



山东鲁抗生物制药有限公司

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CERTIFICATE OF ANALYSIS

COA No.:0029

Product name:Tylosin Tartrate	Issuing Date: 2020 / 10/20
Batch No.:T2010243	MFG Date: 2020/ 10/01
Packing size:25kg/drum	Retest Date: 2023 / 09/30
Quantity: 172drums 4300kg / 3947.400BOU	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	5.6
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%
	Any unspecified impurity	≤0.20%
	Total impurities	≤5.0%
Tyramine	≤0.35%	<0.35%
Loss on drying	≤4.5%	2.3%
Sulfated ash	≤2.5%	0.2%
Assay (dried basis)	Not less than 900 IU/mg	940IU/mg
Butyl acetate (in-house)	≤5000ppm	446ppm
Microbiology (in-house)	TAMC≤1000 cfu/g	100cfu/g
	TYMC≤ 100 cfu/g	10cfu/g
Histamine	≤2ppm	<2ppm

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

Remarks: R0-CEP 2015-379-Rev 00

Reporter: 胡红艳

Reviewer: 桑宇萍

QC Manager: 王利军

