

**ALKALI METALS LIMITED.,**

Plot.No.36, 37&amp;38, J.N. PharmaCity, Parawada, Visakhapatnam-531 021.

**Manufactured For THINQ PHARMA-CRO LIMITED****CERTIFICATE OF ANALYSIS (R1)**

<b>Name of the Product :</b>	Benzocaine USP		
<b>Batch No:</b>	BNZ 22040016	<b>Dispatched Qty.:</b>	150.00Kg
<b>Date of Manufacturing:</b>	October - 2021	<b>Date of Expiry/Retest:</b>	September - 2025
<b>Analytical Report No.:</b>	CB/0017/22	<b>Date of Analysis:</b>	13/04/2022
<b>Release Date:</b>	08/09/2022	<b>Page No:</b>	1 of 2
<b>Reference Specification No.:</b> AML/FPS/BZ3006-02			

S.No	Tests	Specifications	Results
1	<b>Description</b>	Small, white crystals or white crystalline powder.	White crystalline powder
2	<b>Solubility</b>	Very slightly soluble in water, freely soluble in alcohol, in chloroform and in ether. Dissolves in dilute acids.	Complies
3	<b>Identification</b>		
	a) By Infrared absorption	The infrared absorption spectrum of sample as potassium bromide dispersion should be concordant with similarly recorded spectrum of benzocaine working standard.	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	<b>Loss on drying (% w/w)</b>	Not more than 0.5	0.11
5	<b>Residue on ignition (% w/w)</b>	Not more than 0.1	0.02
6	<b>Chloride</b>	No turbidity is produce immediately	Complies
7	<b>Heavy metals (ppm)</b>	Not more than 10	Less than 10

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AML/QCD-003/F-01/00

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S.No	Tests	Specifications	Results
8	<b>Organic impurities (% w/w)</b>		
	Amino benzoic acid	Not more than 0.10	Not Detected
	Ethyl 4-nitrobenzoate	Not more than 0.10	Not Detected
	Any other unspecified impurity	Not more than 0.10	0.04
	Total impurities	Not more than 1.0	0.06
9	Assay by HPLC (% w/w on dried basis)	Not less than 98.0 to Not more than 102.0	99.7
<b>Additional test if any:</b>			
10	<b>Residual solvents (ppm)</b>		
	Ethanol	Not more than 5000	Not Detected
	Toluene	Not more than 890	71

Remarks: The Product **Complies** / ~~Does not comply~~ as per above specifications.

	Prepared By	Reviewed By	Released By
Name	T. Ramesh	R. Ravi	M.V.N. Satyanarayana
Signature	(R)	R. Ravi	(M.V.N.)
Date	08/09/2022	08/09/2022	08/09/2022

AML/QCD-003/F-01/00

