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

常州制药厂有限公司 检验专用章

CERTIFICATE OF ANALYSIS

Analysis No. : D-250042

Product	DOXYCYCLINE HYCLATE		
Batch NO.	D250315	Date Received	Mar. 23, 2025
Strength	API	Manufacturing Date	Mar. 22, 2025
Quantity	152.5Kg	Retest Date	Mar. 22, 2028
According with	USP	Report Date	Mar. 31, 2025
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	Yellow crystalline powder
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	2.3
Water	Between 1.4% and 2.8%	1.9%
Organic impurities	Methacycline NMT 2.0%	Not detected
	4-Epidoxycycline NMT 0.5%	Not detected
	Doxycycline related compound A (6-epidoxycycline) NMT 2.0%	0.77%
	Doxycycline related compound F NMT 1.0%	0.54%
	Maximum individual unspecified impurity NMT 0.10%	Not detected
	Total impurity NMT 2.5%	1.3%
#Residual Solvents	Acetaldehyde NMT 100ppm	4ppm
	Methanol NMT 200ppm	14ppm
	Ethyl acetate NMT 5000ppm	116ppm
#Ethanol	Between 4.3% and 5.5%	5.0%
#Chloromethane	NMT 30ppm	1ppm
#Chloroethane	NMT 250ppm	40ppm
Assay	Doxycycline Hyclate has a potency equivalent to NLT 800 μg/mg and NMT 920 μg/mg of doxycycline ($C_{22}H_{24}N_2O_8$)	854μg/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: 2025.03.31

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