

Lot: 0070115

北 大 医 药 股 份 有 限 公 司
SOUTHWEST SYNTHETIC PHARMACEUTICAL CORP., LTD.

检 验 报 告 书
质量检验章
CERTIFICATE OF ANALYSIS

产 品 Product	磺 胺 嘧 啶 SULFADIAZINE	报 告 书 编 号 Certificate No.	77-024-1406074
批 号 Batch No.	PX ₁ -SD-1406081	报 告 书 日 期 Certificate Date	2014 年 06 月 27 日 Year Month Day
批 量 Batch Size	1000Kg	生 产 日 期 Mfg. Date	2014 年 06 月 24 日 Year Month Day
规 格 Package Size	25Kg/drum	有 效 期 Expiry Date	至 2018 年 06 月 23 日 Year Month Day
检 验 依 据 Specifications	EP8.0 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于磺胺嘧啶 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	0.10ml	
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: 0.08%; Max single unspecified impurity: <0.03% Total impurities: 0.30%	
重金属 Heavy metals	≤20ppm	<20ppm	
干燥失重 Loss on drying	≤0.5%	0.1%	
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)	99.4%	
结 论 Conclusion	本品按 EP8.0 及 COS 检验，结果符合规定。 The product meets EP8.0 and COS specifications.		

质检负责人 *Junte* 2014.6.27 复核人 *2pk* 2014.6.27 报告人 *潘君* 2014.6.27
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