

**CERTIFICATE OF ANALYSIS**

Formally

Product	: PROPYL PARABEN POWDER BP/EP/USP-NF (Code No. 208417) (CAS No. 94-13-3)		
Batch No	: U3/P1/PP/0160424	P.O.No./Date	: 460077/25.04.2024
Pack Size	: 182 X 25 kg	Mfg. Date	: April-2024
Quantity	: 4550 kg	Exp. Date	: March-2029
A.R.No	: U3/QC/FP/24/00194	Date of Release	: 24.04.2024

Sr. No.	TESTS	SPECIFICATIONS-BP/EP/USP-NF	OBSERVATIONS
1	Appearance /Description	White or almost white, crystalline powder. / Small colorless crystals or white powder.	White powder.
2	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.
3	Identification		
	A) Melting Point, °C.	96 °C to 99 °C.	97.2 °C
	B) IR Absorption	Compares to propyl parahydroxybenzoate reference spectrum.	Passes.
4	Appearance of solution	A 10 % w/v solution in ethanol (96 per cent) is clear and not more intensely coloured than reference solution BY ₆ .	Complies.
5	Colour of Solution	The Sample solution is clear and not more intensely colored than alcohol or the Comparison solution.	Complies.
6	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.
7	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.
8	Sulphated Ash/Residue on ignition	NMT 0.1 %, determined on 1.0 gm.	0.05%
9	Residual Solvents. • n-Propanol • Toluene	USP general chapter <467>. Meets the requirements. NMT 5000 ppm NMT 890 ppm	Not detected. 123 ppm
10	Assay by HPLC (as C ₁₀ H ₁₂ O ₃)	98.0% to 102.0%	99.62%

Remarks: Material meets BP-2019/EP9.1/USP42-NF37 specifications.

Cheng
30/04/2024
Prepared By:
(Officer-QC)

30/04/2024
Checked By:
(Manager-QC/Designee)

30/04/2024
Approved By:
(Manager-QA/Designee)

Note: If any batches supply by Ami Organics Limited-Unit-3 for regulatory submission purpose, Information must be notified to Ami Organics Quality Unit.

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