

Lot: C070114



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CERTIFICATE OF ANALYSIS  
化验报告单

产品名称 Name	盐酸丁卡因 Tetracaine Hcl	生产日期 Date of produce	2013/09/24
批号 Batch No.	13092401	报告日期 Date test	2013/10/30
批量 Quantity	185kg	有效期 Expiry date	2016/09/23
检验依据 Inspection basis	EP7		
检测项目 Items	质量标准 QUALITY STANDARDS	检测结果 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	
可溶性 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	5.90	
溶剂残留 Residual Solvents	应符合规定 Conform to standard	符合规定 Complies	
澄清度 Clarity	溶液应澄清 Solution should be clear	符合规定 Complies	
有关物质 Related Substances	应符合规定 Conform to standard	符合规定 Complies	
重金属 Heavy metals	≤10ppm	<10ppm	
干燥失重 Loss on drying	≤1.0%	0.06%	
灼烧残渣 Residue on ignition	≤0.1%	0.04%	
熔点 Melting range	148°C	147.5°C~149.0°C	
含量 Assay(*)	98~101.0%	100.34%	
结论 Conclusion	本品依照EP7标准检测, 结果符合规定 The Sample Complies With Specification of EP7		