

TEST REPORT

Name osample	hGH FRAGMENT 176-191aa	Sample number	25A10829
sample size	1 bottle	Source of samples	end product
examination date	2025-09 - 17	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, endotoxin detection, PH value and 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 and purity all meet the expected requirements. The safety index of endotoxin was in line with the regulations. Conclusion: The quality of this batch of protein samples isqualified.		
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	2.54mg/ml	≥ 2.5 mg/ml	qualified
2	Purity testing	98.05%	$\geq 96\%$	qualified
3	Endotoxin testing	1.0EU/mg	≤ 2 EU/mg/ml	qualified
4	PH price	PH7.0	PH7.0	qualified
5	surface	Whitefine powder	Whitefine 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. Endotoxin detection: The LAL method was used
- 4. Others: such as PH value, appearance, etc.

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



Content test report

1. hGH FRAGMENT 176-191 standard preparation:

We accurately weighed 4.38 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 1ml water

3. Analytical conditions

Analytical instrument: Agilent high performance chromatograph 1290,

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

**Flow phase: A, 20 mmol/L NaH₂ phosphate
B, 100% acetonitrile**

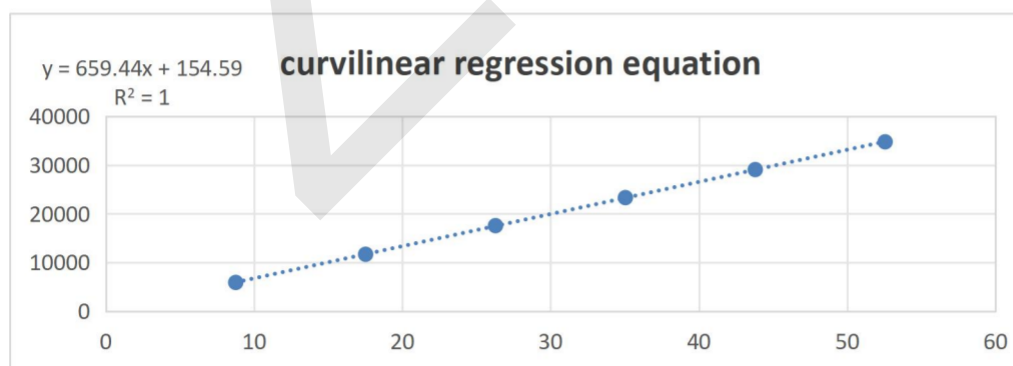
Gradient elution ratio: see right Figure
The detection wavelength is 220 nm

Flow rate: 0.8ml/min

Pressure: 122 bar column temperature: 45°C

4. Regression equation of the result curve

2 μl, 4 μl, 6 μl, 8 μl, 10 μl and 12 μl 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 test sample is 16928.2. Substitute it into the linear regression equation.

