

Analysis Report

Prepared For: _____

Prepared By: _____

Analytical method

Mobile Phase A: Water

Mobile Phase B: Acetonitrile

Wavelength: 225 nm

Testing Site and Date

Testing Site: _____ Testing Date: 02/15/15

Analyte

Product name: 202187-I

Name: 3--- Anastrozole

Condition while received: Well

Storage Condition after received: Room Temperature

There was no discrepancy when sample received.

Analytical Instrument

Equipment: High-Performance Liquid Chromatography

ID Number: HPLC-025

Software: Millennium v. 4.00

Result (original chromatograms see attachment):

Assay Percent %: 102.0%

Analyst: _____ Date: 02/15/15

Auditor: _____ Date: 02/15/15

Project: PF15F0014
Analytical Run: AR15 ANA

Current Date: 2/15/2015
Current Time: 1:51:12 PM

Peak Results
Name: ANA

	SampleName	Name	Sample Type	Area	Retention Time (min)	Concentration	Units	Dilution
1	ANA 5ug/mL	ANA	Standard	31319	4.845	5.00000	ug/mL	1.00
2	ANA 10ug/mL	ANA	Standard	61062	4.845	10.00000	ug/mL	1.00
3	ANA 20ug/mL	ANA	Standard	126930	4.846	20.00000	ug/mL	1.00
4	ANA 50ug/mL	ANA	Standard	313624	4.845	50.00000	ug/mL	1.00
5	ANA 100ug/mL	ANA	Standard	616083	4.846	100.00000	ug/mL	1.00
6	S1 20ug/mL	ANA	Unknown	127898	4.839	20.46248	ug/mL	1.00
7	S120ug/mL	ANA	Unknown	127440	4.844	20.38815	ug/mL	1.00
8	S1 20ug/mL	ANA	Unknown	127636	4.843	20.41996	ug/mL	1.00

Project: PF15F0014

Intercept: 1806.611246

Compound: ANA

Slope: 6162.078074

Analytical Run: AR15 ANA

r: 0.999940

Current Date: 2/15/2015

Fit Type: Linear (1st Order)

