PRODUCT SPECIFICATIONS SHEET

WORLD GRADE ®
ISOPROPYL ALCOHOL, 99%

Meets ACS/USP/FCC/EP/BP/JP Monographs

WORLD/GMP GRADE

Catalog Number: 231WORLD-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (corrected for water) Assay (corrected for water) Assay (wt%)	USP ACS FCC	99.0% min 99.5% min 99.7% min	 99.98%
Appearance	EP/BP/JP	Clear, colorless liquid	Pass
Solubility Solubility in water	EP/BP JP FCC/ACS	Miscible with water and alcohol Miscible with water, ethanol, methanol, diethyl ether To Pass Test	 Pass
Color (APHA)	ACS	10 max	5
Purity 1 – Clarity of Solution	JP	Solution is Clear	Pass
Nonvolatile Substances Purity 3 - Residue on Evaporation Limit of Nonvolatile Residue Nonvolatile Residue Residue after Evaporation	EP/BP JP USP FCC ACS	NMT 20ppm NMT 1.0mg / 20mL NMT 2.5 mg (0.005%) NMT 10 mg/kg 0.001% max	<10ppm <0.2mg <0.5 mg <10 mg/kg <0.001%
Specific Gravity	USP JP FCC	0.783 - 0.787 @ 25°C 0.785-0.788 @ 20°C NMT 0.7840@ 25°C	0.783 0.786 0.783
Identification A - Relative Density@20°C	EP/BP	0.785 - 0.789 g/ml	0.785
Identification A – Infrared Absorption Identification C – Infrared Absorption	USP EP/BP	To Pass Test Compares to standard	Pass Pass
Identification B	USP	To Pass Test	Pass
Identification Test 1 Identification Test 2	JP	Light yellow precipitate is formed Filter paper turns red-brown color	Pass Pass
Identification D	EP/BP	The entire sulfuric acid layer turns violet	Pass
Identification B - Refractive Index@20°C Identification - Refractive Index @20°C Refractive Index @ 20°C	EP/BP FCC USP	1.376 - 1.379 About 1.377 1.376 - 1.378	1.377
Acidity or Alkalinity	EP/BP	To Pass Test	Pass

Acidity Purity 2 – Acidity Acidity (as Acetic Acid)	USP JP FCC	NMT 0.7ml of 0.020N NaOH is required To pass the test NMT 10 mg/kg	Pass Pass Pass
Titrable Acid or Base	ACS	0.0001 meq/g	<0.0001 meq/g
Carbonyl Compounds	ACS	Propionaldehyde 0.002% max Acetone 0.002% max	Pass
Limit of Volatile Impurities	USP	Diethyl Ether NMT 0.1% Acetone NMT 0.1% Diisopropyl Ether NMT 0.1% n-Propyl Alcohol NMT 0.1% 2-Butanol NMT 0.1% Total NMT 1.0%	<0.1% <0.1% <0.1% <0.1% <0.1% <1.0%
Benzene and related substances Benzene (by GC) Total of Impurities (by GC)	EP/BP	 NMT 2ppm NMT 0.3 %	 None Detected <0.03%
Inorganic Impurities - Lead	FCC	NMT 1 mg/kg	<1 mg/kg
Substances Reducing Permanganate	FCC	The pink color is not entirely discharged	Pass
Absorbance	EP/BP	Measured between 230 nm and 310 nm 230nm 0.30max. 250nm 0.10max 270nm 0.03max 290nm 0.02max 310nm 0.01max The spectrum shows a steadily descending curve with no observable peaks or shoulders	 0.11 0.02 0.00 0.00 0.00 Pass
Peroxides Test	EP/BP	No color develops	Pass
Distilling Range 81 – 83°C Distillation Range, 1°C inc. 82.3°C	JP FCC	More than 94% (vol) To Pass Test	Pass Pass
Water, wt % Water, wt/v% Water, wt% Water Determination	EP/BP JP FCC/ACS USP	NMT 0.5% NMT 0.75% NMT 0.2% NMT 0.5%	0.06%

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: Isopropanol 99%-ACS/USP/FCC/EP/BP/JP, Rev. 2.4, 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.