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南京白敬宇制药有限责任公司

NANJING BAIJINGYU PHARMACEUTICAL CO., LTD.

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Add. NO. 29 FANGSHUIDONGLU, NANJING CHEMICAL INDUSTRIAL PARK

成品检验报告单

CERTIFICATE OF ANALYSIS

Code No.: RD-JB-Y332-02

品 名 Product name	氯 霉 素 Chloramphenicol			检验号 Identification No.	1A150082W
产品批号 Batch No.	CH15082	生产日期 Mfg. date	2015-02-13	报告日期 Report date	2015-2-25
批 量 Batch size	500kg	包装规格 Package size	25kg/drum	复验期 Retest date	2019-1
项 目 Parameter	EP8.0/BP2013 标准 Specification of EP8.0/BP2013			检验结果 Results	
性状 Appearance	白色或微灰白色。黄白色结晶性粉末或针状结晶。 A white, greyish-white or yellowish-white, fine, crystalline powder or fine crystals, needles or elongated plates.			微黄白色结晶性粉末 A yellowish-white, fine crystalline powder, needles.	
	微溶于水，易溶于乙醇和丙二醇。本品溶于乙醇中的溶液为右旋，溶于醋酸乙酯中的溶液为左旋。Slightly soluble in water, freely soluble in alcohol and in propylene glycol. Its alcohol solution is dextrorotatory and its ethyl acetate solution is levorotatory.			符合规定 Qualified	
鉴别 Identification					
熔程 Melting range	Between 149℃ and 153℃			149.0~150.4℃	
红外 Infrared absorption spectrophotometry	红外图谱应与标准品图谱一致 spectrophotometry similar to which of chloramphenicol CRS			符合规定 Qualified	
酸碱度 Acidity or alkalinity	取本品0.1g，加20ml无二氧化碳的水，振摇，加0.1ml溴百里酚蓝溶液。指示剂变色时消耗不超过0.1ml 的0.02M盐酸或0.02M氢氧化钠。 To 0.1 g add 20 ml of carbon dioxide-free water R, shake and add 0.1 ml of bromothymol blue solution RI. Not more than 0.1 ml of 0.02 M hydrochloric acid or 0.02 M sodium hydroxide is required to change the colour of the indicator.			符合规定 Qualified	
比旋度 Specific optical rotation	Between +18.5° and +20.5°			+18.95°	
有关物质 Related substances	单一杂质质量≤ 0.5% Individual impurity ≤ 0.5%			<0.5%	
氯化物 Chlorides	≤0.01%			<0.01%	
干燥失重 Loss on drying	≤0.3%			0.15%	
硫酸盐灰分 Sulfated ash	≤0.1%			0.05%	
含量 Assay	98.0% to 102.0%			99.00%	
微生物限度 Microbial limit	细菌数 Bacteria	≤10CFU/g		<10CFU/g	
	霉菌和酵母菌数 Mold & yeast	不得检出/g Absent per g		未检出 Absent	
	大肠埃希菌 Escherichia coli	不得检出/g Absent per g		未检出 Absent	
	铜绿假单胞菌和金黄色葡萄球菌 Pseudomonas aeruginosa & staphylococcus aureus	不得检出/g Absent per g		未检出 Absent	
结论 Conclusion:	本品符合EP8.0/BP2013 标准 The product complies toEP8.0/BP2013.				
包装和贮存 Packaging and storage	遮光保存。 Preserve in well-closed containers, protected from light				

批准人

复核人

制作人

QA Approval: 杨俾英

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