Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Regulation 331A of The Human Medicines Regulation 2012 (SI 2012/1916)

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 Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 19/12/2024, 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 MHRA-GMDP database. 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 which is authentic and is issued by the Medicines and Healthcare Product Regulatory Agency by me, Brian John Grierson, Solicitor and Notary Public on this 7 January 2025

B - G -

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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 Q
N

2. IMPOR

2.1 Q
N

2.2 B
N

2.3 O
N

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. **Country:** United Kingdom of Great Britain and Northern Ireland
Pays / País:

This public document
Le présent acte public / El presente documento público

2. **Has been signed by** Brian John Grierson
a été signé par
ha sido firmado por

3. **Acting in the capacity of** Notary Public
agissant en qualité de
quien actúa en calidad de

4. **Bears the seal / stamp of** The Said Notary Public
est revêtu du sceau / timbre de
y está revestido del sello / timbre de

Certified
Attesté / Certificado

5. **at** London
á / en

6. **the** 21 January 2025
le / el día

7. **by** His Majesty's Principal Secretary of State for Foreign, Commonwealth and Development Affairs
par / por

8. **Number** APO-DBKE-MM36-U6E5-36K7
sous no / bajo el numero

9. **Seal / stamp**
Sceau / timbre
Sello / timbre

FOREIGN, COMMONWEALTH & DEVELOPMENT OFFICE LONDON

10. **Signature** D. Hodges
Signature
Firma

This Apostille is not to be used in the UK and only confirms the authenticity of the signature, seal or stamp on the attached UK public document. It does not confirm the authenticity of the underlying document. Apostilles attached to documents that have been photocopied and certified in the UK confirm the signature of the UK official who conducted the certification only. It does not authenticate either the signature on the original document or the contents of the original document in any way.

If this document is to be used in a country not party to the Hague Convention of the 5th of October 1961, it should be presented to the consular section of the mission representing that country.

To verify this apostille go to www.verifyapostille.service.gov.uk

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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 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

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

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

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

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

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

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

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 1108 Insp GMP/GDP 1108/1893-0019

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

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

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

Christine E. Gray
Head of Compliance Team 2 (GMP and GDP)
inspectionplanning@mhra.gov.uk

Date: 19/12/2024

This certificate of GMP Compliance of a manufacturer is certified as a true copy of the original document which is authentic and is issued by the Medicines and Healthcare Product Regulatory Agency by me, Brian John Grierson, Solicitor and Notary Public on this 7 January 2025.