lote: 012J015

YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD

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CERTIFICATE OF ANALYSIS

WE , YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD , AS A MANUFACTURER OF OXYTETRACYCLINE HYDROCHLORIDE CERTIFY THAT THIS BATCH HAS BEEN MANUFACTURED BY US IN FULL COMPLIANCE WITH EU-GMP REQUIREMENTS AND GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY.

QC

REPORT NO.:50041504031 SOPQC-FP002-03

SAMPLE NAME	OXYTETRACYCLINE HYDROCHLORIDE		
BATCH NO.	YT150402031	SENDING SAMPLE UNIT	WORKSHOP THREE
SPECIFICATION	PHARMACEUTICAL	MANUFACTURING DATE	2015.04.15
BATCH SIZE	1000kg	REPORT DATE	2015.04.18
COS NO.	R0-CEP 2010-080-Rev 01	EXPIRY DATE	2019.04.14

I. ANALYTICAL METHOD: EP8.0/BP2013

II. RESULTS OF ANALYTICAL ITEM:

ITEM	SPECIFICATION	RESULT
APPEARANCE:	YELLOW, CRYSTALLINE POWDER, HYGROSCOPIC	COMPLIES
SOLUBILITY:	FREELY SOLUBLE IN WATER, SPARINGLY SOLUBLE IN ETHANOL(96%). SOLUTIONS IN WATER BECOME TURBID ON STANDING,OWING TO THE PRECIPITATION OF OXYTETRACYCLINE.	COMPLIES
IDENTIFICATION:	A: THIN-LAYER CHROMATOGRAPHY	COMPLIES
	B: REACTION WITH SULPHURIC ACID	COMPLIES
	C: REACTION OF CHLORIDES	COMPLIES
PH:	2.3 TO 2.9	2.4
SPECIFIC OPTICAL ROTATION:	–188° TO –200°	-195°
SPECIFIC ABSORBANCE (353nm)	270 TO 290	279
LIGHT-ABSORBING IMPURITIES		
(430nm):	NOT MORE THAN 0.50	0.18
(490nm):	NOT MORE THAN 0.20	0.04
RELATED SUBSTANCES:		
IMPURITY A	NOT MORE THAN 0.5%	0.15%
IMPURITY B	NOT MORE THAN 2.0%	0.63%
IMPURITY C	NOT MORE THAN 2.0%	1.62%
ANY OTHER IMPURITY	NOT MORE THAN 0.1%	0.04%
TOTAL OF IMPURITIES D, E AND F (ELUTING BETWEEN THE LATTER TWO)	NOT MORE THAN 2.0%	0.39%
HEAVY METALS:	NOT MORE THAN 50 ppm	COMPLIES
WATER:	NOT MORE THAN 2.0%	1.0%
SULFATED ASH:	NOT MORE THAN 0.5%	0.1%
RESIDUAL SOLVENT:		
METHANOL:	NOT MORE THAN 3000 ppm	466ppm
ASSAY (ANHYDROUS SUBSTANCE): CONTENT OF $C_{22}H_{25}ClN_2O_9$	95.0% TO 102.0%	96.5%

III: RESULT AND CONCLUSION: PASS

APPROVED BY: 赵红房 2015.04.18 TESTED BY: 2015.04.18 2015.04.18 CHECKED BY: 2015.4.18