



PHARMCO[®]
by Greenfield Global

SPECIFICATION SHEET

Product Name	Ethyl Alcohol 100% (200 Proof)
Grade	USP/EP/BP/JP Grade
Catalog #	1113992
Date of Manufacture:	DD-MMM-YYYY
Recommended Retest Date:	DD-MMM-YYYY
Manufactured by:	Greenfield Global Inc., 275 Bloomfield Road, Chatham, Ontario, N7M 0N6, Canada
Packaged by:	Greenfield Global LFS Ireland Limited, IDA Business & Technology Park Mountrath Road, Portlaoise, Laois, R32 PXV6, Ireland

TEST	METHOD	SPECIFICATION
Assay (by specific gravity@15.56°C)	USP	NLT 99.5%
Assay (by relative density @20°C)	EP/BP	NLT 99.5% (V/V)
Assay (by relative density @ 20°C)	EP/BP	NLT 99.2% (m/m)
Assay (by specific gravity@15°C)	JP	NLT 99.5%
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
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
Identification Test A (Specific Gravity)	USP	It meets the requirements of the test for specific gravity
Identification A - Relative Density	EP/BP	0.790 - 0.793 @ 20°C
Specific Gravity	USP	NMT 0.7962 @ 15.56°C
Specific Gravity	JP	d 15/15 0.79422 – 0.79679
Identification Test B (Infrared Spectroscopy)	USP	Conforms to IR Spectra
Identification Test B (Infrared Spectroscopy)	EP/BP	Conforms to IR Spectra
Identification	JP	Sample and Reference Spectrum: Both exhibit similar intensities of absorption at the same wave numbers
Identification Test C (Limit of Methanol)	USP	NMT 200 µL/L (200ppm) of Methanol
Color of Solution	USP	The Sample solution has the appearance of water or is not more intensely colored than the Standard solution

Greenfield Global LFS Ireland Limited, IDA Business & Technology Park
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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.
Purity 1 – Clarity and Color of Solution	JP	The mixture remains clear
Appearance	EP/BP	Clear and Colorless, the dilution remains clear when compared with water
Acidity or Alkalinity	USP	The solution is pink (30µg/g, expressed as acetic acid)
Acidity or Alkalinity	EP/BP	The solution is pink (30ppm, expressed as acetic acid)
Purity 2 – Acidity or Alkalinity	JP	Pink color develops
Limit of Nonvolatile Residue	USP	NMT 2.5 mg
Residue on Evaporation	EP/BP	25 ppm, max
Purity 5 - Residue on Evaporation	JP	NMT 2.5 mg
UV Absorbance	USP	NMT 0.30 between 250 and 260 nm
UV Absorbance	USP	NMT 0.10 between 270 and 340 nm
UV Absorbance	USP	NMT 0.40 at 240 nm
UV Absorbance	USP	The spectrum shows a steadily descending curve with no observable peaks or shoulders
UV Absorbance	EP/BP	maximum 0.30 between 250 nm and 260 nm
UV Absorbance	EP/BP	maximum 0.10 between 270 nm and 340 nm
UV Absorbance	EP/BP	maximum 0.40 at 240 nm
UV Absorbance	EP/BP	The spectrum shows a steadily descending curve with no observable peaks or shoulders
Purity 4 - Other Impurities (absorbance)	JP	NMT 0.30 between 250 and 260 nm
Purity 4 - Other Impurities (absorbance)	JP	NMT 0.10 between 270 and 340 nm
Purity 4 - Other Impurities (absorbance)	JP	NMT 0.40 at 240 nm
Purity 4 - Other Impurities (absorbance)	JP	The spectrum shows a steadily descending curve with no observable peaks or shoulders
Organic Impurities - Acetaldehyde and Acetal	USP	NMT 10 µL/L, expressed as acetaldehyde
Organic Impurities - Benzene	USP	NMT 2 µL/L
Organic Impurities - Methanol	USP	NMT 0.5, corresponding to 200 µL/L
Organic Impurities - Sum of all other impurities	USP	NMT 300 µL/L
Volatile Impurities - Acetaldehyde and Acetal	EP/BP	10 ppm V/V max. expressed as acetaldehyde



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Volatile Impurities - Benzene	EP/BP	2 ppm V/V max.
Volatile Impurities - Methanol	EP/BP	NMT 200 ppm V/V
Volatile Impurities - Sum of all other impurities	EP/BP	NMT 300 ppm
Purity 3 – Volatile Impurities - Acetal and Acetaldehyde	JP	NMT 10 ppm V/V expressed as acetaldehyde
Purity 3 – Volatile Impurities - Benzene	JP	NMT 2 ppm V/V
Purity 3 – Volatile Impurities - Methanol	JP	NMT 200 ppm V/V
Purity 3 – Volatile Impurities - Sum of all other impurities	JP	NMT 300 ppm

**LT – Less than, MT – More than, NMT – No more than*

Certification and Compliance Statements

This lot of Anhydrous Ethyl Alcohol complies with all of the current requirements listed in the United States Pharmacopeia, European Pharmacopeia, British Pharmacopeia, and Japanese Pharmacopeia monographs.

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

Other Certification Statements are available on request.

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.