



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	di-Sodium tetra-Borate 10-hydrate (USP-NF, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141644		Prepared by	Sr. Tech Lead
CAS NO.	1303-96-4		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141644/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP-NF, BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	White crystalline powder	Colorless, transparent crystals or white, crystalline powder.	White or almost white, crystalline powder, colourless crystals or crystalline masses, efflorescent.	colorless or white crystals or a white crystalline powder. It is odorless, and has a slightly characteristic, saline taste.
2	Solubility	Soluble in water	Freely soluble in boiling water and in glycerin; soluble in water; insoluble in alcohol.	Soluble in water, very soluble in boiling water, freely soluble in glycerol.	It is freely soluble in glycerin, soluble in water, and practically insoluble in ethanol (95), in ethanol (99.5) and in diethyl ether.
3	Identification 1 (Sodium)	Passes The Test	Should comply formation of a dense precipitate is formed.	1. A dense white precipitate should be formed. 2.Should comply by a voluminous, white, crystalline precipitate formation	(1) Should impart a yellow color flame during flame test. (2) Should produce a white, crystalline precipitate with potassium hexahydroxoantimonate (V) TS.
4	Identification 2 (Borate)	Passes The Test	An intense blue color should be produced	The colour should disappears.	(1) It should burn with a green flame. (2) Turmeric paper should exhibits a red color, which changes to blue with ammonia TS
5	Identification 3	Passes The Test	Not mentioned	The flame should impart a green border.	Not mentioned
6	pH of 4% solution	Between 9.0 and 9.6	Not mentioned	Between 9.0 and 9.6	Between 9.1 and 9.6
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and colorless.	Sample solution should be clear and colorless.
8	Insoluble matter in H2O	NMT 0.025 %	Not mentioned	Not mentioned	Not mentioned
9	Chloride	NMT 0.005%	Not mentioned	Not mentioned	Not mentioned
10	Ammonium	NMT 0.001%	Not mentioned	NMT 10ppm	Not mentioned
11	Phosphate	NMT 0.005 %	Not mentioned	Not mentioned	Not mentioned
12	Sulfate	NMT 0.005%	Not mentioned	NMT 50 ppm	Not mentioned
13	Carbonate and Hydrogen Carbonate	Passes The Test	No effervescence should be observed.	Not mentioned	The solution should not effervesce.
14	Heavy metals	NMT 0.002%	Not mentioned	Not mentioned	NMT 20 ppm
15	Calcium	NMT 0.01%	Not mentioned	NMT 100 ppm	Not mentioned
16	Arsenic		Not mentioned	Not mentioned	NMT 5 ppm
17	Assay	NLT 99.0 % and NMT 103.0 %	Between 99.0 % and 105.0 %	Between 99.0 % and 103.0 %	Between 99.0 % and 103.0 %
18	Residual metals ICP: (according to EMEA/CHMP/SWP/4446/2000)		Not mentioned	Not mentioned	Not mentioned
	Pt	NMT 10 ppm			
	Pd	NMT 10 ppm			
	Ir	NMT 10 ppm			
	Rh	NMT 10 ppm			
	Ru	NMT 10 ppm			
	Os	NMT 10 ppm			
	Mo	NMT 25 ppm			
	Ni	NMT 25 ppm			
	Cr	NMT 25 ppm			

	V	NMT 25 ppm			
	Cu	NMT 250 ppm			
	Mn	NMT 250 ppm			
	Fe	NMT 1300 ppm			
	Zn	NMT 1300 ppm			
19	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage away from direct light	Preserve in tight containers.	Not mentioned	Containers—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.