

Test Report

Sample			
Name	Carbamazepine	Number	W20180408-002
Weight	/	Formulation	/
Receipt Time	2018/04/08	Test Time	2018/04/09-04/17
Specification	Light white power		
Test Requirement			
Test Item	Detection of related substances		
Standards			
Reference	/	Standard Sample	/
Instrument			
Type	HPLC	Version	Welch Wisys 5000

Chromatographic Condition:

Column	Ultisil® XS-C18 (4.6×250mm, 5µm)		
Mobile Phase	A: water/triethylamine/formic acid=1000/0.5/0.5		
	B: acetonitrile/formic acid=1000/0.25		
	Time(min)	A(%)	B(%)
	0	65	35
	10	65	35
	30	40	60
	45	40	60
	46	65	35
Detection	230 nm		
Temperature	30 °C		

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Flow Rate	1 ml/min
Injection Volume	10 μ L
Notes	/

Mobile Phase:

Mobile phase A: take 1000 mL water, add 0.5 mL triethylamine and 0.5 mL formic acid , mix and filter.

Mobile phase B: take 1000 mL acetonitrile, add 0.25 mL formic acid, mix and filter.

Sample Processing:

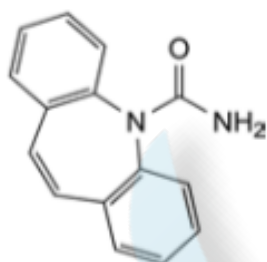
Blank Solution: methanol/water=50/50

Impurity E solution: Take an appropriate amount of impurity E test sample, first dissolve it with a little methanol, and then dilute it with blank solvent to make a 0.2 mg/mL solution

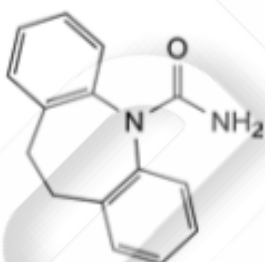
Impurity A, B, C, D, F, G, iminodibenzylcarbonyl chloride and carbamazepine solution are provided by customers.

System suitability solution: Take impurities A, B, C, D, E, F, G, iminodibenzylcarbonyl chloride and carbamazepine solutions 0.1 mg each, mix.

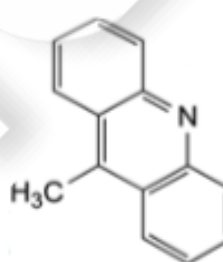
Structures:



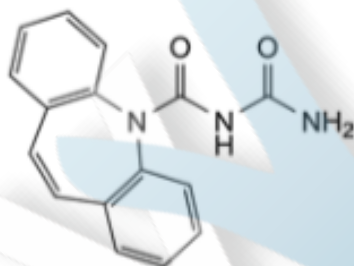
Carbamazepine



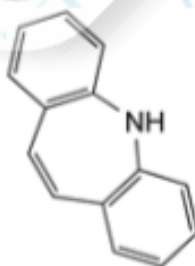
Impurity A



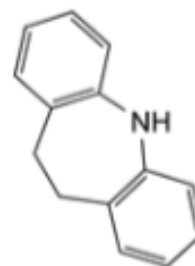
Impurity B



Impurity C

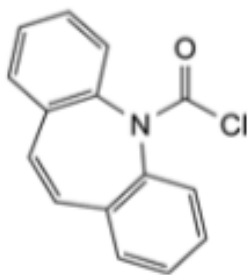


Impurity D

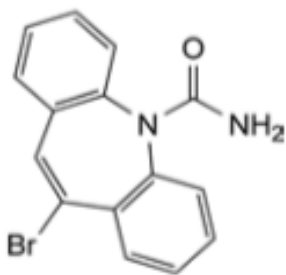


Impurity E

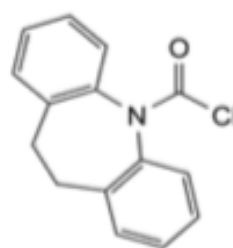
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Impurity F



