

Mahendra Chemicals

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Ref: SOP No.: QC 28

CERTIFICATE OF ANALYSIS

Product Name	: Lidocaine HCl EP		
Batch No.	: MC/LH/0032/23	A.R. No.	: 23FP/0060
Mfg. Date	: Apr - 2023	Sample Qty	: 20 x 5 gm
Exp. Date	: Mar - 2028	Sample Drawn	: 19/04/2023
Batch Size	: 500.0 Kg	Testing Date	: 19/04/2023
Mfg. Lic. No.	: G/25/296	Completion Date	: 20/04/2023

The result of the test / Analysis as per EP-11.0

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.	75°C to 78°C Complies Green color is produced Complies	Between 74 °C to 79 °C IR spectrum of sample match with IR spectrum of standard. A green color must be Produce. Must comply
3.	Appearance of solution	The solution is clear and colourless	Clear and colorless solution
4.	pH	5.20	Between 4.0 to 5.5
5.	Related substance Impurities A Unspecified Impurities Total Impurities	A = 0.0005% Un sp = 0.0014% Total = 0.0028%	NMT 0.01 % NMT 0.10 % NMT 0.5 %
6.	Sulphated Ash	0.03%	NMT 0.1%
7.	Water (by KF) (DETERMINED ON: 0.25G)	6.12%	Between 5.5% and 7.0% w/w
8.	Assay (On anhydrous basis)	99.34%	99.0% To 101.0%
9.	Residual solvent: Acetone Toluene	Acetone : 730.7 ppm Toluene : Not detected	NMT 5000 ppm NMT 890 ppm

Remarks: This product complies with EP 11.0 Specification.

Analysis By	Checked By	Approved By
Sign: @	Sign: [Signature]	Sign: [Signature]
Date: 20/04/23	Date: 20/04/23	Date: 20/04/23
Name: A.J.Patel	Name: V.R.Panchal	Name: H.R.Trivedi
Designation: QC Officer	Designation: QC Manager	Designation: QA Manager

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09/08/2023