



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Caffeine anhydrous (BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	142833		Prepared by	Sr. Tech Lead
CAS NO.	58-08-2		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/142833/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies BP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	White crystals or crystalline powder	White powder or white, glistening needles, usually matted together. It is odorless and has a bitter taste. Its solutions are neutral to litmus.	White or almost white, crystalline powder or silky crystals. It sublimes easily	White, crystals or powder. It is odorless, and has a bitter taste. pH of 1% solution should be between 5.5 and 6.5.
2	Solubility	Sparingly soluble in water	Freely soluble in chloroform; sparingly soluble in water and in alcohol; slightly soluble in ether	Sparingly soluble in water, freely soluble in boiling water, slightly soluble in ethanol (96 per cent). It dissolves in concentrated solutions of alkali benzoates or salicylates.	It is freely soluble in chloroform, sparingly soluble in water, in acetic acid (100) and in acetic anhydride, and slightly soluble in ethanol (95) and in diethyl ether.
3	Identification 1	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Caffeine reference/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Caffeine reference/working standard	Should comply by a white precipitate formation
4	Identification 2	Passes The Test	In assay test, the retention time of the major peak of the Sample solution corresponds to that of the Standard solution,	Sample should melt between 234°C and 239°C	Should comply by turning solution red -purple, which disappears upon the addition of 2 to 3 drops of NaOH TS.
5	Identification 3	Passes The Test	Not mentioned	Should comply by a brown precipitate formation which dissolves by addition of dilute NaOH	Should comply by a yellow color development
6	Identification 4	Passes The Test	Not mentioned	Should comply by intense blue color development	Not mentioned
7	Identification 5	Passes The Test	Not mentioned	Should comply by loss on drying test	Not mentioned
8	Identification 6	Passes The Test	Not mentioned	Should comply by a yellowish-red residue formation which changes to violet red on addition of 0.1 ml of dilute ammonia.	Not mentioned
9	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and colorless	Not mentioned
10	Melting point	Between 234°C and 239°C	Not mentioned	Not mentioned	Between 235° and 238°C
11	Acidity	Passes The Test	Not mentioned	NMT 0.2 ml of 0.01 M NaOH is required to change the colour of the indicator to blue.	Not mentioned
12	Chloride	Not mentioned	Not mentioned	Not mentioned	NMT 0.011%
13	Sulfate	NMT 0.05%	Not mentioned	NMT 500 ppm	NMT 0.024%
14	Heavy metals	NMT 0.001%	Not mentioned	Not mentioned	NMT 10 ppm
15	Related substances	Maximum unknown impurity: NMT 0.1% Total impurities: NMT 0.1%	Maximum unknown impurity: NMT 0.1% Total impurities: NMT 0.1%	Maximum individual impurity: NMT 0.1% Total impurities: NMT 0.1%	NMT 0.1%
16	Readily carbonisable substances	Not mentioned	Not mentioned	Not mentioned	Sample solution should not be more intensely colored than matching Fluid D
17	Sulfated ash	NMT 0.5%	Not mentioned	NMT 0.1%	Not mentioned
18	Residue on ignition	NMT 0.1%	NMT 0.1%	Not mentioned	NMT 0.1%
19	Water	Not mentioned	NMT 0.5%	Not mentioned	Not mentioned
20	Matter insoluble in water	Passes The Test	Not mentioned	Not mentioned	Not mentioned
21	Arsenic	NMT 0.0003%	Not mentioned	Not mentioned	Not mentioned
22	Copper	NMT 0.001%	Not mentioned	Not mentioned	Not mentioned
23	Iron	NMT 0.002%	Not mentioned	Not mentioned	Not mentioned
24	Nickel	NMT 0.001%	Not mentioned	Not mentioned	Not mentioned
25	Lead	NMT 0.001%	Not mentioned	Not mentioned	Not mentioned

26	Loss on drying	NMT 0.5%	NMT 1.0%	NMT 0.5%	NMT 0.5%
27	Assay	Between 98.5% and 101.5% (dried basis)	Between 98.0% and 102.0% Anhydrous basis)	Between 98.5% and 101.5% (dried basis)	NLT 98.5% (dried basis)
28	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Store at room temperature	Preserve in well-closed containers.	Not mentioned	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.