PHARMCO by Greenfield Global

PRODUCT SPECIFICATIONS SHEET

Product Name	Isopropyl Alcohol 99% World/GMP, WORLD GRADE ®
Grade	ACS/USP/FCC/EP/BP/JP Grade
Catalog #	231WORLD

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay	USP	NLT 99.0%	99.94 %
Assay (corrected for water)	ACS	99.5% min	99.94 %
Assay	FCC	NLT 99.5% OF C_3H_8O	99.98 %
Appearance	EP/BP	The solution is clear and colourless	Pass
Appearance	JP	Clear, colorless liquid	Pass
Characters / Solubility	EP/BP	Appearance: clear, colourless liquid. Solubility: miscible with water and with ethanol (96 per cent).	Pass
Solubility	JP	Miscible with water, ethanol, methanol, diethyl ether	Pass
Solubility in water	FCC	After 1 h, the solution is as clear as an equal volume of water.	Pass
Solubility in water	ACS	To Pass Test	Pass
Color, APHA	ACS	10 max	1
Purity 1- Clarity of Solution	JP	Solution is Clear	Pass
Nonvolatile Substances	EP/BP	NMT 20ppm	0 ppm
Purity 3 - Residue on Evaporation	JP	NMT 1.0mg/20mL	0.0 mg
Limit of Nonvolatile Residue	USP	NMT 2.5 mg (0.005%)	0.0 mg
Nonvolatile Residue	FCC	NMT 10 mg/kg	0 mg/kg
Residue after Evaporation	ACS	0.001% max	0.000 %
Specific Gravity	USP	0.783 - 0.787 @25°C	0.783
Specific Gravity	JP	0.785-0.788 @ 20°C	0.787

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Specific Gravity	FCC	NMT 0.7840 @ 25°/25°	0.7832
Identification A - Relative Density	EP/BP	0.785 - 0.789 g/ml @ 20°C	0.785
Identification A - Infrared Spectroscopy	USP	To Pass Test	Pass
Identification B – Infrared Spectroscopy	FCC	The spectrum of the sample exhibits relative maxima at the same wavelengths as those of the reference spectrum	Pass
Identification C - Infrared Absorption	EP/BP	Compares to standard	Pass
Identification Test 1	JP	Light yellow precipitate is formed	Pass
Identification Test 2	JP	Filter paper turns red-brown color	Pass
Identification B	USP	To Pass Test	Pass
Identification C - Limit of Methanol	USP	NMT 0.02%	Pass
Identification D	EP/BP	The entire sulfuric acid layer turns violet	Pass
Identification B - Refractive Index @ 20°C	EP/BP	1.376-1.379	1.377
Identification A - Refractive Index	FCC	1.377 - 1.380 @ 20°	1.377
Refractive Index @ 20°C	USP	1.376-1.378	1.377
Acidity or Alkalinity	EP/BP	To Pass Test	Pass
Acidity	USP	NMT 0.70 ml of 0.020N NaOH is required	0.50 ml
Purity 2 - Acidity	JP	To pass Test	Pass
Acidity (as Acetic Acid)	FCC	NMT 10 mg/kg	LT 10 mg/kg
Titrable Acid or Base	ACS	0.0001 meq/g max	0.0001 meq/g
Carbonyl Compounds - Propionaldehyde	ACS	0.002% max	LT 0.002%
Carbonyl Compounds - Acetone	ACS	0.002% max	0.000 %

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Benzene and related substances - Benzene (by GC)	EP/BP	NMT 2 ppm	0 ppm
Benzene and related substances – Total of Impurities	EP/BP	NMT 0.3%	0.1 %
Inorganic Impurities - Lead	FCC	NMT 1 mg/kg	LT 1 mg/kg
Substances Reducing Permanganate	FCC	The pink color is not entirely discharged	Pass
Absorbance @230nm	EP/BP	0.30 max.	0.09
Absorbance @250nm	EP/BP	0.10 max.	0.02
Absorbance @270nm	EP/BP	0.03 max.	0.00
Absorbance @290nm	EP/BP	0.02 max.	0.00
Absorbance @310nm	EP/BP	0.01 max.	0.00
Absorbance	EP/BP	The spectrum shows a steadily descending curve with no observable peaks or shoulders	Pass
Absorbance @ 230nm	USP	NMT 0.30	0.09
Absorbance @ 250nm	USP	NMT 0.10	0.02
Absorbance @ 270nm	USP	NMT 0.03	0.00
Absorbance @ 290nm	USP	NMT 0.02	0.00
Absorbance @ 310nm	USP	NMT 0.01	0.00
Absorbance Curve	USP	The spectrum shows a steadily descending curve with no observable peaks or shoulders.	Pass
Volatile Impurities – Methanol	FCC	NMT 200 µL/L	LT 200 µL/L
Volatile Impurities – Any single specified impurity	FCC	NMT 1000 µL/L	LT 1000 µL/L
Volatile Impurities – Any other single unspecified impurity	FCC	NMT 1000 µL/L (calculated as ethyl acetate)	LT 1000 µL/L
Volatile Impurities - Sum of all impurities	FCC	NMT 5000 µL/L	LT 5000 µL/L

