



## Hebei Guangxiang Pharmaceutical Co., Ltd.

Add: The East of Jingliu Road, West of Cangzhou Lingang Economic and Technological Development Zone,  
Cangzhou City, Hebei Province, China.

Feb 2, 2021

### Specification of Caffeine Anhydrous

Inspection basis		EP, BP, USP, FCC, CP
Items		Specifications
Characters (FCC11)		White or almost white, crystalline powder or silky white or almost white, crystals.
Solubility		Insoluble in water, soluble in boiling water, slightly soluble in ethanol (96%); Soluble in basic benzoate or salicylate concentrate. Easy to sublimate
Identifications	Identifications A (USP)	The sample spectrum complies with that of the reference standard spectrum.
	Identifications B (USP)	The retention time of the caffeine peak of the sample solution corresponds to that of the standard solution
Appearance of solution (BP, EP)		Solution S is clear and colourless
Acidity (BP, EP)		Not more than 0.2ml of 0.01M sodium hydroxide is required to change the colour of the indicator to blue
Related Substances (BP, EP)		Any other impurity $\leq 0.5$ times the area of solution (a) (0.10%)
		Total impurities $\leq 0.5$ times the area of solution (a) (0.10%)
Melting Point (FCC)		235.0 – 237.5°C
Sulfates (BP, EP)		$\leq 500$ ppm
Water determination (USP)		$\leq 0.5\%$
Sulphated Ash (BP, EP)		$\leq 0.1\%$
Organic impurities (USP)		Individual impurity $\leq 0.1\%$
		Total impurities $\leq 0.1\%$
Assay (USP)		99.0% - 101.0%
Other alkaloids (FCC)		Compliance
Easy carbonization (FCC)		Compliance
Residual solvents (Chloroform, ppm)		$\leq 10$
Heavy metal (CP)		$\leq 10$ ppm
Lead (FCC)		1mg/kg
Microbial Limit		Total aerobic bacteria $\leq 800$ cfu/g
		Total mold and yeast $\leq 80$ cfu/g
		Escherichia coli cannot be detected
		Salmonella cannot be detected
		Coliforms: $< 10$ cfu/g

Mesh size : 95% through 40 Mesh

Storage: Keep in tightly closed container, stored in a natural temperature, ventilated area.