



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	D(+)-Glucose 1-hydrate (USP, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	143140		Prepared by	Sr. Tech Lead
CAS NO.	77938-63-7		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/143140/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, Ph. Eur., BP</i>	USP 2022	EP Version 11.0	JP 18
1	Description	White small crystals	Colorless crystals or white, crystalline or granular powder. It is odorless, and has a sweet taste	white or almost white, crystalline powder	White, crystals or crystalline powder, and has a sweet taste.
2	Solubility	Soluble in water	Very soluble in boiling water; freely soluble in water; soluble in boiling alcohol; slightly soluble in alcohol.	Freely soluble in water, very slightly soluble in ethanol (96 per cent)	Freely soluble in water, sparingly soluble in methanol, and slightly soluble in ethanol
3	Identification 1	Specific optical rotation should be between + 52.5 and + 53.3	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Dextrose Anhydrous reference standard/working standard.	Specific optical rotation should be between + 52.5 and + 53.3	A red precipitate should be produced on boiling with fehlling solution
4	Identification 2	Passes the test	In the assay test,the principal peak from the Sample solution should be similar in retention time and size to the principal peak from Standard solution	In the assay test,the principal peak from the Sample solution should be similar in retention time and size to the principal peak from Standard solution	In the assay test,the principal peak from the Sample solution is similar in retention time and size to the principal peak from Standard solution
5	Identification 3	Passes the test	Not mentioned	By TLC: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 the reference solution	Not mentioned
6	Identification 4	Passes the test	Should comply with water test	Water content should be between 7.5% and 9.5%	Not mentioned
7	Identification 5	Passes the test	Not mentioned	No Red Colour should develop on addition of Resorcinol and hydrochloric acid and heating.	Not mentioned
8	Color and Clarity of Solution/Appearance of solution	Passes the test	The Sample solution should not be more colored than control solution	The solution should be clear and not more intensely coloured than reference solution BY7	Sample solution should be clear and not more intensely colored than reference solution BY7
9	Matter insoluble in water	NMT 0.01%			
10	Conductivity	NMT 20 µS/cm-1	Not mentioned	NMT 20 µS/cm-1	NMT 20 µS/cm-1
11	Dextrin	Passes the test	The sample should dissolve completely.	The substance should dissolve completely	Sample solution should be clear
12	Water	Between 7.5% and 9.5 %	Between 7.5% and 9.5%	Between 7.5% and 9.5%	Between 7.5% and 9.5%
13	Soluble Starch and sulfites	NMT 15 ppm	The liquid should be colored yellow	NMT 15 ppm	NMT 15 ppm
14	Related Substances	Maltose & Isomalt: NMT 0.4% Maltotriose: NMT 0.2% Fructose: NMT 0.15% Maximum unspecified impurity: NMT 0.1% Total impurities: NMT 0.5%	Maltose & Isomalt: NMT 0.4% Maltotriose: NMT 0.2% Fructose: NMT 0.15% Maximum unspecified impurity: NMT 0.1% Total impurities: NMT 0.5%	Maltose & Isomaltose: NMT 0.4% Maltotriose: NMT 0.2% Fructose: NMT 0.15% Maximum unspecified impurity: NMT 0.1% Total impurities: NMT 0.5%	Maltose & Isomalt: NMT 0.4% Maltotriose: NMT 0.2% Fructose: NMT 0.15% Maximum unspecified impurity: NMT 0.1% Total impurities: NMT 0.5%

15	Acidity	Not mentioned	NMT 0.3 ml of 0.02M NaOH is required	Not mentioned	Not mentioned
16	Chloride	Not mentioned	NMT 0.018%	Not mentioned	Not mentioned
17	Sulfate	Not mentioned	NMT 0.025%	Not mentioned	Not mentioned
18	Arsenic	Not mentioned	NMT 1 ppm	Not mentioned	Not mentioned
19	Heavy Metals	NMT 0.0005%	Not mentioned	Not mentioned	NMT 4 ppm
20	Calcium	NMT 0.02%	Not mentioned	Not mentioned	Not mentioned
21	Iron	NMT 0.0005%	Not mentioned	Not mentioned	Not mentioned
22	Residue on ignition	Not mentioned	NMT 0.1%	Not mentioned	Not mentioned
23	Assay (Anhydrous basis)	Between 97.5% and 102.0%	Between 97.5% and 102.0%	Between 97.5% and 102.0%	Between 97.5% and 102.0%
24	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 1 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				
25	Residual solvents	Passes the 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	Preserve in 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.