



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	L-Threonine (Ph. Eur., USP) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	A1419		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	72-19-5		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/A1419/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies Ph. Eur., USP	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, odorless crystals, having a slightly sweet taste	White or almost white, crystalline powder or colourless crystals	White, crystals or crystalline powder. . It is odorless or has a slight, characteristic odor, and has a slightly sweet taste.
2	Solubility	Soluble in water	Freely soluble in water; insoluble in absolute alcohol, in ether, and in chloroform	Soluble in water, practically insoluble in ethanol (96 %)	It is freely soluble in formic acid, soluble in water, and practically insoluble in ethanol (95)
3	Identification 1	Passes test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with threonine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with threonine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Threonine 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 blue colour 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	Specific optical rotation	Between -29.0° - -27.6° (20 deg) Between -29.1° and -26.7° (25 deg)	Between -29.1° and -26.7°	Between -29.0° to -27.6°	Between -29.0° and -26.0°
9	pH	Between 5.0–6.5	Between 5.0–6.5	Between 5.0–6.5	Between 5.2 and 6.2
10	Heavy metals	NMT 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 0.4%	Not mentioned	NMT 0.1%
13	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	Not mentioned
14	Loss on drying	NMT 0.2%	NMT 0.2%	NMT 0.5%	NMT 0.2%
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 ppm	NMT 0.028%
18	Iron	NMT 0.001%	NMT 30 ppm	NMT 10 ppm	Not mentioned
19	Ninhydrin positive substances/related substances	Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5% Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0% By TLC:	Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5%	NMT 0.5%
20	Assay (dried basis)	Between 99.0% and 101.0 %	Between 98.5% and 101.5%	Between 99.0% and 101.0 %	NLT 98.5%
	Storage	Store at room temperature	Preserve in well-closed containers.	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.