



JINAN CHENGHUI-SHUANGDA Chemical Co., Ltd.
济南诚汇双达化工有限公司

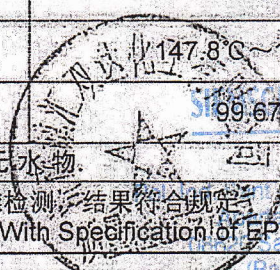
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CERTIFICATE OF ANALYSIS

化验报告单

Lot: 0061012

产品名称 Name	盐酸丁卡因 Tetracaine Hcl	生产日期 Date of produce	2012/08/27
批号 Batch No.	12082712	报告日期 Date test	2012/09/06
批量 Quantity	175kg	有效期 Expiry date	2015/08/26
检验依据 Inspection basis	EP7		
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	5.48	
色谱法纯度 Chromatographic purity	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	不得超过对照品溶液 0.05% Not more than the reference solution (0.05%)	符合规定 Complies	
重金属 Heavy metals	≤10ppm	<10ppm	
干燥失重 Loss on drying	<1.0%	0.05%	
灼烧残渣 Residue on ignition	≤0.1%	0.04%	
熔点 Melting range	148°C	147.8°C~149.4°C	
含量 Assay(*)	98~101.0%	99.67%	
(*) On anhydrous basis. 基于无水物.			
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		



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