

NOTE ACOFARMA, 170171



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检验报告书

CERTIFICATE OF ANALYSIS

品名:	盐酸四环素	批号:	151018-61
Name of product:	Tetracycline hydrochloride	Batch No.:	
数量:	2000 Kg	包装:	25kg/DRUM
Quantity:		Packing:	
生产日期:	2015-10-18	检验编号:	0610
Mfg.Date:		Analysis No.:	
报告日期:	2015-10-24	有效期:	2019-10-11
Report Date:		Expiry Date:	
检验项目	BP 质量标准	EP 质量标准	检验结果
Test Items	Specification	Specification	Results
性状:	黄色结晶性粉末	黄色结晶性粉末	黄色结晶性粉末
Characters:	Yellow crystalline powder	Yellow crystalline powder	Yellow crystalline powder
	在水中溶解, 在乙醇 (96%) 中微溶, 在丙酮中几乎不溶	在水中溶解, 在乙醇 (96%) 中微溶, 在丙酮中几乎不溶	符合规定
	Soluble in water, slightly soluble in ethanol(96 percent), practically insoluble in acetone	Soluble in water, slightly soluble in ethanol(96 percent), practically insoluble in acetone	Positive reaction
鉴别 Identification:	A. TLC	Conform to the reference	Positive reaction (pass)
	B. Color Reaction	To about 2mg add 5ml of sulphuric add the solutio to 2.5ml of water. The color becomes yellow.	Positive reaction (pass)
	C. Chlorides	Reaction of chlorides	Positive reaction (pass)
酸度 Acidity(pH):	1.8~2.8	1.8~2.8	2.30
比旋度 Specific optical rotation (dried substance):	-240° ~ -255°	-240° ~ -255°	-246°
干燥失重 Loss on drying:	≤2.0%	≤2.0%	0.16%
重金属 Heavy metals:	≤50ppm	≤50ppm	<40ppm
硫酸灰分 Sulphated ash:	≤0.5%	≤0.5%	0.03%
有关物质 Related substances:			
4-差向四环素 4-Epitetracycline:	≤3.0%	≤3.0%	1.58%
4-差向脱水四环素 4-Epianhydrotetracycline:	≤0.5%	≤0.5%	ND
脱水四环素 Anhydrotetracycline:	≤0.5%	≤0.5%	0.11%
2-乙酰基-2-去氨基甲基四环素 2-Acetyl-2-decarbamoyletetracycline:	≤1.5%	≤1.5%	0.35%
含量测定 Assay:	95.0%~102.0%	95.0%~102.0%	98.0%
残留溶剂 Residual solvent:			
丙酮 Acetone(G.C.)	≤100ppm		<0.62 ppm
正丁醇 n-Butanol(G.C.)	≤3000ppm		2287 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EP/BP 质量标准规定

Conclusion: The product conforms to standard of EP/BP

负责人: 王冲 2015.10.24 复核员: 王冲 2015.10.24

Person in charge:

Check:

化验员: 肖海燕 2015.10.24

Analyst: