

SAMPLE CERTIFICATE OF ANALYSIS

Product: PROPYL PARABEN USP/NF
Package Size: 55.115 LB DRUM

Certificate Date:
Manufacture Date:
Recertification Date:

Lot Number:

THE FOLLOWING VALUES HAVE BEEN PROVIDED BY THE MANUFACTURER OF THIS PRODUCT.

Characteristic	Specification	Result
Appearance / Description	White or almost white, crystalline powder. / Small colorless crystals or white powder.	White powder
Solubility	Very slightly soluble in water, freely soluble in ethanol (96 per cent) and in methanol. / Freely soluble in alcohol and in ether; slightly soluble in boiling water, very slightly soluble in water.	Complies
Identification		
A. Melting Point, °C	96°C to 99°C	97.8 °C
B. IR Absorption	Compares to propyl parahydroxybenzoate reference spectrum	Passes
Appearance of solution	A 10% w/v solution in ethanol (96 percent) is clear and not more intensely coloured than reference solution BY ₆	Complies
Colour of solution	The sample solution is clear and not more intensely colored than alcohol or the comparison solution	Complies
Acidity	Not more than 0.1 ml of 0.1M Sodium hydroxide solution is required to change the colour of the indicator to blue	0.04 ml of 0.1 M Sodium hydroxide solution is required
Related Substances By HPLC	Impurity A- Not more than 0.5% Unspecified impurities- Not more than 0.5% Total impurities- Not more than 1.0%	Not detected Not detected Not detected
Sulphated Ash / Residue on ignition	NMT 0.1% determined on 1.0 gm	0.04%
Residual Solvents <ul style="list-style-type: none"> n-Propanol Toluene 	USP Chapter <467> Meet requirements. NMT 5000 ppm NMT 890 ppm	Not detected 221ppm
Assay by HPLC (as C ₁₂ H ₁₂ O ₃)	98.0% to 102.0%	99.34%

Remarks: Material passes as per USP/NF specifications.