



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Calcium Chloride 2-hydrate powder (USP, BP, Ph. Eur.) pharma grade		Issue Date	March-23
Product Code	191232		Prepared by	Sr. Tech Lead
CAS NO.	10035-04-8		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/191232/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies (USP, BP, Ph. Eur.)</i>	USP 2022	EP Version 11.0	JP 18
1	Description	White crystalline powder.	White, hard, odorless fragments or granules. Is deliquescent.	White or almost white, crystalline powder, hygroscopic.	White, granules or masses. It is odorless. It is deliquescent.
2	Solubility	Freely soluble in water	Very soluble in boiling water; freely soluble in water, in alcohol, and in boiling alcohol.	Freely soluble in water, soluble in ethanol (96 %).	It is very soluble in water, and soluble in ethanol (95), and practically insoluble in diethyl ether.
3	Identification 1 (Calcium)	Passes The Test	Afetr ddition of ammonium oxalate TS, a white precipitate should be formed.	1.The chloroform layer should be coloured red.	1.Should impart a yellow-red color flame during flame test 2.Should produce a white precipitate after addition of ammonium carbonate TS. 3.Should yield a white precipitate with ammonium oxalate TS 4.Should not produce precipitate, when mixed and heated with 10 drops of potassium chromate TS
4	Identification 2 (Chloride)	Passes The Test	With silver nitrate TS,a curdy precipitate which is insoluble in HNO3 but is soluble in a slight excess of 6 N NH4OH should be produced	1.A curdled, white precipitate should be formed which dissolves in aqueous ammonia solution	1.The gas evolved should turn moistened potassium iodide starch paper blue. 2. Should produce a white precipitate with silver nitrate TS
5	Identification 3	Passes The Test	Not mentioned	should comply with assay test limits	
6	pH	Between 4.5 and 9.2	Between 4.5 and 9.2	Not mentioned	Between 4.5 and 9.2
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution Y6	Sample solution should be clear and colorless
8	Acidity or alkalinity	Passes The Test	Not mentioned	NMT 0.2 ml 0.01 M NaoH is required to produce pink color	
9	Sulfate	NMT 0.03 %	Not mentioned	NMT 300 ppm	NMT 0.024 %
10	Hypochlorite	Not mentioned	Not mentioned	Not mentioned	No blue color should be developed immediately.
11	Magnesium and alkali salts	NMT 0.5 %	NMT 1.0%	NMT 0.5 %	
12	Heavy Metals	Not mentioned	No	Not mentioned	NMT 10 ppm
13	Iron, Aluminium and Phosphate	Passes The Test	No turbidity or precipitate is produced.	Not mentioned	No turbidity or precipitate should be produced.
14	Barium	Not mentioned	Not mentioned	Not mentioned	No turbidity should be produced.
15	Aluminium	NMT 0.0001%	NMT 1 ppm	NMT 1 ppm	
16	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
17	Iron	NMT 0.001 %	Not mentioned	NMT 10 ppm	
18	Assay	Between 99.0 % and 103.0 %	Between 99.0% and 107.0%	Between 97.0 % and 103.0 %	Between 96.7 % and 103.3 %
19	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			
	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			
20	Residual solvents (Ph.Eur/USP)	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage away from direct light	Preserve in tight containers.	In an airtight container	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.					
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