MOLTENI
FARMACEUTICI

DOCUMENTO RILASCIO LOTTO
BATCH RELEASE STATEMENT
RELEASE FOR SALE

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.

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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

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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

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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