



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	D(+)-Glucose anhydrous (USP, BP, Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	141341		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	50-99-7		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/141341/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, BP, Ph. Eur	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.	Product Not Official in Japanese Pharmacopoeia
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 %)	
3	Identification 1	Specific optical rotation should be between + 52.6 to + 53.2	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 to + 53.3	
4	Identification 2	Passes The Test	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	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)	
5	Identification 3	Passes The Test	Water content should be NMT 1.0%	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	
6	Identification 4	Passes The Test	Not mentioned	No red colour should develop	
7	Identification 5	Passes The Test	Not mentioned	Should comply by water test	
8	Color an Clarity of Solution/Appearance of solution	Passes The Test	The Sample solution is clear (its clarity is the same as that of water or its opalescence is not more pronounced than that of the Reference suspension) and not more intensely colored than the Reference solution.	Sample solution should be clear and not more intensely coloured than reference solution BY7	
9	Conductivity	NMT 20 µS/cm-1	NMT 20 µS/cm-1	NMT 20 µS/cm-1	
10	Dextrin	Not mentioned	The sample should dissolve completely.	The sample should dissolve completely.	
11	Soluble Starch and sulfites	NMT 0.0015%	NMT 15 ppm	NMT 15 ppm	
12	Related Substance	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%	Sum of impurity A&B: NMT 0.4% Imputiry C: NMT 0.2% Impurity D: NMT 0.15% Maximum unkdown impurity: NMT 0.1% Total impurities: NMT 0.5%	
13	Acidity or alkalinity	Passes The Test	Not mentioned	Not mentioned	
14	Iron	NMT 0.0005%	Not mentioned	Not mentioned	
15	Matter insoluble in water	NMT 0.01%	Not mentioned	Not mentioned	
16	Barium	Passes The Test	Not mentioned	Not mentioned	
17	Calcium	NMT 0.02%	Not mentioned	Not mentioned	

18	Residue on ignition	NMT 0.1%	Not mentioned	Not mentioned
19	Water	NMT 0.5%	Not mentioned	NMT 1.0%
20	Assay (Anhydrous basis)	Between 97.5% and 102.0%	Between 97.5% and 102.0%	Between 97.5% and 102.0%
21	Elemental Impurities		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			
22	Residual solvents	Passes The Test	Not mentioned	Not mentioned
	Storage	Storage at room temperature	Preserve in well-closed containers.	NA

**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.