Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 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	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	06/11/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

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 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

[1.2.1.15] Other non-sterile medicinal products

Liquid fill capsules of Cytotoxics. Packing for open labelled clinical studies only (no blinding)

[1.2.2] Batch certification

MHRA-GMDP MHRA-GMDP MHRA

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.15] Other non-sterile medicinal products

Liquid fill capsules of 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

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

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

MHRA-GMDP MHRA