




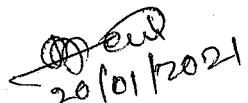

SWATI SPENTOSE PVT. LTD. UNIT-I

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 (BP/EP)		Page No.: 1 of 2
Batch No.	LDB/121007	A. R. No.	FP/21/014
Batch size	877.00 Kg	Released on	20/01/2021
Manufacturing Date	Jan-2021	Expiry Date	Dec-2025

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Appearance	White or almost white, crystalline powder.	White crystalline powder
2.	Solubility	Practically insoluble in Water, very soluble in Ethanol (96%) and in Methylene chloride.	Complies
3.	Identification: First Identification: A, Second Identification: B, C. Note: If First identification performed then Second identification can be omitted.		
	A) IR Spectrum	It should be concordant with Reference/Working standard.	Complies
	B) Melting Point	66°C and 70°C, determined without previous drying	----
	C) Color Test	A Green color is produced.	----
4.	Related Substances (By HPLC)		
	Impurity - A	Not more than 0.005%	Below Detection limit
	Impurity - H	Not more than 0.005%	Not Detected
	Unspecified Impurities	Not more than 0.10%	0.02%
	Total impurities	Not more than 0.5%	0.09%
5.	Chlorides	Maximum 35 ppm	Less than 35 ppm
6.	Sulfates	Not more than 0.1%	Less than 0.1%
7.	Water (By K/F)	Maximum 1.0%	0.33%
8.	Sulphated Ash	Maximum 0.1%	0.03%

Activity	Prepared By	Verified By	Approved By
Sign & Date	 20/01/2021	 20/01/2021	 20/01/2021
Name	Ms. Komal Kumari	Mr. Srihari Pithani	Mr. S.K. Srivastava
Designation	Sr. Officer-QA	Sr. Manager - QC	Head-QA



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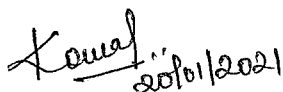
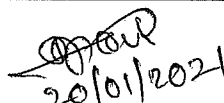
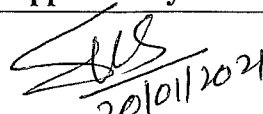
Sr. No.	TEST	SPECIFICATION	RESULTS
9.	Assay (By Titration)	99.0 per cent to 101.0 per cent (Anhydrous substance)	100.0%
10.	Residual Solvent (By GC-HS)	Toluene: Not more than 890 ppm.	0.1 ppm

CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per BP-2019/EP-9.0/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	 20/01/2021	 20/01/2021	 20/01/2021
Name	Ms. Komal Kumari	Mr. Srihari Pithani	Mr. S.K. Srivastava
Designation	Sr. Officer-QA	Sr. Manager - QC	Head-QA