



Test report

测试报告

Sample Information

样品信息

Sample Name 样品名称	Norepinephrine Bitartrate Injection 重酒石酸去甲肾上腺素注射液	Sample properties 样品性状	Liquid 液体
Date of receipt 收样日期	2025/10/30	During testing 测试期间	2025/10/30 ~ 2025/11/05

Test the ingredients and structural formula

测试成分及结构式



Experimental Requirements

实验要求

Under the premise that the detection method parameters and chromatographic column specifications (4.6 × 250 mm, 5 μm) remain unchanged, screen for other suitable C18 chromatographic columns. The specific requirements are as follows:

在检测方法参数和色谱柱规格（4.6*250mm，5μm）不变的前提下，筛其他适用的C18色谱柱，具体要求如下：

The chromatographic peak at around 2.5 minutes (i.e., the solvent peak) shall be a sharp peak and have good resolution from the chromatographic peak at around 3 minutes.

2.5分钟左右的色谱峰（即，溶剂峰）是尖峰，与3分钟左右的色谱峰分离度良好。

The main peak shall elute at approximately 6 minutes (±1 minute).

主峰需在约6分钟（±1分钟）出峰。

The selected chromatographic columns shall be easy to use and store, and columns requiring refrigerated storage shall be excluded.

所选色谱柱的使用与保存需操作简便，不要冷藏保存的柱子。

Reference Method

参考方法

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Chromatographic column: 色谱柱	十八烷基硅烷键合硅胶 (4.6*250mm, 5 μ m)		
Mobile phase A: 流动相 A:	<p>Take approximately 15.601 g of sodium dihydrogen phosphate (ranging from 14.0409 g to 17.1611 g) and about 0.5 g of sodium heptanesulfonate (ranging from 0.45 g to 0.55 g). Dissolve them in water and dilute the solution to 1000 milliliters. Adjust the pH value to 3.0\pm0.2 with phosphoric acid. After filtering through a 0.45 μm aqueous filter membrane and sonicating for 10 minutes, the desired solution is obtained.</p> <p>取磷酸二氢钠约 15.601g (14.0409g~17.1611g), 庚烷磺酸钠约 0.5g (0.45g~0.55g), 加水溶解至 1000ml, 用磷酸调节 pH 值至 3.0\pm0.2, 经 0.45μm 水膜滤过后, 超声 10 分钟后, 即得。</p>		
Mobile phase B: 流动相 B:	<p>Take 990 milliliters of methanol, add 10 milliliters of isopropanol, mix well. After filtering through a 0.45 μm organic filter membrane and sonicating for 10 minutes, the desired solution is obtained.</p> <p>取甲醇 990ml, 加异丙醇 10ml, 混匀, 经 0.45μm 有机滤膜过滤后, 超声 10 分钟后, 即得。</p>		
Flow rate: 流速	1.0 mL/min		
Injection volume: 进样量	20 μ L		
Column temperature: 柱温	25 $^{\circ}$ C		
Detector: 检测器	UV		
Detection wavelength: 检测器波长	280nm		
Gradient program 梯度程序	Gradient Elution 梯度洗脱		
	T (min)	流动相 A	流动相 B
	0	100	0
	4	100	0
	10	99	1
	20	70	30
	25	50	50
	25.1	100	0
35	100	0	
Reagent information 试剂信息			
Reagent Name 试剂名称	Grade 级别	Brand 品牌	
Water 水	Ultrapure water 超纯水	Welch 月旭	
Methanol 甲醇	HPLC 色谱级	Welch 月旭	

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Isopropyl Alcohol 异丙醇	HPLC 色谱级	Aladdin 阿拉丁
Sodium Dihydrogen Phosphate 磷酸二氢钠	AR 分析级	Aladdin 阿拉丁
Sodium Heptanesulfonate 庚烷磺酸钠	AR 分析级	Aladdin 阿拉丁
Phosphoric Acid 磷酸	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 1100	

