



# CERTIFICADO DE ANÁLISIS (COA)

Producto: **Enrofloxacin**

CAS N°: **93106-60-6**

## CERTIFICATE OF ANALYSIS

报告单编号 (COA NO.) TS-QCSA00107001-Report01-07

检字号 (Serial No.) F4062109048

检品名称 Product	恩诺沙星 Enrofloxacin	批号 Batch No.	210912-2
包装 Packaging Size	25kg/桶 (drum)	批量 Batch Size	1202.22Kg
生产日期 MFG Date	12/09/2021 (d/m/y)	报告日期 Reporting Date	15/09/2021 (d/m/y)
执行标准 According to	中国兽药典 2020 年版一部 CVP 2020( I )	复测日期 Retest Date	11/09/2024 (d/m/y)
发货数量 Shipped quantity			

检验项目 Tests	标准规定 Acceptance Criteria	结果 Results
性状 Description	Appearance 微黄色或淡橙黄色结晶性粉末;无臭, 遇光色渐变为橙红色。 Slightly yellow or pale orange-yellow crystalline powder, odorless, The crystals gradually become orange-red under day light.	微黄色结晶性粉末 Slightly yellow crystalline powder
	Solubility 在三氯甲烷中易溶, 在二甲基甲酰胺中略溶, 在甲醇中微溶, 在水中极微溶解; 在氢氧化钠试液中微溶。 Freely soluble in chloroform, sparingly soluble in dimethyl-formamide, slightly soluble in methanol and in sodium hydroxide TS, very slightly soluble in water .	/
熔点 Melting range	221~226°C	222.5-225.0°C
鉴别 Identification	(1) HPLC: 供试品溶液主峰保留时间应与对照品主峰保留时间一致。 HPLC: The retention time of the major peak of the Sample solution corresponds to that of the Standard solution .	符合 Conforms
	(2) IR: 红外光吸收图谱应与对照的图谱一致 IR: Conforms to the reference spectrum.	符合 Conforms
溶液澄清度 Clarity of solution	应澄清 Clear (1g/20ml in 0.5mol/L NaOH Solution )	符合 Conforms
溶液颜色 Colour of solution	不深于黄色或黄绿色 4 号标准比色液 (1g/20ml in 0.5mol/L NaOH Solution) Not more intensely coloured than Y <sub>4</sub> or GY <sub>4</sub>	符合 Conforms
氟喹啉酸 (TLC) Fluoroquinolonic acid	≤0.2%	<0.2%
有关物质 (HPLC) Related substances	(1) 环丙沙星 Ciprofloxacin	≤0.5% 0.04%
	(2) 其它任何单个杂质 Any other single impurity	≤0.3% 0.11%
	(3) 总杂质 Total impurities	≤0.7% 0.11%
干燥失重 Loss on drying	≤0.5%	0.06%
炽灼残渣 Residue on ignition	≤0.2%	0.02%
重金属 Heavy metals	≤20ppm	<20ppm
含量 Assay	按干燥品计算, 含 C <sub>19</sub> H <sub>22</sub> FN <sub>3</sub> O <sub>3</sub> 应不得少于 99.0%。 ≥99.0% (Dried substance)	100.1%

结论: 本品按中国兽药典 2020 年版一部标准检验, 结果符合规定

Conclusion: Conforms to Chinese Veterinary Pharmacopoeia 2020 ( I ) specification for enrofloxacin.

备注(note): 用于外贸

After risk evaluation, elemental impurities meet the requirements.

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El presente documento es copia fiel del original.