FARMA-QUIMICA SUR S.L.

LOTE FARMAQUIMICA:	4332/5
FECHA ACEPTACIÓN Rep. GC:	19/12/14

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/114041	A. R. No.	FP / 14 / 159
Batch size	1125 Kgs	Released on	09/09/2014
Manufacturing Date	July - 2014	Expiry Date	June - 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 76.4°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	5.12
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 %	Not Detected 0.071% 0.071 %
Heavy metals	Not more than 5 ppm	Less than 5 ppm
Water content	Between 5.5 % and 7.0 % w/w	6.89 % w/w
Sulphated ash	Not more than 0.1 % w/w	0.04 % w/w

	Prepared By	Verified By	Approved By	Authorized By
Sign & Date	09/09/14	09/09/14	09/09/14	09/09/14
Name	Mr. Mithlesh Soni	Mrs. Khyati Desai	Mr. S.V. Padwal	Mr. Prashant Wadalkar
Designation	QA Officer	Sr. Executive QC	QA Manager	Head-Pharma

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TEST	SPECIFICATION	RESULTS
Assay (by titration)	Not less than 99.0 % and not more than 101.0 % (anhydrous substance)	99.41 %
Residual Solvent (By GC-HS)	Acetone - Not more than 5000 ppm Toluene - Not More Than 890 ppm	1325.4 ppm 4.4 ppm

CONCLUSION:

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

STORAGE CONDITION:

Protected from light.

	Prepared By	Verified By	Approved By	Authorized By
Sign & Date	09/09/14	09/09/14	09/09/14	09/09/14
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Designation	QA Officer	Sr. Executive QC	QA Manager	Head-Pharma