



202151-w

Purity Test Report by HPLC-MS/UV  
(Letrozole)



## Summary

\* We test the purity of Letrozole by HPLC-MS and the result is 103.89%.

\* We test the purity of Letrozole by HPLC-UV and the result it 97.64%



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## Test Method

*HPLC: Agilent 1260*

*MS: Bruker micrOTOF-Q II*

*Test solution:* Dissolve 2.70 mg of Letrozole RS in Diluent Solution (acetonitrile:water=3:7) and dilute to 250 mL with the same solvent.

*Reference solution:* Dissolve 2.58 mg of Letrozole RS in Diluent Solution (acetonitrile:water=3:7) and dilute to 250 mL with the same solvent. Then dilute the solution to 1/2, 1/4 and 1/8 concentration with Diluent solution.

*Column:*

— size:  $l = 0.125$  m,  $\varnothing = 4.6$  mm, Innoval L1

*Mobile phase* (water and acetonitrile).

*Flow rate* 1 mL/min.

*Detection* Spectrophotometer at 230 nm.

*Injection* 20  $\mu$ L.

MS: ESI, positive ion detection,  $m/z=286.1079 \pm 0.01$



## Test Result

### HPLC-MS

Standard curve R=0.999894

Y=182848.636973x+303801.118063

Result=103.89

For more details, please see the attachments

### HPLC-UV

N.O.	R.T (min)	Concentration (mg/25mL)	Area of UV
1	11.91	0.555625	1382.43
2	11.39	1.11125	2791.21
3	11.37	2.2225	5527.73
4	11.37	4.445	11016.15
5	11.36	8.89	22242.02
S1	11.34	2.56	6370.07
S2	11.42	2.55	6360.20
S3	11.43	2.55	6360.60

y=2500.4311x-21.76458, R=0.99996

Result = 97.64%

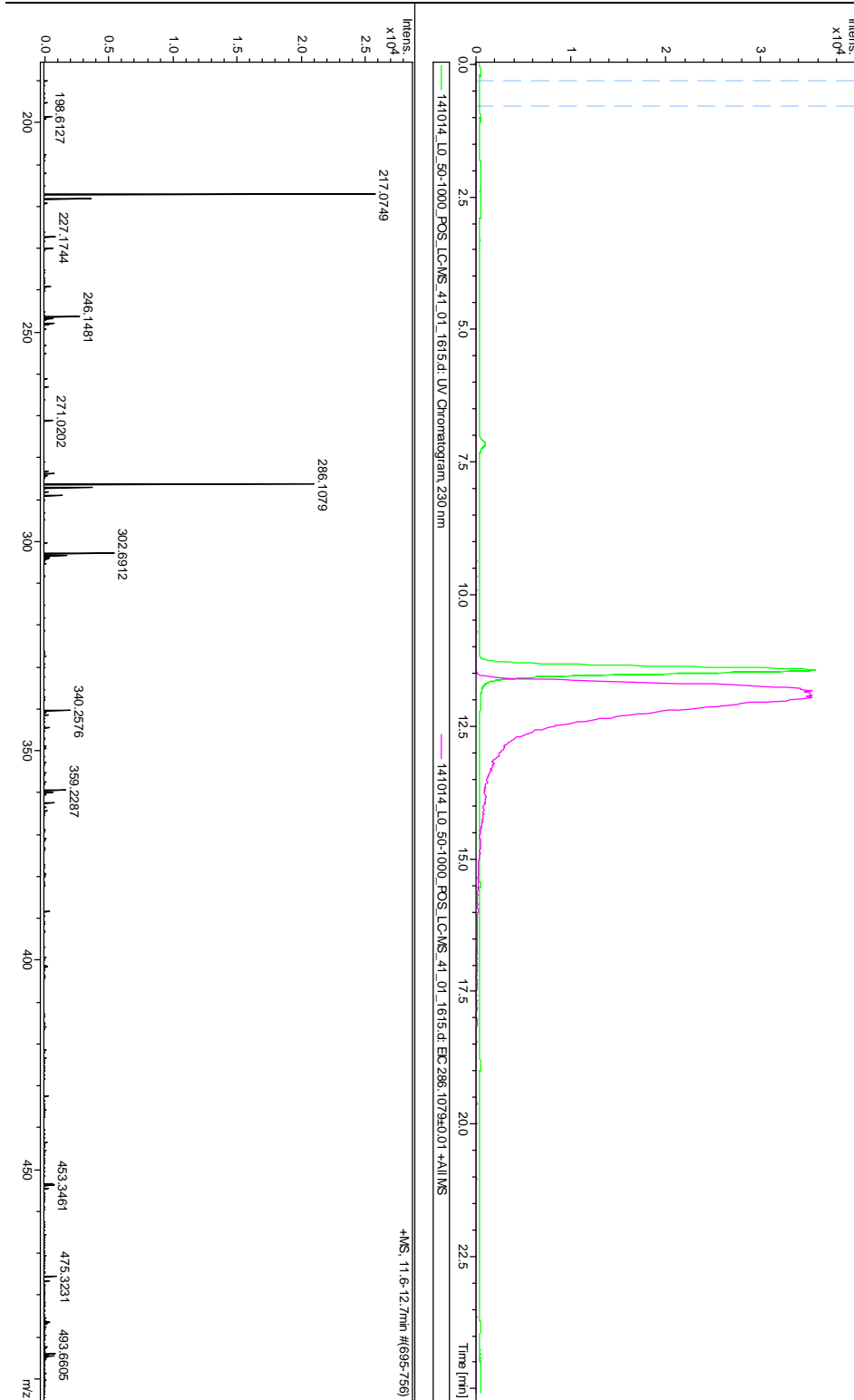
For more details, please see the attachments

