



" clyzo " - Monograph Comparisor



AS PER CURRENT USP 2022/EP11/JP18

Product Name	N-Acetyl-DL-Tryptophan (Ph. Eur, BP) low endotoxin, pharma grade		Issue Date	March-23
Product Code	637763		Prepared by	Sr. Tech Lead
CAS NO.	87-32-1		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/637763/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		<i>Complies Ph. Eur, BP</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Descrption	White to off white crystals or crystalline powder.	Product Not Official in USP pharmacopoeia	White or almost white, crystalline powder, or colourless crystals.Melting point about 205 °C.	Product Not Official in Japanese pharmacopoeia
2	Solubility	Slightly soluble in water. Very soluble in ethanol 96% It dissolves in dilute solutions of alkali.		Slightly soluble in water, very soluble in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides.	
3	Identification 1 (Optical rotation)	Passes The Test		Should compy with optical rotation test	
4	Identification 2 (IR)	Passes The Test		The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with N-Acetyl-DL-Tryptophan reference standard/ working standard.	
5	Identification 3	Not mentioned		By TLC, the principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).	
6	Identification 4	Not mentioned		A blue or greenish-blue colour should develop	
7	Identification 5 (Acetyl Reaction)	Not mentioned		A blue colour should develop at the junction of the two drops; the colour should intensifies and persists for a short time.	
8	Appearance of solution	Passes The Test			
9	Specific rotation	Between -0.1 and +0.1 °		Between -0.1 and +0.1 °	
10	Ammonium	NMT 0.0200 %		NMT 200 ppm	
11	Iron	NMT 0.0010 %		NMT 10 ppm	
12	Residue on Ignition	NMT 0.1%		Not mentioned	
13	Sulfated ash	Not mentioned		NMT 0.1 %	
14	Loss on drying	NMT 0.5 %		NMT 0.5 %	
15	Related Substances	Impurity A,B,C,D,E,F,G,H,I,J,K,L (Each) : NMT 0.25 % Total impurities: NMT 0.5 %		Impurity A,B,C,D,E,F,G,H,I,J,K,L (Each) : NMT 0.25 % Total impurities: NMT0.5 %	
16	Bacterial endotoxins	NMT 20 IU/g		Not mentioned	
17	Microbial Limits	Total Aerobic Microbial Count (TAMC) : NMT10 cfu/g Total combined yeast and moulds (TYMC) : NMT 10 cfu/g		Not mentioned	
18	Assay (dried basis)	Between 99.0 % and 101.0 %		Between 99.0 % and 101.0 %	
19	Residual solvents	Passes The Test		Not mentioned	
	2-Propanol	NMT 5000 ppm			
20	Elemental Impurities		Not mentioned		
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 20 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 10 ppm			
	Ni	NMT 20 ppm			

Tl	NMT 5 ppm			
Au	NMT 10 ppm			
Pd	NMT 10 ppm			
Ir	NMT 10 ppm			
Os	NMT 10 ppm			
Rh	NMT 10 ppm			
Ru	NMT 10 ppm			
Se	NMT 15 ppm			
Ag	NMT 15 ppm			
Pt	NMT 10 ppm			
Li	NMT 55 ppm			
Sb	NMT 120 ppm			
Ba	NMT 140 ppm			
Mo	NMT 25 ppm			
Cu	NMT 250 ppm			
Sn	NMT 600 ppm			
Cr	NMT 25 ppm			
Storage	Store away from direct sunlight		Protected from light.	

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.