



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	D(-)-Mannitol (USP, BP, Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	142067		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	69-65-8		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/142067/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Small white crystals	White, crystalline powder or free-flowing granules. Is odorless and has a sweet taste.	white or almost white crystals or powder. It shows polymorphism	White, crystals, powder or grain. It has a sweet taste with a cold sensation. It shows crystal polymerisation.
2	Solubility	Soluble in water	Freely soluble in water; soluble in alkaline solutions; slightly soluble in pyridine; very slightly soluble in alcohol; practically insoluble in ether	freely soluble in water, practically insoluble in ethanol (96 %).	It is freely soluble in water, and practically insoluble in ethanol (99.5%). It dissolves in sodium hydroxide TS.
3	Identification 1	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Mannitol reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Mannitol reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Mannitol reference standard/working standard
4	Identification 2	Passes The Test	Not mentioned	Sample should comply with melting point test	Not mentioned
5	Identification 3	Specific optical rotation should be between +23 <sup>0</sup> to +25 <sup>0</sup> (on dried basis)	Not mentioned	Specific optical rotation should be between +23 <sup>0</sup> to +25 <sup>0</sup> (on dried basis)	Not mentioned
6	Identification 4	Passes The Test	Not mentioned	In 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)	Not mentioned
7	Clarity and color of solution/Appearance of solution	Passes The Test	The Sample solution is clear and colorless; its clarity is the same as that of water, or its opalescence is not more pronounced than that of the Reference suspension, and it is not more intensely colored than the Standard solution	Sample solution should be clear and colourless	Sample solution should be clear and colorless
8	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 5 ppm
9	Melting range	Between 165°C and 170°C	Between 165°C and 170°C	Between 165°C and 170°C	Between 165°C and 170°C
10	Nickel	NMT 0.0001%	NMT 1 ppm	Not mentioned	NMT 1 ppm
11	Conductivity at 25°C	NMT 20 µS/cm-1	NMT 20 µS/cm-1	NMT 20 µS/cm-1	NMT 20 µS/cm-1
12	Related substances	Sorbitol: NMT 2.0% Sum of Maltitol and Isomalt: NMT 2.0% Unknown impurity: NMT 0.1% Total impurity: NMT 2.0%	Sorbitol: NMT 2.0% Sum of Maltitol and Isomalt: NMT 2.0% Unknown impurity: NMT 0.1% Total impurity: NMT 2.0%	Impurity A- NMT 2.0% Sum of impurity B & C: NMT 2.0% Unknown impurity: NMT 0.1% Total impurities: NMT 2.0%	D-Sorbitol: NMT 2.0% Sum of Maltitol and Isomalt: NMT 2.0% Unknown impurity: NMT 0.1% Total impurities: NMT 2.0%
14	Alkalinity	NMT 0.006 meq/g	Not mentioned	Not mentioned	Not mentioned

15	Matter insoluble in water	NMT 0.01%	Not mentioned	Not mentioned	Not mentioned
16	Residue on ignition	NMT 0.1%	Not mentioned	Not mentioned	Not mentioned
17	Water	NMT 0.5%	Not mentioned	Not mentioned	Not mentioned
18	Reducing sugars	NMT 0.1%	NMT 0.1%	NMT 0.1%	NMT 0.1% as glucose
19	Loss on drying	NMT 0.2%	NMT 0.5%	NMT 0.5%	NMT 0.5%
20	Assay (dried basis)	Between 97.0% and 102.0%	Between 97.0% and 102.0%	Between 97.0% and 102.0%	Between 97.0% and 102.0%
21	Microbial limit	TAMC: NMT 10 <sup>3</sup> CFU/g TYMC: NMT 10 <sup>2</sup> CFU/g Ecoli : Should absent/g Salmonella: Should absent/g	TAMC: NMT 10 <sup>3</sup> CFU/g TYMC: NMT 10 <sup>2</sup> CFU/g Ecoli : Should absent	TAMC: NMT 10 <sup>3</sup> CFU/g TYMC: NMT 10 <sup>2</sup> CFU/g Ecoli : Should absent Salmonella: Should absent	Not mentioned
22	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 0.8 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				
23	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage below 25°C. Storage away from direct light.	Preserve in well-closed containers.	Not mentioned	Containers—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.