Attachments:

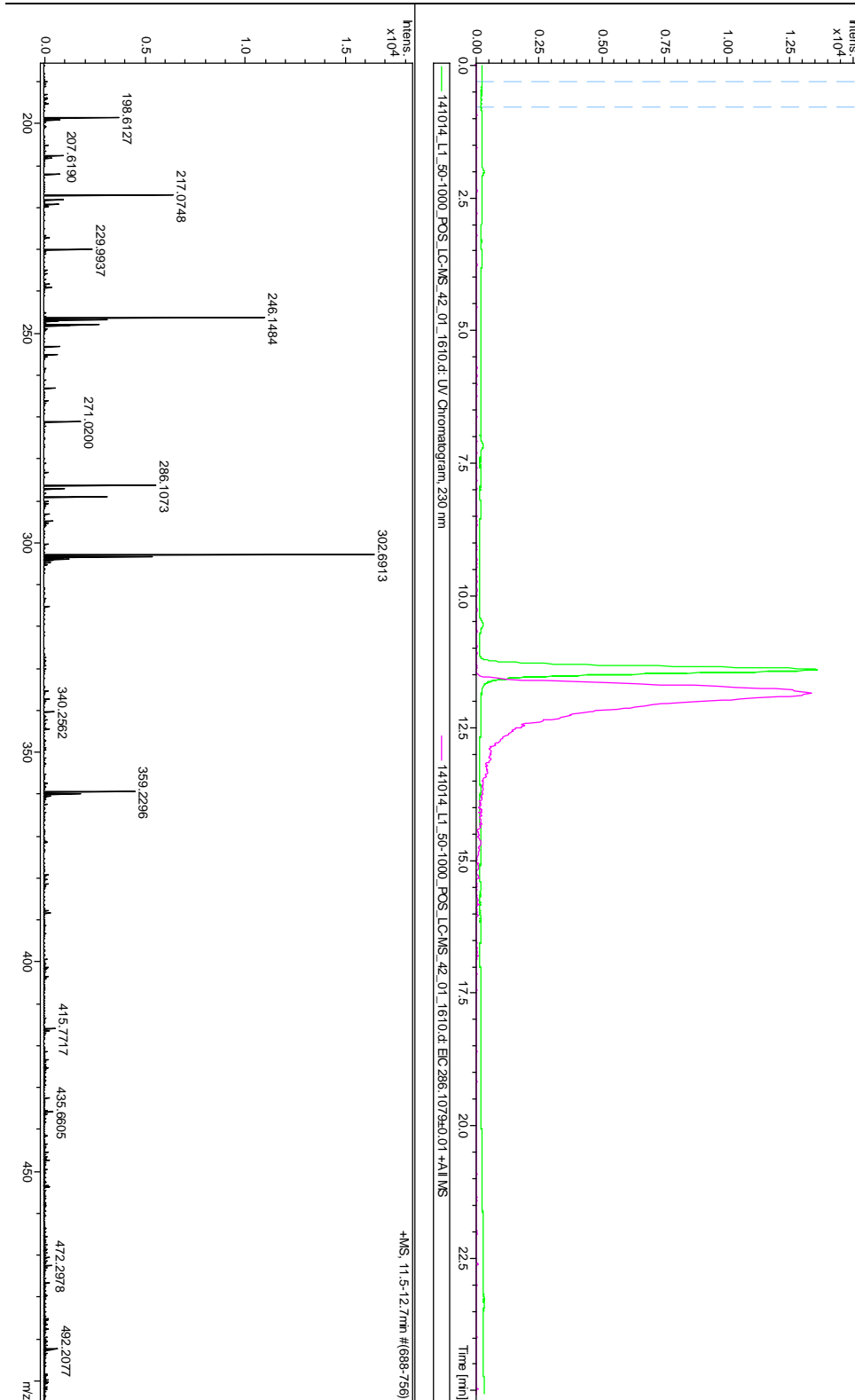
RED: HPLC-MS chromatogram

