



EVEREST ORGANICS LIMITED

CIN : L24230TG1993PLC015426

An ISO 9001:2015 & WHO GMP Certified Company

Corporate Office : 1st Floor, Lakeview Plaza, Plot No. 127&128, Amar Co-Op. Society,
Near Durgamcheruvu, Opp: Madhapur Police Station Road, Hyderabad - 500 033, Telangana, INDIA.
Tel : 040-40040783, 040-23115956, Fax : 040-23115954

METAPHARMACEUTICAL

N DE LOTE:

0020125

CERTIFICATE OF ANALYSIS OMEPRAZOLE E.P

Batch No. : OME/E-261/24
Date of Mfg. : September'2024
Date of Expiry: August'2029

A.R. No. : FPP/OME/0231/24
Date of Analysis : 18.11.2024
Dispatch Quantity : 25.00 Kg

S.No	TESTS	SPECIFICATIONS	RESULTS
01	Description	White or almost white powder.	White powder.
02	Solubility	Very slightly soluble in water, soluble in Methylene Chloride, sparingly soluble in ethanol (96%) and in methanol. It dissolves in dilute solutions of alkali Hydroxides.	Complies
03	Identification By I R	The spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding Omeprazole Working standard.	Complies
04	Appearance of solution	Solution S is clear.	The solution is clear
05	Impurities F and G Absorbance of Solution	Maximum 350 ppm for the sum of the contents Determined at 440 nm is not greater than 0.10 Abs	0.012 Abs
06	Related Substance by HPLC (%)		
	Impurity D	Maximum 0.15 %	0.11 %
	Impurity E	Maximum 0.15 %	0.02 %
	Unspecified impurities	Maximum 0.10 %	0.04 %
	Total Impurities	Maximum 0.5 %	0.24 %
07	Loss On Drying (Under high vacuum at 60°C for 4 hrs)	Maximum 0.20 %	0.12 % w/w
08	Sulfated ash (% w/w)	Maximum 0.10 %	0.05 % w/w

Form No. QC 016-F14 -02

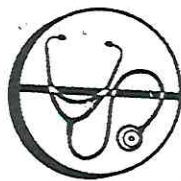
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Regd. Office & Factory : Aroor Village, Sadasivpet Mandal, Sangareddy District,
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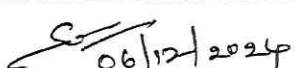
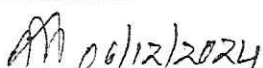
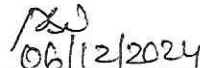
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09	Assay by Titrimetry (% w/w, on dried basis)	Not less than 99.0 % and not more than 101.0 %	99.8 % w/w
10	Residual Solvents by GC HSS		
	Methanol	Not more than 3000 ppm	19 ppm
	Acetone	Not more than 5000 ppm	698 ppm
	Methylene chloride	Not more than 600 ppm	222 ppm
	Chloroform	Not more than 50 ppm	08 ppm
	Toluene	Not more than 890 ppm	22 ppm

Remarks: The material confirms to the above specifications.

	Prepared by	Checked by	Approved by
Name	M. Srinivas	A. Siva Kumar	P.S.N. Murthy
Designation	Asst. Manager - QC	Manager - QC	Asst. Manager - QA
Sign & Date	 06/12/2024	 06/12/2024	 06/12/2024

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