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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-240020

Product	DOXYCYCLINE HYCLATE		
Batch NO.	D240501	Date Received	May. 04, 2024
Strength	API	Manufacturing Date	Apr. 26, 2024
Quantity	803.11Kg	Retest Date	Apr. 26, 2027
According with	USP	Report Date	May. 17, 2024
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%	2.0%
Organic impurities	Methacycline NMT 2.0%	0.18%
	4-Epidoxycycline NMT 0.5%	Not detected
	Doxycycline related compound A (6-epidoxycycline) NMT 2.0%	0.65%
	Doxycycline related compound F NMT 1.0%	0.79%
	Maximum individual unspecified impurity NMT 0.10%	Not detected
	Total impurity NMT 2.5%	1.6%
#Residual Solvents	Acetaldehyde NMT 100ppm	4ppm
	Methanol NMT 200ppm	Not detected
	Ethyl acetate NMT 5000ppm	86ppm
#Ethanol	Between 4.3% and 5.5%	4.8%
#Chloromethane	NMT 30ppm	4ppm
#Chloroethane	NMT 250ppm	58ppm
Assay	Doxycycline Hyclate has a potency equivalent to NLT 800 μg/mg and NMT 920 μg/mg of doxycycline ($C_{22}H_{24}N_2O_8$)	846μg/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: 2024.05.17