PRODUCT SPECIFICATIONS SHEET

Product Name	Glycerin Derived from Natural Ingredients Kosher World/GMP, WORLD GRADE ®
Grade	USP/EP/BP/JP/FCC Grade
Catalog #	349WORLD

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Identification Test A	USP	Conforms to Reference Spectrum	Pass
Identification B – Infrared Absorption	EP	Conforms to Reference Spectrum	Pass
Identification – Infrared Absorption	JP	Conforms to Reference Spectrum	Pass
Identification Test A	FCC	Conforms to Reference Spectrum	Pass
Identification Test B - Limit of DEG	USP	NMT 0.1%	None Detected
Impurity A and Related Substances - Diethylene Glycol	EP	0.1% max	None Detected
Identification Test B - Limit of EG	USP	NMT 0.1%	None Detected
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 B	FCC	Conforms to sample solution	Pass
Impurity A and Related Substances - Diethylene Glycol	EP	0.1% 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
Identification Test C - Gas Chromatography	USP	Conforms to Reference Chromatogram	Pass
Assay on anhydrous basis	USP	99.0-101.0%	100.00 %
Assay on anhydrous basis	EP	98.0 - 101.0% (m/m)	100.00 %

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Assay on anhydrous basis	JP	98.0 - 101.0%	100.00 %
Assay on anhydrous basis	FCC	99.0-101.0%	100.00 %
Inorganic Impurities - Chloride and Sulfate (as Chloride)	USP	NMT 10ppm	LT 10 ppm
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%
Halogenated Compounds	EP	35 ppm max.	LT 35 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 %
Residue on Ignition	JP	NMT 0.01%	0.00 %
Inorganic Impurities - Residue on Ignition	FCC	NMT 0.01%	0.00 %
Inorganic Impurities - Lead	FCC	NMT 1 mg/kg	LT 1 mg/kg
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	0.30 ml
Esters	EP	NLT 8.0 mL 0.1M HCl required	8.5 ml
Purity 10 - Fatty Acids and Esters	JP	NMT 3.0mL 0.1M NaOH consumed	1.50 ml
Organic Impurities - Fatty Acids and Esters	FCC	NMT 1mL 0.5N NaOH consumed	0.30 ml

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
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
Color	USP	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
Purity 1 – Color	JP	No more color than control	Pass
Color	FCC	Not darker than standard	Pass
Specific Gravity	USP	NLT 1.249 @25°C	1.260
Identification C - Relative Density	EP	1.258 - 1.268	1.260
Specific Gravity	JP	NLT 1.258 @ 20°C	1.262
Specific Gravity	FCC	NLT 1.259 @25°C	1.260
Water Determination	USP	NMT 5.0%	0.07 %
Water	EP	NMT 2.0%	0.07 %
Water	JP	NMT 2.0%	0.07 %
Water	FCC	NMT 1.0%	0.07 %
Acidity or Alkalinity	EP	NMT 0.2mL of 0.1M NaOH required	0.1 ml

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Purity 2 – Acidity or Alkalinity	JP	Solution is neutral	Pass
Aldehydes	EP	10ppm max.	LT 10 ppm
Sugars	EP	To Pass Test	Pass
Purity 9 - Acrolein, Glucose or other Reducing Substance	JP	To Pass Test	Pass
Sulfated Ash	EP	NMT 0.01%	0.00 %
Purity 5 - Ammonium	JP	To Pass Test	Pass
Purity 8 – Arsenic	JP	NMT 2 ppm	LT 2 ppm
Purity 7 - Calcium	JP	To Pass Test	Pass
Purity 6 – Heavy Metals	JP	NMT 5 ppm	LT 5 ppm
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
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

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
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 all of the current requirements listed in the United States Pharmacopeia, European Pharmacopeia, Japanese Pharmacopeia, Food Chemical Codex monographs.

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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This product is for further commercial manufacturing, laboratory, or research use, and may be used as an excipient or a process solvent for pharmaceutical purposes. It is not intended for use as an active ingredient in drug manufacturing nor as a medical device or disinfectant. Appropriate/legal use of this product is the responsibility of the user.