



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Salicylic Acid (USP, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141045		Prepared by	Sr. Tech Lead
CAS NO.	69-72-7		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141045/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA Complies USP, BP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	White crystalline powder	White crystals, usually in fine needles, or fluffy, white, crystalline powder. Has a sweetish, followed by an acid, taste and is stable in air.	White or almost white, crystalline powder or white or colourless, acicular crystals	White, crystals or crystalline powder. It has a slightly acid, followed by an acid taste
2	Solubility	Slightly soluble in water	Freely soluble in alcohol and in ether; soluble in boiling water; sparingly soluble in chloroform; slightly soluble in water and in benzene	Slightly soluble in water, freely soluble in ethanol (96%), sparingly soluble in methylene chloride	It is freely soluble in ethanol (95%) and in acetone, and slightly soluble in water
3	Identification 1	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	Sample should melt between 1580C and 1610C	(1) Add soda lime and heat, odor of phenol should be evolved (3) After addition of 5 to 6 drops of dilute iron (III) chloride TS a red color should be produced, which changes to purple and then fades when dilute HCl is added dropwise
4	Identification 2	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Salicylic Acid reference standard/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Salicylic Acid reference standard/working standard	The infrared absorption spectrum of sample should be comparable to spectrum obtained with Salicylic acid reference/working standard
5	Identification 3	Passes The Test	Not mentioned	A violet colour should be produced that persists after the addition of 0.1 mL of acetic acid R	UV absorption spectrum of sample solution and standard solution are comparable to each other and exhibit maxima/minima absorption at the same wavelengths
6	Melting point	Between 159 °C and 161 °C	Not mentioned	Not mentioned	Between 158 °C and 161 °C
7	Chloride	NMT 0.01%	NMT 0.014%	NMT 100ppm	NMT 0.008%
8	Sulfates (SO4)	NMT 0.02%	NMT 0.02%	NMT 200 ppm	NMT 0.019%
9	Heavy metals	NMT 0.002%	Not mentioned	Not mentioned	NMT 10 ppm
10	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and colourless	Not mentioned
11	Related substances	Impurity A: NMT 0.1% Impurity B: NMT 0.05% Impurity C: NMT 0.02% Maximum unknown impurity: NMT 0.05% Total impurities: NMT 0.2%	Impurity A: NMT 0.1% Impurity B: NMT 0.05% Impurity C: NMT 0.02% Maximum unknown impurity: NMT 0.05% Total impurities: NMT 0.2%	Impurity A: NMT 0.1% Impurity B: NMT 0.05% Impurity C: NMT 0.02% Maximum unknown impurity: NMT 0.05% Total impurities: NMT 0.2%	parahydroxybenzoic acid: NMT 2.0% 4-hydroxyisophthalic acid: NMT 2.0% Phenol: NMT 2.0%
12	Matter insoluble in ethanol	Passes The Test	Not mentioned	Not mentioned	Not mentioned
13	Darkened substances by H2SO4	Passes The Test	Not mentioned	Not mentioned	Not mentioned
14	Copper	NMT 0.0005%	Not mentioned	Not mentioned	Not mentioned
15	Iron	NMT 0.0005%	Not mentioned	Not mentioned	Not mentioned
16	Nickel	NMT 0.0005%	Not mentioned	Not mentioned	Not mentioned
17	Lead	NMT 0.0005%	Not mentioned	Not mentioned	Not mentioned
18	Residue on ignition	NMT 0.05%	Not mentioned	Not mentioned	NMT 0.1%
19	Sulfated ash	Not mentioned	Not mentioned	NMT 0.1%	Not mentioned
20	Loss on drying	NMT 0.5%	NMT 0.5%	NMT 0.5%	NMT 0.5%
21	Assay (dried basis)	Between 99.0% and 100.5% (Titrimetry) Between 98.0% and 102.0% (By HPLC)	Between 98.0% and 102.0 %	Between 99.0% and 100.5%	Between 99.5% and 101.0%
22	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage away from direct light.	Preserve in well-closed containers	Protected from light	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.