

CERTIFICATE OF ANALYSIS

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产品名称: 盐酸罗哌卡因 Product Name: Ropivacaine hydrochloride		
代码: RC Code:	生产日期: 2018.06.16 Manuf.Date:	
生产批号: 180601RC Batch NO.:	报告日期: 2018.06.23 Report Date:	
报告单号: A180680 COA NO.:	有效期至: 2020.06.15 Valid to:	
检验标准: 企业标准 Specification: In-house		
检验结果 Analytical Results		
项目 Item	检验标准 Acceptance criteria	结果 Result
性状 Character	白色结晶性粉末 White crystalline powder	白色结晶性粉末 White crystalline powder
溶解性 Solubility	溶于水 Soluble in water	符合规定 Conforms
鉴别 Identification	本品的红外光吸收图谱应与对照图谱一致 IR Spectrum Sample should concordant with spectrum of standard 显氯化物的鉴别反应 It gives a reaction of chloride	与对照图谱一致 concordant with spectrum of standard 呈正反应 Forward reaction
溶液澄清度 Solution clarity	溶液澄清 The solution is clear	溶液澄清 The solution is clear
水分 Water	5.0%~6.0%	5.2%
pH	4.5~6.0	4.8
重金属 Heavy Metals	≤10ppm	<10ppm
杂质 A Impurity A	≤10ppm	0.6ppm
杂质 B Impurity B	≤0.5%	未检出 N.D
有关物质 Related substances	布比卡因(Bupivacaine)≤0.2% 任意单杂(Unspecified impurity)≤0.1% 总杂(Total impurities)≤0.5%	未检出 N.D 0.06% 0.08%
残留溶剂 Related substances	丙酮 (Acetone) ≤0.5% 1-溴丙烷(1-bromopropane)≤0.5% 甲基异丁基酮(Methyl isobutyl ketone)≤0.5%	0.009% 未检出 N.D 0.0004%
含量 Assay	98.5%~101.0% (以无水物计) (Calculated on the anhydrous substance)	99.6%
结论: 合格 Conclusion:		