

Lot no: 0190917



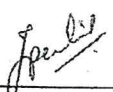
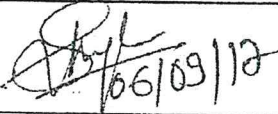
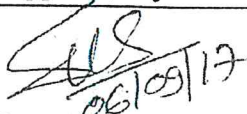
# SWATI SPENTOSE PVT. LTD. UNIT-I

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 (EP)		Page No.: 1 of 2
Batch No.	LDH/117031	A. R. No.	FP/17/189
Batch size	1000.00 Kg	Released on	30/06/2017
Manufacturing Date	Jun-2017	Expiry Date	May-2022

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	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: Between 74°C and 79°C	76°C
		B) IR spectrum: Should be concordant with working standard.	Complies
		C) Colour test: A green colour is produced	Complies
		D) Chloride test: Should be positive	Positive
4.	Appearance of solution	The solution S should be clear and colourless.	Complies
5.	pH	Between 4.0 and 5.5	5.04
6.	Related Substances (By HPLC)		
	Impurity A	Not more than 0.01%	ND
	Unspecified impurities	Not more than 0.10%	0.03%
	Total impurities	Not more than 0.5%	0.03%
7.	Water content	Between 5.5 % and 7.0 % w/w	5.74% w/w
8.	Sulphated ash	Not more than 0.1 % w/w	0.03% w/w

Activity	Prepared By	Verified By	Approved By
Sign & Date	 06/09/17	 06/09/17	 06/09/17
Name	Mr. Jigar Patel	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	Executive-QA	Manager-QC	Corporate Head-QA & QC



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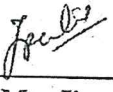
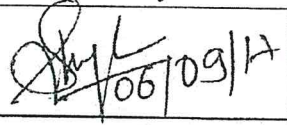
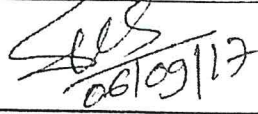
Sr. No.	TEST	SPECIFICATION	RESULTS
9.	Assay (By Titration)	NLT 99.0% and NMT 101.0% (anhydrous substance)	100.1%
10.	Residual Solvent (By GC-HS)	Acetone: Not more than 5000 ppm	1194 ppm
		Toluene: Not more than 890 ppm	Not Detected

#### CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per **EP-9.0** Specification.

#### STORAGE CONDITION:

Protected from light.

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