

Test Report

| Sample information | | | |
|------------------------|---|------------------|------------------------|
| Sample Name | Amoxicillin Clavulanate Potassium Granules | Number | Z20220317-013 |
| Sample Weight | \ | Dosage Form | \ |
| Sample Receipt Date | 2022/06/14-06/16 | Test Period | 2022/06/14-06/16 |
| Test Requirements | | | |
| Test Ingredients | Relative substance | | |
| Reference Standard | | | |
| Reference Standard | Chinese Pharmacopoeia 2020 Edition Volume II | Standard samples | Yes |
| Instrument information | | | |
| Test Instrument | High-performance liquid chromatography | Instrument Model | Thermo Fisher U3000 |

● **Chromatography conditions:**

| | | | |
|--------------|---|--------------------|--------------------|
| Column | Xtimate® C18 (4.6×150mm, 5µm) | | |
| Mobile Phase | Mobile phase A: 0.01 mol/L Potassium Dihydrogen Phosphate Solution (pH 6.0 adjusted with 2 mol/L Sodium Hydroxide Solution). Mobile phase B: 0.01mol/L potassium dihydrogen phosphate solution (adjusted with 2mol/L sodium hydroxide solution section pH6.0)/acetonitrile=20/80 | | |
| | Time | Mobile phase A (%) | Mobile phase B (%) |
| | 0 | 98 | 2 |

Unless otherwise stated, the results shown in this test report refer only to this sample tested. The report can not be copied without the permission of Welch Materials, Inc.

| | | | |
|-------------------------|-----------|----|----|
| | 12 | 75 | 2 |
| | 32 | 70 | 30 |
| | 34 | 98 | 2 |
| | 45 | 98 | 2 |
| Detection | 230nm | | |
| Temperature | 35°C | | |
| Flow Rate | 1.0ml/min | | |
| Injection Volume | 20 µL | | |

● **Mobile phase configuration:**

Mobile phase A: Take weigh 1.36g of potassium dihydrogen phosphate, adjust the pH 6.0 with 2mol/L sodium hydroxide solution, filter, and degas by ultrasonic;

Mobile phase B: take 200ml of mobile phase A, 800ml of acetonitrile, mix well, and degas it by ultrasonic;

● **Sample solution configuration:**

Blank solution: take mobile phase A, that is;

System suitability solution: take an appropriate amount of amoxicillin-clavulanate potassium system suitability reference substance, add mobile phase A to dissolve and dilute to make a solution containing 2.5mg per 1ml;

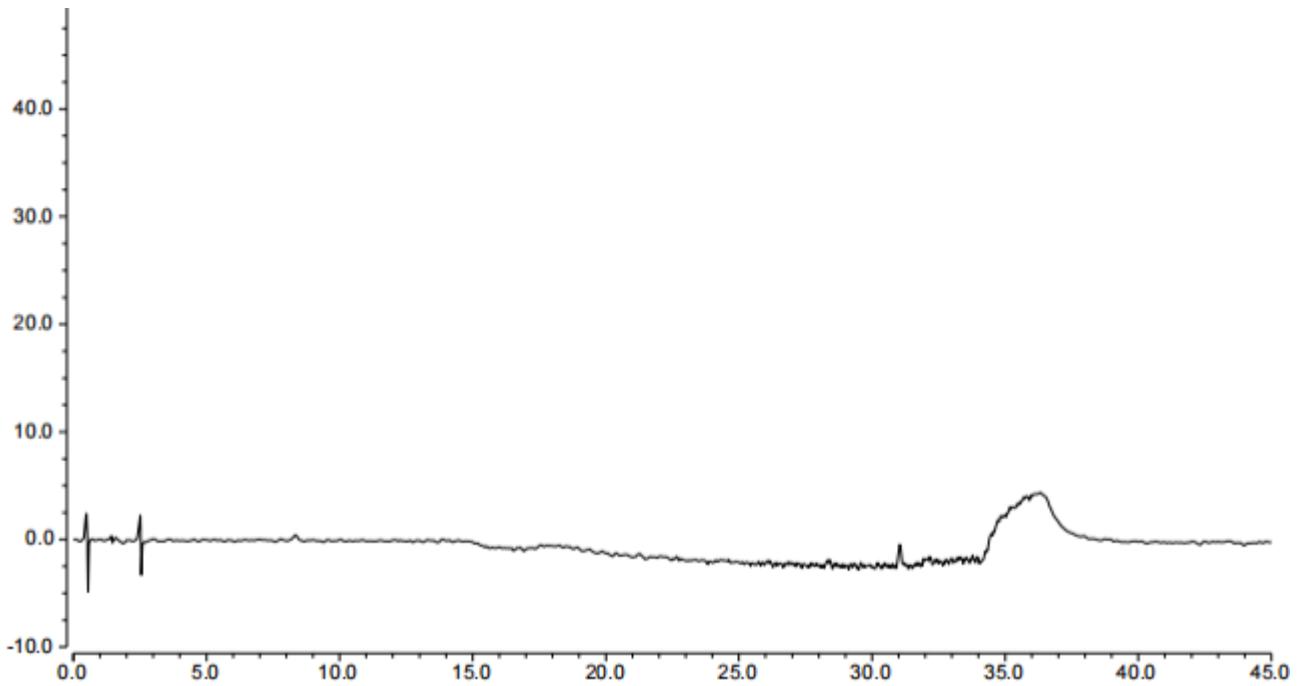
Test solution: Take an appropriate amount of this product powder, add mobile phase A to dissolve and dilute to make a solution containing 2mg of amoxicillin per 1ml, filter, and take the subsequent filtrate to obtain the product;

Control solution: Measure an appropriate amount of the test solution, dissolve and dilute it with mobile phase A to make a solution containing 40ug of amoxicillin per 1ml;

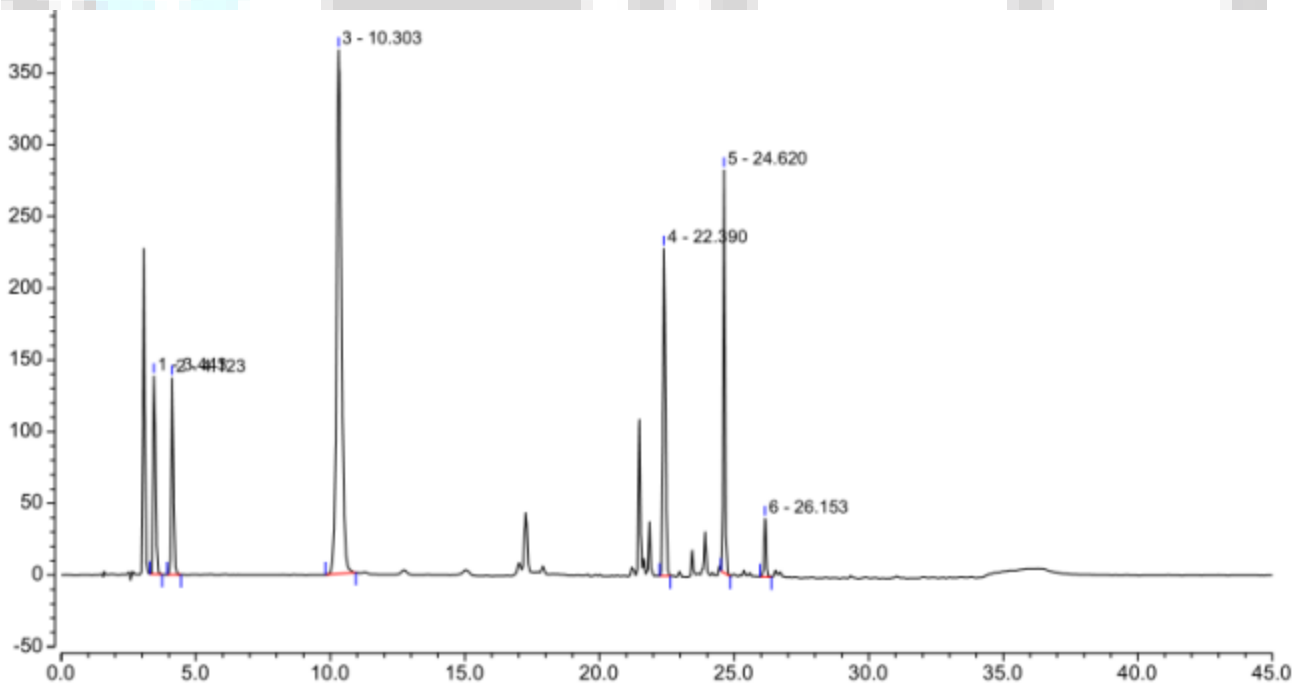
● **Chromatogram and Data:**

1. Blank solution:

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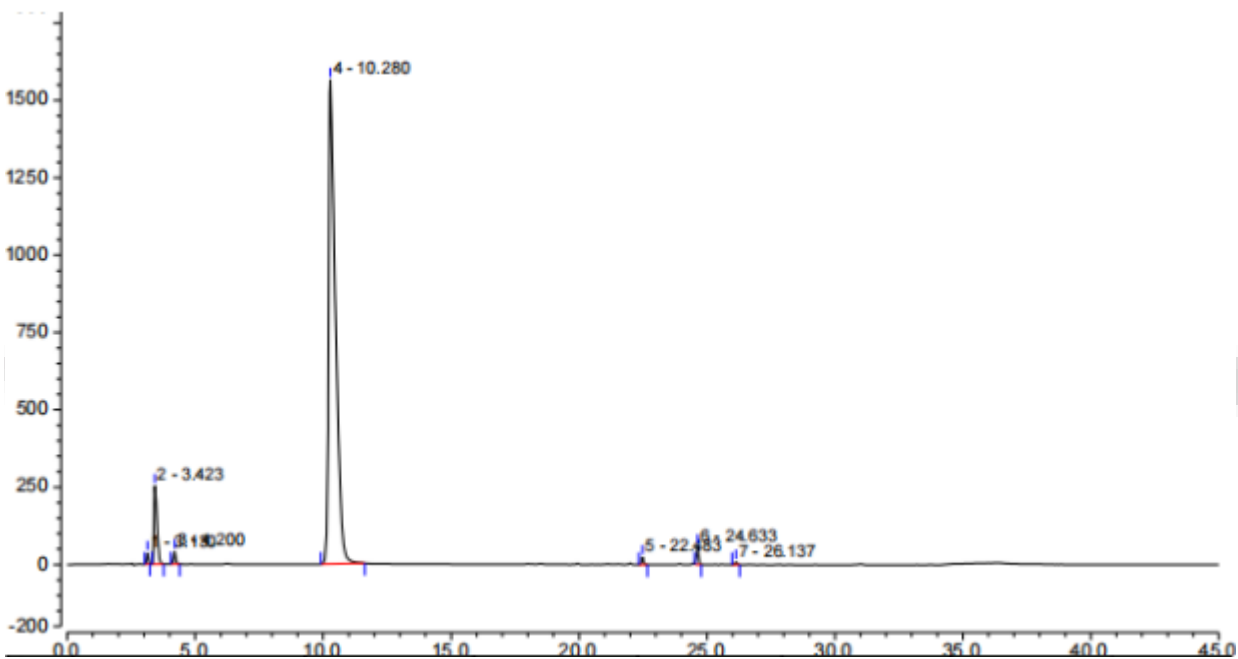
2. System suitability solution:



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| Integration Results | | | | | | |
|---------------------|----------------|--------|-------------|----------------------|-------|----------------|
| | Retention time | Area | Peak Height | Number of plates(EP) | R(EP) | Asymmetry (EP) |
| 1 | 3.443 | 13.273 | 138.056 | 8158 | 4.67 | 1.70 |
| 2 | 4.123 | 12.600 | 137.202 | 14001 | 27.62 | 1.22 |
| 3 | 10.303 | 75.382 | 365.330 | 17745 | 51.53 | 1.14 |
| 4 | 22.390 | 23.222 | 228.467 | 309440 | 16.24 | 1.40 |
| 5 | 24.620 | 21.108 | 280.817 | 741289 | 13.58 | 1.23 |
| 6 | 26.153 | 3.180 | 40.360 | 872833 | n. a. | 1.03 |

