Lote: 0110514

YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD

SITE ADD:22,YANGLI ROAD, YANGZHOU,JIANGSU,CHINA
Tel: +86-514-87770176 Fax: +86-514-87770188

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.

REPORT NO.:S0041403055 SOPQC-FP002-01

SAMPLE NAME	OXYTETRACYCLINE HYDROCHLORIDE		
BATCH NO.	YT140302055	SENDING SAMPLE UNIT	WORKSHOP THREE
SPECIFICATION	PHARMACEUTICAL	MANUFACTURING DATE	2014.03.15
BATCH SIZE	1061.7kg	REPORT DATE	2014.03.21
COS NO.	R0-CEP 2010-080-Rev 01	EXPIRY DATE	2018.03.14

I. ANALYTICAL METHOD: EP7.0/BP2011

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°	-196°
SPECIFIC ABSORBANCE (353nm)	270 TO 290	280
LIGHT-ABSORBING IMPURITIES		
(430nm):	NOT MORE THAN 0.50	0.20
(490nm):	NOT MORE THAN 0.20	0.03
RELATED SUBSTANCES:		
IMPURITY A	NOT MORE THAN 0.5%	0.19%
IMPURITY B	NOT MORE THAN 2.0%	0.73%
IMPURITY C	NOT MORE THAN 2.0%	1.47%
ANY OTHER IMPURITY	NOT MORE THAN 0.1%	0.06%
TOTAL OF IMPURITIES D, E AND F (ELUTING BETWEEN THE LATTER TWO)	NOT MORE THAN 2.0%	0.57%
HEAVY METALS:	NOT MORE THAN 50 ppm	COMPLIES
WATER:	NOT MORE THAN 2.0%	0.7%
SULFATED ASH:	NOT MORE THAN 0.5%	0.1%
RESIDUAL SOLVENT:		
METHANOL:	NOT MORE THAN 3000 ppm	134ppm
ASSAY (ANHYDROUS SUBSTANCE): CONTENT OF $C_{22}H_{25}ClN_2O_9$	95.0% TO 102.0%	96.6%

III: RESULT AND CONCLUSION: PASS

APPROVED BY: 2014.03.21 TESTED BY: 2014.03.21 2014.03.21 CHECKED BY: 2014.03.21