

Glycerin, U.S.P.  
Multi-Compendial  
100% Vegetable Based  
(glycerol)



Material No.: 2143-03

Revision No.: 0

## Product Specification

Meets B.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification
USP - Identification A	Passes Test
USP - Identification B - Diethylene Glycol	≤ 0.10 %
USP - Identification B - Ethylene Glycol	≤ 0.10 %
USP - Identification C	Passes Test
USP - Assay (as HOCH <sub>2</sub> CHOHCH <sub>2</sub> OH) (calculated on anhydrous basis)	99.0 - 101.0 %
USP - Specific Gravity at 25°/25°C	≥ 1.249
USP - Color	Passes Test
USP - Residue on Ignition	≤ 0.01 %
USP - Chloride (Cl)	≤ 0.001 %
USP - Sulfate (SO <sub>4</sub> )	≤ 0.002 %
USP - Chlorinated Compounds (as Cl)	≤ 0.003 %
USP - Fatty Acids and Esters	Passes Test
USP - Water (H <sub>2</sub> O)	≤ 5.0 %
USP - Related Compounds: Individual Impurity	≤ 0.1 %
USP - Related Compounds: Total Impurities	≤ 1.0 %
EP/BP - Identification A	Passes Test
EP/BP - Identification B	Passes Test
EP/BP - Appearance of Solution	Passes Test
EP/BP - Acidity or Alkalinity	Passes Test
EP/BP - Refractive Index, n <sub>D</sub> <sup>20</sup>	1.470 - 1.475
EP/BP - Aldehydes	≤ 10 ppm
EP/BP - Ester	Passes Test
EP/BP - Halogenated Compounds	≤ 35 ppm
EP/BP - Sugars	Passes Test
EP/BP - Chloride (Cl)	≤ 10 ppm
EP/BP - Water (H <sub>2</sub> O)	≤ 2.0 %
EP/BP - Ash (sulfated)	≤ 0.01 %
EP/BP - Impurity A and Related Substances - Impurity A	≤ 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

100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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EP/BP - Impurity A and Related Substances - Other Impurities with $R^T < \text{Glycerol}$	$\leq 0.1 \%$
EP/BP - Impurity A and Related Substances - Total Impurities $R^T > \text{Glycerol}$	$\leq 0.5 \%$
EP - Assay (anhydrous basis)	98.0 - 101.0 %
JP - Assay (anhydrous basis)	98.0 - 101.0 %
JP - Identification	Passes Test
JP - Specific Gravity at 20°/20°C	$\geq 1.258$
JP - Refractive Index, $n^{20}_D$	$\geq 1.470$
JP - Color	Passes Test
JP - Residue on Ignition	$\leq 0.01 \%$
JP - Chloride (Cl)	$\leq 0.001 \%$
JP - Sulfate ( $\text{SO}_4$ )	$\leq 0.002 \%$
JP - Heavy Metals (as Pb)	$\leq 5 \text{ ppm}$
JP - Fatty Acids and Esters(as butyric acid)	Passes Test
JP - Readily Carbonizable Substances	Passes Test
JP - Acidity or Alkalinity	Passes Test
JP - Acrolein, Glucose, and Other Reducing Substances	Passes Test
JP - Ammonium ( $\text{NH}_4$ )	Passes Test
JP - Calcium (Ca)	Passes Test
JP - Arsenic (As)	$\leq 2 \text{ ppm}$
JP - Water ( $\text{H}_2\text{O}$ )	$\leq 2.0 \%$
JP - Ethylene Glycol	$\leq 0.1 \%$
JP - Diethylene Glycol	$\leq 0.1 \%$
JP - Any Other Impurity	$\leq 0.1 \%$
JP - Total Impurities	$\leq 1.0 \%$
Endotoxin Concentration (EU/g)	$\leq 5$

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Test	Specification
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GMP Manufactured Product  
Bulk Pharmaceutical Chemical  
CAUTION: For Manufacturing, processing or repackaging  
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.  
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

A blue horizontal bar containing a white signature of Jamie Ethier. Below the signature, the text 'Jamie Ethier Vice President Global Quality' is printed in white.

Jamie Ethier  
Vice President Global Quality

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