

PRODUCT SPECIFICATIONS SHEET
WORLD GRADE ®
ETHYL ALCOHOL 96% (192 PROOF)
Meets ACS/USP/EP/BP/JP Grade Monographs
HPLC-UV, WORLD/GMP GRADE
Grain Derived Ethanol
 Main Catalog Number: 111WORLDUV192-size code*

Available in the following sizes:

*Refer to Master Price List – Individual package sizes have unique size codes

Manufactured in compliance with cGMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (by GC, corrected for water)	ACS	NLT 95.0%	96.02%
Assay (by relative density @20°C) Assay (by specific gravity@15°C)	EP/BP ¹ JP	95.1% - 96.9% (by volume) 95.1% - 96.9% (by volume)	96.02%
Proof	27CFR 30.23	Lot Analysis	192.0
Characters Description	EP / BP JP	Ethanol is a clear, colorless volatile, flammable liquid, hygroscopic. It is miscible with water and methylene chloride. It burns with a blue, smokeless flame. BP: about 78°C	Pass
Identification A - Relative Density	EP/BP ¹	0.805 – 0.812 @ 20°C	0.808
Specific Gravity	JP ¹	d 15/15 0.80872 – 0.81601	0.81271
Identification Test B (Infrared Spectroscopy)	USP/EP/BP JP	Conforms to IR Spectra Conforms to IR Spectra	Pass 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 30minutes	Pass
Solubility in Water	ACS	To Pass Test	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 Solutions show the same clarity as that of water, or their opalescence is not more pronounced than that of the Standard solution.	Pass
Purity 1 – Clarity and Color of Solution	JP	The mixture remains clear	Pass
Appearance	EP/BP	Clear and Colorless, the dilution remains clear when compared with water	Pass
Acidity or Alkalinity	USP/EP/BP JP	The solution is pink (30ppm, as acetic acid) A light red color develops	Pass Pass
Purity 2 – Acidity or alkalinity			
Titration Acid	ACS	0.0005 meq/g max.	<0.0003 meq/g
Titration Base	ACS	0.0002 meq/g	<0.0001 meq/g
Acetone/Isopropyl Alcohol	ACS	To Pass Test	Pass
Methanol	ACS	0.1% max	<0.1%
Substances Darkened by Sulfuric Acid	ACS	To Pass Test	Pass

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Substances Reducing Permanganate	ACS	To Pass Test	Pass
Limit of Nonvolatile Residue	USP	NMT 2.5 mg	0.5mg
Residue after Evaporation	ACS	0.001% , max	0.0006%
Residue on Evaporation	EP/BP	25 ppm, max	<10 ppm
Purity 5 - Residue on Evaporation	JP	NMT 2.5 mg	0.5mg
UV Absorbance	USP/EP/BP	Examine between 235nm – 340nm. 240nm 0.40 max.	0.34
Purity 4 - Other Impurities (absorbance)	JP	250nm-260nm 0.30 max. 270nm-340nm 0.10 max. The spectrum shows a steadily descending curve with no observable peaks or shoulders	0.15 0.05 Pass
Ultraviolet absorption	ACS	210nm 0.40 max. 220nm 0.25 max. 230nm 0.15 max. 240nm 0.05 max. 270nm – 400nm 0.01 max.	0.34 0.17 0.08 0.03 0.00
Organic Impurities	USP	Methanol 200 ppm	<10 ppm
Volatile Impurities	EP/BP	Acetaldehyde and Acetal 10ppm max	<1 ppm
Purity 3 – Volatile Impurities	JP	Benzene 2ppm max. Sum of all other impurities 300ppm max.	None Detected <50ppm

¹No USP specification for this assay

Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients¹

Reported in µg/g (ppm)

Element	Class	Oral Concentration µg/g	Parenteral Concentration µg/g	Inhalation Concentration µg/g	TYPICAL RESULT (in µg/g) (ppm)
Cd (Cadmium)	1	0.5	0.2	0.2	0.00
Pb (Lead)	1	0.5	0.5	0.5	0.00
As (Arsenic)	1	1.5	1.5	0.2	0.00
Hg (Mercury)	1	3	0.3	0.1	0.00
Co (Cobalt)	2A	5	0.5	0.3	0.00
V (Vanadium)	2A	10	1	0.1	0.00
Ni (Nickel)	2A	20	2	0.5	0.00
Tl (Thallium)	2B	0.8	0.8	0.8	0.00
Au (Gold)	2B	10	10	0.1	0.00
Pd (Palladium)	2B	10	1	0.1	0.00
Ir (Iridium)	2B	10	1	0.1	0.00
Os (Osmium)	2B	10	1	0.1	0.00
Rh (Rhodium)	2B	10	1	0.1	0.00
Ru (Ruthenium)	2B	10	1	0.1	0.00
Se (Selenium)	2B	15	8	13	0.00
Ag (Silver)	2B	15	1	0.7	0.00
Pt (Platinum)	2B	10	1	0.1	0.00
Li (Lithium)	3	55	25	2.5	0.00
Sb (Antimony)	3	120	9	2	0.00
Ba (Barium)	3	140	70	30	0.00
Mo (Molybdenum)	3	300	150	1	0.00
Cu (Copper)	3	300	30	3	0.00
Sn (Tin)	3	600	60	6	0.00
Cr (Chromium)	3	1100	110	0.3	0.00

¹Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.
 Form: Ethanol, Pure, 192, ACS/USP/EP/JP Rev. 2.0, 01/18, PJM

Form: Ethanol, Pure, 192, ACS/USP/EP/JP Rev. 2.3, 10/20, KAD

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.