PRODUCT SPECIFICATIONS SHEET

# WORLD GRADE ®
# ETHYL ACETATE
# MEETS REAGENT ACS/USP/NF/EP/BP GRADE MONOGRAPHS
# WORLD/GMP GRADE

Main Catalog #: 330WORLD-Size Code*

*Individual package sizes have unique size codes

**Manufactured in compliance with cGMP**

| PRODUCT SPECIFICATIONS | MONO GRAPH | LIMITS | TYPICAL RESULT |
|---|---|---|---|
| Assay (corrected for water) | ACS | 99.5%, min | 99.99% |
| Assay | NF | 98.0-102.0% | Pass |
| Identification A<br>Identification A<br>Identification B<br>Identification C<br>Identification D | NF<br>EP/BP<br>EP/BP<br>EP/BP<br>EP/BP | Infrared Absorption <197F><br>Boiling point : 76ºC – 78ºC<br>IR comparable with Reference spectrum<br>It gives the reaction of acetyl<br>It gives the reaction of esters | Pass<br>Pass<br>Pass<br>Pass<br>Pass |
| Specific Gravity @ 25ºC | NF | 0.894-0.898 | 0.8969 |
| Relative density @ 20ºC | EP/BP | 0.898 – 0.902 | 0.9005 |
| Acidity | NF<br><br>EP/BP | NMT 0.10mL of 0.10 N NaOH is required<br>The solution remains pink for not less than 15sec. | Pass<br><br>Pass |
| Readily Carbonizable Substances<br>Reaction with Sulfuric acid<br>Substances Darkened By Sulfuric Acid | NF<br>EP/BP<br>ACS | No dark zone is developed within 15 minutes<br>Interface of the 2 liquids is not colored<br>Passes Test | Pass<br>Pass<br>Pass |
| Chromatographic Purity | NF | Acetaldehyde NMT 0.1%<br>Ethyl isobutyl ether NMT 0.1%<br>Methyl compounds NMT 0.1%<br>Other impurities NMT 0.3% | <0.1%<br><0.1%<br><0.1%<br><0.3% |
| Color (APHA) | ACS | 10 max | <10 |
| Appearance of Solution | EP/BP | To Pass Test | Pass |
| Refractive Index @ 20ºC | EP/BP | 1.370 – 1.373 | 1.3727 |
| Residue After Evaporation<br>Residue on evaporation | ACS<br>EP/BP | 0.003% max.<br>30 ppm max. | <0.001%<br><10 ppm |
| Limit of nonvolatile residue | NF | NMT 0.02% | <0.001% |
| Water | ACS<br>EP/BP | 0.2% max.<br>0.1% max. | 0.03% |
| Titrable Acid, max | ACS | 0.0009 meq/g max | <0.0001meq/g |
| Related substances | EP/BP | NMT 0.2% of the area of the principal peak. | Pass |

**Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients[1]**

Reported in µg/g (ppm)



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| **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 |

[1]Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.

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.



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