PRODUCT SPECIFICATION SHEET

GMP GRADE
GLYCERIN

Meets USP/NF/FCC Monographs
KOSHER
Vegetable derived
With USP<232>, EMA and ICH Q3D Elemental Impurities Test Results

Main Catalog No: 349000GMP-Size Code*

*Refer to Master Price List – Individual package sizes have unique size codes

PRODUCT SPECIFICATIONS	MONO GRAPH	LIMITS	TYPICAL ANALYSIS
Assay on anhydrous basis	USP/FCC	99.0-101.0%	99.9%
Identification Test A	USP/FCC	Conforms to Infrared Spectra	Pass
Identification test B	USP FCC	Ethylene Glycol, NMT 0.1% Diethylene Glycol, NMT 0.1% Conforms to sample solution	<0.1% <0.1% Pass
Identification Test C	USP	Matches GC scan	Pass
Specific Gravity	USP FCC	NLT 1.249@25°C NLT 1.259 @25°C	1.262
Inorganic Impurities - Chloride and Sulfate (as Chloride)	USP	NMT 10ppm	<10 ppm
Inorganic Impurities - Chloride and Sulfate (as Sulfate)	USP	NMT 20ppm	<10 ppm
Inorganic Impurities - Lead	FCC	NMT 1 mg/kg	<1 mg/kg
Organic Impurities - Related Compounds	USP	Individual Impurities NMT 0.1% Total Impurities NMT 1.0%	Pass
Organic Impurities – Limit of Chlorinated Compounds Chlorinated Compounds (as Cl)	USP FCC	NMT 30ppm of Cl NMT 0.003%	<30 ppm <0.003%
Organic Impurities - Fatty Acids and Esters	USP FCC	NMT 1mLof 0.5N NaOH is consumed NMT 4mL of 0.5N NaOH is consumed	Pass Pass
Color	USP/FCC	To Pass Test	Pass
Readily Carbonizable Substances	FCC	To Pass Test	Pass
Residue on Ignition	USP FCC	NMT 0.01% NMT 0.01%	<0.005%
Water	USP FCC	NMT 5.0% NMT 1.0%	0.09%

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/FCC, Rev. 2.1, 01/18, EF

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.