

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 1108 Insp GMP 1108/17762203-0003

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

Part 1

Issued following an inspection in accordance with :

Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : MACFARLAN SMITH LIMITED

Site address : MACFARLAN SMITH LIMITED, THREE TREES ROAD, NEWBIE, ANNAN, DG12 5QH, 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 11/10/2023 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

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- (1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.
 - (2) These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [2000008305] METHYLPHENIDATE HYDROCHLORIDE
- [4000008052] DIHYDROCODEINE HYDROGEN TARTRATE
- [2000006722] OXYCODONE HYDROCHLORIDE
- [4000006570] CODEINE PHOSPHATE HEMIHYDRATE
- [1000007171] BUPRENORPHINE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

METHYLPHENIDATE 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 (eg. Crystallisation)
Salt formation, Crystallisation
- 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

DIHYDROCODEINE HYDROGEN 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 (eg. Crystallisation)
Salt formation, Crystallisation
- 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

OXYCODONE 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 (eg. Crystallisation)
Salt formation, Crystallisation

- 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

CODEINE PHOSPHATE HEMIHYDRATE

- 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 (eg. Crystallisation)
- Salt formation, Crystallisation.

- 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

BUPRENORPHINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
- 3.1.1 Manufacture Of Active Substance Intermediates
- 3.1.4 Other
- Hydrogenation
- 3.5 General Finishing Steps
- 3.5.4 Other
- This intermediate supplied to Edinburgh site for further processing as an API
- 3.6 Quality Control Testing
- 3.6.1 Physical / Chemical testing
- 4 Other Activities
- Only intermediate specification testing

20/10/2023 Name and signature of the authorised person of the Competent Authority of United Kingdom

