

## Certificate of Analysis

Product name: Doxycycline hyclate		
CAS: 24390-14-5		Mfg. Date: 20180630
Batch No. CAT3663		Report Date: 20180730
Batch Size: 1 kg		Exp. Date: 20190630
Analytical Results		
Item	STANDARDS	Result
Appearance	Yellowish crystalline powder	Conform
Water	Between 1.4% and 3.0%	1.9%
pH	Between 2.0 and 3.0	2.2
Related Substances	4-epidoxycycline NMT 0.5%	0.09%
	Methacycline NMT 1.0%	0.09%
	2-acetyl-2-decarbamoylexycycline NMT 0.5%	0.34%
	6-epidoxycycline NMT 2%	0.71%
Single unknown impurity	NMT 0.10%	Not detected
Total impurities	NMT 3.0%	1.2%
Assay	Between 800 and 920 µg/m g	852 µg/mg
Ethanol	Between 4.3% and 5.5%	4.9%
Chloromethane	Not more than 30ppm	1ppm
Chloroethane	Not more than 250ppm	82ppm
Acetaldehyde	Not more than 100ppm	4ppm
Methanol	Not more than 200ppm	Not detected
Ethyl acetate	Not more than 5000ppm	71ppm
Particle size	D(0.5):NMT 100µm	29.7µm
	D(0.9):NMT 250µm	129.6µm
Conclusion: comply (meet all requirements under the DOXYCYCLINE HYCLATE OF USP)		
Remark: particle size < 75µm: 74.1% (v/v)		

Tested: Cheng Li

Checked: Huan Li

Approved: Shuyin Gu