Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 20782
2: Name of authorisation holder	ALMAC PHARMA SERVICES LIMITED
3: Address(es) of manufacturing site(s)	ALMAC PHARMA SERVICES LIMITED, WOODHOUSE BUILDING, CHARNWOOD CAMPUS, 8 BAKEWELL ROAD, LOUGHBOROUGH, LE11 5RB, UNITED KINGDOM ALMAC PHARMA SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, PORTADOWN, CRAIGAVON, NORTHERN IRELAND, BT63 5UA, UNITED KINGDOM
4: Legally registered address of authorisation holder	ALMAC PHARMA SERVICES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, 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	12/05/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ALMAC PHARMA SERVICES LIMITED, WOODHOUSE BUILDING, CHARNWOOD CAMPUS, 8 BAKEWELL ROAD, LOUGHBOROUGH, LE11 5RB, 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)

MHRA-GMDP

[1.2.1.1] Capsules, hard shell
[1.2.1.6] Liquids for internal use
[1.2.1.8] Other solid dosage forms
[1.2.1.13] Tablets
[1.2.1.15] Other non-sterile medicinal products
Other solid dosage forms include powders and granules
[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
[1.5.1.8] Other solid dosage forms
[1.5.1.13] Tablets
[1.5.1.15] Other non-sterile medicinal products
Other solid dosage forms include powders and granules
[1.5.2] Secondary packaging

[1.6] Quality control testing

[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

[2.3.1] Site of Physical Importation
[2.3.2] Importation of Intermediate which undergoes further processing

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ALMAC PHARMA SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, PORTADOWN, CRAIGAVON, NORTHERN IRELAND, BT63 5UA, 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

MHRA-GMDP MHRA

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.13] Tablets

[1.2.1.15] Other non-sterile medicinal products

Other solid dosage forms include powders and granules.

[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

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Other solid dosage forms include powders and granules.

[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

MHRA-GMDP MHRA