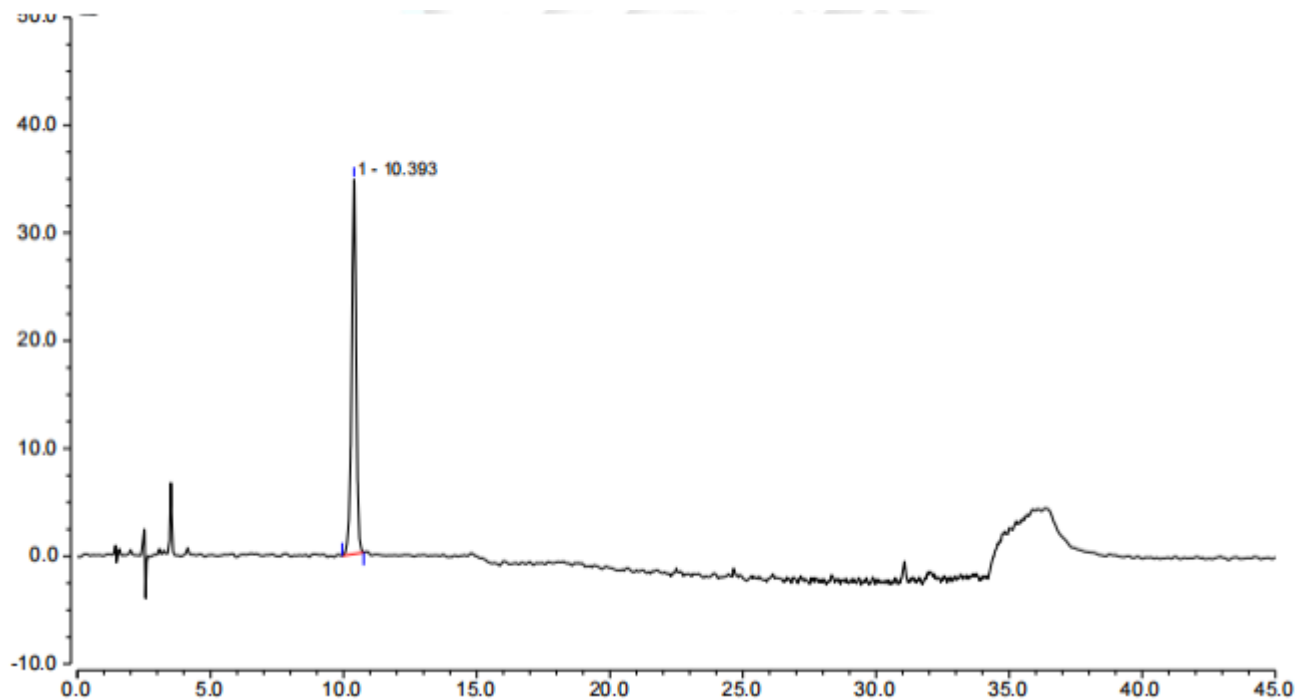
3. Test solution



| Integration Results | | | | | | |
|---------------------|----------------|---------|-------------|----------------------|-------|----------------|
| | Retention time | Area | Peak Height | Number of plates(EP) | R(EP) | Asymmetry (EP) |
| 1 | 3.130 | 2172. | 35.269 | 17567 | 1.97 | 1.08 |
| 2 | 3.423 | 31.934 | 252.169 | 4508 | 4.56 | 2.13 |
| 3 | 4.200 | 3.738 | 41.353 | 14922 | 20.26 | 1.05 |
| 4 | 10.280 | 478.576 | 11564.086 | 7848 | 42.37 | 2.09 |
| 5 | 22.483 | 1.759 | 23.585 | 629064 | 19.20 | 1.02 |
| 6 | 224.633 | 4.305 | 57.636 | 785539 | 13.27 | 1.04 |
| 7 | 26.137 | 0.737 | 9.519 | 811150 | n. a. | 0.93 |

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4. Reference solution



| Integration Results | | | | | | |
|---------------------|----------------|-------|-------------|----------------------|-------|----------------|
| | Retention time | Area | Peak Height | Number of plates(EP) | R(EP) | Asymmetry (EP) |
| 1 | 10.393 | 6.858 | 34.707 | 19403 | n. a. | 0.92 |

Conclusion:

Under these chromatographic conditions, Welch Xtimate® C18 (4.6×150mm, 5µm) can meet the detection requirements.

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