



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: Mar.01.2015		Date of expiry: 有效期至: Feb.28.2017	
Package: 25kg/Fiber drum 包装: 25kg/纸板桶		Batch number: 批号: C5031504017		Quantity 数量: 300kg	
Testing method 检验方法		Refer to USP testing method 参照 USP 检测方法		Series number of testing 检验单号	
				C503150018	
Items tested 检测项目		Specification 规格标准		Result 检测结果	
Characters 性状		White crystals or crystalline powder 白色结晶或结晶性粉末		White crystals 白色结晶	
Identification 鉴定		<p>IR should comply with the reference standard spectrum. 红外光谱应与对照品图谱一致</p> <p>Absorptivities at 278 nm, calculated on the dried basis, do not differ by more than 3.0%. 紫外光谱在 278nm 处的吸收值与对照品差值应不得大于 3.0%</p> <p>An orange-red precipitate is performed. 重氮化-偶合反应生成橙红色沉淀</p>		<p>IR complies with the reference standard spectrum. 红外光谱与对照品图谱一致</p> <p>Absorptivities at 278 nm, calculated on the dried basis, do not differ by more than 3.0%. 紫外光谱在 278nm 处的吸收值与对照品差值不大于 3.0%</p> <p>An orange-red precipitate is performed. 重氮化-偶合反应生成橙红色沉淀</p>	
Melting point 熔点		88 -92°C		90.0-90.5°C	
Loss on drying 干燥失重		Not more than 0.5% 不得超过 0.5%		0.24%	
Readily carbonizable Substances 易碳化物质		The resolution has no more color than matching fluid A. 溶液颜色不深于对照液颜色		Conform 符合规定	
Residue on ignition 炽灼残渣		Not more than 0.1% 不得超过 0.1%		0.04%	
Heavy metals 重金属		Not more than 0.001% 不得超过 0.001%		Conform 符合规定	
Chloride 氯化物		Conform 符合规定		Conform 符合规定	
Assay (HPLC) 含量		98.0%-102.0%		100.16%	
Ordinary impurities 一般杂质		≤1%		Conform 符合规定	
Reaction 化学反应		Conform 符合规定		Conform 符合规定	
Conclusion 结论		Qualified 合格			
Analyst 化验员	鞠荷心	Check 复核	李磊	QA chief 质量负责人	丁松
				Date 日期	2016-01-30

