# " clyzo " - Monograph Comparison

## AS PER CURRENT USP 2022/EP11/JP18

| | | | | | |
|---|---|---|---|---|---|
| | **Product Name** | Ascorbic Acid Ph. Eur.,USP | | **Issue Date** | July-23 |
| | **Product Code** | 140032 | | **Prepared by** | Sr. Tech Lead |
| | **CAS NO.** | 50-81-7 | | **Reviewed by** | Manager Technical |
| | **Manufacturer Name** | **CG Chemikalein GmbH & Co KG** | | **Version no.** | CLYZO/2022/CG/140032/00 |

| Sr. No. | Test | Manufacturer COA | Pharmacopeial Specifications | | |
|---|---|---|---|---|---|
| | | *Complies USP-NF, Ph. Eur.* | *USP 2022* | *EP Version 11.0* | *JP 18* |
| 1 | Descriprion | White or almost white crystalline powder | White or slightly yellow crystals or powder. On exposure to light it gradually darkens. In the dry state, is reasonably stable in air, but in solution rapidly oxidizes. Melts at about 190°C. | White or almost white, crystalline powder or colourless crystals, becoming discoloured on exposure to air and moisture.Melting point at about 190 °C with decomposition | White crystals or white crystalline powder. It is odourless and has an acid taste. Melting point at about 190 °C with decomposition |
| 2 | Solubility | Not mentioned | Freely soluble in water; sparingly soluble in alcohol; insoluble in chloroform, in ether, and in benzene. | Freely soluble in water, sparingly soluble in ethanol (96 per cent). | Freely soluble in water, sparingly soluble in ethanol (95%) practically insoluble in diethyl ether |
| 3 | Identification 1 | Should comply the test | The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Ascorbic acid reference standard/working | The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Ascorbic acid reference standard/working standard | The colour of the solution discharged imemdiately in each case |
| 4 | Identification 2 | Should comply the test | A 20 mg/ml solution reduces alkaline cupri tartarate TS slowly at room temperature but more readily upon heating | Sample solution shows maxima at about 243 nm (determined immediately after dissolution), Specific absorbance at maximum is between 545 to 585 | A blue colour is developes |
| 5 | Identification 3 | Should comply the test | Not mentioned | pH of solution S is between 2.1 and 2.6 | Not mentioned |
| 6 | Identification 4 | Should comply the test | Not mentioned | A grey precipitate is formed | Not mentioned |
| 7 | Optical Rotation | Between +20.5 to +21.5 ° | Between +20.5 to +21.5 ° | Between +20.5 to +21.5 ° | Between +20.5 to +21.5 ° |
| 8 | pH | Not mentioned | Not mentioned | Not mentioned | Between 2.2 and 2.5 |
| 9 | Clarity and colour of solution | Should comply the test | Not mentioned | Sample solution S is clear and not more intensely coloured than reference solution BY7 | The sample solution is clear and colourless |
| 10 | Heavy metals | NMT 10 ppm | Not mentioned | Not mentioned | NMT 20 ppm |
| 11 | Copper | NMT 5 ppm | Not mentioned | NMT 5 ppm | Not mentioned |
| 12 | Iron | NMT 2 ppm | Not mentioned | NMT 2 ppm | Not mentioned |
| 13 | Loss on drying | NA | Not mentioned | Not mentioned | NMT 0.20% (Silica 24 hours) |
| 14 | Residue on Ignition | Not mentioned | NMT 0.1% | Not mentioned | NMT 0.1% |
| 15 | Sulphated Ash | NMT 0.1% | Not mentioned | NMT 0.1% | Not mentioned |
| 16 | Impurity E | Not mentioned | Not mentioned | NMT 0.2% | Not mentioned |
| 17 | Related substances | Not mentioned | Not mentioned | Impurity C & D- NMT 0.15% (each), Maximum unspecified impurity NMT- 0.1%, Total impurities (Excluding impurity C &D)- 0.2% | Not mentioned |
| 18 | Assay | Between 99.0% and 100.5% | Between 99.0% and 100.5% | Between 99.0% and 100.5% | NLT 99.0% (on dried sample) |
| 19 | Microbial limit test<br>Total aerobic microbial count<br>Total yeast and molds count<br>E.Coli<br>Pseudomonas aerugonisa<br>Staphylococcus aureus<br>Salmonella | <br>NMT 100 CFU/g<br>NMT 50 cfu/g<br>Absent/g<br>Absent/g<br>Absent/g<br>Absent/25 g | Not mentioned | Not mentioned | Not mentioned |
| 20 | Bacterial Endotoxins | NMT 2.5 IU/g | Not mentioned | Not mentioned | Not mentioned |
| | Storage | Not mentioned | Store in light resistant tight containers | In a non-metallic container, protected from light. | Store in light resistant tight containers |

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