GREEN: HPLC-UV chromatogram

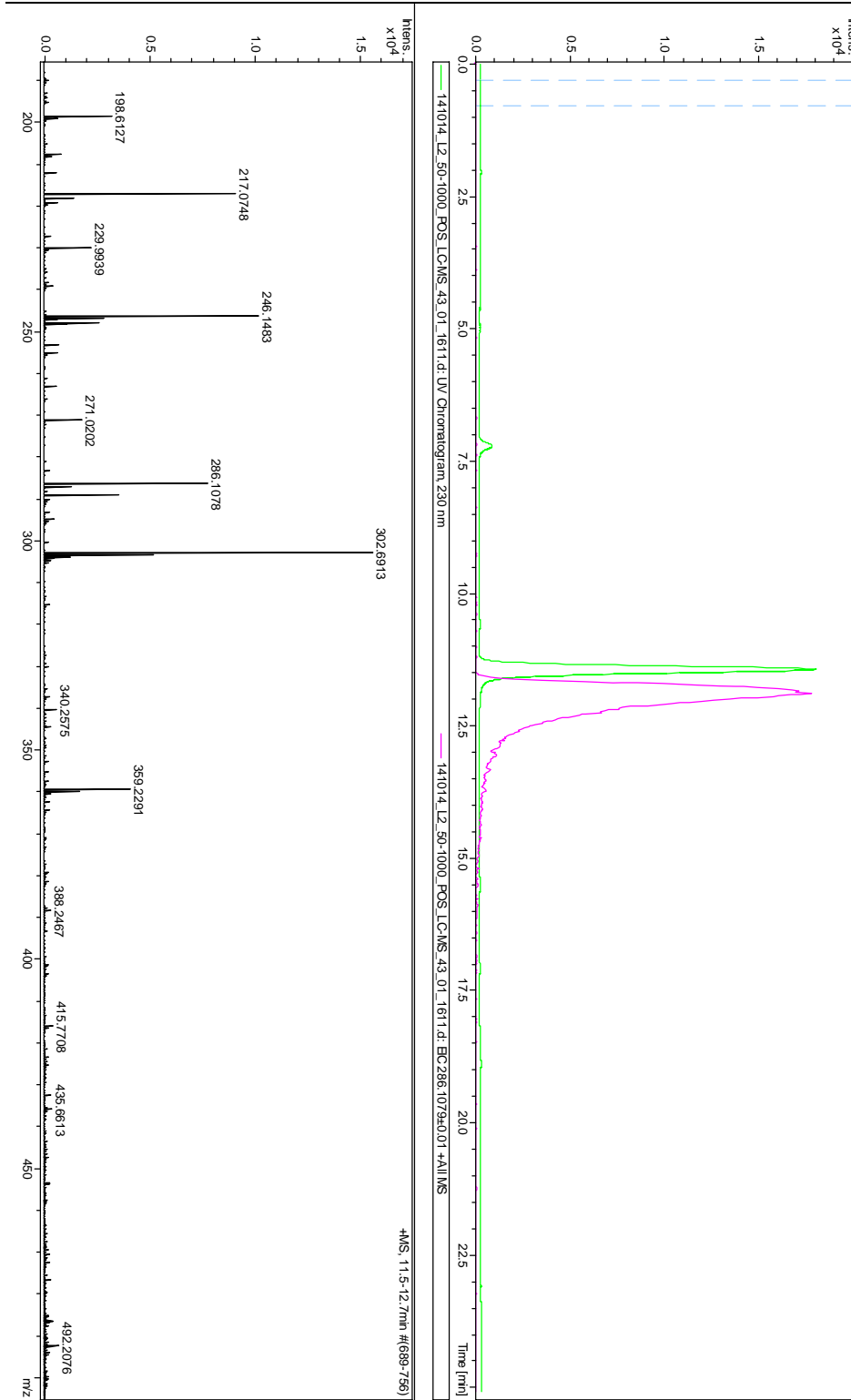
HPLC-UV/MS 1:



