

Kalchem International

Chemicals & Compounding Supplies

Certificate Of Analysis

Product	: Omeprazole		
B. No	: OMPD-0160515	Mfg Date	: May-2015
Quantity	: 25.00kg	Exp Date	: April- 2018
Date of analysis	: 14.05.2015	A.R. Number	: OMPD-0160515
Specifications	: USP	Customer	: M/s.SL.Drugs and Pharmaceuticals

S. No	Test	Specifications	Results
1.	Description	: White or almost white powder.	White powder
2.	Solubility	: Soluble in methylene chloride, sparingly soluble in methanol and in alcohol, very slightly soluble in water.	Complies
3.	Melting point	: 150°C and 160°C	152-156°C
4.	Identification a) IR	: The IR spectrum should concordant with the spectrum of working standard	Complies
	b) TLC	: The Rf value of the principal spot should concordant with standard in the test for chromatogram purity	Conforms
5.	Completeness of solution	: 2.0% solution in MDC should be clear and comparable with same solvent	Complies
6.	Colour of solution (2.0% solution in MDC at 440nm)	: NMT 0.10	0.03
7.	Loss on drying at 60°C for 4 hours under vacuum	: NMT 0.5%	0.21%
8.	Residue on ignition(%w/w)	: NMT 0.1%	0.04%
9.	Heavy metals (%)	: NMT 0.002	Less than 0.002%
10.	Chromatographic purity (%)		
	A)By TLC Individual impurity	: NMT 0.3%	Less than 0.3% Less than 1.0%
	Total impurities	: NMT 1.0%	
	B).By HPLC Individual impurity	: NMT 0.3%	0.2% 0.4%
Total impurities	: NMT 1.0%		
11.	Assay by HPLC (%)	: NLT 98.0% and NMT 102.0%	99.70%

Remarks: The product conforms to above specifications.

Compiled By :	<i>U. Benitez</i>	Checked By :	<i>AW</i>	Approved By :	<i>A. J. ...</i>
Date :	15/5/2015	Date :	15/05/2015	Date :	15.05.2015

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