



新昌县九信药业有限公司
Xinchang JiuXin Pharmaceutical Co.,Ltd

质量检测报告书 Certificate of analysis

报告单编号 (COA NO.) D-QA701-F05-R00

检字号 (serial no.) DK03-1501242-01

检品名称 product	恩诺沙星 enrofloxacin	批号 batch no.	DK03-1501242
包装 packaging size	25kg/桶 (drum)	数量 quantity	625.00kg
生产日期 MFG DATE	24/01/2015(d/m/y)	报告日期 reporting date	25/01/2015 (d/m/y)
标准执行 according to	欧洲药典 7.0 EP7.0	复测日期 retest date	23/01/2017 (d/m/y)

Tests	acceptance criteria	results
appearance	Pale yellowish or light yellow crystalline powder	light yellow crystalline powder
identification	IR: conforms to the spectrum of reference spectrum.	Conforms
Clarity &Color of solution	the solution should be clear or it is not more opalescent than reference suspension II and not more intensely colored than reference solution YG4	Conforms
Related substances	Impurity A $\leq 0.2\%$	$\leq 0.2\%$
	Impurity B $\leq 0.5\%$	0.04
	Impurity C $\leq 0.2\%$	0.01
	Unspecified impurity $\leq 0.20\%$	0.07
	total impurities $\leq 1.0\%$	0.16
heavy metals	$\leq 20\text{ppm}$	$< 20\text{ppm}$
loss on drying	$\leq 1.0\%$	0.09
sulfated ash	$\leq 0.1\%$	0.04
residual solvents	N-ethyl piperazine $\leq 0.5\%$	Not found
	Isoamyl alcohol $\leq 0.5\%$	Not found
	Ethanol $\leq 0.5\%$	0.01
	DMSO $\leq 0.5\%$	Not found
assay(on dried basis)	C ₁₉ H ₂₂ FN ₃ O ₃ 98.5%~101.5%	99.5%

Conclusion: conforms to EP7.0

Reported by: Cai lanlan

Reviewed by: Pan fangfang

Approved by: Cai lanlan