



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Sodium Chloride (Ph. Eur, BP, USP) low endotoxin, IPEC grade		Issue Date	March-23
Product Code	631659		Prepared by	Sr. Tech Lead
CAS NO.	7647-14-5		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/631659/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, BP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	White crystalline powder	Colorless, cubic crystals or white crystalline powder. Has a saline taste.	White or almost white, crystalline powder or colourless crystals or white or almost white pearls.	Colorless or white, crystals or crystalline powder.
2	Solubility	Soluble in water	Freely soluble in water; soluble in glycerin; slightly soluble in alcohol.	Freely soluble in water, practically insoluble in anhydrous ethanol.	Feely soluble in water, and practically insoluble in ethanol (99.5).
3	Identification 1 Sodium	Passes The Test	After addition of potassium pyroantimonate solution R a dense white precipitate should be formed	Should comply by dense white precipitate formation	1. Should develop yellow coloured flame. 2. Should comply with a white, crystalline precipitate with addition of potassium hexahydroxoantimonate (V) TS.
4	Identification 2 chloride	Passes The Test	The precipitate should dissolve easily with the possible exception of a few large particles, which dissolve more slowly.	Should comply by curdled white precipitate formation which dissolves in ammonia	1. When mixed & heated with H ₂ SO ₄ & KMnO ₄ , should evolve an odor of chlorine, which turns moistened KI starch paper blue 2. Should comply by formation of white precipitate after addition of AgNO ₃
5	Appearance of solution	Passes The Test	Sample solution should be clear and colourless	Sample solution should be clear and colourless	Sample solution should be clear and colourless
6	Acidity or alkalinity	Passes The Test	NMT 0.5 mL of 0.01 N HCl or 0.01 N NaOH is required to change the color of this solution.	NMT 0.5 mL of 0.01 M HCl or 0.01 M NaOH is required to change the colour of the indicator.	After addition of 0.5 mL of 0.01 M NaOH, the color of the solution should turn blue
7	Loss on drying	NMT 0.5%	NMT 0.5 %	NMT 0.5 %	NMT 0.5 %
8	Bromides	NMT 0.01%	NMT 100 ppm	NMT 100 ppm	The absorbance of the sample solution should not be more than that of the standard solution.
9	Phosphates	NMT 0.0025%	NMT 25 ppm	NMT 25 ppm	The color of the solution should not be darker than the control solution.
10	Iodides	Passes The Test	No blue color should be observed.	The mixture should not show blue colour	A blue color should not appear
11	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 3 ppm
12	Magnesium and alkaline-earth metals	NMT 0.01%	NMT 100 ppm	NMT 100 ppm	The color of the solution should be a blue.
13	Arsenic	NMT 0.0001%	NMT 1ppm	NMT 1ppm	NMT 2ppm
14	Iron	NMT 0.0002%	NMT 2ppm	NMT 2 ppm	The solution should not have more color than the control solution
15	Barium	Passes The Test	Any opalescence in the test solution should not be more intense than that in the reference solution	Any opalescence in the solution should not be more intense than that in a standard solution	The solution should not have more turbidity than the control solution
16	Ferrocyanides	Passes The Test	No blue color should develop in 10 min.	No blue color should develop in 10 min.	A blue color should not develop within 10 minutes
17	Potassium	NMT 0.05%	Not mentioned	Not mentioned	Not mentioned
18	Sulfate	NMT 0.02%	NMT 200 ppm	NMT 200 ppm	Any turbidity produced should not be more pronounced than control solution.
19	Nitrites	Absorbance NMT 0.01	Absorbance should not be more than 0.01	Absorbance should not be more than 0.01	Not mentioned

20	Assay (dried basis)	Between 99.0% and 100.5 %	Between 99.0% and 100.5 %	Between 99.0% and 100.5 %	Between 99.0% and 100.5 %
21	Microbial limits	TAMC: NMT 102 CFU/g TYMC: NMT 10 CFU/g	NLT 99.0%	Not mentioned	Not mentioned
22	Bacterial Endotoxins	NMT 5 UI/g	Not mentioned	NMT 5 IU/Kg	Not mentioned
23	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 25 ppm			
	As	NMT 1 ppm			
	Hg	NMT 1.5 ppm			
	Co	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 2 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 10 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			
24	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage at room temperature	Preserve in well-closed containers.	NA	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.					
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