

Test Report

Sample			
Name	Arginine hydrochloride injection	Number	W20200615-005
Weight	/	Formulation	/
Receipt Time	2020\06\15	Test Time	2020/06/23-06/24
Description	\		
Test			
Test Item	Arginine		
Standards			
Reference	Provided by customer	Standard Sample	Yes
Instrument			
Type	HPLC	Version	Waters 2695

● **Chromatographic Condition:**

Column	Welch Ultisil® HILIC Amide (4.6×250mm, 5µm)
Mobile Phase	Acetonitrile /0.05M potassium dihydrogen phosphate solution (pH =8.0) =50/50 (single pump)
Wavelength	206 nm
Temperature	30°C
Flow Rate	1 mL/min
Injection Volume	20 µl
Notes	/

● **Preparation of Mobile Phase:**

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Preparation of 0.05M KH_2PO_4 (pH =8.0) solution: accurately weigh 6.801g of KH_2PO_4 in a 1000mL beaker, add 900mL ultra-pure water to stir and dissolve. Add triethylamine to adjust pH to 8.0, then add ultra-pure water to 1000mL. Mix well, pump and filter to obtain;

Preparation of mobile phase solution: take 500mL pure acetonitrile and 500mL prepared 0.05M KH_2PO_4 (pH =8.0) solution, mix well, and degas with by ultrasound to obtain.

● Preparation of Sample Solution:

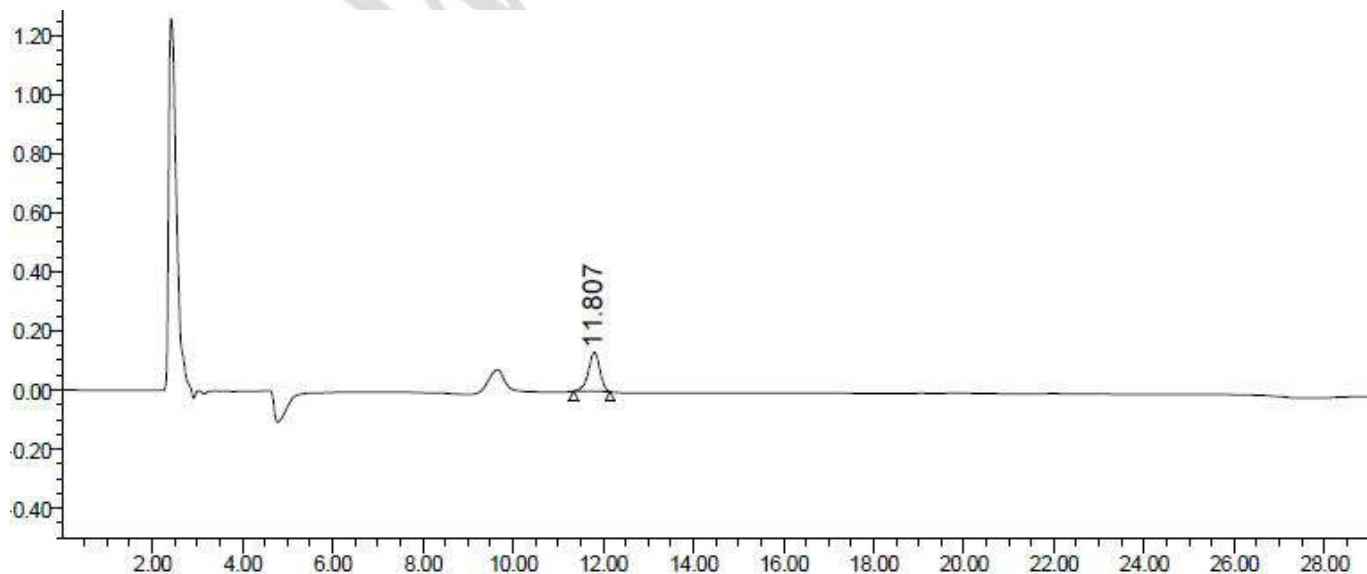
Test solution: precisely transfer 50 μl Arginine hydrochloride injection 50 μl into a 10mL volumetric flask, and dilute it with mobile phase (or ultrapure water) to the scale. Shake well to obtain solution with a concentration of 0.2mg/ mL, then filter and take the filtrate.

