



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Aspartic Acid (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1701		Prepared by	Sr. Tech Lead
CAS NO.	56-84-8		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1701/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, BP	USP 2022	EP Version 11.0	JP 18
1	Description	white to off-white crystalline powder or colorless crystals	White or almost white, crystalline powder, or colorless crystals	White or almost white, crystalline powder or colourless crystals	White, crystals or crystalline powder
2	Solubility	Not Given	Soluble in dilute solutions of alkali hydroxides and in dilute mineral acids; slightly soluble in water; practically insoluble in alcohol and in ether	Slightly soluble in water, practically insoluble in ethanol (96 per cent). It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides	Sparingly soluble in water, and practically insoluble in ethanol (99.5).It dissolves in dilute HCl and in 0.2 M NaOH
3	Identification 1	Passes Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Aspartic Acid reference/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Aspartic Acid reference/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Aspartic Acid reference/working standard
4	Identification 2	Not mentioned	Not mentioned	10% suspension should be strongly acid having pH less than 4.0	Not mentioned
5	Identification 3	Not mentioned	Not mentioned	Specific optical rotation should be between +24.0 ⁰ to +26.0 ⁰ (dried substance)	Not mentioned
6	Identification 4	Not mentioned	Not mentioned	Should comply with enantiomeric Purity Test	Not mentioned
7	Identification 5	Not mentioned	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	Not mentioned
8	Optical Rotation	Between +24.0° to +26.0°	Between +24.0° and +26.0°	Between +24.0° and +26.0°	Between +24.0° and +26.0°
9	pH	Not mentioned	Not mentioned	Not mentioned	Between 2.5 and 3.5
10	Appearance of solution/Clarity and color of solution	Should comply the test	Not mentioned	The solution is clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless
11	Related substances	Maleic Acid: NMT 0.10% Malic acid: NMT 0.20% Fumaric acid: NMT 0.10% Maximum unknown impurity: NMT 0.05% Total unknown impurities: NMT 0.30%	Maleic Acid: NMT 0.05% Malic acid: NMT 0.20% Fumaric acid: NMT 0.20% Maximum unknown impurity: NMT 0.05% Total unknown impurities: NMT 0.10%	Impurity A: NMT 0.2% Impurity B: NMT 0.10% Impurity H: NMT 0.10% Maximum unknown impurity: NMT 0.10% Total impurities: NMT 0.3%	NMT 0.2%
12	Enantiomeric purity (HPLC)	Not mentioned	Not mentioned	Impurity I: NMT 0.3%	Not mentioned
13	Ninhydrin-positive substances(HPLC)	Glutamic acid: NMT 0.2% Alanine: NMT 0.2% Asparagine: NMT 0.2% Any ninhydrin positive substance: NMT 0.1% Total impurities: NMT 1.0%	Not mentioned	Impurity C: NMT 0.2% Impurity D: NMT 0.1% Impurity G: NMT 0.2% Any ninhydrin positive substance: NMT 0.1% Total impurities: NMT 1.0%	Not mentioned
14	Chlorides	NMT 0.02%	NMT 0.02%	NMT 200 ppm	NBMT 0.021%
15	Sulfates	NMT 0.03%	NMT 0.03%	NMT 300 ppm	NMT 0.028%

16	Ammonium	NMT 0.02%	Not mentioned	NMT 0.02%	NMT 0.02%
17	Iron	NMT 0.001%	NMT 10 ppm	NMT 10 ppm	NMT 10 ppm
18	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
19	Loss on drying	NMT 0.5 %	NMT 0.5%	NMT 0.5%	NMT 0.3%
20	Residue on Ignition	NA	NMT 0.1%	Not mentioned	NMT 0.1%
21	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	Not mentioned
22	Assay (dried basis)	98.5 - 101.5 %	Between 98.5% and 101.5%	Between 98.5 % and 101.5 %	Between 98.5 % and 101.0 %
23	Elemental impurities	NA	Not mentioned	Not mentioned	Not mentioned
24	Residual solvent	NA	Not mentioned	Not mentioned	Not mentioned
	Storage	Protect from exposure to the light. Keep tightly closed	Preserve in tight containers	Protected from light	Containers—Tight containers

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.