

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 31890
2. Name or corporate name of registrant
ALMAC SCIENCES LIMITED
3. Permanent or legal address of registrant
ALMAC SCIENCES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, BT63 5QD, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place
ALMAC SCIENCES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, 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
11/07/2023

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 SCIENCES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

AMIFAMPRIDINE PHOSPHATE

2000018682

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates

	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) crystallisation
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

REZAFUNGIN ACETATE

2000019268

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) purification step using Prep Chromatography
	A.4 Other Freeze Drying
E	General Finishing Steps
	E.1 Physical Processing Steps Blending
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

SELEXIPAG

3000017276

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) crystallisation

E	General Finishing Steps
	E.1 Physical Processing Steps micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

ACTIVE SUBSTANCES FOR CLINICAL TRIALS

1000018046

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) crystallisation, distillation, chromatography or similar alternatives
E	General Finishing Steps
	E.1 Physical Processing Steps micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
	E.4 Other Blending & Milling
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

URIDINE TRIACETATE

2000017443

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) crystallisation
E	General Finishing Steps
	E.2 Primary Packaging

	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
- AMIFAMPRIDINE PHOSPHATE (2000018682)
- REZAFUNGIN ACETATE (2000019268)
- SELEXIPAG (3000017276)
- URIDINE TRIACETATE (2000017443)