

TEST REPORT

Name of sample	HGH	Sample number	25B10619-5
sample size	1 bottle	Source of samples	end product
examination date	2025-09- 23	Sample status	freeze-dried powder
Conditions of preservation	2-8°C	inspection personal	QL
facility information	HPLC, ELISA enzyme analyzer, PH meter, etc.		
inspecting item	Protein concentration, purity detection, biological activity, endotoxin detection, PH value, appearance detection		
inspection standard	Refer to ICH (International Technical Requirements for Registration of Human Medicines)		
inspect the conclusion	The protein samples tested in this case are in compliance with relevant ICH standards. The key indexes such as protein concentration, purity and biological activity all meet the expected requirements. Safety indicators such as endotoxins are in line with regulations. Conclusion: The quality of this batch of protein samples is qualified.		
remarks	The instruments and equipment used in the inspection are calibrated and the testing methods are verified.		



TEST REPORT

order number	inspecting item	result	Standard requirements	conclusion
1	Protein concentration detection	11.97mg/ml	$\geq 10.6\text{mg/ml}$	qualified
2	Purity testing	98.48%	$\geq 96\%$	qualified
3	Bioactivity testing	35.92IU/mL	$\geq 32\text{IU/mL}$	qualified
4	Endotoxin testing	1.0EU/mg	$\leq 2\text{EU/mg}$	qualified
5	PH price	PH7.0	PH7.0	qualified
6	surface	White fine powder	White fine powder	qualified

Test items and methods:

- 1. Protein concentration detection: Agilent high performance liquid chromatography (HPLC) was used for determination.
- 2. Purity detection: Agilent high performance liquid chromatography (HPLC) was used for analysis.
- 3. Bioactivity detection: ELISA method was used.
- 4. Endotoxin detection: The LAL method was used to detect endotoxins
- 5. Others: such as PH value, appearance, etc.

Refer to the relevant standards of ICH (International Technical Requirements for Registration of Human Medicines).



Content test report

1. GH reference preparation:

We accurately weighed 6.675 mg of the standard sample, dissolved it in a 1ml volumetric flask and filled it to the scale line.

2. sample preparation :

Take a sample of the finished product and dissolve it in 2mL water

3. Analytical conditions

Analytical instrument: Agilent high performance liquid chromatograph 1290,

Chromatography column: Agilent 5 HC-C18 (250*4.6mm 5 μ m)

Flow phase: A, 20 mmol/L NaH₂ phosphate

B, 100% acetonitrile

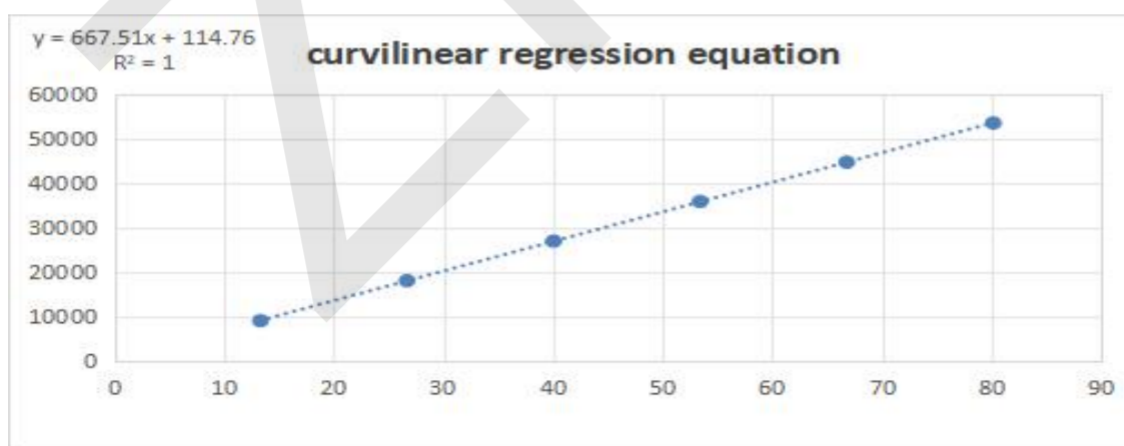
Gradient elution ratio: see right Figure
The detection wavelength is 220 nm

Flow rate: 1. 0ml/min

Pressure: 132 bar column temperature: 45°C

4 Regression equation of the result curve

2 μ l, 4 μ l, 6 μ l, 8 μ l, 10 μ l and 12 μ l standard samples were respectively injected, and then the standard curve equation between the relationship of peak area and protein mass was analyzed.



