

Analysis Report

Prepared For: _____

Prepared By: _____

Analytical method

Mobile Phase A: Water

Mobile Phase B: Methanol

Wavelength: 225 nm

Testing Site and Date

Testing Site: _____ Testing Date: 02/12/15

Analyte

Product name: 202184-sh

Name: L--- Liothyronine Sodium

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 %: 98.0%

Analyst: _____ Date: 02/15/15

Auditor: _____ Date: 02/15/15

Project: PF15F0014
Analytical Run: AR13 L3

Current Date: 2/15/2015
Current Time: 1:49:30 PM

Peak Results
Name: L3

	SampleName	Name	Sample Type	Area	Retention Time (min)	Concentration	Units	Dilution
1	L3 0.500 ug/mL	L3	Standard	14712	15.698	0.50000	mg/mL	1.00
2	L3 1.00 ug/mL	L3	Standard	44393	15.633	1.00000	mg/mL	1.00
3	L3 2.00 ug/mL	L3	Standard	86981	15.638	2.00000	mg/mL	1.00
4	L3 5.00 ug/mL	L3	Standard	254202	15.584	5.00000	mg/mL	1.00
5	L3 10.0 ug/mL	L3	Standard	516185	15.571	10.00000	mg/mL	1.00
6	S 2.00 ug/mL	L3	Unknown	92637	15.619	1.98541	mg/mL	1.00
7	S 2.00 ug/mL	L3	Unknown	89374	15.643	1.92369	mg/mL	1.00
8	S 2.00ug/mL	L3	Unknown	91185	15.650	1.95795	mg/mL	1.00

Project: PF15F0014

Compound: L3

Analytical Run: AR13 L3

Current Date: 2/15/2015

Current Time: 1:49:21 PM

Date Calibrated: 2/13/2015 11:13:26 AM

Date Acquired: 2/12/2015 9:23:01 PM

Intercept: -12339.661003

Slope: 52874.124595

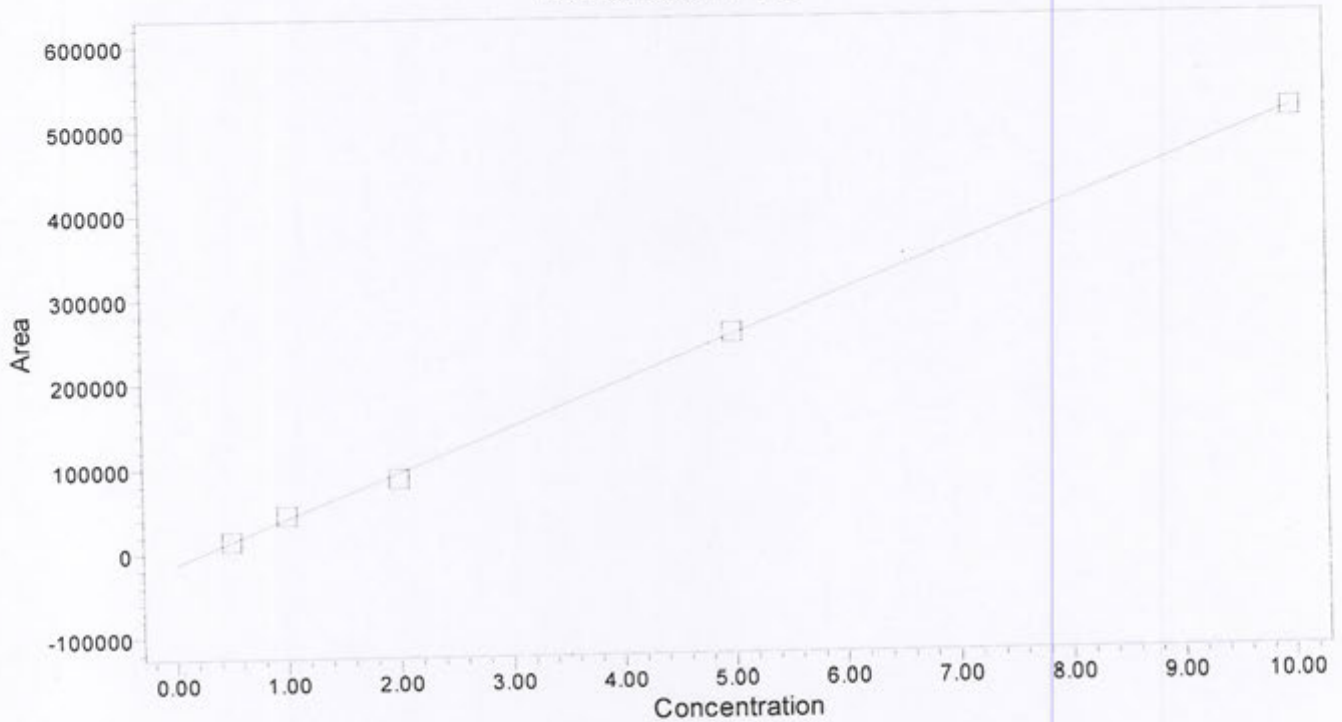
r: 0.999823

Fit Type: Linear (1st Order)

