

**ZHEJIANG HISOAR CHUANNAN PHARMACEUTICAL CO.,LTD.**No.23, 5<sup>th</sup> Donghai Avenue Zhejiang Chemical materials base Linhai zone, Zhejiang, P.R. China

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**Certificate of Analysis**

No.: 21P-006-187

Date: Jul. 20, 2021

ORIGINAL

<b>Product Name</b>	<b>Clindamycin Phosphate</b>		
<b>According to</b>	USP43		
<b>Batch No.</b>	P-006-CN20210701	<b>Net Weight</b>	75kgs
<b>Mfg. Date</b>	Jul. 01, 2021	<b>Retest Date</b>	Jun. 30, 2024
<b>Exp. Date</b>	Jun. 30, 2025		

Testing Items	Specifications	Results
Identification	A: IR spectrum	Complies
	B: The retention time of the major peak of the sample solution corresponds to that of the standard solution ( as obtained in the Assay )	Complies
Crystallinity	Meets the requirements	Complies
pH	Between 3.5 and 4.5	3.9
Water	Max.6.0%	0.5%
Bacterial endotoxins	Max. 0.58EU/mg	<0.58EU/mg
Assay	Min. 758µg/mg(dried basis)	824µg/mg
Individual impurities		
Lincomycin-2-phosphate	≤1.0%	0.22%
Lincomycin	≤0.5%	<0.05%
Clindamycin-B-phosphate	≤1.5%	0.39%
7-Epiclindamycin-2-phosphate	≤0.8%	0.07%
Clindamycin	≤0.5%	0.11%
Clindamycin-3-phosphate	≤0.3%	0.09%
Any other detected individual impurity	≤1.0%	0.06%
Total impurities	≤4.0%	0.94%
Residual solvent		
Chloroform	≤60ppm	<0.4ppm
Pyridine	≤100ppm	<0.6ppm
Ethanol	≤5000ppm	467ppm
Acetone	≤1000ppm	<0.3ppm

浙江海翔川南药业有限公司  
ZHEJIANG HISOAR CHUANNAN PHARMACEUTICAL CO., LTD.

<b>Conclusion</b>	Complies with USP43
<b>Manufacture address</b>	No.23, 5 <sup>th</sup> Donghai Avenue Zhejiang Chemical materials base Linhai zone, Zhejiang, P.R. China
<b>Remarks</b>	Kept in airtight container.

Analyst/Date: 任桂英 2021-07-20

Checker/Date: 任桂英 2021-07-20

QC Dept. Manager/Date: 任桂英 2021-07-20

QA Dept. Approver/Date: 任桂英 2021-07-20