XY-KANG 湖南湘易康 制药有限公司
Hunan Xiangyikang Pharmaceutical Co.,Ltd
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湖南湘易康制药有限公司
检验报告书
Hunan XiangYiKang Pharmaceutical Co., Ltd.
Certificate of Analysis

COA No.: QCL200120200503-13

产品 Product	磺胺嘧啶 **Sulfadiazine**	包装规格 Packaging size	25Kg/桶 25Kg/ drum
批号 Batch No.	L200120200503	批量 Batch size	1000Kg
检验项目 Test	全检 All Items	实验日期 Date of Analysis	15/05/2020
样品来源 Samples origin	原料药车间 API workshop	报告日期 Report date	24/11/2020
取样量 Samples Quantity	300g	生产日期 Manufacturing date	12/05/2020
标准 Standard	EP&CEP	复检日期 Retest date	11/05/2023

检验项目 **Tests**	标准 **Specifications**	结果 **Results**
外观 Appearance	应为白色、黄白色或粉白色结晶粉末或晶体。 White, yellowish-white or pinkish-white, crystalline powder or crystals。	本品为白色结晶粉末。 White crystalline powder.
溶解性 Solubility	几乎不溶于水，微溶于丙酮，微溶于乙醇(96%)。它溶于碱金属氢氧化物和稀的无机酸溶液。.Practically insoluble in water, slightly soluble in acetone, very slightly soluble in ethanol (96 per cent). It dissolves in solutions of alkali hydroxides and in dilute mineralacids.	几乎不溶于水，微溶于丙酮，微溶于乙醇(96%)。它溶于氢氧化钠溶液(85g/L)和稀盐酸溶液。Practically insoluble in water, slightly soluble in acetone, very slightly soluble in ethanol (96 per cent).It is dissolved in 85g/L sodium hydroxide solution and dilute hydrochloric acid solution.
鉴别 Identification		
(1)红外鉴别 IR	红外光谱应与对照图谱一致 The IR spectrum is concordant with the reference spectrum of sulphadiazine	符合规定 Conforms
(2)薄层色谱 Thin-layer chromatography	样品的薄层色谱图应与对照品获得的色谱图一致。 The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.	符合规定 Conforms
(3)处理后熔点 Melting point after recrystallization	经处理后，熔点应为 123 ℃-127℃。 After recrystallisation from toluene R and drying at100℃, melts at 123℃ to 127 ℃.	124-127℃
(4) 化学鉴别 Chemical reaction	本品显芳香胺的第一类鉴别反应。 The differential response of primary aromatic amines.	符合规定 Conforms

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检验项目 Tests	标准 Specifications	结果 Results
测试 TEST		
溶液澄清度 Appearance of solution	溶液不会比黄色、黄蓝色、黄绿色 5 号比色液更深。 The solution is not more intensely coloured than reference solution Y5, BY5 or GY5.	溶液浅于黄色 5 号比色液。 Sample solution is not more intensely colored than reference solution Y5.
酸度 Acidity	不超过 0.2ml 的 0.1mol/L 的氢氧化钠滴定液可使溶液变色。 Not more than 0.2 ml of 0.1M sodium hydroxide is required to change the colour of the indicator.	0.08ml
有关物质 Related substances	Impurity A ≤0.3% Impurity B ≤0.3% Impurity E ≤ 0.2% Impurity F ≤0.15% Unspecified impurities ≤0.05% Total impurities ≤0.5%	Impurity A:<LOQ; Impurity B:0.008%; Impurity E:ND; Impurity F:0.08%; Unspecified impurities:0.03%; Total:0.12%.
炽灼残渣 Sulphated ash	不超过 0.1% NMT 0.1%	0.04%
干燥失重 Loss on drying	不超过 0.5% NMT 0.5%	0.2%
含量 Assay	以干燥品计，含 $C_{10}H_{10}N_4O_2S$ 应为 99. 0%-101. 0%。 99.0% to 101.0% of $C_{10}H_{10}N_4O_2S$, on dried basis.	100.1%
残留溶剂 Residual solvents	醋酸 Acetic acid ≤ 2,000 ppm Dimethylformamide (DMF) ≤800 ppm 肼 Hydrazine ≤ 0.50 ppm	醋酸 Acetic acid:368ppm; DMF:ND 肼 Hydrazine : 0.26 ppm.
结论：本品按上述检验，结果均符合 Ph.Eur .10.0/R0-CEP- 2018-131-Rev 01 的规定。 Conclusion ： The product conforms to Ph.Eur .10.0/R0-CEP- 2018-131-Rev 01.		

Prepared by: 报告人：

Reviewed by: 复核人：

Approved by: 批准人：

检验专用章