Impurity G



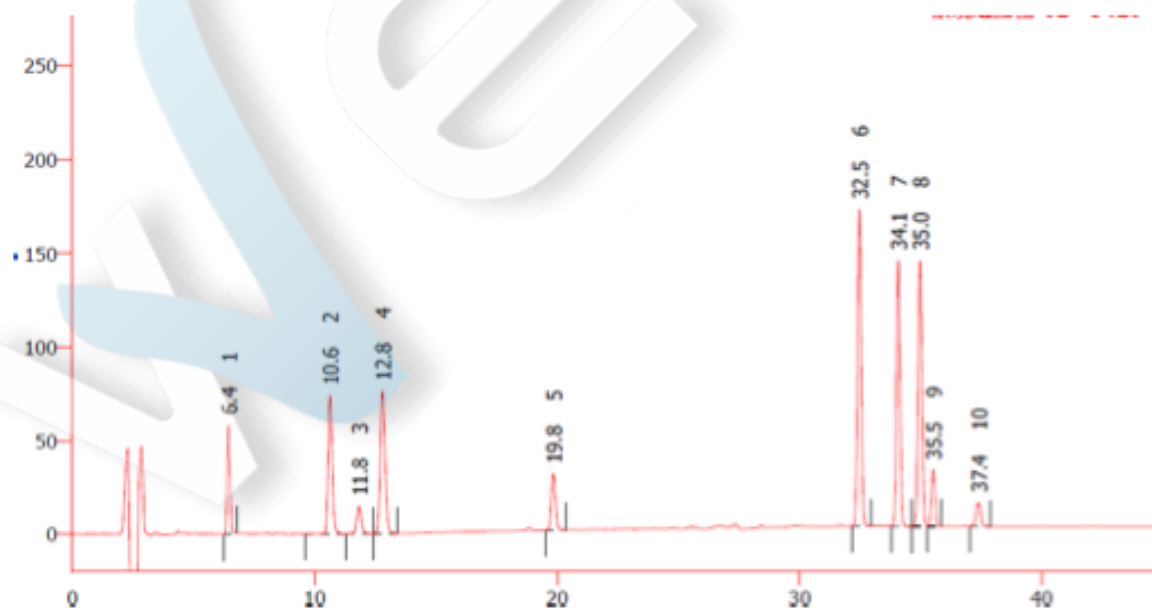
Iminodibenzylcarbonyl chloride

Chromatogram and Data:

