" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**D(-)-Sorbitol (Ph. Eur., USP-NF) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	A2222		**Prepared by**	Sr. Tech Lead
	CAS NO.	50-70-4		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/A2222/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies Ph. Eur., USP-NF	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	Solid	White granules, powder, or crystalline masses. It is odorless, and has a sweet taste with a cold sensation.It is hygroscopic	white or almost white, crystalline powder. It shows polymorphism	White, granules, powder, or crystalline masses. It is odorless, and has a sweet taste with a cold sensation. It is hygroscopic.
2	Solubility	Very soluble in water	Very soluble in water; sparingly soluble in alcohol; and practically insoluble in ethyl ether.	very soluble in water, practically insoluble in ethanol (96 %).	It is very soluble in water, sparingly soluble in ethanol (95), and practically insoluble in diethyl ether.
3	Identification 1	Passes The Test	Should comply by deep pink or wine-red color appearance	In assay test, the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution.	A blue-green color should develop, but no turbidity should be produced.
4	Identification 2	Passes The Test	In the assay test, the retention time of the major peak of the sample solution corresponds to that from the standard solution.	By TLC test, the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a).	Should comply by a reddish purple to red-purple color formation
5	Identification 3	Passes The Test	Not mentioned	The residue should melt in the range 98°C and 104°C	The residue should melt in the range 97°C and 101°C
6	Identification 4	Passes The Test	Not mentioned	Specific optical rotation should be between+ 4.00 and + 7.00 (anhydrous substance)	Not mentioned
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and colourless	Sample solution should be clear and colourless
8	Conductivity	NMT 20 $\mu S \cdot cm^{-1}$	Not mentioned	NMT 20 $\mu S \cdot cm^{-1}$	Not mentioned
9	pH	Between 3.5 and 7.0	Between 3.5 and 7.0	Not mentioned	Not mentioned
10	Chloride	Not mentioned	NMT 0.005%	Not mentioned	NMT 0.005%
11	Sulfate	Not mentioned	NMT 0.01%	Not mentioned	NMT 0.006%
12	Nickel (Ni)	NMT 0.0001%	NMT 1 ppm	Not mentioned	No red color should develop.
13	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 1.3 ppm
14	Glucose	Not mentioned	Not mentioned	Not mentioned	NMT 6.3 mL of 0.02 M KMnO4 is required.
15	Sugars	Not mentioned	Not mentioned	Not mentioned	NMT 6.3 mL of 0.02 M KMnO4 is required.
16	Loss on drying	Not mentioned	Not mentioned	Not mentioned	NMT 2.0%
17	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 5 ppm
18	Water	NMT 1.5%	NMT1.5%	NMT 1.5%	Not mentioned
19	sulfated ash	NMT 0.1%	Not mentioned	Not mentioned	Not mentioned
20	Residue on ignition	Not mentioned	NMT 0.1%	Not mentioned	NMT 0.02%
21	Reducing sugars	NMT 0.2%	NMT 0.3%	NMT 0.2%	Not mentioned
22	Related substances	Maximum individual impurity: NMT 2.0% Total Impurity: NMT 3.0%	Not mentioned	Maximum individual impurity: NMT 2.0% Total Impurity: NMT 3.0%	Not mentioned
23	Microbial contamination	TAMC - NMT 10^3CFU/g TYMC - NMT 10^2CFU/g Escherichia coli - Absent Salmonella - Absent	TAMC - NMT 10^3CFU/g TYMC - NMT 10^2CFU/g	TAMC - NMT 10^3CFU/g TYMC - NMT 10^2CFU/g Escherichia coli - Absent Salmonella - Absent	Not mentioned
24	Assay (Anhydrous basis)	Between 97.0% - 100.5%	Between 91.0% - 100.5%	Between 97.0% and 102.0%	NLT 97.0%
	Storage	Storage at room temperature	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 reprensentive.