



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Chlorobutanol Anhydrous USP 43/NF 38/Ph. Eur. 10.3	athenstaedt Pharmaceuticals	Issue Date	July-23
Product Code	ATHEN-001		Prepared by	Sr. Tech Lead
CAS NO.	57-15-8		Reviewed by	Manager Technical
Manufacturer Name	Athenstaedt GmbH & Co KG		Version no.	CLYZO/ATH/ATHEN-001/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, Ph. Eur, JP	USP 2022	EP Version 11.0	JP 18
1	Description	White or almost white, crystalline powder or colourless crystals, sublimes readily.	Colorless to white crystals, having a characteristic, somewhat camphoraceous, odor and taste. Melts at about 95°C.	White or almost white, crystalline powder or colourless crystals, sublimes readily. Melts at about 95°C.	Product Not Official in Japanese Pharmacopoeia
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).	
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	
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	
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	
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.	
8	Chloride	As per USP: NMT 700 ppm As per EP: NMT 300 ppm	NMT 0.07%	NMT 300 ppm	
9	Impurity A & B	Impurity A: NMT 60 ppm Impurity B: NMT 0.1%	Not mentioned	Impurity A: NMT 60 ppm Impurity B: NMT 0.1%	
10	Water	NMT 1.0%	NMT 1.0%	NMT 1.0%	
11	Residue on ignition	Not mentioned	Not mentioned	Not mentioned	
12	Sulfated ash	NMT 0.1%	Not mentioned	NMT 0.1%	
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%	
14	Bacterial Endotoxium	NMT 0.25 IU/g	Should comply the test	Not mentioned	
	Storage	Not mentioned	Preserve in tight containers, and store at room temperature.	Airtight containers	

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.