Current Time: 1:51:01 PM

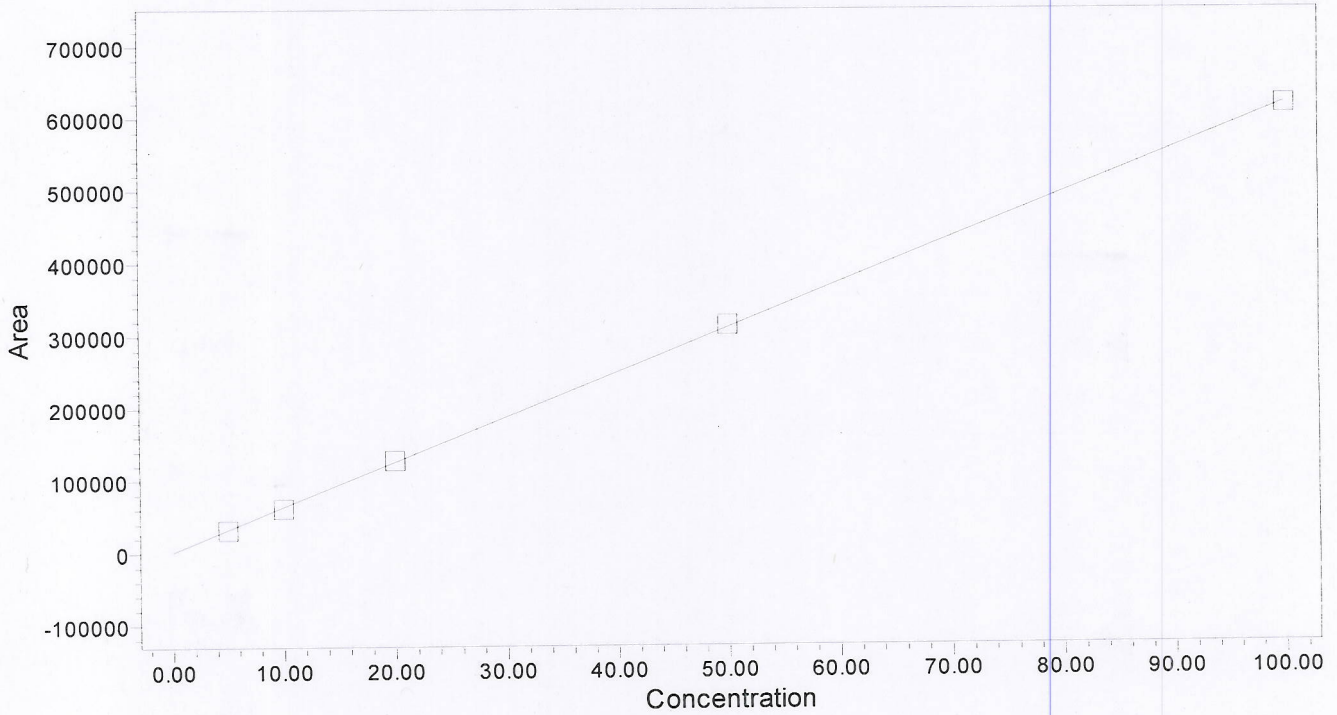
Weighting: None

Date Calibrated: 2/15/2015 1:50:40 PM

Date Acquired: 2/15/2015 1:14:23 PM

Units: ug/mL

Calibration Plot



	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore
1	ANA	W1	5.000000	31319.000000	4.789357	-4.21287	No	No
2	ANA	W2	10.000000	61062.000000	9.616137	-3.83863	No	No
3	ANA	W3	20.000000	126930.000000	20.305388	1.52694	No	No
4	ANA	W4	50.000000	313623.500000	50.602554	1.20511	No	No
5	ANA	W5	100.000000	616083.000000	99.686564	-0.31344	No	No

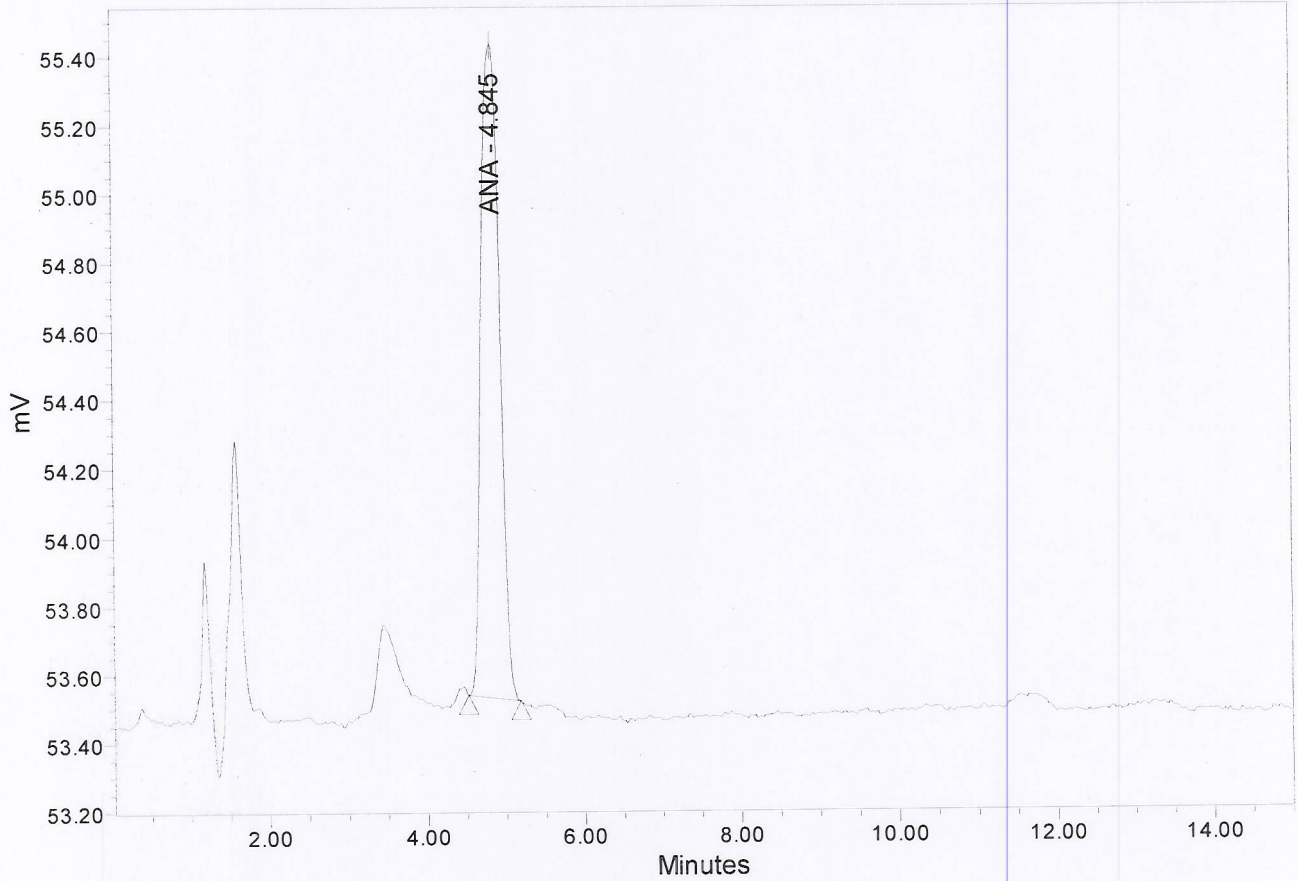
Software Version 4.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:18 PM
Date Acquired: 2/15/2015 11:23:43
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: ANA 5ug/mL
Injection Id: 5133

