



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Tetracaine Hydrochloride USP	CAS No:	136-47-0
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White, fine crystalline, odorless powder.	White crystalline powder.
2	Solubility	Very soluble in water; Soluble in alcohol; insoluble in ether and in benzene	Very soluble in water; Soluble in alcohol; insoluble in ether and in benzene.
3	Identification (IR)	Spectrum should be concordant with Reference/ working standard of Tetracaine hydrochloride.	IR Spectrum concordant with working standard.
4	Identification HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	complies
5	Identification chloride test	White curdy precipitate that is insoluble in nitric acid but is soluble in slight excess of 6N ammonium hydroxide.	complies
6	Residue on ignition	NMT 0.1%	0.03%
7	Water content	NMT 2.0%	0.32%
8	Aminobenzoic acid	NMT 0.4%	0.03%
9	Tetracaine Related Compound-B	NMT 0.4%	0.01%
10	Tetracaine Related Compound-C	NMT 0.4%	Not Detected
11	Individual Unspecified impurity	NMT 0.4%	0.05%
12	Total impurities	NMT 0.8%	0.13%
13	Assay By HPLC	NLT 98.0% and NMT 102.0% of Tetracaine Hydrochloride calculated on anhydrous basis	100.0%
14	Opinion / Compliance	In the opinion of the undersigned, the above-mentioned sample is of Standard Quality. The above-mentioned sample Complies with prescribed specification as per USP-2022	-

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By Sonali Nirmal	Checked by Dadarao Kakde	Approved By Nayna Nehete	
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Date: 23/05/2026

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