



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: Jun.09,2017		Date of Expiry : 有效期至: Jun.08,2019	
Package: 25kg/Fiber drum 包装: 25kg/纸板桶		Batch number: 批号:C0011706007		Quantity: 数量: 75kg	
Testing specifications 检验标准		EP9	Series number of testing 检验单号		ZJC001170028EP
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%			0.02%
Assay(dried substance) 含量 (以干燥品计)		99.0-101.0%			99.6%
Pd 钯		≤1ppm			Not detected 未检出
Heavy metals 重金属		Not more than 0.001%不得超过 0.001%			Conforms 符合规定
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%			100%
		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%			53.7%
Related substances 有关物质		未知单个杂质 Any unspecified impurity≤0.10%			0.0026%
		总杂质 Total impurities≤0.2%			0.003%
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 yeasts 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
Live mites and mite eggs 活螨及螨卵(CP)		No live mite and mite eggs are detected. 不得检出活螨和螨卵			Not detected 未检出
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 报告人	吴芳	QC Director QC 主任	刘军	Qualified person 质量授权人	Date 日期 2017-07-07

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