

**CERTIFICATE OF ANALYSIS**

Product	: METHYL PARABEN POWDER BP/EP/USP-NF (Code No. 160027) (CAS No. 99-76-3)	
Batch No	: U3/P1/MP/0660424	P.O.No./Date : 460077/25.04.2024
Pack Size	: 158 X 25 kg	Mfg. Date : April-2024
Quantity	: 3950 kg	Exp. Date : March-2029
A.R.No	: U3/QC/FP/24/00213	Date of Release : 30.04.2024


Sr. No.	TESTS	SPECIFICATIONS- BP/EP/USP-NF	OBSERVATIONS
1	Description	Colourless crystals or white crystalline powder/Small colorless crystals or white powder.	White powder.
2	Solubility	Freely soluble in ethanol (96per cent), in alcohol, in ether and in methanol; slightly soluble in boiling water.	Complies.
3	Identification		
	A. Melting Point, °C.	125°C to 128°C.	126.2 °C.
	B. IR	Pass	Passes.
	C. TLC	The principle spot in the chromatogram obtained with test solution (b) is similar in position and size to the principle spot in the chromatogram obtained with reference solution (a).	Complies.
	D. Colour test	Passes test.	Passes.
4	Appearance of solution/ Colour of solution	A 10% w/v solution in ethanol (96 per cent) is clear and Not more intensely coloured than reference solution BY6/not more intensely colored than matching fluid G.	Complies.
5	Acidity	Not more than 0.1 ml of 0.1M NaOH Solution required to change colour.	0.04 ml of 0.1 M NaOH Solution.
6	Related substances by HPLC	Impurity A: NMT 0.5 %.	Not detected.
		Unspecified impurity: NMT 0.5%	Not detected.
		Total impurity : NMT 1.0%	Not detected.
7	Residual Solvents. • Methanol	USP general chapter<467>. Meets the requirements. NMT 3000 ppm	129 ppm.
8	Sulphated Ash/Residue on ignition	Not more than 0.1%	0.05%
9	Assay by HPLC (as C ₈ H ₈ O ₃).	98.0 % to 102.0 %.	99.64%

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

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

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

Jhag
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.

Factory: Plot No. 910/1/B, GIDC, JHAGADIA- 393 110, DIST. BHARUCH, GUJARAT, INDIA
Tel No.: +91-7861812602/7861812603

Regd. Office: Plot No. 440/4,5 & 6, Road no. 82/A, G.I.D.C., Sachin, Surat-394230, Gujarat, India.
Tel No.: +91-75730 15366 / 72279 77744

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