MOLTENI
FARMACEUTICI

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

161000858

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

Test	Limit	Result
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

MOLTENI
FARMACEUTICI

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

L. MOLTENI & C. dei F.lli Alitti
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. dei F.lli Alitti
Società di Esercizio
FIRENZE
Direttore Qualità e Sviluppo Tecnologico
Qualified Person
(Dr. Tiziano Petrucciani)

MOLTENI
FARMACEUTICI

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

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
21/3/17

MOLTENI
FARMACEUTICI

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.:	**11701 17**
SCADENZA/EXPIRY DATE:	**03 2020**
CONFEZIONI/BOXES:	**14.817 (17 SAMPLES)**

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

L. MOLTENI & C. DEI F.LLI ALITTI
SOCIETÀ DI ESERCIZIO S.P.A.
QUALITY ASSURANCE
BARBARA PROSPERI
Batch Record Reviewer

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L. MOLTENI & C. dei F.lli Alitti
Società di Esercizio
FIRENZE
Direttore Qualità e Sviluppo Tecnologico
Qualified Person
(Dr. Tiziano Potrucciani)

MOLTENI
FARMACEUTICI

Quality Control - Certificate Nr.: 201701270 Analytical Reference: SCCC1417/10-SCBC1417/12 21/03/2017

Code	Article	Batch Number	Val. months	Expiry date	Rev.
X25001-80	**ORAMORPH Solution 20 mg/mL Bottle 20 mL Chile**	**11701 17**	**36**	**03/2020**	**4**

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Note:

MOLTENI FARMACEUTICI
Scandicci - Firenze
Responsabile Controllo Qualità

JUDGEMENT:

APPROVED

Quality Control Manager
Dr.ssa Maria Adele Rigamonti

Date
21/3/17