5. Conclusion: According to the regression equation calculation, the sample content is 2.54 mg/ml

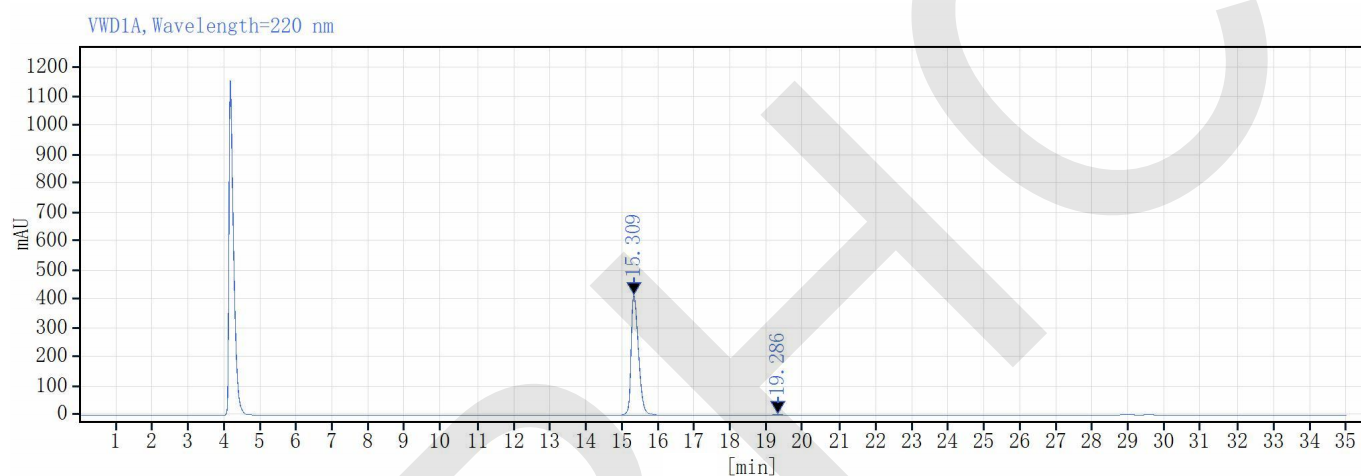
Single-injection report



Agilent Technologies

data file : 2025-09-16 23-22-26+08-00-02.dx
Sequence name: HPLC1290-2025-09-16 20-26-59+08-00
Sample Name: RH standard 1
instrument : HPLC1290
Injection volume: 2.000
acquisition method : RH.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 23:23:03+08:00
position : 64
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
15.309	BV	1.31	5894.38	413.63	99.40	
19.286	BB	0.91	35.87	2.27	0.60	
		sum	5930.26			

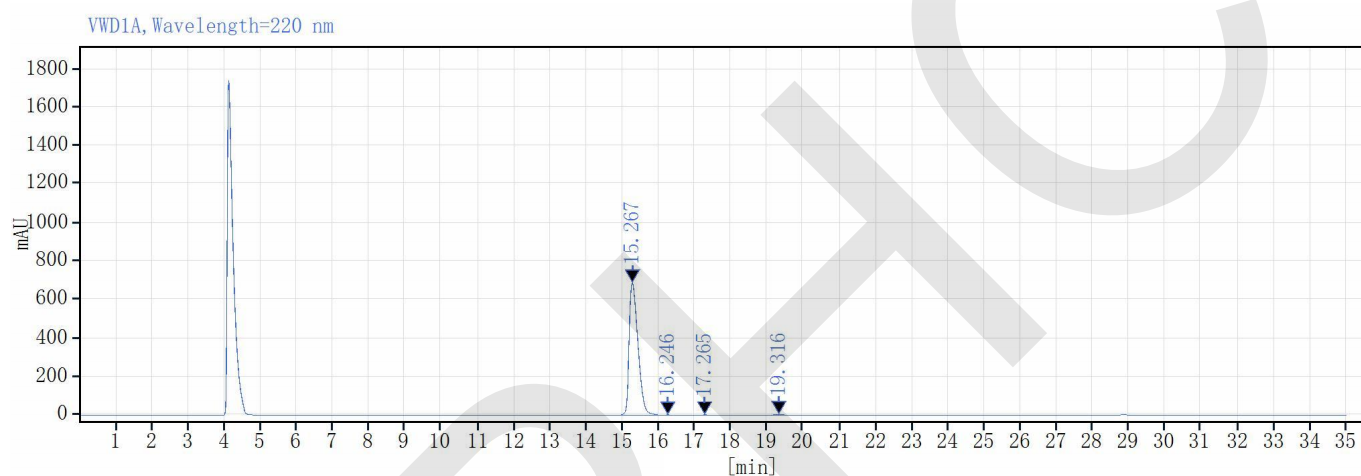
Single-injection report



Agilent Technologies

data file : 2025-09-16 23-58-09+08-00-03.dx
Sequence name: HPLC1290-2025-09-16 20-26-59+08-00
Sample Name: RHstandard 2
instrument : HPLC1290
Injection volume: 4.000
acquisition method : RH.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 23:58:43+08:00
position : 64
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
15.267	BV	1.31	11676.31	687.20	98.96	
16.246	VB	0.62	32.10	1.75	0.27	
17.265	BB	0.62	23.64	2.05	0.20	
19.316	MM m	0.23	67.06	4.42	0.57	
		sum	11799.10			

