

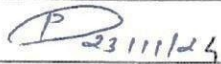
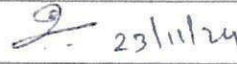
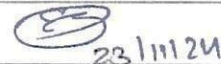
**QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS**

Product	LIDOCAINE	Page No.	01 of 01
Standard for Release	USP (DMF GRADE)	Drug Lic. No.	G/25/1642

Batch No.:	LBAH0501024	Batch Quantity	653.650 Kgs.
Mfg. Date:	OCT-2024	Date of Sampling	04/10/24
Exp. Date:	SEP-2029	Date of Approval	10/10/24
A.R. No.	FP/LB/072/24	Dispatched Quantity	650.000 Kgs.
CAS No.	137-58-6		

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	Description	White or slightly yellow crystalline powder. Has a characteristic odour and stable in air.	White Crystalline Powder.
2.	Solubility	Very soluble in alcohol and in chloroform, freely soluble in benzene and in ether, practically insoluble in water. Dissolves in oils.	Complies
3.	Identification	A) (By IR): The Infrared Spectrum of sample should be concordant with that standard spectrum.	Complies
		B) (By HPLC): The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Complies
4.	Organic Impurities (by HPLC)	Lidocaine related compound H: NMT 0.10 % 2,6-Dimethyl aniline: NMT 0.01 % Any Unspecified Impurity: NMT 0.10 % Total impurities: NMT 0.5 %	0.0003 % 0.0001 % 0.013 % 0.032%
5.	Chloride	Not more than 0.0035 %	Complies
6.	Sulphate	Not more than 0.1 %	Complies
7.	Residue on ignition	Not more than 0.1 % w/w	0.03 %
8.	Assay (By HPLC)	NLT 97.5 % and NMT 102.5 % of C ₁₄ H ₂₂ N ₂ O	99.86 %
9.	Residual solvent (By GC-HS)	Toluene: NMT 890 ppm Benzene: NMT 2 ppm Methylene dichloride: NMT 600 ppm	56 ppm 0.3 ppm ND

Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per USP'2024.

Name	Mr. Pankaj Pateliya	Mr. Somnath Kokate	Mr. Chetan Sardhara
Designation-Dept.	Executive - QC	Sr. Executive - QC	Asst. Manager - QC
Sign. /Date	 23/11/24	 23/11/24	 23/11/24
	Prepared by	Reviewed by	Approved by