

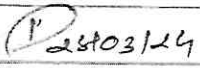
**QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS**

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

Batch No.	BCAH0181023	Batch Quantity	631.450 Kgs.
Mfg. Date	OCT-2023	Date of Sampling	29/10/23
Exp. Date	SEP-2028	Date of Approval	19/12/23
A.R. No.	FP/BC/053/23	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	Complies
3.	A. Identification (By IR)	The infrared absorption spectrum of Benzocaine is concordant with the reference spectrum.	Complies
	B. Identification (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° C 1° C
4.	Related Substances (By HPLC)	Unspecified impurities: NMT 0.1 % Total impurities: NMT 0.2 %	0.05 % 0.09 %
5.	Loss on drying	Not more than 0.5 % w/w	0.17 %
6.	Sulphated Ash	Not more than 0.1 % w/w	0.04 %
7.	Assay	Between 99.0 % and 101.0 %	99.85 %
8.	Residual solvent	Ethanol: 5000 ppm Methanol: 3000 ppm Toluene: 890 ppm Benzene: 2 ppm	2 ppm 162 ppm 1 ppm ND

Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per EP'11.0.

Name	Mr. Rushil Kalariya	Mr. Pankaj Pateliya	Mr. Chetan Sardhara
Designation Dept.	Sr. Officer-QC	Executive-QC	Asst. Manager-QC
Sign. /Date	 28/10/24	 28/10/24	 28/10/24
	Prepared by	Reviewed by	Approved by

Mfg. Site Address: Plot No.- 4710,4711, 4707-A/8, 4707-A/9, GIDC Industrial Estate, Ankleshwar, Dist.- Bharuch- 393 002, Gujarat, India, Phone no.: +91 2646 222525/223525/227289.