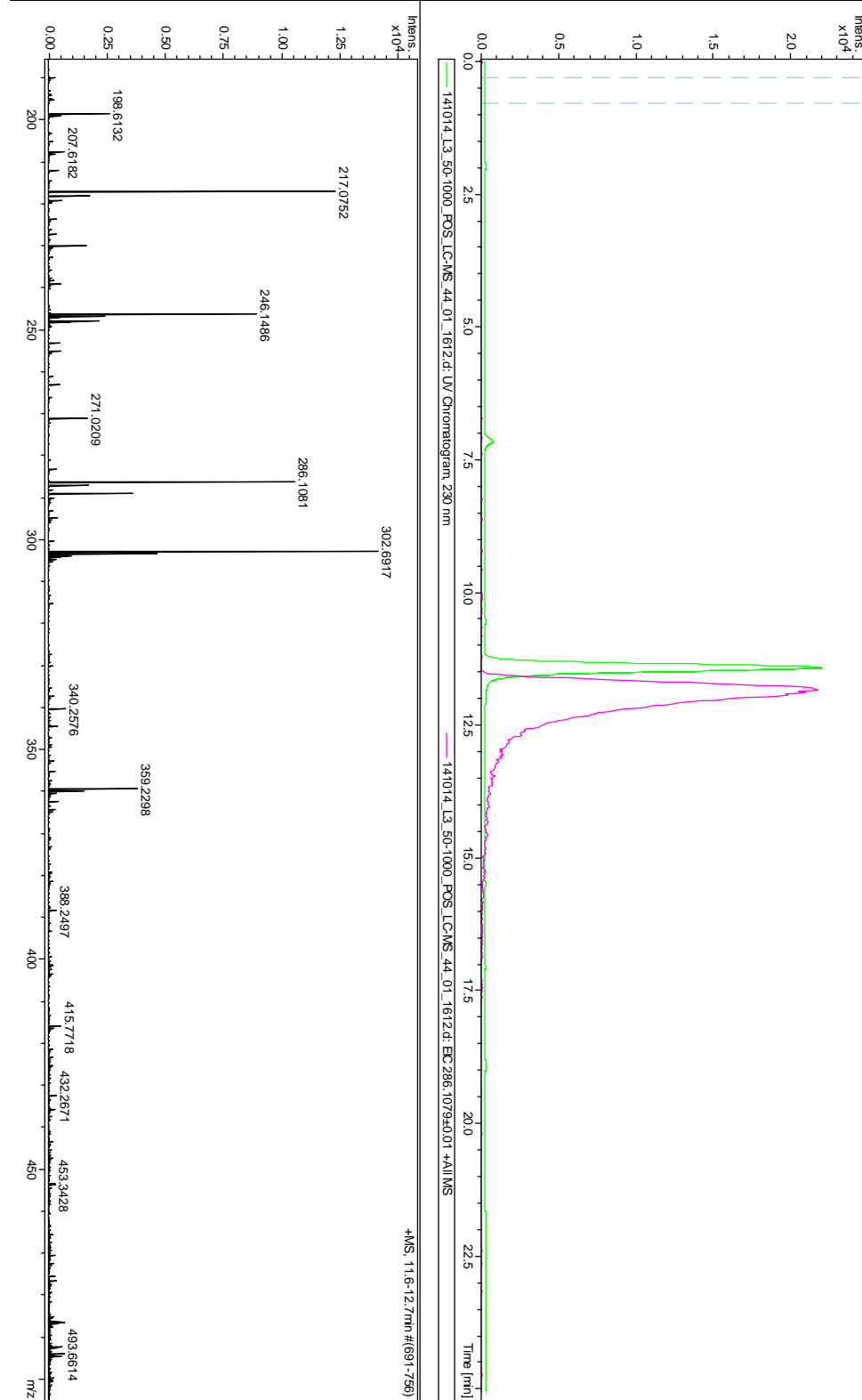
# HPLC-UV/MS 2:



