



Specification For Finished Product	Spec No.: SPE-BEN-FP-001-01	Effective Date : 07/08/2021
	Supersedes : NA	Review Date : 06/08/2023
	Material code : NA	Reference : USP 43
Product Name :	Benzocaine	Page No.: 1 of 1

Sr. No	Test	Specification
1.0	Description	Colourless or White crystalline powder
2.0	Identification	
2.1	By IR	The IR absorption spectrum of the sample must be concordant with the working standard of Benzocaine
2.2	By HPLC	The retention time of the major peak of the sample solution corresponds to that standard solution, as obtained in the Assay.
2.3	Chloride Test	No Turbidity produces immediately
3.0	Loss on Drying (%w/w)	Not more than 1.0%
4.0	Residue on ignition (%w/w)	Not more than 0.1%
5.0	Related substances by HPLC	
5.1	Amino benzoic Acid	Not more than 0.1%
5.2	Ethyl-4-nitrobenzoate	Not more than 0.1%
5.3	Any other Unspecified Impurity	Not more than 0.1%
5.4	Total impurities	Not more than 1.0%
6.0	Assay on dried basis	Not less than 98.0% and Not more than 102.0%
7.0	Residual solvents	
7.1	Ethanol	Not more than 5000 ppm
7.2	Isopropyl alcohol	Not more than 5000 ppm

Remark:

History of revision :

Revision No	Effective Date	Details
00	07/08/2021	Original issue

Prepared by (Sign & Date)	Review by (Sign & Date)	Approved by (Sign & Date)
 07/08/2021	N. S. Patel 07/08/2021	 07/08/2021