

TEST REPORT

Name osample	TIRZEPATIDE	Sample number	25A10908
sample size	1 bottle	Source of samples	end product
examination date	2025-08- 1 6	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	12.00mg/ml	≥ 10 mg/ml	qualified
2	Purity testing	99.46%	$\geq 96\%$	qualified
3	Endotoxin testing	1.0EU/mg	≤ 2 EU/mg	qualified
4	PH price	PH7.0	PH7.0	qualified
5	surface	White fine powder	Whit efine 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. TIR reference preparation:

We accurately weighed 3.35mg of the standard sample, dissolved it in a 1ml volumetric flask and filled it to the scale line.

2. sample preparation :

Take a bottle of finished product sample, and dissolve 2ml of it in water.

3. Analytical conditions

Analytical instrument: Agilent high performance liquid chromatograph 1290,

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

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

Gradient elution ratio: see right Figure →

The detection wavelength is 220 nm

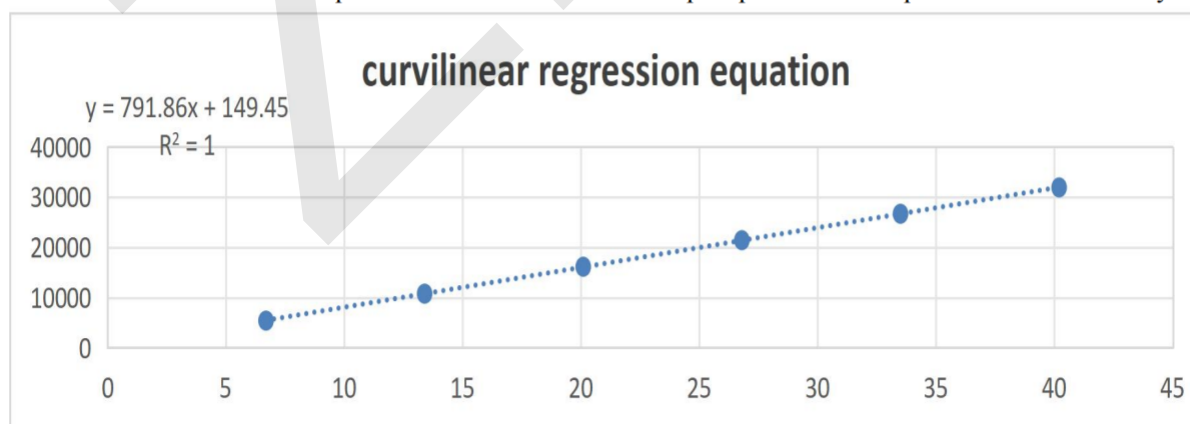
Flow rate: 0.8ml/min

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.

Min	A(%)	B(%)
0	60	40
5	60	40
55	50	50
57	35	65
60	35	65
62	60	40
70	60	40



Standard curve and regression equation

The peak area of the test sample is 4 7 6 7 1 . 2 2 . Substitute it into the linear regression equation.

