



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Dextran 70 (Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	A8479		Prepared by	Sr. Tech Lead
CAS NO.	9004-54-0		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A8479/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	A white to off-white powder. Is hygroscopic.	white or almost white powder.	A white, amorphous powder. It is odorless and tasteless. It is hygroscopic
2	Solubility	Not mentioned	Very soluble in water; sparingly soluble in alcohol	very soluble in water, very slightly soluble in ethanol (96 per cent).	It is practically insoluble in ethanol (95) and in diethyl ether. It dissolves gradually in water.
3	Identification 1	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Dextran 70 reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Dextran 70 reference standard/working standard.	A blue-green color should be develop and turns gradually dark blue-green, on addition of dil.sulphuric acid or acetic acid colour does not change.
4	Identification 2	Passes The Test	Viscosity: The value of the intercept should be between 24 and 29 ml/g	Specific optical rotation should between + 195 and + 201 (dried substance).	Not mentioned
5	Identification 3	Passes The Test	Not mentioned	Should comply with Molecular-mass distribution Test	Not mentioned
6	pH	Not mentioned	Between 4.5 and 7.0	Not mentioned	Between 5.0 and 7.0
7	Viscosity	Not mentioned	Not mentioned	Not mentioned	Between 0.21 and 0.26.
8	Specific optical rotation	Not mentioned	Between +195° and +203°	Not mentioned	Not mentioned
9	Acidic/alkaline react. subst.	Passes The Test	Not mentioned	The solution should be red or orange	Not mentioned
10	Appearance of solution/Colour	Passes The Test	Absorbance at 375 nm shoule NMT 0.15	Solution sample should be clear and colourless	Sample solution should be clear and colorless
11	Nitrogen-containing subst. (as N)	NMT 0.0110 %	NMT 0.01%	NMT 0.0110 %	NMT 0.010%
12	Molecular mass (average)	64000 - 76000	Between 63,000 and 77,000.	Between 64000 and 76000	Not mentioned
13	Molecular mass (10 % high fraction)	NMT 185000	NMT 195,000	NMT 185000	NMT 0.35
14	Molecular mass (10 % low fraction)	NLT 15000	NLT 13,000	NLT 15000	NLT 0.1%
15	Number average molecular weight	Not mentioned	Between 34,000 and 48,000	Not mentioned	Not mentioned
16	Microbial contamination (TAMC)	NMT 100 CFU/g	Not mentioned	NMT 100 CFU/g	Not mentioned
17	Bacterial endotoxins	NMT 16 IU/g	NMT 0.5 USP EU/mL.	NMT 16 IU/g	Not mentioned
18	Antigenic Impurities	Not mentioned	The animals exhibit no evidence of anaphylactoid reactions, such as coughing, bristling of hair, or respiratory distress.	Not mentioned	The animals of first group exhibit no evidence of respiratory distress, collapse or death of the animals for 30 minutes after each intravenous injection and 24 hours later. All the animals of the second group exhibit symptoms of respiratory distress or collapse and not less than 3 animals are killed.:
19	Chloride	Not mentioned	Not mentioned	Not mentioned	NMT 0.018 %
20	Sulfate	Not mentioned	NMT 0.03%	Not mentioned	Not mentioned
21	Heavy Metals	Not mentioned	Not mentioned	Not mentioned	NMT 20 ppm
22	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 1.3 ppm
23	Reducing substances	Not mentioned	Not mentioned	Not mentioned	The titrant consumed for the sample solution should not be less than that for the control solution
24	Loss on drying	NMT 7.0 %	NMT 7.0 %	NMT 7.0 %	NMT 5.0%

25	Alcohol and related compounds	Not mentioned	Should comply the test		
26	Pyrogens	Not mentioned	Not mentioned	Not mentioned	Should comply the test
27	Residue on Ignition	Not mentioned	Not mentioned	Not mentioned	NMT 0.1 %
28	Sulfated ash	NMT 0.3 %	Not mentioned	NMT 0.3 %	Not mentioned
29	Assay	Not mentioned	Not mentioned	Not mentioned	Between 98.0% and 102.0%
30	Residual solvents (GC)	passes test	the total area of peaks from impurities in the Sample solution does not exceed the area of the n-propyl alcohol solution peak.	Ethanol NMT 0.5% Methanol NMT 0.05% Sum of solvents other than ethanol, methanol and propanol NMT 0.05%	Not mentioned
	Storage	Store at Room Temperature	Preserve in well-closed containers. Store at 25°; excursions are permitted between 15° and 30°	Not mentioned	Containers—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.