



CERTIFICATE OF ANALYSIS

Chemical Name	Methyl 4-Hydroxybenzoate
Molecular Formula	C ₈ H ₈ O ₃
Molecular Weight	152.15
Use	Antimicrobial Preservative

NO.	Test	Specifications
1.	Description	White crystalline powder or colorless crystals.
2.	Solubility	Slightly soluble in water, freely soluble in alcohol and in methanol
3.	Identification	A. Infrared absorption <197M>. B. The principle spot obtained in the chromatogram of solution B prepared as directed in the test for chromatographic purity corresponds in size and R _f value to that of the principle spot obtained from standard solution B. C. To about 10 mg in a test tube add 1 ml of sodium carbonate solution, mix, boil for 30 seconds, and cool (Test solution A). Transfer about 10 mg to a second test tube, add 1 ml of sodium carbonate test solution and mix the substance partly dissolves (Test solution B). Prepare a solution of 4- aminoantipyrine in pH 9.0 alkaline borate buffer containing 1 mg per ml. Simultaneously add 5 ml of the 4- aminoantipyrine solution and 0.5 ml of potassium ferricyanide TS to test solution A and Test solution B, and mix: Test solution B becomes yellow to orange- brown and Test solution A becomes orange to red, with the color of Test solution A being clearly more intense than any similar color that may be obtained with Test solution B.
4.	Color of solution	The solution is clear and not more intensely colored than reference solution BYS1.
5.	Acidity	Dissolve 1.0 g in sufficient ethanol (95%) to produce 10 ml. To 2 ml of the solution add 3 ml of ethanol (96%), 5 ml of carbon dioxide- free water and 0.1 ml of Bromocresol green solution. Not more than 0.1ml of 0.1N sodium hydroxide VS is required to change the colour of the solution to blue.
6.	Residue on Ignition	Not more than 0.1%.
7.	Chromatographic Purity	Not more than 0.5%.
8.	Melting Point/Range	Between 125o to 128o
9.	Organic volatile Impurities	Method IV <467>. Meet the requirement.
10.	Assay, w/w	99.0 - 100.5 %

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CERTIFICATE OF ANALYSIS

SODIUM METHYL PARABEN U.S.P

NO.	Test	Specifications
1.	Description	White, hygroscopic powder.
2.	Solubility	Freely soluble in water; sparingly soluble in alcohol; insoluble in fixed oils.
3.	Identification	<p>A. Dissolve 0.5 gm in 5 ml of water, acidify with hydrochloric acid; and filter the resulting precipitate. Wash the precipitate with water and, dry it over silica gel for 5.0 hrs: The infrared absorption spectrum of a mineral oil dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of usp Methyl Paraben RS.</p> <p>B. Ignite about 0.3 gm, cool, and dissolve the residue in about 3 ml of 3 N hydrochloric acid. A platinum wire dipped in this solution imparts an intense, persistent yellow colour to a non- luminous flame.</p>
4.	PH	Between 9.5 to 10.5, determined in a 0.1% w/v solution, appendix 8.11
5.	Water	Not more than 5.0%
6.	Chloride	Not more than 0.035%
7.	Sulphate	Not more than 0.12%
8.	Organic volatile impurities.	To meets the requirement.
9.	Assay on dried basis (As C₈H₇NaO₃)	Between 98.5% to 101.5%
10.	Additional test (Loss OnDrying)	Not more than 5.0%

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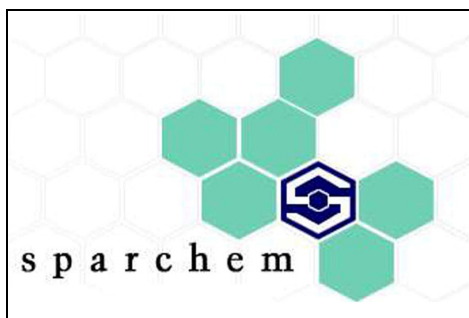
CERTIFICATE OF ANALYSIS

ETHYL PARABEN U.S.P.

Chemical Name	Ethyl Hydroxy Benzoate
Molecular Formula	C ₉ H ₁₀ O ₃
Molecular Weight	166.2
Storage conditions and precautions	Preserve in well-closed containers.
Use	Antimicrobial Preservative

NO.	Test	Specifications
1.	Description solubility	&Small, colourless crystals or white powder.
2.	Solubility	Slightly soluble in water and in glycerin, freely soluble in acetone, in alcohol, in ether and in propylene glycol.
3.	Identification	A. Infrared Absorption <197M>
4.	Melting Range, °C	Between 115°C and 118°C
5.	Acidity	Dissolve 1.0 g in sufficient ethanol (96%) to produce 10 ml. To 2 ml of the solution add 3 ml of ethanol (96%), 5 ml of carbon dioxide-free water and 0.1 ml of Bromocresol green solution. Not more than 0.1 ml of 0.1 N sodium hydroxide VS is required to change the colour of the solution to blue.
6.	Loss drying, w/w	onNot more than 0.5 %.
7.	Residue ignition	onNot more than 0.05 %.
8.	Organic volatile impurities	Method IV <467>: meets the requirements.
9.	Assay, w/w	99.0 % - 100.5 %

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CERTIFICATE OF ANALYSIS

PROPYL PARABEN U.S.P.

