



Lee Pharma Limited

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CERTIFICATE OF ANALYSIS

Product	: Omeprazole	Customer name	: M/s. Columbus Transit, S.A.
Batch No.	: OPFP13031	Date of Manufacture	: Apr. 2013
Batch Size	: 370.4 Kg	Date of Retest	: Mar. 2018
A.R.No.	: CB13249	Date Analyzed	: 26.04.2013
Reference	: EP	Specification No.	: SOPFP01
Storage	: Store in airtight container, protected from light, at a temp. of 2°C to 8°C	Dispatch Quantity	: 5.0 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	IR spectrum of sample is concordant to that of Working standard of Omeprazole.	IR spectrum of sample should be concordant to that of EP 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.)	0.038	Not more than 0.10 (This limit corresponds to 350 ppm of impurity – F and G)
6.0	Related substances by HPLC (%) a. Impurity – D b. Impurity – E c. Unspecified impurity d. Total impurities	0.05 0.05 0.08 0.24	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)	0.13	Not more than 0.2
8.0	Sulphated ash (% w/w)	0.08	Not more than 0.1

Prepared by: *[Signature]*

Date: 31/05/2013

Reviewed by: *[Signature]*

Date: 31/05/2013

Head Quality Control: *[Signature]*

Date: 31/05/2013

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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) a. Methanol b. Acetone c. Toluene d. Triethylamine	Not detected 343 Not detected 39	Not more than 3000 Not more than 3000 Not more than 300 Not more than 200
*11.0	Particle size (µm) 11.1 D ₉₀	8.21	Should less than 20.0
*12.0	Molybdenum(ppm)	0.60	Not more than 25

The product CONFORMS to above specifications.

* Additional tests shall be conducted based on customer requirement.

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