

# Kalchem International

## Chemicals & Compounding Supplies

品名: 盐酸四环素 Name of product: Tetracycline hydrochloride	批号: 150917-61 Batch No.:		
数量: 2000 Kg Quantity:	包装: 25kg/DRUM Packing:		
生产日期: 2015-9-17 Mfg. Date:	报告日期: 2015-9-23 Report Date:		
	有效期: 2019-9-9 Expiry Date:		
检验项目 Test Items	BP 质量标准 Specification	EP 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	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 percent), practically insoluble in acetone	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	符合规定 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	2.39
✓ 比旋度 Specific optical rotation (dried substance):	-240° ~-255°	-240° ~-255°	-245°
✓ 干燥失重 Loss on drying:	≤2.0%	≤2.0%	0.26%
重金属 Heavy metals:	≤50ppm	≤50ppm	<40ppm
硫酸灰分 Sulphated ash:	≤0.5%	≤0.5%	0.04%
有关物质 Related substances:			
4-差向四环素 4-Epitetracycline:	≤3.0%	≤3.0%	1.26%
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%	0.12%
2-乙酰基-2-去氨基四环素 2-Acetyl-2-decarbamoyltetracycline:	≤1.5%	≤1.5%	0.43%
含量测定 Assay:	95.0%~102.0%	95.0%~102.0%	98.1%
残留溶剂 Residual solvent:			
丙酮 Acetone(G.C.)	≤100ppm		<0.62 ppm
正丁醇 n-Butanol(G.C.)	≤3000ppm		1797 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: Conclusion:	本品符合EP/BP 质量标准规定 The product conforms to standard of EP/BP		

**Kalchem International, Inc**  
**224 South Main Street - Lindsay, OK 73052**  
**Toll Free 888-298-9905 | FAX: 405-756-2373**