

The batch has been produced, controlled and stored according to the GMP requirements (ICH Q7) and the documentation (DMF/CEP). CEP NO R1-CEP 2001-349-Rev 01

宁夏启元药业有限公司
NINGXIA QIYUAN PHARMACEUTICAL CO., LTD.

Add: No. 1 QiYuan Str. WangYuan Industrial Area,
YinChuan NingXia China
Postcode: 750101 E-mail: ic@china-qiyuan.com
Tel: 86-951-4066938 Fax: 86-951-4066968

检验报告书

CERTIFICATE OF ANALYSIS

品名: 盐酸四环素 Name of product: Tetracycline hydrochloride	批号: 141021-65 Batch No.:	
数量: 1500 Kg Quantity:	包装: 25kg/CARTON Packing:	
生产日期: 2014-10-21 Mfg Date:	检验编号: 0709 Analysis No.:	
标准依据: 依据欧洲药典8版检验 Specification: Base on EP8	报告日期: 2014-10-27 Report Date:	
	复检期: 2016-10-20 Retest Date:	
	有效期: 2018-10-20 Expiry Date:	
检验项目 Test Items	质量标准 Specification	检验结果 Results
性状: Characters.	黄色结晶性粉末 Yellow, crystalline powder 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 per cent), practically insoluble in acetone	黄色结晶性粉末 Yellow, crystalline powder 符合规定 Positive reaction
鉴别 Identification:	A: TLC Identification B: To about 2mg add 5ml of sulphuric acid, add the solution to 2.5 ml of water C: Reaction of chlorides	Positive reaction (pass) Positive reaction (pass) Positive reaction (pass)
酸度 Acidity(pH):	1.8~2.8	2.45
比旋度 Specific optical rotation:	-240° ~ -255°	-246°
干燥失重 Loss on drying:	≤2.0%	0.28%
重金属 Heavy metals:	≤50ppm	<40ppm
硫酸盐分 Sulphated ash:	≤0.5%	0.03%
4-差向四环素 4-Epitetracycline	≤3.0%	1.61%
4-差向脱水四环素 4-Epitetrahydrotetracycline:	≤0.5%	0.01%
脱水四环素 Anhydrotetracycline:	≤0.5%	0.10%
1-乙酰基-7-去氧甲基四环素 2-Acetyl-2-decarbamoyltetracycline	≤1.5%	0.25%
金霉素 Chlorotetracycline hydrochloride:	≤0.5%	0.07%
其他未知杂质 Any other impurity:	≤0.05%	0.04%
含量测定 Assay:	95.0%~102.0%	97.4%
残留溶剂 Residual solvents:		
丙酮 Acetone(G.C.)	≤100ppm	<0.62ppm
正丁醇 N-butanol(G.C.)	≤3000ppm	2505 ppm
微生物检查 Microbiological examination:		
细菌总数: TAMC:	≤1000cfu/g	Corresponds
霉菌、酵母菌总数: TYMC:	≤100cfu/g	Corresponds
大肠埃希菌: E. coli:	Absence	Corresponds

结论: 本品符合欧洲药典8版
Conclusion: The product conforms to standard of EP8

负责人:
Person in charge:

复核员:
Check:

化验员:
Analyst:

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

ISE 21 B57

Director Técnico