



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Diethylenetriaminepentaacetic Acid Calcium and Trisodium Salt x-hydrate (Ph. Eur.) low in endotoxins IPEC grade		Issue Date	March-23
Product Code	Z4C393		Prepared by	Sr. Tech Lead
CAS NO.	12111-24-9		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/Z4C393/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	White solid, hygroscopic	Product Not Official in USP pharmacopoeia	White or almost white, hygroscopic powder or crystals.	Product Not Official in Japanese pharmacopoeia
2	Solubility	Soluble in water		Freely soluble in water, practically insoluble in ethanol (96 per cent).	
3	Identification 1	Passes The Test		The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with pentetate sodium calcium reference/working standard	
4	Identification 2 (Calcium)	Passes The Test		1.The chloroform layer is coloured red. 2.A white, crystalline precipitate is formed	
5	Identification 3 (Sodium)	Passes The Test		1.A dense white precipitate is formed. 2. A voluminous, white, crystalline precipitate is formed.The precipitate dissolves completely in dil Ammonia solution and does not precipitate with ammonium carbonate solution .	
6	pH of 20% solution	Between 8.0 to 9.5		Between 8.0 to 9.5	
7	Appearance of solution	Passes the test		Sample solution should be clear and colourless	
8	Chloride	NMT 0.1%		NMT 0.1%	
9	Bacterial endotoxins	NMT 0.1 IU/mg		Not mentioned	
10	Methanol	NMT 0.3%		Not mentioned	
11	Impurity A - Nitritriacetic Acid (HPLC.)	NMT 0.1%		NMT 0.1 %	
12	Impurity B - Diethylenetriaminepentaacetic Acid	NMT 1.0%		NMT 1.0%	
13	Water	Between 9.0% and 15.0 %		NMT 15.0 %	
14	Barium	NMT 0.001%		Not mentioned	
15	Iron	NMT 0.002%		NMT 20 ppm	
16	Potassium	NMT 0.05%		Not mentioned	
17	Magnesium	NMT 0.05%		Not mentioned	
18	Nickel	NMT 0.0005%		Not mentioned	
19	Strontium	NMT 0.01%		Not mentioned	
20	Zinc	NMT 0.0005%		Not mentioned	
21	Assay	Between 98.0 % to 102.0 %		Between 98.0 % to 102.0 %	
22	Elemental Impurities			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			
	Storage	Storage away from direct light		In an airtight container, protected from light.	

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.