



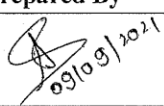
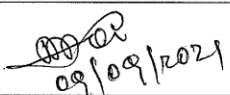
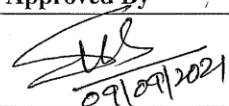
SWATI SPENTOSE PVT. LTD. UNIT-I


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	Prilocaine Hydrochloride (USP)		Page No.: 1 of 2
Batch No.	PRH/121002	A. R. No.	SS01FP21000031
Batch size	167.00 Kg	Released on	08/09/2021
Manufacturing Date	Aug-2021	Retest Date	Jul -2025

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	White, odorless, crystalline powder, having a bitter taste.	White crystalline powder
2.	Solubility	Freely soluble in water and in alcohol; slightly soluble in chloroform; very slightly soluble in acetone; practically insoluble in ether.	Complies
Identification			
3.	A. Infrared Absorption By IR	The IR absorption should be concordant with Reference / Working Standard	Complies
	B. Chloride test	Chloride Should be Positive.	Complies
	C. By HPLC	The retention time of the major peak of the sample solution corresponds to that of standard solution as obtained in assay.	Complies
4.	Assay (By HPLC)	Prilocaine Hydrochloride contain NLT 98.0% and NMT 102.0% of Prilocaine hydrochloride (C ₁₃ H ₂₀ N ₂ O.HCl), calculated on the dried basis.	99.4 %
IMPURITIES			
Inorganic Impurities			
5.	Residue on Ignition	Not more than 0.1%	0.02 %
SPECIFIC TESTS			
6.	Loss on Drying at 105°C for 4 hours	Not more than 0.3%	0.22 %

Activity	Prepared By	Verified By	Approved By
Sign & Date	 09/09/2021	 09/09/2021	 09/09/2021
Name	Mrs. Anisha Tiwari	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Sr. Officer-QA	Sr. Manager - QC	Head-QA

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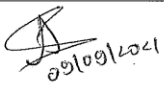
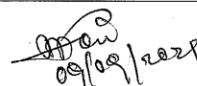
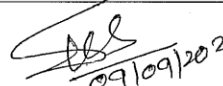
Sr. No.	TEST	SPECIFICATION	RESULTS
7.	Organic Impurities By HPLC	Prilocaine Related compound A: NMT 0.01%	0.002 %
		Any individual unspecified impurity : NMT 0.10%	0.044 %
		Total impurities: NMT 0.2%	0.10 %
8.	Residual solvents (By GC-HS)		
	Acetone	Not more than 5000 ppm	1121 ppm
	Isopropyl Alcohol	Not more than 5000 ppm	194 ppm
	Toluene	Not more than 890 ppm	271 ppm

CONCLUSION:

In opinion of the undersigned, the above-mentioned product **COMPLIES** as per **USP-43/In-House** Specification.

STORAGE CONDITION:

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

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Sign & Date	 09/09/2021	 09/09/2021	 09/09/2021
Name	Mrs. Anisha Tiwari	Mr. Srihari Pithani	Mr. S. K. Srivastava
Designation	Sr. Officer-QA	Sr. Manager - QC	Head-QA