1. Test process:**试验过程****1.1. Chromatographic conditions:****色谱条件**

Chromatographic column: 色谱柱	Ultimate AQ-C18 (4.6×250mm,5μm)
The other chromatographic parameters 其他色谱参数	For specific details, refer to the reference method. 详见参考方法
Notes 注意事项	/

1.2. Solution preparation (溶液配制)**1.2.1. Preparation of mobile phase (流动相配制):**

Mobile phase A: Take approximately 15.601 g of sodium dihydrogen phosphate (ranging from 14.0409 g to 17.1611 g) and about 0.5 g of sodium heptanesulfonate (ranging from 0.45 g to 0.55 g). Dissolve them in water and dilute the solution to 1000 milliliters. Adjust the pH value to 3.0±0.2 with phosphoric acid. After filtering through a 0.45 μm aqueous filter membrane and sonicating for 10 minutes, the desired solution is obtained.

流动相 A: 取磷酸二氢钠约 15.601g (14.0409g~17.1611g), 庚烷磺酸钠约 0.5g (0.45g~0.55g),

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加水溶解至 1000ml, 用磷酸调节 pH 值至 3.0 ± 0.2 , 经 $0.45 \mu\text{m}$ 水膜滤过后, 超声 10 分钟后, 即得。

Mobile phase B: Take 990 milliliters of methanol, add 10 milliliters of isopropanol, mix well. After filtering through a $0.45 \mu\text{m}$ organic filter membrane and sonicating for 10 minutes, the desired solution is obtained.

流动相 B: 取甲醇 990ml, 加异丙醇 10ml, 混匀, 经 $0.45 \mu\text{m}$ 有机滤膜过滤后, 超声 10 分钟后, 即得。

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

None

无

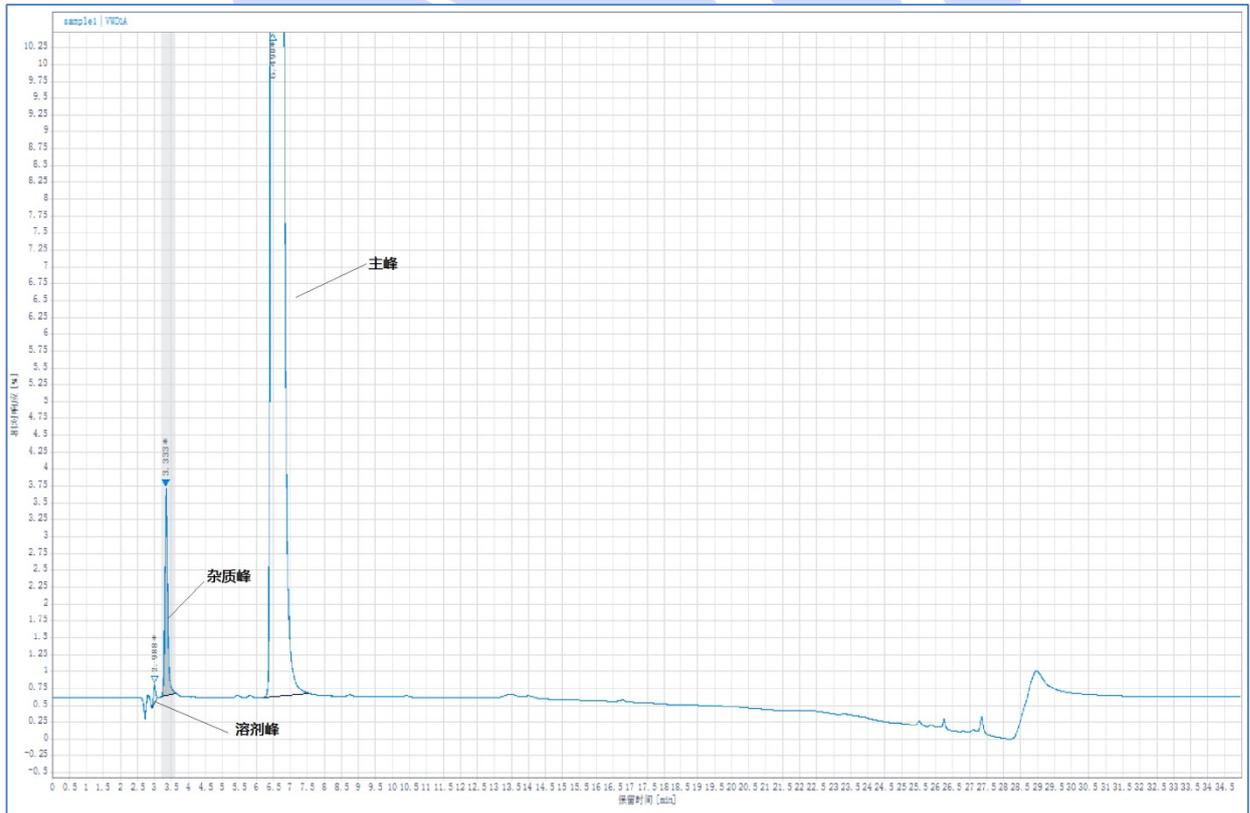
1.2.3. Test solution (测试溶液):

