



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Sodium tetraborate decahydrate powder USP, Ph. Eur.		Issue Date	July-23
Product Code	140061		Prepared by	Sr. Tech Lead
CAS NO.	1303-96-4		Reviewed by	Manager Technical
Manufacturer Name	CG Chemikalein GmbH & Co KG		Version no.	CLYZO/CG/140061/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP-NF, BP, Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Description	White or almost white crystalline powder	Colorless, transparent crystals or white, crystalline powder.	White or almost white, crystalline powder, colourless crystals or crystalline masses, efflorescent.	colorless or white crystals or a white crystalline powder. It is odorless, and has a slightly characteristic, saline taste.
2	Solubility	Not mentioned	Freely soluble in boiling water and in glycerin; soluble in water; insoluble in alcohol.	Soluble in water, very soluble in boiling water, freely soluble in glycerol.	It is freely soluble in glycerin, soluble in water, and practically insoluble in ethanol (95), in ethanol (99.5) and in diethyl ether.
3	Identification 1 (Sodium)	Should comply the test	Should comply formation of a dense precipitate is formed.	1. A dense white precipitate should be formed. 2.Should comply by a voluminous, white, crystalline precipitate formation	(1) Should impart a yellow color flame during flame test. (2) Should produce a white, crystalline precipitate with potassium hexahydroxoantimonate (V) TS.
4	Identification 2 (Borate)	Should comply the test	An intense blue color should be produced	The colour should disappears.	(1) It should burn with a green flame. (2) Turmeric paper should exhibits a red color, which changes to blue with ammonia TS
5	Identification 3	Should comply the test	Not mentioned	The flame should impart a green border.	Not mentioned
6	pH	Between 9.0 and 9.6	Not mentioned	Between 9.0 and 9.6	Between 9.1 and 9.6
7	Ammonium	NMT 10 ppm	Not mentioned	NMT 10 ppm	Not mentioned
8	Appearance of solution	Sample solution should be clear and colorless.	Not mentioned	Sample solution should be clear and colorless.	Sample solution should be clear and colorless.
9	Sulfate	NMT 50 ppm	Not mentioned	NMT 50 ppm	Not mentioned
10	Carbonate and Hydrogen Carbonate	Should comply the test	No effervescence should be observed.	Not mentioned	The solution should not effervesce.
11	Heavy metals	NMT 20 ppm	Not mentioned	Not mentioned	NMT 20 ppm
12	Calcium	NMT 100 ppm	Not mentioned	NMT 100 ppm	Not mentioned
13	Arsenic	NMT 5 ppm	Not mentioned	Not mentioned	NMT 5 ppm
14	Assay	Between 99.0 % and 105.0 %	Between 99.0 % and 105.0 %	Between 99.0 % and 103.0 %	Between 99.0 % and 103.0 %
15	Microbial limit test Total aerobic microbial count Total yeast and molds count E.Coli Pseudomonas aeruginosa Staphylococcus aureus Salmonella	NMT 100 CFU/g NMT 50 cfu/g Absent/g Absent/g Absent/g Absent/25 g	Not mentioned	Not mentioned	Not mentioned
16	Bacterial Endotoxins	NMT 10 IU/g	Not mentioned	Not mentioned	Not mentioned
	Storage	Not mentioned	Preserve in tight containers.	Not mentioned	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.

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.