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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.

REPORT NO.: 50041510002

SOPQC-FP002-04

SAMPLE NAME	OXYTETRACYCLINE HYDROCHLORIDE		
BATCH NO.	YT151002002	TEST REQUEST UNIT	OXYTETRACYCLINE WORKSHOP
SPECIFICATION	PHARMACEUTICAL	MANUFACTURING DATE	2015.09.29
BATCH SIZE	1000kg	REPORT DATE	2015.10.10
COS NO.	R0-CEP 2010-080-Rev 01	EXPIRY DATE	2019.09.28

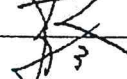


I. ANALYTICAL METHOD:

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 B: REACTION WITH SULPHURIC ACID C: REACTION OF CHLORIDES	COMPLIES COMPLIES COMPLIES
PH:	2.3 TO 2.9	2.4
SPECIFIC OPTICAL ROTATION:	-188° TO -200°	-192°
SPECIFIC ABSORBANCE (353nm)	270 TO 290	282
LIGHT-ABSORBING IMPURITIES		
(430nm):	NOT MORE THAN 0.50	0.13
(490nm):	NOT MORE THAN 0.20	0.02
RELATED SUBSTANCES:		
IMPURITY A	NOT MORE THAN 0.5%	0.27%
IMPURITY B	NOT MORE THAN 2.0%	0.48%
IMPURITY C	NOT MORE THAN 2.0%	1.46%
ANY OTHER IMPURITY	NOT MORE THAN 0.10%	0.08%
TOTAL OF IMPURITIES D, E AND F (ELUTING BETWEEN THE LATTER TWO)	NOT MORE THAN 2.0%	0.34%
HEAVY METALS:	NOT MORE THAN 50 ppm	COMPLIES
WATER:	NOT MORE THAN 2.0%	1.1%
SULFATED ASH:	NOT MORE THAN 0.5%	0.1%
RESIDUAL SOLVENT:		
METHANOL:	NOT MORE THAN 3000 ppm	46ppm
ASSAY (ANHYDROUS SUBSTANCE):	95.0% TO 102.0%	96.3%
CONTENT OF C ₂₂ H ₂₅ ClN ₂ O ₉		

III. RESULT AND CONCLUSION: PASS

APPROVED BY:  TESTED BY:  2015.10.10 CHECKED BY:  2015.10.10

2015.10.10