5. Conclusion: According to the regression equation, the sample content is 12.00mg/ml

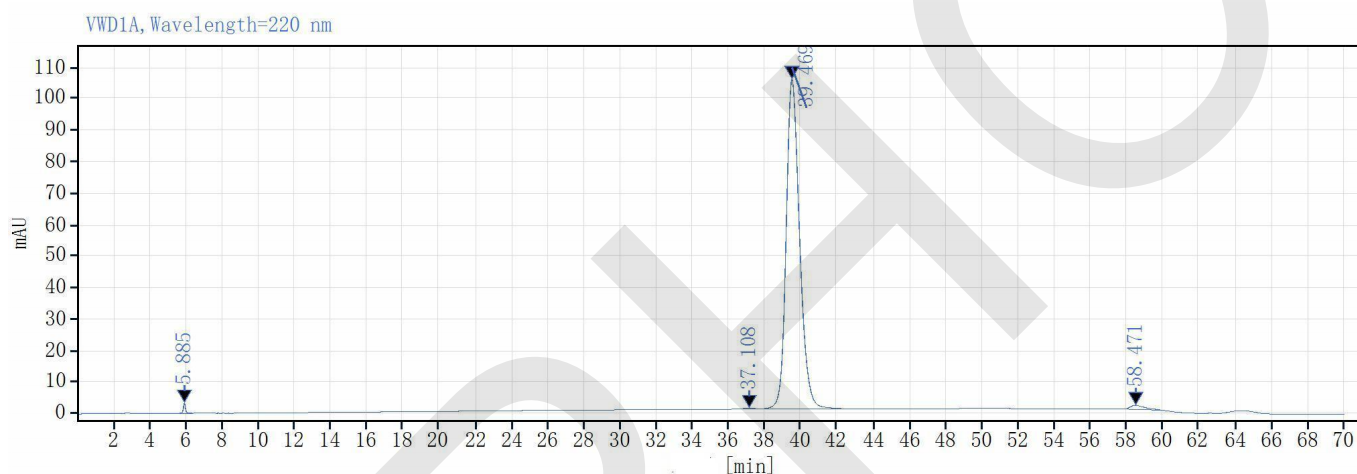
Single sample report



Agilent Technologies

data file : 2025-09-10 20-20-38+08-00-03.dx
Sequence name: HPLC1290-2025-09-10 20-09-25+08-00
Sample Name: TIR standard 1
instrument : HPLC1290
Injection volume: 2.000
acquisition method : TIR.amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual credits

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-10 20:21:25+08:00
position : 20
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
5.885	BB	0.76	27.45	3.26	0.50	
37.108	MM m	0.45	8.26	0.22	0.15	
39.469	BB	4.85	5396.19	104.74	98.03	
58.471	MM m	0.68	72.97	1.27	1.33	
		sum	5504.87			

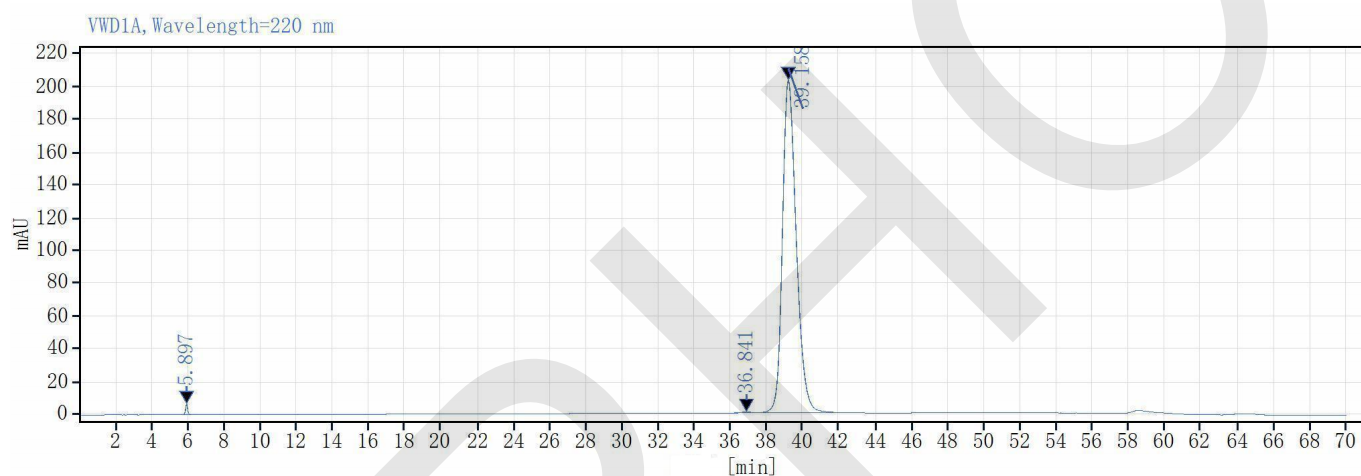
Single sample report



Agilent Technologies

data file : 2025-09-10 21-31-31+08-00-04.dx
Sequence name: HPLC1290-2025-09-10 20-09-25+08-00
Sample Name: TIR standard 2
instrument : HPLC1290
Injection volume: 4.000
acquisition method : TIR.amx
processing method : GC_LC
Area percentage _DefaultMethod.pmx
Manual modification: Manual credits

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-10 21:32:15+08:00
position : 20
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
5.897	BB	0.96	54.56	6.49	0.50	
36.841	MM m	0.49	19.09	0.46	0.18	
39.158	BB	5.61	10763.23	202.75	99.32	
		sum	10836.88			

