



" clyzo " - Monograph Comparison



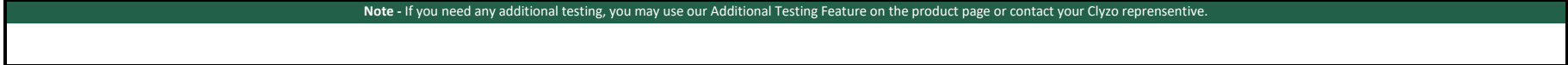
AS PER CURRENT USP 2022/EP11/JP18

Product Name	Sulfanilamide (Ph. Fr., DAB) pure, pharma grade		Issue Date	March-23
Product Code	142823		Prepared by	Sr. Tech Lead
CAS NO.	63-74-1		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/142823/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies (Ph. Fr., DAB)</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Small white crystals	Product not official in USP pharmacopoeia	White or yellowish-white crystals or fine powder	Product not official in Japanese pharmacopoeia
2	Solubility	Slightly soluble in water, sparingly soluble in alcohol		Slightly soluble in water, freely soluble in acetone, sparingly soluble in ethanol (96 %), practically insoluble in methylene chloride. It dissolves in solutions of alkali hydroxides and in dilute mineral acids.	
3	Identification 1	Not mentioned		Should melt between 164.5°C and 166.0°C	
4	Identification 2	Passes The Test		The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Sulfanilamide reference/working standard	
5	Identification 3	Not mentioned		By TLC, in RS test the principal spot in the chromatogram obtained with test solution (a) is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).	
6	Identification 4	Not mentioned		An intense orange or red colour and usually a precipitate of the same colour should be produced.	
7	Melting range	Between 164°C and 167°C		Not mentioned	
8	Acidity	Passes The Test		NMT 0.2 ml of 0.1 M NaOH is required to change the colour of the indicator.	
9	Related substances	Not mentioned		NMT 0.5%	
10	Insoluble matter in HCl	Passes The Test		Not mentioned	
11	Insoluble matter in NaOH	Passes The Test		Not mentioned	
12	Loss on drying	NMT 0.5 %		NMT 0.5%	
13	Residue on ignition	NMT 0.1 %		Not mentioned	
14	Sulfated ash	Not mentioned		NMT 0.1%	
15	Chloride	NMT 0.01 %		Not mentioned	
16	Sulfate	NMT 0.02 %		Not mentioned	
17	Heavy metals	NMT 0.002 %		Not mentioned	
18	Assay (dried basis)	Between 99.0 % and 101.0 %		Between 99.0% and 101.0%	
19	Elemental impurities			Not mentioned	
	Pt	NMT 10 ppm			
	Pd	NMT 10 ppm			
	Ir	NMT 10 ppm			
	Rh	NMT 10 ppm			
	Rh	NMT 10 ppm			
	Os	NMT 10 ppm			
	Mo	NMT 25 ppm			

	Ni	NMT 25 ppm			
	Cr	NMT 25 ppm			
	V	NMT 25 ppm			
	Cu	NMT 250 ppm			
	Mn	NMT 250 ppm			
	Fe	NMT 1300 ppm			
	Zn	NMT 1300 ppm			
20	Storage	Storage away from direct light		Store protected from light	

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.

