

Medicines and Healthcare Products Regulatory Agency

Union Format for Registration of Manufacturer, Importer or Distributor of Active Substances to be used as Starting Materials in Medicinal Products for Human Use

1. Registration Number : UK API 1108
2. Name or corporate name of registrant : MACFARLAN SMITH LIMITED
3. Permanent or legal address of registrant : 10 WHEATFIELD ROAD, EDINBURGH, EH11 2QA, United Kingdom
4. Address(es) of site(s) where registered activities take place : 10 WHEATFIELD ROAD, EDINBURGH, EH11 2QA, United Kingdom
5. National legal basis of registration : API-A111(1)-D2001/83/EC
6. Name of responsible officer of the competent authority of the member state validating the registration : Confidential
7. Signature :
8. Date : 2015-08-26

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

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 : DIPRENORPHINE
(1000018121)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance A.1 Manufacture of active substance intermediates A.3 Salt formation / Purification steps Crystallisation</i>
E	General Finishing Steps
	<i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.1 Physical processing steps Drying, Sieving</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : APOMORPHINE HYDROCHLORIDE
(2000008051)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance A.3 Salt formation / Purification steps Salt Formation, Filtration, Recrystallisation A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.1 Physical processing steps Drying, Milling</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing F.2 Microbiological testing excluding sterility testing</i>

Active Substance : ALOIN
(1000003780)

B	Extraction of Active Substance from Natural Sources
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	<i>B.6 Purification of extracted substance</i> <i>Plant</i> <i>B.1 Extraction of substance from plant source</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Centrifugation, Drying, Milling</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : COCAINE
(1000003943)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.3 Salt formation / Purification steps</i> <i>Recrystallisation</i> <i>A.2 Manufacture of crude active substance</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : CODEINE
(1000003912)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates</i> <i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Crystallisation</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying and milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>

F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : ETORPHINE
(1000018122)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates</i> <i>A.3 Salt formation / Purification steps</i> <i>Crystallisation</i> <i>A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Sieving</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : PETHIDINE HYDROCHLORIDE
(2000008078)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Recrystallisation</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : REMIFENTANIL HYDROCHLORIDE
(2000007435)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.3 Salt formation / Purification steps</i> <i>Salt Formation, Recrystallisation</i> <i>A.2 Manufacture of crude active substance</i>

	<i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Sieving</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.2 Microbiological testing excluding sterility testing</i> <i>F.1 Physical / Chemical testing</i>

Active Substance : MORPHINE HYDROCHLORIDE
(2000008247)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.1 Manufacture of active substance intermediates</i> <i>A.3 Salt formation / Purification steps</i> <i>Crystallisation</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : CODEINE SULFATE
(2000015376)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Crystallisation</i> <i>A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>

F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : PHOLCODINE
(1000009886)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Crystallisation</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : SUFENTANIL CITRATE
(2000006818)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Recrystallisation</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Sieving</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : MORPHINE TARTRATE
(2000008245)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.3 Salt formation / Purification steps</i> <i>Salt formation</i> <i>A.1 Manufacture of active substance intermediates</i>

	<i>A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : BUPRENORPHINE
(1000007171)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Crystallisation</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : BUPRENORPHINE HYDROCHLORIDE
(2000008277)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt Formation, Crystallisation</i> <i>A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>

F	Quality Control Testing
	<i>F.2 Microbiological testing excluding sterility testing</i> <i>F.1 Physical / Chemical testing</i>

Active Substance : FENTANYL
(1000002290)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Recrystallisation</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : DIHYDROCODEINE HYDROGEN TARTRATE
(4000008052)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Crystallisation</i> <i>A.1 Manufacture of active substance intermediates</i> <i>A.2 Manufacture of crude active substance</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : METHYLPHENIDATE HYDROCHLORIDE
(2000008305)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Crystallisation</i>

	A.1 Manufacture of active substance intermediates A.2 Manufacture of crude active substance
E	General Finishing Steps
	E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.1 Physical processing steps Drying, Milling
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 Salt formation, Crystallisation
E	General Finishing Steps
	E.1 Physical processing steps Drying, Milling E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active Substance : HYDROMORPHONE HYDROCHLORIDE
(2000007868)

