

**PRODUCT SPECIFICATIONS SHEET**  
**WORLD/GMP GRADE**  
**GLYCERIN / GLYCEROL**  
 Meets USP, EP, BP, JP, FCC GRADE Monographs

Natural

Kosher

With USP&lt;232&gt;, EMA and ICH Q3D Elemental Impurities Test Results

Main Catalog #: 349WORLD-Size Code\*

*Individual package sizes have unique size codes
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**Manufactured in compliance with cGMP**

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (on anhydrous basis)	EP/JP USP/FCC	98.0 – 101.0% 99.0-101.0%	99.9%
Identification A – Refractive Index Refractive Index	EP JP	1.470-1.475 @ 20°C NLT 1.470 @ 20°C	1.474
Identification B – Infrared Absorption Identification A – Infrared Absorption Identification – Infrared Absorption	EP USP/FCC JP	Conforms to Reference Spectrum	Pass
Identification B – Limit of Diethylene Glycol and Ethylene Glycol	USP	Ethylene Glycol, NMT 0.1% Diethylene Glycol, NMT 0.1%	<0.1% <0.1%
Identification C Identification B	USP FCC	Conforms to Reference Chromatogram	Pass
Identification C – Relative density	EP	1.258 – 1.268	1.263
Appearance of Solution	EP	To pass test	Pass
Purity1 – Color Color	JP USP/FCC	No more color than control Not darker than standard	Pass Pass
Specific Gravity	USP FCC JP	NLT 1.249 @ 25°C NLT 1.259 @ 25°C NLT 1.258 @ 20°C	1.262 1.262 1.263
Acidity or Alkalinity Purity 2 – Acidity or Alkalinity	EP JP	NMT 0.2mL 0.1M NaOH required The solution is neutral	Pass
Purity 3 – Chloride Inorganic Impurities – Chloride and Sulfate Chlorides	JP USP EP	NMT 0.001% NMT 10ppm NMT 10ppm	<0.001% <10ppm <10ppm
Purity 4 – Sulfate Inorganic Impurities – Chloride and Sulfate	JP USP	NMT 0.002% NMT 20ppm	<0.002% <20ppm
Purity 5 - Ammonium	JP	To pass test	Pass
Purity 6 – Heavy Metals Inorganic Impurities – Lead	JP FCC	NMT 5 ppm NMT 1 mg/kg	<1ppm <1mg/kg
Purity 7 - Calcium	JP	To pass test	Pass
Purity 8 – Arsenic	JP	NMT 2 ppm	<2ppm
Purity 9 - Acrolein, Glucose or other Reducing Substance	JP	To pass test	Pass

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Purity 10 - Fatty Acids and Esters	JP	NMT 3.0mL 0.1M NaOH consumed	Pass
Organic Impurities - Fatty Acids and Esters	USP	NMT 1mL 0.5N NaOH consumed	Pass
Organic Impurities - Fatty Acids and Esters	FCC	NMT 4mL 0.5N HCl consumed	Pass
Esters	EP	NLT 8.0 mL 0.1M HCl required	Pass
Purity 11 – Ethylene Glycol, Diethylene Glycol and Related Substances	JP	Individual Impurities NMT 0.1%	Pass
Organic Impurities - Related Compounds	USP	Total Impurities NMT 1.0%	
Impurity A and Related Substances	EP	Impurity A – Diethylene Glycol 0.1% max Impurities with RT <C <sub>3</sub> H <sub>8</sub> O <sub>3</sub> 0.1% max Impurities with RT > C <sub>3</sub> H <sub>8</sub> O <sub>3</sub> 0.5% max	Pass
Purity 12 - Readily Carbonizable Substances	JP	To pass test	Pass
Readily Carbonizable Substances	FCC	To pass test	Pass
Sugars	EP	To pass test	Pass
Organic Impurities – Limit of Chlorinated Compounds	USP	NMT 30ppm	<30ppm
Chlorinated Compounds (as Cl)	FCC	NMT 0.003% max	<0.003%
Halogenated Compounds	EP	35 ppm max	<30ppm
Inorganic Impurities - Residue on Ignition	USP/FCC	NMT 0.01%	<0.01%
Residue on Ignition	JP		
Sulfated Ash	EP		
Aldehydes	EP	10ppm max	<10ppm
Water	JP	NMT 2.0%	0.2%
Water Determination	USP	NMT 5.0%	
Water	FCC	NMT 1.0%	
Water	EP	NMT 2.0%	

Hygroscopic

**Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients**

Reported in µg/g (ppm)

<b>Element</b>	<b>Class</b>	<b>Oral Concentration µg/g</b>	<b>Parenteral Concentration µg/g</b>	<b>Inhalation Concentration µg/g</b>	<b>TYPICAL RESULT (in µg/g) (ppm)</b>
Cd (Cadmium)	1	0.5	0.2	0.2	0.00
Pb (Lead)	1	0.5	0.5	0.5	0.00
As (Arsenic)	1	1.5	1.5	0.2	0.00
Hg (Mercury)	1	3	0.3	0.1	0.00
Co (Cobalt)	2A	5	0.5	0.3	0.00
V (Vanadium)	2A	10	1	0.1	0.00
Ni (Nickel)	2A	20	2	0.5	0.00
Tl (Thallium)	2B	0.8	0.8	0.8	0.00
Au (Gold)	2B	10	10	0.1	0.00
Pd (Palladium)	2B	10	1	0.1	0.00
Ir (Iridium)	2B	10	1	0.1	0.00
Os (Osmium)	2B	10	1	0.1	0.00
Rh (Rhodium)	2B	10	1	0.1	0.00
Ru (Ruthenium)	2B	10	1	0.1	0.00
Se (Selenium)	2B	15	8	13	0.00
Ag (Silver)	2B	15	1	0.7	0.00
Pt (Platinum)	2B	10	1	0.1	0.00
Li (Lithium)	3	55	25	2.5	0.00
Sb (Antimony)	3	120	9	2	0.00
Ba (Barium)	3	140	70	30	0.00
Mo (Molybdenum)	3	300	150	1	0.00
Cu (Copper)	3	300	30	3	0.00
Sn (Tin)	3	600	60	6	0.00
Cr (Chromium)	3	1100	110	0.3	0.00

Form: Glycerin, USP, EP, BP, JP, FCC, Rev. 2.2, 12/18, PJM

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.