

ZHEJIANG HISOAR CHUANNAN PHARMACEUTICAL CO.,LTD.

No.23, 5th Donghai Avenue Zhejiang Chemical materials base Linhai zone, Zhejiang, P.R. China

Tel. No.:+86-(576)-89088197 Fax No.:+86-(576)-89088258

Certificate of Analysis

No.: 21P-006-187

Date: Jul. 20, 2021

ORIGINAL

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

| | |
|----------------------------|--|
| Conclusion | Complies with USP43 |
| Manufacture address | No.23, 5 th Donghai Avenue Zhejiang Chemical materials base Linhai zone, Zhejiang, P.R. China |
| Remarks | 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