" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**Chlorobutanol Hemihydrate Sifted USP 43/NF 38/Ph. Eur. 10.3**	athenstaedt Pharmaceuticals	**Issue Date**	July-23
	Product Code	ATHEN-002		**Prepared by**	Sr. Tech Lead
	CAS NO.	6001-64-5		**Reviewed by**	Manager Technical
	Manufacturer Name	**Athenstaedt GmbH & Co KG**		**Version no.**	CLYZO/ATH/ATHEN-002/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur, JP	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Descriprion	White or almost white, crystalline powder or colourless crystals	Colorless to white crystals, having a characteristic, somewhat camphoraceous, odor and taste. Melts at about 76°C.	White or almost white, crystalline powder or colourless crystals, sublimes readily.Melts at about 78°C.	Colorless or white crystals. It has a camphoraceous odor.Melting point: NLT 76^{0}C. It slowly volatilizes in air.
2	Solubility	Not mentioned	Freely soluble in alcohol, in ether, in chloroform, and in volatile oils; soluble in glycerin; slightly soluble in water.	Slightly soluble in water, very soluble in ethanol (96 per cent), soluble in glycerol (85 per cent).	It is very soluble in methanol, in ethanol (95) and in diethyl ether, and slightly soluble in water
3	Identification 1	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Chlorobutanol reference/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Chlorobutanol reference/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Chlorobutanol reference/working standard	Should comply by a yellow precipitate formatiomn and the odor of iodoform should be perceptible
4	Identification 2	In the assay test, the retention time of the chlorobutanol peak of the Sample solution corresponds to that of the Standard solution,	In the assay test, the retention time of the chlorobutanol peak of the Sample solution corresponds to that of the Standard solution,	Not mentioned	The disagreeable odor of phenyl isoc-yanide (poisonous) should be perceptible
5	Identification 3	Should comply with water test	Not mentioned	Should comply with water test	
6	Appearance of solution	Sample solution should not be more opalescent than reference suspension II and not more intensely coloured than reference solution BY5	Not mentioned	Sample solution should not be more opalescent than reference suspension II and not more intensely coloured than reference solution BY5	Not mentioned
7	Acidity/Reaction	As per USP: Water should be neutral to litmus As per EP: NMT 1.0 ml of 0.01 M NaOH is required to change the colour of the indicator to blue.	Water should be neutral to litmus	NMT 1.0 ml of 0.01 M NaOH is required to change the colour of the indicator to blue.	Sample solution should be neutral
8	Chloride	As per USP: NMT 700 ppm As per EP: NMT 100 ppm	NMT 0.07%	NMT 100 ppm	NMT 0.071%
9	Impurity A & B	Impurity A: NMT 60 ppm Imourity B: NMT 0.1%	Not mentioned	Impurity A: NMT 60 ppm Imourity B: NMT 0.1%	Not mentioned
10	Water	As per USP: NMT 6.0% As per EP: Between 4.5% and 5.5%	NMT 6.0%	Between 4.5% and 5.5%	NMT 6.0%
11	Residue on ignition	Not mentioned	Not mentioned	Not mentioned	NMT 0.1%
12	Sulfated ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
13	Assay (Anhydrous basis)	As per USP: Between 98.0% and 100.5% As per EP: Between 98.0% and 101.0%	Between 98.0% and 100.5%	Between 98.0% and 101.0%	NLT 98.0%
14	Bacterial Endotoxium	NMT 0.25 IU/g	Should comply the test	Not mentioned	Not mentioned
	Storage	Not mentioned	Preserve in tight containers, and store at room temperature.	Airtight 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.