Auto-Scaled Chromatogram



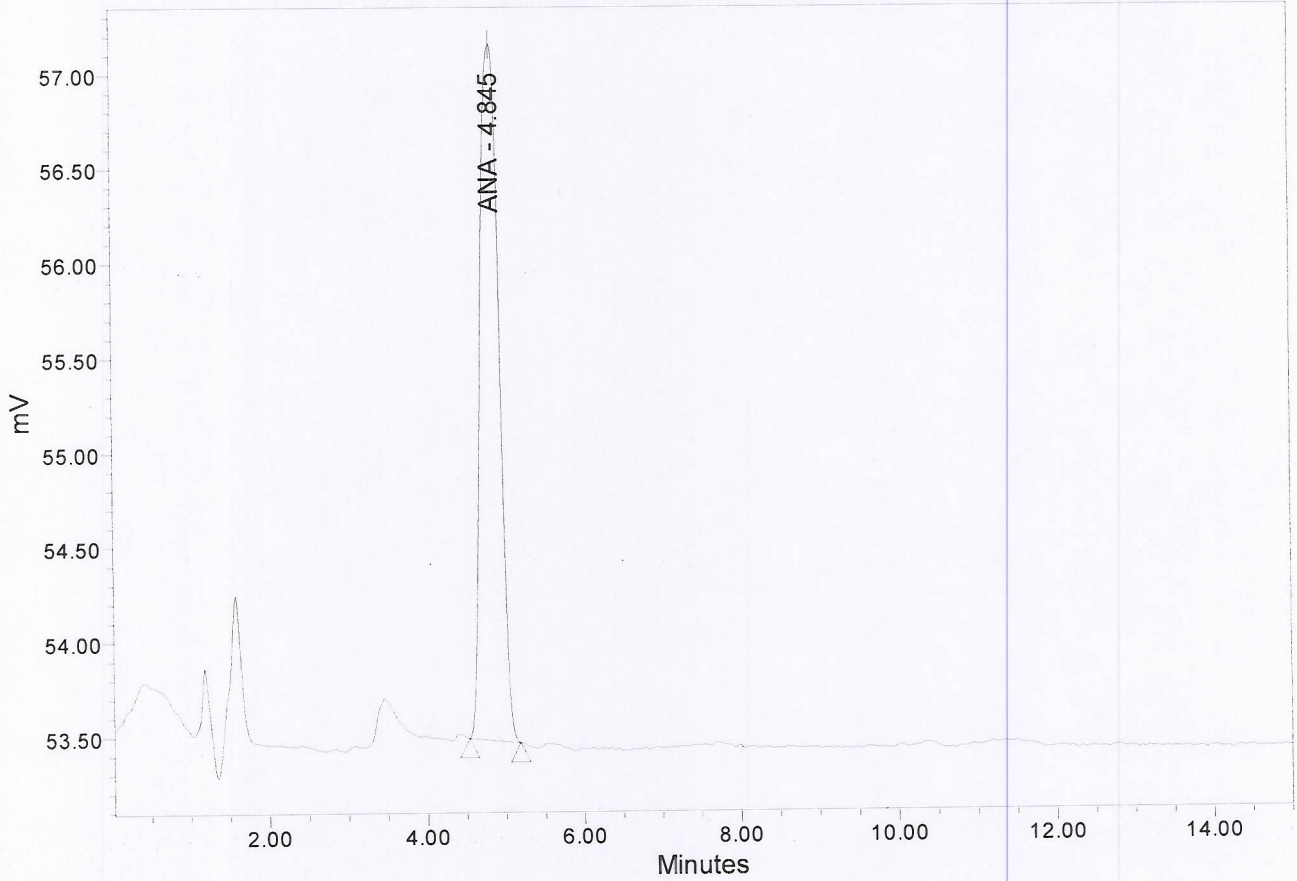
Name	SampleName	RT	Height	Area	Vial	% Area	
1	ANA	ANA 5ug/mL	4.845	1907	31319	1	100.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:23 PM
Date Acquired: 2/15/2015 11:39:30
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: ANA 10ug/mL
Injection Id: 5136

