



# 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 HYDROCHLORIDE MONOHYDRATE (BP/EP)		Page No.: 1 of 2
Batch No.	LDH/120084	A. R. No.	FP/20/341
Batch size	1000.00 Kg	Released on	12/10/2020
Manufacturing Date	Nov-2020	Expiry Date	Oct-2025

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Appearance	White or almost white, crystalline powder.	White crystalline powder
2.	Solubility	Very soluble in water, freely soluble in Ethanol (96 per cent).	Complies
3.	<b>Identification</b> First Identification: B, D. Second identification: A, C, D. Note: If First identification performed then Second identification can be omitted.		
	A) Melting point	74 °C to 79 °C, determined without previous drying.	----
	B) IR spectrum	The IR absorption should be concordant with Reference/Working Standard.	Complies
	C) Colour test	A Green color is produced.	----
	D) Chloride test	It gives reaction (a) of chlorides	Complies
4.	Appearance of Solution	Solution S is clear and colorless.	Complies
5.	pH	Between 4.0 and 5.5	5.20
6.	<b>Related Substances (By HPLC)</b>		
	Impurity-A	Not more than 0.005%	0.0006%
	Impurity-H	Not more than 0.005%	Not Detected
	Unspecified impurities	Not more than 0.10%	Below Detection Limit
	Total impurities	Not more than 0.5%	0.02%
7.	Water content	5.5 % to 7.0 %, determined on 0.25 g.	6.06%

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

Nº lote ACOFARMA:

214797

Firma y fecha

07/09/21



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8.	Sulphated ash	Maximum 0.1%, determined on 1.0 g.	0.02%
9.	Assay (By HPLC)	Not less than 99.0% and not more than 101.0% (calculate on anhydrous substance)	99.6%
10.	Residual Solvent (By GC-HS)	Acetone: Not more than 5000 ppm	1410 ppm
		Toluene: Not more than 890 ppm	Below Detection Limit

### CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per BP-2019/EP-9.6/In-House Specification.

❖ CEP No.: R1-CEP 2013-103-Rev 00

### STORAGE CONDITION:

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

Nº lote ACOFARMA:

214797

Firma y fecha:

*Kumari*  
07/01/21

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