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YANGZHOU PHAR, ACEUTICAL CO., LTD
WORKING STANDARD CERTIFICATE OF ANALYSIS

REPORT NO.:037

SOPQC-CP001-03

SAMPLE NAME	DOXYGYCLINE HYDROCHLORIDE (DOXYCYCLINE HYCLATE)	MANUFACTURING DATE	2015.09.18
BATCH NO.	YD20130037	EXPIRY DATE	2020.09.17
SPECIFICATION	PHARMACEUTICAL	REPORT DATE	2015.11.19
QUANTITY	1.0g	USE BEFORE	2016.11.18

ANALYTICAL METHOD:

I. RESULTS OF ANALYTICAL ITEM

ITEM	SPECIFICATIONS	RESULT
APPEARANCE:	YELLOW CRYSTALLINE POWDER, HYGROSCOPIC	COMPLIES
SOLUBILITY:	FREELY SOLUBLE IN WATER AND IN METHANOL, SPARINGLY SOLUBLE IN ETHANOL (96%), IT DISSOLVES IN SOLUTIONS OF ALKALI HYDROXIDES AND CARBONATES.	COMPLIES
IDENTIFICATION:	A. INFRARED ABSORPTION B. REACTION OF CHLORIDES	COMPLIES COMPLIES
PH:	2.0 TO 3.0	2.4
SPECIFIC OPTICAL ROTATION:	-105° TO -120°	-112°
SPECIFIC ABSORBANCE (349nm):	0.300 TO 0.335	0.309
LIGHT-ABSORBING IMPURITIES (490nm):	NOT MORE THAN 0.07	0.01
RELATED SUBSTANCES:		
6-EPIDOXCYCLINE:	NOT MORE THAN 2.0%	1.56%
METACYCLNE:	NOT MORE THAN 2.0%	0.32%
TAIL OF THE MAIN PEAK:	NOT MORE THAN 0.5%	0.31%
ANY OTHER IMPURITY:	NOT MORE THAN 0.5%	NOT DETECTED
ETHANOL:	4.3% TO 6.0%	5.0%
HEAVY METALS:	NOT MORE THAN 50 ppm	<30ppm
WATER:	1.4% TO 2.8%	1.9%
SULFATED ASH:	NOT MORE THAN 0.4%	0.1%
ASSAY: CONTENT OF $C_{22}H_{24}N_2O_8$	95.0% to 102.0%	99.48%
(ANHYDROUS FREE SUBSTANCE)		

II. RESULT AND CONCLUSION: PASS

L/C NO.:0393MLC0039314 NBPL BD-1107-25959

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APPROVED BY: *[Signature]*TESTED BY: *[Signature]*CHECKED BY: *[Signature]*