



山东鲁抗生物制造有限公司

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CERTIFICATE OF ANALYSIS

COA No.: 0110

Product name: Tylosin Tartrate

Issuing Date: 2019 / 09 / 26

Batch No.: T1909206

MFG. Date: 2019 / 09 / 20

Packing size: 25kg/drum

EXP. Date: 2022 / 09 / 19

Quantity: 131 drums 3275kg / 3029.375BOU

Workshop: 607

Reference: EP 9.3

Item		Specification	Result
Appearance		Almost white or slightly yellow powder	Slightly yellow powder
Solubility		Freely soluble in water, in ethanol (96%) and in methylene chloride, practically insoluble in heptane.	Conform
Identification		A. IR test: identified with Tylosin tartrate CRS.	Positive
		B. Reaction: a green colour is produced.	Positive
Appearance of solution		The solution is clear and not more intensely coloured than reference solution Y ₃	Clear, <Y ₃
pH		5.0 ~ 7.2	5.4
Composition	Tylosin A	≥80.0%	93.7%
	Sum of tylosin A, B, C and D	≥95.0%	98.1%
Related substances	Impurity A	≤2.0%	0.68%
	Sum of impurities eluting between impurity A and Tylosin C	≤2.0%	0.55%
	Impurity N	≤1.0%	0.23%
	Impurity O	≤1.0%	0.10%
	Impurity E	≤0.5%	0.05%
	Impurity R	≤0.5%	0.04%
	Impurity S	≤0.5%	0.11%
	Any other impurity	≤0.50%	Not detected
	Total impurities	≤5.0%	1.9%
Tyramine		≤0.35%	<0.35%
Loss on drying		≤4.5%	2.7%
Sulfated ash		≤2.5%	0.1%
Assay as is basis		—	925IU/mg
Assay (dried basis)		Not less than 900 IU/mg	951IU/mg

Conclusion: The above results comply with EP9.3. ☒

Remarks: —

Reporter: 胡明

Reviewer: 王浩华

袁红丽 2019年09月27日

QC Manager: 何松