Take this solution and inject directly.

取本品直接进样。

2. Chromatogram and data (谱图和数据)

(1) Analysis spectrum of Test solution (测试溶液分析图谱):



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Figure 1 Typical Chromatogram of Single Injection
 图 1 单个进样典型图

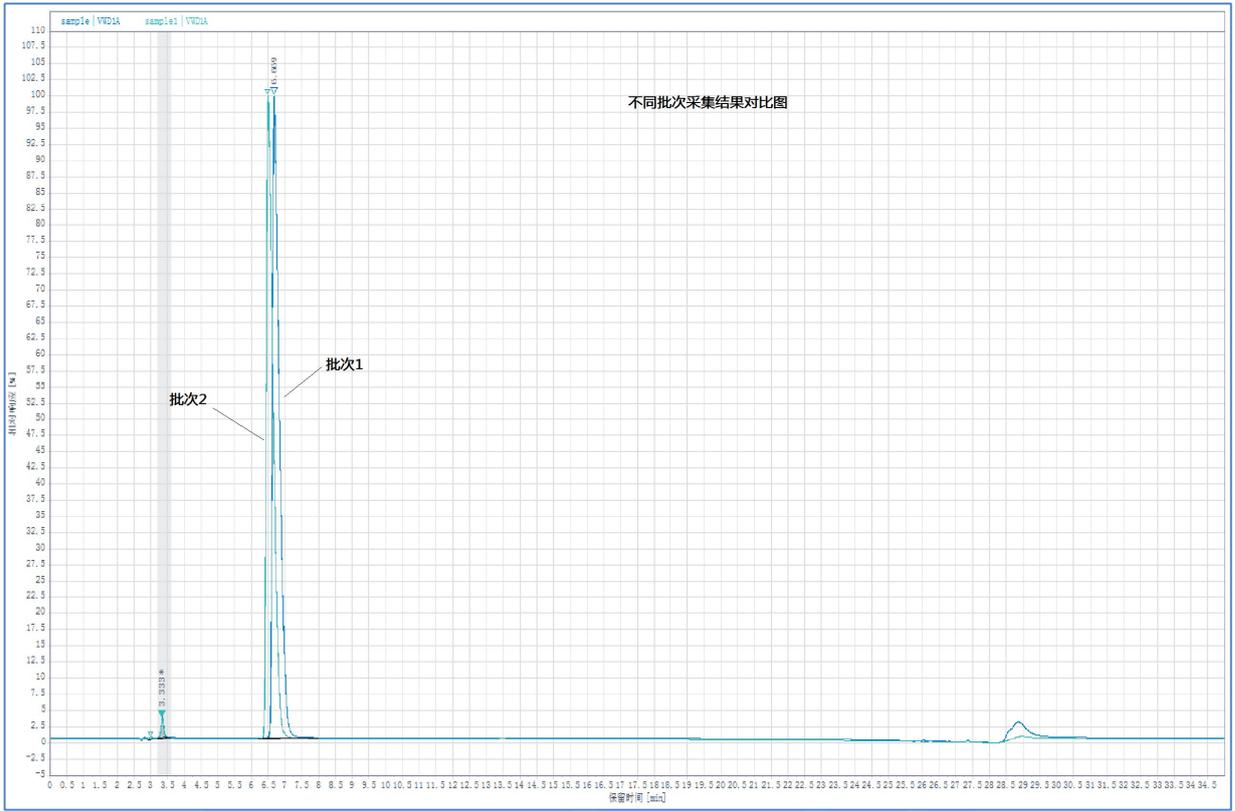


Figure 2 Comparison Chart of Test Results from Different Batches
 图 2 不同批号测试结果对比图

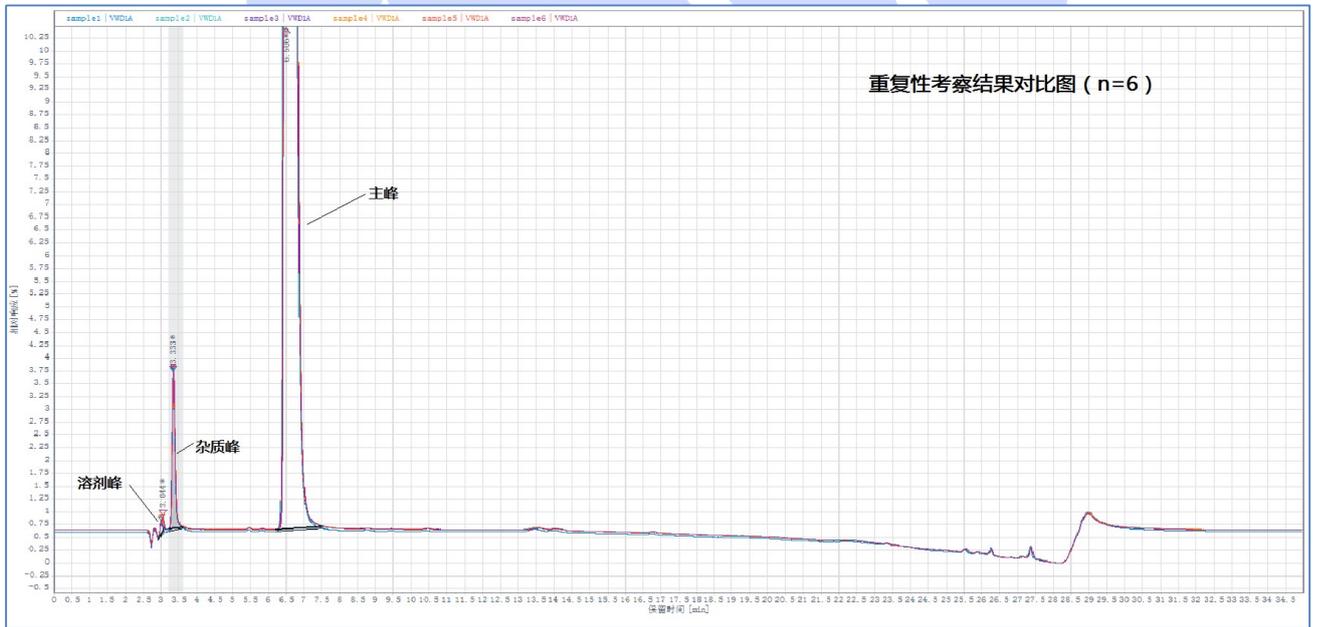


Figure 3 Comparison Chart of Repeatability Test Results (n=6)

图 3 重复性测试结果对比图 (n=6)

