

Test Report

Sample			
Name	Oxytetracycline	Number	W20200319-002
Weight	/	Formulation	/
Receipt Time	2020/03/19	Test Time	2020/03/21-03/23
Description	\		
Test			
Test Item	Related substance		
Standards			
Reference	2015 Chinese Pharmacopoeia II	Standard Sample	Yes
Instrument			
Type	HPLC	Version	Thermo Fisher U3000

● **Chromatographic Condition:**

Column	Welch Xtimate® C18 (4.6×250mm, 5µm)
Mobile Phase	Ammonium acetate solution/acetonitrile =88/12
Wavelength	280 nm
Temperature	30°C
Flow Rate	1.0 mL/min
Injection Volume	10 µl
Notes	/

● **Preparation of Mobile Phase:**

Unless otherwise stated, the results shown in this test report refer only to this sample tested.

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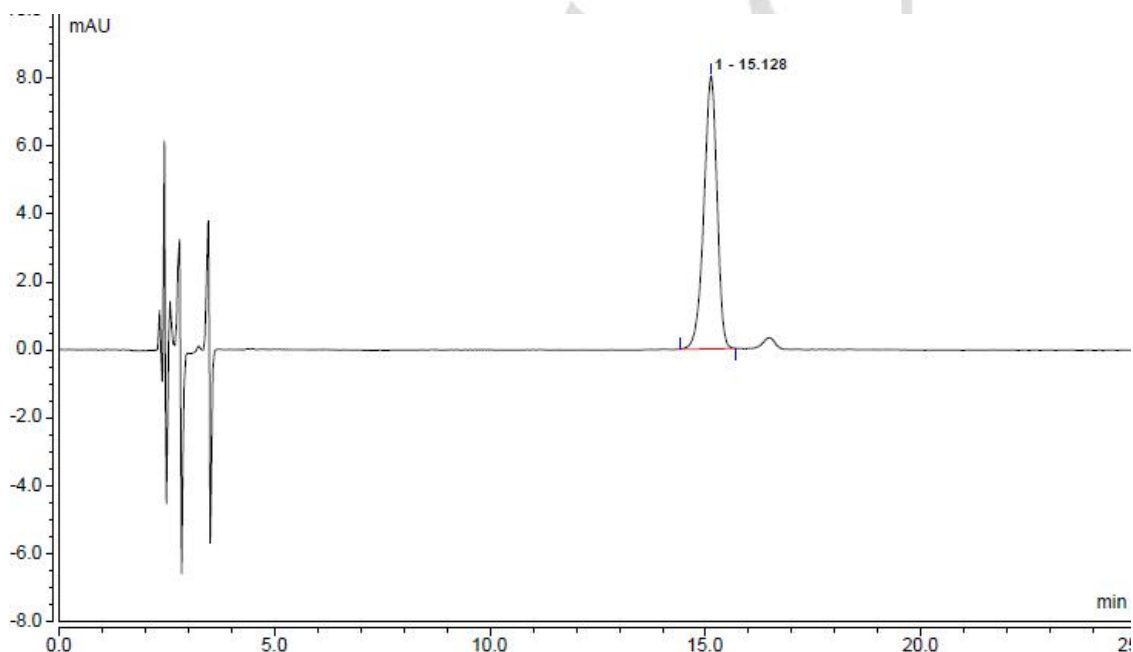
Ammonium acetate solution: 0.25mol/L ammonium acetate solution: 0.05mol/L
 ethylenediamine tetraacetic acid disodium solution: triethylamine =100:10:1, adjust pH to 7.5 with acetic acid. Filter with ultrasound to degas;
 Mobile phase: take 60ml of acetonitrile and 440mL of ammonium acetate solution, then mix well. Degas with untrasound to obtain.

● **Preparation of Sample Solution:**

Test solution: take a proper amount of sample. Add 0.01mol/L hydrochloric acid solution to dissolve and prepare a solution containing about 0.5mg in 1mL;
 Reference solution: accurately weigh 2mL of the test solution, and put it into a 100mL flask. Dilute it with 0.01mol/L hydrochloric acid solution to the scale, and shake well;

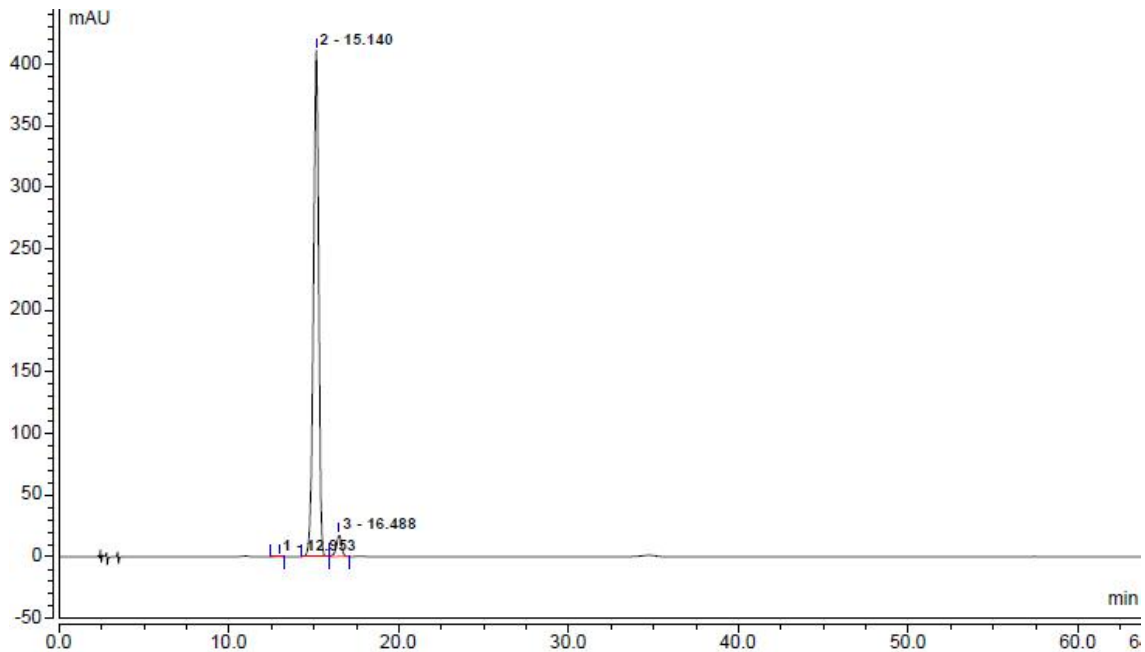
● **Chromatogram and Data:**

1. Reference solution



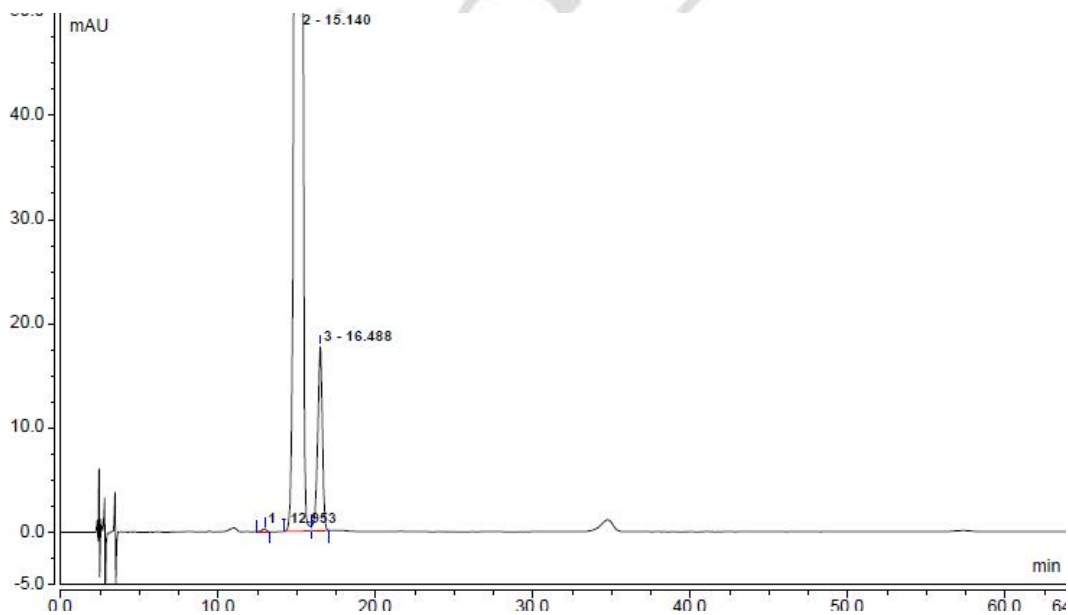
No.	Peak	Rt min	Height mAU	Area mAU*min	Resolution(EP)	Asymmetry(EP)	Plates(EP)
1		15.128	8.037	2.847	n.a.	0.89	12019

2. Test solution (fullscale)



No.	Peak	Rt min	Height mAU	Area mAU*min	Resolution(EP)	Asymmetry(EP)	Plates(EP)
1		12.953	0.324	0.097	4.44	0.78	14158
2		15.140	410.789	145.445	2.50	0.88	12009
3		16.488	17.676	6.090	n.a.	0.87	15563

3. Test solution (enlarge)



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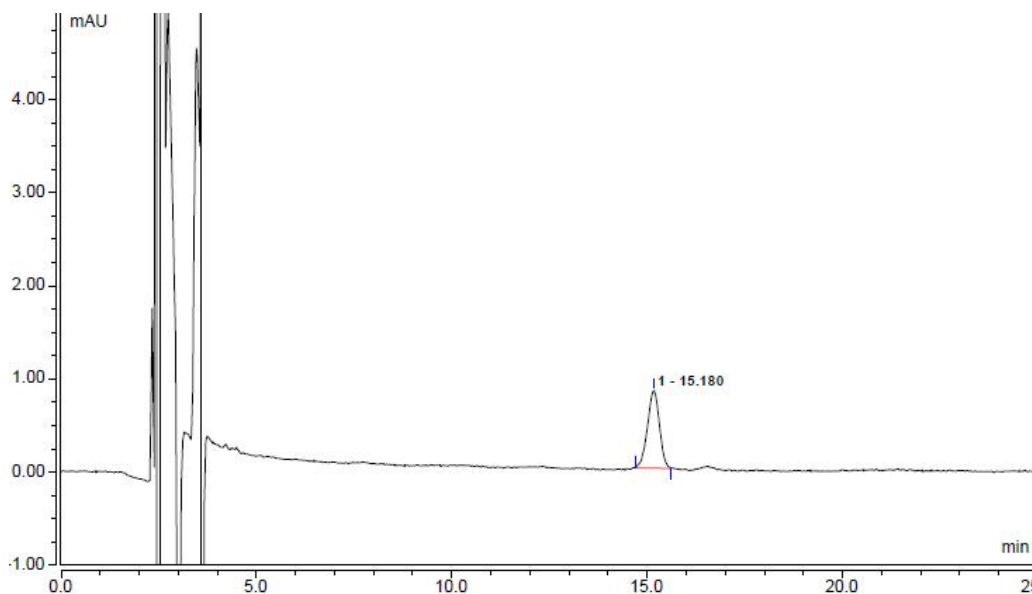
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3. Sensibility of solution



No.	Peak	Rt min	Height mAU	Area mAU*min	Resolution(EP)	Asymmetry(EP)	Plates(EP)
1		15.180	0.841	0.296	61.8	0.91	12087

● conclusion

Using Xtimate® C18 (4.6×250mm, 5µm) under this chromatographic condition can meet the test requirements.

Signature

Test: Xiaofei Lu

Revise: Xiaomei Wu

Date: 2020/03/23

Date: 2020/03/23

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