

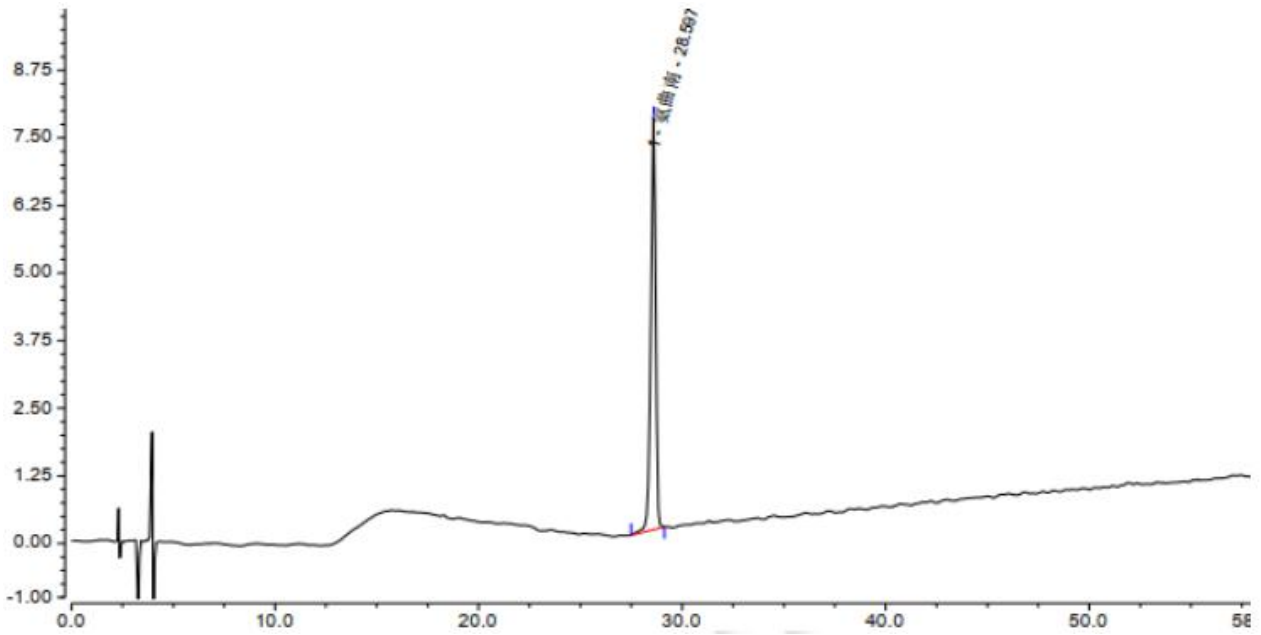
Determination of aztreonam related substance for injection by Ultisil ODS-3

Method:

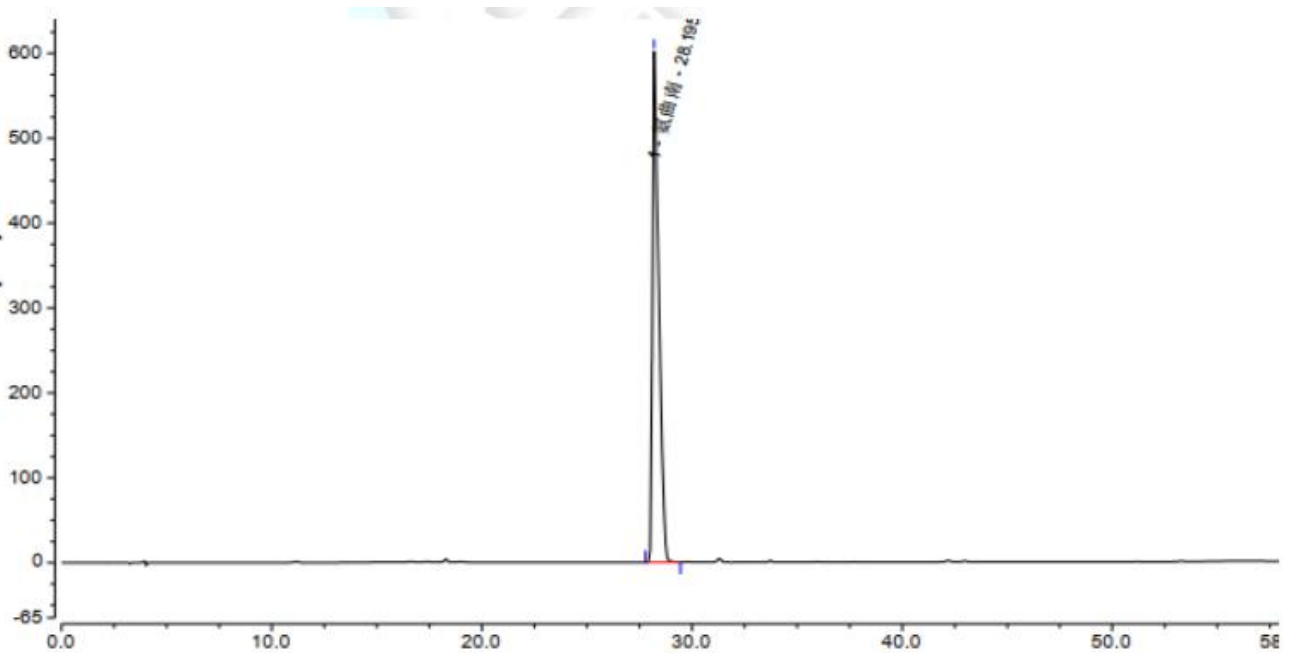
Column	Ultisil® ODS-3 (4.6×250mm, 5µm)		
Mobile Phase	0.01mol/L ammonium formate: Take 0.63g ammonium formate, add 1000mL Wahaha water to dissolve, adjust the pH to 3.0 with formic acid, shake well, and ultrasonic degassification to obtain.		
	Acetonitrile: chromatographic grade acetonitrile is obtained.		
	Time (min)	0.01 mol/L ammonium formate	acetonitrile
	0	96	4
	8	96	4
	18	90	10
	23	90	10
	53	65	35
	58	65	35
	59	96	4
70	96	4	
Detection	254nm		
Temperature	35°C		
Flow Rate	1.0 ml/min		
Injection Volume	10 µL		
Note	/		

