

Material No.: 9421-03

Revision No.: 0

## **Product Specification**

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

Test	Specification
NF - Assay (C <sub>6</sub> H <sub>5</sub> CH <sub>2</sub> OH)	98.0 - 100.5 %
NF - Clarity of Solution	Passes Test
NF - Color of Solution	Passes Test
NF - Identification	Passes Test
NF - Peroxide Value	≤5
NF - Benzaldehyde and Other Related Substances - Benzaldehyde	≤ 0.15 %
NF - Related Substances - Cyclohexylmethanol	≤ 0.10 %
NF - Benzaldehyde and Other Related Substances - Total Other Peaks <rt alcohol<="" benzyl="" of="" td=""><td>≤ 0.04 %</td></rt>	≤ 0.04 %
NF - Benzaldehyde and Other Related Substances - Total Other Peaks Greater Than RT of Benzyl Alcohol	≤ 0.3 %
NF - Refractive Index, n <sup>2</sup> D	1.538 - 1.541
NF - Acidity	Passes Test
NF - Residue on Evaporation	≤ 0.05 %
NF - Benzene	≤ 2 ppm
Solubility	Passes Test
EP/BP - Assay (C <sub>6</sub> H <sub>5</sub> CH <sub>2</sub> OH)	98.0 - 100.5 %
EP/BP - Identification	Passes Test
EP/BP - Acidity	Passes Test
EP/BP - Appearance of Solution	Passes Test
EP/BP - Refractive Index, n <sup>2</sup> ^D	1.538 - 1.541
EP/BP - Benzaldehyde and Other Related Substances - Benzaldehyde	≤ 0.15 %
EP/BP - Related Substances - Cyclohexylmethanol	≤ 0.10 %
EP/BP - Benzaldehyde and Other Related Substances - Total Other Peaks <rt alcohol<="" benzyl="" of="" td=""><td>≤ 0.04 %</td></rt>	≤ 0.04 %
EP/BP - Benzaldehyde and Other Related Substances - TOTAL OTHER PEAKS >RT OF BENZYL ALCOHOL	≤ 0.3 %
EP/BP - Peroxide Value	≤5
EP/BP - Residue on Evaporation	≤ 0.05 %
JP - Assay (C <sub>6</sub> H <sub>5</sub> CH <sub>2</sub> OH)	98.0 - 100.5 %
JP - Identification	Passes Test
JP - Refractive Index, n <sup>2</sup> o^D	1.538 - 1.541



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Test	Specification
JP - Specific Gravity at 20°/20°C	1.043 - 1.049
JP - Clarity and Color of Solution	Passes Test
JP - Acidity	Passes Test
JP - Benzaldehyde and Other Related Substances - Benzaldehyde	≤ 0.15 %
JP - Related Substances - Cyclohexylmethanol	≤ 0.10 %
JP - Benzaldehyde and Other Related Substances - Total Other Peaks <rt alcohol<="" benzyl="" of="" td=""><td>≤ 0.04 %</td></rt>	≤ 0.04 %
JP - Benzaldehyde and Other Related Substances - TOTAL OTHER PEAKS >RT OF BENZYL ALCOHOL	≤ 0.3 %
JP - Peroxide Value	≤5
JP - Residue on Evaporation	≤ 0.05 %

GMP Manufactured Product

**Bulk Pharmaceutical Chemical** 

CAUTION: For Manufacturing, processing or repackaging

This product is not intended for use in preparing parenteral dosage forms.

The Class 1 solvent Benzene is likely to be present below 2 ppm. The actual analysis of Benzene is reported for each lot.

The Class 2 solvent Toluene is likely to be present and is process controlled to  $<30\ ppm.$ 

No other Class 1, 2 or 3 residual solvents are likely to be present.

Packaging Site: Paris Mfg Ctr & DC

