



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Sodium Carbonate anhydrous (USP-NF, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141648		Prepared by	Sr. Tech Lead
CAS NO.	497-19-8		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141648/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP-NF, BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	White powder	Colorless crystals, or white, crystalline powder or granules. Is stable in air under ordinary conditions	white or almost white, crystalline powder or colourless, transparent crystals, efflorescent.	White crystals or crystalline powder, A 10% solution is alkaline & is hygroscopic.
2	Solubility	Soluble in water	Very soluble in boiling water; freely soluble in water	freely soluble in water, practically insoluble in ethanol (96 %).	Freely soluble in water, and practically insoluble in ethanol (95) and in diethyl ether
3	Identification 1 Carbonates	Passes The Test	1. After addition of acid, should generate a gas, which produces a white precipitate immediately, when passed into calcium hydroxide TS 2. Should exhibit a red color with 1 drop of henolphthalein TS	A white precipitate should be formed that dissolves on addition of an excess of HCl R1.	1. After addition of dilute HCl, should generate a gas, which produces a white precipitate immediately, when passed into calcium hydroxide TS 2. After addition of magnesium sulfate TS, should produce a white precipitate, which dissolves by addition of dilute acetic acid. 3. Should exhibit a red color with 1 drop of henolphthalein TS
4	Identification 2 Sodium	Passes The Test	After addition of potassium pyroantimonate solution R a dense white precipitate should be formed	1. After addition of potassium pyroantimonate solution a dense white precipitate should be formed 2. After addition of methoxyphenyl acetic reagent a voluminous, white, crystalline precipitate should be formed which dissolve in ammonia	1. Should develop yellow coloured flame. 2. Should comply with a white, crystalline precipitate with addition of potassium hexahydroxoantimonate (V) TS.
5	Identification 3	Passes The Test	Not mentioned	10% solution should be strongly alkaline	Not mentioned
6	Appearance of solution	Passes The Test	Not mentioned	Solution is cleared and not more intensely colored reference solution Y6	Sample solution should be clear and colorless
7	Alkali hydroxides and bicarbonates	Passes The Test	Not mentioned	Sample solution should remain clear	Not mentioned
8	Chloride	NMT 0.01%	Not mentioned	NMT 50 ppm	NMT 0.071%
9	Sulfates	NMT 0.025%	Not mentioned	NMT 100 ppm	Not mentioned
10	Iron	NMT 0.001%	Not mentioned	NMT 20 ppm	Not mentioned
11	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10ppm
12	Nitrogen compounds	NMT 0.005%	Not mentioned	Not mentioned	Not mentioned
13	Phosphate	NMT 0.005%	Not mentioned	Not mentioned	Not mentioned
14	Calcium	NMT 0.01%	Not mentioned	Not mentioned	Not mentioned
15	Potassium	NMT 0.05%	Not mentioned	Not mentioned	Not mentioned
16	Magnesium	NMT 0.01%	Not mentioned	Not mentioned	Not mentioned
17	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 3.1 ppm
18	water	Not mentioned	NMT 0.5%	Not mentioned	Not mentioned
19	Matter insoluble in water	NMT 0.025%	Not mentioned	Not mentioned	Not mentioned
20	Loss on Drying	NMT 0.5%	Not mentioned	NMT 1.0%	NMT 2.0%
21	Assay	Between 99.5 and 100.5 %	Between 99.5 and 100.5 %	Between 36.7% and 40.0 %	NLT 99.0%
	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			

22	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				
23	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Store at room temperature	Preserve in well-closed containers	In an airtight container	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.