

YANCHENG SU HAI PHARMACEUTICAL CO., Ltd.

CERTIFICATE OF ANALYSIS

Add.:Huafeng Industrial Park, Dafeng Port Economic Development Zone, Dafeng City, Jiangsu Province, China
224100

NO: (11001) 150011

NAME		DOXYCYCLINE HYCLATE	
BATCH NO.	1512002	MFG. DATE	2015.12.16
NET WEIGHT PER DRUM	25kg	DATE OF REPORT	2015.12.23
BATCH SIZE	1000.1kg	RE-TEST DATE	2019.12.15
SPECIFICATION	EP8.4		
ANALYSIS RESULT			
TEST ITEMS		TEST RESULTS	ACCEPTANCE CRITERIA
Characters		Complies	Yellow, hygroscopic, crystalline powder. Freely soluble in water and in methanol, sparingly soluble in ethanol (96 per cent). It dissolves in solutions of alkali hydroxides and carbonates.
Identification	HPLC	Complies	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).
	Color reaction with sulfuric acid	Complies	A yellow color develops.
	Reaction of chlorides	Complies	Positive reaction
pH		2.4	2.0~3.0
Absorbance		0.02	≤0.07
Water		2.0%	1.4%~2.8%
Sulfated ash		0.05%	≤0.4%
Heavy metals		<50ppm	≤50ppm
Ethanol		5.1%	4.3%~6.0%
Impurity A(6-epidoxycycline)		1.4%	≤2.0%
Impurity F (2-Acetyl-2-decarboxyamidodoxycycline)		0.64%	≤1.2%
Impurity B(Methacycline)		0.23%	≤0.5%
Impurity C(4-epidoxycycline)		0.02%	≤0.2%
Any unspecified impurity		ND	≤0.10%
Total impurities		2.24%	≤3.0%
Assay(C ₂₂ H ₂₅ ClN ₂ O ₈)		98.7%	95.0%~102.0%
Conclusion		Conforming to EP8.4	
TESTED BY	[Signature]		
REVIEWED BY	[Signature] 2015.12.23	APPROVED BY	[Signature] 2015.12.23