Glycerin

Derived from Natural Ingredients Kosher

World/GMP, WORLD GRADE ®

Grade: USP/EP/BP/JP/FCC **Catalog number:** 349WORLD

Test	Mono-graph	Specification	Typical Result
Identification Test A	USP	Conforms to Reference Spectrum	Pass
Identification A – Refractive Index	EP	1.470-1.475 @ 20°C	1.474
Refractive Index	JP	NLT 1.470 @ 20°C	1.474
Identification Test A	FCC	Conforms to Reference Spectrum	Pass
Identification Test B - Limit of DEG	USP	NMT 0.1%	None Detected
Identification Test B - Limit of EG	USP	NMT 0.1%	None Detected
Identification B – Infrared Absorption	EP	Conforms to Reference Spectrum	Pass
Identification – Infrared Absorption	JP	Conforms to Reference Spectrum	Pass
Identification Test B	FCC	Conforms to sample solution	Pass
Identification Test C - Gas Chromatography	USP	Conforms to Reference Chromatogram	Pass
Identification C - Relative Density	EP	1.258 - 1.268	1.263
Assay on anhydrous basis	USP	99.0-101.0%	100.0%
Assay on anhydrous basis	EP	98.0 - 101.0% (m/m)	100.0%
Assay on anhydrous basis	JP	98.0 - 101.0%	100.0%
Assay on anhydrous basis	FCC	99.0-101.0%	100.0%

Test	Mono-graph	Specification	Typical Result
Inorganic Impurities - Chloride and Sulfate (as Chloride)	USP	NMT 10ppm	LT 10 ppm
Inorganic Impurities - Chloride and Sulfate (as Sulfate)	USP	NMT 20ppm	LT 20 ppm
Purity 4 – Sulfate	JP	NMT 0.002%	LT 0.002%
Inorganic Impurities - Residue on Ignition	USP	NMT 0.01%	0.00%
Inorganic Impurities – Lead	FCC	NMT 1 mg/kg	LT 1 mg/kg
Residue on Ignition	JP	NMT 0.01%	0.00%
Inorganic Impurities - Residue on Ignition	FCC	NMT 0.01%	0.00%
Organic Impurities- Related Compounds- Individual Impurities	USP	NMT 0.1%	None Detected
Organic Impurities - Related Compounds - Total Impurities	USP	NMT 1.0%	None Detected
Organic Impurities – Limit of Chlorinated Compounds	USP	NMT 30ppm of Cl	LT 30 ppm
Organic Impurities - Fatty Acids and Esters	USP	NMT 1mL 0.5N NaOH consumed	0.25mL
Organic Impurities - Fatty Acids and Esters	FCC	NMT 1mL 0.5N NaOH consumed	0.25mL
Impurity A and Related Substances- Impurities with RT<C3H8O3	EP	0.1% max	None Detected
Impurity A and Related Substances- Impurities with RT>C3H8O4	EP	0.5% max	None Detected
Purity 11–EG, DEG and Related Subs - Individual Impurities	JP	NMT 0.1%	None Detected
Purity 11–EG, DEG and Related Subs - Total Impurities	JP	NMT 1.0%	None Detected

Test	Mono-graph	Specification	Typical Result
Impurity A and Related Substances - Diethylene Glycol	EP	0.1% max	None Detected
Water Determination	USP	NMT 5.0%	0.05%
Color	USP	Not darker than standard	Pass
Purity 1 – Color	JP	No more color than control	Pass
Color	FCC	Not darker than standard	Pass
Characters	EP	Aspect: syrupy liquid, unctuous to the touch, colorless or almost colorless, clear, very hygroscopic. Solubility: miscible with water and with ethanol (96 per cent), slightly soluble in acetone, practically insoluble in fatty oils and in essential oils	Pass
Appearance of Solution	EP	Test solution is clear and colorless	Pass
Specific Gravity	USP	NLT 1.249 @25°C	1.2610
Specific Gravity	JP	NLT 1.258 @ 20°C	1.2630
Specific Gravity	FCC	NLT 1.259 @25°C	1.2610
Water Determination	USP	NMT 5.0%	0.05%
Acidity or Alkalinity	EP	NMT 0.2mL of 0.1M NaOH required	0.1mL
Purity 2 – Acidity or Alkalinity	JP	Solution is neutral	Pass
Aldehydes	EP	10ppm max.	LT 10 ppm
Esters	EP	NLT 8.0 mL 0.1M HCl required	9.4mL
Purity 10 - Fatty Acids and Esters	JP	NMT 3.0mL 0.1M NaOH consumed	1.25mL
Halogenated Compounds	EP	35 ppm max.	LT 35 ppm
Sugars	EP	To Pass Test	Pass