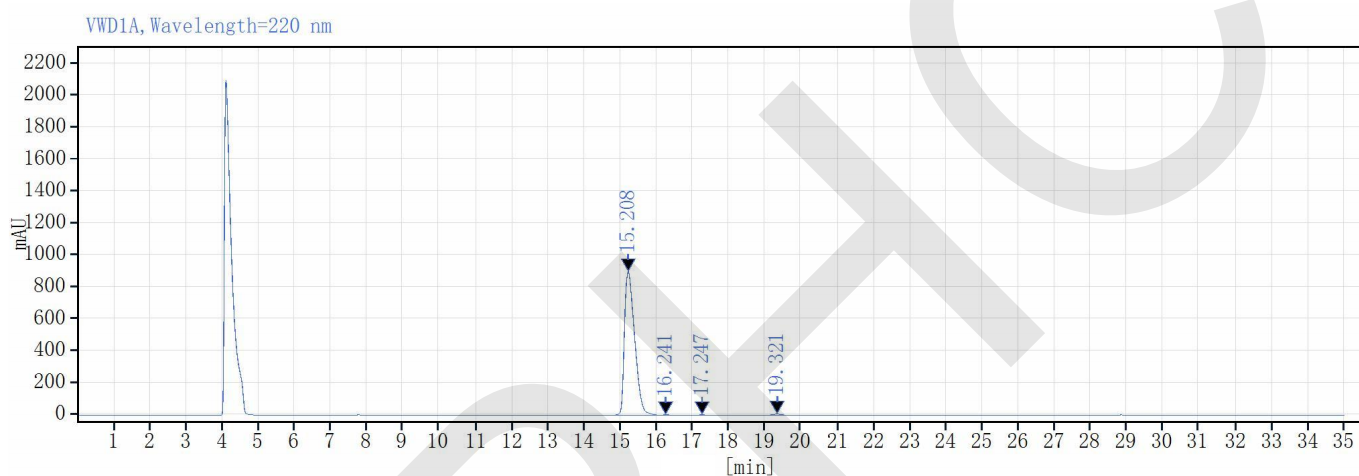
Single-injection report



Agilent Technologies

data file : 2025-09-17 00-33-49+08-00-04.dx
Sequence name: HPLC1290-2025-09-16 20-26-59+08-00
Sample Name: RHstandard 3
instrument : HPLC1290
Injection volume: 6.000
acquisition method : RH.amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-17 00:34:26+08:00
position : 64
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
15.208	VV	1.34	17553.05	896.38	98.92	
16.241	VB	0.63	50.52	2.71	0.28	
17.247	BB	0.62	35.63	3.13	0.20	
19.321	MB m	0.24	104.68	6.73	0.59	
		sum	17743.88			

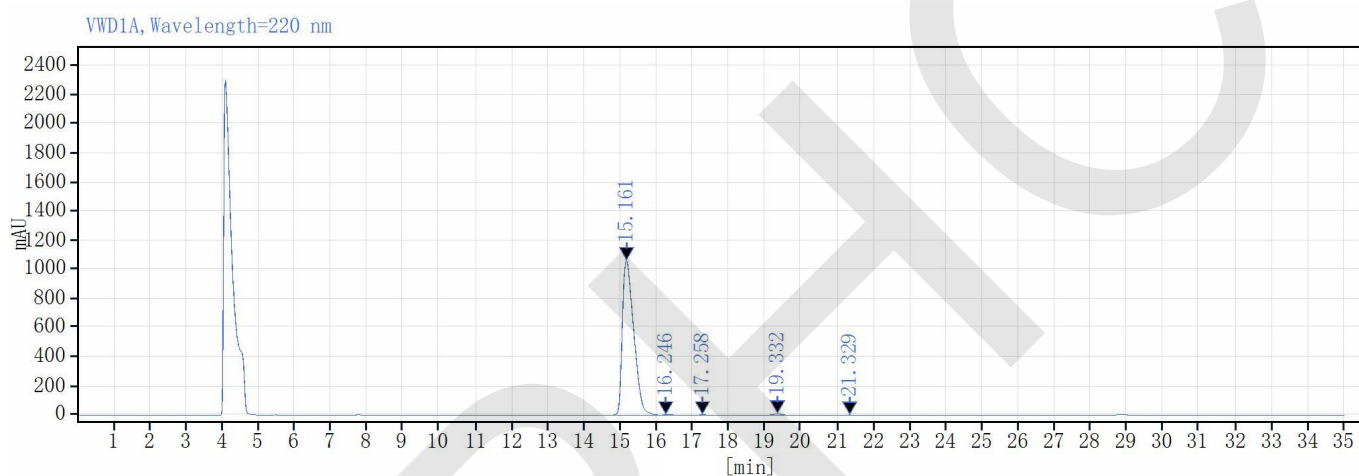
Single-injection report



Agilent Technologies

data file : 2025-09-17 01-09-31+08-00-05.dx
Sequence name: HPLC1290-2025-09-16 20-26-59+08-00
Sample Name: RHstandard 4
instrument : HPLC1290
Injection volume: 8.000
acquisition method : RH.amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-17 01:10:11+08:00
position : 64
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
15.161	VV	1.38	23303.60	1064.22	98.84	
16.246	VB	0.63	67.37	3.63	0.29	
17.258	BB	0.62	47.57	4.19	0.20	
19.332	BB	0.91	143.44	9.06	0.61	
21.329	BB	0.41	15.73	1.71	0.07	
		sum	23577.71			

