Ethyl Acetate

World/GMP, WORLD GRADE ®

Grade: ACS/USP/NF/EP/BP **Catalog number:** 330WORLD

Test	Mono-graph	Specification	Typical Result
Assay (corrected for water)	ACS	99.5%, min	99.99%
Assay	NF	98.0-102.0%	99.96%
Identification A	NF	Infrared Spectroscopy	Pass
Identification A	EP/BP	Boiling point: 76°C-78°C	Pass
Identification B	EP/BP	IR comparable with Reference spectrum	Pass
Identification C	EP/BP	It gives the reaction of acetyl	Pass
Identification D	EP/BP	It gives the reaction of esters	Pass
Specific Gravity @ 25°C	NF	0.894-0.898	0.8970
Refractive Index @ 20°C	EP/BP	1.370-1.373	1.3720
Relative Density @ 20°C	EP/BP	0.898-0.902	0.9020
Acidity	NF	NMT 0.10 mL of 0.10N NaOH is required	0.05 mL
Acidity	EP/BP	The solution remains pink for not less than 15 sec.	Pass
Substances Darkened by Sulfuric Acid	ACS	Passes Test	Pass
Readily Carbonizable Substances	NF	No dark zone develops within 15 minutes	Pass
Reaction with Sulfuric Acid	EP/BP	Interface between the 2 liquids is not colored	Pass
Chromatographic Purity – Acetaldehyde	NF	NMT 0.1%	None Detected
Chromatographic Purity - 1-Ethoxy-2-methylpropane	NF	NMT 0.1%	None Detected

Test	Mono-graph	Specification	Typical Result
Chromatographic Purity - Methyl compounds	NF	NMT 0.1%	None Detected
Chromatographic Purity - Other impurities	NF	NMT 0.3%	None Detected
Related substances	EP/BP	NMT 0.2% of the area of the principal peak.	LT 0.1%
Color (APHA)	ACS	10 max.	1
Appearance of Solution	EP/BP	The solution is clear and colorless	Pass
Characters	EP/BP	Appearance: clear, colourless, volatile liquid. Solubility: soluble in water, miscible with acetone, with ethanol (96 per cent) and with methylene chloride.	Pass
Residue After Evaporation	ACS	0.003% max.	0.000%
Residue on evaporation	EP/BP	30 ppm max.	0
Limit of nonvolatile residue	NF	NMT 0.02%	0.00%
Water	ACS	0.2% max.	0.01%
Water	EP/BP	0.1% max.	0.02%
Titrable Acid	ACS	0.0009 meq/g max	0.0003 meq/g
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

Test	Mono-graph	Specification	Typical Result
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 has been processed and packaged in compliance with excipient Good Manufacturing Practices.

This product complies with all of the current requirements listed in the United States Pharmacopeia, National Formulary, European Pharmacopeia, British Pharmacopeia, 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 Ethyl Acetate. Only Class 2 and Class 3 residual solvents may appear as impurities / related substances / low level contaminants in Ethyl Acetate. 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.

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