



XI'AN JULONG BIO-TECH CO.,LTD

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Certificate of Analysis-Doxycycline Hyclate

Product Name	Doxycycline Hyclate	Batch No	JL-20210208
Quantity	10Kg	Analysis Date	Feb,09th,2021
Mfg. Date	Feb,08th,2021	Exp. Date	Feb,07th,2023
Package	25KG per drum	Standard	GMP/USP/EP
Items	Specifications	Results	
Appearance	Yellow crystalline powder	Conforms	
Identification	TLC	Conforms	
	sulphuric acid reaction a yellow colour develops	Conforms	
	it gives reaction of chlorides	Conforms	
PH	2.0~3.0	2.3	
Specific absorbance	at 349nm e(1%) 300~355	320	
Specific optical rotation	-105 ~ -120°	-110°	
Heavy metals:	≤50ppm	< 20ppm	
Light-absorbing impurities	at 490nm ≤0.07	0.03	
Related substances	6-epidoxycycline ≤2.0%	1.6%	
	metacycline ≤2.0%	0.1%	
	4-epidoxycycline ≤0.5% (ep5)	Not found	
	4-epi-6-epidoxycycline ≤0.5% (ep5)	Not found	
	oxytetracycline ≤0.5% (ep5)	Not found	
	any other impurity ≤0.5%	Not found	
	not identified impurities ≤0.1% (ep5)	Not found	
Ethanol	4.3~6.0% (m/m)	4.5%	
Sulphated ash	≤0.4%	0.05%	
Water	1.4~2.8%	1.8%	
Assay	95.0~102.0% (c22h25cln2o8) based on anhydrous, ethanol-free substance	98.6%	
Conclusion	Conform with USP32		

QC MANAGER: 董卓

INSPECTOR: 张赞

ANALYST: 王胜利

