



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.: 50041703018

SOPQC-FP002-07

SAMPLE NAME	OXYTETRACYCLINE HYDROCHLORIDE		
BATCH NO.	YT170302018	TEST REQUEST UNIT	OXYTETRACYCLINE WORKSHOP
SPECIFICATION	PHARMACEUTICAL	MANUFACTURING DATE	2017.03.01
BATCH SIZE	1000kg	REPORT DATE	2017.03.06
COS NO.	RI-CEP 2010-080-Rev 00	EXPIRY DATE	2021.02.28

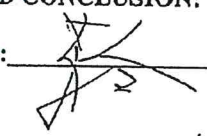

I. ANALYTICAL METHOD:

EP9.0

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:	B: EXAMINE THE CHROMATOGRAMS OBTAINED IN THE TEST FOR RELATED SUBSTANCES C: REACTION WITH SULPHURIC ACID D: REACTION OF CHLORIDES	COMPLIES COMPLIES
PH:	2.3 TO 2.9	2.4
LIGHT-ABSORBING IMPURITIES		
(430nm):	NOT MORE THAN 0.50	0.17
(490nm):	NOT MORE THAN 0.20	0.04
RELATED SUBSTANCES:		
IMPURITY A	NOT MORE THAN 0.5%	0.32%
IMPURITY B	NOT MORE THAN 1.0%	0.45%
IMPURITY C	NOT MORE THAN 2.0%	1.54%
IMPURITY D	NOT MORE THAN 0.2%	0.02%
IMPURITY E	NOT MORE THAN 0.2%	0.04%
ANY OTHER IMPURITY	NOT MORE THAN 0.1%	0.07%
TOTAL OF IMPURITIES	NOT MORE THAN 3.5%	2.44%
WATER:	NOT MORE THAN 2.0%	0.8%
SULFATED ASH:	NOT MORE THAN 0.2%	0.1%
RESIDUAL SOLVENT:		
METHANOL:	NOT MORE THAN 3000 ppm	1508ppm
ASSAY (ANHYDROUS SUBSTANCE):	94.5% TO 102.0%	97.0%
CONTENT OF $C_{22}H_{25}ClN_2O_9$		

III: RESULT AND CONCLUSION: PASS

APPROVED BY:  TESTED BY: 袁明阳 2017.03.06 赵静 2017.03.06 CHECKED BY:  2017.03.06

2017.03.06