

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 20782
2: Name of authorisation holder	ALMAC PHARMA SERVICES LIMITED
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, WOODHOUSE BUILDING, CHARNWOOD CAMPUS, 8 BAKEWELL ROAD, LOUGHBOROUGH, LE11 5RB, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ALMAC PHARMA SERVICES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, UNITED KINGDOM
6: Legal Basis of authorisation	ANNEX 1 and/ or ANNEX 2
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
8: Authorisation Date	Confidential
9: Annexes attached	22/03/2024
	Annex 1 and/or Annex 2

### 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile products</b>

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 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

Other solid dosage forms include powders and granules.

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological medicinal products**

[ 1.3.2 ] Batch certification

[ 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

**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