1. Blank solution



2. System suitability solution

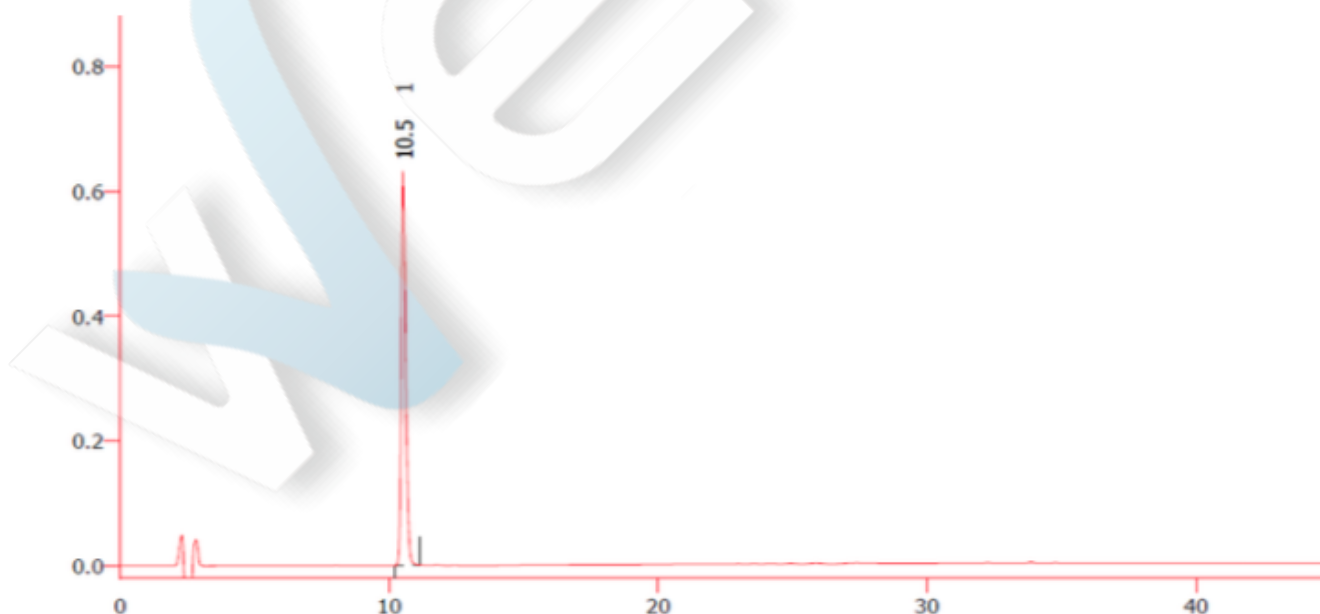


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Results

Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	6.438	486.003	58.220	13588		1.164
2	10.627	884.036	73.891	18956	15.857	1.120
3	11.818	196.162	14.608	19345	3.684	1.084
4	12.792	1069.741	76.388	19310	2.756	1.109
5	19.833	358.499	30.001	63673	20.687	1.053
6	32.458	1784.091	169.082	214385	42.564	1.015
7	34.063	1457.051	142.150	245948	5.798	1.015
8	34.962	1560.314	141.983	225388	3.164	1.014
9	35.512	340.867	30.173	223843	1.854	1.009
10	37.392	168.829	12.641	175639	5.737	0.996
Total		8305.596	749.137			

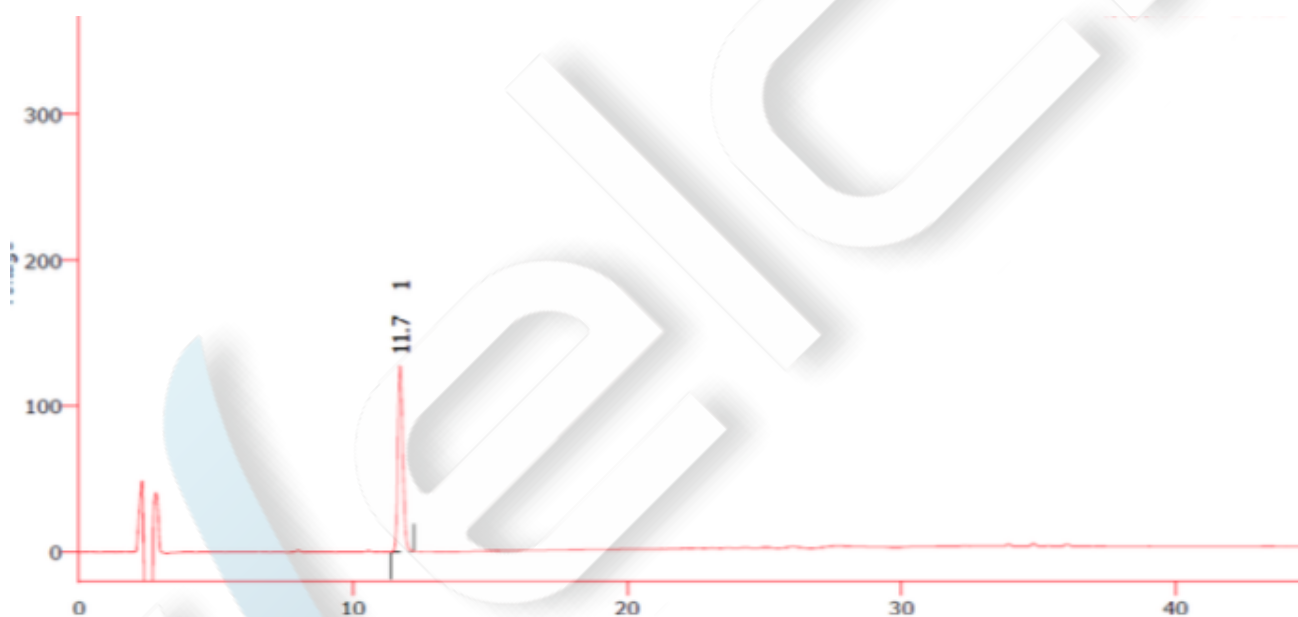
3. Carbamazapine



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Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	10.525	7319.347	631.511	18941		1.224
Total		7319.347	631.511			

