

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 1108
2. Name or corporate name of registrant MACFARLAN SMITH LIMITED
3. Permanent or legal address of registrant MACFARLAN SMITH LIMITED, 10 WHEATFIELD ROAD, EDINBURGH, EH11 2QA, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place MACFARLAN SMITH LIMITED, 10 WHEATFIELD ROAD, EDINBURGH, EH11 2QA, UNITED KINGDOM
MACFARLAN SMITH LIMITED, THREE TREES ROAD, NEWBIE, ANNAN, DG12 5QH, 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 06/12/2023

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

MACFARLAN SMITH LIMITED, 10 WHEATFIELD ROAD, EDINBURGH, EH11 2QA, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

FENTANYL CITRATE
2000007584

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) Salt formation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CODEINE SULFATE

2000015376

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

SUFENTANIL CITRATE

2000006818

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) Salt formation, Recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

HYDROMORPHONE HYDROCHLORIDE

2000007868

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) Salt formation, Recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

OXYCODONE

1000007438

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 Drying and milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

MORPHINE HYDROCHLORIDE

2000008247

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 Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

APOMORPHINE HYDROCHLORIDE

2000008051

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) Salt Formation, Filtration, Recrystallisation

E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

METHYLPHENIDATE HYDROCHLORIDE

2000008305

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

COCAINE

1000003943

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) Recrystallisation
E	General Finishing Steps

	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

DIAMORPHINE HYDROCHLORIDE

2000007776

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) Salt Formation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

REMIFENTANIL HYDROCHLORIDE

2000007435

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) Salt Formation, Recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

NALOXONE HYDROCHLORIDE

2000008238

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) Salt formation, Recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

BUPRENORPHINE HYDROCHLORIDE

2000008277

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) Salt Formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MORPHINE SULFATE

4000006163

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

DIAMORPHINE

1000003221

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) Recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

ALFENTANIL HYDROCHLORIDE

2000008540

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) Salt Formation, Filtration, Recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FENTANYL

1000002290

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) Recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging

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

Active substance

DIHYDROCODEINE HYDROGEN TARTRATE

4000008052

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

COCAINE HYDROCHLORIDE

2000007943

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing

	F.1 Physical / Chemical testing
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Active substance

CODEINE

1000003912

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 Drying and milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

MORPHINE

1000010779

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 Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

MORPHINE TARTRATE

2000008245

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) Salt formation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

CODEINE PHOSPHATE HEMIHYDRATE

4000006570

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

BUPRENORPHINE

1000007171

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 Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

OXYCODONE HYDROCHLORIDE

2000006722

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

PHOLCODINE

1000009886

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 Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FENTANYL CITRATE (2000007584)
CODEINE SULFATE (2000015376)
SUFENTANIL CITRATE (2000006818)
HYDROMORPHINE HYDROCHLORIDE (2000007868)
OXYCODONE (1000007438)
MORPHINE HYDROCHLORIDE (2000008247)
APOMORPHINE HYDROCHLORIDE (2000008051)
METHYLPHENIDATE HYDROCHLORIDE (2000008305)
COCAINE (1000003943)
DIAMORPHINE HYDROCHLORIDE (2000007776)
REMIFENTANIL HYDROCHLORIDE (2000007435)
NALOXONE HYDROCHLORIDE (2000008238)
BUPRENORPHINE HYDROCHLORIDE (2000008277)
MORPHINE SULFATE (4000006163)
DIAMORPHINE (1000003221)
ALFENTANIL HYDROCHLORIDE (2000008540)
FENTANYL (1000002290)
DIHYDROCODEINE HYDROGEN TARTRATE (4000008052)
COCAINE HYDROCHLORIDE (2000007943)
CODEINE (1000003912)
MORPHINE (1000010779)
MORPHINE TARTRATE (2000008245)
CODEINE PHOSPHATE HEMIHYDRATE (4000006570)
BUPRENORPHINE (1000007171)
OXYCODONE HYDROCHLORIDE (2000006722)
PHOLCODINE (1000009886)

Name and address of the site

1. MANUFACTURING OPERATIONS

Active substance

METHYLPHENIDATE HYDROCHLORIDE

2000008305

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

OXYCODONE HYDROCHLORIDE

2000006722

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

BUPRENORPHINE

1000007171

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.4 Other Hydrogenation
E	General Finishing Steps
	E.4 Other This intermediate supplied to Edinburgh site for further processing as an API
F	Quality Control Testing
	F.1 Physical / Chemical testing
	Other Activities Only intermediate specification testing

Active substance

DIHYDROCODEINE HYDROGEN TARTRATE

4000008052

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) Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

CODEINE PHOSPHATE HEMIHYDRATE

4000006570

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) Salt formation, Crystallisation.
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
- METHYLPHENIDATE HYDROCHLORIDE (2000008305)
 - OXYCODONE HYDROCHLORIDE (2000006722)
 - DIHYDROCODEINE HYDROGEN TARTRATE (4000008052)
 - CODEINE PHOSPHATE HEMIHYDRATE (4000006570)