

**QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS**

Product	BENZOCAINE	CEP No.	R0-CEP 2022-102-Rev 00
Standard for Release	EP (CEP GRADE)	Drug Lic. No.	G/25/1642

Batch No.	BCAH0851025	Batch Quantity	652.950 Kgs.
Mfg. Date	OCT-2025	Date of Sampling	10/10/25
Exp. Date	SEP-2030	Date of Approval	13/10/25
A.R. No.	FP/BC/139/25	Dispatched Qty.	25.000 Kgs.
C.A.S. No.	94-09-7		

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	Description	White or almost white, crystalline powder or colorless crystals.	White crystalline powder
2.	Solubility	Very slightly soluble in water, freely soluble in ethanol (96 %).	Complies
3.	A. Identification (By IR)	The infrared absorption spectrum of Benzocaine is concordant with the reference spectrum.	Complies
	B. Identification (By Melting Point)	Determination- A: 89° C to 92° C Determination- B: the absolute difference between the melting point of the mixture and the value obtained in determination A is not greater than 2° C.	90.5 ° C 0.1 ° C
4.	Related Substances	Unspecified impurities: NMT 0.10 % Total impurities: NMT 0.2 %	BDL BDL
5.	Loss on drying	Not more than 0.5 % w/w	0.19 %
6.	Sulphated Ash	Not more than 0.1 % w/w	0.03 %
7.	Assay	Between 99.0 % and 101.0 %	99.59 %
8.	Residual Solvents (By GC-HS)	Ethanol: NMT 5000 ppm Methanol: NMT 3000 ppm Toluene: NMT 890 ppm Benzene: NMT 2 ppm	ND 241 ppm 1.6 ppm ND

Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per EP^{11.6}.

Name	Mr. Manoj Salunke	Mr. Somnath Kokate	Mr. Samir Mehta
Designation-Dept.	Executive-QC	Sr. Executive-QC	Manager-QC
Sign. /Date	<i>Manoj</i> 15/10/25	<i>Somnath</i> 15/10/25	<i>Samir</i> 15/10/25
	Prepared by	Reviewed by	Approved by