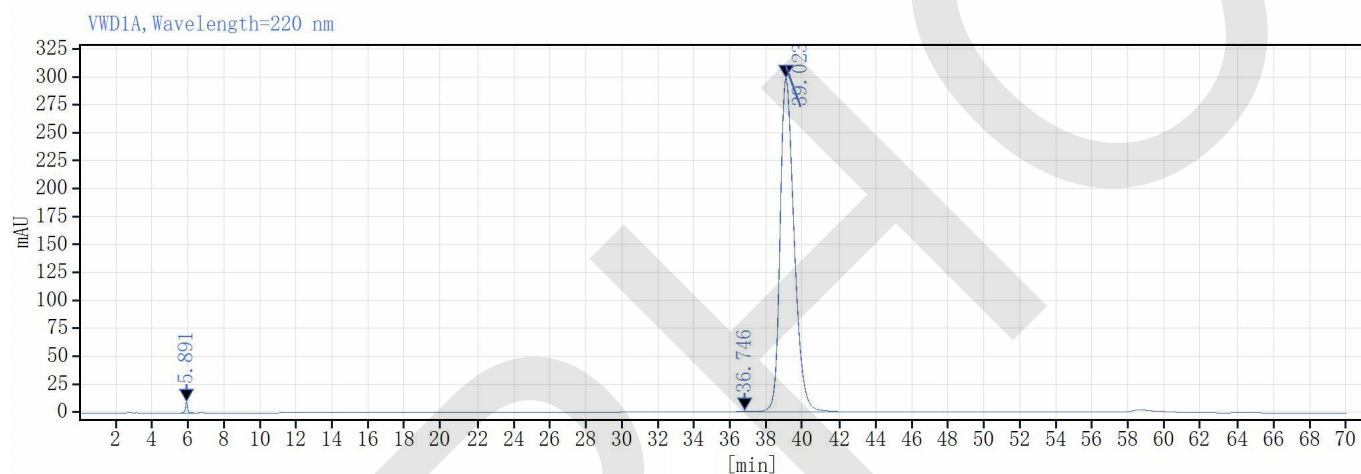
Single sample report



Agilent Technologies

data file : 2025-09-10 22-42-20+08-00-05.dx
Sequence name: HPLC1290-2025-09-10 20-09-25+08-00
Sample Name: TIR standard 3
instrument : HPLC1290
Injection volume: 6.000
acquisition method : TIR.amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual credits

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-10 22:43:06+08:00
position : 20
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
5.891	BB	0.82	81.47	9.70	0.50	
36.746	MM m	0.50	27.95	0.67	0.17	
39.023	BB	6.54	16129.34	298.77	99.33	
	sum		16238.76			

Single sample report



Agilent Technologies

data file : 2025-09-10 23-53-12+08-00-06.dx

Sequence name: HPLC1290-2025-09-10 20-09-25+08-00

project name : Agilent 1290 Infinity

Sample Name: TIR standard 4

handlers : QL

instrument : HPLC1290

Date of sample intake: 2025-09-10 23:53:59+08:00

Injection volume: 8.000

position : 20

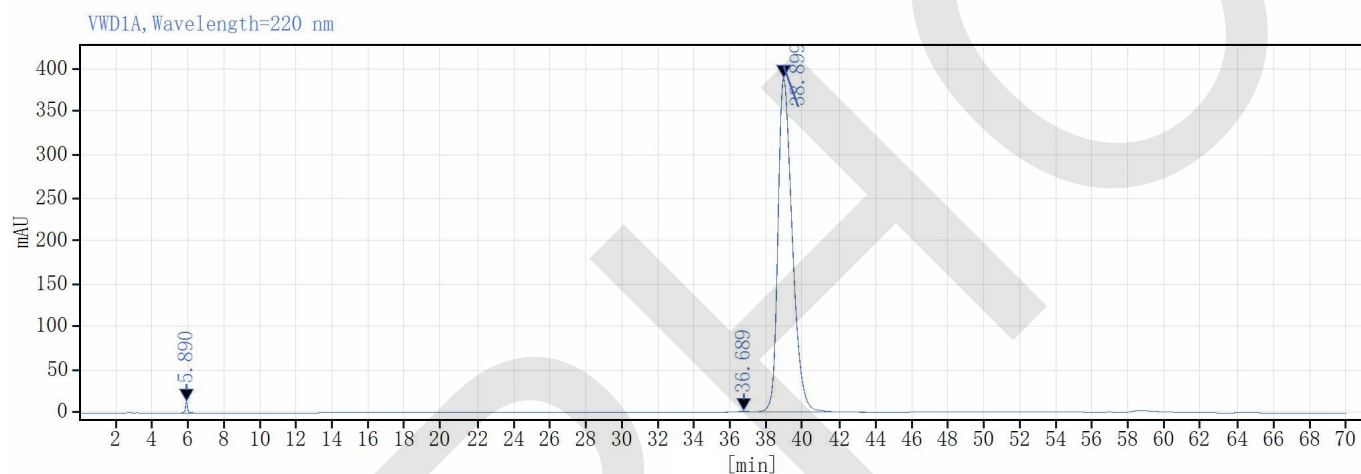
acquisition method : TIR.amx

type : sample

processing method : GC_LC
Area percentage _DefaultMethod.pmx

Sample content: 0.00

Manual modification: Manual credits



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
5.890	BB	0.98	108.27	12.87	0.50	
36.689	MM m	0.49	35.94	0.89	0.17	
38.899	BB	6.46	21415.94	388.52	99.33	
		sum	21560.15			