Auto-Scaled Chromatogram



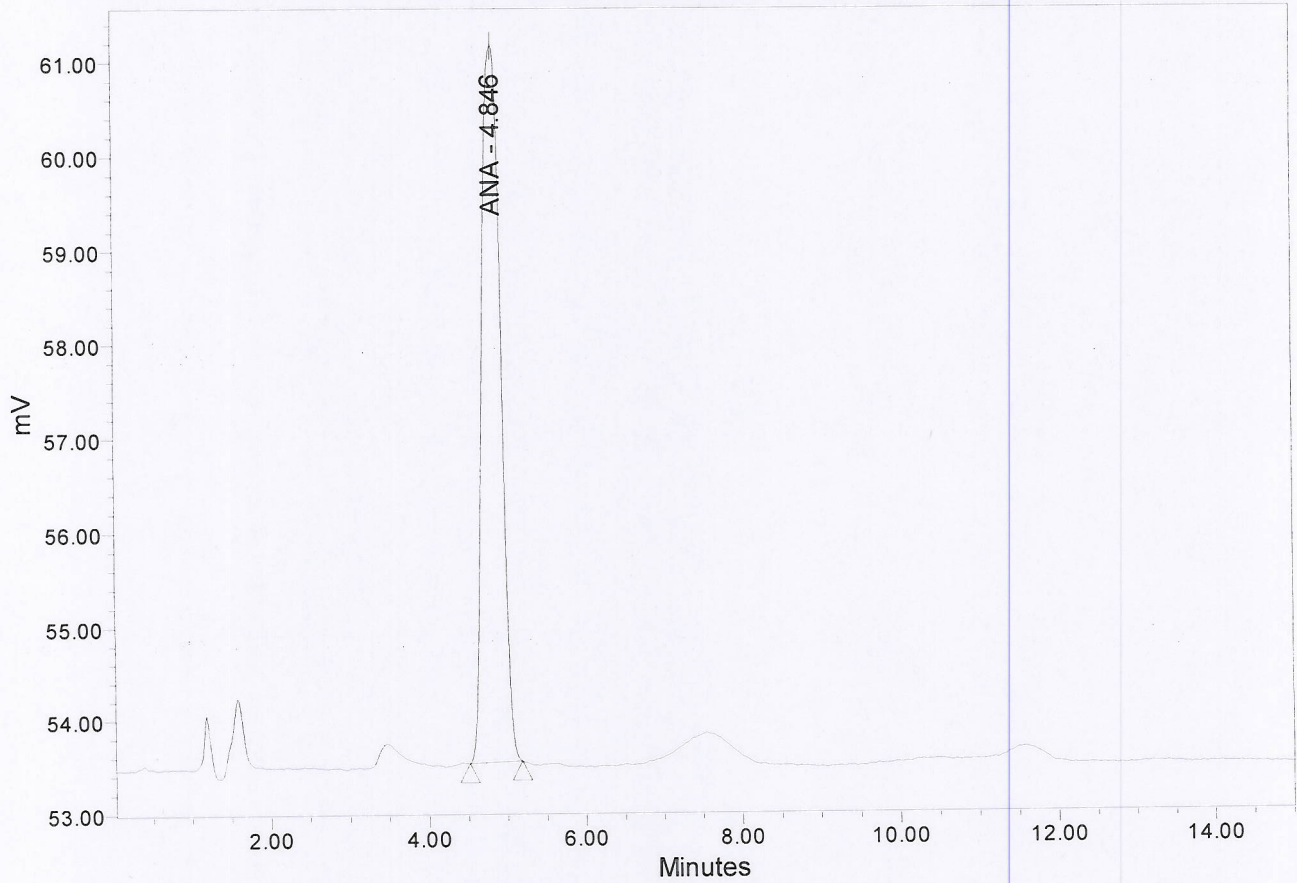
Name	SampleName	RT	Height	Area	Vial	% Area	
1	ANA	ANA 10ug/mL	4.845	3688	61062	2	100.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:28 PM
Date Acquired: 2/15/2015 11:55:17
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: ANA 20ug/mL
Injection Id: 5139

