

**PRODUCT SPECIFICATIONS SHEET**  
**WORLD GRADE ®**  
**ETHYL ALCOHOL**  
**Absolute, Dehydrated, Anhydrous, 200 Proof, Pure Ethanol**  
**Meets ACS/USP/EP/BP/JP/FCC GRADE Monographs**  
**WORLD/GMP GRADE**  
*Grain Derived Ethanol*

Catalog Number: 111WEXCP200-Size Code\*

\*Individual package sizes have unique size codes

**This product is manufactured in compliance with the EXCiPACT Standard for Pharmaceutical Excipients and conforms to the ACS/USP/EP/BP/JP/FCC Ethanol monographs.**

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) Assay (by specific gravity@25°C)	Internal USP EP/BP JP FCC	NLT 99.9% NLT 99.5% NLT 99.5% NLT 99.5% NLT 94.9%	99.99%
Proof	27CFR 30.23	Lot Analysis	200.0
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	It meets the requirements of the test for Specific Gravity	Pass
Identification A - Relative Density	EP/BP	0.790 – 0.793 @ 20°C	0.7905
Specific Gravity	USP JP	NMT 0.7962 at 15.56C $d_{15}^{15}$ 0.79422 – 0.79679	0.7937 0.79434
Specific Gravity	FCC	Not more than 0.8096 @ 25.0°C	0.7871
Identification Test B (Infrared Spectroscopy) Identification 1 Identification (Infrared Spectra)	USP/EP/BP JP FCC	Conforms to IR Spectra	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 30 minutes	Pass
Water (wt%)	ACS	0.2%, max	0.02%
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

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Color (APHA)	ACS	10 max	<10
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 NH <sub>3</sub> )	FCC	<3 mg/kg	Pass
Titration Acid	ACS	0.0005 meq/g max.	<0.0003 meq/g
Titration Base	ACS	0.0002 meq/g max.	<0.0001 meq/g
Organic Impurities - Fusel Oil	FCC	To Pass Test	Pass
Acetone	ACS	0.001% max.	<0.001%
Isopropyl Alcohol		0.003% max.	<0.003%
Organic Impurities – Ketones, Isopropyl Alcohol	FCC	To Pass Test	Pass
Methanol	ACS	0.1% max	<0.1%
Organic Impurities – Substances Darkened by Sulfuric Acid	ACS/FCC	To Pass Test	Pass
Organic Impurities – Substances Reducing Permanganate	ACS/FCC	To Pass Test	Pass
Inorganic Impurities - Lead	FCC	NMT 0.5 mg/kg	Pass
Limit of Nonvolatile Residue	USP	The weight of the residue does not exceed 2.5 mg	0.5mg
Nonvolatile Residue	FCC	NMT 0.003%	<0.001%
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. 240nm 0.40 max. 250nm-260nm 0.30 max. 270nm-340nm 0.10 max.	0.29 0.11 0.02
Purity 4 - Other Impurities (absorbance)	JP	The spectrum shows a steadily descending curve with no observable peaks or shoulders	Pass
Organic Impurities	USP	Methanol 200 ppm max.	<5 ppm
Volatile Impurities	EP/BP	Sum of Acetal and Acetaldehyde 10 ppm max.	None Detected
Purity 3 – Volatile Impurities	JP	Benzene 2 ppm max. Total of all other impurities 300 ppm max.	None Detected <50ppm
Organic Impurities – Methanol and Other Volatile Impurities	FCC	Methanol 200 ppm max. Any other single impurity 1000 ppm max. Sum of all impurities 5000 ppm max.	<5 ppm <1 ppm <20 ppm

**Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients<sup>1</sup>**

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

<sup>1</sup>Includes 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/FCC Rev. 3.2, 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.