



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

METAPHARMACEUTICA

N DE LOTE:

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Page 1 of 1

CJ-042D

产品名称: Name of Product:	茶碱 THEOPHYLLINE ANHYDROUS	取样日期: Sampling Date:	2021-01-13	报告日期: Report Date:	2021-01-20
批号: Batch No.:	21018	生产日期: Date of Manufacturing:	2021-01-06	复验期: Retest Date:	2026-01
批量: Quantity:	1010 kg	检验记录号: Record No.:	203096164	报告编号: Report No.:	203096164
标准依据: Reference Standard:	英国药典2021版/欧洲药典10.0版 BP2021/EP10.0/R1-CEP1998-004-Rev07			物料代码: Product code:	011-30
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		0.07		
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		0.07		
硫酸盐灰份(%) Sulphated ash (%)	≤0.1		0.01		
含量(%, 干品计) Assay (% on dried basis)	99.0-101.0		100.0		

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:

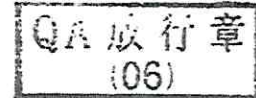
QC Manager:

复核者:

Rechecked by:

报告者:

Reported by:



2021.1.20