Test Report

1. Method and Conditions

Sample Information	
Sample	Calcium folinate
Trait	Solid
Requirement	Peaks elute in specified order, and the resolution between the main peak and adjacent impurity peaks must be greater than 1.0.
Method Source	Client
Instrument	Agilent 1260
Condition 1	
Column	Ultisil® XB-C18 (4.6×250 mm, 5 μm)
Mobile Phase	Na_2HPO_4 buffer solution with 0.1% Bu_4NOH (pH=7.8) / Methanol = 78/22
Flow Rate	1.0 mL/min
Injection Volume	10 μL
Column Temperature	40 °C
Detector	UV
Wavelength	280 nm

Preparation/Pretreatment:

1) Mobile Phase:

Weigh 2.2 g of Na_2HPO_4 and 8 mL of 10% Bu_4NOH, dissolve and dilute to 780 mL with ultrapure water. Adjust the pH to 7.8 with phosphoric acid, mix well, and filter. Mix the solution with 220 mL of methanol, and degas by ultrasonication.

2) System Suitability Solution:

Take 1 vial of the mixture of calcium folinate and impurities (provided by the client), dissolve and dilute to 100 mL with ultrapure water. Mix well, filter, and use the subsequent filtrate.

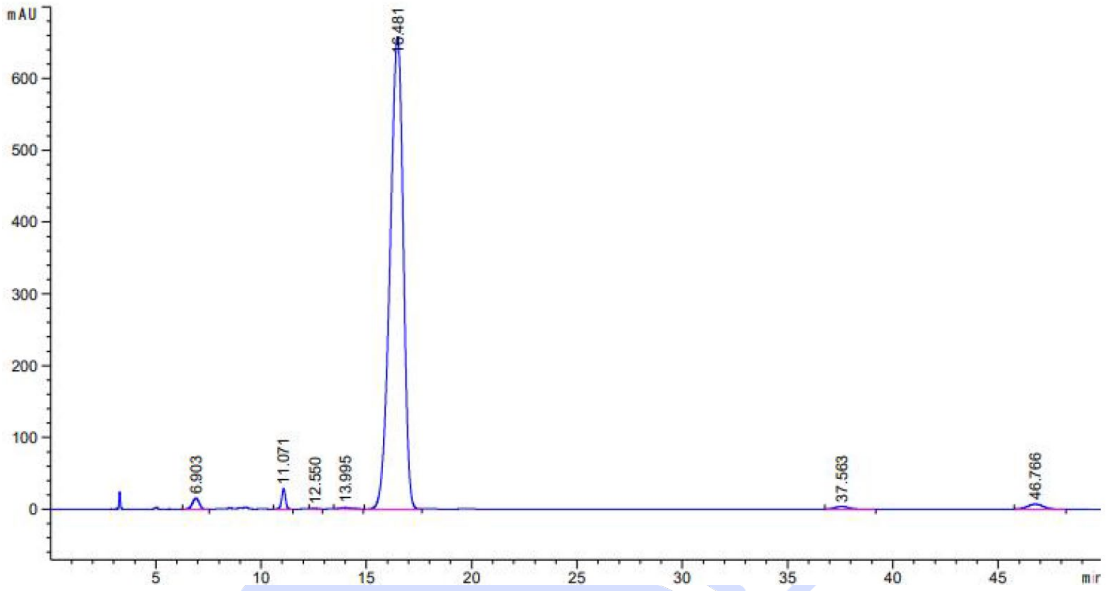
3) Spiked System Suitability Solution:

Take 950 μL of the system suitability solution and mix with 50 μL of 1 mg/mL Impurity 7 solution. Shake well.

