



SHANDONG LUKANG SHELILE PHARMACEUTICAL CO., LTD

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Lot: 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; ✓ B: HPLC; ✓ 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 ✓ TYMC≤100 cfu/g ✓	220cfu/g ✓ 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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