



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	D(+)-Lactose 1-hydrate (USP-NF, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141375		Prepared by	Sr. Tech Lead
CAS NO.	10039-26-6		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141375/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, BP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Small white crystals	White, free-flowing powder.	white or almost white, crystalline powder.	White, crystals, powder or granulated powder
2	Solubility	Freely soluble in water	Freely soluble in water; practically insoluble in alcohol.	Freely soluble in water, practically insoluble in ethanol (96 %)	Freely soluble in water, and practically insoluble in ethanol (99.5%)
3	Identification 1	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Lactose reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Lactose reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Lactose reference standard/working standard
4	Identification 2	Passes The 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 the reference solution	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
5	Identification 3	Passes The Test	Not mentioned	Sample solution should develop a red colour	Not mentioned
6	Identification 4	Passes The Test	Not mentioned	Sample to comply to the water test	Not mentioned
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution BY7	Not mentioned
8	Clarity and color of solution	Passes The Test	Absorbance : NMT 0.04	Not mentioned	The sample solution should be clear, and colorless or nearly colorless and has no more color than the control solution
9	Specific rotation (anhydrous basis)	Between +54.4° and +55.9°	Between +54.4° and +55.9°	Between +54.4° and +55.9°	Between +54.4° and +55.9°
10	Acidity or alkalinity	Passes The Test	The solution should be colorless, and NMT 0.4 mL of 0.1 M NaOH is required to produce a pink or red color.	The solution should be colorless, and NMT 0.4 mL of 0.1 M NaOH is required to produce a pink or red color.	The solution should be colorless, and NMT 0.4 mL of 0.1 M NaOH is required to produce a pink or red color.
11	Heavy metals	NMT 0.0005%	Not mentioned	Not mentioned	NMT 5 ppm
12	Matter insoluble in water	Passes The Test	Not mentioned	Not mentioned	Not mentioned
13	Chloride	NMT 0.01%	Not mentioned	Not mentioned	Not mentioned
14	Sulfated ash	NMT 0.02%	Not mentioned	Not mentioned	Not mentioned
15	Residue on ignition	NMT 0.1%	NMT 0.1%	Not mentioned	NMT 0.1%
16	Sulfated ash	NMT 0.30 at 230 nm, 0.10 at 250 nm, 0.03 at 270 nm, 0.02 at 290 nm and 0.01 at 310 nm.	Not mentioned	NMT 0.1%	Not mentioned
17	Protein and light absorbing impurities :	Absorbance: NMT 0.25 in range 210 and 220 nm, NMT 0.07 in the range 270 and 300 nm, NMT 0.04 nm at 400 nm	Absorbance: NMT 0.25 in range 210 and 220 nm, NMT 0.07 in the range 270 and 300 nm	Absorbance: NMT 0.25 in range 210 and 220 nm, NMT 0.07 in the range 270 and 300 nm, NMT 0.04 nm at 400 nm	Absorbance: NMT 0.25 in range 210 and 220 nm, NMT 0.07 in the range 270 and 300 nm
18	Loss on drying	NMT 0.5%	NMT 1.0%	Not mentioned	NMT 0.5%
19	Water	Between 4.5% and 5.5%	Between 4.5% and 5.5%	Between 4.5% and 5.5%	Between 4.5% and 5.5%
20	Microbial limits	TAMC: NMT 100 CFU/g TYMC: NMT 50 CFU/g E.Coli: Should be absent Salmonella: Should be absent	TAMC: NMT 10 ² CFU/g TYMC: NMT 5x10 ¹ CFU/g E.Coli: Should be absent	TAMC: NMT 10 ² CFU/g E.Coli: Absent	TAMC: NMT 10 ² CFU/g TYMC: NMT 5x10 ¹ CFU/g E.Coli: Should be absent Salmonella: Should be absent

21	Elemental Impurities				
	Cd	NMT 0.5 ppm			
	Pb	NMT 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 5 ppm			
	Au	NMT 10 ppm			
	Pd	NMT 10 ppm			
	Ir	NMT 10 ppm			
	Os	NMT 10 ppm	Not mentioned	Not mentioned	Not mentioned
	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	Not mentioned
	Storage	Storage at room temperature	Preserve in tight 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 representative.					
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