

# CERTIFICATE OF ANALYSIS

BG-GX/ZB/04.008-02

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Name 品名		Anhydrous Caffeine 无水咖啡因	Manufacture Date 生产日期	May 31, 2023
Batch No 批号		2012305079	Expiry Date 有效期	May 30, 2028
Package 包装		20kg /carton	Test Date 检验日期	June 1, 2023
Batch Size 批数量		18000kg	Reporting time 报告日期	November 11, 2023
Inspection basis 检验依据		EP 11.0, BP 2023, USP2021, FCC12, ChP2020 欧洲药典 11.0, 英国药典 2023, 美国药典 2021, 美国食品化学药品典 12, 中国药典 2020 年版		
Items 分析项目		Specifications 质量标准	Test Method 检验方法	Results 检验结果
Characters 性状		This product is white or nearly white, crystalline powder or filamentous crystals 本品为白色或近白色, 结晶性粉末或丝状晶体	FT	
Identifications 鉴别	Identifications A 鉴别 A	The sample spectrum complies with that of the reference standard spectrum 样品图谱应与对照品图谱一致	USP	
	Identifications B 鉴别 B	The retention time of the caffeine peak of the sample solution corresponds to that of the standard solution 供试品溶液中咖啡因色谱峰的保留时间应与对照品溶液中咖啡因色谱峰的保留时间一致	USP2021	Complies 符合规定
Appearance of solution 溶液外观		Solution S is clear and colourless 溶液 S 为澄清无色的	BP 2023 EP 11.0	Complies 符合规定
Acidity 酸度		Not more than 0.2mL of 0.01M sodium hydroxide is required to change the colour of the indicator to blue. 不超过 0.2ml 0.01M 的氢氧化钠使指示剂颜色变为蓝色。	BP 2023 EP 11.0	Complies 符合规定
Related Substances 有关物质		Any other impurity $\leq 0.5$ times the area of the principal peak in the chromatogram obtained with reference solution(a)(0.10%) 任一杂质峰面积 $\leq 0.5$ 倍对照溶液 (a) 主峰面积 (0.10%)	BP 2023 EP 11.0	0.02%
		Total Impurities $\leq 0.5$ times the area of the principal peak in the chromatogram obtained with reference solution(a)(0.10%) 总杂 $\leq 0.5$ 倍对照溶液 (a) 主峰面积 (0.10%)	BP 2023 EP 11.0	0.04%
Melting Point 熔点		235~238℃		Complies 符合规定
Sulfates 硫酸盐		$\leq 500$ ppm		Complies 符合规定

## CHECKED