



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

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|--------------------------|---|--|--------------------|---------------------|
| Product Name | Ethanol 96% v/v (Ph.Eur,BP,USP)GMP-IPEC grade | | Issue Date | March-23 |
| Product Code | 631085 | | Prepared by | Sr. Tech Lead |
| CAS NO. | 64-17-5 | | Reviewed by | Manager Technical |
| Manufacturer Name | PanReac AppliChem | | Version no. | CLYZO/PAN/631085/01 |

| Sr. No. | Test | Pharmacopeial Specifications | | | |
|---------|---|---|---|---|---|
| | | Manufacturer COA <i>Complies Ph. Eur, BP, USP</i> | USP 2022 | EP Version 11.0 | JP 18 |
| 1 | Description | Clear, colourless liquid. Density about 0.805 | Clear, colorless, mobile, volatile liquid. Has a characteristic odor and produces a burning sensation on the tongue. Is readily volatilized even at low temperatures, and boils at about 78°. Is flammable. | Colourless, clear, volatile, flammable liquid, hygroscopic. It burns with a blue, smokeless flame. Boiling point about 78°C | A clear, colorless liquid. It is flammable and burns with a light blue flame on ignition. It is volatile. |
| 2 | Solubility | Miscible with water and most of the solvents | Miscible with water and with practically all organic solvents. | Miscible with water and with methylene chloride. | It is miscible with water. |
| 3 | Identification 1 | IR passes test | The infrared absorption spectrum obtained with sample should be concordant with reference spectrum of ethanol 96% | The infrared absorption spectrum obtained with sample should be concordant with reference spectrum of ethanol 96% | The infrared absorption spectrum obtained with sample should be concordant with reference spectrum of ethanol |
| 4 | Identification 2 | Passes test | Should comply by specific gravity | Should comply by specific gravity | Not mentioned |
| 5 | Identification 3 | Passes test | Should comply by methanol limit test | After a few minutes, an intense blue colour appears on the paper and becomes paler after 10-15 min. | Not mentioned |
| 6 | Identification 4 | Passes the test | Not mentioned | A yellow precipitate should be formed within 30 minutes | Not mentioned |
| 7 | Specific gravity @15.56°C | Between 0.812 and 0.816 Between 0.805 and 0.812 (at 20°C) | Between 0.812 and 0.816 @15.56°C | Between 0.805 and 0.812 @ 20°C | Between 0.80872 and 0.81601 @ 15°C |
| 8 | Clarity and colour of solution/Appearance of solution | Passes the test | Sample solution A & B show the same clarity as that of water, or their opalescence is not more pronounced than that of Standard suspension A | The sample solution should be clear and colourless when compared with water | The sample solution should be clear when compared with water |
| 9 | Color of solution | Passes the test | The Sample solution has the appearance of water or is not more intensely colored than the Standard solution. | Not mentioned | Not mentioned |
| 10 | Other impurities (Absorbance) | Absorbances at 240 nm: NMT 0.40, Between 250 nm and 260 nm : NMT 0.30, Between 270 nm and 340 nm: NMT 0.10 | Absorbances at 240 nm: NMT 0.40, Between 250 nm and 260 nm : NMT 0.30, Between 270 nm and 340 nm: NMT 0.10 | Absorbances at 240 nm: NMT 0.40, Between 250 nm and 260 nm : NMT 0.30, Between 270 nm and 340 nm: NMT 0.10 | Absorbances at 240 nm: NMT 0.40, Between 250 nm and 260 nm : NMT 0.30, Between 270 nm and 340 nm: NMT 0.10 |
| 11 | Acidity or alkalinity (in CH ₃ COOH) | NMT 0.0030% | Pink colour should be developed (NMT 30 ppm as acetic acid) | Pink colour should be developed (NMT 30 ppm as acetic acid) | After addition 1.0 ml of 0.01 M NaOH should develop a pink color. |
| 12 | Volatile impurities (organic impurities) | Acetaldehyde + Acetal: NMT 10 ppm Benzene: NMT 2 ppm Methanol: NMT 200 ppm Total impurities: NMT 300 ppm | Acetaldehyde + Acetal: NMT 10 ppm Benzene: NMT 2 ppm Methanol: NMT 200 ppm Total impurities: NMT 300 ppm | Methanol: NMT 200 ppm Acetaldehyde + Acetal: NMT 10 ppm Benzene: NMT 2 ppm Total impurities: NMT 300 ppm | Acetaldehyde + Acetal: NMT 10 ppm Benzene: NMT 2 ppm Total impurities: NMT 300 ppm |
| 13 | Other impurities (Absorbance) | Not mentioned | Absorbances at 240 nm: NMT 0.40, Between 250 nm and 260 nm : NMT 0.30, Between 270 nm and 340 nm: NMT 0.10 | Absorbance at 240 nm: NMT 0.40, Between 250 nm and 260 nm : NMT 0.30, Between 270 nm and 340: NMT 0.10. | Absorbances at 240 nm: NMT 0.40, Between 250 nm and 260 nm : NMT 0.30, Between 270 nm and 340 nm: NMT 0.10 |
| 14 | Residue on evaporation (non volatile residue) | NMT 25 ppm | NMT 25 ppm | NMT 25 ppm | NMT 25 ppm |

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|----|----------------------|---|---|---|---|
| 15 | Assay | Between 92.6% and 95.2% (w/w) (at 20°C) Between 92.3% and 93.8% (w/w) (at 15.56°C) Between 95.1% and 96.9% (v/v) (at 20°C) Between 94.9% and 96.0% (at 15.560C) (v/v) | Between 94.9% and 96.0%, by volume, at 15.56°C | Between 95.1% and 96.9%, by volume, at 20.0°C | Between 95.1% and 96.9%, by volume, at 15.0°C |
| 16 | Elemental Impurities | | Not mentioned | Not mentioned | Not mentioned |
| | Cd | NMT 0.2 ppm | | | |
| | Pb | NMT 0.5 ppm | | | |
| | Assay | NMT 1.5 ppm | | | |
| | Hg | NMT 0.3 ppm | | | |
| | CO | NMT 0.5 ppm | | | |
| | V | NMT 1 ppm | | | |
| | Ni | NMT 2 ppm | | | |
| | Tl | NMT 0.8 ppm | | | |
| | Au | NMT 1 ppm | | | |
| | Pd | NMT 1 ppm | | | |
| | Ir | NMT 1 ppm | | | |
| | Os | NMT 1 ppm | | | |
| | Rh | NMT 1 ppm | | | |
| | Ru | NMT 1 ppm | | | |
| | Se | NMT 8 ppm | | | |
| | Ag | NMT 1 ppm | | | |
| | Pt | NMT 1 ppm | | | |
| | Li | NMT 25 ppm | | | |
| | Sb | NMT 9 ppm | | | |
| | Ba | NMT 70 ppm | | | |
| | Mo | NMT 25 ppm | | | |
| | Cu | NMT 30 ppm | | | |
| | Sn | NMT 60 ppm | | | |
| | Cr | NMT 25 ppm | | | |
| 17 | Residual solvent | Passes the test | Not mentioned | Not mentioned | Not mentioned |
| | Storage | Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition. Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up. | Preserve in tight containers, protected from light. | Protected from light | Store in tight containers, protected from light |

Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.

Disclaimer - The information above is solely for your consideration. We do not recommend or affirm the suitability for any specific end use. We suggest the users should research & verify the specifications in accordance with their intended usage.