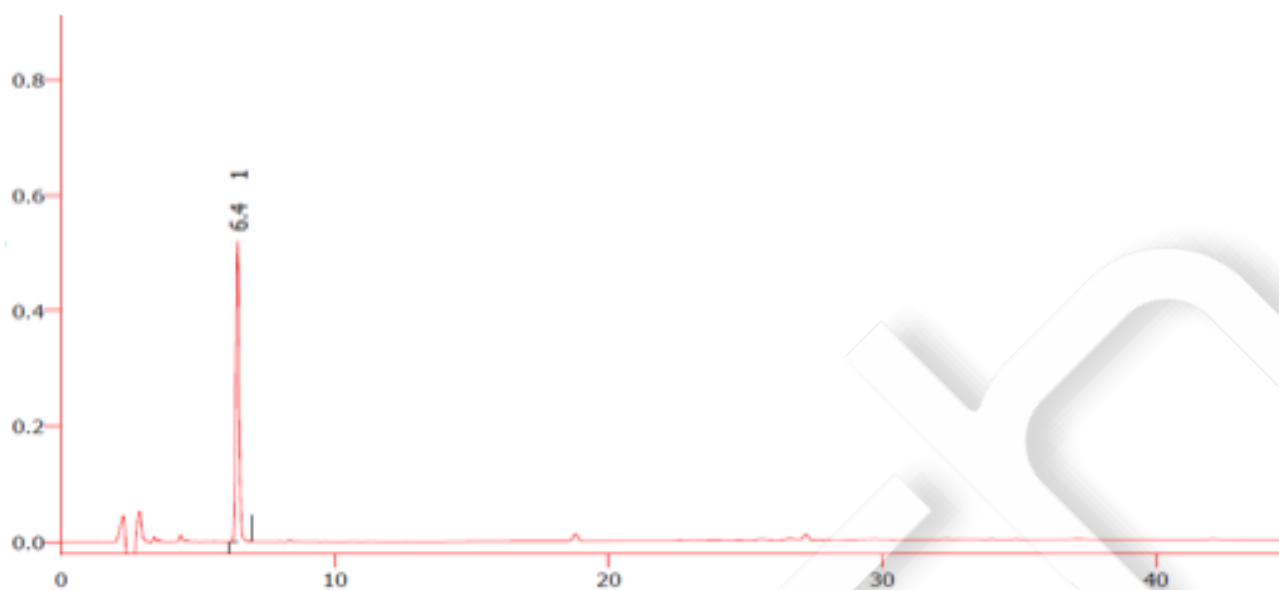
4. Impurity A:



Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	11.715	1623.183	127.409	19329		1.188
Total		1623.183	127.409			

