



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 (EP)	Page No. 1 of 1
Batch No.	LDB/114007	A. R. No. FP / 14 / 025
Batch size	562 kg	Released on 13/08/2014
Manufacturing Date	Jan - 2014	Expiry Date Dec - 2018

TEST	SPECIFICATION	RESULT
Characteristics	White or almost white, crystalline powder.	A white crystalline powder
Solubility	Practically insoluble in water, very soluble in ethanol (96%) and in Methylene chloride.	Practically insoluble in water, very soluble in ethanol (96%) and in Methylene chloride.
Identification	A) IR Spectrum: It should be concordant with working standard. B) Melting point: Between 66°C and 70°C C) Color Test : A green color develops.	A) IR Spectrum: Is concordant with working standard. B) Melting point: 68°C C) Color Test: Positive.
Related Substances (By HPLC)	Impurity A: Not more than 0.01% Individual unknown Impurity: Not more than 0.10% Total impurities: Not more than 0.5%	0.001% 0.06% 0.07%
Chloride	Not more than 35 ppm	Less than 35 ppm
Sulphate	NMT 0.1%	Complies
Water (By K/F)	Not more than 1.0% w/w	0.14%
Sulphated Ash	Not more than 0.1 % w/w	0.06%
Assay (By Titration)	Not less than 99.0% and not more than 101.0%(Calculated on anhydrous basis)	99.87%
Residual Solvent (By GC-HS)	Toluene NMT 890 ppm	63.1 ppm

CONCLUSION:

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

STORAGE CONDITION:

Protected from light.

Sign & Date	Prepared By	Verified By	Approved By	Authorized By
	 13/08/14	 13/08/14	 13/08/14	 13/08/14
Name	Ms. Pooja Singh	Mrs. Bhakti Patel	Mr. S.V. Padwal	Mr. Prashant Wadalkar
Designation	QA Officer	QC Manager	QA Manager	Head-Pharma