PRODUCT SPECIFICATIONS SHEET

WORLD GRADE ®
GLYCERIN / GLYCEROL

Meets USP, EP, BP, JP, FCC GRADE Monographs

Natural

Kosher

WORLD/GMP GRADE

Main Catalog #: 349WORLD-Size Code*

*Individual package sizes have unique size codes

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 Organic Impurities - Fatty Acids and Esters Esters	JP USP/FCC EP	NMT 3.0mL 0.1M NaOH consumed NMT 1mL 0.5N NaOH consumed NLT 8.0 mL 0.1M HCl required	Pass Pass Pass
Purity 11 – Ethylene Glycol, Diethylene Glycol and Related Substances Organic Impurities - Related Compounds	JP USP	Individual Impurities NMT 0.1% Total Impurities NMT 1.0%	Pass
Impurity A and Related Substances	EP	Impurity A – Diethylene Glycol 0.1% max Impurities with RT <$C_3H_8O_3$ 0.1% max Impurities with RT > $C_3H_8O_3$ 0.5% max	Pass
Purity 12 - Readily Carbonizable Substances Readily Carbonizable Substances	JP FCC	To pass test To pass test	Pass Pass
Sugars	EP	To pass test	Pass
Organic Impurities – Limit of Chlorinated Compounds Chlorinated Compounds (as Cl) Halogenated Compounds	 USP FCC EP	 NMT 30ppm NMT 0.003% max 35 ppm max	 <30ppm <0.003% <30ppm
Inorganic Impurities - Residue on Ignition Residue on Ignition Sulfated Ash	USP/FCC JP EP	NMT 0.01%	<0.01%
Aldehydes	EP	10ppm max	<10ppm
Water Water Determination Water Water	JP USP FCC EP	NMT 2.0% NMT 5.0% NMT 1.0% NMT 2.0%	0.2%

Hygroscopic

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

Reported in µg/g (ppm)

Element	**Class**	**Oral Concentration µg/g**	**Parenteral Concentration µg/g**	**Inhalation Concentration µg/g**	**TYPICAL RESULT** (in µg/g) (ppm)
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. 2.5, 04/20, RAC

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.