

PRODUCT SPECIFICATIONS SHEET
WORLD GRADE ®
ETHYL ALCOHOL 95%
Meets ACS/USP/EP/BP/JP/FCC GRADE Monographs
WORLD/GMP GRADE
Grain Derived Ethanol
 Catalog Number: 111GMP190-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)	ACS	NLT 95.0%	95.01%
Assay (by specific gravity@15.56°C)	USP ¹	94.9% - 96.0% (by volume)	95.01%
Assay (by specific gravity@25°C)	FCC	NLT 94.9%	
Proof	27CFR 30.23	Lot Analysis	190.0
Characters	EP/BP	Ethanol is a clear, colorless volatile, flammable liquid, hygroscopic. It is miscible with water and methylene chloride.	Pass
Description	JP	It burns with a blue, smokeless flame. BP: about 78°C	Pass
Identification Test A (Specific Gravity)	USP ¹	It meets the specifications of the test for Specific Gravity	Pass
Specific Gravity	USP ¹	0.812 - 0.816 @ 15.56°C	0.8158
Specific Gravity	FCC	Not more than 0.8096 @ 25.0oC	0.8092
Identification Test B (Infrared Spectroscopy)	USP/EP/BP	Conforms to IR Spectra	Pass
Identification 1	JP		
Identification (Infrared Spectra)	FCC		
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
Solubility in Water	FCC	No haze or turbidity develops	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 solution A and Sample solution B 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	USP/EP/BP	The solution is pink (30ppm, as acetic acid)	Pass
Purity 2 – Acidity or alkalinity	JP	A light red color develops	Pass
Acidity (as acetic acid)	FCC	<0.003%	Pass
Alkalinity (as NH3)	FCC	<3 mg/kg	Pass

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT	
Titration Acid	ACS	0.0005 meq/g max.	<0.0003 meq/g	
Titration Base	ACS	0.0002 meq/g	<0.0001 meq/g	
Organic Impurities - Fusel Oil	FCC	To Pass Test	Pass	
Acetone/Isopropyl Alcohol	ACS	To Pass Test	Pass	
Organic Impurities - Ketones, Isopropyl Alcohol	FCC	To Pass Test	Pass	
Methanol	ACS	0.1% max	<0.1%	
Inorganic Impurities - Lead	FCC	NMT 0.5 mg/kg	Pass	
Organic Impurities - Substances Darkened by Sulfuric Acid	ACS/FCC	To Pass Test	Pass	
Organic Impurities - Substances Reducing Permanganate	ACS/FCC	To Pass Test	Pass	
Limit of Nonvolatile Residue	USP	NMT 2.5 mg	0.5mg	
Nonvolatile Residue	FCC	NMT 0.003%	<0.001%	
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 JP	Examine between 235nm – 340nm		
Purity 4 - Other Impurities (absorbance)		240nm	0.40 max.	0.24
		250nm-260nm	0.30 max.	0.09
		270nm-340nm	0.10 max.	0.02
		The spectrum shows a steadily descending curve with no observable peaks or shoulders.	Pass	
Organic Impurities	USP EP/BP JP	Methanol	200 ppm max.	<5 ppm
Volatile Impurities		Sum of Acetal and Acetaldehyde	10 ppm max.	<1 ppm
Purity 3 – Volatile Impurities		Benzene	2 ppm max.	<1 ppm
		Total of all other impurities	300 ppm max.	<20 ppm
Organic Impurities – Methanol and Other Volatile Impurities	FCC	Methanol	200 ppm max.	<5 ppm
		Any other single impurity	1000 ppm max.	<1 ppm
		Sum of all impurities	5000 ppm max.	<20 ppm

¹No EP/BP/JP specifications 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, 190, GMP, Rev. 2.5, 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.