



Shandong Xinhua Pharmaceutical Co., Ltd.

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

Tel: 0533-2166666; Fax: 0533-2161991

Certificate of Analysis

CJ-0420

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产品名称: 茶碱 Name of Product: THEOPHYLLINE ANHYDROUS	取样日期: 2021-01-13 Sampling Date:	报告日期: 2021-01-19 Report Date:
批号: 21017 Batch No.:	生产日期: 2021-01-06 Date of Manufacturing:	复验期: 2026-01 Retest Date:
批量: 1010 kg Quantity:	检验记录号: 203096163 Record No.:	报告编号: 203096163 Report No.:
标准依据: 英国药典2021版/欧洲药典10.0版 Reference Standard: BP2021/EP10.0/R1-CEP1998-004-Rev07	物料代码: 011-30 Product code:	

项 目 Items	指 标 Specifications	检验结果 Results
性状 Characters	白色或几乎白色结晶性粉末 White/almost white crystalline powder	白色结晶性粉末 White crystalline powder
鉴别: 红外鉴别 Identification: IR	应符合规定 Conform	符合规定 Conform
干燥失重 (%) Loss on drying (%)	≤0.5	0.02
溶液外观 Appearance of solution	应澄清无色 Clear and Colourless	澄清, 无色 Clear and colourless
酸度 Acidity	应符合规定 Conform	符合规定 Conform
有关物质: 杂质A (%) Related Substances: Impurity A (%)	≤0.1	未检出 Not detected
杂质B (%) Impurity B (%)	≤0.1	忽略不计(<0.05) Disregard(<0.05)
杂质C (%) Impurity C (%)	≤0.1	未检出 Not detected
杂质D (%) Impurity D (%)	≤0.1	未检出 Not detected
其它单个杂质 (%) Other single impurity (%)	≤0.1	忽略不计(<0.05) Disregard(<0.05)
总杂质 (%) Total impurities (%)	≤0.5	忽略不计(<0.05) Disregard(<0.05)
重金属 (ppm) Heavy metals(ppm)	≤20	≤20
干燥失重 (%) Loss on drying (%)	≤0.5	0.02
硫酸盐灰份 (%) Sulphated ash (%)	≤0.1	0.01
含量 (% 干品计) Assay (% on dried basis)	99.0-101.0	99.7



结 论:

Conclusion:

本品按 英国药典2021版/欧洲药典10.0版 检验, 上述项目符合规定
The product is tested in accordance with BP2021/EP10.0/R1-CEP1998-004-Rev07. The above items meet the requirement.

QA放行人:

Released by QA:

放行日期:

Release Date:

质检负责人:

QC Manager:

复核者:

Rechecked by:

报告者:

Reported by:

2021.1.19