Chemical Name Propyl 4-Hydroxybenzoate

Molecular Formula C₁₀H₁₂O₃

Molecular Weight 180.20

Use Antimicrobial Preservative

NO.	Test	Specifications
1.	Description	Small, colorless crystals or white powder.
2.	Solubility	Very slightly soluble in water, freely soluble in alcohol and in ether; slightly soluble in boiling water.
3.	Identification	Infrared absorption <197M>.
4.	Melting Range	Between 95 °C and 98 °C.
5.	Organic Impurities	volatile Method IV <467>. Meet the requirement.
6.	Acidity	Heat 0.75 g in 15 ml of water at 80o for 1 minute, cool, and filter: the filtrate is neutral or acidic to litmus. To 10 ml of the filtrate add 0.20 ml of 0.10 N sodium hydroxide and 2 drops of methyl red TS: the solution is yellow.
7.	Loss on drying (w/w)	Dry it over silica gel for 5 hours. It loses not more than 0.5% of its weight.
8.	Residue on Ignition, (w/w)	Not more than 0.05%
9.	Assay, (w/w)	99.0 - 100.5%

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CERTIFICATE OF ANALYSIS

SODIUM PROPYL PARABEN U.S.P

Chemical Name	Sodium Propyl 4-Hydroxybenzoate
Molecular Formula	C ₁₀ H ₁₁ NaO ₃
Molecular Weight	202.2
Storage conditions and precautions	Store in a well-closed containers.
Use	Antimicrobial Preservative

NO.	Test	Specifications
1.	Description	White powder. It is odorless and hygroscopic.
2.	Solubility	Freely soluble in water; sparingly soluble in alcohol; insoluble in fixed oils.
3.	Identification	<p>A. Dissolve 0.5 gm in 5 ml of water, acidify with hydrochloric acid; and filter the resulting precipitate. Wash the precipitate with water and, dry it over silica gel for 5.0 hrs: The infrared absorption spectrum of a mineral oil dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of usp Propyl Paraben RS.</p> <p>B. Ignite about 0.3 gm, cool, and dissolve the residue in about 3 ml of 3 N hydrochloric acid. A platinum wire dipped in this solution imparts an intense, persistent yellow colour to a nonluminous flame.</p>
4.	PH	Between 9.5 to 10.5 (1 gm in 1000 ml)
5.	Water	Not more than 5.0%
6.	Chlorides	Not more than 0.035%.
7.	Sulphate	Not more than 0.12%.
8.	Organic volatile impurities	Method-I<497> meets the requirement,
9.	Assay on dried basis (As C ₁₀ H ₁₁ NaO ₃)	Between 98.5% to 101.5%.

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CERTIFICATE OF ANALYSIS

BUTYL PARABEN U.S.P.

Chemical Name	Butyl 4-Hydroxy Benzoate
Molecular Formula	C ₁₁ H ₁₄ O ₃
Molecular Weight	194.23
CAS Number	94-26-8
Packing	25 kg, 20 kg (4 x 5 kg)
The Shelf-life	5 years
Storage conditions and precautions	Preserve in well-closed containers.
Use	Antimicrobial Preservative

NO.	Test	Specifications
1.	Description solubility	&Small, colourless crystals or white powder.
2.	Solubility	Slightly soluble in water and in glycerin, freely soluble in acetone, in alcohol, in ether and in propylene glycol.
3.	Identification	A. Infrared Absorption <197M>
4.	Melting Range, °C	Between 68°C and 72°C
5.	Acidity	Dissolve 1.0 g in sufficient ethanol (96%) to produce 10 ml. To 2 ml of the solution add 3 ml of ethanol (96%), 5 ml of carbon dioxide-free water and 0.1 ml of Bromocresol green solution .Not more than 0.1 ml of 0.1 N sodium hydroxide VS is required to change the colour of the solution to blue.
6.	Loss on drying, w/w	Not more than 0.5 %.
7.	Residue on ignition	Not more than 0.05 %.
8.	Organic volatile impurities	Method IV <467>: meets the requirements.
9.	Assay, w/w	99.0 % - 100.5 %

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