

# Mahendra Chemicals



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## CERTIFICATE OF ANALYSIS

Product Name: Lidocaine HCL EP	
Batch No.: MC /LH /0026 /16	A.R. No.: FP /0035 /16
Mfg. Date: Feb - 2016	Sample Qty: 20 x 5 gm
Exp. Date Jan - 2021	Sample Drawn: 18.02.2016
Batch Size: 500.0 kg	Testing Date: 18.02.2016
Mfg. Lic. No.: G/296	Completion Date: 19.02.2016

### The result of the test / Analysis as per EP 8.0

Sr. No	TESTS	RESULTS OF ANALYSIS	LIMITS
1.	Characters	A white crystalline powder. Very soluble in water, freely soluble in ethanol	white or almost white crystalline powder. Very soluble in water, freely soluble in ethanol
2.	Identification A Melting Point B IR C Reaction of alcoholic Pot. Hydroxide solution D Reaction of chloride.	76°C to 78°C Complies Green color is produced  Complies	Between 74 °C to 79 °C Must be comply with EP A green color must be Produce. Must comply.
3.	Appearance of solution	The solution is clear and colourless	Clear and colorless solution
4.	pH	4.98	Between 4.0 to 5.5
5.	Related substance Impurities A Unspecified Impurities Total Impurities	A = Not Detected Un sp = 0.0341% Total = 0.0341%	NMT 0.01 % NMT 0.10 % NMT 0.5 %
6.	Heavy metals	Less than 5 ppm.	NMT 5 ppm
7.	Sulphated Ash	0.040%	N.M.T. 0.1%
8.	Water (by KF) (DETERMINED ON 0.25G)	6.07%	Between 5.5% and 7.0% w/w
9.	Assay (On anhydrous basis)	99.73%	99.0% To 101.0%
10.	Residual solvent Acetone Toluene	Acetone 1240.88 ppm Toluene : 3.91 ppm	NMT 5000 ppm NMT 890 ppm

Remarks: This product complies with EP 8.0 Specification.

This is certified that this batch is manufactured in full compliance with GMP requirement of local Regulatory Authority. GMP Certificate No. 1602994 Date: 27.01.2016 Validity: 27.01.2016 to 27.07.2016

Certificate: The above Batch has been manufactured in full compliance with GMP number "1602994" and "Batch Production record checked and approved, no deviation, no reworking and reprocessing."

Analysis By		Checked By		Approved By	
Sign		Sign		Sign	
Date	19/02/16	Date	19/02/16	Date	19/02/16
Name	S. M. Vaghela	Name	C.R. Patel	Name	V.R. Panchal
Designation	Q.C Chemist	Designation	Sr. Executive QA	Designation	QA/QC Manager