

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



Factory: +91-08458-277149/250 Office: +91-40-29808045/462/463, 23770338/339

26/07/21

**CERTIFICATE OF ANALYSIS**

Product	: Omeprazole Ph.Eur	Customer name	: M/s. Meta Pharmaceutical
Batch No.	: OPFP21028	Date of Manufacture	: Jun. 2021
Batch Size	: 370.00 kg	Date of Retest	: May 2026
A.R.No.	: CB21322	Date Analyzed	: 15.06.2021
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	The IR spectrum of sample is concordant to that of standard of Omeprazole.	The IR spectrum of sample should be concordant to that of Ph.Eur. / Standard of Omeprazole.
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)	0.024	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	0.10	Not more than 0.15
	6.2 Impurity – E	0.02	Not more than 0.15
	6.3 Unspecified impurity	0.02	Not more than 0.10
	6.4 Total impurities	0.13	Not more than 0.5
7.0	Loss on drying (% w/w)	0.10	Not more than 0.2
8.0	Sulphated ash (% w/w)	0.06	Not more than 0.1

Prepared by: *[Signature]*  
Date: 18/06/2021

Reviewed by: *[Signature]*  
Date: 18/06/2021

Head Quality Control: *[Signature]*  
Date: 18/06/2021

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S. No.	TEST	RESULT	SPECIFICATION
9.0	Assay by potentiometry (% w/w) (On dried basis)	100.2	Not less than 99.0 and Not more than 101.0
10.0	Residual solvents by GC HS (ppm)		
	10.1 Methanol	Not detected	Not more than 3000
	10.2 Acetone	85	Not more than 3000
	10.3 Toluene	14	Not more than 300
	10.4 Triethylamine	17	Not more than 200
11.0	Molybdenum content by ICP-MS (ppm)	1.7	Not more than 25
*12.0	Particle size (µm)		
	12.1 D <sub>90</sub>	5.14	Should be less than 10.0

The product CONFORMS to above specifications.

\* Additional tests conducted based on customer requirement.

Prepared by: Suma

Reviewed by: PP

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