

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



Material No.: 2143-01  
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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EP/BP – Impurity A and Related Substances – Other Impurities with R <sup>AT</sup> <Glycerol	≤ 0.1 %
EP/BP – Impurity A and Related Substances – Total Impurities R <sup>AT</sup> >Glycerol	≤ 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	≥ 1.258
JP – Refractive Index, n <sup>20</sup> D	≥ 1.470
JP – Color	Passes Test
JP – Residue on Ignition	≤ 0.01 %
JP – Chloride (Cl)	≤ 0.001 %
JP – Sulfate (SO <sub>4</sub> )	≤ 0.002 %
JP – Heavy Metals (as Pb)	≤ 5 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 (NH <sub>4</sub> )	Passes Test
JP – Calcium (Ca)	Passes Test
JP – Arsenic (As)	≤ 2 ppm
JP – Water (H <sub>2</sub> O)	≤ 2.0 %
JP – Ethylene Glycol	≤ 0.1 %
JP – Diethylene Glycol	≤ 0.1 %
JP – Any Other Impurity	≤ 0.1 %
JP – Total Impurities	≤ 1.0 %
Endotoxin Concentration (EU/g)	≤ 5

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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