

北大国际医院集团西南合成制药股份有限公司

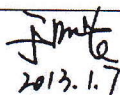
SOUTHWEST SYNTHETIC PHARMACEUTICAL CORP., LTD.

药品检验报告书

CERTIFICATE OF ANALYSIS

产 品 Product	磺 胺 嘧 啶 SULFADIAZINE	报告书编号 Certificate No.	77-024-1301062
批 号 Batch No.	PX ₁ -SD-1301062	报告书日期 Certificate Date	2013 年 01 月 07 日 Year Month Day
批 量 Batch Size	1000Kg	生 产 日 期 Mfg. Date	2013 年 01 月 05 日 Year Month Day
规 格 Package Size	25Kg/drum	有 效 期 Expiry Date	至 2017 年 01 月 04 日 Year Month Day
检 验 依 据 Specifications	EP7.5 及 COS	检 品 来 源 Sample From	二分厂 No.2 Branch Plant
检 验 项 目 ANALYSIS CONTENT	检 验 标 准 SPECIFICATIONS	检 验 结 果 ANALYSIS RESULTS	
性 状 Characteristics	白色、淡黄白色或带粉白色的结晶性粉末或结晶。 几乎不溶于水，微溶于丙酮，极微溶于乙醇（96%）。 溶于氢氧化碱溶液和稀无机酸。 White, yellowish-white or pinkish-white, crystalline powder or crystals. Practically insoluble in water, slightly soluble in acetone, very slightly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and in dilute mineral acids.	Yellowish-white crystalline powder. Practically insoluble in water, slightly soluble in acetone, very slightly soluble in ethanol (96%). It dissolves in sodium hydroxide solution and dilute hydrochloric acid.	
鉴 别 Identification	A:样品的红外吸收光谱应与磺胺嘧啶 CRS 的红外光谱一致 A: The infrared absorption spectrum of sample corresponds to that of Sulfadiazine CRS.	Meets.	
溶 液 色 Appearance of solution	≤Y ₅ , BY ₅ or GY ₅	<Y ₅	
酸 度 Acidity	≤0.2ml	0.09ml	
有 关 物 质 Related substances	杂质 A ≤0.3%, Impurity A ≤0.3%; 杂质 B ≤0.3%, Impurity B ≤0.3%; 杂质 E ≤0.2%, Impurity E ≤0.2%; 杂质 F ≤0.15%, Impurity F ≤0.15%; 单个未知杂质 ≤0.05%, Single unspecified impurity ≤0.05%. 杂质总量 ≤0.5%, Total impurities ≤0.5%	Impurity A: not detected; Impurity B: not detected; Impurity E: not detected; Impurity F: 0.07%; Max single unspecified impurity: 0.04%; Total impurities: 0.19%	
重 金 属 Heavy metals	≤20ppm	<20ppm	
干 燥 失 重 Loss on drying	≤0.5%	0.2%	
硫 酸 盐 灰 分 Sulphated ash	≤0.1%	0.06%	
醋 酸 钙 Calcium acetate	≤10ppm	<10ppm	
水 合 肼 Hydrazine hydrate	≤10ppm	<10ppm	
含 量 Assay	99.0%-101.0%(On the dried basis)	100.0%	
结 论 Conclusion	本品按 EP7.5 及 COS 检验，结果符合规定。 The product meets EP7.5 and COS specifications.		

质检负责人



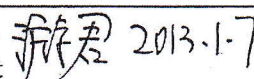
QC Manager

复核人

Supervisor

报告人

Analyst



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