Preparation of reference solution: accurately weigh 1.0mg of arginine reference, add mobile phase (or ultra-pure water) to a constant volume of 5mL. Shake well to obtain reference solution with a concentration of 0.2mg/ mL, filter it, and take the filtrate.

Blank solution: take the prepared mobile phase, filter it to obtain.

● Chromatogram and Data:

(1) Test solution(dissolve with ultrapure water)



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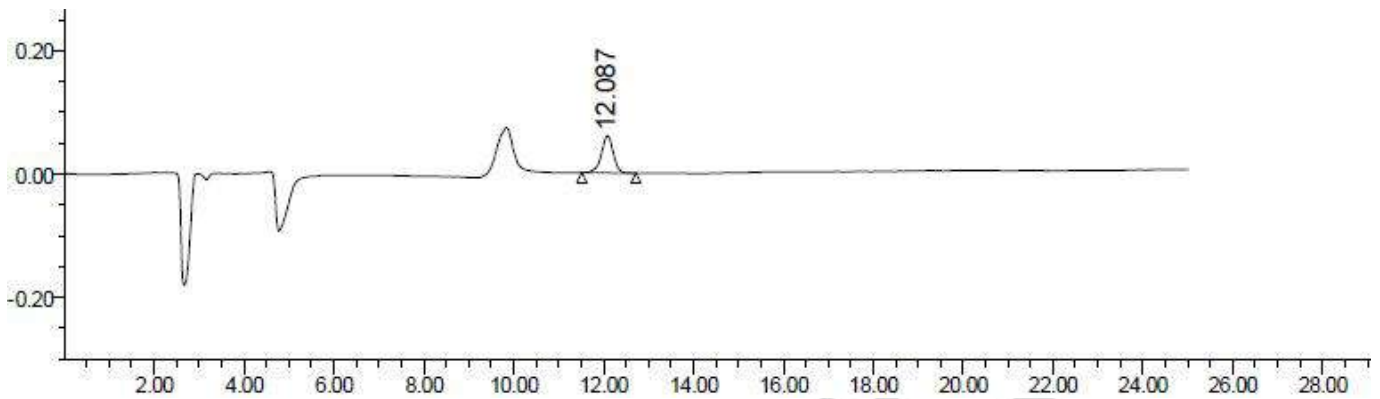
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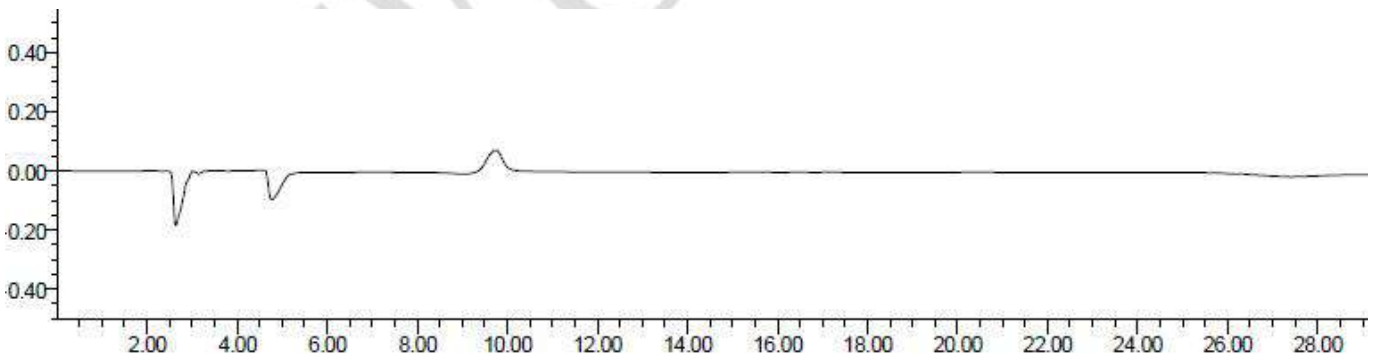
	Rt	Area	Height	Resolution	Tailing factor	Plates (USP)
1	11.807	2329918	132015		9.070048e-001	1.059608e+004

(2) Reference solution (dissolve with ultrapure water)



	Rt	Area	Height	Resolution	Tailing factor	Plates (USP)
1	12.087	1110244	60510		9.429665e-001	1.062317e+004

(3) Blank ultrapure water:



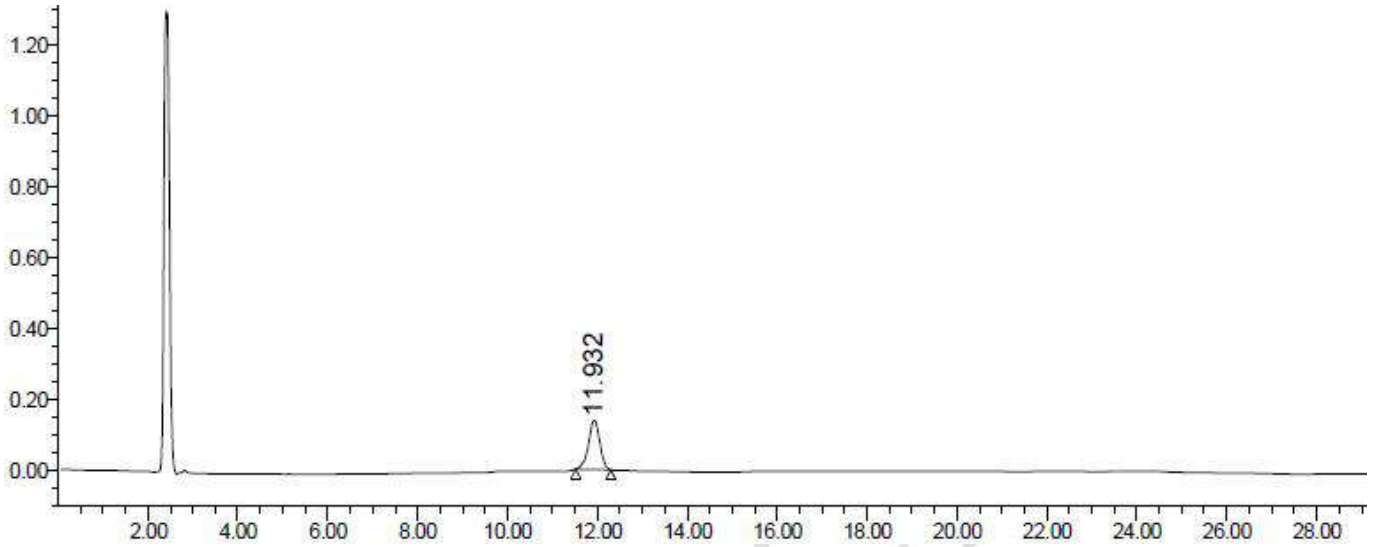
(4) Arginine hydrochloride injection(dissolve with mobile phase)

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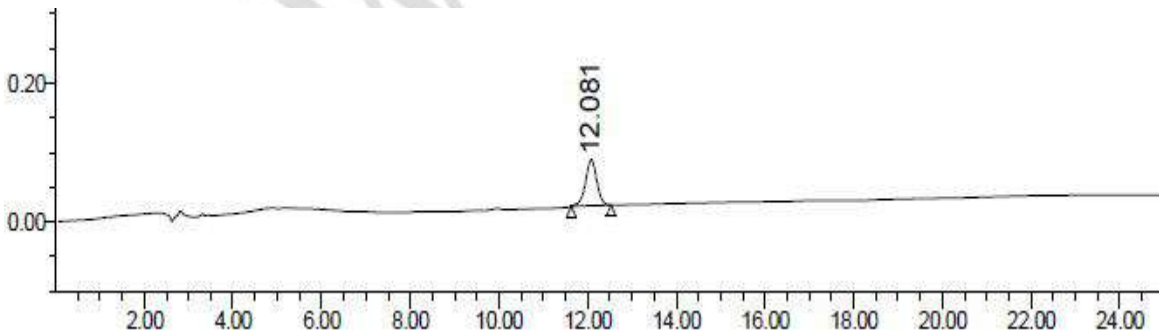
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	Rt	Area	Height	Resolution	Tailing factor	Plates (USP)
1	11.932	2434840	139402		9.369932e-001	1.091788e+004

(5) Reference solution (dissolve with mobile phase)



	Rt	Area	Height	Resolution	Tailing factor	Plates (USP)
1	12.081	1173353	66066		9.464130e-001	1.097143e+004

