METAPHARMACEUTICAL

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TAGOOR LABORATORIES PRIVATE LIMITED

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Certificate of Analysis								
Product Name	1:	OMEPRAZOLE, EP						
Batch No.	+-	OPZ-12625	CAS No.	:	73590-58-6			
Quantity	+	25.0 kgs	Analysis Completed on	:	12/08/2025			
Analytical Report No.	1:	AR/FP/OPZ/012625	Mfg. Date	:	Aug'-2025			
Timery treat zespess zes		The second secon	Re-Test Date	1	Jul'-2030			

		: Jul'-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	ı 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	
	Related subs	tan	ces (By HPI	.C %)		
	Impurity D 6. Impurity E Any Unspecified Impurity			Not more than 0.15%	0.03%	
6				Not more than 0.15%	Not detected	
0.			d Impurity	Not more than 0.10%	0.06%	
	Total Impurities			Not more than 0.5%	0.2%	
7.	Loss on drying			Not more than 0.2 % w/w	0.16%w/w	
8.	Sulfated ash	5		Not more than 0.1% w/w	0.05%w/w	
9.	Assay by Potentiometry (On dried basis)			Not less than 99.0% and not more than 101.0%	99.7%w/w	
	Residual Sol	ver	ts by HSGC			
	Methanol			Not more than 3000 ppm	BDL	
10	Acetone			Not more than 5000 ppm	BDL	
10.	Dichloromet	har	ne	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				T 1	
11.	Acetic acid			Not more than 5000ppm	Not detected	
Rema	Remarks . The materi		The materi	ial Complies / does not complies to the specifications		
Storage Condition : Store an air tight container, protected from light, at a temperature between 2°C to 8°C.						
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Compiled by:	Warell	Checked by:		Authorized Signatory: ()	
Date:	15/10/2015	Date:	istichous	Date:	15/10/none
2	(0) (0 2000)				Degra 1 of 1

Form No. : QC-002-F02-01

Page 1 of 1