Auto-Scaled Chromatogram



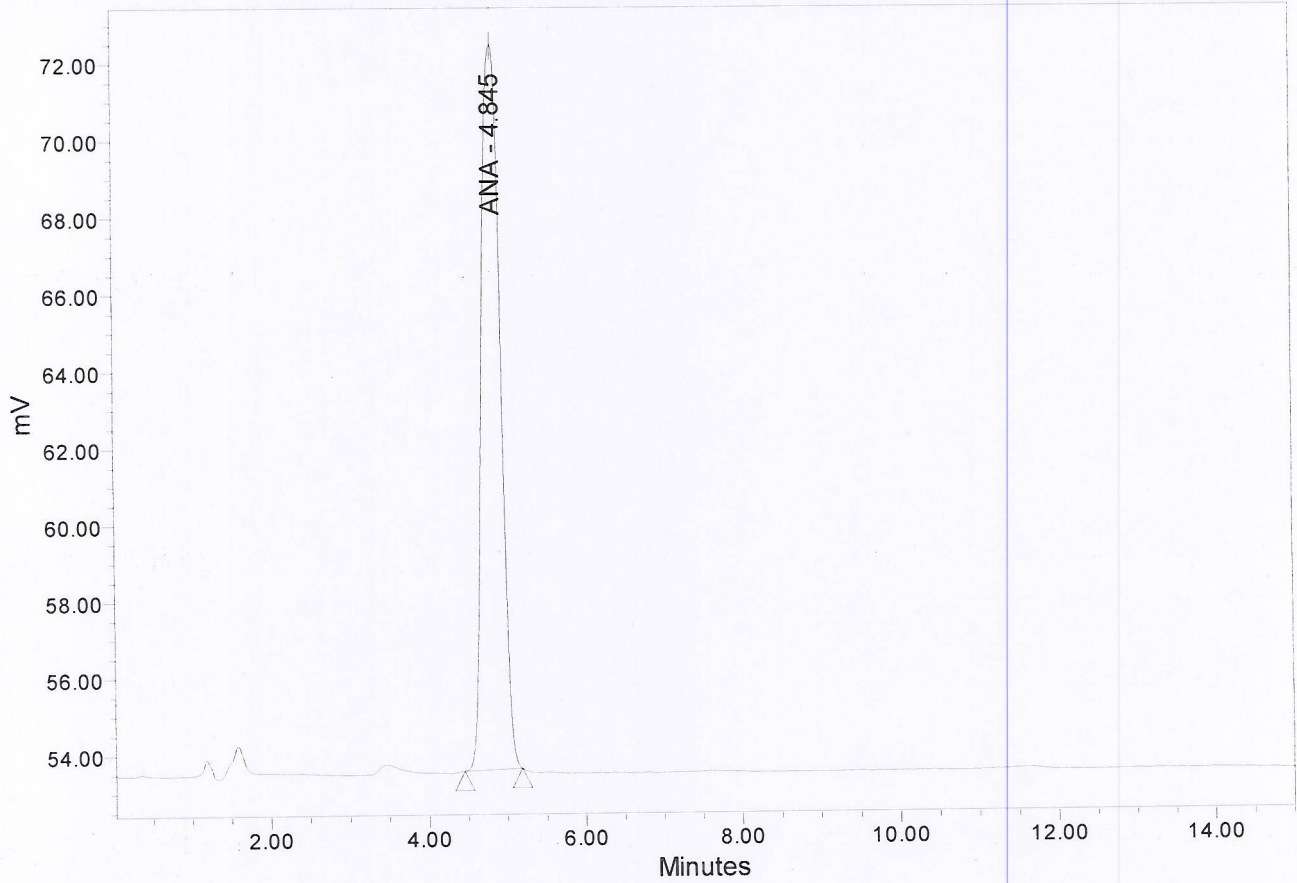
Name	SampleName	RT	Height	Area	Vial	% Area	
1	ANA	ANA 20ug/mL	4.846	7645	126930	3	100.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:30 PM
Date Acquired: 2/15/2015 12:11:05
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: ANA 50ug/mL
Injection Id: 5142

Auto-Scaled Chromatogram



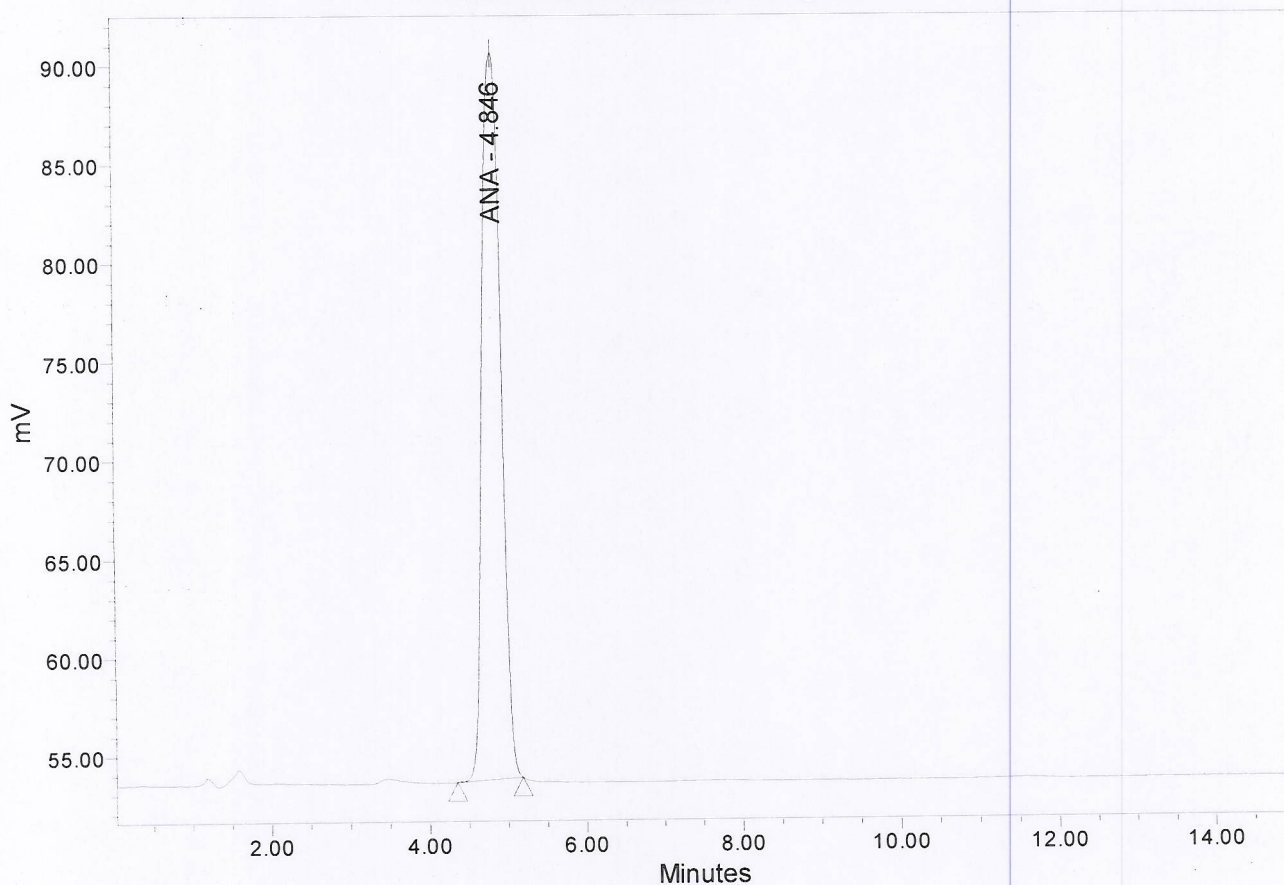
Name	SampleName	RT	Height	Area	Vial	% Area	
1	ANA	ANA 50ug/mL	4.845	18922	313624	4	100.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:31 PM
Date Acquired: 2/15/2015 12:26:54
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: ANA 100ug/mL
Injection Id: 5150

Auto-Scaled Chromatogram



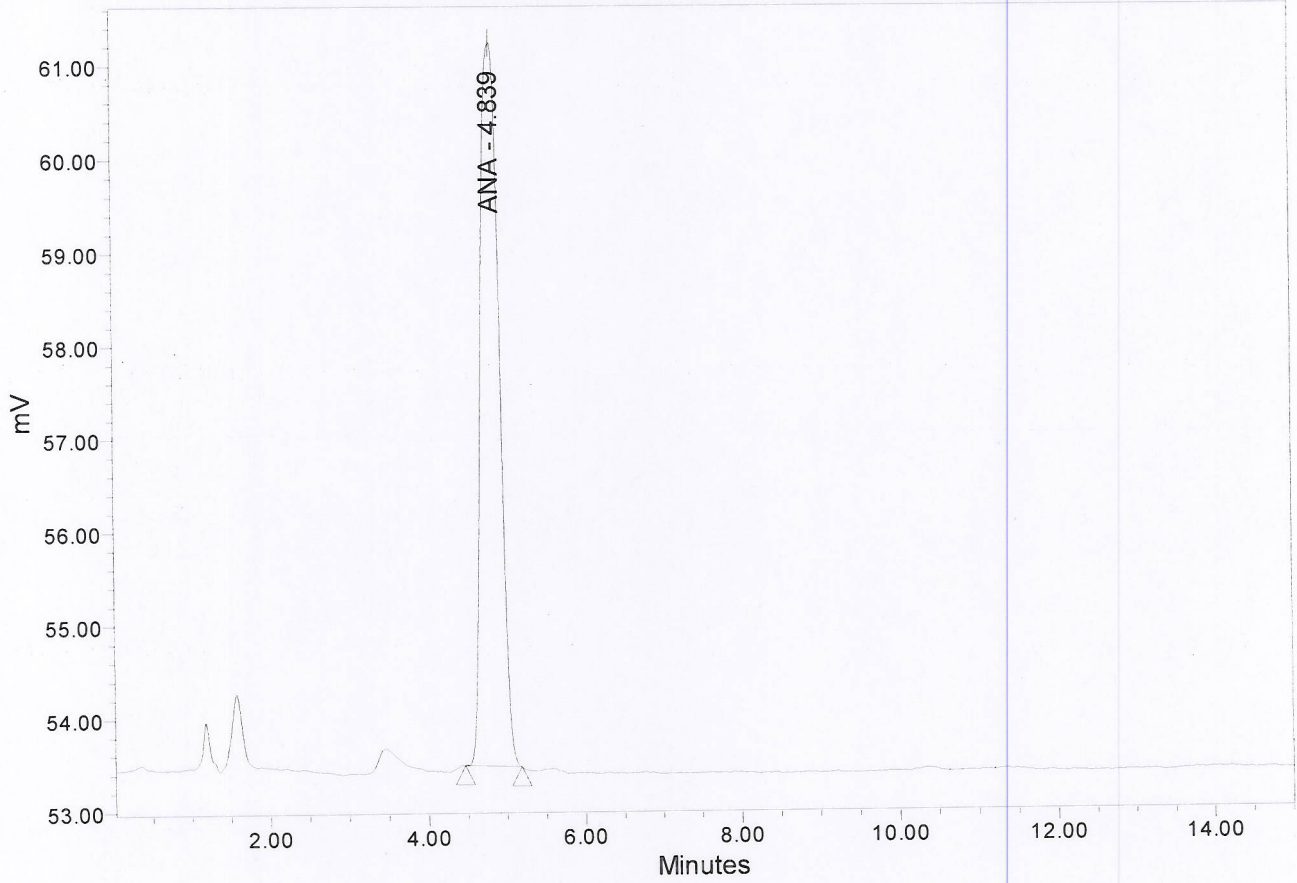
Name	SampleName	RT	Height	Area	Vial	% Area	
1	ANA	ANA 100ug/mL	4.846	36920	616083	5	100.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:33 PM
Date Acquired: 2/15/2015 12:42:44
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: S1 20ug/mL
Injection Id: 5153

