



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	D(+)-Galactose low endotoxin (Ph. Eur.) pure, pharma grade	 PanReac AppliChem ITW Reagents	Issue Date	March-23
Product Code	Z42173		Prepared by	Sr. Tech Lead
CAS NO.	59-23-4		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/Z42173/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Desriprion	Solid	A white, crystalline or finely granulated powder	white or almost white, crystalline or finely granulated powder	Product Not Official in Japanese pharmacopoeia
2	Solubility	Soluble in water	Soluble in water; very slightly soluble in alcohol	freely soluble or soluble in water, very slightly soluble in ethanol (96 %).	
3	Identification 1	passes test	The infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with Galactose RS/WS	The infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with Galactose RS/WS	
4	Identification 2	passes test	The retention time of the major peak of the Sample solution corresponds to the galactose peak of the Standard solution, as obtained in the Assay.	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 reference solution (a).	
5	Identification 3	passes test	An orange or red precipitate should be formed.	An orange or red precipitate should be formed.	
6	Appearance of solution	passes test	The Sample solution should not more intensely colored than the Control solution	Sample solution should be clear and not more intensely coloured than reference solution B8	
7	Acidic/alkaline react. subst.	passes test	NMT 1.5 mL of 0.01 N NaOH is required.	NMT 1.5 mL of 0.01 M NaOH is required to change the colour of the indicator to pink.	
8	Lead	Not Mentioned	NMT 0.5 ppm	Not mentioned	
9	Barium	Not Mentioned	Any opalescence in the Sample solution should not be more intense than that in the Standard solution	Not mentioned	
10	Water	NMT 1.0 %	NMT 1.0%	NMT 1.0 %	
11	Optical Rotation	NA	Between +78.0° and +81.5°	Not mentioned	
12	Protein	NMT 0.01%	Not mentioned	NMT 0.01%	
13	Related subst. (HPLC) (Ph.Eur)	Sum of impurity A & B: NMT 1.0% Maximum unknown impurity: NMT 0.3% Total impurities: NMT 2.0%	Lactose and 1,6-galactosylgalactose: NMT 0.6% Galacturonic acid: NMT 0.6% Dextrose: NMT 0.6% Tagatose: NMT 0.6% Dulcitol: NMT 0.6% Arabinose: NMT 0.6% Maximum unknown impurity: NMT 0.2% Total impurities: NMT 1.0%	Sum of impurity A & B: NMT 1.0% Maximum unknown impurity: NMT 0.3% Total impurities: NMT 2.0%	

14	Microbial Enumeration Tests & Tests For Specified Microorganisms	TAMC: NMT 100 CFU/g	TAMC: NMT 10 ³ CFU/g TYMC: NMT 10 ² CFU/g E.Coli- Should be absent Salmonella-Should be absent. S.Aureus: Should be absent Pseudomonas: Should be absent	TAMC: NMT 10 ² CFU/g
15	Sulfated ash	NMT 0.1 %		NMT 0.1 %
16	Residue on Ignition	NMT 0.1%	NMT 0.1%	
17	Assay (anhydr. subst.)	Between 97.0% and 102.0 %	Between 98.0% and 102.0%	Between 97.0 % and 102.0 %
18	Bacterial Endotoxin	NMT 10 IU/g	Not mentioned	Not mentioned
	Storage	Store at room temperature	Preserve in a tight container	Air 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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