Standard curve and regression equation

The peak area of the sample after detection is 40085.79. It is inserted into the linear regression equation.

5. Conclusion: According to the regression equation calculation, the sample content is 11.97mg/ml, $\approx$ 35.92IU

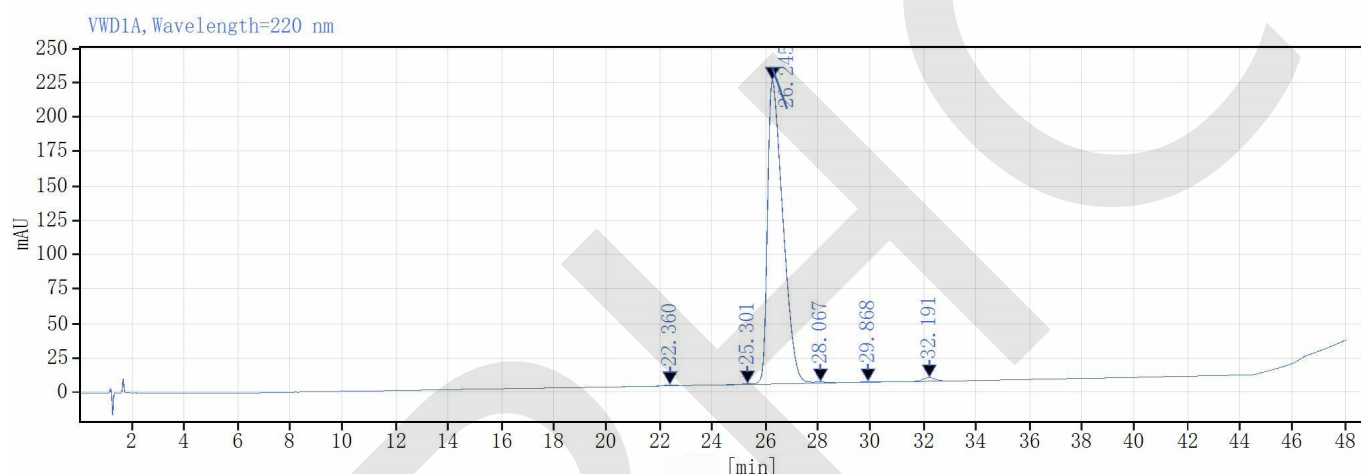
Single-injection report



Agilent Technologies

data file : 2025-09-15 19-39-41+08-00-01.dx
Sequence name: HPLC1290-2025-09-15 19-39-32+08-00
Sample Name: GH reference substance 1
instrument : HPLC1290
Injection volume: 2.000
acquisition method : GH-amx
processing method : GC_LC
 Area percentage_DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-15 19:40:26+08:00
position : 53
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
22.360	MM m	0.37	20.04	0.68	0.22	
25.301	BM m	0.50	21.68	0.53	0.24	
26.245	MM m	0.61	8948.31	220.94	98.14	
28.067	MM m	0.41	27.70	0.82	0.30	
29.868	MM m	0.47	11.93	0.31	0.13	
32.191	BB	1.73	87.80	2.60	0.96	
		sum	9117.46			

