

lot: 0020314

# HEBEI SHENGXUE DACHENG PHARMACEUTICAL CO.,LTD

No.50, Shengxue Road, Luancheng Shijiazhuang 051430 China

Tel: +86-0311 85219663

Fax: +86-0311 85219656

## CERTIFICATE OF ANALYSIS

Product Name: OXYTETRACYCLINE HCL		Batch No: Y1-1308081-1
Net Weight: 25 kg/drum	No.of Packing: 19drums	Quantity: 475 kg
Mfg. Date: 2013-8-08	Date of Report: 2013-8-13	Expiry Date: 2017-8-07
According to: EP7		Report No.: 1308-005

TEST ITEMS	SPECIFICATION	TEST RESULTS
CHARACTERS		
Appearance	Yellow, crystalline powder, hygroscopic.	Complies
Solubility	Freely soluble in water, sparingly soluble in ethanol. Solutions in water become turbid on standing,owing to the precipitation of oxytetracycline.	Complies
IDENTIFICATION		
	A. TLC results	Complies
	B. colour reaction with sulfuric acid	Positive
	C. reaction of chlorides	Positive
TESTS		
pH	2.3 to 2.9	2.4
Specific optical rotation	-188 to -200	- 191
Specific absorbance	270 to 290 determined at 353nm	275
Light absorbing impurities	Absorption at 430nm has a maximum of 0.50	0.16
	Absorption at 490nm has a maximum of 0.20	0.03
Related substance		
impurity A	Not more than 0.5%	0.2%
impurity B	Not more than 2.0%	0.6%
impurity C	Not more than 2.0%	1.6%
total of impurities D,E and F	Not more than 2.0%	0.3%
any other detected impurities	Not more than 0.1%	undetected
Heavy metals	Maximum 50 ppm	<50 ppm
Water	Maximum 2.0%	1.2%
Sulfated ash	Maximum 0.5%	0.08 %
Residual solvent (methanol)	Not more than 3000 ppm	606ppm
ASSAY (anhydrous substance)	95.0% to 102.0%	97.9%

**Conclusion: This product complies with EP7.**

Director of QC Dept: Li wenjie

Inspector: Wang minran



Remark: This batch was manufactured in full compliance with GMP requirements of the local regulatory authority.