

COCREATE GLOBAL TECHNOLOGIES PRIVATE LIMITED**U21009KA2023PTC179006****Registered address:** FFK Towers, #445, 2nd Floor, 17th Cross Road, Sector 4, HSR Layout, Bangalore, Bangalore South, Karnataka - 560102, India.**Email:** info@scimplify.com**Website:** www.scimplify.com**CERTIFICATE OF ANALYSIS****Product Name - OMEPRAZOLE, USP**

S. No.	TEST	SPECIFICATION	RESULT
1	Description	A white to off white powder	White powder
2	Solubility	Soluble in MDC, Sparingly soluble in methanol and alcohol, very slightly soluble in water.	Complies
3	Identification by		
	HPLC	The retention time of major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
	Infrared specification	The IR absorption spectrum of the sample preparation should concordant with same preparation of the Omeprazole reference / working standard.	Complies
4	Organic Impurities by HPLC:-		
	5-methoxy-1H-benzimidazole-2-thiol	Not more than 0.15%	ND
	Omeprazole N-oxide (Omeprazole related compound -E)	Not more than 0.15%	0.05
	Omeprazole sulfone N-oxide (Omeprazole related compound- I)	Not more than 0.15%	ND
	Desmethoxy Omeprazole	Not more than 0.15%	0.01
	Omeprazole sulfone (Omeprazole related compound- A)	Not more than 0.15%	0.09
	Omeprazole -4-chloro analog	Not more than 0.15%	0.01
	Ufiprazole	Not more than 0.15%	0.08
	Any other impurities	Not more than 0.10%	0.09
	Total impurities	Not more than 1.00%	0.38
5	Residue on ignition	Not more than 0.10%w/w	0.04

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6	Completeness of solution	20mg/ml solution of Omeprazole in methylene chloride should Be clear as solvent	Complies
7	Limit of Omeprazole related compounds F&G	The absorbance at 440 nm is NMT 0.10	Complies
8	Loss On drying	Not more than 0.5%w/w	0.22%
9	Assay by HPLC (on dried basis)	98.0%w/w -102.0%w/w	99.60%

Remarks: The material complies as per above specification.

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