



检 验 报 告

CERTIFICATE OF ANALYSIS

产品名称 (Product Name) : Prilocaine hydrochloride 盐酸丙胺卡因 批号 (Batch NO.): 20160831 报告日期(Report Date) :20160831 执行标准 (Perform Standard): USP36		
分析项目 Item of Analysis	标准 Standard	分析结果 Result of Analysis
性状 Description	White crystalline powder, odorless, bitter taste 白色结晶性粉末,无臭, 有苦味	Complies 符合规定
	Freely soluble in water and in alcohol , slightly soluble in chloroform, very slightly soluble in acetone, not soluble in ether 在水和乙醇中易溶, 在氯仿中溶解, 在丙酮中极微溶, 在乙醚中不溶	Complies 符合规定
熔点 Melting Point	166~169°C	167.1~168.8°C
Single impurity 单一杂质	≤0.2%	0.01%
Total impurity 总杂质	≤0.5%	0.02%
Relative Substances A 有关物质 A	≤0.01%	0.0039%
Loss on drying 干燥失重	≤0.3%	0.04%
Residue on ignition 炽灼残渣	≤0.1%	0.08%
Heavy metals 重金属	≤0.002%	<0.002%
Residual solvents 溶剂残留	Should be to match with the standard 应符合规定	符合规定 Conforms
含量 Assay	99.0% ~101.0%	99.49%
结论: 符合 USP36 Conclusion: Conform USP36 审查者 (Exam)  化验者 (Analyst)  复核者 (Checker) 		