

Analysis Report

Prepared For: _____

Prepared By: _____

Analytical method

Mobile Phase A: 0.1% Formic Acid in Water

Mobile Phase B: 0.1% Formic Acid in Acetonitrile

Testing Site and Date

Testing Site: _____

Testing Date: 10/09/14

Analyte

Name: Letrozole (LE)

Condition while received: Well

Storage Condition after received: Room Temperature

There was no discrepancy when sample received.

Analytical Instrument

Equipment: High-Performance Liquid Chromatography with Mass Spectrometric (MS/MS) Detection

ID Number: HPLC-023/MSMS-017

Software: MassLynx v.4.1

Result (original mass-spectrogram see attachment):

The sample has same Mass Transition with the standard.

The compound in sample is Letrozole.

Assay Percent%: 98.0

Analyst: _____

Date: 10/09/14

Auditor: _____

Date: 10/09/14

Letrozole (LE)
Molecular weight:285.30

HPLC-023 Condition
Solvent A: 0.1% Formic Acid in Water
Solvent B: 0.1% Formic Acid in Acetonitrile
Mobile Phase: Solvent A:Solvent B (30:70, v/v)
Flow Rate (mL/min): 0.300

MSMS-017 Condition:

Cone (V)	30
Collision (eV)	10
Dwell Time (secs)	0.3
Delay Time (secs)	0.00
Ionization Mode	ES+
Source Temperature	130
Desolvation	350
Cone Gas (L/hr)	83
Desolvation Gas	803
Capillary (kV)	2.5
Hex 1 (V)	35
Aperture (V)	0
Hex 2 (V)	1.0
LM/HM Resolution 1	12.0
Ion Energy 1 (V)	0.5
LM/HM Resolution 2	12.0
Ion Energy 2 (V)	1.0
Entrance	-1.0
Exit	1.0
Multiplier (V)	650

	Standard	Sample
Mass Transition	285.96>216.75	285.96>216.75

LE
LE STA 01 1 (0.044)

Scan ES+
6.71e7



LE 10
LE STA 02 1 (0.044)

