MOLTENI FARMACEUTICI

Quality Control - Certificate Nr.: 202301046

Code	Article	Batch Number	Quantity	Rev.	Reference
1457-0	MORFINA SOLFATO	2302000205	100000 G	8	Ph. Eur c.e. + CEP

Supplier	Supplier Batch	Manufacturer	Manufacturing	Inspection Lot	Retest date	Expiry date
MACFARLAN SMITH LIMITED	22-00282	MACFARLAN SMITH LIMITED	10 2022	10000018872	09 2027	09/2027

Tests	Specification		Units	Results
NIR identification	positive	----		Complies
Appearance	white or almost white, crystalline powder		----	Complies
Solubility	soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in toluene		----	Complies
Identification A	according to morphine sulfate CRS		----	Complies
Identification E	it givers the reaction of sulfates (Eur.Ph. 2.3.1)		----	Complies
Appearence of solution	solution S is clear and not more intensely coloured than reference solution Y6 or BY6		----	Complies
Acidity or alkalinity	according to Eur.Ph.		----	Complies
Specific optical rotation	≥ -110	≤ -107	(°)	-109
Impurity B		≤ 0.4	% w/w	0.02
Impurity C		≤ 0.2	% w/w	<0.05
Impurity E		≤ 0.2	% w/w	<0.05
Impurity A		≤ 0.2	% w/w	0.07
Impurity D		≤ 0.2	% w/w	0.08
Impurity F		≤ 0.2	% w/w	<0.05
Any other unspecified impurity		≤ 0.10	% w/w	<0.050
Total impurities		≤ 1.0	% w/w	0.17
Iron	maximum 5		ppm	Complies
Water	≥ 10.4	≤ 13.4	% w/w	12.0
Sulphated ash		≤ 0.1	% w/w	0.00
Ethanol		≤ 5000	ppm	0
Methanol		≤ 3000	ppm	0
Content (anhydrous substance)	≥ 98.0	≤ 102.0	% w/w	99.0
Total aerobic microbial count (TAMC)		≤ 1000	cfu/g	<10
Total yeast and mould count (TYMC)		≤ 100	cfu/g	<10

JUDGEMENT: APPROVED

Electronic Signature performed by: **Quality Control Manager - QP Deputy** **Oreste Rendace** **Date: 09/03/2023 09:35:36**

The signature above is an electronic signature whose value falls exclusively within the company boundaries; in the event that the true copy of the original electronic record (signed electronically) has to pass these boundaries, it must be signed manually, followed by the date of printing of the document.

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VERANOVA™

Certificate of Analysis

Product Morphine Sulfate Grade BP, PhEur, USP		Manufacturing Lot No. 22-00282
Date of Manufacture Oct 2022	Retest Date Sep 2027	Product Code 300311

Test	Specification	Result
Appearance	White to almost white crystalline powder	White crystalline powder
Solution Colour	Clear, not more intensely coloured than Y6 or BY6	Clear, not more intensely coloured than Y6 or BY6
Identification	Complies with test	Complies with test
Identification by IR	Complies with test	Complies with test
Acidity [PhEur]	Not more than 0.2ml of 0.02M Sodium Hydroxide or 0.02M Hydrochloric Acid	Complies with test
Sulfated Ash (Residue on Ignition)	Not more than 0.1%	Not more than 0.1%
Specific Optical Rotation [PhEur]	-107° to -110° (anhydrous solvent free basis)	-108.7 °
Related Substances (HPLC)		
Impurity A	≤ 0.1%	0.07 %
Impurity B	≤ 0.1%	<0.05 %
Impurity C	≤ 0.1%	<0.05 %
Impurity D	≤ 0.1%	0.09 %
Impurity E	≤ 0.1%	<0.05 %
Impurity F	≤ 0.1%	<0.05 %
Unspecified Impurity (Each)	≤ 0.10 %	<0.05 %
Total Impurites	≤ 1.0%	0.16 %
Residual Solvents		
Ethanol	Ethanol ≤ 0.5% [5000ppm]	5 ppm
Methanol	Methanol ≤ 0.1% [1000ppm]	0 ppm
Water (KF)	10.4% to 13.4%	11.9 %
Iron	Not more than 5ppm	Not more than 5ppm
Assay [PhEur]	98.0% to 102.0% (anhydrous solvent free basis)	99.9 %
Particle Size	0% greater than 400 micron	0% Greater than 400µ

VERANOVA™

Certificate of Analysis

Product Morphine Sulfate Grade BP, PhEur, USP		Manufacturing Lot No. 22-00282
Date of Manufacture Oct 2022	Retest Date Sep 2027	Product Code 300311

Test	Specification	Result
Specific Optical Rotation [USP]	-107° to -109.5° (anhydrous solvent free basis)	-109.0 °
Acidity [USP]	Not more than 0.5ml of 0.020N Sodium Hydroxide	Complies with test
Chloride	Complies with test	Complies with test
Ammonium Salts	Complies with test	Complies with test
Limit of Foreign Alkaloids	Complies with test	Complies with test
Assay [USP]	98.0% to 102.0% (anhydrous solvent free basis)	99.5 %
Bacterial Endotoxins	Less than 7 EU/mg	<0.0159114 EU/mg

	Name and Title	Signature	Date
Approved By:	Ronak Joshi Senior QA Officer	This is an electronic signature.	17-Jan-23 3:50:27PM

Complies with the current monograph of : **BP, PhEur, USP**

Certificate of Suitability **R1-CEP 2001-239-Rev 06**

The above lot was processed, tested, and packaged in compliance with Company Quality Standards, cGMPs and other applicable regulations.