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt formation / Purification steps Salt formation, Recrystallisation A.1 Manufacture of active substance intermediates A.2 Manufacture of crude active substance
E	General Finishing Steps
	E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.1 Physical processing steps Drying, Milling

F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : OPIUM TINCTURE
(2000008161)

B	Extraction of Active Substance from Natural Sources
	<i>B.6 Purification of extracted substance Plant B.1 Extraction of substance from plant source</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : OXYCODONE
(1000007438)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance A.1 Manufacture of active substance intermediates A.3 Salt formation / Purification steps Crytsallisation</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.1 Physical processing steps Drying and milling E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : OXYCODONE HYDROCHLORIDE
(2000006722)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates A.2 Manufacture of crude active substance A.3 Salt formation / Purification steps Salt formation, Crystallisation</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps Drying, Milling</i>

	<i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : HYDROCODONE BITARTRATE
(4000009774)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.3 Salt formation / Purification steps</i> <i>Salt formation</i> <i>A.2 Manufacture of crude active substance</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : FENTANYL CITRATE
(2000007584)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.3 Salt formation / Purification steps</i> <i>Salt formation</i> <i>A.2 Manufacture of crude active substance</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : DIAMORPHINE
(1000003221)

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of crude active substance A.1 Manufacture of active substance intermediates A.3 Salt formation / Purification steps Recrystallisation
E	General Finishing Steps
	E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.1 Physical processing steps Drying, Milling
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active Substance : MORPHINE SULFATE
(4000006163)

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt formation / Purification steps Salt formation, Crystallisation A.2 Manufacture of crude active substance A.1 Manufacture of active substance intermediates
E	General Finishing Steps
	E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.1 Physical processing steps Drying, Milling
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active Substance : DIAMORPHINE HYDROCHLORIDE
(2000007776)

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of crude active substance A.1 Manufacture of active substance intermediates A.3 Salt formation / Purification steps Salt Formation
E	General Finishing Steps
	E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.1 Physical processing steps

	<i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.2 Microbiological testing excluding sterility testing</i> <i>F.1 Physical / Chemical testing</i>

Active Substance : COCAINE HYDROCHLORIDE
(2000007943)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates</i> <i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Crystallisation</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : METHADONE HYDROCHLORIDE
(2000008337)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Recrystallisation</i> <i>A.1 Manufacture of active substance intermediates</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Milling</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : NALTREXONE HYDROCHLORIDE
(2000007614)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.1 Manufacture of active substance intermediates</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt formation, Recrystallisation</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> <i>E.1 Physical processing steps</i> <i>Drying, Milling</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : ALFENTANIL HYDROCHLORIDE
(2000008540)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.2 Manufacture of crude active substance</i> <i>A.1 Manufacture of active substance intermediates</i> <i>A.3 Salt formation / Purification steps</i> <i>Salt Formation, Filtration, Recrystallisation</i>
E	General Finishing Steps
	<i>E.1 Physical processing steps</i> <i>Drying, Sieving</i> <i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i>
F	Quality Control Testing
	<i>F.1 Physical / Chemical testing</i>

Active Substance : MORPHINE
(1000010779)

A	Manufacture of Active Substance by Chemical Synthesis
	<i>A.1 Manufacture of active substance intermediates</i> <i>A.2 Manufacture of crude active substance</i> <i>A.3 Salt formation / Purification steps</i> <i>Crystallisation</i>
E	General Finishing Steps
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>E.1 Physical processing steps</i>

	Drying, Milling E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
F	Quality Control Testing
	F.1 Physical / Chemical testing
Active Substance : NALOXONE HYDROCHLORIDE (2000008238)	
A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt formation / Purification steps Salt formation, Recrystallisation A.1 Manufacture of active substance intermediates A.2 Manufacture of crude active substance
E	General Finishing Steps
	E.1 Physical processing steps Drying, Milling E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
F	Quality Control Testing
	F.2 Microbiological testing excluding sterility testing F.1 Physical / Chemical testing