

Factory: Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (Dist.), Pin code: 502319
Telangana, India.

[Signature]
28/06/2023



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CERTIFICATE OF ANALYSIS

Product	: Omeprazole Ph.Eur.	Customer name	: M/s. Meta Pharmaceutical
Batch No.	: OZ23018	Date of Manufacture	: Jun. 2023
Batch Size	: 370.50 kg	Date of Retest	: May 2028
A.R.No.	: FP0623031	Date Analyzed	: 20.06.2023
Reference	: Ph.Eur.	Specification No.	: SOPFP01
Storage	: Store in an airtight container, protected from light, at a temperature of 2°C to 8°C.	Dispatch Quantity	: 25.0 kg

S. No.	TEST	RESULT	SPECIFICATION
1.0	Appearance	Almost white powder.	White or almost white powder.
2.0	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.	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.
3.0	Identification by IR	Complies	The IR spectrum of sample should be concordant to that of Omeprazole CRS/ Working standard.
4.0	Appearance of solution (2 % w/v solution in methylene chloride)	Solution S is clear	Solution S should be clear.
5.0	Absorbance at 440 nm (Abs) (Impurity- F and G)	0.004	Not more than 0.10 (This limit corresponds to 350 ppm of impurity – F and G)
6.0	Related substances by HPLC (%) 6.1 Impurity – D 6.2 Impurity – E 6.3 Unspecified impurity 6.4 Total impurities	Not detected 0.01 (BLD) (LOD:0.0134) Not detected 0.01	Not more than 0.15 Not more than 0.15 Not more than 0.10 Not more than 0.5
7.0	Loss on drying (% w/w)	0.09	Not more than 0.2
8.0	Sulfated ash (% w/w)	0.04	Not more than 0.1

Prepared by: *[Signature]*
Date: 20/06/23

Reviewed by: *[Signature]*
Date: 20/06/23

Head Quality Control: *[Signature]*
Date: 20/06/2023

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S. No.	TEST	RESULT	SPECIFICATION
9.0	Assay by potentiometry (% w/w) (On dried basis)	99.7	Not less than 99.0 and Not more than 101.0
10.0	Residual solvents by GC HS (ppm) 10.1 Methanol 10.2 Acetone 10.3 Toluene 10.4 Triethyl amine	Not detected 129 Not detected 19	Not more than 3000 Not more than 3000 Not more than 300 Not more than 200
11.0	Molybdenum content by ICP-MS (ppm)	1.3 (BLD) (LOD:10.40)	Not more than 150
*12.0	Particle size (µm) 12.1 D ₉₀	4.40	Should be less than 10.0

The product CONFORMS to above specifications.

* Additional tests conducted based on customer requirement.

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