxics in dedicated high containment facilities. Initial dispensing of drug substance is carried out in an isolation cabinet. Packaging: Strip and/or blister packing |

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.6] Human or animal extracted products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.17] Other non-sterile medicinal products
Cytotoxics

[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

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing