

Controllo Qualità - Certificato Nr. : 201604199 Riferimento Analitico: SCCH3016/07-SCBH3016/08 16/09/2016 Pag. 1 di 1

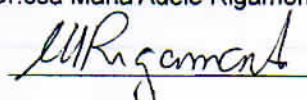
Codice	Prodotto	Lotto int.	Quantità	Rev.	Riferimento
1457-0	MORFINA SOLFATO	161000888	100000 GR 5		Eur.Ph.6.7+CEP

Fornitore	Lotto	Produttore	Produzione	Analisi	Ricontrollo
MacFarlan Smith Limite	16-00019	MacFarlan Smith Limited	05 2016	16 /09 /2016	04 2021

Saggi	Specifiche	Unità di misura	Risultato
Identificazione NIR	positiva		corrisponde
Aspetto	polvere cristallina bianca o quasi bianca	---	corrisponde
Solubilità	solubile in acqua, molto poco solubile in etanolo 96%, praticamente insolubile in toluene	---	corrisponde
Identificazione A	conforme Eur.Ph. CRS	---	corrisponde
Identificazione E	conforme Eur.Ph. 2.3.1	---	corrisponde
Aspetto della soluzione	la soluzione S è limpida, <= G6 o BG6	---	corrisponde
Acidità o alcalinità	conforme Eur.Ph.	---	corrisponde
Potere rotatorio spec.	≥ -110 ≤ -107	(°)	-110
Impurezza B	≤ 0.4	% p/p	0.04
Impurezza C	≤ 0.2	% p/p	<0.05
Impurezza E	≤ 0.2	% p/p	<0.05
Impurezza A	≤ 0.2	% p/p	0.05
Impurezza D	≤ 0.2	% p/p	<0.05
Impurezza F	≤ 0.2	% p/p	<0.05
Ogni altra impurezza non specificata	≤ 0.10	% p/p	0.080
Totale impurezze	≤ 1.0	% p/p	0.17
Ferro	max 5	ppm	corrisponde
Acqua	≥ 10.4 ≤ 13.4	% p/p	12.8
Ceneri solforiche	≤ 0.1	% p/p	0.00
Etanolo	≤ 5000	ppm	68
Metanolo	≤ 3000	ppm	0
Titolo sul secco	≥ 98.0 ≤ 102.0	% p/p	99.9
Conta totale microrganismi aerobi (TAMC)	≤ 1000	ufc/g	<10
Conta totale lieviti e muffe (TYMC)	≤ 100	ufc/g	<10

**GIUDIZIO FINALE: APPROVATO**

Responsabile C.Q.  
Dr.ssa Maria Adele Rigamonti



Data

16/09/16

161000888



# Johnson Matthey Macfarlan Smith

## Fine Chemicals Division

10 Wheatfield Road, Edinburgh, EH11 2QA  
Telephone: +44 (0)131 337 2434, Fax: +44 (0)131 337 4436

### Certificate of Analysis

#### Product

**MORPHINE SULFATE BP, PhEur**

Batch No:

16-00019

Date of Manufacture:

May 2016

Date of Retest:

April 2021

<u>Test</u>	<u>Limit</u>	<u>Result</u>
Appearance	White to almost white crystalline powder	White to almost white crystalline powder
Solution Colour	Clear, not more than Y <sub>6</sub> or BY <sub>6</sub> .	Clear, less than Y <sub>6</sub> or BY <sub>6</sub> .
Identity	Complies with tests	Complies with tests.
Acidity or Alkalinity	Not more than 0.2ml of 0.02M Sodium hydroxide or 0.02M Hydrochloric acid	Complies with tests.
Sulfated Ash	Not more than 0.1%	Not more than 0.1%.
Specific Optical Rotation	-107° to -110°	-109.2°.
Related Impurities (HPLC)	No Ph Eur named impurity > 0.1%. No un-named impurity > 0.10% Total impurities not more than 1.0%	No impurity > 0.09%. None > 0.10%. Total impurities 0.15%
Ethanol	Not more than 5000ppm (0.5%)	81 ppm.
Methanol	Not more than 1000ppm (0.1%)	<50 ppm.
Water (KF)	10.4% to 13.4%	12.3 %.
Iron	Not more than 5ppm	Not more than 5ppm.
Assay	98.0% to 102.0% (anhydrous solvent free basis)	100.1 % (anhydrous solvent free basis)
Particle Size	0% greater than 400 micron	0% greater than 400 micron

Complies with the current monograph of: **BP, PhEur.**  
Certificate of Suitability: **R1-CEP 2001-239-Rev 05**

Mr G M Burton BSc, MCQI  
Director of Quality & Regulatory Compliance

Consignee: L Molteni & C del Flli Alitti  
Italy

Order No: 39815

Date of Issue: 07 July 2016

Macfarlan Smith Limited  
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