PRODUCT SPECIFICATIONS SHEET

Product Name	Ethyl Alcohol 95% (190 Proof) Grain GRADE ® World/GMP, WORLD
Grade	ACS/USP/EP/BP/JP/FCC Grade
Catalog #	111GMP190

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (by GC, corrected for water)	ACS	NLT 95.0%	95.01 %
Assay (by specific gravity@ 15.56°C)	USP	94.9% - 96.0% (by volume)	95.01 %
Assay (by specific gravity@25°C)	FCC	NLT 94.9%	95.01 %
Proof	27CFR 30.23	Lot Analysis	190.0
Characters / Solubility	EP/BP	Appearance: colourless, clear, volatile, flammable liquid, hygroscopic. Solubility: miscible with water and with methylene chloride. It burns with a blue, smokeless flame. BP: about 78°C	Pass
Description	JP	Ethanol is a clear, colorless liquid. It is miscible with water. It is flammable and burns with a light blue flame on ignitions. It is volatile. BP 78 - 79°C	Pass
Specific Gravity	USP	0.812 – 0.816 @ 15.56°C	0.8158
Specific Gravity @ 15.56°C	FCC	Not more than 0.8161 @ 15.56°C	0.8158
Specific Gravity @ 25.0°C	FCC	Not more than 0.8096 @ 25.0°C	0.8093
Identification Test B (Infrared Spectroscopy)	USP	Conforms to IR Spectra	Pass
Identification Test B (Infrared Spectroscopy)	EP/BP	Conforms to IR Spectra	Pass
Identification	JP	Sample and Reference Spectrum: Both exhibit similar	Pass

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
		intensities of absorption at the same wave numbers.	
Identification by Infrared Absorption	FCC	Conforms to IR Spectra	Pass
Identification Test C (Limit of Methanol)	USP	NMT 200 µL/L (200ppm) of Methanol	Pass
Identification Test C	EP/BP	An intense blue color appears on the paper and becomes paler after 10-15 minutes	Pass
Identification Test D	EP/BP	A yellow precipitate is formed within 30 minutes	Pass
Solubility in Water	ACS	To Pass Test	Pass
Solubility in Water	FCC	No haze of turbidity develops	Pass
Color of Solution	USP	The Sample solution has the appearance of water or is not more intensely colored than the Standard solution	Pass
Clarity of Solution	USP	Sample solution A and Sample solution B show the same clarity as that of water, or their opalescence is not more pronounced than that of the Standard suspension A.	Pass
Purity 1 – Clarity and Color of Solution	JP	The mixture remains clear	Pass
Color (APHA)	ACS	10 max.	1
Appearance	EP/BP	Clear and Colorless, the dilution remains clear when compared with water	Pass
Titrable Acid	ACS	0.0005 meq/g max.	0.0001 meq/g
Acidity or Alkalinity	USP	The solution is pink (30µg/g, expressed as acetic acid)	Pass

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Acidity or Alkalinity	EP/BP	The solution is pink (30ppm, expressed as acetic acid)	Pass
Purity 2 – Acidity or alkalinity	JP	Pink color develops	Pass
Acidity (as acetic acid)	FCC	NMT 0.5 mL of 0.02N sodium hydroxide is required to restore the pink color. (NMT 0.003%)	Pass
Titrable Base	ACS	0.0002 meq/g max.	0.0001 meq/g
Alkalinity (as NH3)	FCC	NMT 0.2 mL of 0.02N sulfuric acid is required to restore the red color. (NMT 3 mg/kg)	Pass
Substances Darkened by Sulfuric Acid	ACS	To Pass Test	Pass
Organic Impurities – Substances Darkened by Sulfuric Acid	FCC	The mixture is colorless or has no more color than either the acid or the sample before mixing.	Pass
Substances Reducing Permanganate	ACS	To Pass Test	Pass
Organic Impurities – Substances Reducing Permanganate	FCC	The pink color does not entirely disappear.	Pass
Residue after Evaporation	ACS	0.001%, max	0.000 %
Limit of Nonvolatile Residue	USP	NMT 2.5 mg	0.0 mg
Residue on Evaporation	EP/BP	25 ppm, max	0 ppm
Purity 5 - Residue on Evaporation	JP	NMT 2.5 mg	0.0 mg
Nonvolatile Residue	FCC	NMT 0.003%	0.001 %
UV Absorbance	USP	NMT 0.40 at 240 nm	0.27
UV Absorbance	EP/BP	maximum 0.40 at 240 nm	0.27
Purity 4 - Other Impurities (absorbance)	JP	NMT 0.40 at 240 nm	0.27

