

## ***Medicines and Healthcare Products Regulatory Agency***

CERTIFICATE NUMBER: **UK API 1108 Insp GMP 1108/1893-0013**

# **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**<sup>1, 2</sup>

### **Part 1**

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/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**

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC .

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 **2015-06-15** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>3</sup>
- The principles of GMP for active substances<sup>3</sup> referred to in Article 47 of Directive 2001/83/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.

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

## Part 2

Human Medicinal Products
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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)**  
**HYDROCODONE BITARTRATE( en)**  
**DIAMORPHINE( en)**  
**ALOIN( en)**  
**METHADONE HYDROCHLORIDE( en)**  
**ALFENTANIL HYDROCHLORIDE( en)**  
**MORPHINE TARTRATE( en)**  
**HYDROMORPHONE HYDROCHLORIDE( en)**  
**FENTANYL CITRATE( en)**  
**PETHIDINE HYDROCHLORIDE( 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)**

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
<b><i>Blocks 12, 13, 14, 18, 19, 108, 114, 118, 120, Block 2 (Packaging)</i></b>			<b><i>Includes QC testing in Block 18 laboratories</i></b>	<b><i>confidential</i></b>

***2015-07-17***

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***  
Fax: ***Confidential***