



YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD

SITE ADD: 22, YANGLI ROAD, YANGZHOU, JIANGSU PROVINCE, CHINA

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CERTIFICATE OF ANALYSIS

WE, YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD., AS 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.: 50012104081

SOPQC-FP001-14

SAMPLE NAME	DOXYCYCLINE HYCLATE		
BATCH NO.	YD210401081	TEST REQUEST UNIT	DOXYCYCLINE WORKSHOP
SPECIFICATION	PHARMACEUTICAL	MANUFACTURING DATE	2021.04.11
BATCH SIZE	1230.3kg	REPORT DATE	2021.04.13
CCS NO.	R1-CEP 2000-163-Rev 06	RETEST DATE	2025.04.10

I. ANALYTICAL METHOD:

EPI0.0

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:	3.0 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%	1.20%
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-decarboxydoxycycline):	NOT MORE THAN 1.3%	0.88%
Unspecified impurities:	NOT MORE THAN 0.10%	<0.05%
Total impurities:	NOT MORE THAN 3.0%	2.14%
ETHANOL:	4.3% TO 6.0%	4.9%
WATER:	1.4% TO 2.8%	2.0%
SULFATED ASH:	NOT MORE THAN 0.4%	0.1%
RELATED SUBSTANCES BY GC:		
Chloromethane:	NOT MORE THAN 300 ppm	70ppm
Chloroethane:	NOT MORE THAN 600 ppm	95ppm
ASSAY: CONTENT OF $C_{22}H_{24}N_2O_8$	95.0% TO 102.0%	97.3%
(ANHYDROUS AND ETHANOL-FREE SUBSTANCE)		

III. RESULT AND CONCLUSION: PASS

APPROVED BY: [Signature] DRAFTED BY: [Signature] CHECKED BY: [Signature]
2021.04.13 2021.04.14 2021.04.13

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