Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 1108 Insp GMP 1108/1893-0016

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the 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. 111(1) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/12/2019, it is considered that it complies with the principles of GMP for active substances

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 only valid 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.

This Certificate of GMP Compliance of a Manufacturer is certified as a true copy of the original document by Ms Leanne Marion Hammell, Solicitor and Notary Public in Edinburgh on this fourth day of March Two Thousand and Twenty Attorney c/o Pinsent Masons LLP

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 1108 Insp GMP 1108/1893-0016

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

MHRA

APOSTILLE (Convention de La Haye du 5 octobre 1961)		
1. **Country:** Pays / Pais:	United Kingdom of Great Britain and Northern Ireland	
This public document Le présent acte public / El presente documento público		
2. **Has been signed by** a été signé par ha sido firmado por	Leanne Hammell	
3. **Acting in the capacity of** agissant en qualité de quien actúa en calidad de	Notary Public	
4. **Bears the seal / stamp of** est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public	
Certified Attesté / Certificado		
5. **at** á / en	London	6. **the** le / el día 24 March 2020
7. **by** par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs	
8. **Number** sous no / bajo el numero	APO-1891798	
9. **Seal / stamp** Sceau / timbre Sello / timbre	FOREIGN AND COMMONWEALTH OFFICE LONDON	10. **Signature** Signature Firma N. Lawrence

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2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

DIPRENORPHINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Sieving
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

ETORPHINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Sieving
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

MORPHINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

MORPHINE TARTRATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

FENTANYL

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

ALOIN

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
3.2.1 Plant Source Extraction 3.2.6 Plant Source Purification

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
3.5.1 Physical Processing Steps
Centrifugation, Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing
3.6.1 Physical / Chemical testing

4 Other Activities
Not Authorised

OXYCODONE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)

Salt formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Drying, Milling

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

NALTREXONE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

CODEINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying and milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

COCAINE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

MORPHINE SULFATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

DIAMORPHINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

OPIUM TINCTURE

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
3.2.1 Plant Source Extraction 3.2.6 Plant Source Purification

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.6 Quality Control Testing
3.6.1 Physical / Chemical testing

4 Other Activities
Not Authorised

NALOXONE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

SUFENTANIL CITRATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Sieving
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

METHYLPHENIDATE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

PHOLCODINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

FENTANYL CITRATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

MORPHINE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

HYDROMORPHONE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

DIAMORPHINE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt Formation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

CODEINE PHOSPHATE HEMIHYDRATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

CODEINE SULFATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

REMIFENTANIL HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt Formation, Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Sieving
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

BUPRENORPHINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

DIHYDROCODEINE HYDROGEN TARTRATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

COCAINE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

OXYCODONE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Crytsallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying and milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

BUPRENORPHINE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt Formation, Crystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

ALFENTANIL HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt Formation, Filtration, Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Sieving
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

APOMORPHINE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Salt Formation, Filtration, Recrystallisation

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, Milling
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing
3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 1108 Insp GMP 1108/1893-0016

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

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

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 20/02/2020

This Certificate of GMP Compliance of a Manufacturer is certified as a true copy of the original by me Leanne Mandy Hammell, Solicitor and Notary Public in Edinburgh on this fourth day of March Two Thousand and Twenty -

Attorneys c/o Pinsent Masons LLP