

Methylparaben  
NF - GenAR®



Material No.: 6215-18  
Revision No.: 0

## Product Specification

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets N.F. Requirements, Meets J.P. Chemical Specifications, GMP Manufactured Product

Test	Specification
NF - Identification A	Passes Test
NF - Identification B	Passes Test
NF - Color of Solution	Passes Test
NF - Acidity	Passes Test
NF - Related Substances - p-Hydroxybenzoic Acid	≤ 0.5 %
NF - Related Substances - Unspecified Impurities (each)	≤ 0.5 %
NF - Related Substances - Total Impurities	≤ 1.0 %
NF - Residue on Ignition	≤ 0.1 %
Assay (C <sub>8</sub> H <sub>8</sub> O <sub>3</sub> )(NF)	98.0 - 102.0 %
JP - Identification	Passes Test
JP - Melting Point	125 - 128 °C
JP - Clarity and Color of Solution	Passes Test
JP - Acidity (JP)	Passes Test
JP - Heavy Metals	≤ 20 ppm
JP-RelatedSubstances- p-Hydroxybenzoic Acid	≤ 0.5 %
JP-Related Substances-Unspecified Impurities (each)	≤ 0.5 %
JP-Related Substances-Total Impurities	≤ 1.0 %
JP - Residue on Ignition	≤ 0.10 %
JP - Assay (C <sub>8</sub> H <sub>8</sub> O <sub>3</sub> )	98.0 - 102.0 %
EP/BP - Assay (C <sub>8</sub> H <sub>8</sub> O <sub>3</sub> )	98.0 - 102.0 %
EP/BP - Appearance of Solution	Passes Test
EP/BP - Identification A	Passes Test
EP/BP - Identification B	Passes Test
EP/BP - Acidity	Passes Test
EP/BP - Related Substances - Impurity A	≤ 0.5 %
EP/BP - Related Substances - Unspecified Impurities (each)	≤ 0.5 %
EP/BP - Related Substances - Total Impurities	≤ 1.0 %
EP/BP - Sulfated Ash	≤ 0.1 %

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For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700  
Avantor Performance Materials, LLC  
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Test	Specification
Methanol (CH <sub>3</sub> OH)(by GC), For Information Only	ppm

GMP Manufactured Product  
Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Only the Class 2 solvent Methanol is present. Residual concentration is <3000 ppm.

Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Packaging Site: Paris Mfg Ctr & DC

  
Jamie Ethier  
Vice President Global Quality

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