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济南诚汇双达化工有限公司

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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	2014/10/26
批号 Batch No.	14102602	报告日期 Date test	2014/11/02
检验依据 Inspection basis	EP8	有效期 Date of Expire	2017/10/25
检测项目 Items	质量标准 QUALITY STANDARDS	检验结果 RESULTS	
性状 Description	应为白色或类白色结晶状粉末 White or almost white,crystalline power	类白色结晶状粉末 Almost white,crystalline power	
可溶性 Solubility	Matching with the working standard	符合规定 Complies	
鉴别 Identification	A.By UV, To match with working standard	符合规定 Complies	
	B: Dissolve 100 mg in 10 mL of water, and add 1 mL of potassium thiocyanate solution (1 in 4): a crystalline precipitate is formed. Recrystallize the precipitate from water, and dry at 80 for 2 hours: it melts between 130 and 132 .	符合规定 Complies	
	C. A solution of 100 mg in 5 mL of water meets the requirements of the tests for Chloride	符合规定 Complies	
	D Solution S gives Reaction of Chlorides	符合规定 Complies	
PH	4.5~6.5	5.56	
溶剂残留 Residual Solvents	应符合规定 Conform to standard	符合规定 Complies	
澄清度 Claruty	溶液应澄清 Solution should be clear	符合规定 Complies	
有关物质 Related Substance	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 Resiue on ignition	≤0.1%		
熔点 Melting range	148℃	147.4℃~149.4℃	
含量 Assay	99~101.0%	99.43%	
结论 Conclusion	本品依照 EP8 标准检测, 结果符合规定 The Sample Complies With Specification of EP8		

