

Omeprazole

CODE ARTICLE: 8940	BATCH: 0127072	Active pharmaceutical ingredient
TEST DATE: 19/04/2024	TEST: QC-00263485	
EXPIRY DATE: 28/02/2026	FABRICATION DATE: 04/03/2024	MR: 345,40
CAS: 73590-58-6	FORMULA: C17H19N3O3S	
STORAGE: Conservare a 2-8°C , al riparo dalla luce. (Store in tightly closed containers between 2 and 8 ° C.)		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM			WHITE OR ALMOST WHITE POWDER	PH.EUR.*
COLOUR	CONFORM			White	PH.EUR.*
SOLUBILITY					
SOLUBLE		IN DICHLOROMETHANE			PH.EUR.*
SOLUBLE		VERY SLIGHTLY SOLUBLE IN WATER			PH.EUR.*
SOLUBLE		MODERATELY SOLUBLE IN ETHANOL 96			PH.EUR.*
SOLUBLE		SPARINGLY SOLUBLE IN METHANOL			PH.EUR.*
SOLUBLE		SOLUTIONS OF ALKALI HYDROXIDES			PH.EUR.
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
DISSOLUTION ASPECT	CONFORM -			Limpid	PH.EUR.*
IMPURITIES F AND G (440nm)	<350 MG/KG			0.10	PH.EUR.*
RELATED SUBSTANCES (HPLC)					
IMPURITY D	<LQ=0,05% (PASS) -			<=1,5xArea SR B (<=0,15%)	PH.EUR.*
IMPURITY E	<LQ=0,05% (PASS) -			<=1,5xArea SR B (<=0,15%)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,06% (PASS) -			<=Area SR B (<=0,10%)	PH.EUR.*
TOTAL IMPURITIES	0,1% (PASS) -			<=5xArea SR B (<=0,5%)	PH.EUR.*
LOSS ON DRYING	0,03 %		-	0,2	PH.EUR.*
SULPHATED ASHES	0 %		-	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99 %		99	101	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	207 ppm		0,0	1.000	Manufacture's Standard
ACETONE	452 ppm		0,0	1.500	Manufacture's Standard
METHYLENE CHLORIDE	N.D. ppm			<=100	Manufacture's Standard
BENZENE	N.D. ppm			1	Manufacture's Standard
TOLUENE	1 ppm			300	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer: 44722 (China) Manufacturer Batch: A-20412403001 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



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TEST	RESULTS	Units	MIN	MAX	METHOD
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM				
Risk Assessment Evaluation for Nitrosamines	CONFORM				



Silvia Sancho-Tello Ripoll
Technical Director.

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