" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**D-Pantothenic Acid Calcium Salt (Ph. Eur., USP) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	A7213		**Prepared by**	Sr. Tech Lead
	CAS NO.	137-08-6		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/A7213/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur.	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	Solid	Slightly hygroscopic, white powder. It is odorless and has a bitter taste.	White or almost white, slightly hygroscopic powder	A white powder, it shows crystal polymorphism.It is hygroscopic. pH of 5% solution should be between 7.0 and 9.0
2	Solubility	Not mentioned	Freely soluble in water; soluble in glycerin; practically insoluble in alcohol, in chloroform, and in ether.	Freely soluble in water, slightly soluble in ethanol (96 %) and practically insoluble in heptane	It is 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 Calcium pantothenate reference/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Calcium pantothenate reference/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Calcium Pantothenate reference/working standard
4	Identification 2	Passes The Test	Specific optical rotation shoul be between 25.0^0 and $+27.5^0$	Should comply by specific optical rotation test	Should comply by turing solution red -purple, which disappears upon the addition of 2 to 3 drops of NaOH TS.
5	Identification 3	Passes The Test	After addition of ammonium oxalate TS, a white precipitate should be formed which is insoluble in 6 N acetic acid but dissolves in hydrochloric acid.	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 the reference solution.	1. Should comply by a yellow-red flame development 2. After addition of ammonium carbonate TS, a white precipitate should be formed 3. Should comply by a white precipitate formation with ammonium oxalate TS
6	Identification 4	Passes The Test	Not mentioned	Should comply by turning methylene chloride layer red.	Not mentioned
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and colorless	Not mentioned
8	Optical Rotation	Between +25.5° - +27.5°	Not mentioned	Between 25.5^0 and 27.5^0	Between $+25.0^0$ and $+28.5^0$
9	pH	Between 6.8 - 8.0	Not mentioned	Between 6.8 and 8.0	Not mentioned
10	Calcium	Between 8.2% - 8.6 %	Between 8.2% and 8.6%	Not mentioned	Not mentioned
11	Alkalinity	Passes The Test	After addition of 1.0 ml 0.10 N HCL and phenolphthalein indicator, pink color should not be developed within 30 seconds	Not mentioned	Not mentioned
12	Chloride	NMT 0.02 %	Not mentioned	NMT 200 ppm	Not mentioned
13	Impurity A and other aminocarboxylic acid impurities	NMT 0.50 %	Not mentioned	NMT 0.5%	Not mentioned
14	Alkaloid	Not mentioned	Not mentioned		No white turbidity should be produced
15	Heavy metals	NMT 0.002 %	Not mentioned	Not mentioned	NMT 20 ppm

16	Related substances(HPLC)	Impurity B: max. 0.8 % Impurity C: max. 0.5 % Impurity E: max. 0.25 % Impurity H: max. 0.15 % Each unspecified impurity: max. 0.10 % Total impurities: max. 1.5 %	Not mentioned	Impurity B: NMT 0.8% Impurity C: NMT 0.3% Impurity E: NMT 0.25% Impurity H: NMT 0.15% Maximum unknown impurity: NMT 0.1% Total impurities: NMT 1.2%	Impurity at RRT 06: NMT 0.6% Impurity at RRT 0.8: NMT 0.5% Impurity at RRT 1.5: NMT 0.3% Any other impurity: NMT 0.15% Total impurities: NMT 1.2%
17	Loss on drying	NMT 3.0 %	NMT 5.0%	NMT 3.0%	NMT 5.0%
18	Assay (dried basis)	Between 98.0 - 102.0 % (titrimetric) Between 98.0% and 102.0% (By HPLC)	Between 98.0% and 102.0% (dried basis)	Between 98.0% and 101.0%	Between 98.0% and 102.0% (dried basis)
	Storage	Store at room temperature	Preserve in tight containers	In an airtight container.	Tight containers.

Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo reprensentive.

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.