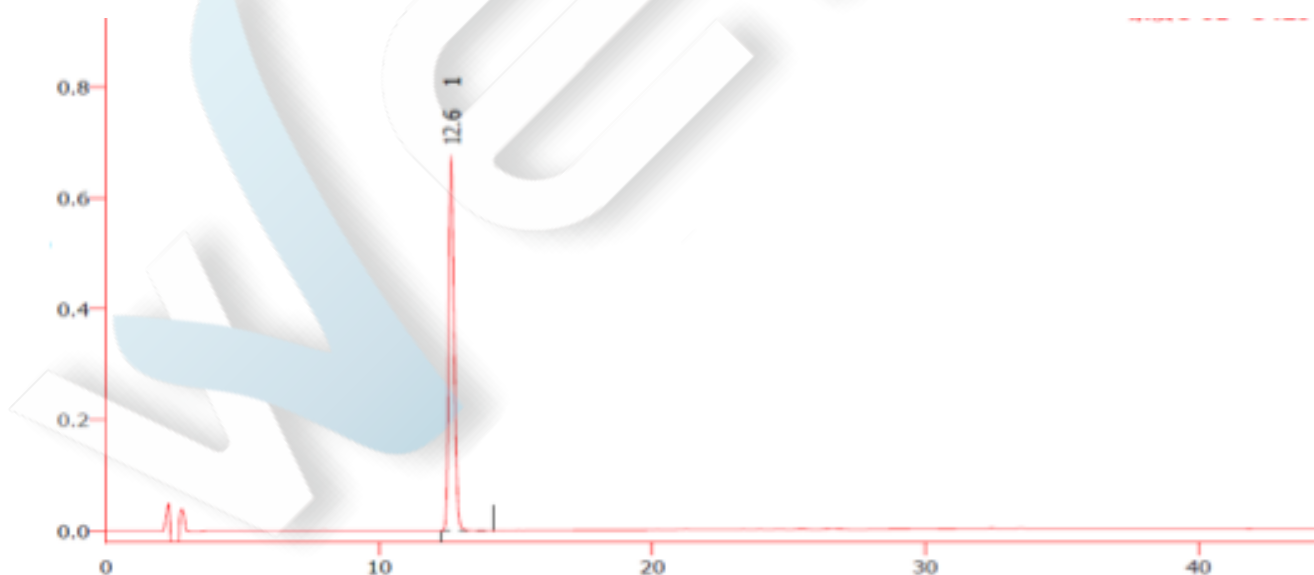
5. Impurity B

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Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	6.448	4359.849	521.220	13987		1.000
Total		4359.849	521.220			

6. Impurity C



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Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	12.632	9288.811	676.358	19730		1.219
Total		9288.811	676.358			

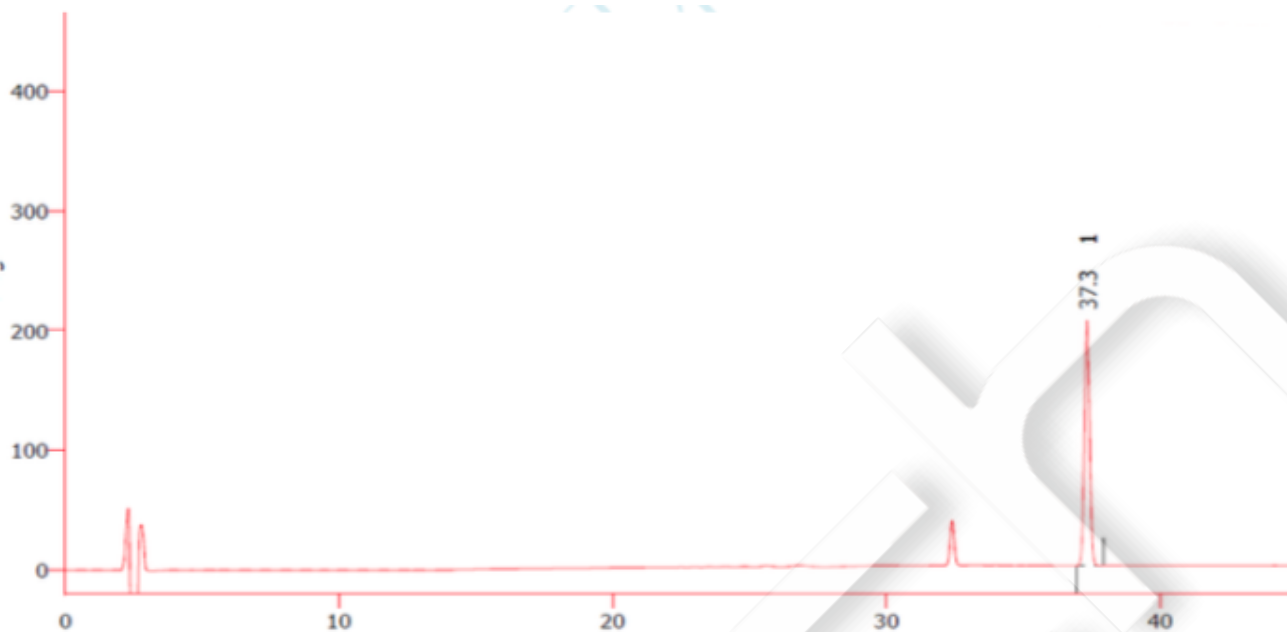
7. Impurity D



Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	32.302	16769.958	1571.722	203995		1.024
Total		1679.958	1571.772			