Weighting: None

Units: mg/mL

Calibration Plot



	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore
1	L3	W1	0.500000	14712.000000	0.511624	2.32476	No	No
2	L3	W2	1.000000	44393.000000	1.072976	7.29759	No	No
3	L3	W3	2.000000	86981.000000	1.878436	-6.07820	No	No
4	L3	W4	5.000000	254202.000000	5.041061	0.82121	No	No
5	L3	W5	10.000000	516185.000000	9.995904	-0.04096	No	No

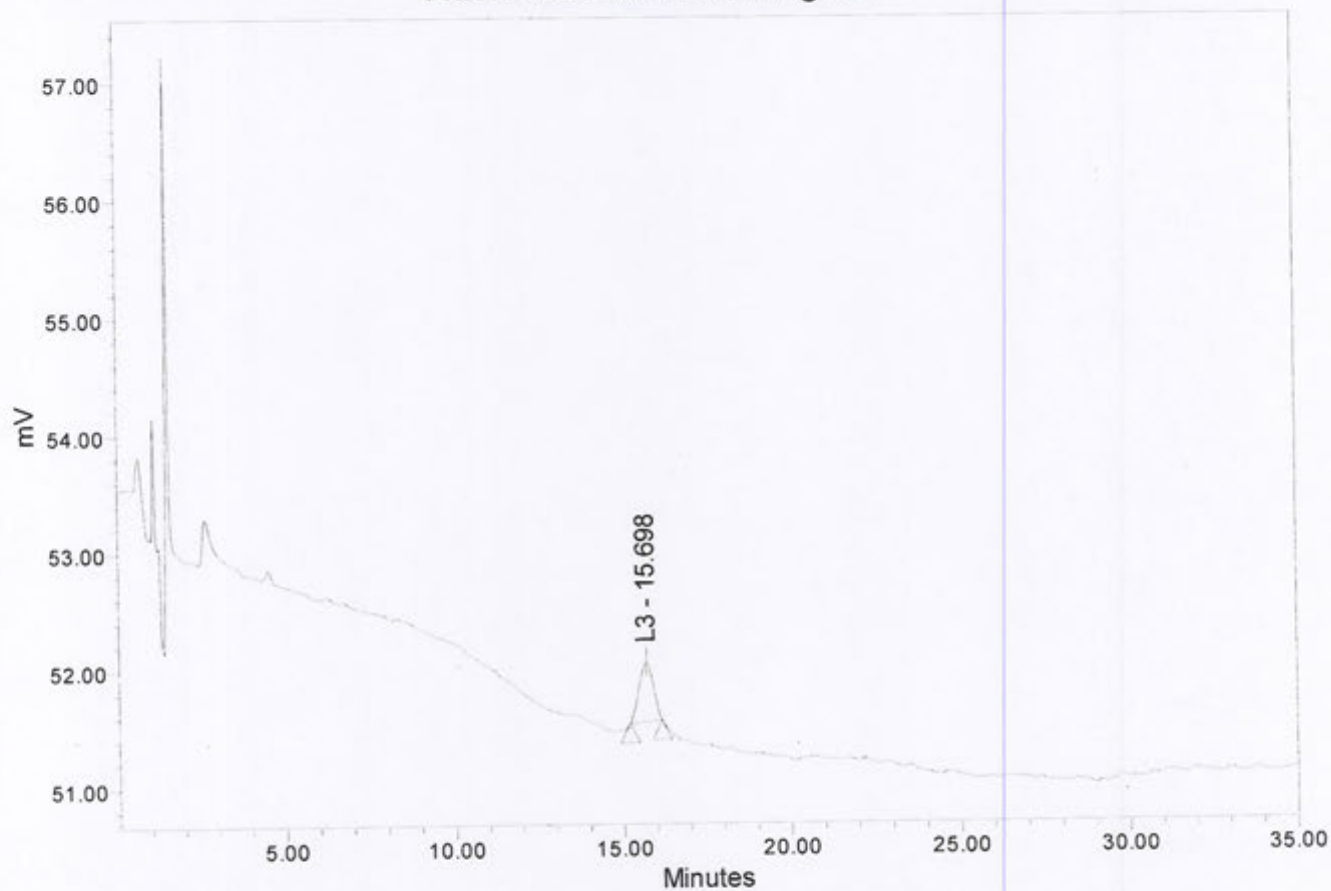
Software Version 4.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:48:48 PM
Date Acquired: 2/12/2015 5:12:22 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: L3 0.500 ug/mL
Injection Id: 4774

