PRODUCT SPECIFICATIONS SHEET

WORLD/GMP GRADE
GLYCERIN

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

Natural

Kosher

With USP<232>, EMA and ICH Q3D Elemental Impurities Test Results

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	EP	Meets Requirements of Test	Pass
Identification D	EP	Meets Requirements of Test	Pass
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 1.265
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

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Purity 9 - Acrolein, Glucose or other Reducing Substance	JP	To pass test	Pass
Purity 10 - Fatty Acids and Esters Organic Impurities - 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 NMT 4mL 0.5N HCl consumed NLT 8.0 mL 0.1M HCl required	Pass 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[1]

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

[1]Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.

Form: Glycerin, USP, EP, BP, JP, FCC, Rev. 2.1, 02/17, EF