

METROCHEM API PRIVATE LIMITED

Unit-IV: Plot No: 34B, 40B & 60B, Jawaharlal Nehru Pharmacy, Thanam Village, Parawada Mandal, Anakapalli District-531021, Andhra Pradesh, India. CIN: U24239TG2002PTC039223
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CERTIFICATE OF ANALYSIS

Product Name	OMEPRAZOLE	Reference	USP
Batch Number	OMP-P/25001	A.R. No.	ARFP11250092
Mfg. Date	NOV/2025	Exp. Date	OCT/2030
Dispatch Quantity	350.00 Kg	Date of Release	03/12/2025
Specification No.	FP/OMP/SP/01-09	Market Mode	US Market
Customer Name	M/s.ZUVCHEM.	Page No.	1 of 2

S.No.	Test	Result	Specification
1.0	Description	White powder	White to off white powder.
2.0	Solubility	Complies	Soluble in Dichloromethane, sparingly soluble in methanol and in ethanol and very slightly soluble in water
3.0	Identification by		
	a) IR	Complies	The IR absorption spectrum of the sample should be concordant with that of standard spectrum.
	b) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay by HPLC.
4.0	Completeness of solution	Complies	2% solution in methylene chloride should be clear and comparable with same solvent.
5.0	Loss on Drying (% w/w) (at 60°C for 4 hours under vacuum)	0.23	Not more than 0.5
6.0	Residue on ignition (% w/w)	0.04	Not more than 0.1
7.0	Organic purity by HPLC (% w/w)		
	5-Methoxy-1H-benzimidazole-2-thiol	Not detected	Not more than 0.15
	Omeprazole N-oxide (Omeprazole related compound E)	BDL	Not more than 0.15
	Omeprazole sulfone N-oxide (Omeprazole related compound I)	Not detected	Not more than 0.15
	Desmethoxy Omeprazole	BQL	Not more than 0.15
	Omeprazole sulfone (Omeprazole related compound A)	Not detected	Not more than 0.15
	Omeprazole 4-Chloro analog	0.01	Not more than 0.15

	Prepared by	Checked by	Approved by
Name	G.Syam	E.Bangaru Naidu	K. Kurmi Naidu
Signature			
Date	04/12/2025	04/12/25	04/12/2025

Format No.: QA037-F01-05-010922

Volume • Quality



Corporate Office: The Watermark, 3rd Floor, Plot No 11, Survey No 9, Whitefields, Kondapur, Hitech City, Hyderabad 500084, Telangana State, India. Tel: +91-40-69069999



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S.No.	Test	Result	Specification
	Ufiprazole	BDL	Not more than 0.15
	Any other individual impurity	Not detected	Not more than 0.10
	Total impurities	0.01	Not more than 1.0
8.0	Limit of Omeprazole related compounds F and G in A° (2.0% solution in methylene chloride at 440nm)	0.02	The absorbance is Not more than 0.10, (Corresponding to Not more than 350ppm of the sum of Omeprazole related compounds F and G)
9.0	Assay by HPLC (%w/w) (On dried basis)	99.7	Not less than 98.0 and Not more than 102.0
10.0	Residual solvents by GC-HSS (ppm) Method-I		
	Methanol	Not detected	Not more than 3000
	Ethanol	Not detected	Not more than 5000
	Acetone	BDL	Not more than 5000
	Ethyl acetate	BDL	Not more than 5000
	Toluene	BDL	Not more than 890
	Residual solvents by GC-HSS (ppm) Method-II		
Triethylamine	BDL	Not more than 200	

Storage Condition: Preserve in tight containers, and store in cold place, protected from moisture.

Remarks: The material Complies / ~~Does not comply~~ as per the above specification.

	Prepared by	Checked by	Approved by
Name	G.Syam	E.Bangaru Naidu	K. Kurmi Naidu
Signature			
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