

METAPHARMACEUTICAL

N° DE LOTE:

TAGOOR LABORATORIES PRIVATE LIMITED

Factory: (Unit-I), Survey. 29, Tupakulagudem Village, Pochavaram Panchayat,
Tallapudi Mandal, East Godavari District, Andhra Pradesh -534341, INDIA.

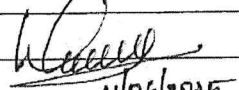
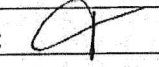

www.tagoorlabs.com

TAGOOR

Certificate of Analysis

Name of the Product	:	OMEPRAZOLE, EP			
Batch No.	:	OPZ-07825	CAS No	:	73590-58-6
Quantity	:	25.0 kg	Analysis completed on	:	10/06/2025
Analytical Report No.	:	AR/FP/OPZ/007825	Mfg.Date	:	Jun'-2025
			Re-Test Date	:	May'-2030

S.No.	TEST	Specifications	Results
1.	Description	A White or almost white powder.	Almost white powder
2.	Solubility	Very slightly soluble in water Soluble in methylene chloride. Sparingly soluble in ethanol (96%) and methanol. It dissolves in dilute solution of alkali hydroxides.	Complies
3.	Identification By IR	The Infra-Red absorption spectrum of the sample should exhibit maxima only at the same wavelength as that of similar preparation of Omeprazole working standard.	Complies
4.	Appearance of the solution	Solution S is clear.	Complies
5.	Impurity F and G	Maximum 350 ppm for the sum of the contents. The Absorbance of the solution S determined at 440 nm is not more than 0.10 ⁰ A	0.02
6.	Related substances (By HPLC %)		
	Impurity D	Not more than 0.15%	0.04%
	Impurity E	Not more than 0.15%	Not detected
	Any Unspecified Impurity	Not more than 0.10%	0.03%
	Total Impurities	Not more than 0.5%	0.1%
7.	Loss on drying	Not more than 0.2 % w/w	0.15%w/w
8.	Sulfated ash	Not more than 0.1% w/w	0.03%w/w
9.	Assay by Potentiometry (On dried basis)	Not less than 99.0% and not more than 101.0%	99.8%w/w
10.	Residual Solvents by HSGC		
	Methanol	Not more than 3000 ppm	BDL
	Acetone	Not more than 5000 ppm	BDL
	Dichloromethane	Not more than 600 ppm	Not detected
	Toluene	Not more than 890 ppm	Not detected
	Tri ethyl amine	Not more than 5000 ppm	Not detected
11.	Residual Solvents by HPLC		
	Acetic acid	Not more than 5000ppm	Not detected
Remarks	:	The material Complies / does not complies to the specifications	
Storage Condition	:	Store an air tight container, protected from light, at a temperature between 2	

Compiled by :		Checked by :		Authorized Signatory :	
Date :	11/06/2025	Date :	11/06/2025	Date :	11/06/2025

Form No. : QC-002-F02-01

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 04/07/2025