



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Methionine (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1340		Prepared by	Sr. Tech Lead
CAS NO.	63-68-3		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141090/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, Ph. Eur		USP 2022	EP Version 11.0
1	Description	Solid	White crystals, having a characteristic odor and taste.	White or almost white, crystalline powder or colourless crystals.	White, crystals or crys talline powder. It has a characteristic odor.
2	Solubility	Soluble in water	Soluble in water, in warm dilute alcohol, and in dilute mineral acids; insoluble in ether, in absolute alcohol, in benzene, and in acetone	Soluble in water, very slightly soluble in ethanol(96%)	It is freely soluble in formic acid, soluble in water, and very slightly soluble in ethanol (95%). It dissolves in dilute hydrochloric acid.
3	Identification 1	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Methionine reference standard/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Methionine reference standard/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Methionine reference standard/working standard
4	Identification 2	Passes The Test	Not mentioned	Should comply with specific optical rotation test	Not mentioned
5	Identification 3	Passes The 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 The Test	Not mentioned	A dark red colour should develop	Not mentioned
7	Specific optical rotation	Between '+22.4° and +24.7° (6M HCl) 'Between '+ 22.5° and + 24.0° (25% HCl)	Between '+22.4° and +24.7°	Between '+ 22.5° and + 24.0°	'Between '+21.0° and +25.0°
8	Loss on drying	NMT 0.3%	NMT 0.3%	NMT 0.5%	NMT 0.30%
9	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and colourless	sample solution should be clear and colourless
10	Residue on ignition/Sulfated ash	NMT 0.1%	NMT 0.4%	NMT 0.1%	NMT 0.1%
11	PH	Between 5.6 and 6.1 (1%) Between 5.5 and 6.5 (2.5%)	Between 5.6 and 6.1	Between 5.5 and 6.5	Between 5.2 and 6.2
12	Heavy metalas	Not mentioned	Not mentioned	Not mentioned	NMT 20 ppm
13	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2ppm
14	Chloride	NMT 0.02%	NMT 0.05%	NMT 200 ppm	NMT 0.021%
15	Sulfate	NMT 0.03%	NMT 0.03%	nmt 300 ppm	NMT 0.028%
16	Iron	NMT 0.001%	NMT 30 PPM	NMT 10 ppm	NA
17	Ammonium	NMT 0.02%	Not mentioned	NMT 200 ppm	NMT 0.02%
18	Related compounds	Methionine sulfoxide : NMT 0.1% N-Acetyl-d,l-methionine: NMT 0.2% Maximum unknown impurity: NMT 0.1% Total impurities: NMT 0.3% As PER EP Maximum unknown impurity: NMT 0.1% Total impurities: NMT 0.3%	Methionine sulfoxide : NMT 0.1% N-Acetyl-d,l-methionine: NMT 0.2% Maximum unknown impurity: NMT 0.1% Total impurities: NMT 0.3%	Maximum unknown impurity: NMT 0.1% Total impurities: NMT 0.3%	NMT 0.5%
19	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	Storage 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.