100

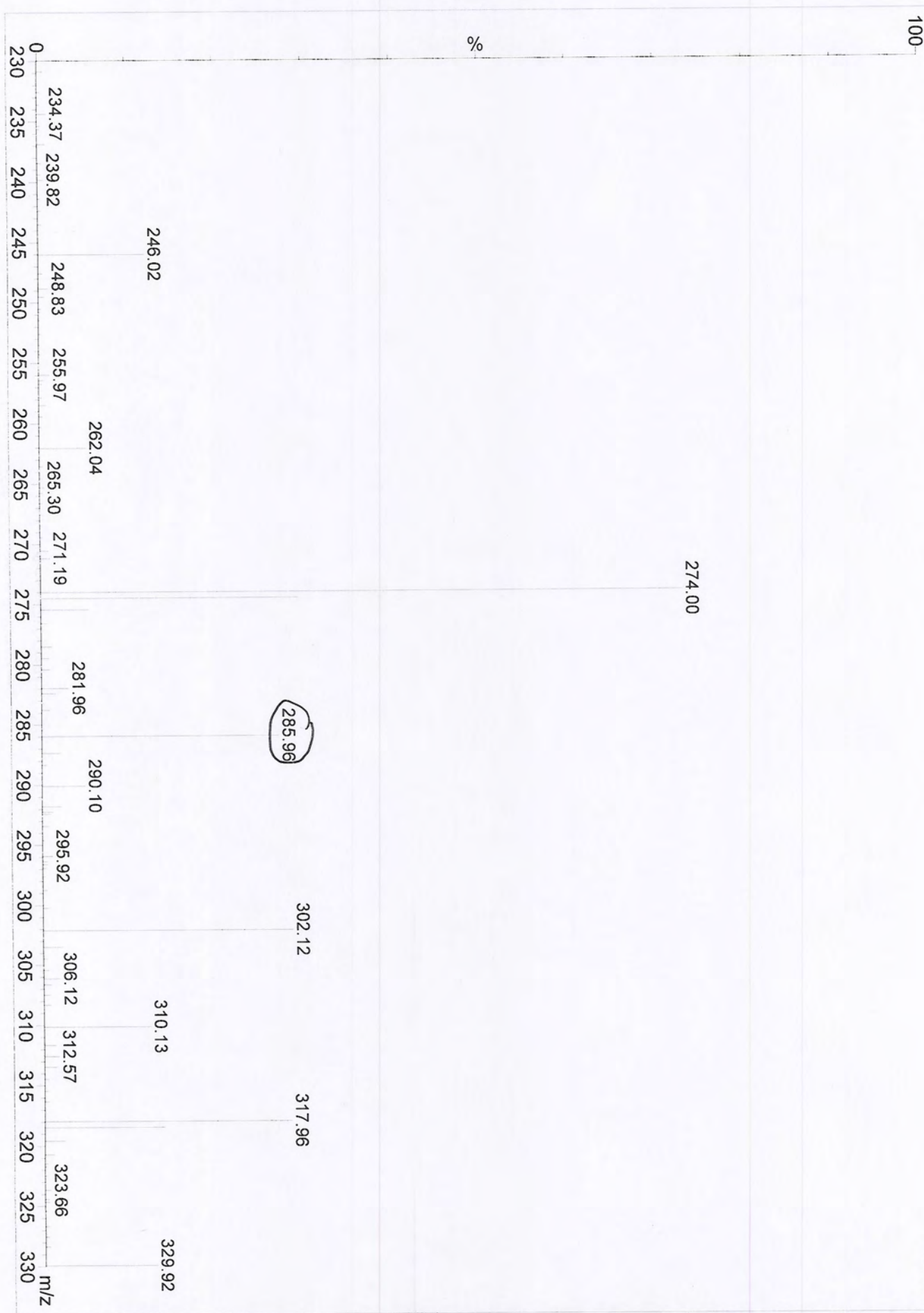
216.75

Daughters of 286ES+
1.22e7



LE
LE SAMPLE 01 1 (0.044)

