Medicines and Healthcare Products Regulatory Agency

CERTIFICATE NUMBER : ***UK API 1108 Insp GMP 1108/1893-0016 [V]***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of United Kingdom confirms the following:
The manufacturer :***MACFARLAN SMITH LIMITED***
Site address :***10 WHEATFIELD ROAD, EDINBURGH, EH11 2QA, United Kingdom***

Is an active substance manufacturer that has been inspected in accordance with Art. 80(1) of Directive 2001/82/EC transposed in the following national legislation:
The Current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-12-10*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 51 of Directive 2001/82/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Manufacture of active substance. Names of substances subject to inspection :
METHYLPHENIDATE HYDROCHLORIDE(en)
MORPHINE SULFATE(en)
CODEINE SULFATE(en)
REMIFENTANIL HYDROCHLORIDE(en)
SUFENTANIL CITRATE(en)
OXYCODONE HYDROCHLORIDE(en)
DIHYDROCODEINE HYDROGEN TARTRATE(en)
NALOXONE HYDROCHLORIDE(en)
CODEINE PHOSPHATE HEMIHYDRATE(en)
APOMORPHINE HYDROCHLORIDE(en)
ETORPHINE(en)
MORPHINE HYDROCHLORIDE(en)
DIAMORPHINE(en)
ALOIN(en)
ALFENTANIL HYDROCHLORIDE(en)
MORPHINE TARTRATE(en)
HYDROMORPHONE HYDROCHLORIDE(en)
FENTANYL CITRATE(en)
OPIUM TINCTURE(en)
COCAINE HYDROCHLORIDE(en)
BUPRENORPHINE(en)
FENTANYL(en)
COCAINE(en)
DIPRENORPHINE(en)
MORPHINE(en)
DIAMORPHINE HYDROCHLORIDE(en)
NALTREXONE HYDROCHLORIDE(en)
PHOLCODINE(en)
BUPRENORPHINE HYDROCHLORIDE(en)
OXYCODONE(en)
CODEINE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance :METHYLPHENIDATE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Salt formation, Crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

	which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :MORPHINE SULFATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation, Crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :CODEINE SULFATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Salt formation, Crystallisation
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Milling 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :REMIFENTANIL HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.1.3 Salt formation / Purification steps: Salt Formation, Recrystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :SUFENTANIL CITRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation, Recrystallisation 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Drying, Sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :OXYCODONE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Salt formation, Crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :DIHYDROCODEINE HYDROGEN TARTRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation, Crystallisation 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :NALOXONE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation, Recrystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :CODEINE PHOSPHATE HEMIHYDRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Salt formation, Crystallisation 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :APOMORPHINE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Salt Formation, Filtration, Recrystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :ETORPHINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Crystallisation 3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

	which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :MORPHINE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Crystallisation
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :DIAMORPHINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Recrystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :ALOIN

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance

	Plant 3.2.1 Extraction of substance from plant source
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Centrifugation, Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :ALFENTANIL HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Salt Formation, Filtration, Recrystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Sieving 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :MORPHINE TARTRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Milling 3.5.3 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)

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :HYDROMORPHONE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Salt formation, Recrystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :FENTANYL CITRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Salt formation 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :OPIUM TINCTURE

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance Plant 3.2.1 Extraction of substance from plant source
3.5	**General Finishing Steps**

	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :COCAINE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Salt formation, Crystallisation 3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :BUPRENORPHINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Crystallisation 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :FENTANYL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Recrystallisation

	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :COCAINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Recrystallisation 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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) 3.5.1 Physical processing steps: Drying, Milling
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :DIPRENORPHINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Crystallisation
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.1 Physical processing steps: Drying, Sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :MORPHINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :DIAMORPHINE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt Formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

Active Substance :NALTREXONE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation, Recrystallisation

	3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :PHOLCODINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Milling 3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :BUPRENORPHINE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Salt Formation, Crystallisation 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.3 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) 3.5.1 Physical processing steps: Drying, Milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**

	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :OXYCODONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt Formation, Filtration, Recrystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying and milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :CODEINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt Formation, Filtration, Recrystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying and milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

2020-02-20

Name and signature of the authorised person of the Competent Authority of United Kingdom

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Confidential
Medicines and Healthcare Products Regulatory Agency
Tel:***Confidential***
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