

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



Material No.: 2143-01
Batch No.: 0000234930
Manufactured Date: 2019/04/29
Retest Date: 2024/04/27
Release Date: 2019/07/16
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Identification A	Passes Test	PT
USP – Identification B – Diethylene Glycol	<= 0.10 %	< 0.10
USP – Identification B – Ethylene Glycol	<= 0.10 %	< 0.10
USP – Identification C	Passes Test	PT
USP – Assay (as HOCH ₂ CHOHCH ₂ OH) (calculated on anhydrous basis)	99.0 – 101.0 %	99.6
USP – Specific Gravity at 25°/25°C	>= 1.249	1.261
USP – Color	Passes Test	PT
USP – Residue on Ignition	<= 0.01 %	< 0.01
USP – Chloride (Cl)	<= 0.001 %	< 0.001
USP – Sulfate (SO ₄)	<= 0.002 %	< 0.002
USP – Chlorinated Compounds (as Cl)	<= 0.003 %	< 0.003
USP – Fatty Acids and Esters(as butyric acid)	Passes Test	PT
USP – Water (H ₂ O)	<= 5.0 %	0.1
USP – Related Compounds: Individual Impurity	<= 0.1 %	0.1
USP – Related Compo unds: Total Impurities	<= 1.0 %	< 1.0
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Acidity or Alkalinity	Passes Test	PT
EP/BP – Refractive Index, n ²⁰ D	1.470 – 1.475	1.474
EP/BP – Aldehydes	<= 10 ppm	< 10
EP/BP – Ester	Passes Test	PT

For questions on this Certificate of Analysis 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

Test	Specification	Result
EP/BP – Halogenated Compounds	<= 35 ppm	< 35
EP/BP – Sugars	Passes Test	PT
EP/BP – Chloride (Cl)	<= 10 ppm	< 10
EP/BP – Water (H ₂ O)	<= 2.0 %	0.1
EP/BP – Ash (sulfated)	<= 0.01 %	< 0.01
EP/BP – Impurity A and Related Substances – Impurity A	<= 0.1 %	< 0.1
EP/BP – Impurity A and Related Substances – Other Impurities with R ^{AT} <Glycerol	<= 0.1 %	< 0.1
EP/BP – Impurity A and Related Substances – Total Impurities R ^{AT} >Glycerol	<= 0.5 %	< 0.5
EP – Assay (anhydrous basis)	98.0 – 101.0 %	99.4
JP – Assay (anhydrous basis)	98.0 – 101.0 %	99.6
JP – Identification	Passes Test	PT
JP – Specific Gravity at 20°/20°C	>= 1.258	1.262
JP – Refractive Index, n ²⁰ D	>= 1.470	1.474
JP – Color	Passes Test	PT
JP – Residue on Ignition	<= 0.01 %	< 0.01
JP – Chloride (Cl)	<= 0.001 %	< 0.001
JP – Sulfate (SO ₄)	<= 0.002 %	< 0.002
JP – Heavy Metals (as Pb)	<= 5 ppm	< 5
JP – Fatty Acids and Esters(as butyric acid)	Passes Test	PT
JP – Readily Carbonizable Substances	Passes Test	PT
JP – Acidity or Alkalinity	Passes Test	PT
JP – Acrolein, Glucose, and Other Reducing Substances	Passes Test	PT
JP – Ammonium (NH ₄)	Passes Test	PT
JP – Calcium (Ca)	Passes Test	PT
JP – Arsenic (As)	<= 2 ppm	< 2
JP – Water (H ₂ O)	<= 2.0 %	< 2.0
JP – Ethylene Glycol	<= 0.1 %	< 0.1
JP – Diethylene Glycol	<= 0.1 %	< 0.1
JP – Any Other Impurity	<= 0.1 %	< 0.1
JP – Total Impurities	<= 1.0 %	< 0.1
Endotoxin Concentration (EU/g)	<= 5	< 1

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

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impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: 00005030
Manufacturer source batch: CB049865192



Jamie Ethier
Vice President Global Quality

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