" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**Kanamycin Sulfate (Ph. Eur., BP) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	A4789		**Prepared by**	Sr. Tech Lead
	CAS NO.	5965-95-7		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/A4789/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies (Ph. Eur., BP)	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	Solid	White, odorless, crystalline powder.	white or almost white, crystalline powder. Hygroscopic	A white powder.
2	Solubility	Passes The Test	Freely soluble in water; insoluble in acetone, in ethyl acetate,	freely soluble in water, practically insoluble in acetone and in ethanol (96 per cent).	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 Kanamycin Sulfate reference/working standard	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).	By TLC:the principal spot obtained from the sample solution and the spot from the standard solution show a purple-brown color and the same Rf value.
4	Identification 2 (Sulfate)	Passes The Test	A.With barium chloride TS, solutions of sulfates yield a white precipitate that is insoluble in hydrochloric acid and in nitric acid. B.With lead acetate TS, neutral solutions of sulfates yield a white precipitate that is soluble in ammonium acetate TS. C.Hydrochloric acid produces no precipitate when added to solutions of sulfates (distinction from thiosulfates).	1. After addition of barium chloride solution a white precipitate is formed. 2.On addition iodine, the suspension remains yellow (distinction , but is decolorised by adding stannous chloride solution . Boil the mixture. No coloured precipitate is formed	After addition of barium chloride TS: a white precipitate should be formed.
5	Identification 3	Passes The Test	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Should comply by blue-violet color development	Should comply by a blue purple color development
6	Identification 4	Passes The Test	Not mentioned	The crystals melt at about 235 °C, with decomposition.	Not mentioned
8	Crystallinity	Not mentioned	Meets the requirements	Not mentioned	Not mentioned
9	Optical Rotation	Between +112° and +123°	Not mentioned	Between +112° and +123°	Between $+112^0$ and $+123^0$
10	pH	Between 6.5 and 8.5	Between 6.5 and 8.5	Between 6.5 and 8.5	Between 6.0 and 7.5
11	Sulfate	Between 15.0 % - 17.0 %	Not mentioned	Between 15.0% and 17.0%	NLT 15.0%
12	Loss on drying	NMT 1.5 %	NMT 4.0%	NMT 1.5%	NMT 4.0%
13	Sulfated ash	NMT 0.5%	Not mentioned	NMT 0.5%	Not mentioned
14	Residue on Ignition	Not mentioned	NMT 1.0%	Not mentioned	NMT 0.5 %
15	Bacterial Endotoxins Test	Not mentioned	NMT 0.67 USP Endotoxin Unit/mg	Not mentioned	Not mentioned
16	Heavy Metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
17	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 1 ppm
18	Abnormal toxicity	Passes The Test	Not mentioned	Not mentioned	Not mentioned
19	Organic Impurities	Not mentioned	NMT 3.0%	Not mentioned	NMT 1.5%
20	Kanamycin B	NMT 4.0 %	Not mentioned	NMT 4.0 %	Not mentioned
21	Assay (dried basis)	NLT 750 I.U./mg	NLT 750 µg/mg	NLT 750 IU/mg	Between 750 and 832 µg/mg
	Storage	Store at Room Temperature	Preserve in tight containers.	Air tight containers	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 reprensentive.