

METAPHARMACEUTICAL

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14/04/2023



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/722032	A. R. No. SS01FP22000567
Batch size	1000.00 Kg	Released on 25/01/2023
Manufacturing Date	Dec-2022	Expiry Date Nov-2027

Sr. No.	TEST	SPECIFICATION	RESULTS
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
3.	Identification		
	A) IR Spectrum	It should be concordant with Reference/Working standard.	Complies
	B) Melting Point	66°C and 70°C, determined without previous drying	67.3°C
	C) Color Test	A Green color is produced.	Complies
4.	Related Substances (By HPLC)		
	Impurity - A	Not more than 0.005%	Not Detected
	Impurity - H	Not more than 0.005%	Not Detected
	Unspecified Impurities	Not more than 0.10%	0.007%
	Total impurities	Not more than 0.5%	0.02%
5.	Chlorides	Maximum 35 ppm	Less than 35 ppm
6.	Sulfates	Not more than 0.1%	Less than 0.1 %
7.	Water (By K/F)	Maximum 1.0%	0.09%

Activity	Prepared By	Verified By	Approved By
Sign & Date	VINITH 30/01/2023	30/01/2023	30/01/2023
Name	Mr. Vinith Gawas	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Executive-QA	Sr. Manager - QC	Head-QA

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8.	Sulphated Ash	Maximum 0.1%	0.03%
9.	Assay (By Titration)	99.0 per cent to 101.0 per cent (Anhydrous substance)	100.1%
10.	Residual Solvent (By GC-HS)	Toluene: Not more than 890 ppm.	Not detected

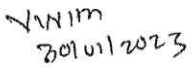
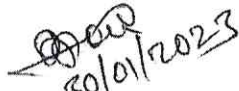
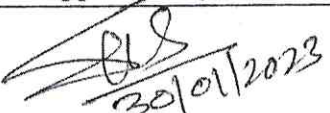
CONCLUSION:

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°C ,Excursion allowed upto 40°C

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

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Sign & Date	 30/01/2023	 30/01/2023	 30/01/2023
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