



CHANGZHOU PHARMACEUTICAL FACTORY

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Report NO.: Fm-QC-DR-002-01-[5]
Related SOP: QC-D-002
Executive Date: 2022.11.10

CERTIFICATE OF ANALYSIS

Analysis No. : D-230015

Product	DOXYCYCLINE HYCLATE		
Batch NO.	ED230205	Date Received	Feb. 16, 2023
Strength	API	Manufacturing Date	Feb. 08, 2023
Quantity	800Kg	Retest Date	Feb. 08, 2026
Accordinging with	USP	Report Date	Mar. 09, 2023
Package	Two layers of LDPE bags (Inner layer is sealed with nylon ties, and the outer layer is sealed by hot pressing) into a four-fold composite film bag, placed into a fiber drum		

Tests	Specifications	Results
Appearance	Yellow crystalline powder	Complies
Identification	IR: Spectrum conforms to Standard	Complies
	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Complies
	Chemical Identification Tests, Chloride: Meets the requirements	Complies
Crystallinity	Meets the requirements	Complies
pH	Between 2.0 and 3.0	2.4
Water	Between 1.4% and 2.8%	1.9%
Organic impurities	Methacycline NMT 2.0%	0.12%
	4-Epidoxycycline NMT 0.5%	0.05%
	Doxycycline related compound A (6-epidoxycycline) NMT 2.0%	0.90%
	Doxycycline related compound F NMT 1.0%	0.88%
	Maximum individual unspecified impurity NMT 0.10%	0.05%
	Total impurity NMT 2.5%	2.00%
#Residual Solvents	Acetaldehyde NMT 100ppm	7ppm
	Methanol NMT 200ppm	30ppm
	Ethyl acetate NMT 5000ppm	124ppm
#Ethanol	Between 4.3% and 5.5%	5.2%
#Chloromethane	NMT 30ppm	3ppm
#Chloroethane	NMT 250ppm	48ppm
Assay	Doxycycline Hyclate has a potency equivalent to NLT 800 µg/mg and NMT 920 µg/mg of doxycycline (C ₂₂ H ₂₄ N ₂ O ₈)	840µg/mg

Note: # - is different from USP.

Conclude: The results above meet all requirements in USP Doxycycline Hyclate Monograph, official date 1-Jun-2022.

QC Manager:

Handwritten signature and date: 2023.03.09