2. Chromatograms and Data

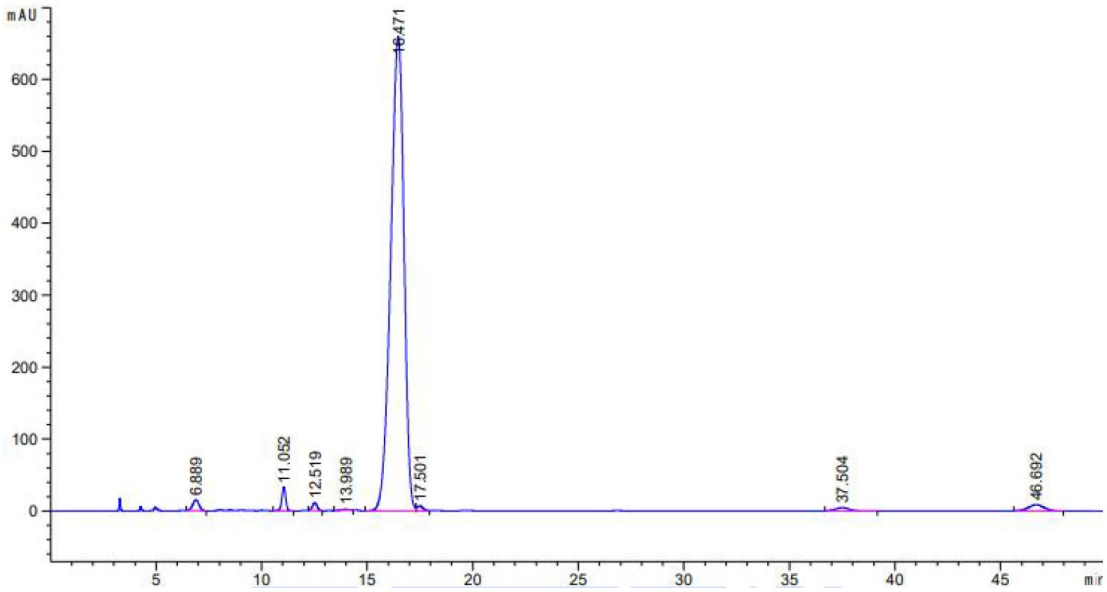
1) System Suitability Solution:

Unless otherwise stated, the results shown in this test report refer only to this sample tested.
The report shall not be copied without the permission of Welch Materials, Inc.
This copy is a translation of its original version. Translation may not be 100% correct.



#	Ret. Time (min)	Peak Area (mAU×s)	Height (mAU)	Sym.	Width (min)	Plates	Res.	Select.
1	6.903	337.68521	15.31326	1.03	0.3560	2084		
2	11.071	355.64673	28.47117	1.01	0.1917	18483	8.94	1.60
3	12.550	15.19559	0.90812	0.71	0.2667	12272	3.79	1.13
4	13.995	79.67955	1.96194	0.66	0.6167	2853	1.92	1.12
5	16.481	28743.5	658.10327	1.28	0.6844	3213	2.25	1.18
6	37.563	179.82568	3.91717	0.91	0.6933	16262	17.98	2.28
7	46.766	370.60693	7.06711	1.00	0.8133	18317	7.18	1.24

2) Spiked System Suitability Solution:



Unless otherwise stated, the results shown in this test report refer only to this sample tested.
The report shall not be copied without the permission of Welch Materials, Inc.
This copy is a translation of its original version. Translation may not be 100% correct.

#	Ret. Time (min)	Peak Area (mAU×s)	Height (mAU)	Sym.	Width (min)	Plates	Res.	Select.
1	6.889	323.01010	15.21704	1.04	0.3367	2321		
2	11.052	421.48029	33.35899	1.02	0.1931	18136	9.23	1.60
3	12.519	166.81927	10.83192	0.97	0.2433	14660	3.95	1.13
4	13.989	37.80275	1.31721	1.65	0.4717	4872	2.42	1.12
5	16.471	28660.3	659.54919	1.28	0.6808	3243	2.53	1.18
6	17.501	144.67308	7.10478	0.78	0.3503	13827	1.17	1.06
7	37.504	209.77000	4.58753	0.92	0.6933	16210	22.52	2.14
8	46.692	447.09079	8.54801	1.02	0.8133	18257	7.17	1.24

3. Conclusion

Using the Welch Ultisil® XB-C18 (4.6×250 mm, 5 µm) column under the specified condition, the requirements of the client can be met.

Unless otherwise stated, the results shown in this test report refer only to this sample tested.
The report shall not be copied without the permission of Welch Materials, Inc.
This copy is a translation of its original version. Translation may not be 100% correct.