



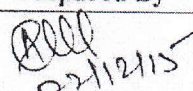
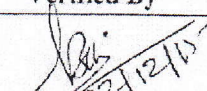
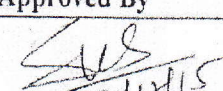
# SWATI SPENTOSE PVT. LTD. UNIT-I

Manufacturing Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C., Vapi-396 195, Gujarat, India

## QUALITY ASSURANCE DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name	LIDOCAINE HYDROCHLORIDE (EP)	Page No.: 1 of 2
Batch No.	LDH/115057	A. R. No.
Batch size	1175.00 Kg	Released on
Manufacturing Date	Dec-2015	Expiry Date
		Nov-2020

TEST	SPECIFICATION	RESULTS
Description	White or almost white, crystalline powder.	White crystalline powder.
Solubility	Very soluble in water, freely soluble in ethanol (96 %).	Complies
Identification	A) Melting point: Between 74°C and 79°C B) IR spectrum: Should be concordant with Working standard. C) Colour test: A green colour is produced D) Chloride test: Should be positive	A) Melting point 77°C B Complies C) Complies D) complies
Appearance of solution	The solution S should be clear and colourless.	Solution is clear and colourless.
pH	Between 4.0 and 5.5	5.13
Related Substances (By HPLC)	Impurity A: Not more than 0.01 % Unspecified Impurities: Not more than 0.10 % Total impurities: Not more than 0.5 %	0.001% 0.01% 0.04%
Heavy metals	Not more than 5 ppm	Less than 5 ppm
Water content	Between 5.5 % and 7.0 % w/w	6.33 %w/w
Sulphated ash	Not more than 0.1 % w/w	0.03%w/w

	Prepared By	Verified By	Approved By
Sign & Date	 22/12/15	 22/12/15	 22/12/15
Name	Mr. Amit Dwivedi	Mr. Vinod Bais	Mr. S. K. Srivastava
Designation	Officer-QA	Manager-QC	Corporate Head-QA & QC





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### QUALITY ASSURANCE DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name	LIDOCAINE HYDROCHLORIDE (EP)		Page No.: 2 of 2
Batch No.	LDH/115057	A. R. No.	FP/15/292
Batch size	1175.00 Kg	Released on	22/12/2015
Manufacturing Date	Dec-2015	Expiry Date	Nov-2020

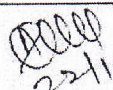
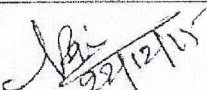
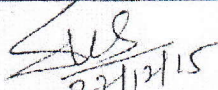
TEST	SPECIFICATION	RESULTS
Assay (By titration)	Not less than 99.0 % and not more than 101.0 % (anhydrous substance)	99.6 %
Residual Solvent (By GC-HS)	Acetone: Not more than 5000 ppm Toluene: Not more than 890 ppm	346 ppm Nil

#### CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per EP-8.5 specification.

#### STORAGE CONDITION:

Protected from light.

	Prepared By	Verified By	Approved By
Sign & Date	 22/12/15	 22/12/15	 22/12/15
Name	Mr. Amit Dwivedi	Mr. Vinod Bais	Mr. S. K. Srivastava
Designation	Officer-QA	Manager-QC	Corporate Head-QA & QC