

The batch has been manufactured in full compliance with GMP number HAG/030210/3GMP-NXA and Batch production record checked and approved, no deviation, no reworking and reprocessing. GMP Number: HAG/030210/3GMP-NXA Issue date: 2010-02-03 Valid for three years



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检验报告书

Lot: 0260713

CERTIFICATE OF ANALYSIS

品名: 盐酸四环素 Name of product: Tetracycline hydrochloride	批号: 120628-63 Batch No.:	
数量: 25kg × 80 CARTON (2000kgs) Quantity:	报告日期: 2012年7月4日 Report Date:	
生产日期: 2012年6月28日 Mfg. Date:	复检期: 2014年6月27日 Retest Date:	
检验编号: 0391 Analysis No.:	有效期: 2016年6月27日 Expiry Date:	
标准依据: 依据欧洲药典7版检验 Specification: Base on EP7		
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	黄色结晶性粉末 Yellow, crystalline powder
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	2.35
比旋度 Specific optical rotation:	-240° ~ -255°	-248°
干燥失重 Loss on drying:	≤ 2.0%	0.10%
重金属 Heavy metals:	≤ 50ppm	< 40ppm
硫酸灰分 Sulphated ash:	≤ 0.5%	0.06%
4-差向四环素 4-Epitetracycline:	≤ 3.0%	1.46%
4-差向脱水四环素 4-Epianhydrotetracycline:	≤ 0.5%	0.03%
脱水四环素 Anhydrotetracycline:	≤ 0.5%	0.28%
2-乙酰基-2-去氨基甲基四环素 2-Acetyl-2-decarbamoyltetracycline:	≤ 1.5%	0.55%
金霉素 Chlortetracycline hydrochloride:	≤ 0.5%	0.14%
其他未知杂质 Any other impurity:	≤ 0.05%	0.03%
含量测定 Assay:	95.0% ~ 102.0%	98.0%
残留溶剂 Residual solvents:		
丙酮 Acetone (G.C.):	≤ 100ppm	< 100ppm
正丁醇 N-butanol (G.C.):	≤ 3000ppm	2275 ppm
微生物检查 Microbiological examination:		
细菌总数 TAMC:	≤ 1000cfu/g	< 1 cfu/g
霉菌、酵母菌总数 TYMC:	≤ 100cfu/g	< 1 cfu/g
大肠埃希菌 E. coli:	Absence	Absence

结论: 本品符合欧洲药典7版

Conclusion: The product conforms to standard of EP7

负责人: 郑朝辉
Person in charge:

复核员: 王明
Check:

化验员: 王明
Analyst: