



Test report

测试报告

Sample Information			
样品信息			
Sample Name 样品名称	Norfloxacin Lactate 乳酸诺氟沙星	Sample properties 样品性状	Solid 固体
Date of receipt 收样日期	2025/09/11	During testing 测试期间	2025/09/12 ~ 2025/09/18
Test the ingredients and structural formula			
测试成分及结构式			
 Norfloxacin Lactate 乳酸诺氟沙星			
Experimental Requirements			
实验要求			
<p>The peak shape of norfloxacin needs to be improved. The blank solvent shows no interference. In the chromatogram of the reference solution, the theoretical plate number of the main peak, calculated based on norfloxacin, should be not less than 1500.</p> <p>诺氟沙星峰峰型需改善, 空白溶剂无干扰, 对照品溶液图中, 主峰理论塔板数按诺氟沙星计算应不低于 1500。</p>			
Reference Method			
参考方法			
/			
Reagent information			
试剂信息			
Reagent Name	Grade	Brand	

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试剂名称	级别	品牌
Water 水	Ultrapure water 超纯水	Welch 月旭
Acetonitrile 乙腈	HPLC 色谱级	Welch 月旭
Phosphoric acid 磷酸	AR 分析级	Aladdin 阿拉丁
Triethylamine 三乙胺	AR 分析级	Aladdin 阿拉丁
Instrument Information 仪器信息		
Test instruments 测试仪器	Instrument Model 仪器型号	
High Performance liquid chromatograph 高效液相色谱仪	Agilent 1260	

1. Test process:

试验过程

1.1. Chromatographic conditions:

色谱条件

Chromatographic column: 色谱柱	Ultimate XB-C18 (4.6×150mm,3μm)
Mobile phase: 流动相	0.025 mol/L phosphoric acid solution (adjusted to pH 2.2 with triethylamine) - acetonitrile (87:13) 0.025mol/L 磷酸溶液 (用三乙胺调节 pH 至 2.2) - 乙腈 (87:13)
Flow rate: 流速	1.0 mL/min
Injection volume: 进样量	20μL
Column temperature: 柱温	35 °C
Detector: 检测器	UV
Detection wavelength: 检测器波长	278nm
Gradient program: 梯度程序	isocratic elution 等度
Notes 注意事项	/

1.2. Solution preparation (溶液配制)

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1.2.1. Preparation of mobile phase (流动相配制):

0.025 M Phosphoric Acid Solution: Weigh 2.45 g of phosphoric acid, dissolve it in pure water to a total volume of 1000 ml, and after dissolving thoroughly, adjust the pH to 2.2 with triethylamine; the solution is obtained.

0.025M 磷酸溶液: 称取磷酸 2.45g 溶于至 1000ml 纯水中, 充分溶解后使用三乙胺调节 pH 至 2.2, 即得。

Measure 870 ml of 0.025 M phosphoric acid solution and 130 ml of ultrapure water, mix them thoroughly, then perform suction filtration to obtain the solution.

量取 0.025M 磷酸溶液 870ml, 超纯水 130ml, 充分混匀后抽滤即得。

1.2.2. Blank solution、Diluent (空白溶液、稀释剂):

Pure water.

纯水

0.1 M Hydrochloric Acid Solution: Measure 9 ml of hydrochloric acid, place it in a 1000 ml volumetric flask, dissolve it with an appropriate amount of ultrapure water, cool it down to room temperature, then dilute it to the mark, shake well, and the solution is obtained.

0.1M 盐酸溶液: 量取 9ml 盐酸置 1000ml 量瓶中, 用超纯水适量溶解, 放冷至室温, 并稀释至刻度, 摇匀, 即得。

1.2.3. Test solution (测试溶液):

Test solution: Take approximately 25 mg of Norfloxacin Lactate, accurately weigh it, place it in a 25 ml volumetric flask, add 2 ml of 0.1 M hydrochloric acid solution to dissolve it, dilute with water to the mark, and shake well; accurately measure 1.5 ml of the above solution, place it in a 50 ml volumetric flask, dilute with water to the mark, shake well, and the solution is obtained.

供试品溶液: 取乳酸诺氟沙星约 25mg, 精密称定, 置 25ml 量瓶中, 加 0.1M 盐酸溶液 2ml 使溶解, 用水稀释至刻度, 摇匀; 精密量取上述溶液 1.5ml 置 50ml 量瓶中, 用水稀释至刻度摇匀即得。

Reference substance solution: Take approximately 25 mg of norfloxacin reference substance, accurately weigh it, place it in a 25 ml volumetric flask, add 2 ml of 0.1 M hydrochloric acid solution to dissolve it, dilute with water to the mark, and shake well; accurately measure 1.5 ml of the above solution, place it in a 50 ml volumetric flask, dilute with water to the mark, shake well,

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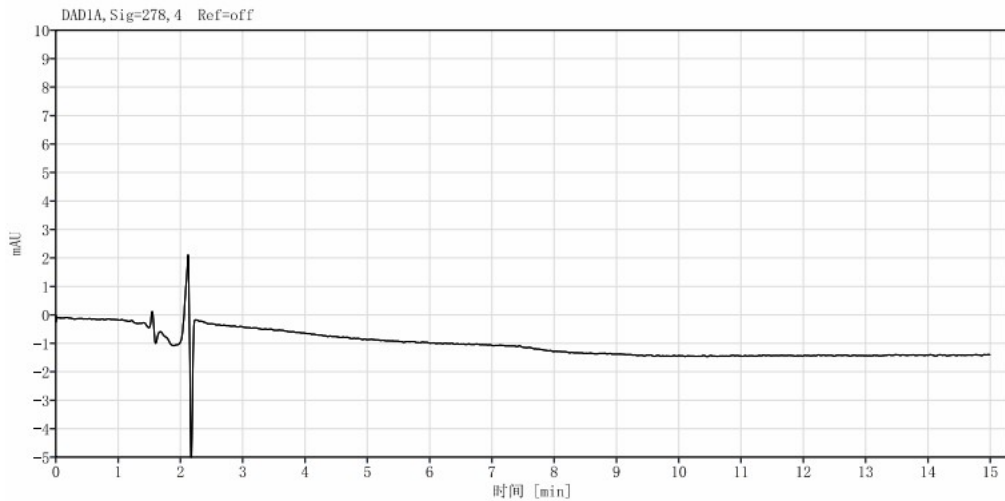


and the solution is obtained.

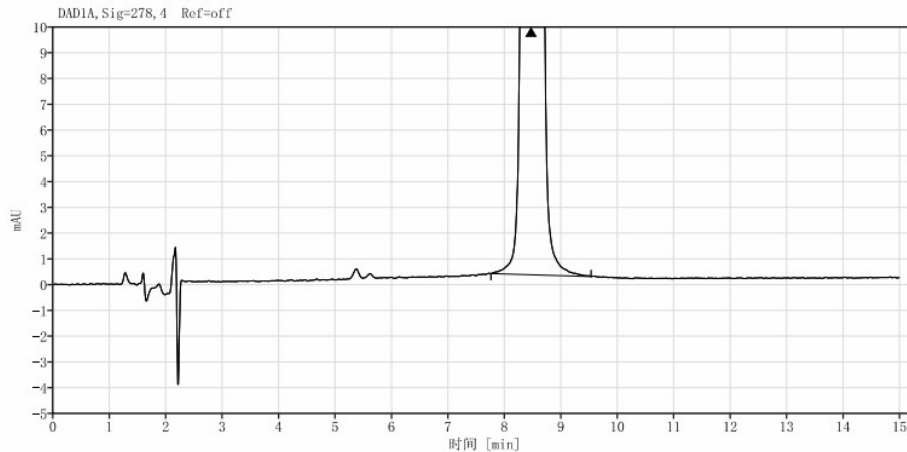
对照品溶液: 取诺氟沙星对照品约 25mg, 精密称定, 置 25ml 量瓶中, 加 0.1M 盐酸溶液 2ml 使溶解, 用水稀释至刻度, 摇匀; 精密量取上述溶液 1.5ml 置 50ml 量瓶中, 用水稀释至刻度摇匀即得。

2. Chromatogram and data (谱图和数据)

(1) Analysis spectrum of blank solvent (空白溶剂分析图谱):



(2) Analysis spectrum of Test solution (供试品溶液分析图谱):



信号: DAD1A, Sig=278, 4 Ref=off						
名称	保留时间 [min]	峰面积	峰面积%	塔板数	分离度	峰 拖尾因子
	8.47	3705.45	100.00	12388		1.12
总和		3705.45				

(3) Analysis spectrum of reference solution (对照溶液分析图谱):

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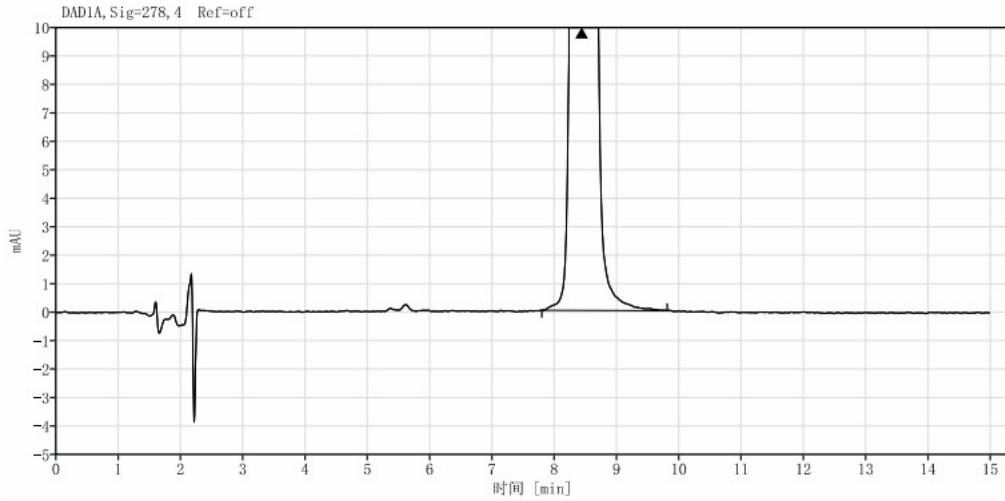
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信号: DAD1A, Sig=278, 4 Ref=off

名称	保留时间 [min]	峰面积	峰面积%	塔板数	分离度	峰拖尾因子
	8.44	4887.40	100.00	11504		1.17
总和		4887.40				

3. Conclusion (结论)

When analyzing the content of norfloxacin lactate under this chromatographic condition using the Welch Ultimate XB-C18 chromatographic column (4.6×150mm, 3μm), the fronting issue of the target compound peak can be effectively improved. This meets the customer's testing requirements.

使用月旭色谱柱 Ultimate XB-C18 (4.6×150mm, 3μm) 在此色谱条件下分析乳酸诺氟沙星含量, 目标物峰前沿问题可以有效改善, 满足客户检测检测需求。

Report signature (报告签字)

Tester(测试): Kaden (王进富)

Reviewer(审核): Jeff (王祝超)

Date (日期): 2025/09/18

Date (日期): 2025/09/18

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