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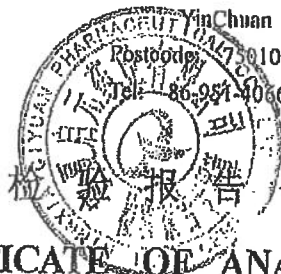
宁夏启元药业有限公司
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检验报告书

QYPF-ZB-B297

CERTIFICATE OF ANALYSIS

品名: 盐酸四环素 Name of product: Tetracycline hydrochloride		批号: 210131- 62 Batch No.:
数量: 2000 Kg Quantity:	包装: 25kg/CARTON Packing:	报告日期: 2021-02-10 Report Date:
生产日期: 2021-01-31 Mfg. Date:	检验编号 0054 Analysis No.:	复检期: 2023-01-22 Retest Date:
CEP NO.: R1-CEP 2001-349-Rev 04 标准依据: 依据欧洲药典10版检验 Specification: Base on EP10		有效期: 2025-01-22 Expiry Date:

检验项目 Test Items	质量标准 Specification	检验结果 Results
性状 Characters:	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.	Yellow, crystalline powder ✓ Positive reaction ✓
鉴别 Identification:	A. TLC B. Color Reaction C. Chlorides	Positive reaction (pass) ✓ Positive reaction (pass) ✓ Positive reaction (pass) ✓
酸度 Acidity (pH):	1.8 ~ 2.8	2.49 ✓
比旋度 Specific optical rotation (dried substance):	-240° ~ -255°	-245° ✓
干燥失重 Loss on drying:	≤ 2.0%	0.12% ✓
硫酸灰分 Sulphated ash:	≤ 0.5%	0.04% ✓
4-差向四环素 4-Epitetracycline:	≤ 3.0%	1.05% ✓
4-差向脱水四环素 4-Epi-anhydrotetracycline:	≤ 0.5%	ND ✓
脱水四环素 Anhydrotetracycline:	≤ 0.5%	0.09% ✓
2-乙酰基-2-去氧氨基四环素 2-Acetyl-2-decarbamoyltetracycline:	≤ 1.5%	0.70% ✓
盐酸金霉素 Chlorotetracycline hydrochloride:	≤ 0.6%	0.15% ✓
其他未知杂质 Any other impurity:	≤ 0.05%	0.04% ✓
含量测定 Assay (on dry basis):	95.0% ~ 102.0%	98.2% ✓
残留溶剂 Residual solvents:		
丙酮 Acetone (G.C.):	≤ 100 ppm	12 ppm
正丁醇 N-butanol (G.C.):	≤ 3000 ppm	1504 ppm

结论: 本品符合欧洲药典10版

Conclusion: The product conforms to standard of EP10 ✓

负责人:

Person in charge: 刘力嘉

复核员:

Check: 王小波

化验员:

Analyst: 樊嵘