

Product Specifications Sheet

Harmonized USP/BP/EP/JP Alcohol Absolute, Dehydrated, Anhydrous (200 PROOF) Pure SYNTHETIC ETHANOL

Meets USP/BP/EP/JP Monographs

CATALOG NUMBER: zp1110EP/JP20S

| THE COT | MONO | CDE CHEICA TION | TYPICAL |
|--|------------------------|--|---|
| TEST | GRAPH | SPECIFICATION | RESULT |
| Assay (by specific gravity@15.56°C) Assay (by relative density @20°C) Assay (by specific gravity@15°C) | USP EP/BP JP | NLT 99.5% | 99.99% |
| Proof | 27CFR 30.23 | Lot Analysis | 200.0 |
| 11001 | 27CFR 30.23 | Ethanol is a clear, colorless volatile, flammable liquid, hygroscopic. | 200.0 |
| Characters Description | EP / BP JP | It is miscible with water and methylene chloride. It burns with a blue, smokeless flame. BP: about 78°C | Pass |
| Identification Test A (Specific Gravity) Identification A - Relative Density | USP EP/BP | It meets the requirements of the test for Specific Gravity 0.790 – 0.793 @ 20°C | Pass 0.7905 |
| Specific Gravity | USP JP | NMT 0.7962 at 15.56C d ^{15/} ₁₅ 0.79422 – 0.79679 | 0.7938 0.79434 |
| Identification Test B (Infrared Spectroscopy) Identification (1) Identification Test C | USP/BP/EP JP USP | Conforms to IR Spectra Conforms to IR Spectra NMT 200 µL/L (200ppm) of Methanol | Pass Pass Pass |
| (Limit of Methanol) Identification Test C | BP/EP | An intense blue color appears on the paper and becomes paler after 10-15 minutes | Pass |
| Identification Test D | BP/EP | A yellow precipitate is formed within 30minutes | Pass |
| Color of Solution | USP/JP | 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 Standard suspension A. | Pass |
| Purity 1 – Clarity and Color of Solution | JP | The mixture remains clear | Pass |
| Appearance | BP/EP | Clear and Colorless. Dilution remains clear when compared with water | Pass |
| Acidity or Alkalinity | USP/BP/EP | The solution is pink (30ppm, as acetic acid) | Pass |
| Purity 2 – Acidity or alkalinity | JP | A light red color develops | Pass |
| Limit of Nonvolatile Residue | USP | The weight of the residue does not exceed 2.5 mg | 0.5mg |
| Residue on Evaporation | EP/BP | 25 ppm, max | <10 ppm |
| Purity 5 - Residue on Evaporation | JP | NMT 2.5 mg | 0.5mg |
| UV Absorbance Purity 4 - Other Impurities (absorbance) | USP/BP/EP 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 | 0.29 0.11 0.02 Pass |
| Organic Impurities Volatile Impurities Purity 3 – Volatile Impurities | USP EP/BP JP | Methanol 200 ppm Acetaldehyde and Acetal 10ppm max Benzene 2ppm max. Sum of all other impurities 300ppm max. | <5 ppm None Detected None Detected <10 ppm |

Form: Ethanol, Pure, 200, Synthetic Rev. 1.7, 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.