

CERTIFICATE OF ANALYSIS
Benzocaine USP

TEST	RESULT	METHOD REFERENCE	SPECIFICATION
Description	White crystalline powder. Is odourless, is stable in air.	USP	Small white crystals or white, crystalline powder. Is odourless, is stable in air, and exhibits local anesthetic properties when place upon the tongue.
Solubility	Complies	USP	Very slightly soluble in water, freely soluble in alcohol, in chloroform and in ether. Sparingly soluble in almond oil and olive oil. Dissolves in dilute acids.
Identification A.IR	Concordant	USP<197K>	IR spectrum of the sample dispersed in KBr shall be concordant with that of working standard.
A.UV Absorbance	Complies	USP<197U>	Absorptiviteis at 278nm calculated on the dried basis do not differ by more than 3%.
A.Color Reaction	Complies	USP	An orange-red precipitate is formed.
Melting Range	89 - 91	USP Class I<741>	Between 88-92°C (end of melting does not exceed 2°C)
Reaction	Complies	USP	A red color is produced.
Loss on Drying	0.31	USP <731>	Not more than 1.0% w/w (dry it over phosphorous pentoxide for 3hrs)
Readily Carbonizable Substances	Complies	USP <271>	The solution has no more color than matching fluid A.
Residue on Ignition	0.05	USP <281>	Not more than 0.1% w/w
Chloride	Complies	USP	No turbidity produced immediately.
Heavy Metals	Less than 0.001	USP<231> Method-II	Not more than 0.001%
Ordinary Impurities	Less than 1	USP<466>	Not more than 1%
Assay	99.4	USP	Not less than 98.0% and not more than 102.0% w/w (dried over phosphorous pentoxide for 3 hrs)
Additional Test: Particle Size 80 mesh (180 microns) passes through	Complies	In house	Less than 100%

REMARKS: The product conforms to USP & Customer's specification.

* Data based on manufacturer's document

Josh

Quality Control

