




" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Asparagine 1-hydrate (Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	A1668		Prepared by	Sr. Tech Lead
CAS NO.	5794-13-8		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1668/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White crystals or a crystalline powder. It melts at about 234°C	white or almost white, crystalline powder or colourless crystals.	Product Not Official in Japanese pharmacopoeia
2	Solubility		Soluble in water; practically insoluble in alcohol and in ether. Its solutions are acid to litmus.	slightly soluble in water, practically insoluble in ethanol (96 per cent) and in methylene chloride.	
3	Identification 1	Passes the Test	In the assay test, the retention time of the major peak of the Sample solution corresponds to that of the Standard solution.	Should comply with specific optical rotation test	
4	Identification 2	Passes the Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Asparagine Monohydrate reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Asparagine Monohydrate reference standard/working standard.	
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.	
6	Identification 4	Passes the Test	Not mentioned	Should comply with loss on drying test	
7	Appearance of solution	Passes the Test	Not mentioned	Sample solution should be clear and colourless	
8	pH	Between 4.0 and 6.0	Not mentioned	Between 4.0 and 6.0	
9	Specific optical rotation	Between + 33.7 ⁰ and + 36.0 ⁰	Between +33.0 ⁰ and +36.5 ⁰	Between+ 33.7 ⁰ to + 36.0 ⁰	
10	Chlorides	NMT 0.02%	Not mentioned	NMT 200 PPM	
11	Sulfates	NMT 0.02%	Not mentioned	NMT 200 PPM	
12	Lead	Not mentioned	NMT 5 ppm	Not mentioned	
13	Ammonium	NMT 0.1 %	Not mentioned	NMT 0.1 %	
14	Iron	NMT 0.001%	Not mentioned	NMT 10 ppm	
15	Related substances	Impurity A: NMT 0.5 % Impurity C: NMT 0.1 % Unspecified Impurities: for each impurity NMT 0.05% Total: NMT 0.8 %	Asparagine related compound A: NMT 1.0% Aspartic acid: NMT 1.0% Maximum unknown impurity: NMT 0.5% Total impurities: NMT 3.0%	Impurity A: NMT 0.5 % Impurity C: NMT 0.1 % Unspecified Impurities: for each impurity NMT 0.05% Total: NMT 0.8 %	
16	Loss on drying	Between 10.5 % to 12.5 %	Between 11.5% and 12.5%	Between 10.5 % and 12.5 %	
17	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1 %	
18	Residue on ignition	Not mentioned	NMT 0.1%	Not mentioned	
19	Microbial contamination	Not mentioned	TAMC: NMT 10 ³ CFU/g TYMC: NMT 10 ² CFU/g	Not mentioned	
20	Assay (dried basis)	Between 99.0 % to 101.0 %	Between 95.5% and 102.0%	Between 99.0 % to 101.0 %	
21	Elemental impurities		Not mentioned	Not mentioned	
	Hg	NMT 1.5 ppm			
	Ni	NMT 20 ppm			
	As	NMT 1.5 ppm			
	V	NMT 10 ppm			
	Co	NMT 5 ppm			
	Tl	NMT 1 ppm			
	Cr	NMT 25 ppm			
	Cd	NMT 0.5 ppm			
	Ru	NMT 10 ppm			
	Ag	NMT 15 ppm			

	Sb	NMT 120 ppm			
	Au	NMT 10 ppm			
	Pt	NMT 10 ppm			
	Se	NMT 15 ppm			
	Rh	NMT 10 ppm			
	Li	NMT 55 ppm			
	Sn	NMT 600 ppm			
	Ob	NMT 0.5 ppm			
	Iron	NMT 10 ppm			
	Ba	NMT 140 ppm			
	Pd	NMT 10 ppm			
	Os	NMT 10 ppm			
	Mo	NMT 25 ppm			
	Cu	NMT 250 ppm			
	Storage	Store at room temperature	Preserve in well-closed, light-resistant containers. Store at room temperature.	Not mentioned	

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.