

Lot: 2080619



# 山东鲁抗生物制造有限公司

Shandong Lukang Biomanufacturing Co., Ltd.

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## CERTIFICATE OF ANALYSIS

COA No.: 0044

Product name: Tylosin Tartrate	Issuing Date: 2019 / 04 / 25
Batch No.: T1904095	MFG. Date: 2019 / 04 / 20
Packing size: 25kg/drum	EXP. Date: 2022 / 04 / 19
Quantity: 99 drums 2475kg / 2289.375 BOU	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 <sub>3</sub>	Clear, <Y <sub>3</sub>
pH	5.0 ~ 7.2	5.6
Composition	Tylosin A	≥80.0%
	Sum of tylosin A, B, C and D	≥95.0%
Related substances	Impurity A	≤2.0%
	Sum of impurities eluting between impurity A and Tylosin C	≤2.0%
	Impurity N	≤1.0%
	Impurity O	≤1.0%
	Impurity E	≤0.5%
	Impurity R	≤0.5%
	Impurity S	≤0.5%
	Any other impurity	≤0.50%
	Total impurities	≤5.0%
Tyramine	≤0.35%	<0.35%
Loss on drying	≤4.5%	2.6%
Sulfated ash	≤2.5%	0.3%
Assay as is basis	—	925 IU/mg
Assay (dried basis)	Not less than 900 IU/mg	950 IU/mg

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

Remarks: —

Reporter: 胡明

Reviewer: 桑宇萍

QC Manager: 周松