



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

	Product Name	Sodium Acetate 3-hydrate (Ph. Eur, BP, USP) GMP IPEC grade		Issue Date	March-23
	Product Code	631632		Prepared by	Sr. Tech Lead
	CAS NO.	6131-90-4		Reviewed by	Manager Technical
	Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/631632/01
Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	Small crystals, White	Colorless, transparent crystals, or white, granular crystalline powder, or white flakes. It is odorless or has a faint acetous odor, and has a slightly bitter, saline taste. It is efflorescent in warm, dry air	White or almost white, crystalline powder or colourless crystals.	Colorless crystals or a white crystalline powder. It is odorless or has a slight, acetous odor. It has a cool, saline and slightly bitter taste
2	Solubility	Soluble in water	Very soluble in water; soluble in alcohol	Very soluble in water, soluble in ethanol (96%)	Very soluble in water, freely soluble in acetic acid (100%), soluble in ethanol (95%), and practically insoluble in diethyl ether
3	Identification 1 Acetate	Passes test	Should comply by a dark color or a blue precipitate.	Should comply by a dark color or a blue precipitate.	1. Should comply by odor of acetic acid. (2) Should comply by odor of ethyl acetate (3) Should comply by a red-brown colour and subsequently a red-brown precipitate
4	Identification 2 Sodium	Passes test	Should comply by a dense precipitate is formed.	Should comply by a dense precipitate is formed.	(1) During flame test, a yellow color develops. (2) Should comply by a white, crystalline precipitate formation
5	Identification 3	Passes test	Not mentioned	Should comply by loss on drying test	Not mentioned
6	pH	Between 7.5 and 9.0	Between 7.5 and 9.2	Between 7.5 and 9.0	Not mentioned
7	Appearance of solution/clarity of solution	Passes test	Not mentioned	Sample solution is clear and colourless	Sample solution should be clear and colourless
8	Insoluble matter in Water	NMT 0.05%	NMT 0.05 %	Not mentioned	Not mentioned
9	Reducing substances	Passes test	Not mentioned	The pink colour should persists for atleast one hour	The red color of the solution does not disappear
10	Acidity or alkalinity	Not mentioned	Not mentioned	Not mentioned	After addition of 1.0 ml 0.01M HCl , the red color disappears
11	Chloride	NMT 0.0200%	NMT 350 ppm	NMT 200 ppm	NMT 0.011%
12	Sulfates	NMT 0.003%	NMT 50 ppm	NMT 200 ppm	NMT 0.017%
13	Calcium and Magnesium (as Ca)	NMT 0.005%	No turbidity should be produced within 5 minutes	NMT 50 ppm	NMT 0.5 ml of 0.01 M disodium dihydrogen ethylenediamine tetraacetate is required
14	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
15	Iron	NMT 0.0010%	Not mentioned	NMT 10 ppm	Not mentioned
16	Potassium	Passes test	No precipitate should be produced	Not mentioned	Not mentioned
17	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
18	Loss on drying	Between 39.0% and 40.5%	Between 38.0% and 41.0%	Between 39.0% and 40.5%	Between 39.0% and 40.5%
19	Assay (dried basis)	Between 99.0% and 101.0%	Between 99.0% and 101.0%	Between 99.0% and 101.0%	NLT 99.5%
	Elemental impurities				
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			

20	As	NMT 1.5 ppm	Not mentioned	Not mentioned	Not mentioned
	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			
21	Residual Solvent	Passes test	Not mentioned	NA	Not mentioned
	Storage	Room Temperature	Preserve in tight containers	In an airtight container	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.					
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.					