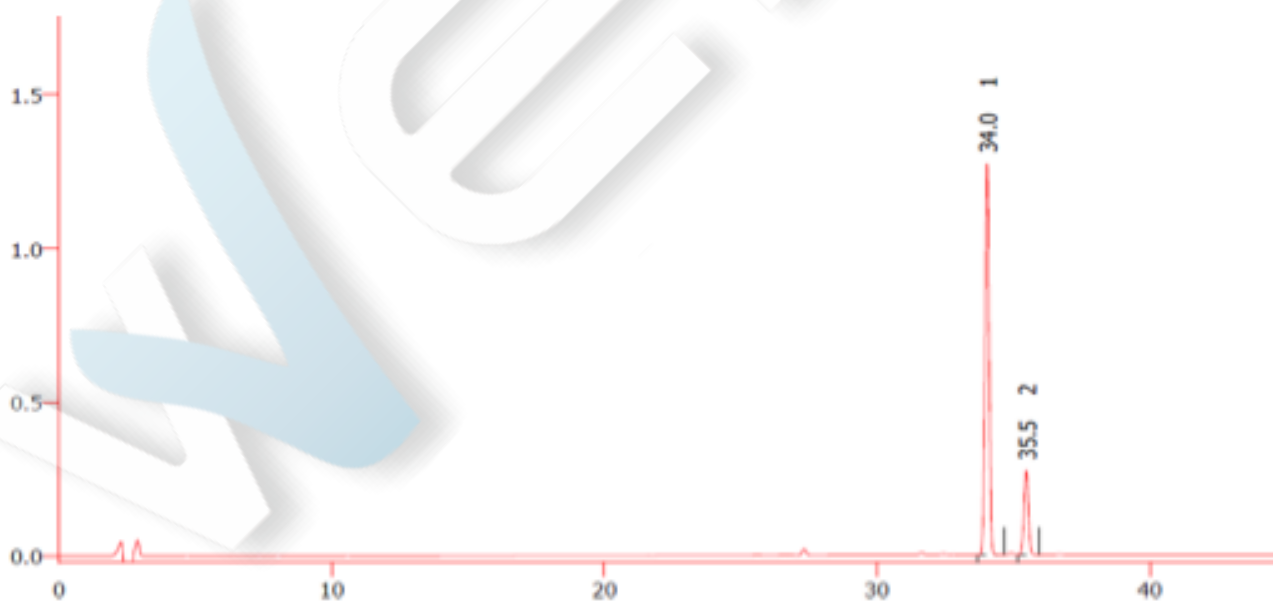
8. Impurity E

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Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	37.328	2731.066	205.000	177856		1.016
Total		2731.066	205.000			

