Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number	UK API 20782
2. Name or corporate name of registrant	ALMAC PHARMA SERVICES LIMITED
3. Permanent or legal address of registrant	ALMAC PHARMA SERVICES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	ALMAC PHARMA SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, PORTADOWN, CRAIGAVON, NORTHERN IRELAND, BT63 5UA, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	05/06/2026

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
FIDAXOMICIN (3000016807)	**BIOCON LIMITED**, BIOCON SPECIAL ECONOMIC ZONE, PLOT NO. 2, 3 & 4, PHASE IV, BOMMASANDRA-JIGANI LINK ROAD, BOMMASANDRA POST, BANGALORE, IN-560099, INDIA	

MHRA-GMDP MHRA-GMDP MHRA

MACROGOL 3350 (2000012179)	**THE DOW CHEMICAL COMPANY**, ST CHARLES OPERATIONS, LOUISIANA HIGHWAY 3142, HAHNVILLE, 70057, UNITED STATES
MIRDAMETINIB (3000024505)	**PATHEON API INCORPORATED**, 6173 EAST OLD MARION HIGHWAY, FLORENCE, 29506-9330, UNITED STATES
SODIUM CHLORIDE (1000009536)	**AVANTOR PERFORMANCE MATERIALS**, 7001 MARTIN LUTHER KING BOULEVARD, PARIS, 40361, UNITED STATES
ENTRECTINIB (1000018107)	**F HOFFMANN-LA ROCHE AG**, GRENZACHERSTRASSE 124, BASEL, CH-4070, SWITZERLAND
MIGLUSTAT (1000000278)	**LONZA AG**, LONZASTRASSE, VISP, CH-3930, SWITZERLAND
OMADACYCLINE TOSYLATE (2000019343)	**CARBOGEN AMCIS AG**, HAUPTSTRASSE 171, BUBENDORF, CH-4416, SWITZERLAND
MIGALASTAT HYDROCHLORIDE (2000009471)	**CARBOGEN AMCIS AG**, HAUPTSTRASSE 171, BUBENDORF, CH-4416, SWITZERLAND
SODIUM HYDROGEN CARBONATE (3000010012)	**AVANTOR PERFORMANCE MATERIALS**, 7001 MARTIN LUTHER KING BOULEVARD, PARIS, 40361, UNITED STATES
SAPROPTERIN DIHYDROCHLORIDE (4000008948)	**DOTTIKON EXCLUSIVE SYNTHESIS AG**, HEMBRUNNSTRASSE 17, DOTTIKON, CH-5605, SWITZERLAND
LINACLOTIDE (1000017589)	**POLYPEPTIDE LABORATORIES INC.**, 365 MAPLE AVENUE, TORRANCE, 90503, UNITED STATES **CORDEN PHARMA COLORADO**, 2075 NORTH 55TH STREET, BOULDER, 80301, UNITED STATES

MHRA-GMDP