Ethyl Alcohol 50%

Grain Derived

Catalog number: 111000100

Test	Mono-graph	Specification	Typical Result
Assay (v/v)	Internal	49.50% - 50.50%	50.01 %
Proof	27CFR 30	Lot Analysis	100.0
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
Specific Gravity	Internal	0.9332 -0.9352 @ 15.56°C	0.9342
Specific Gravity	Internal	0.9306-0.9326 @ 20.00°C	0.9316
Identification Test B (Infrared Spectroscopy)	USP	Conforms to IR Spectra	Pass
Identification by Infrared Absorption	FCC	Conforms to IR Spectra	Pass
Organic Impurities - Methanol	USP	NMT 200µL/L	1 µL/L
Organic Impurities - Methanol	FCC	200 ppm max.	1 ppm
Organic Impurities - Acetaldehyde and Acetal	USP	NMT 10µL/L, expressed as acetaldehyde	0 µL/L
Organic Impurities - Benzene	USP	NMT 2µL/L	1 µL/L
Organic Impurities - Sum of all other impurities	USP	NMT 300µL/L	1 µL/L
Organic Impurities - Fusel Oil	FCC	No foreign odor is perceptible when the last traces of alcohol leave the paper.	Pass

Test	Mono-graph	Specification	Typical Result
Organic Impurities - Ketones, Isopropyl Alcohol	FCC	No precipitate forms within 3 min.	Pass
Organic Impurities - Any other single impurity	FCC	1000 ppm max.	1 ppm
Organic Impurities - Sum of all impurities	FCC	5000 ppm max.	0 ppm
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
Organic Impurities - Substances Reducing Permanganate	FCC	The pink color does not entirely disappear.	Pass
Inorganic Impurities - Lead	FCC	NMT 0.5 mg/kg	LT 0.5 mg/kg
Limit of Nonvolatile Residue	USP	NMT 2.5 mg	0.0 mg
Nonvolatile Residue	FCC	NMT 0.003%	0.000 %
Acidity or Alkalinity	USP	The solution is pink (30µg/g, expressed as acetic acid)	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
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
UV Absorbance	USP	NMT 0.40 at 240 nm	0.02
UV Absorbance	USP	NMT 0.30 between 250 and 260 nm	0.01
UV Absorbance	USP	NMT 0.10 between 270 and 340 nm	0.00
Solubility in Water	FCC	No haze or turbidity develops	Pass

Certification and Compliance Statements

This product complies with all of the current requirements listed in the United States Pharmacopeia, Food Chemical Codex and National Formulary monographs with the exception of assay and specific gravity.

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 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. 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>.

Greenfield products are for further commercial manufacturing, laboratory use, or research. Greenfield is not registered with the United States Food and Drug Administration (FDA) as a drug manufacturing facility. Greenfield products are not registered with the FDA as active pharmaceutical ingredients in drug manufacturing.
Appropriate/legal use of all products are the responsibility of the user and subject to applicable local laws and regulations.