

CERTIFICATE OF ANALYSIS

Hebei Guangxiang Pharmaceutical Co., Ltd.

河北广祥制药有限公司检验报告单

BG-GX/ZB/04.008-02

Rev06/2024 P1 / 2

Name		Anhydrous Caffeine	Manufacture Date	2024.09.23
Batch No		2012409090	Expiry Date	2029.09.22
Package		20kg/Carton	Test Date	2024.09.24
Batch Size		20000 kg	Reporting time	2024.10.06
Inspection basis		EP 11.0, BP 2023, USP2023, FCC12, CP2020		
Items		Specifications		Results
Characters (FCC12)		White or almost white, crystalline powder or silky white or almost white, crystals.		Complies
Solubility (BP 2023、EP 11.0)		Sparingly soluble in water, freely soluble in boiling water, slightly soluble in ethanol (96%). It dissolves in concentrated solutions of alkali benzoates or salicylates. It sublimes readily.		Complies
Identifications	Identifications A (USP2023)	The sample spectrum complies with that of the reference standard spectrum.		Complies
	Identifications B (USP2023)	The retention time of the caffeine peak of the sample solution corresponds to that of the standard solution		Complies
Appearance of solution (BP 2023、EP 11.0)		Solution S is clear and colourless		Complies
Acidity (BP 2023、EP 11.0)		Not more than 0.2mL of 0.01M sodium hydroxide is required to change the colour of the indicator to blue		Complies
Related Substances (BP 2023、EP 11.0)		Any other impurity $\leq$ 0.5times the area of solution (a) (0.10%)		0.03%
		Total Impurities $\leq$ 0.5times the area of solution (a) (0.10%)		0.04%
Melting Point (FCC12)		235.0-237.5℃		Complies
Sulfates (BP 2023、EP 11.0)		$\leq$ 500ppm		Complies

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Rev06/2024 P2 / 2

Name	Anhydrous Caffeine	Manufacture Date	2024.09.23
Batch No	2012409090	Expiry Date	2029.09.22
Package	20kg/Carton	Test Date	2024.09.24
Batch Size	20000kg	Reporting time	2024.10.06
Inspection basis	EP 11.0, BP 2023, USP2023, FCC12, CP2020		
Items	Specifications	Results	
Water determination (USP2023)	≤0.5%	0.1%	
Sulphated Ash (BP 2023、EP 11.0)	≤0.1%	0.06%	
Organic impurities (USP2023)	Individual impurity≤0.1%	0.03%	
	Total Impurities≤0.1%	0.05%	
Assay (USP2023)	99.0%-101.0%	99.6%	
Other alkaloids (FCC)	Compliance	Complies	
Easy carbonization (FCC)	Compliance	Complies	
Heavy metal (CP)	≤10ppm	Complies	
Lead (FCC)	≤0.5ppm	Complies	
Arsenic	≤1.5ppm	Complies	
Mercury	≡ 0.1mg/kg	Complies	
Microbial Limit (CP)	Total aerobic bacteria ≤800cfu / g	Complies	
	Total mold and yeast ≤80cfu / g	Complies	
	Escherichia coli cannot be detected	Not detected	
	Coliforms:<10 cfu/g	Not detected	
	Staphylococcus Aureus Negative/25g	Complies	
	Total number of colonies<1000 cfu/g	Complies	
	Salmonella cannot be detected	Not detected	
Conclusion: The product complies with Caffeine test method EP 11.0, BP 2023, USP2023, FCC12, CP2020			