

## SWATI SPENTOSE PVT. LTD. UNIT-I

Mfg. Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India. Ph.: 0260-2433133, 2401533

CERTIFICATE OF ANALYSIS

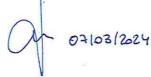
Product Name	LIDOCAINE (BP/EP)		Page No.: 1 of 2
Batch No.	LDB/723003	A. R. No.	SS01FP23000087
Batch size	1000.00 Kg	Released on	24/02/2023
Manufacturing Date	Jan-2023	Expiry Date	Dec-2027

Sr. No.	TEST	SPECIFICATION RESULT				
1.	Appearance	White or almost white, crystalline powder.	White crystalline powder			
2.	Solubility Practically insoluble in Water, very soluble in Ethanol and in Methylene chloride.		Complies			
	Identification					
3.	A) IR Spectrum	It should be concordant with Reference/Working standard.	Complies			
	B) Melting Point	66°C and 70°C, determined without previous drying	67.0°C			
*	C) Color Test	A Green color is produced.	Complies			
	Related Substances (By HPLC)					
	Impurity - A	Not more than 0.005%	Not Detected			
4.	Impurity - H	Not more than 0.005%	Not Detected			
	Unspecified Impurities	Not more than 0.10%	0.0077%			
	Total impurities	Not more than 0.5%	0.02%			
5.	Chlorides	Chlorides Maximum 35 ppm				
6.	Sulfates	Not more than 0.1%	Less than 0.1 %			
7.	Water (By K/F)	Vater (By K/F) Maximum 1.0% 0.11%				

Activity	Prepared By	Verified By	Approved By
Sign & Date	11×11×123	03/06/2023	03/06/2029
Name	Mr. Vinith Gawas	Mr.Srihari Pithani	Mr. S. K. Srivastava
Designation	Executive-QA	Sr. Manager - QC	Head-QA

METAPHARMACEUTICAL

N DE LOTE:





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Sr. No. TEST		SPECIFICATION	RESULTS	
8.	Sulphated Ash	Maximum 0.1%	0.04%	
9.	Assay (By Titration)	99.0 per cent to 101.0 per cent (Anhydrous substance)	100.2%	
10.	Residual Solvent (By GC-HS)  Toluene: Not more than 890 ppm.		Not detected	

## CONCLUSION:

In opinion of the undersigned, the above mentioned product COMPLIES as per BP-2022/EP-11.0 Specifications.

## STORAGE CONDITION:

Preserve in well closed container, Protected from light, Store at a temperature not exceeding  $30^{\circ}\text{C}$  ,Excursion allowed upto  $40^{\circ}\text{C}$ 

CEP no: R1-CEP 2013-138-Rev 00

Activity	Prepared By	Verified By	Approved By
Sign & Date	MNIM	-0000 1202A	018
Name	Mr. Vinith Gawas	Mr.Srihari Pithani	Mr. S. K. Srivastava
Designation	Executive-QA	Sr. Manager - QC	Head-QA

METAPHARMACEUTICAL