YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD

SITE ADD:22,YANGLI ROAD, YANGZHOU,JIANGSU,CHINA
Tel: +86-514-87770176 Fax: +86-514-87770178

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.: 50042403080 SOPQC-FP002-18

SAMPLE NAME	OXYTETRACYCLINE HYDROCHLORIDE		
BATCH NO.	YT240302080	TEST REQUEST UNIT	OXYTETRACYCLINE WORKSHOP
SPECIFICATION	PHARMACEUTICAL	MANUFACTURING DATE	2024.03.21
BATCH SIZE	1000kg	REPORT DATE	2024.03.26
CEP NO.	R1-CEP 2010-080-Rev 03	RETEST DATE	2028.03.20

I. ANALYTICAL METHOD: EP11.0

II. RESULTS OF ANALYTICAL ITEM:

ITEM	SPECIFICATION	RESULT
APPEARANCE:	YELLOW, HYGROSCOPIC, CRYSTALLINE POWDER.	COMPLIES
IDENTIFICATION:	B: EXAMINE THE CHROMATOGRAMS OBTAINED IN THE ASSAY	COMPLIES
	C: REACTION WITH SULFURIC ACID	COMPLIES
	D: REACTION OF CHLORIDES	COMPLIES
PH:	2.3 TO 2.9	2.4
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%	0.24%
IMPURITY B	NOT MORE THAN 1.0%	0.62%
IMPURITY C	NOT MORE THAN 2.0%	1.53%
IMPURITY D	NOT MORE THAN 0.2%	<0.05%
IMPURITY E	NOT MORE THAN 0.2%	<0.05%
IMPURITY D+E+F	NOT MORE THAN 1.0%	0.31%
ANY OTHER IMPURITY	NOT MORE THAN 0.1%	<0.05%
TOTAL OF IMPURITIES	NOT MORE THAN 3.5%	2.70%
WATER:	NOT MORE THAN 2.0%	1.3%
SULFATED ASH:	NOT MORE THAN 0.2%	0.1%
RESIDUAL SOLVENT:		
METHANOL:	NOT MORE THAN 3000 ppm	383ppm
ASSAY (ANHYDROUS SUBSTANCE): CONTENT OF $C_{22}H_{25}ClN_2O_9$	94.5% TO 102.0%	97.4%

III: RESULT AND CONCLUSION: PASS

APPROVED BY: 2024.03.26 DRAFTED BY: 2024.03.26 CHECKED BY: 2024.03.26

METAPHARMACEUTICAL

N DE LOTE: 016024

14/10/2024