



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Sodium Hydrogen Carbonate (USP, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141638		Prepared by	Sr. Tech Lead
CAS NO.	144-55-8		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141638/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur., BP	USP 2022	EP Version 11.0	JP 18
1	Description	White Crystalline powder	White, crystalline powder. Is stable in dry air, but slowly decomposes in moist air	white or almost white, crystalline powder.	white, crystals or crystalline powder. It is odorless, and has a characteristic, saline taste. It slowly decomposes in moist air.
2	Solubility	Soluble in water	Soluble in water; insoluble in alcohol.	soluble in water, practically insoluble in ethanol (96 per cent). When heated in the dry state or in solution, it gradually changes into sodium carbonate	It is soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.
3	Identification 1 carbonates and bicarbonates	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 produce a white precipitate immediately. 2.A cold solution (1 in 20) of a soluble bicarbonate remains unchanged or is only slightly colored by phenolphthalein TS.	Addition of dilute acetic acid into sample solution gives effervescent and gives off a colourless and odourless gas. On heating in 5 mL of barium hydroxide solution R. A white precipitate is formed that dissolves on addition of an excess of hydrochloric acid 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. exhibits only a slightly red color upon addition of 1 drop of phenolphthalein 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 R a dense white precipitate should be formed 2. After addition of methoxyphenylacetic reagent R a voluminous, white, crystalline precipitate should be formed which dissolve in ammonia .On addition of ammonium carbonate solution R. No precipitate is formed	1. Should develop yellow coloured flame. 2. Should comply with a white, crystalline precipitate with addition of potassium hexahydroxantimonate (V) TS.
5	Identification 3	Passes the test	Not mentioned	Addition of phenolphthalein solution produce a pale pink colour . Heat; gas is evolved and the solution becomes red	Not mentioned
6	Appearance of solution	Passes the test	Not mentioned	Sample Solution should be clear and colourless	Sample solution should be clear and colorless
7	Insoluble substances	Passes the test	The resulting solution should be complete and clear.	Not mentioned	Not mentioned
8	pH	Not mentioned	Not mentioned	Not mentioned	Between 7.9 and 8.4.
9	Chloride	NMT 0.005%	NMT 0.015%	NMT 150 ppm	NMT 0.040 %
10	Sulfur compounds	NMT 0.015%	NMT 0.015%	Not mentioned	Not mentioned
11	Sulfate (SO4)	NMT 0.01%	Not mentioned	NMT 150 ppm	Not mentioned
12	Carbonate	passes test	The solution does not assume more than a faint pink color immediately	The pH of freshly prepared sample solution should not be more than 8.6	Not mentioned
13	Phosphate	NMT 0.002%	Not mentioned	Not mentioned	Not mentioned
14	Ammonia	NMT 0.002%	NMT 20 ppm	NMT 20 ppm	Not mentioned
15	Arsenic	NMT 0.00015%	NMT 2 ppm	Not mentioned	NMT 2 ppm
16	Calcium	NMT 0.01%	NMT 0.01%	NMT 100 ppm	Not mentioned
17	Iron	NMT 0.0005%	NMT 5 ppm	NMT 20 ppm	Not mentioned
18	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 5 ppm

19	Loss on drying	NMT 0.25%	NMT 0.25%	Not mentioned	Not mentioned
20	Assay (On Dry Basis)	Between 99.0% and 100.5%	Between 99.0% and 100.5%	Between 99.0% and 101.0%	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 test	Not mentioned	Not mentioned	Not mentioned
	Storage	Keep container tightly closed in a dry and well-ventilated place.	Preserve in well-closed containers.	Not mentioned	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.