HPLC-UV/MS 3:

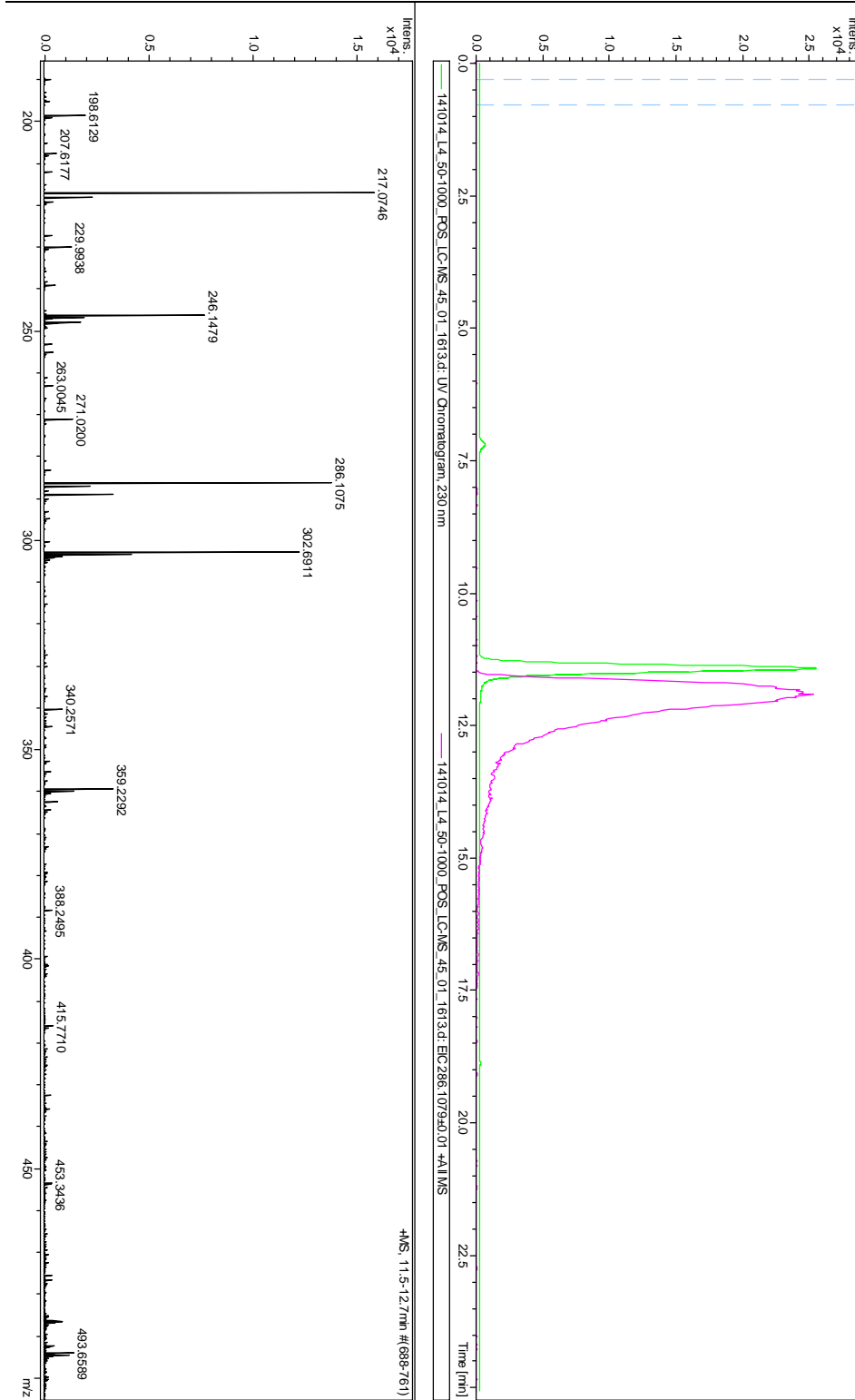


# HPLC-UV/MS 4:

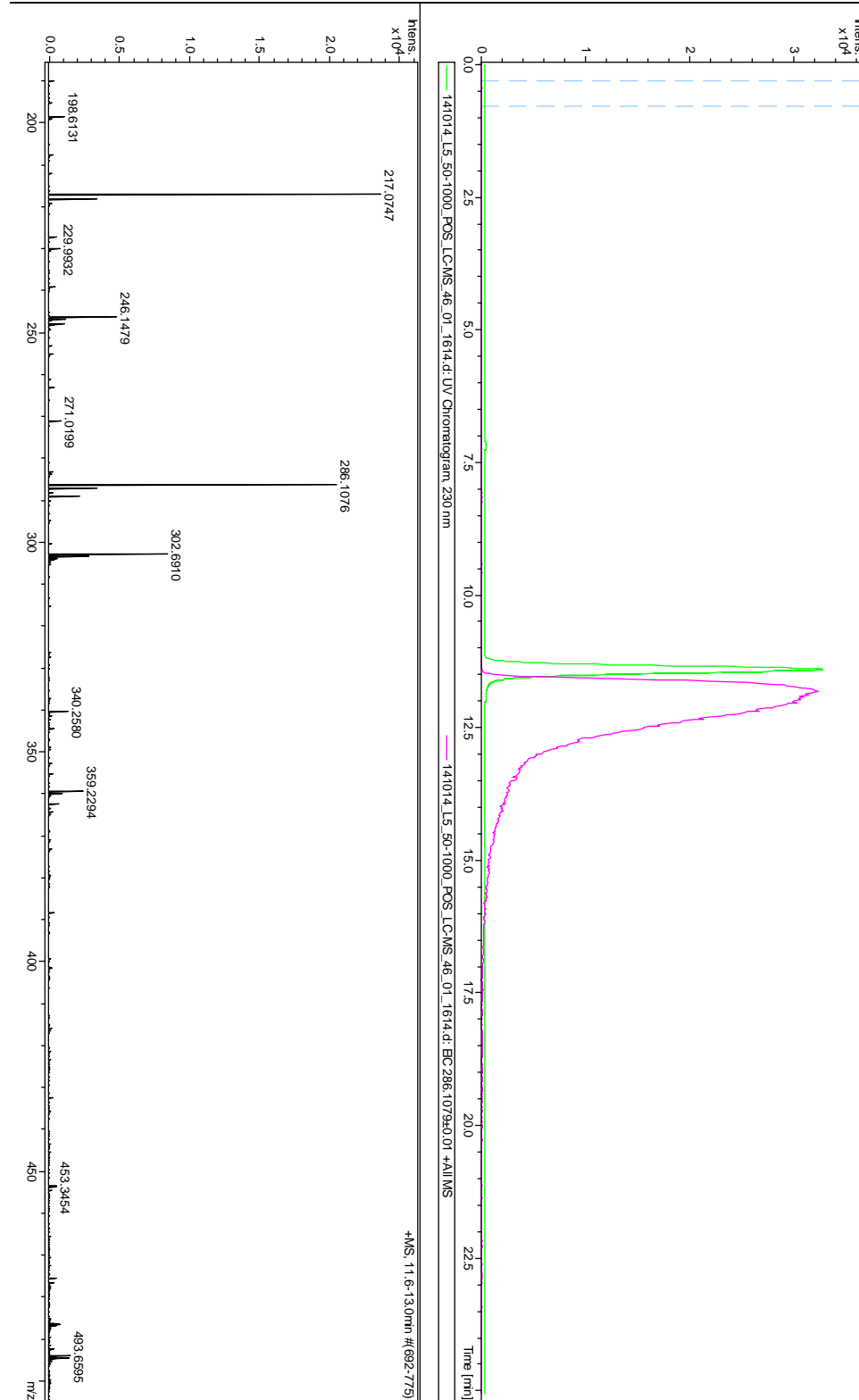




HPLC-UV/MS 5:



HPLC-UV/MS S1:





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Peak	RT [min]	Peak Height [mAU]	Integral [%]	Peak Area [mAU*s]	HWB [min]	Integral Region [min]
28	1.97	0.15	0.05	3.2	0	1.79 - 2.06
89	6.73	0.04	0.02	1	0	6.57 - 6.80
93	7.18	3.22	1.49	97	0	6.97 - 7.47
96	7.78	0.08	0.04	2.6	0	7.61 - 7.97
135	10.57	0.2	0.11	6.9	0.0996	10.38 - 10.76
144	11.43	177.58	97.64	6360.9	0	11.12 - 12.49
184	15.04	0.13	0.06	4.1	0	14.86 - 15.20
187	15.47	0.32	0.16	10.3	0.1883	15.29 - 15.66
208	17.05	0.02	0.01	0.4	0	17.03 - 17.19
228	18.87	0.35	0.19	12.1	0	18.66 - 19.09
285	23.03	0.05	0.03	1.7	0	22.88 - 23.20