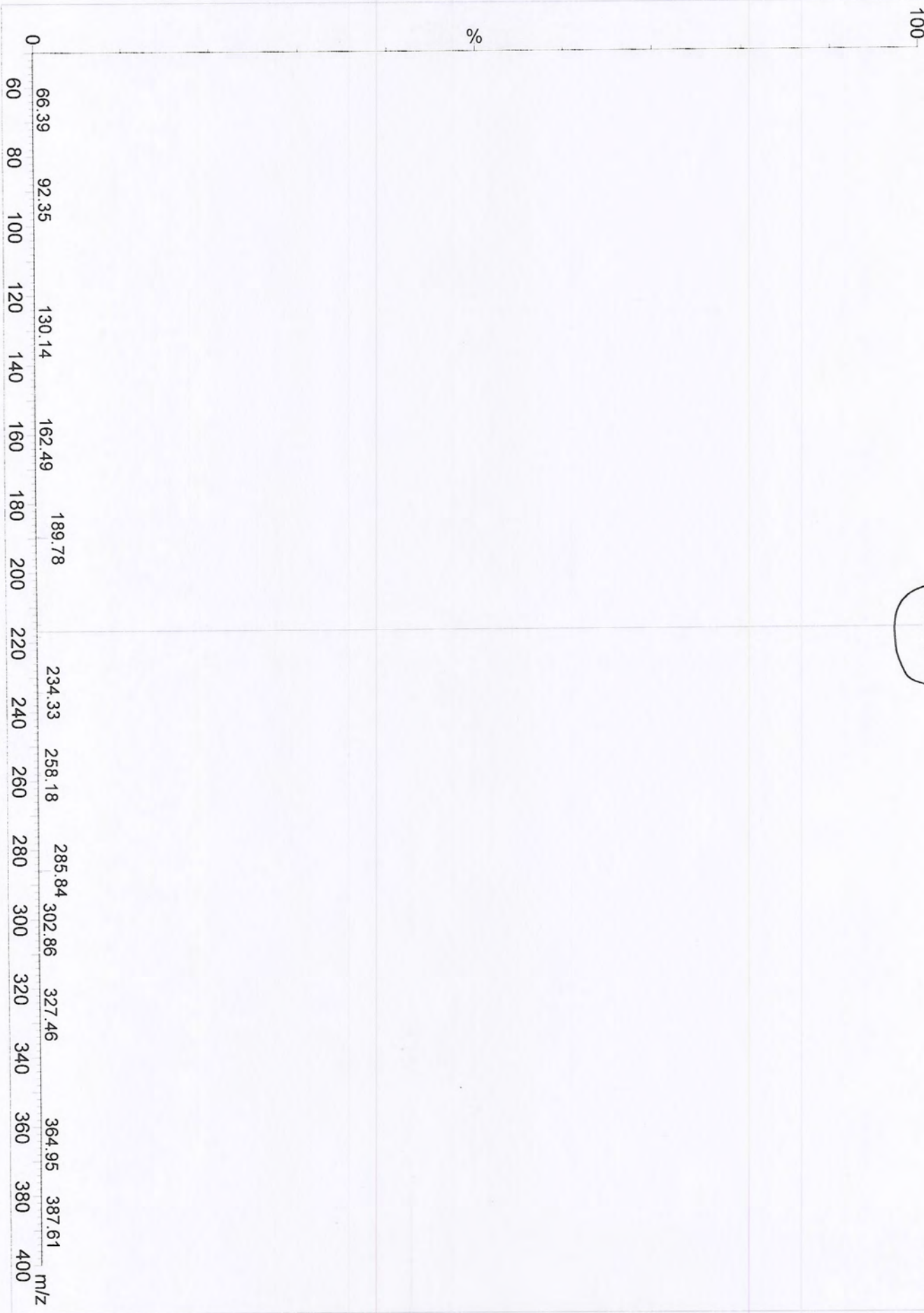
Scan ES+
6.30e7



LE 10
LE SAMPLE 02 1 (0.044)

216.75

Daughters of 286ES+
8.26e6



Quantify Compound Summary Report MassLynx 4.1

Dataset: _____
 Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time
 By _____
 Reason processing data
 Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time
 By _____

Method: _____ 09 Oct 2014 12:21:20

Calibration: 09 Oct 2014 12:25:38

Compound name: LE

Correlation coefficient: $r = 0.999461$, $r^2 = 0.998921$

Calibration curve: $0.972564 * x + 8.35312$


Response type: External Std, Area

Curve type: Linear, Origin: Exclude, Weighting: Null, Axis trans: Ln

#	Sample Text	ID	Type	Area	Conc.	%Dev	Factor1	RT	Primary Flags	Response
1	LE Std 5.00 ng/mL	W1	Standard	21343	5.26	5.29	1.0	2.29	bb	21343.387
2	LE Std 10.0 ng/mL	W2	Standard	38008	9.53	-4.72	1.0	2.29	bb	38008.023
3	LE Std 20.0 ng/mL	W3	Standard	76120	19.5	-2.70	1.0	2.31	bb	76119.953
4	LE Std 50.0 ng/mL	W4	Standard	190836	50.1	0.139	1.0	2.32	bb	190836.188
5	LE Std 100 ng/mL	W5	Standard	382349	102	2.30	1.0	2.31	bb	382349.031
6	LE Sample 20.0 ng/mL		Analyte	191019	50.1		1.0	2.31	bb	191018.641
7	LE Sample 20.0 ng/mL		Analyte	189150	49.6		1.0	2.33	bb	189149.531
8	LE Sample 20.0 ng/mL		Analyte	180324	47.2		1.0	2.33	bb	180323.875

