	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/122030	A. R. No.
Batch size	1000.00 Kg	Released on
Manufacturing Date	Sep-2022	Expiry Date
		Aug-2027

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 has characteristic odour and is stable in air
2.	Solubility	Very soluble in Alcohol and in Chloroform; freely soluble in Benzene and in Ether; practically insoluble in Water. Dissolves in oils.	Complies

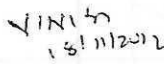
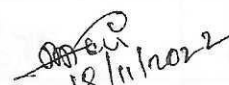
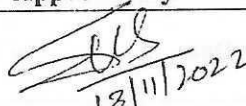
IDENTIFICATION


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 $C_{14}H_{22}N_2O$.	99.1%

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%	BLOQ
		Related compound H: Not more than 0.005%	Not detected
		Any unspecified impurity: Not more than 0.10%	BLOQ
		Total Impurities: Not more than 0.5%	0.01 %

Activity	Prepared By	Verified By	Approved By
Sign & Date	 13/11/2022	 18/11/2022	 18/11/2022
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	

Product Name	LIDOCAINE (USP)		Page No.: 2 of 2
Batch No.	LDB/122030	A. R. No.	SS01FP22000398
Batch size	1000.00 Kg	Released on	29/10/2022
Manufacturing Date	Sep-2022	Expiry Date	Aug-2027

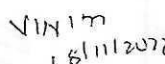

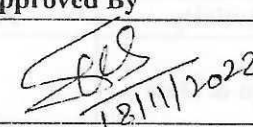
Sr. No.	TEST	SPECIFICATION	RESULTS
9.	*Residual Solvent	Toluene: Not more than 890 ppm.	Not detected

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	 18/11/2022	 18/11/2022	 18/11/2022
Name	Mr. Vinith Gawas	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Executive - QA	Sr. Manager - QC	Head-QA