



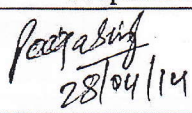
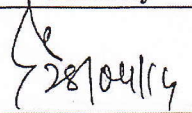
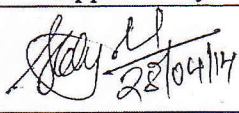
SWATI SPENTOSE PVT. LTD. UNIT-I

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 / 114031	A. R. No.	FP / 14 / 087
Batch size	1200 Kgs	Released on	28/04/2014
Manufacturing Date	Apr - 2014	Expiry Date	Mar - 2019

TEST	SPECIFICATION	RESULTS
Description	White or almost white, crystalline powder.	White, crystalline powder.
Solubility	Very soluble in water, freely soluble in ethanol (96 %).	Very soluble in water, freely soluble in ethanol (96 %).
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 78°C B) IR spectrum: Concordant with working standard. C) Colour test: A green colour is produced. D) Chloride test: positive.
Appearance of solution	The solution S is clear and colourless.	Solution is clear and colourless.
pH	Between 4.0 and 5.5	5.14
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 %	0.005% 0.013 % 0.039 %
Heavy metals	Not more than 5 ppm	Less than 5 ppm
Water content	Between 5.5 % and 7.0 % w/w	6.50 % w/w
Sulphated ash	Not more than 0.1 % w/w	0.05 % w/w

	Prepared By	Verified By	Approved By
Sign & Date	 28/04/14	 28/04/14	 28/04/14
Name	Ms. Pooja Singh	Mrs. Bhakti Patel	Mr. S.V. Padwal
Designation	QA Officer	QC Manager	QA Manager



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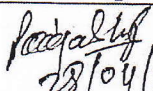
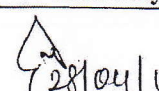
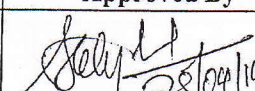
TEST	SPECIFICATION	RESULTS
Assay (by titration)	Not less than 99.0 % and not more than 101.0 % (anhydrous substance)	99.57 %
Residual Solvent (By GC-HS)	Acetone - Not more than 5000 ppm Toluene - Not More Than 890 ppm	1303.3 ppm 20.7 ppm

CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per EP-8.0 specification.

STORAGE CONDITION:

Protected from light.

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