

PRODUCT SPECIFICATIONS SHEET
WORLD GRADE ®
ETHYL ALCOHOL 95.5% (191 PROOF)
Harmonized
Meets ACS/USP/EP/BP/JP Grade Monographs
WORLD/GMP GRADE
Grain Derived Ethanol
 Catalog Number: 111WORLD191-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% | 95.52% |
| Assay (by specific gravity@15.56°C) | USP | 94.9% - 96.0% (by volume) | 95.52% |
| Assay (by relative density @20°C) | EP/BP | 95.1% - 96.9% (by volume) | |
| Assay (by specific gravity@15°C) | JP | 95.1% - 96.9% (by volume) | |
| Proof | 27CFR 30.23 | Lot Analysis | 191.0 |
| Identification A - Specific Gravity | USP | 0.812 - 0.816 @ 15.56°C | 0.8129 |
| Identification A - Relative Density | EP/BP | 0.805 - 0.812 @ 20°C | 0.8097 |
| Specific Gravity | JP | $d^{15/15}$ 0.80872 - 0.81601 | 0.81441 |
| Identification Test B (Infrared Spectroscopy) | USP/EP/BP | Conforms to IR Spectra | Pass |
| Identification 1 | JP | 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 30minutes | Pass |
| Solubility in Water | ACS | To Pass Test | Pass |
| Solubility | EP/BP | Miscible with water and with methylene chloride | |
| 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 Reference. The mixture remains clear | Pass |
| Purity 1 – Clarity and Color of Solution | JP | | 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 |
| 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 |
| Substances Reducing Permanganate | ACS | To Pass Test | Pass |

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

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, 191, ACS/USP/EP/JP Rev. 2.7, 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.