

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

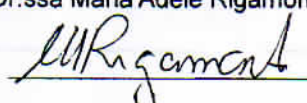
Codice	Prodotto	Lotto int.	Quantità	Rev.	Riferimento
1457-0	MORFINA SOLFATO	161000888	100000 GR 5		Eur.Ph.6.7+CEP

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 ₆ or BY ₆ .	Clear, less than Y ₆ or BY ₆ .
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
Wheatfield Road, Edinburgh, EH11 2QA, Registered in Scotland No 35640

**DOCUMENTO RILASCIO LOTTO
BATCH RELEASE STATEMENT
RELEASE FOR SALE**

COPIA CONFORME ALL'ORIGINALE

CODICE/CODE: **X25001-80**

PRODOTTO/PRODUCT: **ORAMORPH SOLUTION 20 MG/ML BOTTLE 20 ML CHILE**

LOTTO N./BATCH N.: **11601 17**

SCADENZA/EXPIRY DATE: **03 2020**

CONFEZIONI/BOXES: **14.517 (17 SAMPLES)**

DAQ/ BATCH RECORD REVIEW/  DATA/DATE **21 MAR 2017**

SOCIETÀ DI ESERCIZIO S.P.A.
QUALITY ASSURANCE
BARBARA PROSPERI
Batch Record Reviewer

Certifico che il lotto sopra menzionato è stato prodotto, confezionato e controllato nel rispetto delle Norme di Buona Fabbricazione ed in conformità con la documentazione di Autorizzazione all'Immissione in Commercio fornita dal committente.

Questo prodotto viene rilasciato per il commercio.



I hereby certify that the above mentioned product has been manufactured, packed and tested in accordance with cGMPs and in compliance with Marketing Authorization documentation provided by the customer.

This product is released for sale.

QUALIFIED PERSON /  DATA/DATE **21 MAR 2017**

L. MOLTENI & C. del F.lli ALTI
Società di Esercizio
FIRENZE
Direttore Qualità e Sviluppo Tecnologico
Qualified Person
(Dr. Tiziano Petruccioli)

Quality Control - Certificate Nr.: 201701269 Analytical Reference: SCCC1317/10-SCBC1317/11 21/03/2017 Pag. 1 of 1

Code	Article	Batch Number	Val. months	Expiry date	Rev.
X25001-80	ORAMORPH Solution 20 mg/mL Bottle 20 mL Chile	11601 17	36	03/2020	4
Manufacturing	Analysis	Manufacturer	Internal reference	Reference	
03 2017	21/03/2017	L. Molteni & C.	170011601	Dossier	
Tests	Specification	Units	Results		
Description	a clear nearly colourless liquid, free from suspended particles	----	Complies		
Odour	almost imperceptible	----	Complies		
Colour of the solution	not more intensely coloured than reference solution BY6	----	Complies		
Clarity of solution	not more opalescent than reference solution I	----	Complies		
Morphine identification	RT = RT std	----	Complies		
Sulphate identification	conforming to Eur.Ph.	----	Complies		
Sodium benzoate identification	RT = RT std	----	Complies		
Disodium edetate identification	conforming to colorimetric test	----	Complies		
pH of the solution	≥ 2.2 ≤ 3.0	----	2.6		
Morphine sulphate	≥ 19.0 ≤ 21.0	mg/mL	19.9		
Pseudomorphine	≤ 1.0	% w/w	<0.03		
Morphine N-oxide	≤ 0.5	% w/w	<0.03		
Any unspecified degradation product	≤ 0.1	%	0.08		
Total decomposition	≤ 1.0	%	0.10		
Related compounds (codeine phosphate)	≤ 0.5	% w/w	0.04		
Sodium benzoate	≥ 0.090 ≤ 0.110	%w/v	0.099		
Disodium edetate dihydrate	≥ 0.009 ≤ 0.011	%w/v	0.010		
Total aerobic microbial count (TAMC)	≤ 100	cfu/mL	0		
Total yeast and mould count (TYMC)	≤ 10	cfu/mL	0		
E. coli	absent in 1 mL	----	Absent		
Average volume	≥ 20.0	mL	20.3		
Packaging compliance	it must comply	----	Complies		

Note:

MOLTENI FARMACEUTICI

Scandicci - Firenze

Responsabile Controllo Qualità

JUDGEMENT:

APPROVED

Quality Control Manager
Dr.ssa Maria Adele Rigamonti

Date

[Signature]

21/3/17

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BATCH RELEASE STATEMENT
RELEASE FOR SALE**

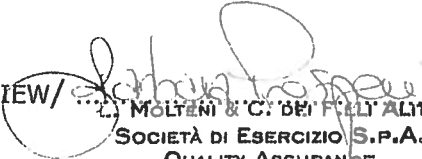
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SCADENZA/EXPIRY DATE: **03 2020**

CONFEZIONI/BOXES: **14.817 (17 SAMPLES)**

DAQ/ BATCH RECORD REVIEW/  DATA/DATE **21 MAR 2017**
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QUALITY ASSURANCE
BARBARA PROSPERI
Batch Record Reviewer

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Direttore Qualità e Sviluppo Tecnologico
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Note:

MOLTENI FARMACEUTICI

Scandicci - Firenze

Responsabile Controllo Qualità

JUDGEMENT:

APPROVED

Quality Control Manager
Dr. ssa Maria Adele Rigamonti

Date

[Signature]

21/3/17