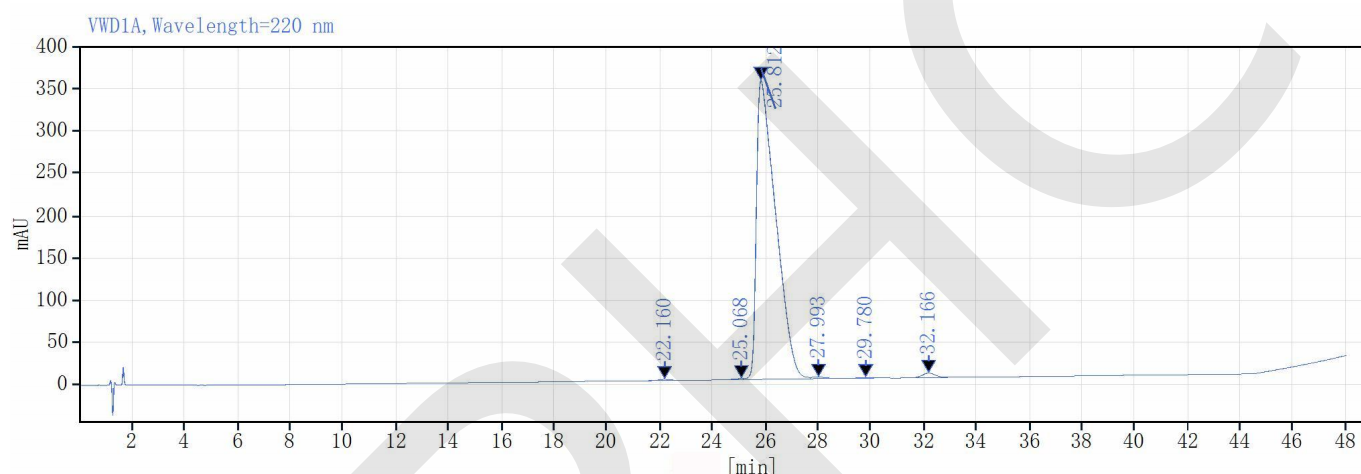
Single-injection report



Agilent Technologies

data file : 2025-09-15 20-34-26+08-00-03.dx
Sequence name: HPLC1290-2025-09-15 19-39-32+08-00
Sample Name: GH reference substance 2
instrument : HPLC1290
Injection volume: 4.000
acquisition method : GH-amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-15 20:35:18+08:00
position : 53
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
22.160	MM m	0.45	44.49	1.40	0.24	
25.068	BM m	0.38	38.09	1.28	0.21	
25.812	MM m	0.72	17966.22	353.91	98.06	
27.993	MM m	0.48	66.74	1.74	0.36	
29.780	MM m	0.46	22.62	0.58	0.12	
32.166	BB	1.79	183.29	5.35	1.00	
sum			18321.45			

