Propylene Glycol

World/GMP, WORLD GRADE®

Grade: USP/EP/JP/FCC **Catalog number:** 369WORLD

Test	Mono-graph	Specification	Typical Result
Identification A – Infrared Absorption	USP	Conforms to Reference Spectrum	Pass
Identification D – Infrared absorption spectrophotometry	EP	Conforms to Reference Spectrum	Pass
Identification – Infrared Absorption	FCC	Conforms to Reference Spectrum	Pass
Identification B – Limit of DEG and EG	USP	Diethylene Glycol, NMT 0.10%	None Detected
Ethylene glycol and diethylene glycol	EP	Diethylene Glycol, NMT 0.10%	None Detected
Purity 7 - Diethylene Glycol	JP	NMT 0.1%	None Detected
Identification B – Limit of DEG and EG	USP	Ethylene Glycol, NMT 0.10%	None Detected
Ethylene glycol and diethylene glycol	EP	Ethylene Glycol, NMT 620ppm	None Detected
Purity 7 - Ethylene Glycol	JP	NMT 0.1%	None Detected
Identification C – GC	USP	Conforms to Reference Chromatogram	Pass
Assay (on anhydrous basis)	USP	NLT 99.5%	99.99 %
Assay (on anhydrous basis)	FCC	NLT 99.5%	99.99 %
Inorganic Impurities - Residue on Ignition	USP	NMT 3.5mg	LT 3.5 mg
Residue on Ignition	JP	NMT 0.005%	LT 0.001%
Residue on Ignition	FCC	NMT 0.007%	LT 0.001%
Inorganic Impurities – Chloride and Sulfate	USP	NMT 70ppm as Chloride	LT 70 ppm
Purity 2 - Chloride	JP	NMT 0.007%	0.001 %

Test	Mono-graph	Specification	Typical Result
Inorganic Impurities – Chloride and Sulfate	USP	NMT 60ppm as Sulfate	LT 60 ppm
Purity 3 - Sulfate	JP	NMT 0.002%	LT 0.002%
Specific Gravity	USP	1.035 – 1.037 @ 25°C	1.035
Specific Gravity	JP	1.035 - 1.040 @ 20°C	1.036
Specific Gravity	FCC	1.035 – 1.037 @ 25°C	1.035
Acidity	USP	NMT 0.20 mL 0.10 N NaOH	0.05 mL
Acidity	EP	NMT 8.3 mL 0.01 M NaOH	0.7 mL
Purity 1 - Acidity	JP	The solution has red color	Pass
Acidity	FCC	To Pass Test	Pass
Water	USP	NMT 0.2%	0.03 %
Water	EP	NMT 0.2%	0.03 %
Water	JP	0.5% Max.	0.03 %
Inorganic Impurities - Water	FCC	0.2% Max.	0.03 %
Appearance	EP	The substance to be examined is clear and not more intensely coloured than reference solution B_9	Pass
Distilling Range	JP	184 - 189°C, no less than 95% volume	Pass
Distilling Range	FCC	Between 185°C – 189°C	Pass
Oxidizing Substances	EP	Meets Requirements of Test	Pass
Reducing Substances	EP	Meets Requirements of Test	Pass
Sulfated Ash	EP	0.01% max	LT 0.01%
Identification (1)	JP	The crystals melt between 174C – 178C	Pass

Test	Mono-graph	Specification	Typical Result
Identification (2)	JP	Characteristic odor is evolved	Pass
Purity 4 – Heavy Metals	JP	NMT 5 ppm	LT 5 ppm
Purity 5 – Arsenic	JP	NMT 2ppm	LT 1 ppm
Purity 6 – Glycerin	JP	No odor of acrolein is perceptible	Pass
Purity 7 - Total Impurities	JP	NMT 1.0%	LT 1.0%
Inorganic Impurities - Lead	FCC	NMT 1 mg/kg	LT 1 mg/kg
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
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

Test	Mono-graph	Specification	Typical Result
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 is processed and packaged in compliance with excipient Good Manufacturing Practices.

This product complies with all of the current requirements listed in the United States Pharmacopeia, European Pharmacopeia, Japanese Pharmacopeia, and Food Chemical Codex.

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 Propylene Glycol.

Greenfield Products are for further commercial manufacturing, laboratory use, or research. Greenfield is not registered with the United States Food and Drug Administration (FDA) as a drug manufacturing facility. Greenfield products are not registered with the FDA as active pharmaceutical ingredients in drug manufacturing.

Appropriate/legal use of all products are the responsibility of the user and subject to applicable local laws and regulations.