



**Lee Pharma Limited**

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

**CERTIFICATE OF ANALYSIS**

Product	:	Omeprazole Ph.Eur.	Customer name	:	-
Batch No.	:	OPFP20025	Date of Manufacture	:	Apr. 2020
Batch Size	:	373.0 kg	Date of Retest	:	Mar. 2025
A.R.No.	:	CB20259	Date Analyzed	:	24.04.2020
Reference	:	Ph.Eur.	Specification No.	:	SOPFP01
Storage	:	Store in airtight container, protected from light, at a temp. of 2°C to 8°C	Dispatch Quantity	:	-

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	IR spectrum of sample is concordant to that of Working standard of Omeprazole.	IR spectrum of sample should be concordant to that of Ph.Eur. CRS/ Working standard of Omeprazole.
4.0	Appearance of solution (2 % w/v solution in MDC)	Solution S is clear	Solution S should be clear
5.0	Absorbance at 440 nm Impurity F and G (Abs.)	0.06	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	0.05 0.01 0.03 0.11	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) ( At 60°C for 4 hr )	0.06	Not more than 0.2
8.0	Sulphated ash (% w/w)	0.08	Not more than 0.1

Prepared by:   
Date: 16/05/2020

Reviewed by:   
Date: 16/05/2020

Head Quality Control:   
Date: 16/05/2020

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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 10.2 Acetone 10.3 Toluene 10.4 Triethylamine	9 174 Not detected 18	Not more than 3000 Not more than 3000 Not more than 300 Not more than 200
*11.0	Particle size (µm) 11.1 D <sub>90</sub>	7.17	Should less than 10.0
12.0	Molybdenum(ppm)	3.46	Not more than 25

The product CONFORMS to above specifications.

\*Additional tests shall be conducted based on customer requirement.

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*16/05/2020*

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