

CERTIFICATE OF ANALYSIS

Product Name	Clindamycin phosphate	Batch NO.	RY190707
Production date	2019.07.07	Expired Date	2022.07.06
CAS NO.	24729-96-2	Standard	USP41
Tests	Limits	Test results	
Appearance	White to off-white, hygroscopic, crystalline powder, is odorless or practically odorless, and has a bitter taste	White, hygroscopic, crystalline powder, is odorless, and has a bitter taste	
Solubility	Freely soluble in water, slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically in soluble in chloroform, in benzene, and in ether	Conforms	
Identification	IR: consistent with that obtained with Clindamycin phosphate reference standard.	Conforms	
	IR: the retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Conforms	
Crystallinity	Meets the requirements	Conforms	
PH	3.0~4.5	3.8	
Water	≤6.0%	1.0%	
Bacterial endotoxin	≤0.58IU/mg	<0.58IU/mg	
Related substances	Lincomycin phosphate ≤1.0%	0.3%	
	Lincomycin ≤5.0%	N.D.	
	Clindamycin B phosphate ≤1.5%	0.6%	
	7-Epiclindamycin phosphate≤0.8%	0.3%	
	Clindamycin 3-phosphate≤0.3%	0.1%	

	Clindamycin $\leq 0.5\%$	0.1%
	Any single impurity $\leq 1.0\%$	0.3%
	The total impurities $\leq 4.0\%$	2.1%
Residual solvents	Ethanol $\leq 5000\text{ppm}$	472ppm
	Acetone $\leq 5000\text{ppm}$	N.D.
	Chloroform $\leq 60\text{ppm}$	N.D.
	Pyridine $\leq 200\text{ppm}$	N.D.
Microbial limit	Total number of aerobe $\leq 800\text{cfu/g}$	2cfu/g
	Total yeasts&moulds count $\leq 80\text{cfu/g}$	$< 1\text{cfu/g}$
	Escherichia coli:absent	N.D.
Assay	$\geq 780 \mu\text{g/mg}$	838 $\mu\text{g/mg}$
Conclusion: This batch meets USP41&in-house standard.		

Tested by: Esther

Checked by: Alice

Approved by: Mich