



Swati Spentose Pvt.Ltd. Unit-I  
Plot No.- A-1/2102, 2103 & A-2/2120, Phase-III, G.I.D.C,  
Vapi-396195, Dist-Valsad,  
Gujarat. India. Ph. No. 0260-2433133

### Certificate Of Analysis

Product Name: Lidocaine BP/EP

Product Name	Lidocaine BP/EP	A.R. No.	SS01FP23000832
Batch No.	LDB/723032	Date of Release	06/12/2023 18:07
Batch Size	856.000 Kg	Storage Condition	NMT 30°C & Excursion upto 40°C
Mfg. Date	Oct/2023	Expiry Date	Sep/2028

S. No.	TEST	SPECIFICATION	RESULT
1	Appearance	White or almost white crystalline powder	White crystalline powder.
2	Solubility		
2.1	In Water	Practically Insoluble in Water	Practically Insoluble in Water.
2.2	In Ethanol	Very Soluble in Ethanol (96%)	Very Soluble in Ethanol (96%).
2.3	In Methylene Chloride	Very Soluble in Methylene Chloride	Very Soluble in Methylene Chloride.
3	Identification By Infrared Absorption (By IR)	The Infrared absorption spectrum of sample should be concordant with the standard spectrum of lidocaine.	The Infrared absorption spectrum of sample is concordant with the standard spectrum of lidocaine.
4	Identification By Melting Point	66°C to 70°C determined without previous drying	67.3°C
5	Identification By Color Test	A Green color develops	A Green color develop.
6	Related Substances (By HPLC)		
6.1	Impurity-A	Not More Than 0.005%	Not Detected
6.2	Impurity-H	Not More Than 0.005%	Not Detected
6.3	Unspecified Impurities	Not More Than 0.10%	0.0252 %
6.4	Total Impurities	Not More Than 0.5%	0.03 %
7	Chlorides	Maximum 35 ppm	Less than 35 ppm.
8	Sulfates	Maximum 0.1%	Less than 0.1%
9	Water	Maximum 1.0%	0.05 %
10	Sulfated Ash	Maximum 0.1%	0.038 %
11	Residual Solvent (By GC-HS)		
11.1	Toluene	Not More Than 890 ppm	0 ppm
12	Assay (By Titration)	Between 99.0% and 101.0% (anhydrous substance)	99.9 %

Remarks: APPROVED (Sample Conforms to above Specification)

STORAGE CONDITION: Preserve in well closed container, protected from light. Store at a temperature not exceeding 30°C. Excursion allowed up to 40°C. \*CEP No: - R1-CEP 2013-138-Rev 00

<b>Prepared By</b>		<b>Reviewed By</b>	<b>Approved By</b>
Ayush.Patel(QA Executive / Desig)		Vinith.Gawas(QA Manager / Designe)	P.N.Rao(Quality Head)
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