



浙江国邦药业有限公司

ZHEJIANG GUOBANG PHARMACEUTICAL CO., LTD.

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质量检验报告书

CERTIFICATE OF ANALYSIS

ORDER NO.: 45106302

检字号 (Serial No.) F4061307079

产品名称 Product	恩诺沙星 enrofloxacin	批号 Batch No.	130716-3
包装 Packaging Size	25Kg/drum	数量 Batch Size	800Kg
生产日期 MFG DATE	16/07/2013 (d/m/y)	检测日期 Testing Date	19/07/2013 (d/m/y)
检验依据 According to	欧洲药典 (EP7)	有效日期 Report Date	15/07/2016 (d/m/y)

检验项目 Tests		标准规定 Acceptance Criteria	检验结果 Results
性状 Description	Appearance	浅黄色或淡黄色结晶性粉末 Pale yellowish or light yellow, crystalline powder	符合规定 Conforms
	Solubility	几乎不溶于水, 易溶于二氯甲烷, 微溶于甲醇 Practically insoluble in water, freely soluble in methylene chloride, slightly soluble in methanol.	/
鉴别 Identification		IR: 红外光吸收图谱应与对照品的图谱一致 IR: Conforms to the spectrum of enrofloxacin CRS.	符合 Conforms
溶液外观 Appearance of solution		不深于 II 号浊度标准液和不深于黄绿色 4 号比色液。 Not more opalescent than reference suspension II and not more intensely coloured than reference solution GY ₄ .	符合 Conforms
杂质 A Impurity A		≤0.2%	符合 Conforms
有关物质 Related substance		(1) ≤0.5% (2) ≤0.2% (3) ≤0.20% (4) Total Impurities ≤1.0%	(1) 0.04% (2) 未检出 Not detected (3) 0.06% (4) 0.06%
干燥失重 Loss on drying		≤1.0%	0.07%
硫酸盐次分 Sulphated ash		≤0.1%	<0.01%
重金属 Heavy metals		≤20ppm	Conforms
残留溶剂 Residual solvents		(1) ≤200ppm (2) ≤100ppm (3) ≤200ppm (4) ≤100ppm (5) N,N-dimethylformamide ≤800ppm	/
含量 Assay (dried substance)		按干燥品计算, 含 C ₁₉ H ₂₂ FN ₃ O ₃ 应为 98.5%~101.5%。 98.5%~101.5% (dried substance)	100.3%

结论: 本品按欧洲药典 7 版标准检验, 结果符合规定

Conclusion: Conforms to EP7 specification for enrofloxacin.

备注 (Note): * Once every 3 months N,N-dimethylformamide: Once a year

报告人: 郭建颖
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FAGRON IBÉRICA, S.A.U.
Corresponde al lote de Fagron:

U3110173

Director Técnico