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QYPF-ZB-B297

CERTIFICATE OF ANALYSIS

品名: Name of product:	盐酸四环素 Tetracycline hydrochloride	批号: Batch No.:	210420-63
数量: Quantity:	1000 Kg	报告日期: Report Date:	2021-04-24
生产日期: Mfg.Date:	2021-04-20	有效期: Expiry Date:	2025-04-10
	包装: Packing:		
	25kg./CARTON		
	检验编号: Analysis No.:		
	0175		

标准依据: 依据欧洲药典/英国药典检验
Specification: Base on EP/BP

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:	Yellow crystalline powder	Yellow crystalline powder	Yellow crystalline powder
	Soluble in water, slightly soluble in ethanol(96 percent), practically insoluble in acetone. It dissolves in solutions of alkali hydroxides and carbonates, solutions in water become turbid on standing, owing to the precipitation of Tetracycline.		Positive reaction
鉴别 Identification:	A. TLC B. Color Reaction C. Chlorides	Conform to the reference To about 2mg add 5ml of sulfuric acid, a violet-red colour develops. Add the solution to 2.5ml of water. The color becomes yellow.	Positive reaction (pass) Positive reaction (pass)
酸度 Acidity(pH):	1.8~2.8	1.8~2.8	Positive reaction (pass)
比旋度 Specific optical rotation (dried substance):	-240° ~ -255°	-240° ~ -255°	2.55 -245°
干燥失重 Loss on drying:	≤2.0%	≤2.0%	0.12%
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%	1.15%
4-差向脱水四环素 4-Epianhydrotetracycline:	≤0.5%	≤0.5%	0.03%
脱水四环素 Anhydrotetracycline:	≤0.5%	≤0.5%	0.09%
2-乙酰基-2-去酰胺基四环素 2-Acetyl-2-decarbamoyletetracycline:	≤1.5%	≤1.5%	0.45%
含量测定 Assay(on dry basis):	95.0%~102.0%	95.0%~102.0%	98.8%
残留溶剂 Residual solvent:			
丙酮 Acetone(G.C.)	≤100ppm		11 ppm
正丁醇 n-Butanol(G.C.)	≤3000ppm		2047 ppm

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: 孙海燕 2021.4.24
Person in charge:

复核员: 孙海燕 2021.4.24
Check:

化验员: 朱新 2021.4.24
Analyst:

