



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Methyl Paraben USP/NF, Ph. Eur.		Issue Date	July-23
Product Code	110060		Prepared by	Sr. Tech Lead
CAS NO.	99-76-3		Reviewed by	Manager Technical
Manufacturer Name	CG Chemikalein GmbH & Co KG		Version no.	CLYZO/CG/110060/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		<i>Complies USP/NF, Ph. Eur.</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Description	White or almost white, crystalline powder or colourless crystals.	White, crystalline powder or colorless crystals.	White or almost white, crystalline powder or colourless crystals.	Colorless crystals or a white crystalline powder
2	Solubility	Not mentioned	Freely soluble in alcohol and in methanol; slightly soluble in water	Very slightly soluble in water, freely soluble in ethanol (96 %) and in methanol	Freely soluble in methanol, in ethanol (95) and in acetone,
3	Identification 1	Should comply the test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Methylparaben reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Methyl parahydroxybenzoate reference standard/working	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Methyl parahydroxybenzoate reference standard/working
4	Identification 2	Should comply the test	Sample should melt between 125 ^o C and 128 ^o C	Sample should melt between 125 ^o C and 128 ^o C	Not mentioned
5	Identification 3	Should comply the test	Not mentioned	In TLC test, the principal spot in the chromatogram obtained with test solution (b) is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a)	Not mentioned
6	Melting point	Between 125 ^o C and 128 ^o C	Not mentioned	Not mentioned	Between 125 ^o C and 128 ^o C
7	Color of solution	Should comply the test	The Sample solution is clear and not more intensely colored than alcohol or the Comparison solution.	Sample solution S is clear and not more intensely coloured than reference solution BY6	The sample solution is clear and not more intensely colored than the control solution
8	Acidity	NMT 0.1 mL of 0.1 M NaOH is required to change the colour of the indicator to blue.	NMT 0.1 mL of 0.1 M NaOH is required to change the colour of the indicator to blue.	NMT 0.1 mL of 0.1 M NaOH is required to change the colour of the indicator to blue.	NMT 0.1 mL of 0.1 M NaOH is required to change the colour of the indicator to blue.
9	Heavy metals	NMT 20 ppm	Not mentioned	Not mentioned	NMT 20 ppm
10	Residue on ignition	NMT 0.1%	NMT 0.1%	Not mentioned	NMT 0.1%
11	Sulfated ash	Not mentioned	Not mentioned	NMT 0.1%	Not mentioned
12	Related substances	Impurity A: NMT 0.5% Unknown impurity: NMT 0.5% Total impurities: NMT 1.0%	Parahydroxybenzoic acid: NMT 0.5% Unknown impurity: NMT 0.5% Total impurities: NMT 1.0%	Impurity A: NMT 0.5% Unknown impurity: NMT 0.5% Total impurities: NMT 1.0%	Parahydroxybenzoic acid: NMT 0.5% Unknown impurity: NMT 0.5% Total impurities: NMT 1.0%
13	Assay	'Between 98.0% and 102.0%	'Between 98.0% and 102.0%	'Between 98.0% and 102.0%	'Between 98.0% and 102.0%
14	Microbial limit test Total aerobic microbial count Total yeast and molds count E.Coli Pseudomonas aeruginosa Staphylococcus aureus Salmonella	NMT 100 CFU/g NMT 50 cfu/g Absent/g Absent/g Absent/g Absent/25 g	Not mentioned	Not mentioned	Not mentioned
15	Bacterial Endotoxins	NMT 10 IU/g	Not mentioned	Not mentioned	Not mentioned
12	Residual solvent	Should comply the test	Not mentioned	Not mentioned	Not mentioned
24	Storage	Not mentioned	Preserve in well-closed containers.	Not mentioned	Containers—Well-closed containers

Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.