



# 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 (EP)		Page No.: 1 of 2
Batch No.	LDH/719008	A. R. No.	FP/19/094
Batch size	1000.00 Kg	Released on	04/04/2019
Manufacturing Date	Mar-2019	Expiry Date	Feb-2024

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%)	Complies
3.	Identification		
	A) Melting point	74°C to 79°C, determined without previous drying.	77.4°C
	B) IR spectrum	Should be concordant with Reference / Working Standard.	Complies
	C) Colour test	A green colour is produced.	Complies
	D) Chloride test	It gives reaction (a) of chlorides.	Complies
4.	Appearance of solution	The solution S should be clear and colourless.	Complies
5.	pH	Between 4.0 and 5.5	5.20
6.	Related Substances (By HPLC)		
	Impurity A	Not more than 0.01%	0.0005%
	Unspecified impurities	Not more than 0.10%	0.03%
	Total impurities	Not more than 0.5%	0.06%
7.	Water content	5.5 % to 7.0 %, determined on 0.25 g.	6.32 %
8.	Sulphated ash	Maximum 0.1%, determined on 1.0 g.	0.03%

Activity	Prepared By	Verified By	Approved By
Sign & Date	<i>Komal</i> 04/04/19	<i>Mukesh</i> 04/04/19	<i>S.K. Srivastava</i> 04/04/19
Name	Ms. Komal Kumari	Mr. Mukesh Patel	Mr. S. K. Srivastava
Designation	Officer-QA	Sr. Executive-QC	Corporate Head-QA & QC



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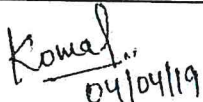
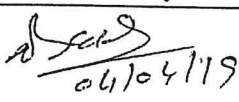
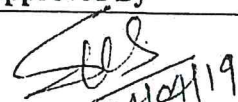
Sr. No.	TEST	SPECIFICATION	RESULTS
9.	Assay (By Titration)	99.0 % to 101.0 % (anhydrous substance)	100.2%
10.	Residual Solvent (By GC-HS)	Acetone: Not more than 5000 ppm	1271 ppm
		Toluene: Not more than 890 ppm	0.58 ppm

### CONCLUSION:

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

### STORAGE CONDITION:

Protected from light.

Activity	Prepared By	Verified By	Approved By
Sign & Date	 04/04/19	 04/04/19	 04/04/19
Name	Ms. Komal Kumari	Mr. Mukesh Patel	Mr. S. K. Srivastava
Designation	Officer-QA	Sr. Executive-QC	Corporate Head-QA & QC