Single sample report



Agilent Technologies

data file : 2025-09-10 01-04-06+08-00-07.dx

Sequence name: HPLC1290-2025-09-10 20-09
-25+08-00

project name : Agilent 1290 Infinity

Sample Name: TIR standard 5

handlers : QL

instrument : HPLC1290

Date of sample intake: 2025-09-10 01:04:57+08:00

Injection volume: 10.000

position : 20

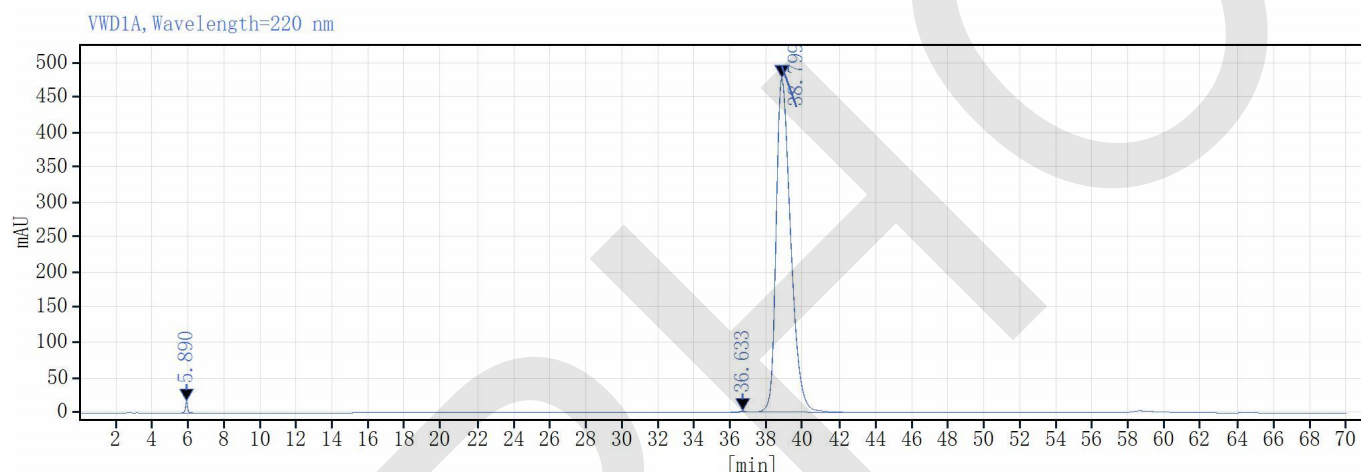
acquisition method : TIR.amx

type : sample

processing method : GC_LC
Area percentage _DefaultMethod.pmx

Sample content: 0.00

Manual modification: Manual credits



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
5.890	BB	0.97	135.26	16.00	0.50	
36.633	MM m	0.55	44.77	1.08	0.17	
38.799	BB	6.58	26678.50	476.67	99.33	
	sum		26858.52			

