



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Sodium Benzoate (USP-NF, BP, Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	141637		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	532-32-1		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/141637/01

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	White, odorless or practically odorless, granular or crystalline powder, stable in air	White or almost white, crystalline or granular powder or flakes, slightly hygroscopic	White, granules, crystals or crystalline powder. It is odorless, and has a sweet and saline taste.
2	Solubility	Freely soluble in water	Freely soluble in water; soluble in 90% alcohol; sparingly soluble in alcohol	Freely soluble in water, sparingly soluble in ethanol (90% V/V)	Freely soluble in water, slightly soluble in ethanol (95%), and practically insoluble in diethyl ether
3	Identification 1	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Sodium Benzoate reference standard/working standard	Not mentioned	Not mentioned
4	Identification 2 Benzoate	Passes The Test	Not mentioned	1. After moistening of sample with 0.2 ml to 0.3 ml of H <sub>2</sub> SO <sub>4</sub> and gentle warming, a white sublimate should be deposited on the inner wall of the tube. 2. Residue should melt between 1200C and 1240C	1. The residue should melt between 1200C and 1240C 2. After addition of ferric (III) chloride ts, a light yellow-red precipitate should be produced
5	Identification 3 Sodium	Passes The Test	Should comply by dense white precipitate formation	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 hexahydroxantimonate (V) TS.
6	Identification 4	Passes The Test	In the assay test, the retention time of the major peak of the Sample solution corresponds to that of the Standard solution	Not mentioned	Not mentioned
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution Y6	Sample solution should be clear and colourless
8	Holgenated compounds	Ionised chlorine: NMT 0.02% Total Chlorine: NMT 0.03%	Not mentioned	Ionised chlorine: NMT 200 ppm Total Chlorine: NMT 300 ppm	Not mentioned
9	Acidity or alkalinity	Passes The Test	The pink color produced, if any, should be discharged by the addition of 0.20 ml of 0.10 N H <sub>2</sub> SO <sub>4</sub> .	Not more than 0.2 ml of 0.1 M NaOH or 0.1 M HCl is required to change the colour of the indicator.	After addition of 0.40 ml of 0.1 M NaOH, a red color should be developed.
10	Chlorinated compounds	Not mentioned	Not mentioned	Not mentioned	The solution should not be turbid than the control solution
11	Sulfates	Not mentioned	Not mentioned	Not mentioned	NMT 0.120%
12	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
13	Heavy metals	NMT 0.001%	Not mentioned	Not mentioned	NMT 20 ppm
14	Phthalic acid	Not mentioned	Not mentioned	Not mentioned	The green fluorescence of the sample solution should not be more intense than that of the control solution
15	Loss on drying	NMT 1.5%	Not mentioned	NMT 2.0%	NMT 1.5%

16	Water	NMT 1.5%	NMT 1.5%	Not mentioned	Not mentioned
17	Matter insoluble in water	Passes The Test	Not mentioned	Not mentioned	Not mentioned
18	Assay	Between 99.0% and 100.5% (by titrimetry) Between 99.0% and 101.0% (By HPLC)	Between 99.0% and 101.0% (anhydrous basis)	Between 99.0% and 100.5% (dried sample)	NLT 99.0% (dried sample)
19	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				
20	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage at room temperature	Preserve in well-closed containers	Not mentioned	Well-closed 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.