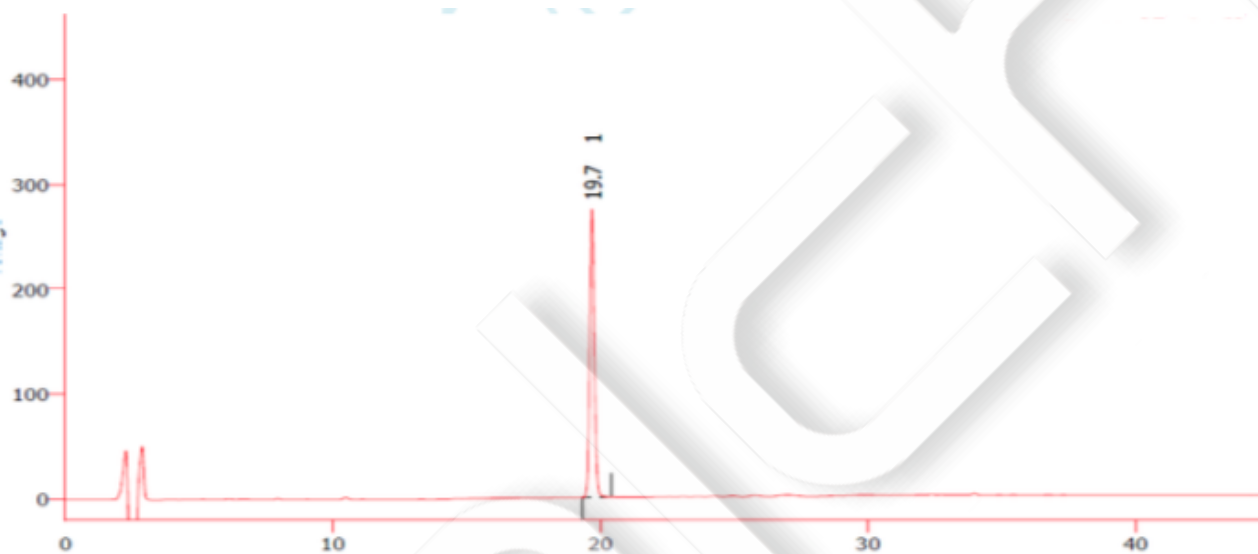
9. Impurity F



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Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	34.040	13084.249	1271.571	245611		1.000
2	35.473	3092.542	275.541	223360	4.999	1.009
Total		16176.791	1547.114			

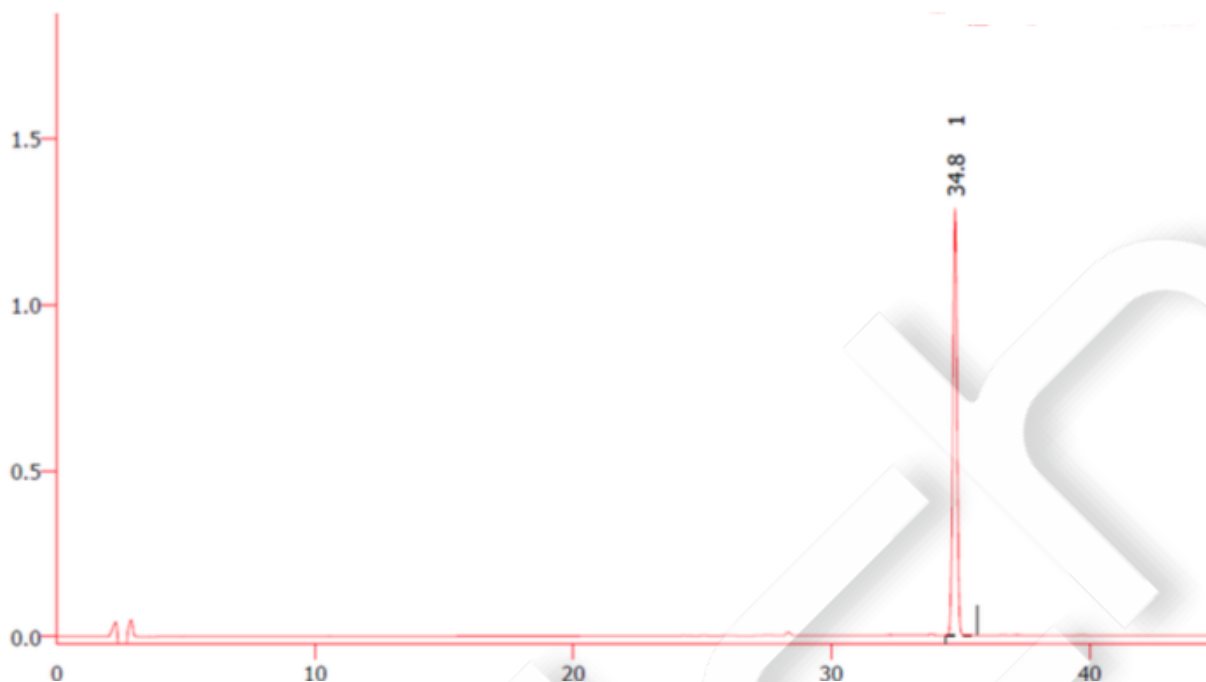
10. Impurity G



Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	19.678	3337.351	274.976	60483		1.105
Total		3337.351	274.976			

11. Iminodibenzylcarbonyl chloride

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Peak No.	Rt (min)	Peak Area (mAU*min)	Peak Height (mAU)	Theoretical plate	R	Tailing Factor
1	34.790	14218.761	1286.074	223180		0.991
Total		14218.761	1286.074			

Conclusion:

Ultisil® XS-C18 (4.6×250 mm, 5 μm) has reached the requirement to test this sample under this chromatographic condition.

Signature

Test: Xiaomei Wu

Date: 2018-04-17

Revise: Deyong Guo

Date: 2018-04-17

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