



SHANDONG LUKANG SHELILE PHARMACEUTICAL CO., LTD

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Lote: 0210315

### Certificate of Analysis

|               |                                     |
|---------------|-------------------------------------|
| Date of Issue | JUN. 10, 2014                       |
| Product Name  | Tylosin Tartrate For Veterinary Use |
| Batch No.     | 1405092                             |
| Quantity      | 729.600BOU                          |
| Net Weight    | 800KG                               |
| Packing       | 25KG/Drum                           |
| Mfg. Date     | MAY. 26, 2014                       |
| Exp. Date     | MAY. 25, 2017 ✓                     |

| Items                                    | Specifications                                             | Results                |
|------------------------------------------|------------------------------------------------------------|------------------------|
| Description                              | Almost or slightly yellow powder ✓                         | Almost white powder ✓  |
| Identification                           | A: IR absorption; ✓<br>B: HPLC; ✓<br>C: Colour reaction. ✓ | Conform ✓              |
| pH                                       | 5.0~7.2 ✓                                                  | 5.8 ✓                  |
| Unknown impurity 1 (RRT≈0.40)            | ≤0.4% ✓                                                    | Not detected ✓         |
| Desmycinostylosin (RRT≈0.47)             | ≤2.0% ✓                                                    | 0.8% ✓                 |
| Unknown impurity 2 (RRT≈0.77)            | ≤1.0% ✓                                                    | Not detected ✓         |
| Tylosin A Aldol (RRT≈0.87)               | ≤0.4% ✓                                                    | 0.2% ✓                 |
| Unknown impurity 3 (RRT≈1.69)            | ≤0.4% ✓                                                    | Not detected ✓         |
| Any other detectable impurity (RRT≈0.74) | ≤0.2% ✓                                                    | 0.2% ✓                 |
| Tylosin A                                | ≥80.0% ✓                                                   | 93.4% ✓                |
| Tylosins (A+B+C+D)                       | ≥95.0% ✓                                                   | 98.7% ✓                |
| Loss on drying                           | ≤4.5% ✓                                                    | 1.4% ✓                 |
| Sulphated ash                            | ≤2.5% ✓                                                    | 0.1% ✓                 |
| Tyramine                                 | ≤0.35% ✓                                                   | ≤0.35% ✓               |
| Butyl acetate by GC                      | ≤0.05% ✓                                                   | Not detected ✓         |
| Assay (on anhydrous basis)               | ≥800 IU/mg ✓                                               | 926IU/mg ✓             |
| MICROBIOLOGY                             | TAMC≤1000 cfu/g ✓<br>TYMC≤100 cfu/g ✓                      | 220cfu/g ✓<br>0cfu/g ✓ |

CONCLUSION: THE ABOVE RESULTS COMPLY WITH EP8.0; COS NO: R1-CEP 2001-186-Rev 01 ✓

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Quality Assurance

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