

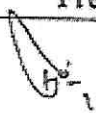
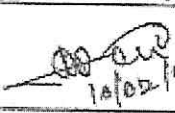
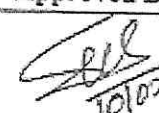
SWATI SPENTOSE PVT. LTD. UNIT-I

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 (EP)	Page No.: 1 of 2
Batch No.	LDB/120020	A. R. No.
Batch size	890.00 Kg	Released on
Manufacturing Date	Sep-2020	Expiry Date
		Aug-2025

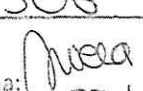
Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Appearance	White or almost white, crystalline powder.	White crystalline powder
2.	Solubility	Practically insoluble in Water, very soluble in Ethanol (96%) and in Methylene chloride.	Complies
3.	Identification: First Identification: A, Second Identification: B, C. Note: If First identification performed then Second identification can be omitted.		
	A) IR Spectrum	It should be concordant with Reference/Working standard.	Complies
	B) Melting Point	66°C and 70°C, determined without previous drying	----
	C) Color Test	A Green color is produced.	----
4.	Related Substances (By HPLC)		
	Impurity - A	Not more than 0.005%	Below Detection Limit
	Impurity - H	Not more than 0.005%	Not Detected
	Unspecified Impurities	Not more than 0.10%	0.05%
	Total impurities	Not more than 0.5%	0.08%
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%	0.21%
8.	Sulphated Ash	Maximum 0.1%	0.02%

Activity	Prepared By	Verified By	Approved By
Sign & Date	 10/02/2021	 10/02/2021	 10/02/2021
Name	Mr. Himanshu Rai	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Officer-QA	Sr. Manager-QC	Head-QA

Nº lote ACOFARMA:

213506

Firma y fecha:

 29/06/21



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 (EP)		Page No.: 2 of 2
Batch No.	LDB/120020	A. R. No.	FP/20/258
Batch size	890.00 Kg	Released on	28/09/2020
Manufacturing Date	Sep-2020	Expiry Date	Aug-2025

Sr. No.	TEST	SPECIFICATION	RESULTS
9.	Assay (By Titration)	99.0 per cent to 101.0 per cent (Anhydrous substance)	100.1%
10.	Residual Solvent (By GC-MS)	Toluene: Not more than 890 ppm.	3 ppm

CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per EP-10/In-house Specifications.

❖ CEP no.: R1-CEP 2013-138-Rev 00

STORAGE CONDITION:

Preserve in well closed container, protected from light. Store at a temperature not exceeding 30 °C. Excursion allowed up to 40°C.

Nº lote ACOFARMA:
2J3506
Firma y fecha: [Signature]
29/06/21

Activity	Prepared By	Verified By	Approved By
Sign & Date	<u>[Signature]</u> 10/02/2021	<u>[Signature]</u> 10/02/2021	<u>[Signature]</u> 10/02/2021
Name	Mr. Himanshu Rai	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Officer-QA	Sr. Manager-QC	Head-QA