

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 20782
2: Name of authorisation holder	ALMAC PHARMA SERVICES LIMITED ALMAC PHARMA SERVICES LIMITED, WOODHOUSE BUILDING, CHARNWOOD CAMPUS, 8 BAKEWELL ROAD, LOUGHBOROUGH, LE11 5RB, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	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	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	18/06/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
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 [1.2.1.6] Liquids for internal use

- [1.2.1.8] Other solid dosage forms
- [1.2.1.13] Tablets
- [1.2.1.17] 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
 - [1.5.1.17] 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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.1] Sterile Products</p> <ul style="list-style-type: none"> [1.1.3] Batch certification <p>[1.2] Non-sterile products</p> <ul style="list-style-type: none"> [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) <ul style="list-style-type: none"> [1.2.1.1] Capsules, hard shell [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets [1.2.1.17] Other non-sterile medicinal products <ul style="list-style-type: none"> Other solid dosage forms include powders and granules. [1.2.2] Batch certification <p>[1.3] Biological medicinal products</p> <ul style="list-style-type: none"> [1.3.2] Batch certification <ul style="list-style-type: none"> [1.3.2.4] Gene therapy products
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[1.3.2.5] Biotechnology products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.1.17] 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

[2.1.1] Microbiological: sterility

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[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