



SWATI SPENTOSE PVT. LTD. UNIT-I

Mfg. Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India. Ph.: 0260-2433133, 2401533

CERTIFICATE OF ANALYSIS

Product Name	LIDOCAINE (USP)		Page No.: 1 of 2
Batch No.	LDB/722011	A. R. No.	SS01FP22000054
Batch size	1000.00 Kg	Released on	02/03/2022
Manufacturing Date	Jan-2022	Expiry Date	Dec-2026

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	White or slightly yellow, crystalline powder has a characteristic odor and is 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

IDENTIFICATION

3.	A) By IR	The infrared absorption spectrum of sample Should be concordant with working standard.	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.	Assay by HPLC	Not less than 97.5% and not more than 102.5% of $C_{14}H_{22}N_2O$.	99.2%

IMPURITIES

Inorganic Impurities

5.	Residue on ignition	Not more than 0.1%.	0.040 %
6.	Chloride	Not more than 0.0035%.	Less than 0.0035%
7.	Sulfate	Not more than 0.1%.	Less than 0.1%
8.	Organic Impurities (By HPLC)	2,6-Dimethylaniline: Not more than 0.005%	0.0001 %
		Related compound H: Not more than 0.005%	0.0001%
		Any unspecified impurity: Not more than 0.10%	0.009 %
		Total Impurities: Not more than 0.5%	0.03 %

Activity	Prepared By	Verified By	Approved By
Sign & Date	 09/03/2022	 09/03/2022	 09/03/2022
Name	Mr. Vinith Gawas	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Executive - QA	Sr. Manager - QC	Head-QA



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CERTIFICATE OF ANALYSIS

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9.	Residual Solvent	Toluene: Not more than 890 ppm.	Not detected

CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per **USP-43/In-House** Specifications.

STORAGE CONDITION:

Preserve in well closed container, protected from light. Store at a temperature not exceeding 30 °C. Excursion allowed up to 40°C.

Activity	Prepared By	Verified By	Approved By
Sign & Date	VINITH 09/03/2022	 09/03/2022	 09/03/2022
Name	Mr. Vinith Gawas	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Executive - QA	Sr. Manager - QC	Head-QA