Auto-Scaled Chromatogram



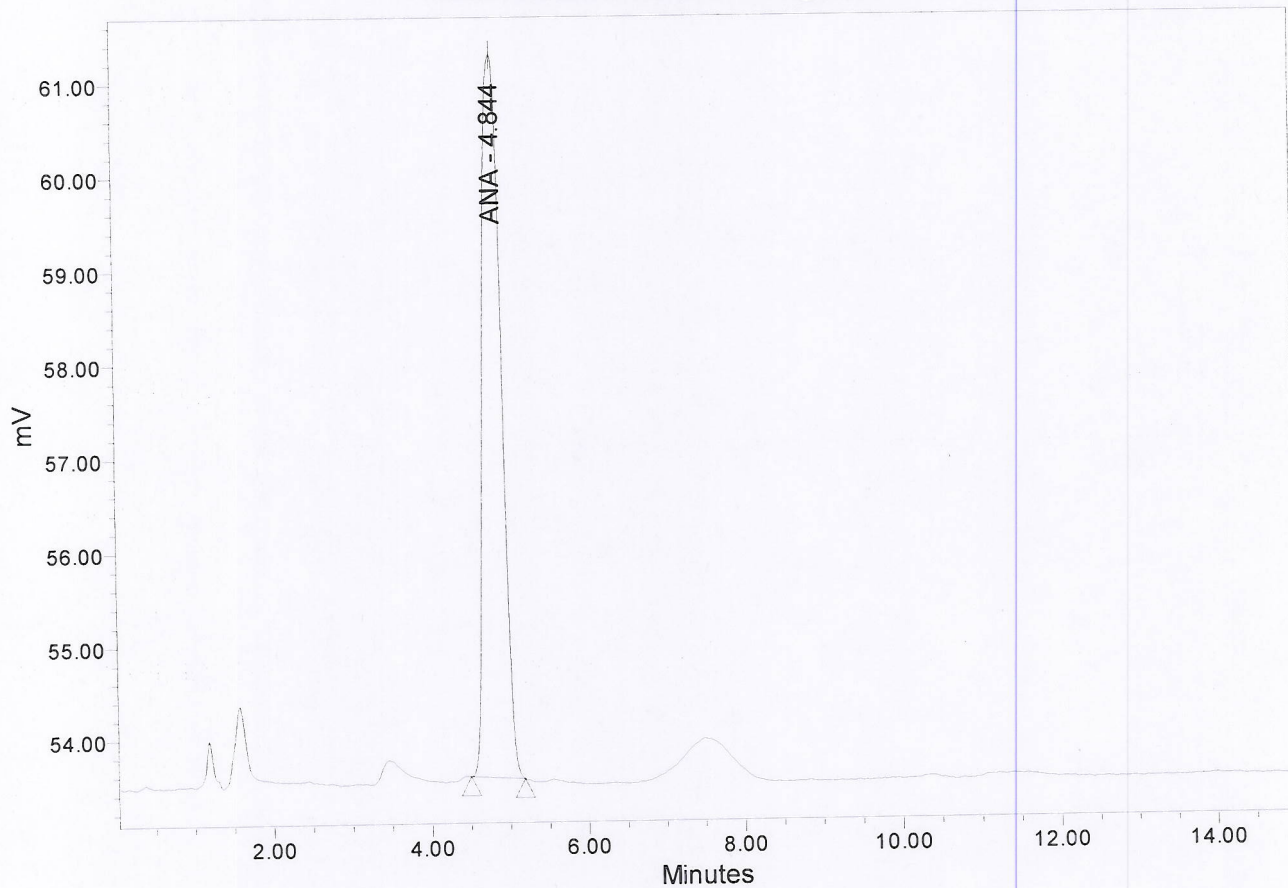
Name	SampleName	RT	Height	Area	Vial	% Area	
1	ANA	S1 20ug/mL	4.839	7771	127898	6	100.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:35 PM
Date Acquired: 2/15/2015 12:58:33
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: S120ug/mL
Injection Id: 5156