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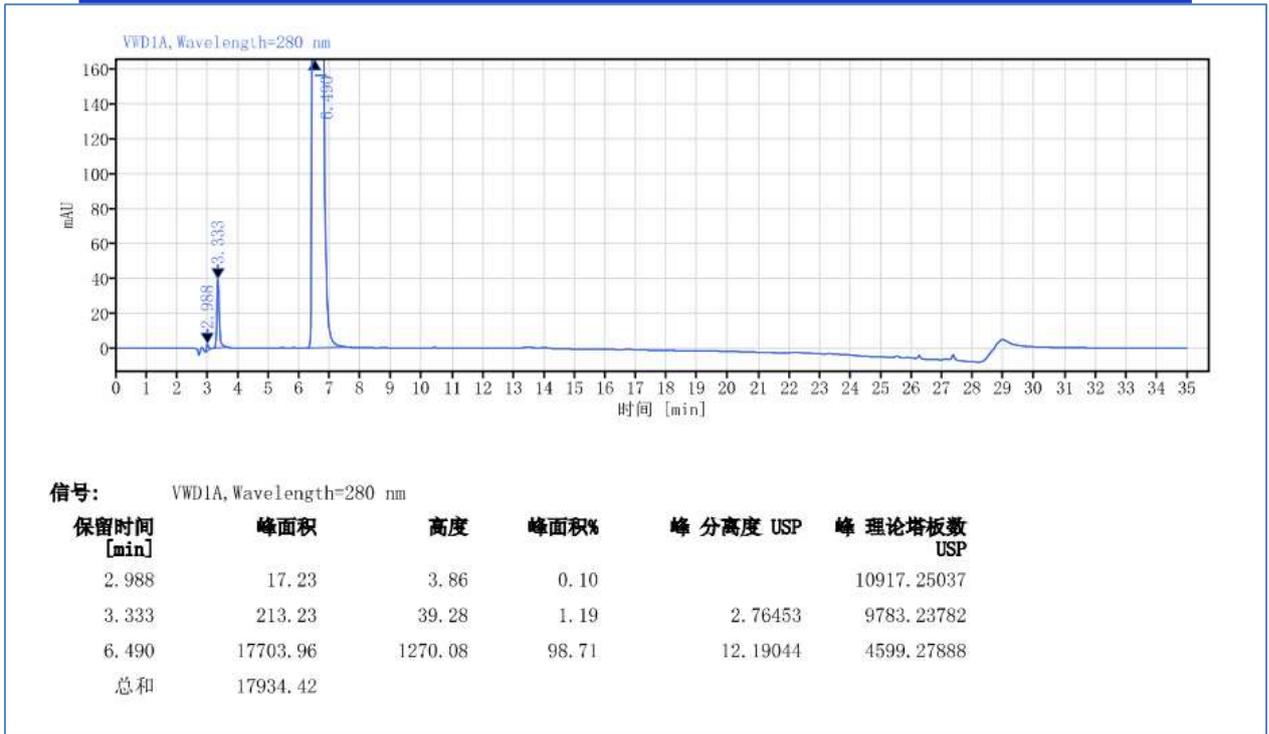


Figure 4 Collection Results (Taking a Single Collection Result as an Example)

图 4 采集结果 (以单个采集结果为例)

3. Conclusion (结论)

When the Yuexu chromatographic column Ultimate AQ - C18 (4.6 × 250 mm, 5 μm) is used under these chromatographic conditions, the main peak elutes with a retention time of approximately 6 minutes (±1 minute). The solvent peak presents a sharp shape, and its resolution from the impurity peak at around 3 minutes meets the requirements. Meanwhile, this chromatographic column is easy to store and requires no refrigeration. A repeatability test was conducted using this column, and the test results indicated good repeatability. In conclusion, this chromatographic column meets all the aforementioned requirements of the customer.

使用月旭色谱柱 Ultimate AQ-C18 (4.6×250mm, 5μm) 在此色谱条件下, 主峰保留时间在 6 分钟 (±1 分钟) 左右出峰, 溶剂峰峰型为尖峰的, 与约 3 分钟的杂质峰的分度满足要求, 同时该款色谱柱的储藏简单, 无需冷藏; 采用该款色谱柱进行重复性考察, 考察结果显示重复性良好; 综上所述, 该款色谱柱, 满足客户上述的所有要求。

Report signature (报告签字)

Tester(测试): Kaden (王进富)

Date (日期): 2025/11/05

Reviewer(审核): Jeff (王祝超)

Date (日期): 2025/11/05

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