

ZHEJIANG WEPON PHARMACEUTICAL CO., LTD.

QUALITY SPECIFICATIONS

REPORT NO. 2017072671

Add:28# North Baizhang Road,Chengdong Street ,Wenling,Zhejiang
Tel:0086-576-6823098,6183928

NAME	CLINDAMYCIN PHOSPHATE	BATCH NO.	170726
MANUFACTURE DATE	JUL. 26. 2017	EXPIRY DATE	JUL. 25. 2020
SAMPLE DATE	AUG. 31. 2017	EXPORT DATE	SEP. 6. 2017
AMOUNT	300KGS	PACKAGE	10KG/DRUM
QUALITY BASIS: USP38			
CONCLUSION:IT IS MEETING THE ERQUIRENENTS OF USP 38			
QUALITATION LEADER	RECHECKER	ANALYST	

STIPULATION TEST

ITEMS TESTED	STIPULATION OF USP 38		RESULTS
CHARACTERISTICS	WHITE OR ALMOST WHITE CRYSTALLINE POWDER		CONFORM
IDENTIFICATION	IR	IR SPECTRUM SHOULD CORRESPOND TO THAT OF THE REFERENCE STANDARD	CONFORM
	HPLC	RETENTION TIME OF THE SAMPLE SHOULD BE CONSISTENT WITH THE REFERENCE	CONFORM
CRYSTALLINITY	MEETS THE REQUIREMENTS		CONFORM
PH	BETWEEN 3. 5 AND 4. 5		3. 8
WATER	NOT MORE THAN 6. 0%		0. 5%
BACTERAL ENDOTOXINS	≤0.58 E.U.OF ENDOTOXINS PER MILLIGRAM		CONFORM
RELATED SUBSTANCES	LINCOMYCIN PHOSPHATE ≤1. 0%		0. 4%
	LINCOMYCIN ≤0. 5%		0.008%
	CLINDAMYCIN B PHOSPHATE ≤1. 5%		0. 7%
	7-EPICLINDAMYCIN B PHOSPHATE≤0. 8%		0. 1%
	CLINDAMYCIN 3- PHOSPHATE≤0. 3%		0. 02%
	CLINDAMYCIN≤0. 5%		0. 1%
	INDIVIDUAL UNKNOWN IMPURITY≤1. 0%		0. 2%
	TOTAL IMPURITES≤4. 0%		2. 0%
RESIDUAL SOLVENTS	ETHANOL≤5000 PPM		46PPM
	ACETONE≤5000 PPM		NO DETECTED
	METHANOL≤3000PPM		NO DETECTED
	CHLOROFORM<60PPM		NO DETECTED
	DMF<200PPM		NO DETECTED
	PYRIDINE ≤200 PPM		NO DETECTED
POTENCY	NOT LESS THAN 758U/MG CLINDAMYCIN ON THE ANHYDROUS SUBSTANCE		822U/MG
PARTICLE SIZE	50%<50μm		10μm
	90%<90μm		30μm
	100%<200μm		100μm