



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Glutamic Acid (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1704		Prepared by	Sr. Tech Lead
CAS NO.	56-86-0		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1704/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		<i>Complies Ph. Eur., USP</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Description	Solid	A white, crystalline powder, its solution are acidic	A white or almost white, crystalline powder or colourless crystals	White, crystals or crystalline powder. It has a slight characteristic and acid taste. It shows polymorphism
2	Solubility	Soluble in water	1 g dissolves in about 3 mL of water. It is almost insoluble in alcohol and in ether	Freely soluble in boiling water, slightly soluble in cold water, practically insoluble in acetic acid, in acetone and in ethanol (96 %)	Slightly soluble in water, and practically insoluble in ethanol. It dissolves in 2M HCl
3	Identification 1	Passes test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Glutamic Acid reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Glutamic Acid reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Glutamic Acid reference standard/working standard
4	Identification 2	Passes test	Not mentioned	Should comply with specific optical rotation test	Not mentioned
5	Identification 3	Passes test	Not mentioned	By TLC: the principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a)	Not mentioned
6	Identification 4	Passes test	Not mentioned	Should comply by red color development	Not mentioned
7	Appearance of solution	Passes test	Not mentioned	Sample solution should be clear and colourless	Sample solution should be clear and colorless
8	Optical rotation	Between +31.5 ^o and +32.5 ^o (in 2M HCl) Between +30.5 ^o - +32.5 ^o (in 1M HCl)	Between +31.5 ^o and +32.5 ^o	Between + 30.5 ^o to + 32.5 ^o	Between +31.5 ^o and +32.5 ^o
9	pH	Not mentioned	Not mentioned	Not mentioned	Between 2.9 and 3.9
10	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
11	Residue on Ignition	NA	NMT 0.1%	Not mentioned	NMT 0.1%
12	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	Not mentioned
13	Loss on drying	NMT 0.1 %	NMT 0.1%	NMT 0.5%	NMT 0.3%
14	Related Compounds/Ninhydrin positive substances	NMT 0.5%	Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0%	NMT 0.5%	Individual impurity NMT: 0.2% Total impurities: NMT 0.6%
15	Ammonium	NMT 0.02 %	Not mentioned	NMT 200 ppm	NMT 0.02%
16	Chloride	NMT 0.02 %	NMT 0.02%	NMT 200 ppm	NMT 0.021%
17	Sulfate	NMT 0.02 %	NMT 0.02%	NMT 300 ppm	NMT 0.028%
18	Iron	NMT 0.001 %	NMT 10 ppm	NMT 10 ppm	NMT 10 ppm
19	Assay (dried subst.)	Between 98.5% and 100.5 %	Between 98.5% and 101.5%	Between 98.5% and 100.5%	Between 99.0% and 101.0%
20	Elemental Impurities	Should comply the test	Not mentioned	Not mentioned	Not mentioned
	Storage	Keep container tightly closed in a dry and well-ventilated place	Preserve in tight containers, and store at controlled room temperature.	Protected from light	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.