



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Urea crystalline (USP, BP, Ph. Eur.) pharma grade	 ITW Reagents	Issue Date	March-23
Product Code	191754		Prepared by	Sr. Tech Lead
CAS NO.	57-13-6		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/191754/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	White crystalline powder	Colorless to white, prismatic crystals, or white, crystalline powder, or small white pellets. Is practically odorless, but may gradually develop a slight odor of ammonia upon long standing. Its solutions are neutral to litmus.	White or almost white, crystalline powder or transparent crystals, slightly hygroscopic.	Colorless to white, crystals or crystalline powder. It is odorless, and has a cooling, saline taste. A 1% solution is neutral.
2	Solubility	Miscible with water, alcohol, ether and trichloromethane	Freely soluble in water and in boiling alcohol; practically insoluble in chloroform and in ether.	Very soluble in water, soluble in ethanol (96 %), practically insoluble in methylene chloride.	It is very soluble in water, freely soluble in boiling ethanol (95), soluble in ethanol (95), and very slightly soluble in diethyl ether.
3	Identification 1	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with urea reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with urea reference standard/working standard.	Should comply by a reddish purple color development
4	Identification 2	Melting point should be between 132°C and 135°C	In assay test, the retention time of the major peak of the sample solution corresponds to that of the standard solution.	Melting point should be between 132°C and 135°C	Should comply by a white, crystalline precipitate formation
5	Identification 3	Passes The Test	Not mentioned	Should comply by a white, crystalline precipitate formation	Not mentioned
6	Identification 4	Passes The Test	Not mentioned	Should comply by a reddish-violet colour formation	Not mentioned
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and colourless.	Not mentioned
8	Alkanity	Passes The Test	Not mentioned	After addition of 0.4 mL of 0.01 M HCl, the solution becomes red to orange.	Not mentioned
9	Biuret	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
10	Ammonium	NMT 0.05%	Not mentioned	NMT 500 ppm	Not mentioned
11	Chloride	NMT 0.007%	Not mentioned	Not mentioned	NMT 0.007%
12	Sulfate	NMT 0.01%	Not mentioned	Not mentioned	NMT 0.01%
13	Loss on drying	NMT 1.0%	Not mentioned	NMT 0.1%	Not mentioned
14	Ethanol-insoluble substances	Not mentioned	NMT 0.04%	Not mentioned	NMT 0.04%
15	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 20 ppm
16	Residue on ignition	NMT 0.1%	NMT 0.1%	Not mentioned	NMT 0.1%
17	Sulfated ash	Not mentioned	Not mentioned	NMT 0.1%	Not mentioned
18	Matter insoluble in ethanol	NMT 0.04%			
19	Organic impurities:	Related compound A: NMT 0.1% Maximum unspecified impurity: NMT 0.1% Total Impurities: NMT 2.0%	Related compound A: NMT 0.1% Maximum unspecified impurity: NMT 0.1% Total Impurities: NMT 2.0%	Not mentioned	Not mentioned

20	Assay	Between 98.5% and 101.5 % (By titrimetry) Between 98.0% and 102.0 % (By HPLC)	Between 98.0% and 102.0 %	Between 98.5% and 101.5 %	NLT 99.0%
21	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 0.8 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				
22	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage at room temperature	Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.	Protected from light.	Tight containers away from fire

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.