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阳光药业

常州市阳光药业有限公司

CHANGZHOU SUNLIGHT PHARMACEUTICAL CO., LTD

检验报告单

Certificate of Analysis

Product name: Benzocaine 产品名称: 苯佐卡因		Date of manufacture: 生产日期: Feb.24,2018 ✓		Date of Expiry: 有效期至: Feb.23,2021 ✓	
Package: 25kg/Fiber drum 包装: 25kg/纸板桶		Batch number: 批号: C0011803001 ✓		Quantity: 数量: 1000kg	
Testing specifications 检验标准		EP9	Series number of testing 检验单号		ZJC001180008EP
Items tested 检测项目		Specification 规格标准			Result 检测结果
Characters 性状		Appearance: White or almost white, crystalline powder or colorless crystals 外观: 白色或几乎白色结晶粉末, 或无色结晶			White crystals 白色结晶
		Solubility: Very slightly soluble in water, freely soluble in ethanol(96%). 溶解性: 极微溶于水, 易溶于乙醇 (96%)			Conforms 符合规定
		Infrared absorption spectrum therewith corresponding spectrum 红外光吸收图谱应与对照图谱一致			Conforms 符合规定
Loss on drying 干燥失重		≤0.5%			0.1%
Sulphated ash 硫酸盐灰份		≤0.1%			0.01%
Assay(dried substance) 含量 (以干燥品计)		99.0-101.0%			100.5%
Pd 钯		≤1ppm			Not detected 未检出
Granularity 粒度		Not less than 90% of particles pass 20 mesh 能通过 20 目筛的颗粒及粉末不得小于 90%			99%
		Not more than 90% of particles pass 40 mesh 能通过 40 目筛的颗粒及粉末不得大于 90%			46.2%
Related substances 有关物质		未知单个杂质 Any unspecified impurity ≤0.10% 总杂质 Total impurities ≤0.2%			0.0044% 0.004%
Total aerobic microbial count 需氧菌总数(CP)		Not more than 10 ³ cfu/g 不得超过 10 ³ cfu/g			<10 cfu/g
Total yeast and molds count 酵母菌和霉菌总数(CP)		Not more than 10 ² cfu/g 不得超过 10 ² cfu/g			<10 cfu/g
E.Coli 大肠埃希菌(CP)		Negative 不得检出			Not detected 未检出
Staphylococcus aureus 金黄色葡萄球菌(CP)		Negative 不得检出			Not detected 未检出
Pseudomonas aeruginosa 铜绿假单胞菌(CP)		Negative 不得检出			Not detected 未检出
Conclusion 结论		Qualified 合格			
Reporter/Date 报告人/日期	徐强 2018-04-19	QC Director/Date QC 主任/日期	刘军 2018-04-19	Qualified person/Date 质量受权人/日期	2018.04.19

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