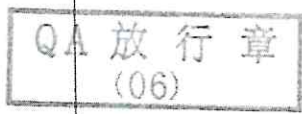


产品名称: Name of Product:	茶碱 THEOPHYLLINE ANHYDROUS	取样日期: Sampling Date:	2023-01-16	报告日期: Report Date:	2023-01-23
批号: Batch No.:	23019	生产日期: Date of Manufacturing:	2023-01-09	复验期: Retest Date:	2028-01
批 量: Quantity:	1010 kg	检验记录号: Record No.:	233510004	报告编号: Report No.:	233510004
标准依据: Reference Standard:	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	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 (%)	≤0.10			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			忽略不计 (<0.05)	
干燥失重 (%) Loss on drying (%)	≤0.5			0.05	
硫酸盐灰化 (%) 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	



结 论: 本品按 EP11.0/COS 检验, 上述项目符合规定
Conclusion: 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: 苏蕊 放行日期: 2023.01.29 质检负责人: 王田田
Released by QA: 苏蕊 Release Date: 2023.01.29 QC Manager: 王田田

复核者: 王田田 报告者: 王田田
Rechecked by: 王田田 Reported by: 王田田

DE LOT: N
METAPHARMACEUTICAL

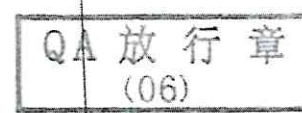
METAPHARMACEUTICAL

DE LOT: N
0070225
04/02/2025

Page 1 of 1

产品名称: 茶碱 Name of Product: THEOPHYLLINE ANHYDROUS	取样日期: 2023-01-16 Sampling Date:	报告日期: 2023-01-23 Report Date:
批 号: 23019 Batch No.:	生产日期: 2023-01-09 Date of Manufacturing:	复验期: 2028-01 Retest Date:
批 量: 1010 kg Quantity:	检验记录号: 233510004 Record No.:	报告编号: 233510004 Report No.:
标准依据: EP11.0/COS Reference Standard: req. of EP11.0 and R1-CEP-1998-004-Rev 07		物料代码: 011-03 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 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) Disregard (<0.05)
杂质C (%) Impurity C (%)	≤ 0.1	忽略不计 (<0.05) Disregard (<0.05)
杂质D (%) Impurity D (%)	≤ 0.1	未检出 Not detected
其它单个杂质 (%) Other single impurity (%)	≤ 0.10	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	0.05
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



结 论: 本品按 EP11.0/COS 检验, 上述项目符合规定
Conclusion: 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
Released by QA: 孙芳 Release Date: 2023.01.29 QC Manager: 田田
复核者: 田田 报告者: 田田
Rechecked by: 田田 Reported by: 田田