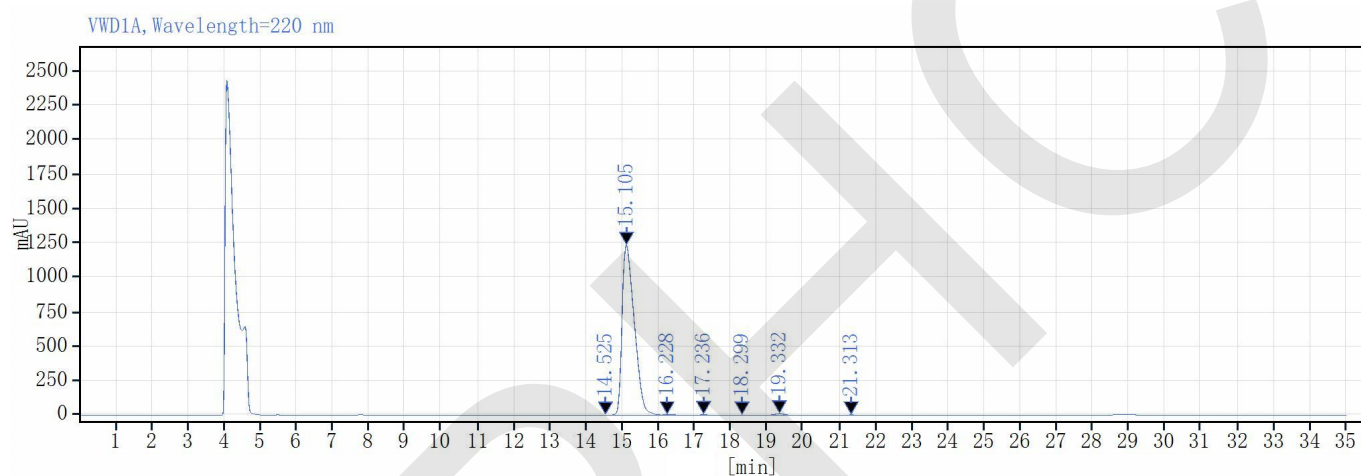
Single-injection report



Agilent Technologies

data file : 2025-09-17 01-45-16+08-00-06.dx
Sequence name: HPLC1290-2025-09-16 20-26-59+08-00
Sample Name: RHstandard 5
instrument : HPLC1290
Injection volume: 10.000
acquisition method : RH.amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-17 01:45:58+08:00
position : 64
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
14.525	VV	0.36	29.12	1.86	0.10	
15.105	VV	1.41	29060.24	1237.70	98.67	
16.228	VB	0.63	83.95	4.48	0.29	
17.236	BB	0.62	59.63	5.29	0.20	
18.299	BB	0.39	17.12	1.90	0.06	
19.332	BB	0.94	179.56	11.27	0.61	
21.313	BV	0.41	21.22	2.21	0.07	
sum			29450.86			