288	23.5	0.01	0.01	0.4	0	23.30 - 23.52
306	24.73	0.01	0.01	0.4	0	24.51 - 24.74

# QuantAnalysis Summary Report

## Batch Info

Batch [REDACTED] L.btc  
Instrument micrOTOF-Q II Operator BDAL@DE  
Acquisition Date 10/14/2014 9:44:38 PM

## Method Parameter

Def. Injection Volume 20.000000 Accuracy Limit (%) 20

## Compound Type Chromatogram Ret. Time Calib.Mode

Letrozole Target EIC 286.109±0.02 ±All 11.9 min Area

## File Summary

#	File Name	Via I	Sample Name	Sample Type	Calib Level	Calib Action
1	141014_L0_50-1000_POS_LC-MS_41_01_1609.d	41	141014_L0_50-1000_POS_LC-MS	Sample	-	-
2	141014_L1_50-1000_POS_LC-MS_42_01_1610.d	42	141014_L1_50-1000_POS_LC-MS	Calibration	1	New
3	141014_L2_50-1000_POS_LC-MS_43_01_1611.d	43	141014_L2_50-1000_POS_LC-MS	Calibration	2	New
4	141014_L3_50-1000_POS_LC-MS_44_01_1612.d	44	141014_L3_50-1000_POS_LC-MS	Calibration	3	New
5	141014_L4_50-1000_POS_LC-MS_45_01_1613.d	45	141014_L4_50-1000_POS_LC-MS	Calibration	4	New
6	141014_L5_50-1000_POS_LC-MS_46_01_1614.d	46	141014_L5_50-1000_POS_LC-MS	Calibration	5	New
7	141014_L0_50-1000_POS_LC-MS_41_01_1615.d	41	141014_L0_50-1000_POS_LC-MS	Sample	-	-
8	141014_L0_50-1000_POS_LC-MS_41_01_1616.d	41	141014_L0_50-1000_POS_LC-MS	Sample	-	-

# QuantAnalysis Summary Report

Compound: **Letrozole**

#	Theor. Conc	Area Target Cmpd	Calc. Conc.	Accuracy
1		774890	2.58	
2	0.6	400284	0.53	95.0
3	1.1	513260	1.15	103.1
4	2.2	718168	2.27	102.0
5	4.4	1103201	4.37	98.4
6	8.9	1933546	8.91	100.3
7		859109	3.04	
8		889825	3.20	

Calibration Block No.: 1

