" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**L-Tryptophan (Ph. Eur., USP) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	A1645		**Prepared by**	Sr. Tech Lead
	CAS NO.	73-22-3		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/A1645/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies Ph. Eur., USP	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Descriprion	Solid	White to slightly yellowish-white crystals or crystalline powder, having a slightly bitter taste	White or almost white, crystalline or amorphous powder	White to yellowish white, crystals or crystalline powder
2	Solubility	Soluble in water	Soluble in hot alcohol and in dilute hydrochloric acid	Sparingly soluble in water, slightly soluble in ethanol (96 per cent). It dissolves in dilute solutions of mineral acids and alkali hydroxides	It is freely soluble in formic acid, slightly soluble in water, and very slightly soluble in ethanol (95).It dissolves in dilute hydrochloric acid.
3	Identification 1	passes test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with tryptophan reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with tryptophan reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained withL-Tryptophan 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 the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution	Not mentioned
6	Identification 4	passes test	Not mentioned	Should comply by a purple-blue color development	Not mentioned
7	Appearance of solution	passes test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear
8	Specific optical rotation	Between -33.0^0 and -30.0^0 (20 deg) Between -32.8^0 and -29.4^0 (25 deg)	Between -32.8^0 and -29.4^0	Between -33.0^0 to -30.0^0	Between -33.0^0 and -30.0^0
9	pH	Between 5.5 and 7.0	Between 5.5–7.0	Not mentioned	Between 5.4 and 6.4
10	Heavy metals	NMT 0.0015 %	Not mentioned	Not mentioned	NMT 20 ppm
11	Arsenic	Not Mentioned	Not mentioned	Not mentioned	NMT 2 ppm
12	Residue on Ignition	NA	NMT 0.1%	Not mentioned	NMT 0.1%
13	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	Not mentioned
14	Loss on drying	NMT 0.3 %	NMT 0.3%	NMT 0.5%	NMT 0.3%
15	Chlorides	NMT 0.02 %	NMT 0.05%	NMT 200 ppm	NMT 0.021%
16	Ammonium	NMT 0.02 %	Not mentioned	NMT 0.02%	NMT 0.02%
17	Sulfate	NMT 0.03 %	NMT 0.03%	NMT 300 pppm	NMT 0.028%
18	Iron	NMT 0.002 %	NMT 30 ppm	NMT 20 ppm	Not mentioned
19	Ninhydrin positive substances/related substances	Maximum individual impurity NMT 0.2% Total impurities: NMT 0.5%	Not mentioned	Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5%	NMT 0.5%

20	Impurity A and other related substances(HPLC)	Impurity A: NMT 10 ppm Sum of impurities with a retention time less than that of tryptophan: NMT 100 ppm Sum of impurities with a retention time greater than that of tryptophan : NMT 300 ppm	Impurity A: NMT 10 ppm Sum of impurities with a retention time less than that of tryptophan: NMT 100 ppm Sum of impurities with a retention time greater than that of tryptophan : NMT 300 ppm	Impurity A: NMT 10 ppm Sum of impurities with a retention time less than that of tryptophan: NMT 100 ppm Sum of impurities with a retention time greaterthan that of tryptophan and up to 1.8 times the retention time of N-acetyltryptophan: NMT 300 ppm impurities	Not mentioned
21	Assay (dried basis)	Between 98.5 % and 101.0 %	Between 98.5% and 101.5%	Between 98.5 % and 101.0 %	NLT 98.5%
	Storage	Keep container tightly closed in a dry and well-ventilated place	Preserve in well-closed containers.	Protected from light.	Tight light resistant containers.

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