



新昌县九信药业有限公司

Xinchang JiuXin Pharmaceutical Co.,Ltd

质量检测报告书

Certificate of analysis

报告单号 (COA no.) ST020105H.00

检品名称 product	盐酸土霉素 oxytetracycline hydrochloride	批号 batch no.	Y21306062
包装 packaging size	25kg/package	数量 quantity	975kg
生产日期 MFG DATE	22/06-2013 (d/m/y)	报告日期 reporting date	25/06/2013(d/m/y)
执行标准 according to	英国药典 2011 版 BP2011	失效日期 Expiry date	21/06/2017(d/m/y)

Tests	acceptance criteria	results
Characters	yellow crystalline powder	Conforms
identification	A. Thin-layer chromatography results	Conforms
	B. Colour reaction with sulfuric acid	
	C. Give reaction (a) of chlorides	
PH	2.3~2.9	2.7
absorbance	270~290	284
specific optical rotation	-188° ~-200°	-191°
heavy metals	≤50ppm	<50ppm
light absorbing impurities	430nm<0.50	0.19
	490nm<0.20	0.04
related substances	Impurity A ≤0.5	0.18
	Impurity B ≤2.0	0.39
	Impurity C ≤2.0	1.2
	Total of impurities D,E and F ≤2.0	0.49
	4-epitetracycline ≤0.5	0.09
	Any unspecified impurity ≤0.10	<0.1
	Total impurities ≤3.0	2.4
residue on ignition	≤0.5%	0.23%
water	≤2.0%	1.1%
Assay	95.0%~102.0%	98.3%
Methanol (PPM)	≤3000	416

结论: 本品按英国药典 2011 版标准检验, 结果符合标准

Conclusion: conforms to BP 2011.

Reported by: Cai lanlan

reviewed by: Pan fangfang

approved by: Cai lanlan