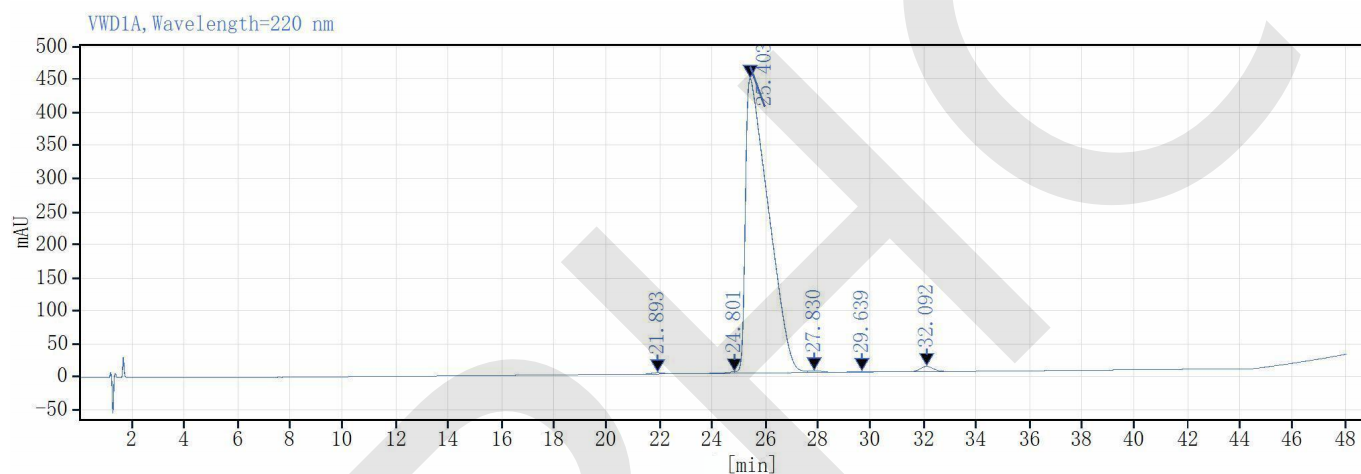
Single-injection report



Agilent Technologies

data file : 2025-09-15 21-29-20+08-00-05.dx
Sequence name: HPLC1290-2025-09-15 19-39-32+08-00
Sample Name: GH reference substance 3
instrument : HPLC1290
Injection volume: 6.000
acquisition method : GH-amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-15 21:30:12+08:00
position : 53
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
21.893	BB	1.36	65.98	2.09	0.24	
24.801	BM m	0.45	61.87	2.29	0.23	
25.403	MM m	0.79	26893.26	445.45	98.02	
27.830	MM m	0.51	87.81	2.47	0.32	
29.639	MM m	0.65	53.52	1.04	0.20	
32.092	BB	1.90	275.18	7.93	1.00	
		sum	27437.62			

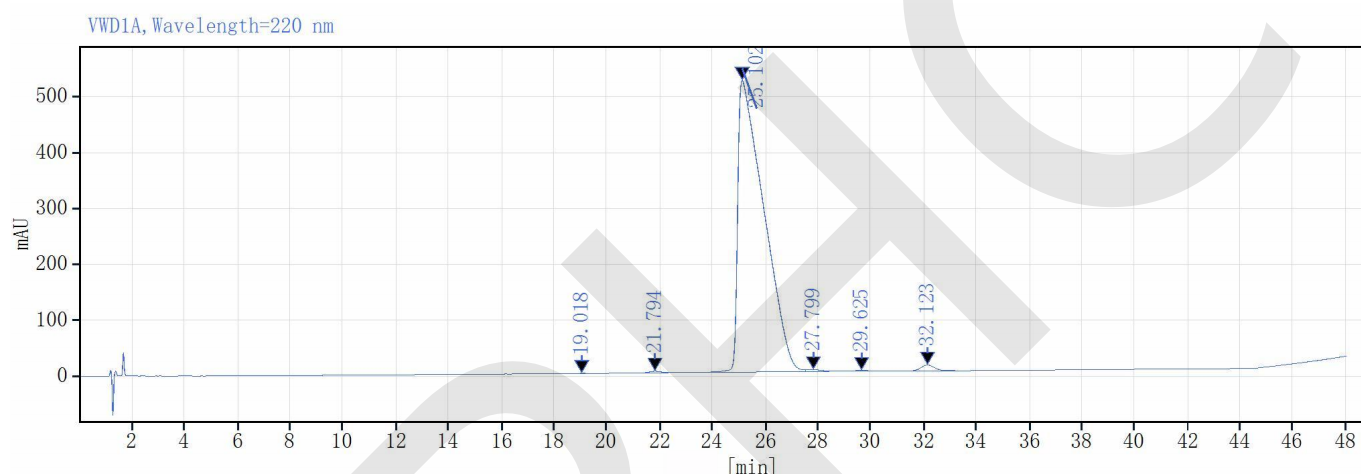
Single-injection report



Agilent Technologies

data file : 2025-09-15 22-24-15+08-00-07.dx
Sequence name: HPLC1290-2025-09-15 19-39-32+08-00
Sample Name: GH reference substance 4
instrument : HPLC1290
Injection volume: 8.000
acquisition method : GH-amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-15 22:25:08+08:00
position : 53
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
19.018	MM m	0.62	17.88	0.35	0.05	
21.794	BB	1.41	88.93	2.88	0.24	
25.102	BM m	0.91	35825.95	523.99	98.14	
27.799	MM m	0.55	123.54	3.17	0.34	
29.625	MM m	0.62	64.87	1.29	0.18	
32.123	BB	2.37	383.50	10.59	1.05	
		sum	36504.67			

