

**PRODUCT SPECIFICATIONS SHEET**  
**WORLD/GMP GRADE**  
**ETHYL ALCOHOL 95%**  
**Meets ACS/USP/EP/BP/JP/FCC GRADE Monographs**  
**With USP<232>, EMA and ICH Q3D Test Results**  
*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 <sup>1</sup> | 94.9% - 96.0% (by volume)  | 95.01%         |
| Assay (by specific gravity@25oC)         | FCC              | NLT 94.9%  |                |
| Proof                                    | 27CFR<br>30.23   | Lot Analysis   | 190.0          |
| Identification A - Specific Gravity      | USP <sup>1</sup> | 0.812 - 0.816 @ 15.56°C  | 0.8158         |
| Specific Gravity                         | JP               | d <sup>15/15</sup> 0.809 – 0.816   | 0.816          |
| Specific Gravity                         | FCC              | Not more than 0.8096 @ 25.0°C  | 0.8092         |
| Identification Test B                    | USP/EP/BP        | Conforms to IR Spectra   | Pass           |
| Identification 1                         | JP               | Conforms to IR Spectra   | 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   |                |
| Solubility in Water                      | FCC              | No haze or turbidity develops  | 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. | 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           |
| Titration Acid                           | ACS              | 0.0005 meq/g max.  | <0.0003 meq/g  |
| Titration Base                           | ACS              | 0.0002 meq/g   | <0.0001 meq/g  |
| Fusel Oil                                | FCC              | To Pass Test   | Pass           |
| Acetone/Isopropyl Alcohol                | ACS              | To Pass Test   | Pass           |
| Ketones, Isopropyl Alcohol               | FCC              | To Pass Test   | Pass           |

Form: Ethanol, Pure, 190, GMP, Rev. 2.0, 06/16, KAD

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| TEST                                     | MONO-GRAPH      | SPECIFICATION   | TYPICAL RESULT |         |
|--|-----------------|---|----------------|---------|
| Methanol                                 | ACS<br>FCC      | 0.1% max<br>To Pass Test  | <0.1%<br>Pass  |         |
| Lead                                     | FCC             | NMT 0.5 mg/kg   | Pass           |         |
| Substances Darkened by Sulfuric Acid     | ACS/FCC         | To Pass Test  | Pass           |         |
| 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<br>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           |         |
| Volatile Impurities                      | USP/EP/BP<br>JP | Methanol  | 200 ppm        | <5 ppm  |
| Purity 3 – Volatile Impurities           |                 | Sum of Acetal and Acetaldehyde  | 10ppm max      | <1 ppm  |
|  |                 | Benzene   | 2ppm max.      | <1 ppm  |
|  |                 | Total of all other impurities   | 300ppm max.    | <20 ppm |

<sup>1</sup>No EP/BP/JP specifications for this assay

**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, 190, GMP, Rev. 2.0, 06/16, KAD

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**PRODUCT SPECIFICATIONS SHEET**  
**WORLD/GMP GRADE**  
**ETHYL ALCOHOL**  
**Absolute, Dehydrated, Anhydrous, 200 Proof, Pure Ethanol**  
**Meets ACS/USP/EP/BP/JP/FCC GRADE Monographs**  
With USP<232>, EMA and ICH Q3D Test Results  
*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)<br>Assay (by specific gravity@15.56°C)<br>Assay (by relative density @20°C)<br>Assay (by specific gravity@15°C)<br>Assay (by specific gravity@25°C) | Internal USP<br>EP/BP<br>JP<br>FCC | NLT 99.9%<br>NLT 99.5%<br>NLT 99.5%<br>NLT 99.5%<br>NLT 94.9%  | 99.99%         |
| Proof   | 27CFR<br>30.23                     | Lot Analysis   | 200.0          |
| Identification A - Specific Gravity   | USP                                | NMT 0.7962 @ 15.56°C   | 0.7937         |
| Identification A - Relative Density   | EP/BP                              | 0.790 – 0.793 @ 20°C   | 0.7905         |
| Specific Gravity  | JP                                 | $d_{15}^{15}$ 0.794 – 0.797  | 0.794          |
| Specific Gravity  | FCC                                | Not more than 0.8096 @ 25.0°C  | 0.7871         |
| Identification Test B   | USP/EP/BP                          | Conforms to IR Spectra   | Pass           |
| Identification I  | JP                                 | Conforms to IR Spectra   | 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  |                |
| 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           |
| 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 Reference. | 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           |

Form: Ethanol, Pure, 200, ACS/USP/EP/JP/FCC Rev. 2.5, 06/16, KAD

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| 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 max.   | <0.0001 meq/g           |
| Fusel Oil                                | FCC        | To Pass Test  | Pass                    |
| Acetone                                  | ACS        | 0.001% max.   | <0.001%                 |
| Isopropyl Alcohol                        |            | 0.003% max.   | <0.003%                 |
| Ketones, Isopropyl Alcohol               | FCC        | To Pass Test  | Pass                    |
| Methanol                                 | ACS<br>FCC | 0.1% max<br>To Pass Test  | <0.1%<br>Pass           |
| Substances Darkened by Sulfuric Acid     | ACS/FCC    | To Pass Test  | Pass                    |
| Substances Reducing Permanganate         | ACS/FCC    | To Pass Test  | Pass                    |
| 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.<br>240nm 0.40 max.<br>250nm-260nm 0.30 max.<br>270nm-340nm 0.10 max. | 0.29<br>0.11<br>0.02    |
| Purity 4 - Other Impurities (absorbance) | JP         | The spectrum shows a steadily descending curve with no observable peaks or shoulders                | Pass                    |
| Volatile Impurities                      | USP/EP/BP  | Methanol 200 ppm max.<br>Sum of Acetal and Acetaldehyde 10ppm max                                   | <5 ppm<br>None Detected |
| Purity 3 – Volatile Impurities           | JP         | Benzene 2ppm max.<br>Total of all other impurities 300ppm   | None Detected<br><50ppm |

Form: Ethanol, Pure, 200, ACS/USP/EP/JP/FCC Rev. 2.5, 06/16, KAD

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

Reported in µg/g (ppm)

| <b>Element</b>  | <b>Class</b> | <b>Oral Concentration µg/g</b> | <b>Parenteral Concentration µg/g</b> | <b>Inhalation Concentration µg/g</b> | <b>TYPICAL RESULT (in µg/g) (ppm)</b> |
|-----------------|--------------|--------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|
| 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. 2.5, 06/16, KAD

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