



YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD

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CERTIFICATE OF ANALYSIS

WE, YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD., AS A MANUFACTURER OF DOXYCYCLINE HYCLATE HEREBY 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.: 50012012069

SOPQC-FP001-14

SAMPLE NAME	DOXYCYCLINE HYCLATE		
BATCH NO.	YD201201069	TEST REQUEST UNIT	DOXYCYCLINE WORKSHOP
SPECIFICATION	PHARMACEUTICAL	MANUFACTURING DATE	2020.12.16
BATCH SIZE	1231.7kg	REPORT DATE	2020.12.18
COS NO.	R1-CEP 2000-165-Rev 06	RETEST DATE	2024.12.15

I. ANALYTICAL METHOD:

EP10.0

II. RESULTS OF ANALYTICAL ITEM:

ITEM	SPECIFICATIONS	RESULT
APPEARANCE:	YELLOW, CRYSTALLINE POWDER, HYGROSCOPIC.	COMPLIES
IDENTIFICATION:	A: EXAMINE THE CHROMATOGRAMS OBTAINED IN THE ASSAY	COMPLIES
	B: REACTION WITH SULPHURIC ACID	COMPLIES
	C: REACTION OF CHLORIDES	COMPLIES
PH:	2.0 TO 3.0	2.4
ABSORBANCE (490nm):	NOT MORE THAN 0.07	0.02
RELATED SUBSTANCES:		
Impurity A (6-epidoxycycline):	NOT MORE THAN 2.0%	1.27%
Impurity B (metacycline):	NOT MORE THAN 0.5%	NOT DETECTED
Impurity C (4-epidoxycycline):	NOT MORE THAN 0.2%	0.06%
Impurity F (2-acetyl-2-decarbamoyleidoxycycline):	NOT MORE THAN 1.2%	0.88%
Unspecified impurities:	NOT MORE THAN 0.10%	<0.05%
Total impurities:	NOT MORE THAN 3.0%	2.21%
ETHANOL:	4.3% TO 6.0%	4.7%
WATER:	1.4% TO 2.8%	1.8%
SULFATED ASH:	NOT MORE THAN 0.4%	0.1%
RELATED SUBSTANCES BY GC:		
Chloromethane:	NOT MORE THAN 300 ppm	68ppm
Chloroethane:	NOT MORE THAN 600 ppm	116ppm
ASSAY: CONTENT OF $C_{23}H_{25}ClN_2O_8$	95.0% TO 102.0%	97.0%
(ANHYDROUS AND ETHANOL-FREE SUBSTANCE)		

III. RESULT AND CONCLUSION: PASS

APPROVED BY: PZ DRAFTED BY: JZ CHECKED BY: JZ
2020.12.18 2020.12.18 2020.12.18