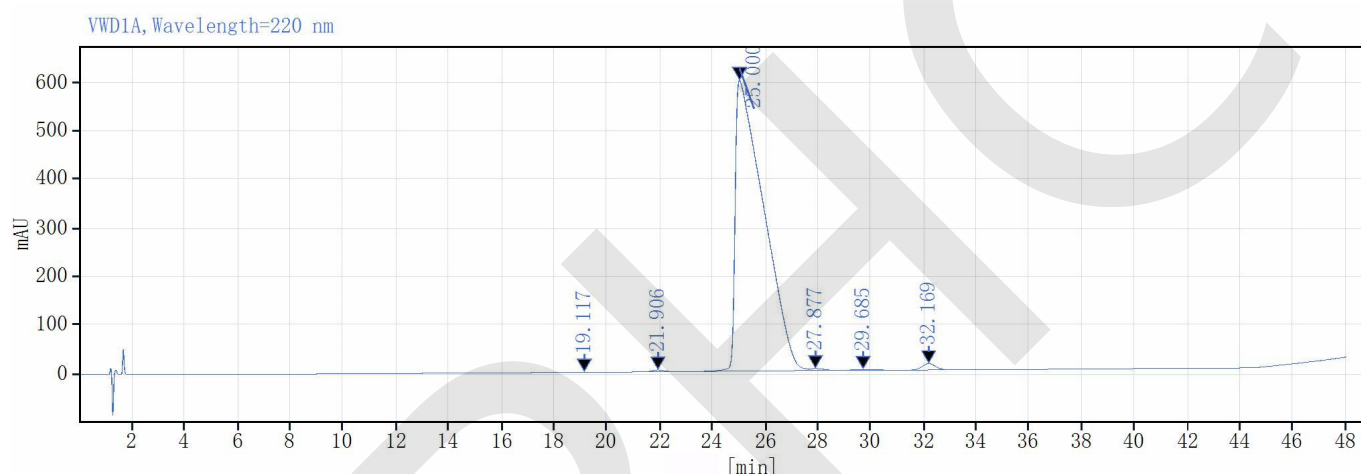
Single-injection report



Agilent Technologies

data file : 2025-09-15 23-19-11+08-00-09.dx
Sequence name: HPLC1290-2025-09-15 19-39-32+08-00
Sample Name: GH reference substance 5
instrument : HPLC1290
Injection volume: 10.000
acquisition method : GH-amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-15 23:20:05+08:00
position : 53
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
19.117	MM m	0.54	21.03	0.47	0.05	
21.906	BM m	0.54	138.95	3.79	0.31	
25.000	BM m	0.99	44679.50	598.43	98.10	
27.877	MM m	0.54	144.40	3.90	0.32	
29.685	BB	2.28	102.94	1.79	0.23	
32.169	BB	1.99	459.62	13.11	1.01	
		sum	45546.44			

