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METAPHARMACEUTICAL

N DE LOTE: 017122

酒石酸泰乐菌素检验报告
Certificate of Analysis for Tylosin Tartrate

25/11/2022

LK 舍 QC-TYT-02（6）-07

报告编号（COA No.）：020	报告日期（Date of Issue）：10/03/2022(M/D/Y)
批　　号（Batch No.）：TYTB2209185	生产日期（MFG. Date）：09/18/2022(M/D/Y)
包装规格（Packing）：25kg/Drum（Tailing16.78kg）	复验期至（Retest Date）：09/17/2025(M/D/Y)
数量（Quantity）：181Drums，4516.78kg，4051.552Bou	生产单位（Manufacturer）：Shelile Company Workshop 607

检验依据：《酒石酸泰乐菌素欧洲注册质量标准》（Test criteria：EU Registration Specification of Tylosin Tartrate）

检验项目 (Items)	标准规定 (Specifications)	检验结果 (Results)	项目结论 (Conclusion)
【外观】Appearance	Almost white or slightly yellow powder	Almost white powder	Conform
【溶解性】Solubility	Freely soluble in water, in ethanol(96%) and in methylene chloride, practically insoluble in heptane.	Conform	Conform
【鉴别】Identification	IR test:Complies with reference	Conform	Conform
	Reaction:Green colour	Conform	Conform
【溶液外观】Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y_3	Conform	Conform
【pH】	5.0—7.2	6.1	Conform
【酪胺】Tyramine	≤0.35%	<0.15%	Conform
【组份】Composition	A≥80.0%	93.5%	Conform
	A+B+C+D≥95.0%	98.4%	Conform
【有关物质】Related substances	impurity A: Maximum 2.0%	0.46%	Conform
	sum of impurities eluting between impurity A and tylosin C: Maximum 2.0%	0.28%	Conform
	impurity N: Maximum 1.0%	0.17%	Conform
	impurity O: Maximum 1.0%	0.07%	Conform
	impurity E: Maximum 0.5%	0.06%	Conform
	impurity R: Maximum 0.5%	0.20%	Conform
	impurity S: Maximum 0.5%	0.22%	Conform
	any other specified impurity :Maximum 0.50%	Not detected	Conform
	any other unspecified impurity : Maximum 0.20%	Not detected	Conform
	total impurity :Maximum 5.0%	1.7%	Conform
【干燥失重】Loss on Drying	≤4.5%	2.9%	Conform
【硫酸灰分】Sulphated ash	≤2.5%	0.1%	Conform
【干品含量】Assay (dried basis)	Not less than 900IU/mg	924IU/mg	Conform
【组胺】Histamine	Not more than 2ppm	Not detected	Conform
【乙酸丁酯】Butyl Acetate	≤5000ppm	418ppm	Conform
【微生物限度】Microbial Limit	TAMC Not more than 1000cfu/g	100cfu/g	Conform
	TYMC Not more than 100cfu/g	5cfu/g	Conform

结论：本品以上项目按照《欧洲注册质量标准》现行版检验，结果符合规定。
Conclusion:The above test results conform to EP10.0
备注(Remarks)：COS NO.:RO-CEP 2015-379-Rev 01

报告人 Reporter 周桂弘　　复核人 Reviewer 王冰　　质检负责人 QC Manager