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
UV Absorbance	USP	NMT 0.30 between 250 and 260 nm	0.11
UV Absorbance	EP/BP	maximum 0.30 between 250 nm and 260 nm	0.11
Purity 4 - Other Impurities (absorbance)	JP	NMT 0.30 between 250 and 260 nm	0.11
UV Absorbance	USP	NMT 0.10 between 270 and 340 nm	0.02
UV Absorbance	EP/BP	maximum 0.10 between 270 nm and 340 nm	0.02
Purity 4 - Other Impurities (absorbance)	JP	NMT 0.10 between 270 and 340 nm	0.02
UV Absorbance	USP	The spectrum shows a steadily descending curve with no observable peaks or shoulders	Pass
UV Absorbance	EP/BP	The spectrum shows a steadily descending curve with no observable peaks or shoulders	Pass
Purity 4 - Other Impurities (absorbance)	JP	The spectrum shows a steadily descending curve with no observable peaks or shoulders	Pass
Inorganic Impurities – Lead	FCC	NMT 0.5 mg/kg	LT 0.5 mg/kg
Acetone/Isopropyl Alcohol	ACS	To Pass Test	Pass
Organic Impurities – Ketones, Isopropyl Alcohol	FCC	No precipitate forms within 3 min.	Pass
Methanol	ACS	0.1% max	Pass
Organic Impurities - Methanol	USP	NMT 200µL/L	2 µL/L
Volatile Impurities - Methanol	EP/BP	NMT 200 ppm V/V	2 ppm
Purity 3 – Volatile Impurities - Methanol	JP	NMT 200 ppm V/V	2 ppm
Organic Impurities – Methanol	FCC	200 ppm max.	2 ppm

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Organic Impurities - Acetaldehyde and Acetal	USP	NMT 10µL/L, expressed as acetaldehyde	0 µL/L
Volatile Impurities - Acetaldehyde and Acetal	EP/BP	10 ppm V/V max. expressed as acetaldehyde	0 ppm
Purity 3 – Volatile Impurities - Acetal and Acetaldehyde	JP	NMT 10 ppm V/V as acetaldehyde	0 ppm
Organic Impurities - Benzene	USP	NMT 2µL/L	0 µL/L
Volatile Impurities - Benzene	EP/BP	2ppm V/V max.	0 ppm
Purity 3 – Volatile Impurities - Benzene	JP	NMT 2ppm V/V	0 ppm
Organic Impurities – Any other single impurity	FCC	1000 ppm max.	1 ppm
Organic Impurities - Sum of all other impurities	USP	NMT 300µL/L	4 µL/L
Volatile Impurities - Sum of all other impurities	EP/BP	NMT 300 ppm	4 ppm
Purity 3 – Volatile Impurities - Sum of all other impurities	JP	NMT 300 ppm	4 ppm
Organic Impurities – Sum of all impurities	FCC	5000 ppm max.	4 ppm
Organic Impurities – Fusel Oil	FCC	No foreign odor is perceptible when the last traces of alcohol leave the paper.	Pass
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
Co (Cobalt)	USP<232>	Lot Analysis	0.00 ppm
Cr (Chromium)	USP<232>	Lot Analysis	0.00 ppm

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TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
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 complies with all of the current requirements listed in the United States Pharmacopeia (USP), European Pharmacopeia (EP), British Pharmacopeia (BP), Japanese Pharmacopeia (JP), Food Chemical Codex (FCC), and American Chemical Society (ACS) monographs except for EP/BP and JP Assay tests, EP/BP Identification A – Relative Density test, and JP Specific Gravity test due to the variability in ethanol concentration limits in respective compendial monographs.

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

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 Ethyl Alcohol 95% (190 Proof). Only Class 2 and Class 3 residual solvents may appear as impurities / related substances / low level contaminants in Ethanol. 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.

Recommended retest period excludes UV Absorbance for pure Ethyl Alcohol unless packaged in glass or UV protected drums (see shelf-life statement).

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.