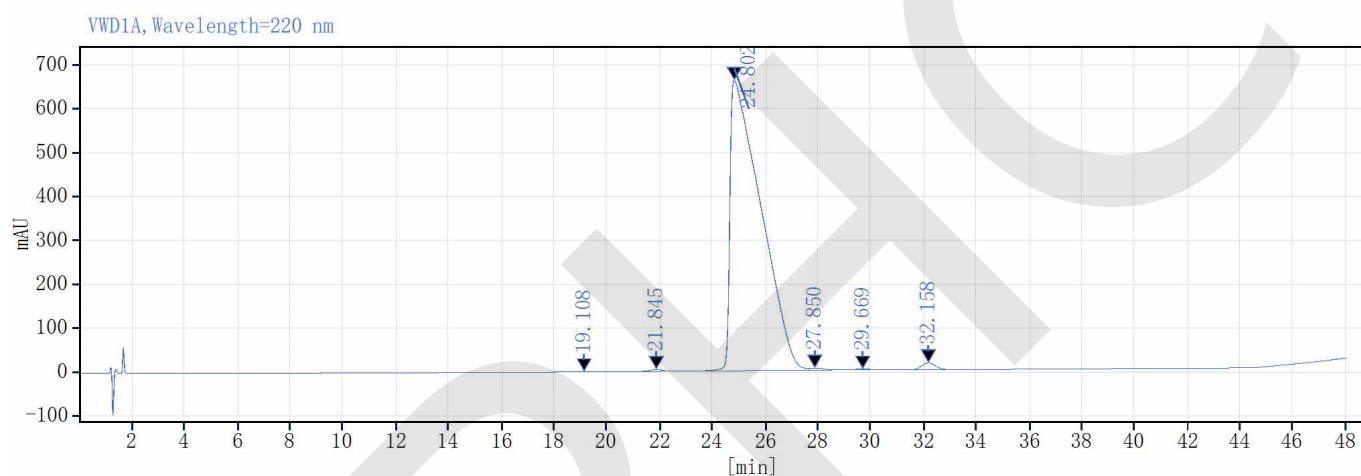
Single-injection report



Agilent Technologies

data file : 2025-09-16 00-14-10+08-00-11.dx
Sequence name: HPLC1290-2025-09-15 19-39-32+08-00
Sample Name: GH reference substance 6
instrument : HPLC1290
Injection volume: 12.000
acquisition method : GH-amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-16 00:15:06+08:00
position : 53
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
19.108	MM m	0.54	23.43	0.53	0.04	
21.845	BM m	0.55	166.01	4.57	0.30	
24.802	BM m	1.06	53513.04	659.95	98.08	
27.850	MM m	0.54	163.14	4.47	0.30	
29.669	BB	2.24	118.48	2.07	0.22	
32.158	BB	2.46	578.96	15.75	1.06	
		sum	54563.06			

Single-injection report



Agilent Technologies

data file : 2025-09-23 11-07-28+08-00-03.dx

Sequence name: HPLC1290-2025-09-23 09-41-22+08-00

project name : Agilent 1290 Infinity

Sample Name: GH 25B10619-5 Sample

handlers : QL

instrument : HPLC1290

Date of sample intake: 2025-09-23 11:08:21+08:00

Injection volume: 5.000

position : 17

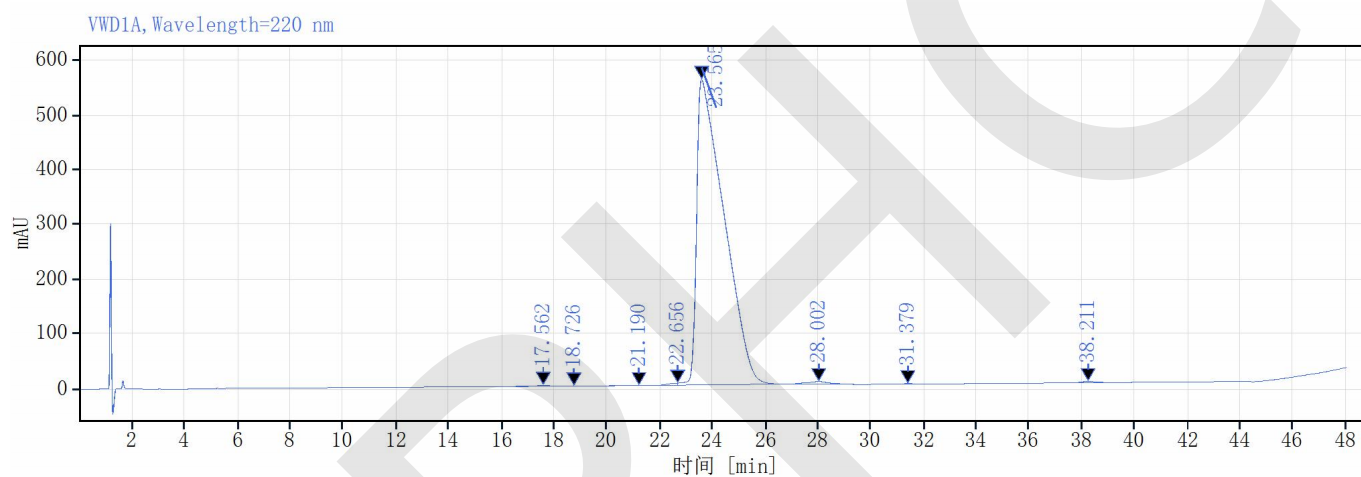
acquisition method : GH-amx

type : sample

processing method : GC_LC
Area percentage _DefaultMethod.pmx

Sample content: 0.00

Manual modification: Manual points



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
17.562	MB m	0.55	81.12	2.06	0.20	
18.726	MM m	0.48	8.51	0.30	0.02	
21.190	MM m	1.06	30.53	0.35	0.07	
22.656	BM m	0.42	92.71	3.67	0.23	
23.565	MB m	0.95	40085.79	558.73	98.48	
28.002	BB	2.55	298.72	4.93	0.73	
31.379	MM m	0.39	29.34	0.98	0.07	
38.211	BB	1.47	77.49	2.30	0.19	
sum			40704.21			