

PRODUCT SPECIFICATIONS SHEET
WORLD/GMP GRADE
ETHYL ALCOHOL
Absolute, Dehydrated, Anhydrous, 200 Proof, Pure Ethanol
Meets ACS/USP/EP/BP/JP GRADE Monographs
 With USP<232>, EMA and ICH Q3D Test Results
 BET Tested
Grain Derived Ethanol
 Catalog Number: 111WORLD200BET-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (by GC, corrected for water)	Internal ACS	NLT 99.9% NLT 99.5%	99.98%
Assay (by specific gravity@15.56°C) Assay (by specific gravity@15.56°C) Assay (by relative density @20°C) Assay (by specific gravity@15°C)	Internal USP EP/BP JP	NLT 99.9% NLT 99.5%	99.99%
Proof	27CFR 30.23	Lot Analysis	200.0
Characters Description	EP / BP JP	Ethanol is a clear, colorless volatile, flammable liquid. It is miscible with water and methylene chloride. It burns with a blue, smokeless flame. BP: about 78°C	Pass
Identification Test A Identification A - Relative Density	USP EP/BP	It meets the requirements of the test for Specific Gravity 0.790 – 0.793 @ 20°C	Pass 0.7905
Specific Gravity	USP JP	NMT 0.7962 at 15.56C d ¹⁵ / ₁₅ 0.79422 – 0.79679	0.7938 0.79434
Identification Test B Identification I	USP/EP/BP JP	Conforms to IR Spectra Conforms to IR Spectra	Pass 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
Water (wt%)	ACS	0.2%, max	0.02%
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
Color (APHA)	ACS	10 max	<10
Clarity of Solution	USP	Sample Solutions show the same clarity as that of water, or their opalescence is not more pronounced than that of Standard suspension A.	Pass
Purity 1 – Clarity and Color of Solution	JP	The mixture remains clear	Pass
Appearance	EP/BP	Clear and Colorless. Dilution remains clear when compared with water	Pass
Acidity or Alkalinity Purity 2 – Acidity or alkalinity	USP/EP/BP JP	The solution is pink (30ppm, as acetic acid) A light red color develops	Pass Pass
Titration Acid	ACS	0.0005 meq/g max.	<0.0003 meq/g

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Titration Base	ACS	0.0002 meq/g	<0.0001 meq/g
Acetone	ACS	0.001% max.	<0.001%
Isopropyl Alcohol		0.003% max.	<0.003%
Methanol	ACS	0.1% max	<0.1%
Substances Darkened by Sulfuric Acid	ACS	To Pass Test	Pass
Substances Reducing Permanganate	ACS	To Pass Test	Pass
Limit of Nonvolatile Residue	USP	The weight of the residue does not exceed 2.5 mg	0.5mg
Residue on Evaporation	ACS	NMT 0.001%	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	
Purity 4 - Other Impurities (absorbance)	JP	240nm 0.40 max. 250nm-260nm 0.30 max. 270nm-340nm 0.10 max.	0.29 0.11 0.02
		The spectrum shows a steadily descending curve with no observable peaks or shoulders	Pass
Organic Impurities	USP	Methanol 200 ppm	<5 ppm
Volatile Impurities	EP/BP	Acetaldehyde and Acetal 10ppm max	None Detected
Purity 3 – Volatile Impurities	JP	Benzene 2ppm max.	None Detected
		Sum of all other impurities 300ppm max.	<50ppm
Endotoxin Limit	Custom	0.5 EU/mL max.	Pass

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, 200, ACS/USP/EP/JP, BET, Rev. 1.7, 11/17, PJM

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.