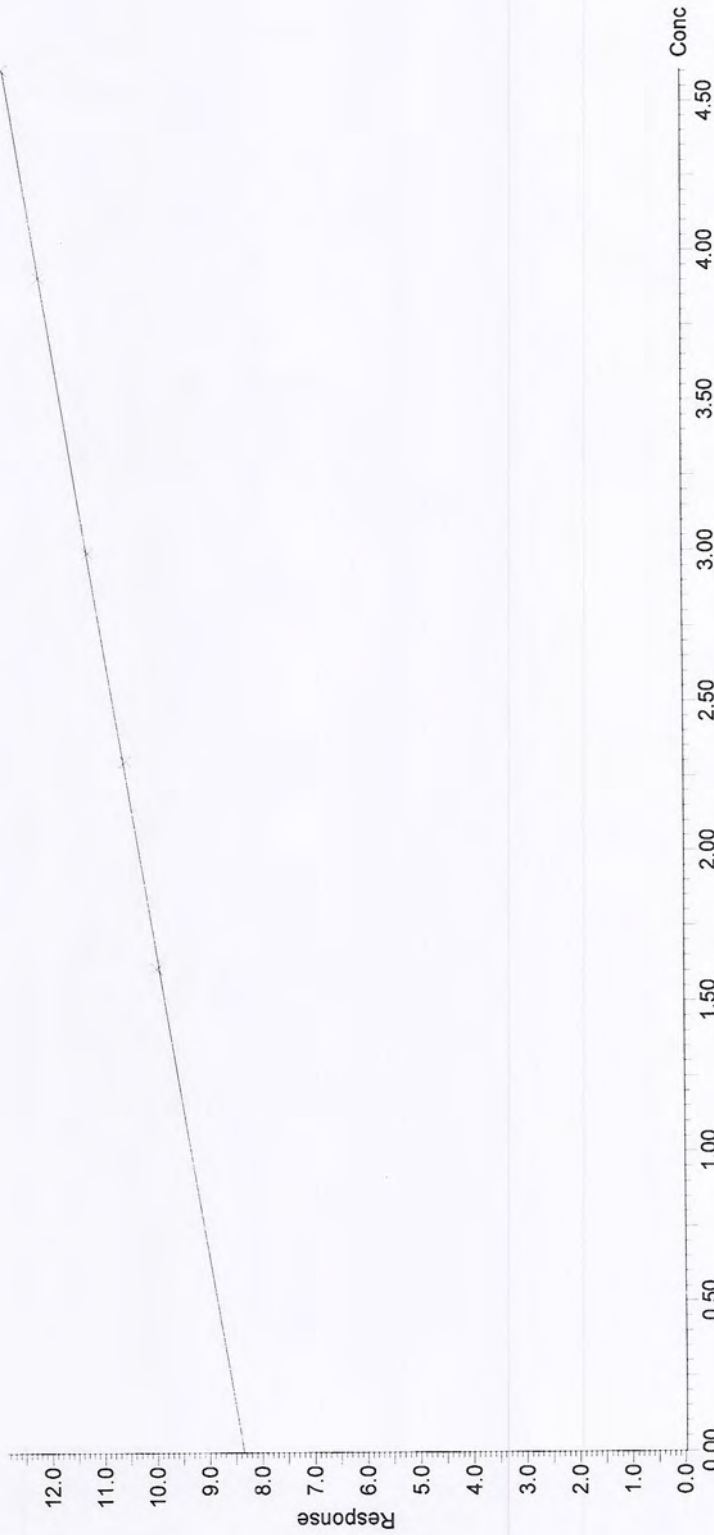
① correction. ZH. 10/09/14

Quantify Calibration Report MassLynx 4.1

Dataset:  Thursday, October 09, 2014 12:26:17 China Standard Time
Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time
By
Reason processing data
Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time
By

Method:  09 Oct 2014 12:21:20
Calibration: 09 Oct 2014 12:25:38

Compound name: LE
Correlation coefficient: $r = 0.999461$, $r^2 = 0.998921$
Calibration curve: $0.972564 * x + 8.35312$
Response type: External Std, Area
Curve type: Linear, Origin: Exclude, Weighting: Null, Axis trans: Ln

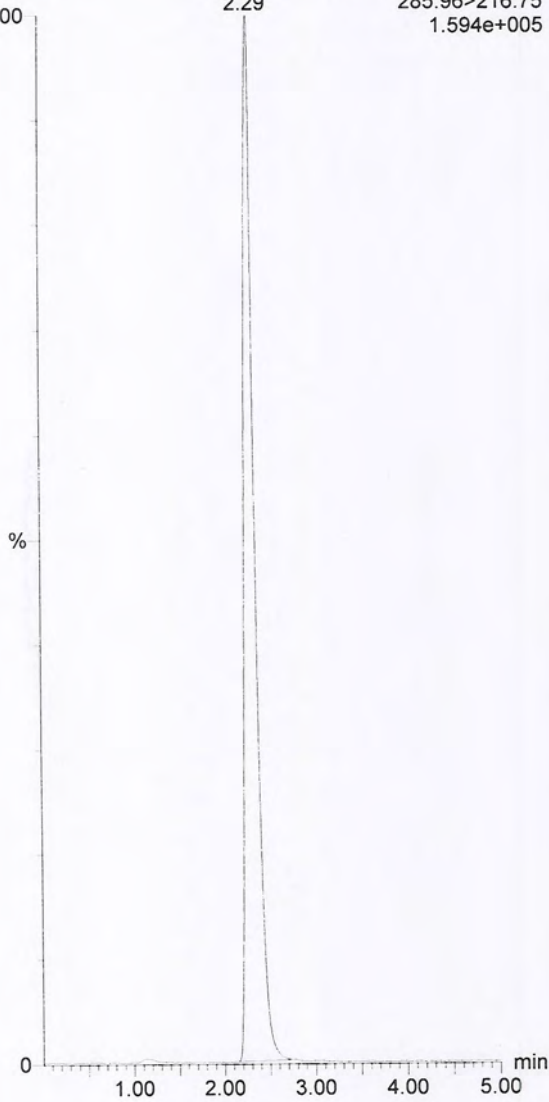


Dataset: [REDACTED]
Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time
By [REDACTED]
Reason processing data
Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time
By [REDACTED]

