

山东新华制药股份有限公司
Shandong Xinhua Pharmaceutical Co., Ltd.

East Chemical Zone of Zibo High & New Technology Development Zone, Zibo, Shandong, P. R. China

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Certificate of Analysis

KFY-068I

产品名称: 咖啡因 Name of Product: CAFFEINE ANHYDROUS	取样日期: 2021-09-01 Sampling Date:	报告日期: 2021-09-06 Report Date:
批号: 21081381 Batch No.:	生产日期: 2021-08-28 Date of Manufacturing:	失效期: 2025-08 Expiry Date:
批量: 7200 kg Quantity:	检验记录号: 213315630 Record No.:	报告编号: 213315630 Report No.:
标准依据: 英国药典2021版/欧洲药典10.0版/美国药典2021版 Reference Standard: BP2021/EP10.0/USP2021/R1-CEP2003-027-Rev03		物料代码: 010-01 Product code:
项 目 Items	指 标 Specifications	检验结果 Results
外观 Appearance 鉴别: 红外 Identification: IR 高效液相 HPLC 熔点(°C) Melting point (°C) 溶液外观 Appearance of solution 酸度(0.01mol/L NaOH, ml) Acidity(0.01mol/L NaOH, ml) 有机杂质: 单个杂质 (%) Organic impurities: individual impurity (%) 总杂质 (%) Total impurities (%) 硫酸盐 (ppm) Sulfate (ppm) 重金属 (以Pb计) (%) Heavy metals(on Pb basis)(%) 干燥失重 (%) Loss on drying (%) 炽灼残渣 (%) Residue on ignition (%) 硫酸盐灰份 (%) Sulphated ash (%) 含量(以干品计) (%) Assay (on dried basis)(%) 残留溶剂(氯仿, ppm) Residual solvents(Chloroform, ppm) HPLC含量(%, 干品计) Assay (%, on dried basis) (HPLC)	白色或几乎白色结晶性粉末或带丝光的白色或几乎白色结晶 White or almost white crystalline powder or silky white or almost white crystals 应与对照品的红外光谱一致 Conforms to reference spectrum 应与标准保留时间一致 Conforms to the chromatogram of the Standard preparation 234-239 应澄清、无色 Clear and colorless ≤0.2 ≤0.1 ≤0.1 ≤500 ≤0.001 ≤0.5 ≤0.1 ≤0.1 98.5-101.5 ≤60 98.5-101.0	白色结晶性粉末 White crystalline powder 与对照品的红外光谱一致 Conforms to reference spectrum 与标准保留时间一致 Conforms to the chromatogram of the Standard preparation 236.5 澄清、无色 Clear and colorless 符合规定 Conform 0.02 0.03 <500 ≤0.001 0.06 0.02 0.02 99.9 符合规定 Conform 100.0



结论: 本品按 英国药典2021版/欧洲药典10.0版/美国药典2021版 检验, 上述项目符合规定
Conclusion: The product is tested in accordance with BP2021/EP10.0/USP2021/R1-CEP2003-027-Rev03. The above items meet the requirement.

备注: 粒度/Particle size: Pass 40 mesh: 99.6% (≥95%)
Remark:

QA放行人: 放行日期: 2021.9.6 质检负责人: 复核者: 报告者: 田田
Released by QA: 田田 Release Date: 2021.9.6 QC Manager: 田田 Rechecked by: 田田 Reported by: 田田
2021.9.6