Test	Mono-graph	Specification	Typical Result
Chlorides	EP	NMT 10ppm	LT 10 ppm
Purity 3 – Chloride	JP	NMT 0.001%	LT 0.001%
Chlorinated Compounds (as Cl)	FCC	NMT 0.003%	LT 0.003%
Water	EP	NMT 2.0%	0.05%
Water	JP	NMT 2.0%	0.05%
Water	FCC	NMT 1.0%	0.05%
Sulfated Ash	EP	NMT 0.01%	0.00%
Purity 5 – Ammonium	JP	To Pass Test	Pass
Purity 6 – Heavy Metals	JP	NMT 5 ppm	LT 5 ppm
Purity 7 – Calcium	JP	To Pass Test	Pass
Purity 8 – Arsenic	JP	NMT 2 ppm	LT 2 ppm
Purity 9 - Acrolein, Glucose or other Reducing Substance	JP	To Pass Test	Pass
Purity 12 - Readily Carbonizable Substances	JP	To Pass Test	Pass
Readily Carbonizable Substances	FCC	To Pass Test	Pass
Ag (Silver)	USP<232>	Lot Analysis	0.00 ppm
As (Arsenic)	USP<232>	Lot Analysis	0.00 ppm
Au (Gold)	USP<232>	Lot Analysis	0.00 ppm
Ba (Barium)	USP<232>	Lot Analysis	0.00 ppm
Cd (Cadmium)	USP<232>	Lot Analysis	0.00 ppm

Test	Mono-graph	Specification	Typical Result
Co (Cobalt)	USP<232>	Lot Analysis	0.00 ppm
Cr (Chromium)	USP<232>	Lot Analysis	0.00 ppm
Cu (Copper)	USP<232>	Lot Analysis	0.00 ppm
Hg (Mercury)	USP<232>	Lot Analysis	0.00 ppm
Ir (Iridium)	USP<232>	Lot Analysis	0.00 ppm
Li (Lithium)	USP<232>	Lot Analysis	0.00 ppm
Mo (Molybdenum)	USP<232>	Lot Analysis	0.00 ppm
Ni (Nickel)	USP<232>	Lot Analysis	0.00 ppm
Os (Osmium)	USP<232>	Lot Analysis	0.00 ppm
Pb (Lead)	USP<232>	Lot Analysis	0.00 ppm
Pd (Palladium)	USP<232>	Lot Analysis	0.00 ppm
Pt (Platinum)	USP<232>	Lot Analysis	0.00 ppm
Rh (Rhodium)	USP<232>	Lot Analysis	0.00 ppm
Ru (Ruthenium)	USP<232>	Lot Analysis	0.00 ppm
Sb (Antimony)	USP<232>	Lot Analysis	0.00 ppm
Se (Selenium)	USP<232>	Lot Analysis	0.00 ppm
Sn (Tin)	USP<232>	Lot Analysis	0.00 ppm
Tl (Thallium)	USP<232>	Lot Analysis	0.00 ppm
V (Vanadium)	USP<232>	Lot Analysis	0.00 ppm

Certification and Compliance Statements

This product has been processed and packaged in compliance with applicable Good Manufacturing Practices.

This product complies with of the current requirements listed in the United States Pharmacopeia, European Pharmacopeia, Japanese Pharmacopeia, Food Chemical Codex monographs. Certain test data have been supplied by third parties.

This product is not derived, nor does it come in contact with, any materials derived from bovine or other animal sources.

No chemicals whatsoever are used as solvents at any point in the manufacture, processing or packaging of Glycerin. Only Class 2 and Class 3 residual solvents may appear as impurities / related substances / low level contaminants in Glycerin. Concentration of Class 2 Option 1 and Class 3 residual solvents is below limits in the current USP/NF General Chapter <467> and ICH Q3C Impurities: Residual Solvents.

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