

产品名称: Name of Product:	茶碱 THEOPHYLLINE ANHYDROUS	取样日期: Sampling Date:	2023-01-16	报告日期: Report Date:	2023-01-23
批 号: Batch No.:	23019	生产日期: Date of Manufacturing:	2023-01-09	复验期: Retest Date:	2028-01
批 量: Quantity:	1010 kg	检验记录号: Record No.:	233510004	报告编号: Report No.:	233510004
标准依据: Reference Standard:	EP11.0/COS req. of EP11.0 and R1-CEP-1998-004-Rev 07			物料代码: Product code:	011-03
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 or 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		0.05		
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)		
杂质C (%) Impurity C (%)	≤0.1		Disregard(<0.05)		
杂质D (%) Impurity D (%)	≤0.1		忽略不计(<0.05)		
其它单个杂质 (%) Other single impurity (%)	≤0.1		未检出 Not detected		
总杂质 (%) Total impurities (%)	≤0.5		忽略不计(<0.05)		
重金属 (ppm) Heavy metals (ppm)	≤20		≤20		
干燥失重 (%) Loss on drying (%)	≤0.5		0.05		
硫酸盐灰份 (%) Sulphated ash (%)	≤0.1		0.01		
含量 (% 干品计) Assay (% on dried basis)	99.0-101.0		99.9		
粒度: 60目筛上物 (%) Particle size: On 60 mesh (%)	实测值 real result		89.0		
80目筛上物 (%) on 80 mesh (%)	实测值 real result		5.0		
100目筛上物 (%) on 100 mesh (%)	实测值 real result		0.8		
120目筛上物 (%) on 120 mesh (%)	实测值 real result		2.7		
筛底 (%) On the pan (%)	实测值 real result		2.1		
QC 检验专用章 (3) QA 放行章 (06)					
结 论: Conclusion:	本品按 EP11.0/COS 检验, 上述项目符合规定 The product is tested in accordance with req. of EP11.0 and R1-CEP-1998-004-Rev 07. The above items meet the requirement.				

QA放行人: 孙芳 放行日期: 2023.01.29 质检负责人: 田田 复核者: 田田 报告者: 田田
Released by QA: 孙芳 Release Date: 2023.01.29 QC Manager: 田田 Rechecked by: 田田 Reported by: 田田

METAPHARMACEUTICAL

N DE LOTE:

0470725

29/07/2025