

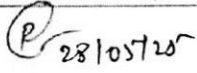
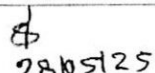
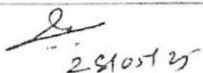
QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product	BENZOCAINE	Page No.	01 of 01
Standard for Release	USP (DMF GRADE)	Drug Lic. No.	G/25/1642

Batch No.	BCAH0240525	Batch Quantity	652.000 Kgs.
Mfg. Date	MAY-2025	Date of Sampling	25/05/25
Exp. Date	APR-2030	Date of Approval	28/05/25
A.R. No.	FP/BC/043/25	Dispatched Qty.	650.000 Kgs.
C.A.S. No.	94-09-7		

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	Description	Small, white crystals or white crystalline powder, odourless	White crystalline powder.
2.	Solubility	Freely soluble in ethanol, in chloroform, and in ether; sparingly soluble in almond oil and in olive oil; very slightly soluble in water. Dissolves in dilute acids.	Complies
3.	A. Identification (By IR)	The infrared spectrum of sample should be concordant with that standard of Benzocaine.	Complies
	B. Identification (By 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
4.	Organic Impurities (By HPLC)	Amino benzoic acid: NMT 0.10% Ethyl 4-nitrobenzoate: NMT 0.10% Any other unspecified impurity: NMT 0.10% Total Impurities: NMT 1.0 %	ND ND 0.016 % 0.033 %
5.	Chlorides	No turbidity is produced immediately.	Complies
6.	Loss on drying	Not more than 1.0 %	0.20 %
7.	Residue on ignition	Not more than 0.1 %	0.02 %
8.	Assay (By HPLC)	Between 98.0% and 102.0% (on dried basis)	99.89 %
9.	Residual Solvents (By GC-HS)	Ethanol: NMT 5000 ppm Methanol: NMT 3000 ppm Toluene: NMT 890 ppm Benzene: NMT 2 ppm	ND ND ND ND
10.	Particle Size (Dry Method)	100 % passes through 400 mesh	Complies

Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per USP'2024.

Name	Mr. Rahul Girase	Mr. Manoj Salunke	Mr. Somnath Kokate
Designation-Dept.	Officer-QC	Executive-QC	Sr. Executive-QC
Sign. /Date	 28/05/25	 28/05/25	 28/05/25
	Prepared by	Reviewed by	Approved by

Mfg. Site Address: Plot no. 4710, 4711, 4707-A/8, 4707-A/9, GIDC Industrial Estate Ankleshwar,
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