

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 |
|--|

[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