



EVEREST ORGANICS LIMITED

CIN : L24230TG1993PLC015426

An ISO 9001:2015 & WHO GMP Certified Company

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CERTIFICATE OF ANALYSIS OMEPRAZOLE USP – 42

Batch No. : OME/E-058/21

Q.C. Ref. No. : FPP/OME/0050/21

Date of Mfg. : March'2021

Date of Analysis : 16.03.2021

Date of Expiry : February'2025

Dispatch Quantity : 300.00 Kg

NDC NUMBER: (51838-100-01), ID/FEI: 915038921/3008616840

S.No	TESTS	SPECIFICATIONS	RESULTS
01	Description	White to off white powder	White powder
02	Solubility	Soluble in Dichloromethane, sparingly soluble in Methanol and in Alcohol. Very slightly soluble in Water.	Complies
03	Identification		
	a) By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the assay.	Complies
	b) By I R	The infrared absorption spectrum of the test sample should match with that of working standard.	Complies
04	Residue on ignition	Not more than 0.10 % w/w	0.06 % w/w
05	Organic impurities		
	5-Methoxy-1H-benzimidazole-2-thiol	Not more than : 0.15 %	Not detected
	Omeprazole N-oxide	Not more than : 0.15 %	0.01 %
	Omeprazole Sulfone N-oxide	Not more than : 0.15 %	Not detected
	Desmethoxy Omeprazole	Not more than : 0.15 %	Not detected
	Omeprazole Sulfone	Not more than : 0.15 %	0.03 %
	Omeprazole-4-chloro analog	Not more than : 0.15 %	Not detected
	Ufiprazole	Not more than : 0.15 %	Not detected
	Any other individual impurity	Not more than : 0.10 %	0.02 %
	Total Impurities	Not more than : 1.0 %	0.09 %
06	Completeness of solution	Solution should be clear	Complies
07	Limit of Omeprazole Related compounds F and G	The absorbance is NMT 0.10 corresponding to NMT 350 ppm of the sum of the Omeprazole related compounds F and G.	0.006

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