

## 寿光富康制药有限公司

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## CERTIFICATE OF ANALYSIS

REPORT NO: QC16120234

REGISTER NO: ZLJL-0510-02

REGISTER NO. 2202 0010 02

|                                                                                     |                                                                                                          |               |                     |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|---------------|---------------------|
| PRODUCT                                                                             | Trimethoprim                                                                                             | PHARMACOPOEIA | EP8.0               |
| BATCH NO.                                                                           | A-20111612003                                                                                            | GROSS WEIGHT  | 27.5 Kg/Drum        |
| BATCH QUANTITY                                                                      | 2000Kg                                                                                                   | NET WEIGHT    | 25Kg/Drum           |
| MANUFACTURE DATE                                                                    | DEC.02,2016                                                                                              | RETEST DATE   | NOV.2021            |
| ANALYSIS DATE                                                                       | DEC.03,2016                                                                                              | REPORT DATE   | DEC.10,2016         |
| TEST ITEM                                                                           | STANDARDS REQUIRED                                                                                       |               | TEST RESULTS        |
| Characters                                                                          | white or yellowish-white powder                                                                          |               | Almost white powder |
| Identification                                                                      |                                                                                                          |               |                     |
| C:IR                                                                                | IR Conforms to the CRS (2.2.24)                                                                          |               | Complies            |
| Test                                                                                |                                                                                                          |               |                     |
| Appearance of solution                                                              | The solution is not more intensely coloured than reference solution BY <sub>7</sub> (2.2.2, Method II ). |               | Complies            |
| Related substances(HPLC)                                                            | (2.2.29)                                                                                                 |               |                     |
| A:                                                                                  |                                                                                                          |               |                     |
| Any impurity                                                                        | ≤0.10%                                                                                                   |               | 0.03%               |
| Total impurities                                                                    | ≤0.2%                                                                                                    |               | 0.05%               |
| B:                                                                                  |                                                                                                          |               |                     |
| Any impurity                                                                        | ≤0.10%                                                                                                   |               | 0.03%               |
| Total impurities                                                                    | ≤0.2%                                                                                                    |               | 0.04%               |
| Impurity K. (GC)                                                                    | ≤5ppm (2.2.28)                                                                                           |               | 1.4ppm              |
| Heavy metals                                                                        | ≤20ppm(2.4.8)                                                                                            |               | <20ppm              |
| Loss on drying                                                                      | ≤1.0% (2.2.32)                                                                                           |               | 0.2%                |
| Sulphated ash                                                                       | ≤0.1%(2.4.14)                                                                                            |               | 0.04%               |
| Assay% on dry basis                                                                 | 98.5%-101.0%(2.2.20)                                                                                     |               | 100.1%              |
| Results: The commodity meets the standard of EP8.0. COS No. R1-CEP 2005-115-Rev 01. |                                                                                                          |               |                     |

Examiner: Wang Xiaohong

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Checker: Liu Xiaoping

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