(6) Blank mobile phase solution

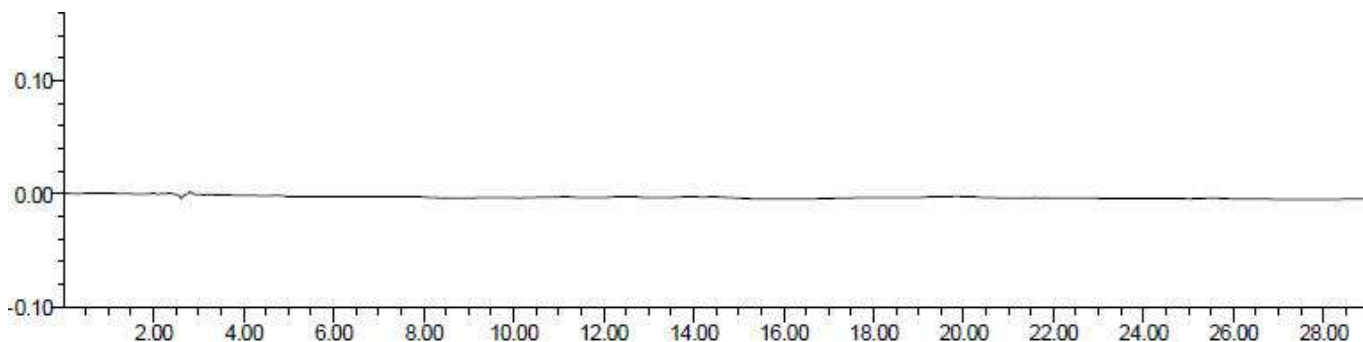
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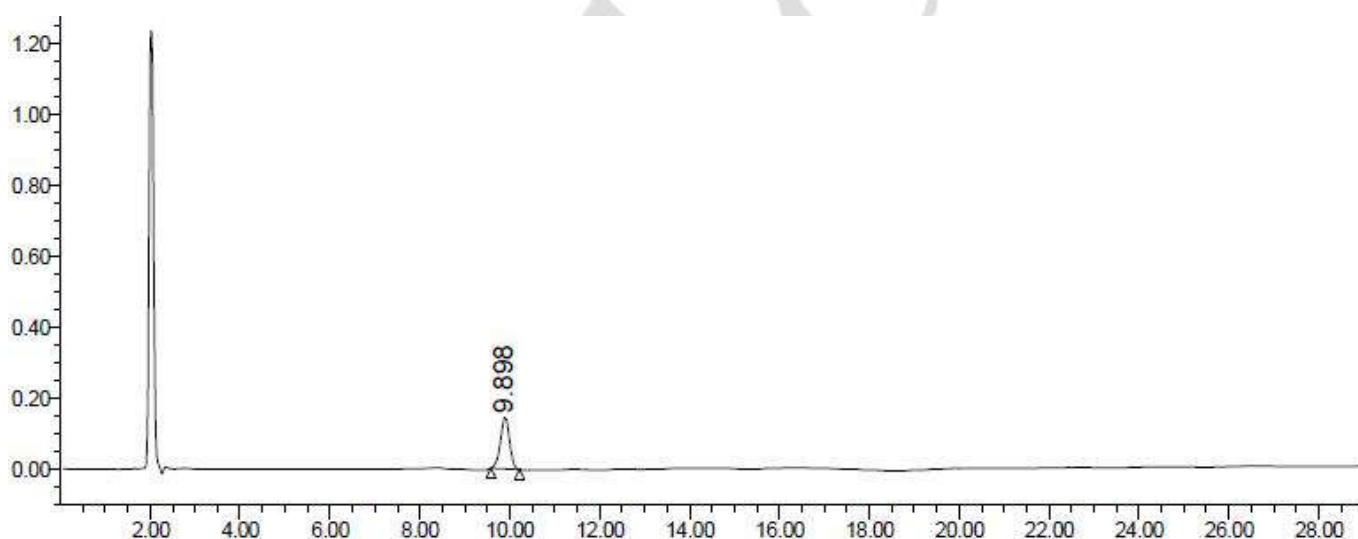
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(7) Adjust flow rate to 1.2ml/min, column temperature is 40°C:



	Rt	Area	Height	Resolution	Tailing factor	Plates (USP)
1	9.898	2044929	145156		9.681692e-001	1.140270e+004

● **Conclusion:**

Conclusion: Using HILIC Amide (4.6×250mm, 5µm) under this chromatographic condition can meet the test requirements.

Signature

Test: Yanzhi Chen

Date: 2020/06/24

Revise: Xiaomei Wu

Date: 2020/06/24

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