PRODUCT SPECIFICATIONS SHEET

WORLD GRADE ™
PROPYLENE GLYCOL

Meets USP/EP/JP/FCC Grade Monographs

Kosher

WORLD/GMP GRADE

Catalog Number: 369WORLD-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (on anhydrous basis) Assay, wt%	USP FCC	NLT 99.5%	99.93%
Identification A – Infrared Absorption	USP/FCC	Conforms to Reference Spectrum	Conforms
Identification A – Relative Density Specific Gravity	EP USP/FCC JP	1.035 - 1.040 @ 20°C 1.035 – 1.037 @ 25°C 1.035 – 1.040 @ 20°C	1.038 1.035 1.038
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 B – Refractive Index	EP	1.431 – 1.433 @ 20°C	1.432
Identification C – GC	USP	Conforms to Reference Chromatogram	Pass
Identification C – Boiling Point Distilling Range Distilling Range	EP JP FCC	184°C – 189°C No less than 95% volume Between 185°C – 189°C	Pass Pass Pass
Identification D	EP	Meets Requirements of Test	Pass
Identification (1)	JP	The crystals melt between 174C – 178C	Pass
Identification (2)	JP	Characteristic odor is evolved	Pass
Acidity Purity 1 - Acidity	USP EP FCC JP	NMT 0.20 mL 0.10N NaOH NMT 0.05 mL 0.1M NaOH To Pass Test The solution has red color	Pass
Inorganic Impurities - Residue on Ignition Residue on Ignition Residue on Ignition	USP JP FCC	NMT 3.5mg NMT 0.005% NMT 0.007%	<3.5mg <0.005% <0.005%
Inorganic Impurities – Chloride and Sulfate Purity 2 - Chloride	USP JP	NMT 70ppm as Chloride NMT 0.007%	<10ppm <0.001%
Inorganic Impurities – Chloride and Sulfate Purity 3 - Sulfate	USP JP	NMT 60ppm as Sulfate NMT 0.002%	<10ppm <0.001%
Inorganic Impurities - Heavy Metals Purity 4 – Heavy Metals Heavy Metals	USP JP EP	NMT 5 ppm	Pass
Elemental Impurities	USP <232> & <233>	Complies with requirements	Complies*
Lead	FCC	NMT 1 mg/kg	<1 mg/kg
Purity 5 – Arsenic	JP	NMT 2ppm	Pass

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Purity 6 – Glycerin	JP	No odor of acrolein is perceptible	Pass
Oxidizing Substances	EP	Meets Requirements of Test	Pass
Reducing Substances	EP	Meets Requirements of Test	Pass
Sulfated Ash	EP	0.01% max	<0.01%
Water	USP/EP/FCC JP	0.20% Max. 0.5% Max.	0.03%

*For specific results on individual metals, please inquire.

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.

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