

产品名称: 茶碱 Name of Product: THEOPHYLLINE ANHYDROUS	取样日期: 2020-08-08 Sampling Date:	报告日期: 2020-08-15 Report Date:
批号: 20273 Batch No.:	生产日期: 2020-08-05 Date of Manufacturing:	失效期: 2024-08 Expiry Date:
批 量: 512 kg Quantity:	检验记录号: 203087031 Record No.:	报告编号: 203087031 Report No.:
标准依据: Reference Standard:	美国药典43版 USP43	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	0.04
炽灼残渣 (%) Residue on ignition (%)	≤ 0.15	0.02
含量(HPLC, 以干品计) (%) Assay (HPLC, on dried basis) (%)	97.0-102.0	99.3
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: 本品按美国药典43版检验, 上述项目符合规定
Conclusion: The product is tested in accordance with USP43. The above items meet the requirement.

QA放行人: 放行日期: 2020.8.20 质检负责人: 复核者: 报告者:

Released by QA: Release Date: 2020.8.20 QC Manager: Rechecked by: Reported by:

