

Lot: 0580118

Tai Rui
泰瑞制药

宁夏泰瑞制药股份有限公司
NINGXIA TAIRUI PHARMACEUTICAL CO., LTD

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分析证

CERTIFICATE OF ANALYSIS

Batch C91170909 Has Been Manufactured In Full Compliance With GMP Number (2016) SHOUYAO GMP ZHENGZI 30001 And Batch C91170909 Production Record Checked And Approved, No Deviation, No Reworking And Reprocessing.

品名 Product name	酒石酸泰乐菌素 Tylosin tartrate	检验单号 COA No	a600
批号 Batch NO.	C91170909	包装规格 Packing	15kg/箱(Carton)
数量 Quantity	1170kg(1087.632kga)	生产日期 Mfg. date	Sep.04.2017
有效期 Expiry date	Sep.03.2020	分析日期 Analysis Date	Sep.13.2017
Quality Standard	RO-CEP 2014-123-Rev 00		
检测依据 Test method	《欧洲药典》EP		
检验项目 Test Items	标准规定 Specifications	检验结果 Test Results	项目结论 Items Conclusion
性状 Description	应为类白色或淡黄色粉末, 具有吸湿性。 Almost white or slight yellow powder, hygroscopic.	本品为淡黄色粉末, 具有吸湿性 Pale yellow powder, hygroscopic	符合规定 Complies
溶解性 Solubility	本品易溶于水 and 二氯甲烷, 微溶于无水乙醇, 可溶于稀的无机酸溶液。 Freely soluble in methylene chloride; slightly soluble in anhydrous ethanol. It dissolves in dilute solutions of mineral acids.	符合规定 Complies	符合规定 Complies
溶液的外观 Appearance of solution	溶液应澄清: 颜色应<Y _s The solution is clear, and not more intensely coloured than reference solution Y _s	符合规定 Complies	符合规定 Complies
鉴别 Identification	呈正反应 Positive	呈正反应 Positive	符合规定 Complies
	HPLC 色谱图应符合规定 Conforms HPLC Chromatogram	符合规定 Complies	符合规定 Complies
	红外光谱图应符合规定 Conforms IR Spectrum	符合规定 Complies	符合规定 Complies
pH	5.0-7.2	6.22	符合规定 Complies
干燥失重 Loss on drying	≤4.5%	2.16%	符合规定 Complies
炽灼残渣 Residue on Ignition	≤2.5%	0.36%	符合规定 Complies
酪胺 Tyramine	样品溶液吸收度不得大于对照品溶液吸收度 (≤0.35%) Absorption of sample solution is not more than the control solution	0.04%	符合规定 Complies
泰乐菌素组分 Tylosin Compositions	Tylosin A ≥80.0% A+B+C+D ≥95%	92.80% 98.11%	符合规定 Complies
残留溶剂 Limit of residual solvents	乙酸丁酯 ≤5000ppm butyl acetate ≤5000ppm	1240ppm	符合规定 Complies
	正丁醇 ≤5000ppm n-butyl alcohol ≤5000ppm	3960ppm	符合规定 Complies
	杂质 A (Impurity A) ≤1.0%	0.74%	符合规定 Complies
有关物质 Related Substances (%)	杂质 J (Impurity J) ≤0.5%	0.11%	符合规定 Complies
	杂质 N (Impurity N) ≤0.5%	0.21%	符合规定 Complies
	杂质 O (Impurity O) ≤0.5%	<DL	符合规定 Complies
	杂质 G+H+I (Sum of Impurity G,H,I) ≤1.0%	0.28%	符合规定 Complies
	杂质 E (Impurity E) ≤0.50%	<DL	符合规定 Complies
	杂质 R (Impurity R) ≤0.50%	<DL	符合规定 Complies
	杂质 S (Impurity S) ≤0.50%	<DL	符合规定 Complies
	杂质 Q (Impurity Q) ≤0.3%	0.12%	符合规定 Complies
	其它杂质 (Any other Imp.) ≤0.20%	<DL	符合规定 Complies
	总质 (Total Imp.) ≤5.0%	1.46%	符合规定 Complies
	杂质 B (Impurity B) ≤1.0%	0.52%	符合规定 Complies
	杂质 EE (Impurity EE) ≤0.50%	0.36%	符合规定 Complies
含量 Potency	≥800u/mg	929.6u/mg 950.1u/mg (干品)	符合规定 Complies
结论 Conclusion	经检验, 本品符合《欧洲药典》的规定。 Complies with the specification of EP.		

编制人:

Prepared by:

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