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CERTIFICATE OF ANALYSIS

产品名称 Name	盐酸丁卡因 Tetracaine Hcl		
批号 Batch No.	20130329	生产日期 Date of produce	2013-03-29
报告日期 Date test	2013-04-03	有效期至 Exp. Date	2015-03-28
检测项目 Items	质量标准 QUALITY STANDARDS		检验结果 RESULTS
性状 Description	应为白色结晶状粉末 A white,crystalline power		白色结晶状粉末 A white,crystalline power
Solubility	Matching with the working standard		符合规定 Complies
鉴别 Identification	A.By IR, To match with working standard		符合规定 Complies
	B: To 10ml of solution S add 1ml of ammonium thiocyanate solution R.A white,crystalline precipitate is formed which,after recrystallisation from water R and drying at 80°C for 2h,melts at about 131°C		符合规定 Complies
	C. To about 5mg add 0.5ml of fuming nitric acid R .Evaporate to dryness on a water-bath,allow to cool and dissolve the residue in 5ml of acetone R.Add 1ml of 0.1M alcoholic potassium hydroxide.A violet colour develops		符合规定 Complies
	D. Solution S gives reaction of chlorides.		符合规定 Complies
PH	4.5~6.5		5.39
澄清度 Clarity	溶液应澄清 Solution should be clear		符合规定 Complies
有关物质 Related Substances	ImpurityA 杂质 A≤0.05%		未检出 Not detected
	ImpurityB 杂质 B≤0.1%		0.011%
	ImpurityC 杂质 C≤0.1%		未检出 Not detected
	Single unknown impurity 未知单杂≤0.1%		0.07%
	Total impurities 总杂质≤0.5%		0.08%
重金属 Heavy metals	≤10ppm		<10ppm
干燥失重 Loss on drying	<1.0%		0.03%
硫酸灰分	≤0.1%		0.04%
熔点 Melting range	134°C~147°C		145.5°C~146.8°C
含量 Assay	99~101.0% On anhydrous basis.基于无水物.		99.39%
结论 Conclusion	本品依照 USP34 标准检测, 结果符合规定 The Sample Complies With Specification of USP34		

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