F&A PHARMA

Mahendra Chemicals

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Ref. SOP No.: QC 28

CERTIFICATE OF ANALYSIS

Product Name	: Lidocaine HCl EP		
Batch No.	: MC/LH/0005/24	A.R. No.	: 24FP/0005
Mfg. Date	: Jan - 2024	Sample Qty	: 20 x 5 gm
Exp. Date	: Dec - 2028	Sample Drawn	: 08/01/2024
Batch Size	: 500.0 Kg	Testing Date:	: 08/01/2024
Mfg. Lic. No.	: G/25/296	Completion Date	: 12/01/2024

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.	 75.6°C to 77.5°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	5.29	Between 4.0 to 5.5
5.	Related substance Impurity A Unspecified Impurity Total Impurities	 A = 0.0020% Un sp = Not detected Total = 0.0114%	 NMT 0.01 % NMT 0.10 % NMT 0.5 %
6.	Sulphated Ash	0.02%	NMT 0.1%
7.	Water (by KF) (DETERMINED ON 0.25G)	6.88%	Between 5.5% and 7.0% w/w
8.	Assay (On anhydrous basis)	99.64%	99.0% To 101.0%
9.	Residual solvent Acetone Toluene	 Acetone : 803.5 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	Sign
Date 12/01/24	Date 12/01/24	Date 12/01/24
Name : J.B.Patel	Name : V.R.Panchal	Name H.R.Trivedi
Designation : QC Officer	Designation: QC Manager	Designation: QA Manager

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26/02/2024.

COPY QA APPROVED
Date 15.02.24
Signature
F&A PHARMA-Handels GmbH