



alchem International, Inc
Compounding Chemicals You Can Trust

PRODUCT:	DOXYCYCLINE HYCLATE, EP	EXPIRATION DATE:	12/10/2023
FINISHED LOT NO:	YD191201033	MFG DATE:	12/11/2019
CAS#	24390 – 14 - 5	SPECIFICATIONS:	EP9.0
MANUFACTURE:	YANGZHOU LIBERTY PHARMACEUTICAL CO.,LTD	COUNTRY OF ORIGIN:	CHINA

Certificate of Analysis

TEST CRITERIA	SPECIFICATIONS	RESULTS
DESCRIPTION	Yellow crystalline powder, hygroscopic.	Complies
SOLUBILITY	VERY SOLUBLE IN WATER, SPARINGLY SOLUBLE IN ALCOHOL.	Complies
*IDENTIFICATION		Conforms
IDENTIFICATION	a) Examine the chromatograms obtained in the Assay.	Complies
	(b) Reaction with Sulphuric Acid	Complies
	(c) Reaction of chlorides	Complies
ABSORBANCE: (490nm):	NMT 0.07	0.02
pH	2.0 to 3.0	2.4
RELATED SUBSTANCES		
Impurity A (4 – Epidoxycycline)	NMT 0.2%	1.33%
Impurity B (Methacycline)	NMT 0.5%	NOT DETECTED
Impurity C (6 – Epidoxycycline)	NMT 0.2%	0.07%

Impurity F (2 - acetyl - 2-decarbamoxyldoxycycline)	NMT 1.2%	0.98%
UNSPECIFIED IMPURITIES	NMT 0.10%	NOT DETECTED
TOTAL IMPURIES	NMT 3.0%	2.38%
WATER DETERMINATION	1.4% - 2.8%	1.9%
SULFATED ASH	NMT 0.4%	0.1%
ETHANOL	Between 4.3% and 6.0%	4.7%
RELATED SUBSTANCES BY GC:	Chloromethane NMT 300ppm Chloroethane NMT 600ppm	72 ppm 138 ppm
ASSAY: CONTENT OF C ₂₂ H ₂₅ CIN ₂ O ₈	95.0% TO 102%	97.7%
*ASSAY		*845 mcg/mg

(ANHYDROUS AND ETHANOL-FREE SUBSTANCE)

Conclusion: This material conforms to EP9.0

*Kalchem International additional testing

DATE OF RELEASE: 07/07/20 ANALYSIS # ETX-200701-0029

APPROVED BY/ DATE: _____

Kalyn R Tabor, Quality Control