Chromatogram and Data:

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.

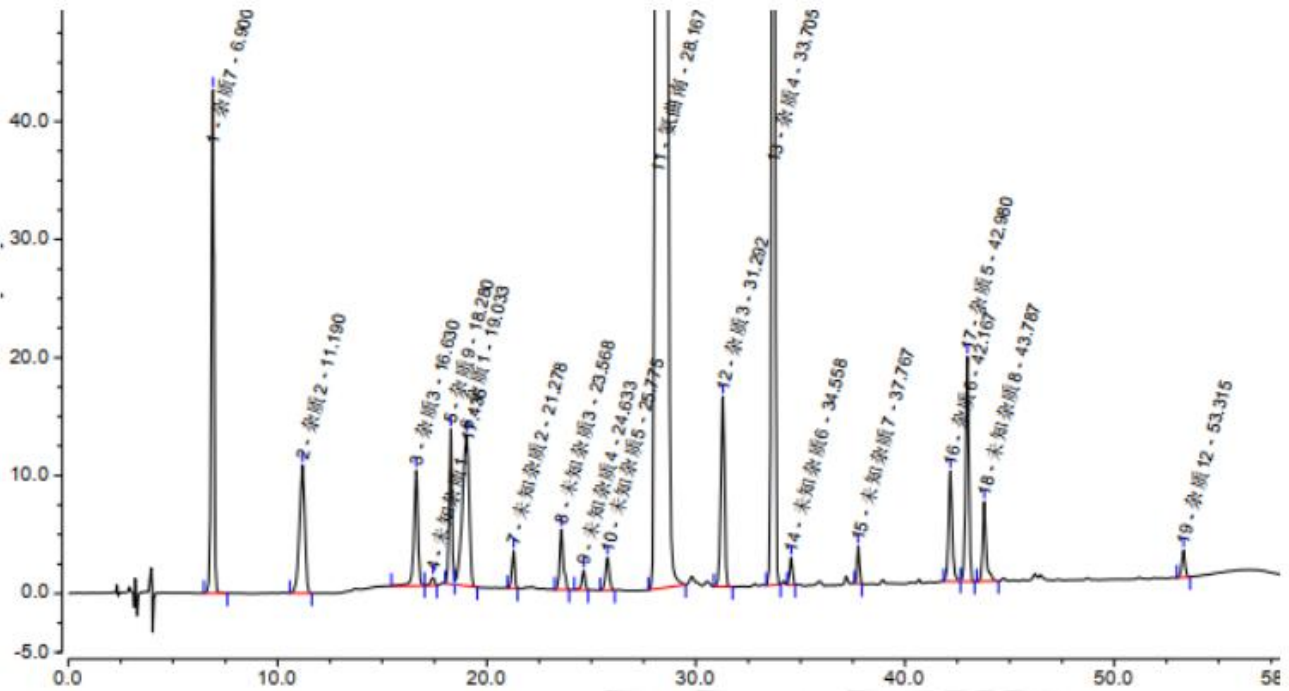


Name	Retention time/min	Area	Height	Number of plates	Asymmetry/EP	Degree of separation (USP)
Aztreonam	28.597	2.086	7.606	75046	0.86	N.a.



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Name	Retention time/min	Area	Height	Number of plates	Asymmetry/EP	Degree of separation (USP)
Aztreonam	28.195	209.149	601.883	40527	2.15	N.a.



Retention time/min	Area	Height	Number of plates	Asymmetry/EP	Degree of separation
6.900	5.979	42.641	16795	0.88	12.80
11.190	3.204	10.845	9506	0.85	14.04
16.630	2.142	9.776	43780	0.85	2.58
17.435	0.149	0.724	51032	n.a.	3.12
18.280	1.980	13.116	97926	0.87	1.81
19.033	4.798	12.765	16133	0.77	5.43
21.278	0.467	3.169	138215	0.89	9.25
23.568	1.022	5.096	124277	1.21	4.01
24.633	0.289	1.634	138553	0.83	3.89
25.775	0.588	2.775	101799	0.94	5.40
28.167	218.171	622.959	39709	2.23	7.11
31.292	3.266	16.094	156511	0.88	8.70
33.705	18.305	118.869	316606	0.94	3.60
34.558	0.345	2.319	344162	0.91	14.80
37.767	0.401	3.181	575162	0.92	17.74
42.167	1.909	9.353	319974	1.08	2.88
42.980	3.292	19.066	412126	0.95	3.08
43.787	1.296	6.742	462637	1.64	35.24
53.315	0.418	2.291	561255	0.93	n.a.

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Conclusion:

Welch Ultisil® ODS-3 (4.6×250mm, 5µm) was used for determination under this chromatographic condition, which can meet the requirements of detection.

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