



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

|                          |   |  |                    |                     |
|--------------------------|---|--|--------------------|---------------------|
| <b>Product Name</b>      | 1-Methyl-2-Pyrrolidone (BP, Ph. Eur., USP-NF)<br>pure, pharma grade |  | <b>Issue Date</b>  | March-23            |
| <b>Product Code</b>      | 143080  |  | <b>Prepared by</b> | Sr. Tech Lead       |
| <b>CAS NO.</b>           | 872-50-4  |  | <b>Reviewed by</b> | Manager Technical   |
| <b>Manufacturer Name</b> | PanReac AppliChem   |  | <b>Version no.</b> | CLYZO/PAN/143080/01 |

| Sr. No. | Test                       | Manufacturer COA   |   | Pharmacoepial Specifications  |  |
|---------|----------------------------|--|---|---|--|
|         |                            | Complies (BP, Ph. Eur., USP-NF)  | USP 2022  | EP Version 11.0   | JP 18  |
| 1       | Description                | liquid, Clear, Colourless, hygroscopic. Boiling point about 202°C, Relative density: about 1.033 | A clear, colorless to very slightly yellow liquid. Boiling point: about 202°. Refractive index: about 1.469   | Clear, colourless liquid. Boiling point : about 204 °C. Relative density: about 1.034. Refractive index: about 1.469.                               | Product Not Official in Japanese pharmacopoeia |
| 2       | Solubility                 | Miscible with water.   | Miscible with water and with most organic solvents including alcohol, ketones, and aromatic and chlorinated hydrocarbons.                           | Miscible with water and with ethanol (96 per cent)  |  |
| 3       | Identification 1           | Passes The Test  | The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Mythylpyrrolidone reference/working standard | The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Mythylpyrrolidone reference/working standard |  |
| 4       | Appearance                 | Passes The Test  | Sample solution should be not more intensely colored than the Comparison solution.  | Sample should be clear and colorless  |  |
| 5       | Alkalinity                 | Passes The Test  | NMT 8.0 ml of 0.02M HCl should be required  | NMT 8.0 ml of 0.02M HCl should be required  |  |
| 6       | Related substances:        | Maximum individual unknown impurity: NMT 01%<br>Total impurities: NMT 0.3%                       | Maximum individual unknown impurity: NMT 01%<br>Total impurities: NMT 0.3%  | Maximum individual unknown impurity: NMT 01%<br>Total impurities: NMT 0.3%  |  |
| 7       | Water                      | NMT 0.1 %  | NMT 0.1%  | NMT 0.1%  |  |
| 8       | Assay                      | NLT 99.5 %   | Not mentioned   | Not mentioned   |  |
| 9       | Elemental Impurities       |  | Not mentioned   | Not mentioned   |  |
|         | Cd                         | NMT 0.5 ppm  |   |   |  |
|         | Pb                         | NMT 0.5 ppm  |   |   |  |
|         | As                         | NMT 1.5 ppm  |   |   |  |
|         | Hg                         | NMT 1.5 ppm  |   |   |  |
|         | CO                         | NMT 5 ppm  |   |   |  |
|         | V                          | NMT 10 ppm   |   |   |  |
|         | Ni                         | NMT 20 ppm   |   |   |  |
|         | Tl                         | NMT 0.8 ppm  |   |   |  |
|         | Au                         | NMT 10 ppm   |   |   |  |
|         | Pd                         | NMT 10 ppm   |   |   |  |
|         | Ir                         | NMT 10 ppm   |   |   |  |
|         | Os                         | NMT 10 ppm   |   |   |  |
|         | Rh                         | NMT 10 ppm   |   |   |  |
|         | Ru                         | NMT 10 ppm   |   |   |  |
|         | Se                         | NMT 15 ppm   |   |   |  |
|         | Ag                         | NMT 15 ppm   |   |   |  |
|         | Pt                         | NMT 10 ppm   |   |   |  |
|         | Li                         | NMT 55 ppm   |   |   |  |
|         | Sb                         | NMT 120 ppm  |   |   |  |
|         | Ba                         | NMT 140 ppm  |   |   |  |
|         | Mo                         | NMT 25 ppm   |   |   |  |
|         | Cu                         | NMT 250 ppm  |   |   |  |
|         | Sn                         | NMT 600 ppm  |   |   |  |
|         | Cr                         | NMT 25 ppm   |   |   |  |
| 10      | Residual solvents (Ph.Eur) | Passes The Test  | Not mentioned   | Not mentioned   |  |
|         | Storage                    | Storage away from direct light   | Preserve in light-resistant containers.   | Store 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.