Method: [REDACTED] 09 Oct 2014 12:21:20
Calibration: 09 Oct 2014 12:25:38

Name: AR5201, Date: 09-Oct-2014, Time: 11:03:51, ID: W1, Description: LE Std 5.00 ng/mL

LE
AR5201
100
LE 2.29
MRM of 1 channel, ES+
285.96>216.75
1.594e+005



#	Name	Area	Conc.	RT.	Primary Flags
1	LE	21343	5.3	2.29	bb

Dataset:

Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time

By

Reason processing data

Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time

By

Name: AR5202, Date: 09-Oct-2014, Time: 11:10:32, ID: W2, Description: LE Std 10.0 ng/mL

LE

AR5202

LE
2.29

MRM of 1 channel, ES+
285.96>216.75
2.754e+005



#	Name	Area	Conc.	RT	Primary Flags
1	LE	38008	9.5	2.29	bb

Dataset:

Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time

By

Reason processing data

Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time

By

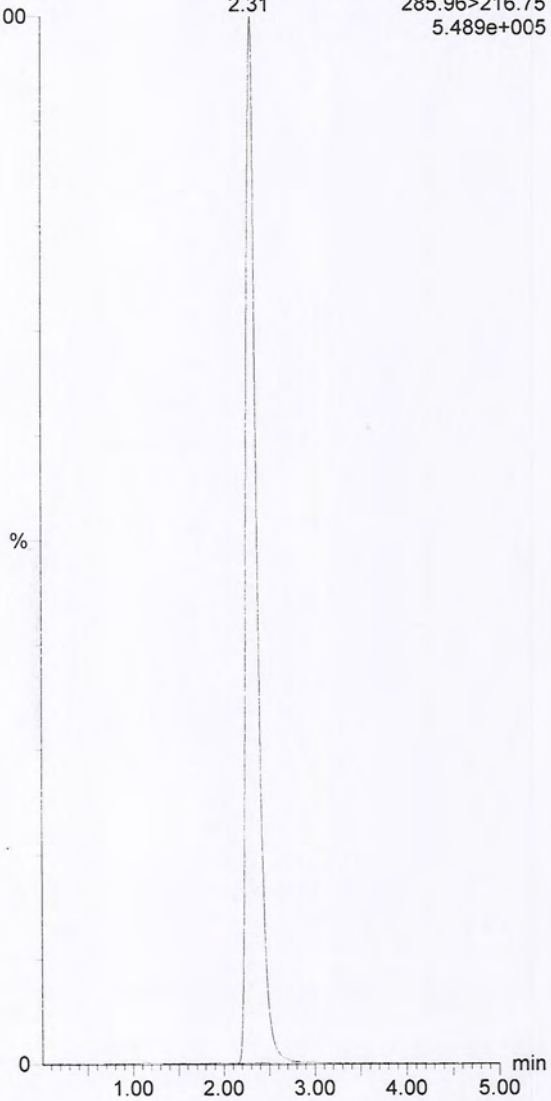
Name: AR5203, Date: 09-Oct-2014, Time: 11:17:15, ID: W3, Description: LE Std 20.0 ng/mL

LE

AR5203

LE
2.31

MRM of 1 channel, ES+
285.96>216.75
5.489e+005



#	Name	Area	Conc.	RT.	Primary Flags
1	LE	76120	19.5	2.31	bb

Dataset:

Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time

By

Reason processing data

Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time

By

Name: AR5204, Date: 09-Oct-2014, Time: 11:23:56, ID: W4, Description: LE Std 50.0 ng/mL

LE

AR5204

LE

MRM of 1 channel, ES+

285.96>216.75

1.394e+006

100

2.32

%

0

1.00 2.00 3.00 4.00 5.00 min

# Name	Area	Conc.	RT.	Primary Flags
1 LE	190836	50.1	2.32	bb

Dataset:

Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time

By

Reason processing data

Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time

By

Name: AR5205, Date: 09-Oct-2014, Time: 11:30:39, ID: W5, Description: LE Std 100 ng/mL

LE

AR5205

LE
2.31

MRM of 1 channel, ES+
285.96>216.75
2.820e+006



# Name	Area	Conc.	RT.	Primary Flags
1 LE	382349	102.3	2.31	bb

Dataset:

Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time

By

Reason processing data

Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time

By

Name: AR5206, Date: 09-Oct-2014, Time: 11:37:20, ID: , Description: LE Sample 20.0 ng/mL

LE

AR5206

LE

MRM of 1 channel, ES+

2.31

285.96>216.75

1.387e+006



#	Name	Area	Conc.	RT	Primary Flags
1	LE	191019	50.1	2.31	bb

Dataset:

Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time

By

Reason processing data

Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time

By

Name: AR5207, Date: 09-Oct-2014, Time: 11:44:02, ID: , Description: LE Sample 20.0 ng/mL

LE

AR5207

LE
2.33

MRM of 1 channel, ES+
285.96>216.75
1.366e+006



#	Name	Area	Conc.	RT.	Primary Flags
1	LE	189150	49.6	2.33	bb

Dataset:

Signature: At Thursday, October 09, 2014 12:26:17 China Standard Time

By

Reason processing data

Printed: At Thursday, October 09, 2014 12:27:39 China Standard Time

By

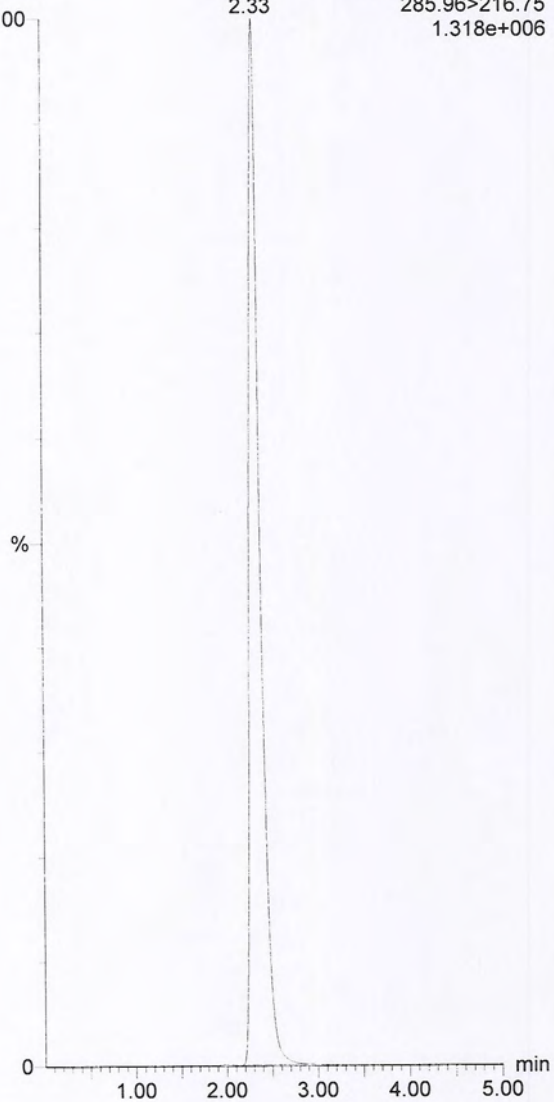
Name: AR5208, Date: 09-Oct-2014, Time: 11:50:44, ID: , Description: LE Sample 20.0 ng/mL

LE

AR5208

LE
2.33

MRM of 1 channel, ES+
285.96>216.75
1.318e+006



#	Name	Area	Conc.	RT	Primary Flags
1	LE	180324	47.2	2.33	bb

AR52

Letrozole

HPLC Condition

Solvent A: 0.1% Formic Acid in Water

Solvent B: 0.1% Formic Acid in Acetonitrile

Mobile Phase: Solvent A:Solvent B (30:70 v/v)

Flow Rate (mL/min): 0.3

Column: Waters Atlantis dC18, 150 × 2.1 mm, 5 µm, Column

	Calculated Conc.(ng/mL)	Mean Actual Conc.(ng/mL)	Theoretical Conc.(ng/mL)	Assay Percent %
S1-1	50.1	49.0	50.0	98.0
S1-2	49.6			
S1-3	47.2			