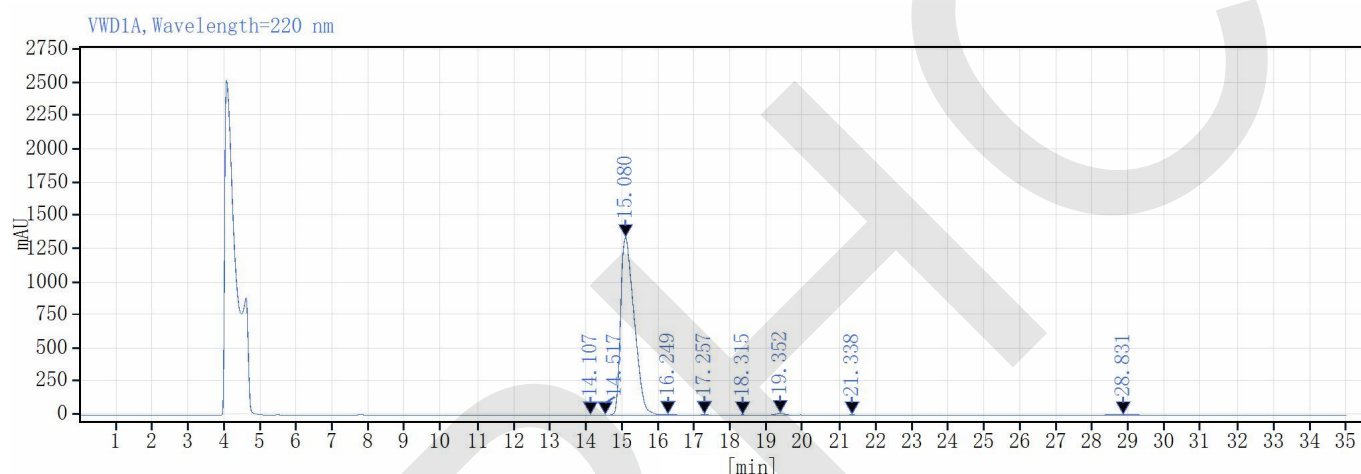
Single-injection report



Agilent Technologies

data file : 2025-09-17 02-21-03+08-00-07.dx
Sequence name: HPLC1290-2025-09-16 20-26-59+08-00
Sample Name: RHstandard 6
instrument : HPLC1290
Injection volume: 12.000
acquisition method : RH.amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-17 02:21:46+08:00
position : 64
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
14.107	BV	0.53	27.89	1.83	0.08	
14.517	VV	0.32	32.74	2.26	0.09	
15.080	VV	1.47	34750.91	1338.16	98.29	
16.249	VB	0.63	100.61	5.39	0.28	
17.257	VB	0.62	72.94	6.35	0.21	
18.315	BB	0.39	20.72	2.29	0.06	
19.352	BB	0.92	215.60	13.56	0.61	
21.338	BV	0.42	25.16	2.58	0.07	
28.831	BB	1.94	108.46	1.71	0.31	
sum			35355.02			

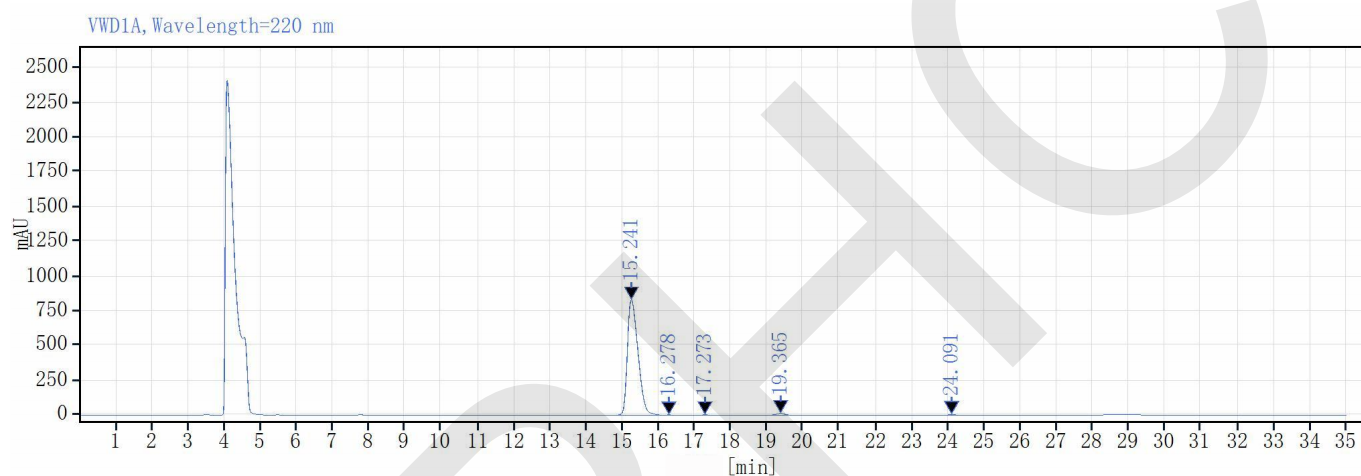
Single-injection report



Agilent Technologies

data file : 2025-09-17 03-32-41+08-00-09.dx
Sequence name: HPLC1290-2025-09-16 20-26-59+08-00
Sample Name: RH25A10829 Sample
instrument : HPLC1290
Injection volume: 10.000
acquisition method : RH.amx
processing method : GC_LC
 Area percentage_DefaultMethod.pmx
Manual modification: Manual points

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-17 03:33:23+08:00
position : 68
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
15.241	VV	1.38	16928.20	831.43	98.05	
16.278	VB	0.61	46.05	2.45	0.27	
17.273	BB	0.60	40.19	3.63	0.23	
19.365	BB	0.93	195.46	12.24	1.13	
24.091	BB	0.73	54.35	4.81	0.31	
	sum		17264.25			