

1002 ACOFARMA: 151412

宁夏启元药业有限公司检验报告书
NINGXIA QIYUAN PHARMACEUTICAL CO., LTD
NO.1 QIYUAN STR., WANGYUAN INDUSTRIAL AREA, YINCHUAN NINGXIA CHINA
CERTIFICATE OF ANALYSIS

品名: 盐酸四环素		批 号: 140618-63	
Name of product: Tetracycline Hydrochloride		Batch No.:	
数量: 1000 Kg	包装: 25kg/DRUM	报告日期: 2014-6-23	
Quantity :	Packing:	Report Date:	
生产日期: 2014-6-18	检验编号: 0364	有效期: 2018-6-17	
Mfg. Date:	Analysis No.:	Expiry Date:	
检验项目: Test Items:	BP2012 质量标准 Specification	EP8 质量标准 Specification	检验结果 Results
性状: Characters:	黄色结晶性粉末 Yellow,crystalline 在水中溶解,在乙醇 (96)中微溶,在丙 酮中几乎不溶 Soluble in water,slightly soluble in ethanol(96 percent),practically insoluble in acetone	黄色结晶性粉末 Yellow,crystalline 在水中溶解,在乙醇 (96)中微溶,在丙 酮中几乎不溶 Soluble in water,slightly soluble in ethanol(96 percent),practically	黄色结晶性粉末 Yellow,crystalline powder 符合规定 Positive reaction
鉴别 Identification:	Positive reaction	Positive reaction	Positive reaction
酸度 Acidity(pH):	1.8 - 2.8	1.8 - 2.8	2.36
比旋度 Specific optical rotation:	-240°~ -255°	-240°~ -255°	-247°
干燥失重 Loss on drying:	≤ 2.0%	≤ 2.0%	0.30%
重金属 Heavy metals : 硫酸灰分 Sulphated ash:	≤50ppm ≤0.5%	≤50ppm ≤0.5%	<40ppm 0.02%
4-差向四环素 4-Epitetracycline:	≤3.0%	≤3.0%	1.60%
4-差向脱水四环素	≤ 0.5%	≤ 0.5%	0.01%
4-Epianhydrotetracycline :			
脱水四环素 Anhydrotetracycline :	≤ 0.5%	≤ 0.5%	0.10%
2-乙酰基-2-去氨基甲基四环素:			
2-Acetyl-2-decarbamoyletetracycline:	≤ 1.5%	≤ 1.5%	0.49%
含量测定 Assay:	95.0~102.0%	95.0~102.0%	97.8%
残留溶剂 Residual solvents:			
丙酮 Acetone (G.C.)	≤ 100ppm		<0.62 ppm
正丁醇 N-butanol(G.C.)	≤ 3000ppm		2350ppm
微生物检查 Microbiological examination:			
细菌总数 TAMC:	≤1000 cfu/g		Corresponds
霉菌、酵母菌总数 TYMC:	≤100 cfu/g		Corresponds
大肠埃希菌总数 E.coli:	Absence		Corresponds

结论: 本品符合EP/BP质量标准规定

Conclusion: The product conforms to standard of EP8 /BP

负责人: 郑海萍

复核员: 张

化验员: 王

THE BATCH HAS BEEN MANUFACTURED IN FULL COMPLIANCE WITH GMP NUMBER: NX20130004, ISSUE DATE: APRIL 7, 2013, VALIDITY DATE: APRIL 6, 2018 AND BATCH PRODUCTION RECORD CHECKED AND APPROVED, NO DEVIATION, NO REWORKING AND REPROCESSING.