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Limit of Volatile Impurities - Methanol	USP	NMT 0.02%	LT 0.02%
Limit of Volatile Impurities - Diethyl Ether	USP	NMT 0.1%	LT 0.1%
Limit of Volatile Impurities - Acetone	USP	NMT 0.1%	None Detected
Limit of Volatile Impurities - Diisopropyl Ether	USP	NMT 0.1%	LT 0.1%
Limit of Volatile Impurities - n-Propyl Alcohol	USP	NMT 0.1%	LT 0.1%
Limit of Volatile Impurities - 2-Butanol	USP	NMT 0.1%	LT 0.1%
Limit of Volatile Impurities - Individual unspecified	USP	NMT 0.1%	LT 0.1%
Limit of Volatile Impurities - Total	USP	NMT 1.0%	LT 0.1%
Peroxides Test	EP/BP	No color develops	Pass
Distilling Range 81-83°C	JP	More than 94% (vol)	Pass
Distillation Range	FCC	Within a range of 1°, including 82.3°	Pass
Water, wt%	EP/BP	NMT 0.5%	0.04 %
Water, wt/v%	JP	NMT 0.75%	0.04 %
Water, wt%	ACS	NMT 0.2%	0.04 %
Water	FCC	NMT 0.2%	0.04 %
Water Determination	USP	NMT 0.5%	0.04 %
Ag (Silver)	USP<232>	Lot Analysis	0.00 ppm
As (Arsenic)	USP<232>	Lot Analysis	0.00 ppm
Au (Gold)	USP<232>	Lot Analysis	0.00 ppm
Ba (Barium)	USP<232>	Lot Analysis	0.00 ppm
Cd (Cadmium)	USP<232>	Lot Analysis	0.00 ppm

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Co (Cobalt)	USP<232>	Lot Analysis	0.00 ppm
Cr (Chromium)	USP<232>	Lot Analysis	0.00 ppm
Cu (Copper)	USP<232>	Lot Analysis	0.00 ppm
Hg (Mercury)	USP<232>	Lot Analysis	0.00 ppm
Ir (Iridium)	USP<232>	Lot Analysis	0.00 ppm
Li (Lithium)	USP<232>	Lot Analysis	0.00 ppm
Mo (Molybdenum)	USP<232>	Lot Analysis	0.00 ppm
Ni (Nickel)	USP<232>	Lot Analysis	0.00 ppm
Os (Osmium)	USP<232>	Lot Analysis	0.00 ppm
Pb (Lead)	USP<232>	Lot Analysis	0.00 ppm
Pd (Palladium)	USP<232>	Lot Analysis	0.00 ppm
Pt (Platinum)	USP<232>	Lot Analysis	0.00 ppm
Rh (Rhodium)	USP<232>	Lot Analysis	0.00 ppm
Ru (Ruthenium)	USP<232>	Lot Analysis	0.00 ppm
Sb (Antimony)	USP<232>	Lot Analysis	0.00 ppm
Se (Selenium)	USP<232>	Lot Analysis	0.00 ppm
Sn (Tin)	USP<232>	Lot Analysis	0.00 ppm
Tl (Thallium)	USP<232>	Lot Analysis	0.00 ppm
V (Vanadium)	USP<232>	Lot Analysis	0.00 ppm

Certification and Compliance Statements

This product is processed and packaged in compliance with Good Manufacturing Practices.

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This product complies with all of the current requirements listed in the United States Pharmacopeia, European Pharmacopeia, British Pharmacopeia, Japanese Pharmacopeia, Food Chemical Codex, American Chemical Society monographs.

This product is not derived, nor does it come in contact with, any materials derived from bovine or other animal sources.

No chemicals whatsoever are used as solvents at any point in the manufacture, processing or packaging of Isopropyl Alcohol. Only Class 2 and Class 3 residual solvents may appear as impurities / related substances / low level contaminants in IPA. Concentration of Class 2 Option 1 and Class 3 residual solvents is below limits in the current USP/NF General Chapter <467> and ICH Q3C Impurities: Residual Solvents.

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.