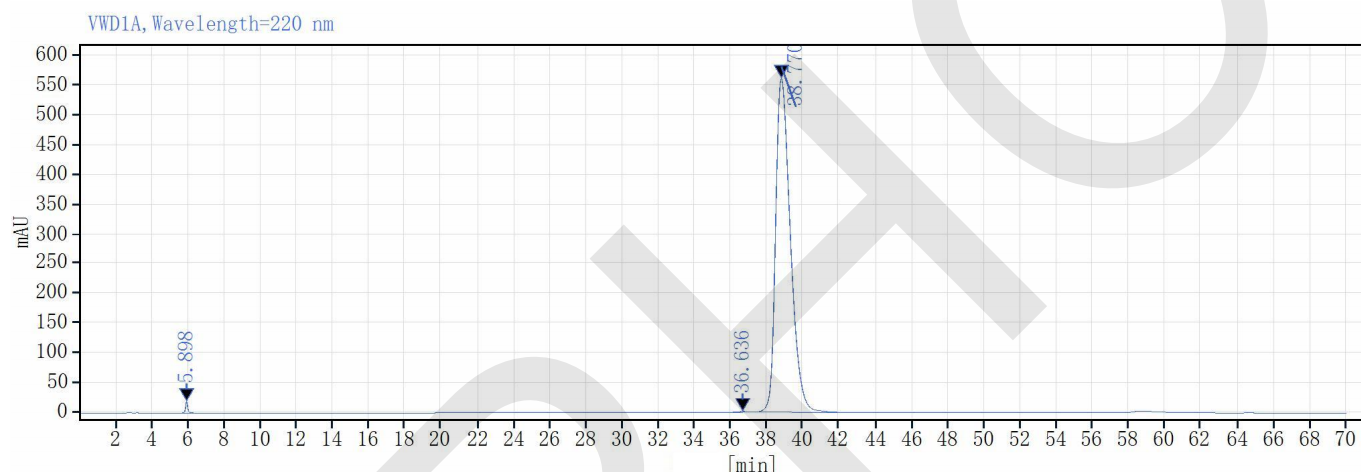
Single sample report



Agilent Technologies

data file : 2025-09-10 02-15-02+08-00-08.dx
Sequence name: HPLC1290-2025-09-10 20-09-25+08-00
Sample Name: TIR standard 6
instrument : HPLC1290
Injection volume: 12.000
acquisition method : TIR.amx
processing method : GC_LC
 Area percentage _DefaultMethod.pmx
Manual modification: Manual credits

project name : Agilent 1290 Infinity
handlers : QL
Date of sample intake: 2025-09-10 02:15:54+08:00
position : 20
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
5.898	BB	0.97	161.73	19.09	0.50	
36.636	MM m	0.52	51.31	1.25	0.16	
38.770	BB	6.41	31927.80	560.57	99.34	
	sum		32140.84			

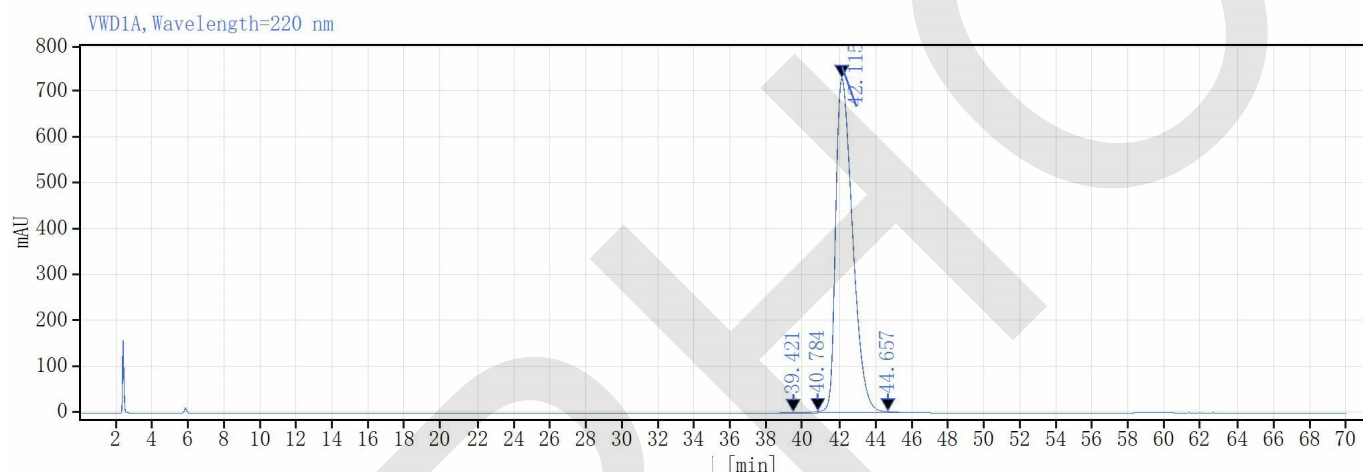
Single-injection report



Agilent Technologies

data file : 2025-09-16 21-35-38+08-00-02.dx
Sequence name: HPLC1290-2025-09-16 20-24-35+08-00
Sample Name: TIR 25A10908 Sample
instrument : HPLC1290
Injection volume: 10.000
acquisition method : TIR.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 21:36:26+08:00
position : 66
type : sample
Sample content: 0.00



signal : VWD1A, Wavelength=220 nm

retention time	type	peak width [min]	peak area	altitude	peak area %	name
39.421	MM m	0.67	73.71	1.42	0.15	
40.784	MM m	0.42	85.31	3.35	0.18	
42.115	MM m	1.02	47671.22	730.55	99.46	
44.657	MB m	0.58	99.26	2.83	0.21	
		sum	47929.50			