

Certificate of Analysis

产品名称: 茶碱 Name of Product: THEOPHYLLINE ANHYDROUS	取样日期: 2023-08-11 Sampling Date:	报告日期: 2023-08-20 Report Date:
批号: 23214 Batch No.:	生产日期: 2023-08-04 Date of Manufacturing:	失效期: 2027-08 Expiry Date:
批量: 1010 kg Quantity:	检验记录号: 233455026 Record No.:	报告编号: 233455026 Report No.:
标准依据: 美国药典2023版 Reference Standard: USP2023		物料代码: 011-31 Product code:
项 目 Items	指 标 Specifications	检验结果 Results
外观 Appearance	白色, 无臭, 结晶粉末, 味苦 White, odorless, crystalline powder, having a bitter taste	白色, 无臭, 结晶粉末, 味苦 White, odorless, crystalline powder, having a bitter taste
鉴别: IR Identification: IR	应与对照品的红外光谱一致 Conforms to reference spectrum	与对照品的红外光谱一致 Conforms to reference spectrum
保留时间 Retention time	应与标准溶液主峰的保留时间一致 Conforms to the chromatogram of the Standard preparation	与标准溶液主峰的保留时间一致 Conforms to the chromatogram of the Standard preparation
干燥失重 (%) Loss on drying (%)	≤0.5	0.03
炽灼残渣 (%) Residue on ignition (%)	≤0.15	0.05
含量(HPLC, 以干品计) (%) Assay (HPLC, on dried basis)(%)	97.0-102.0	100.0
有机杂质: 总杂质 (%) Organic impurities: Total impurities(%)	≤0.5	忽略不计(<0.05) Disregard(<0.05)
其它未知单个杂质 (%) Any other individual unspecified impurity(%)	≤0.10	忽略不计(<0.05) Disregard(<0.05)
茶碱有关物质C (%) Theophylline related compound C(%)	≤0.10	未检出 Not detected
茶碱有关物质B (%) Theophylline related compound B(%)	≤0.10	未检出 Not detected
茶碱有关物质D (%) Theophylline related compound D(%)	≤0.10	未检出 Not detected
咖啡因 (%) Caffeine(%)	≤0.10	未检出 Not detected
结论: Conclusion:	本品按 美国药典2023版 检验, 上述项目符合规定 The product is tested in accordance with USP2023 . The above items meet the requirement.	
备注: Remark:	粒度: Particle size: Less than 75um (≥90%):98.7%	

QA放行人: 孙芳 放行日期: 2023.08.30 质检负责人: 翔刁印龙 复核者: 于田田 报告者: 于田田
Released by QA: 孙芳 Release Date: 2023.08.30 QC Manager: 翔刁印龙 Rechecked by: 于田田 Reported by: 于田田 2023.08.20