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

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

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[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

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