Auto-Scaled Chromatogram



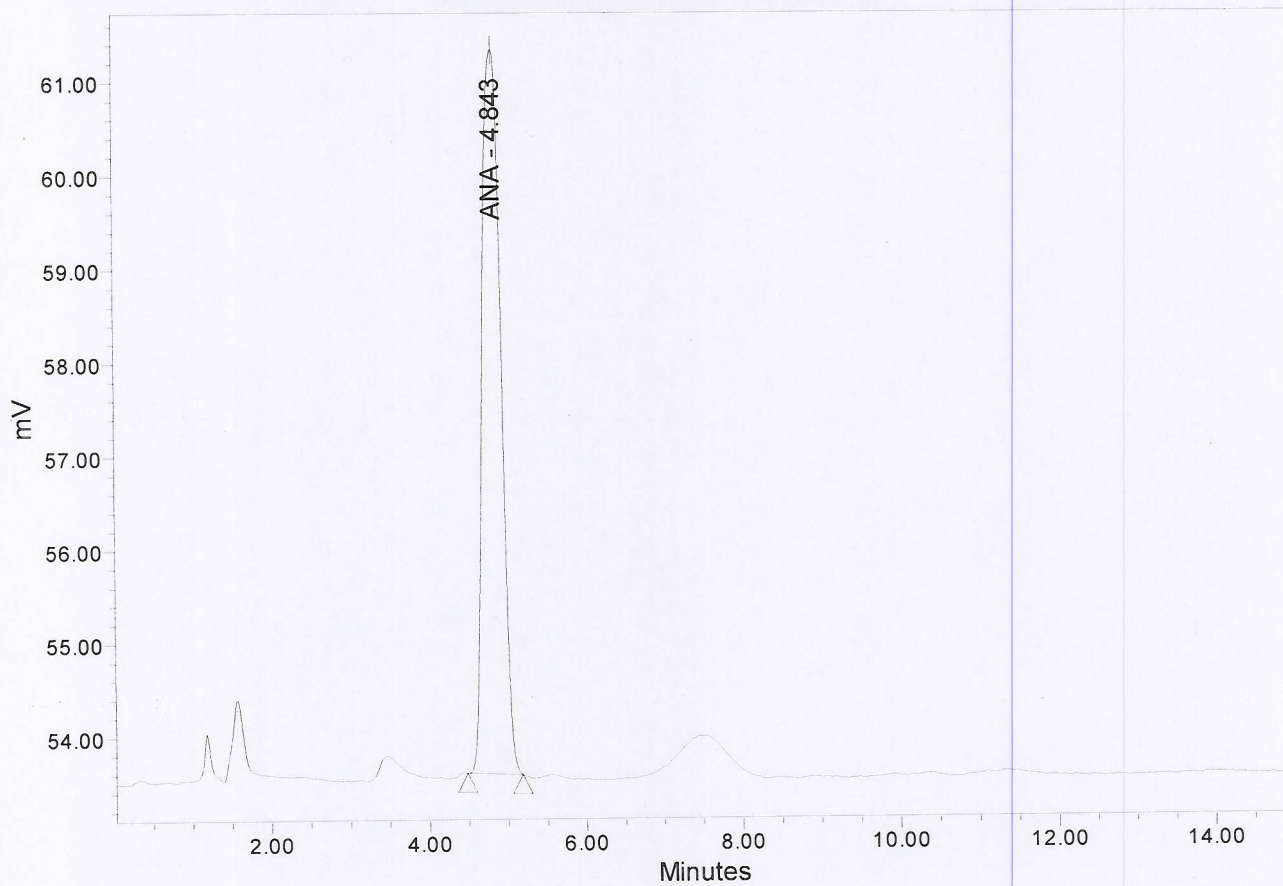
Name	SampleName	RT	Height	Area	Vial	% Area
1 ANA	S120ug/mL	4.844	7742	127440	7	100.00

Project: PF15F0014
Compound: ANA

Current Date: 2/15/2015
Current Time: 1:51:37 PM
Date Acquired: 2/15/2015 1:14:23 PM
Date Calibrated: 2/15/2015 1:50:40 PM

Analytical Run: AR15 ANA
Text: S1 20ug/mL
Injection Id: 5159

Auto-Scaled Chromatogram



Name	SampleName	RT	Height	Area	Vial	% Area	
1	ANA	S1 20ug/mL	4.843	7761	127636	8	100.00

AR15 Anastrozole

HPLC Condition

Solvent A: Water

Solvent B: Acetonitrile

Mobile Phase: Solvent A:Solvent B (60:40, v/v)

Flow Rate (mL/min): 1.00

Wavelength:225 nm

Column: ZORBAX Eclipse Plus dC18, 150 × 4.6 mm, 5 μm, Agilent

	Calculated Conc.(ug/mL)	Mean Actual Conc.(ug/mL)	Theoretical Conc.(ug/mL)	Assay Percent %
S1-1	20.5	20.4	20.0	102.0
S1-2	20.4			
S1-3	20.4			