

TAGOOR LABORATORIES PRIVATE LIMITED

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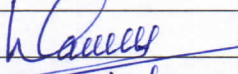


Factory: (Unit-I), Survey. 29, Tupakulagudem Village, Pochavaram Panchayat,
Tallapudi Mandal, East Godavari District, Andhra Pradesh -534341, INDIA.

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Certificate of Analysis

Name of the Product	:	OMEPRAZOLE, EP 11			
Batch No.	:	OPZ-11324	CAS No	:	73590-58-6
Quantity	:	100.0 kgs	Analysis completed on	:	18/08/2024
Analytical Report No.	:	AR/FP/OPZ/01130824	Mfg.Date	:	Aug'-2024
			Re-Test Date	:	Jul'-2029

S.No.	TEST	Specifications	Results
1.	Description	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 IR absorption spectrum of the sample preparation should concordant with same preparation of the Omeprazole working standard.	Complies
4.	Appearance of the solution	Solution S is clear.	Complies
5.	Impurity F and G		
	Absorbance at 440 nm	Not more than 0.10	0.02
	Related substances by HPLC		
	Impurity D	Not more than 0.15%	BQL
	Impurity E	Not more than 0.15%	0.01%
	Unspecified Impurities	Not more than 0.10%	BQL
	Total Impurities	Not more than 0.5%	0.02%
7.	Loss on drying	Not more than 0.2 % w/w	0.14%w/w
8.	Sulfated ash	Not more than 0.1% w/w	0.04%w/w
9.	Assay by Potentiometry (On dried basis)	Not less than 99.0% and not more than 101.0%	99.5%w/w
	Residual Solvents by HSGC		
	Methanol	Not more than 3000 ppm	128 ppm
	Acetone	Not more than 5000 ppm	99 ppm
	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
	Residual Solvents by HPLC		
	Acetic acid	Not more than 5000ppm	Not detected
Remarks	:	The material Complies / does not comply to the specifications	
Storage Condition	:	Store an air tight container, protected from light, at a temperature between 2°C to 8°C.	

Compiled by :		Checked by :		Authorized Signatory :	
Date :	24/08/2024	Date :	24/08/2024	Date :	24/08/2024