



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

|                          |   |  |                    |                    |
|--------------------------|---|--|--------------------|--------------------|
| <b>Product Name</b>      | Pyridoxine Hydrochloride (Ph. Eur., USP) pure, pharma grade |  | <b>Issue Date</b>  | March-23           |
| <b>Product Code</b>      | A8093   |  | <b>Prepared by</b> | Sr. Tech Lead      |
| <b>CAS NO.</b>           | 58-56-0   |  | <b>Reviewed by</b> | Manager Technical  |
| <b>Manufacturer Name</b> | PanReac AppliChem   |  | <b>Version no.</b> | CLYZO/PAN/A8093/01 |

| Sr. No. | Test   | Manufacturer COA   |  | Pharmacopeial Specifications  |   |
|---------|--|--|--|---|---|
|         |  | Complies USP, Ph. Eur  | USP 2022   | EP Version 11.0   | JP 18   |
| 1       | Description  | Solid  | White to practically white crystals or crystalline powder. Is stable in air, and is slowly affected by sunlight. Its solutions have a pH of about 3.                 | White or almost white, crystalline powder. Melting point about 205 °C, with decomposition.  | White to pale yellow crystalline powder. It is gradually affected by light. Melting point: about 206°C (with decomposition)   |
| 2       | Solubility   | Freely soluble in water  | Freely soluble in water; slightly soluble in alcohol; insoluble in ether.  | Freely soluble in water, slightly soluble in ethanol (96 per cent)  | It is freely soluble in water, slightly soluble in ethanol (99.5), and practically insoluble in acetic anhydride and in acetic acid.  |
| 3       | Identification 1                                       | Passes The Test  | Not mentioned  | UV absorption spectrum of sample shows maxima at 288-296 nm having specific absorbance between 425 to 445, at 248 to 256 nm 175 to 195 and at 320 to 327 nm 345 to 365                                | UV absorption spectrum of sample should exhibit maxima at the same wavelength as standard solution  |
| 4       | Identification 2                                       | Passes The Test  | The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Pyridoxine Hydrochloride reference standard/working standard. | The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Pyridoxine Hydrochloride reference standard/working standard.                                  | The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Pyridoxine Hydrochloride reference standard/working standard.  |
| 5       | Identification 3                                       | Passes The Test  | Should comply by a white precipitate formation with silver nitrate which is insoluble in nitric acid but soluble in excess ammonia                                   | Should comply by a white precipitate formation with silver nitrate which is insoluble in nitric acid but soluble in excess ammonia  | 1. Should comply by a white precipitate formation with silver nitrate which is insoluble in nitric acid but soluble in excess ammonia 2. Should evolve an odor of chlorine, when mixed with H2SO4, KMnO4 and heated. The gas evolved should turn moistened potassium iodide starch paper blue |
| 6       | Identification 4                                       | Passes The Test  | Not mentioned  | By TLC, the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution | Not mentioned   |
| 7       | Chloride   | Between 16.9% and 17.6%  | Between 16.9% and 17.6% (dried basis)  | Not mentioned   | Not mentioned   |
| 8       | Appearance of solution/ Clarity and colour of solution | Passes The Test  | Not mentioned  | Sample solution should be clear and not more intensely coloured than reference solution Y7  | Sample solution should be clear and colourless  |
| 9       | pH   | Between 2.4 and 3.0  | Not mentioned  | Between 2.4 and 3.0   | Between 2.5 and 3.5   |
| 10      | Related Substances                                     | Impurity B: NMT 0.15%<br>Maximum individual unknown impurity: NMT 0.1%<br>Total impurities: NMT 0.2% | Not mentioned  | Impurity B: NMT 0.15%<br>Maximum individual unknown impurity: NMT 0.1%<br>Total impurities: NMT 0.2%  | NMT 0.25%   |
| 11      | Heavy metals   | Not mentioned  | Not mentioned  | Not mentioned   | NMT 30 ppm  |
| 12      | Loss on drying   | NMT 0.5%   | NMT 0.5%   | NMT 0.5   | NMT 0.30%   |
| 13      | Sulfated Ash   | NMT 0.1%   | Not mentioned  | NMT 0.1%  | NMT 0.1%  |
| 14      | Residue on Ignition                                    | Not mentioned  | NMT 0.1%   | Not mentioned   | NMT 0.1%  |
| 15      | Assay (dried basis)                                    | Between 98.0% and 102.0% (by HPLC)<br>Between 99.0% and 101.0% (By titrimetry)                       | Between 98.0% and 102.0%   | Between 99.0% and 101.0%  | Between 98.0% and 101.0%  |
|         | Storage  | Storage at room temperature  | Preserve in tight, light-resistant containers  | Protected from light  | Containers—Tight containers.<br>Storage—Light-resistant   |

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.