CHANGZHOU PHARMACEUTICAL FACTORY

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Report NO.:Fm-QC-DR-002-01-[1]
Related SOP:QC-D-002
Executive Date: 2020.01.01

CERTIFICATE OF ANALYSIS

Analysis No. : D-200008

Product	DOXYCYCLINE HYCLATE	Batch NO.	ED200308
Specification	API	Manufacturing Date	Mar. 22, 2020
Quantity	800Kg	Retest Date	Mar. 22, 2023
Presentation	Plastic bag	Report Date	Apr. 20, 2020
According with	USP		

Tests	Specifications		Results
Appearance	Yellow crystalline powder		Complies
Identification	IR: Spectrum conforms to Standard		Complies
Crystallinity	Meets the requirements		Complies
pH	Between 2.0 and 3.0		2.4
Water	Between 1.4% and 2.8%		2.0%
Organic impurities	Method 1	4-Epidoxycycline NMT 0.5%	0.06%
		Methacycline NMT 2%	0.31%
		6-epidoxycycline NMT 2%	0.96%
		#Largest Individual Unknown impurity NMT 0.10%	Not detected
	Method 2	#2-acetyl-2-decarbamoyldoxycycline NMT 1.2%	0.90%
	#Total impurity(include method 1 and 2) NMT 2.5%		2.23%
#Residual Solvents	Acetaldehyde	Not more than 100ppm	8ppm
	Methanol	Not more than 200ppm	Not detected
	Ethyl acetate	Not more than 5000ppm	147ppm
Ethanol	Between 4.3% and 5.5%		5.2%
#Chloromethane	Not more than 30ppm		2ppm
#Chloroethane	Not more than 250ppm		83ppm
Assay	Between 800 and 920 μg/mg		838μg/mg

Note: # - is different from USP.

Conclude: The results above meet all requirements under DOXYCYCLINE HYCLATE in USP.

Qualified Person: 张国庆

Quality Control Department: 常药厂有限公司 检验专用章 (1)