

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

Catalog Number: 111WORLD200-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%<br>NLT 99.5%   | 99.98%            |
| Assay (by specific gravity@15.56°C)           | Internal       | NLT 99.9%  | 99.99%            |
| Assay (by specific gravity@15.56°C)           | USP            | NLT 99.5%  |                   |
| Assay (by relative density @20°C)             | EP/BP          | NLT 99.5%  |                   |
| Assay (by specific gravity@15°C)              | JP             | NLT 99.5%  |                   |
| Assay (by specific gravity@25°C)              | FCC            | NLT 94.9%  |                   |
| Proof   | 27CFR<br>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.<br>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<br>JP      | NMT 0.7962 @ 15.56°C<br>d <sup>15</sup> / <sub>15</sub> 0.79422 – 0.79679  | 0.7937<br>0.79434 |
| Specific Gravity                              | FCC            | Not more than 0.8096 @ 25.0°C<br>Not more than 0.8161 @ 15.56°C  | 0.7871<br>0.7936  |
| Identification Test B (Infrared Spectroscopy) | USP/EP/BP      | Conforms to IR Spectra   | Pass              |
| Identification (Infrared Spectra)             | JP             | Conforms to IR Spectra   | Pass              |
| Identification (Infrared Spectra)             | 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              |
| Color (APHA)                                  | ACS            | 10 max   | <10               |

| TEST  | MONO-GRAPH | SPECIFICATION  | TYPICAL RESULT               |
|---|------------|--|------------------------------|
| 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%  | <0.003%                      |
| Alkalinity (as NH <sub>3</sub> )                          | FCC        | <3 mg/kg   | <3 mg/kg                     |
| 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, Isopropyl Alcohol                                | ACS        | To Pass Test   | Pass                         |
| Organic Impurities - Ketones, Isopropyl Alcohol           | FCC        | To Pass Test   | Pass                         |
| Methanol  | ACS        | 0.1% max   | <0.1%                        |
| Substances Darkened by Sulfuric Acid                      | ACS        | To Pass Test   | Pass                         |
| Organic Impurities – Substances Darkened by Sulfuric Acid | FCC        | To Pass Test   | Pass                         |
| Substances Reducing Permanganate                          | ACS        | To Pass Test   | Pass                         |
| Organic Impurities – Substances Reducing Permanganate     | FCC        | To Pass Test   | Pass                         |
| Inorganic Impurities - Lead                               | FCC        | NMT 0.5 mg/kg  | <0.5 mg/kg                   |
| 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 after 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.<br>250nm-260nm 0.30 max.<br>270nm-340nm 0.10 max.<br>The spectrum shows a steadily descending curve with no observable peaks or shoulders      | 0.29<br>0.11<br>0.02<br>Pass |
| Organic Impurities  | USP        | Methanol 200 ppm max.  | <5 ppm                       |
| Volatile Impurities                                       | EP/BP      | Acetal and Acetaldehyde 10 ppm max.  | None Detected                |
| Purity 3 – Volatile Impurities                            | JP         | Benzene 2 ppm max.<br>Total of all other impurities 300 ppm max.   | None Detected<br><50ppm      |
| Organic Impurities - Methanol and Other                   | FCC        | Methanol 200 ppm max.<br>Any other single impurity 1000 ppm max.   | <5 ppm<br>None Detected      |
| Volatile Impurities                                       |            | Sum of all impurities 5000 ppm max.  | None Detected                |

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

Reported in  $\mu\text{g/g}$  (ppm)

| Element         | Class | Oral Concentration $\mu\text{g/g}$ | Parenteral Concentration $\mu\text{g/g}$ | Inhalation Concentration $\mu\text{g/g}$ | TYPICAL RESULT (in $\mu\text{g/g}$ ) (ppm) |
|-----------------|-------|------------------------------------|--|--|--|
| Cd (Cadmium)    | 1     | 0.5                                | 0.2                                      | 0.3                                      | 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. 3.3, 07/21, 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.