

" clyzo " - Monograph Compariso

AS PER CURRENT USP 2022/EP11/JP18



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ls	sue Date		March-23					
Ρ	repared by		Sr. Tech Lead					
R	eviewed by		Manager Technical					

	Product Name	L-Tyrosine (Ph. Eur., USP) pure, pharma grade	Deer Deere 🐔	Issue Date	March-23			
	Product Code	A1677	PanReac 🍫	Prepared by	Sr. Tech Lead			
	CAS NO.	60-18-4	AppliChem	Reviewed by	Manager Technical			
	Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1677/01			
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		Manufacturer COA	Pharmacopeial Specifications					
Sr. No.	Test	Complies Ph. Eur., USP	USP 2022	EP Version 11.0	JP 18			
1	Descriprion	Solid	White, odorless, tasteless crystals or crystalline	White or almost white, crystalline powder or	White, crystals or a crystalline powder			
			powder	colourless crystals				
2	Solubility	Soluble in water	Very slightly soluble in water; insoluble in alcohol	Very slightly soluble in water, practically insoluble	Freely soluble in formic acid, and practically			
			and in ether	in ethanol (96 per cent). It dissolves in dilute	insoluble in water and in ethanol (99.5). It			
				mineral acids and in dilute solutions of alkali	dissolves in dilute hydrochloric acid and in			
				hydroxides	ammonia TS			
3	Identification 1	Passes test	The Infrared absorption spectrum obtained with	The Infrared absorption spectrum obtained with	The Infrared absorption spectrum obtained with			
			sample should be concordant with spectrum	sample should be concordant with spectrum	sample should be concordant with spectrum			
			obtained withTyrosine reference	obtained withTyrosine reference	obtained withTyrosine reference			
-	Identification 2	D	standard/working standard	standard/working standard	standard/working standard			
4	Identification 2	Passes test	Not mentioned	Should comply with specific optical rotation test	UV absorption spectrum obtained with sample			
					should exhibit maxima at same wavelength and similar intensity as standard			
5	Identification 3	Passes test	Not mentioned	By TLC, the principal spot in the chromatogram	Not mentioned			
5	Identification 5	rasses test	Not mentioned	obtained with the test solution is similar in	Not mentioned			
				position, colour and size to the principal spot in				
				the chromatogram obtained with the reference				
				solution				
6	Identification 4	Passes test	Not mentioned	A dark red colour should be produced	Not mentioned			
7	Identification 5	Passes test	Not mentioned	An orange-red colour should be produced	Not mentioned			
8	Appearance of solution	Passes test	Not mentioned	Sample solution should be clear and not more	Sample solution should be clear and colorless			
				intensely coloured than reference solution Y7				
9	Specific optical rotation	Between - 11.2 ^o and - 9.8 ^o (at 25 deg) Between -	Between -11.2 ⁰ and -9.8 ⁰	Between -12.3 ⁰ and -11.0 ⁰	Between -12.5 ⁰ and -10.5 ⁰			
		12.3 ⁰ and – 11.0 ⁰ (at 20 deg)						
10	Heavy metals	NMT. 0.0015 %	Not mentioned	Not mentioned	NMT 10 ppm			
11	Residue on Ignition	NA	NMT 0.4%	Not mentioned	NMT 0.1%			
12	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	Not mentioned			
13	Loss on drying	NMT 0.3%	NMT 0.3%	NMT 0.5%	NMT 0.3%			
14	Chlorides	NMT 0.02 %	NMT 0.04%	NMT 200 ppm	NMT 0.021%			
15	Ammonium	NMT 0.02 %	Not mentioned	NMT 0.02%	NMT 0.02%			
16	Sulfate	NMT 0.03 %	NMT 0.04%	NMT 300 pppm	NMT 0.028%			
17	Iron	NMT 0.001 %	NMT 30 ppm	NMT 10 ppm	NMT 10 ppm			
18	Ninhydrin positive substances /related substances	Impurity A: NMT 0.5% Maximum	Maximum unknown impurity: NMT 0.5% Total	Impurity A: NMT 0.5%	NMT 0.2%			
		unknown impurity: NMT 0.2% Total impurities: NMT 0.6%	impurities: NMT 2.0%	Maximum unknown impurity: NMT 0.2% Total				
		y TLC Maximum unknown impurity: NMT 0.5%		impurities: NMT 0.6%				
		Total impurities: NMT 2.0%						
19	Assay (dried basis)	Between 99.0 % and 101.0 %	Between 98.5% and 101.5%	Between 99.0 % and 101.0 %	Between 99.0 % and 101.0 %			
	Storage	Keep container tightly closed in a dry and well-ventilated	Preserve in well-closed containers	Protected from light	Tight containers			
		place			<u> </u>			
	Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo reprensentive.							

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.