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ZHEJIANG TIAN TAI PHARMACEUTICAL CO., LTD.

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## CERTIFICATE OF ANALYSIS

Report No. 12-0055Name of product Clindamycin HydrochlorideMaterial No. 04003DBatch No. 120609X8Quantity 223.10KgPackage 25Kg/DrumMfg Date 2012-06-05Report Date 2012-06-10Retest Date 2015-06-05

| Items                     | Specification                                              | Results                  |
|---------------------------|------------------------------------------------------------|--------------------------|
| Characters                | White or almost white crystalline powder                   | White crystalline powder |
| Solubility                | Very soluble in water, slightly soluble in alcohol.        | Conform                  |
| Identification            | A. IR Conform                                              | Conform                  |
|                           | D. Chlorides reaction Conform                              | Conform                  |
| Specific optical rotation | +135°~ +150°                                               | +143°                    |
| pH                        | 3.0~5.0                                                    | 3.8                      |
| Related Substances        | Clindamycin B ≤2.0%                                        | 0.57%                    |
|                           | 7-epiclindamycin ≤4.0%                                     | 0.94%                    |
|                           | Any other impurity ≤1.0%                                   | 0.21%                    |
|                           | Total of impurity ≤6.0%                                    | 2.2%                     |
| Residual solvents         | Acetone ≤5000ppm                                           | 164ppm                   |
|                           | Ethanol ≤5000ppm                                           | No detected              |
|                           | N,N-Dimethylformamide ≤880ppm                              | No detected              |
|                           | Chloroform ≤60ppm                                          | No detected              |
| Water                     | 3.0~6.0%                                                   | 4.1%                     |
| Sulphated ash             | ≤0.5%                                                      | 0.06%                    |
| Assay                     | Anhydrous substance, 91.0~102.0% $C_{18}H_{34}Cl_2N_2O_5S$ | 98.6%                    |
| Conclusion                | Complies with EP7.0                                        |                          |

QC 陆明

QA 陆明