



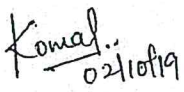
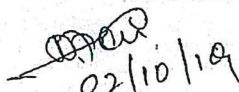

SWATI SPENTOSE PVT. LTD. UNIT-I

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/119044	A. R. No.	FP/19/280
Batch size	1000.00 Kg	Released on	19/09/2019
Manufacturing Date	Sep-2019	Expiry Date	Aug-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	5.12
6.	Related Substances (By HPLC)		
	Impurity-A	Not more than 0.005%	0.0003 %
	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%	0.04 %
7.	Water content	5.5 % to 7.0 %, determined on 0.25 g.	6.37 %

Activity	Prepared By	Verified By	Approved By
Sign & Date	 02/10/19	 02/10/19	 02/10/19
Name	Ms. Komal Kumari	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Officer-QA	Sr. Manager-QC	Corporate Head-QA & QC



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8.	Sulphated ash	Maximum 0.1%, determined on 1.0 g.	0.03%
9.	Assay (By Titration)	99.0 % to 101.0 % (anhydrous substance)	100.3 %
10.	Residual Solvent (By GC-MS)	Acetone: Not more than 5000 ppm	1207 ppm
		Toluene: Not more than 890 ppm	0.46 ppm

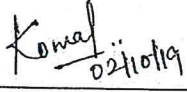
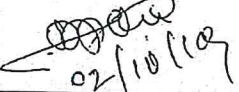

CONCLUSION:

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

❖ CEP No.: RO-CEP 2013-103-Rev 01

STORAGE CONDITION:

Protected from light.

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Sign & Date	 02/10/19	 02/10/19	 02/10/19
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Designation	Officer-QA	Sr. Manager-QC.	Corporate Head-QA & QC