Auto-Scaled Chromatogram



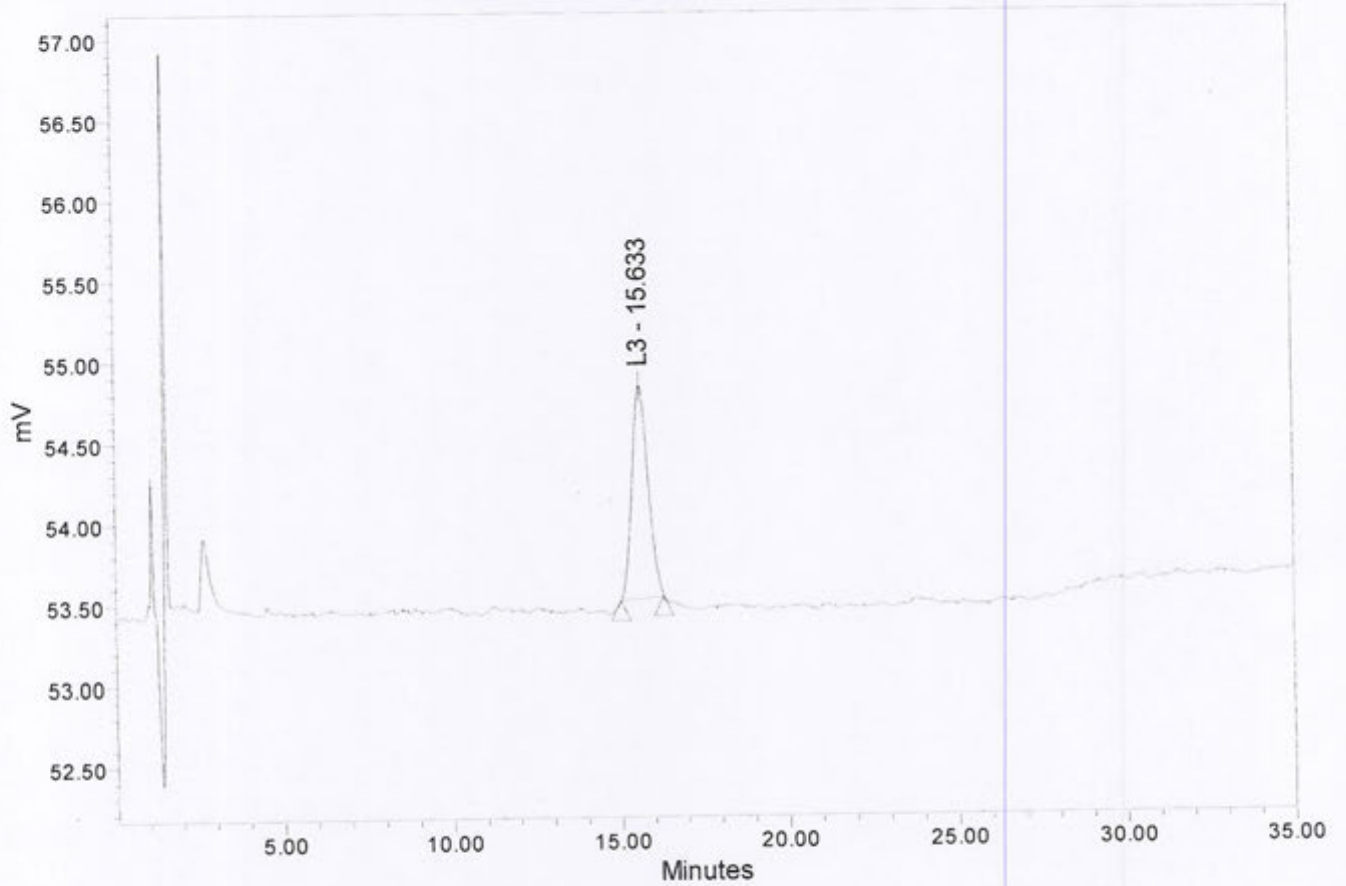
Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	L3 0.500 ug/mL	15.698	498	14712	1	100.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:48:54 PM
Date Acquired: 2/12/2015 5:48:09 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: L3 1.00 ug/mL
Injection Id: 4777

Auto-Scaled Chromatogram



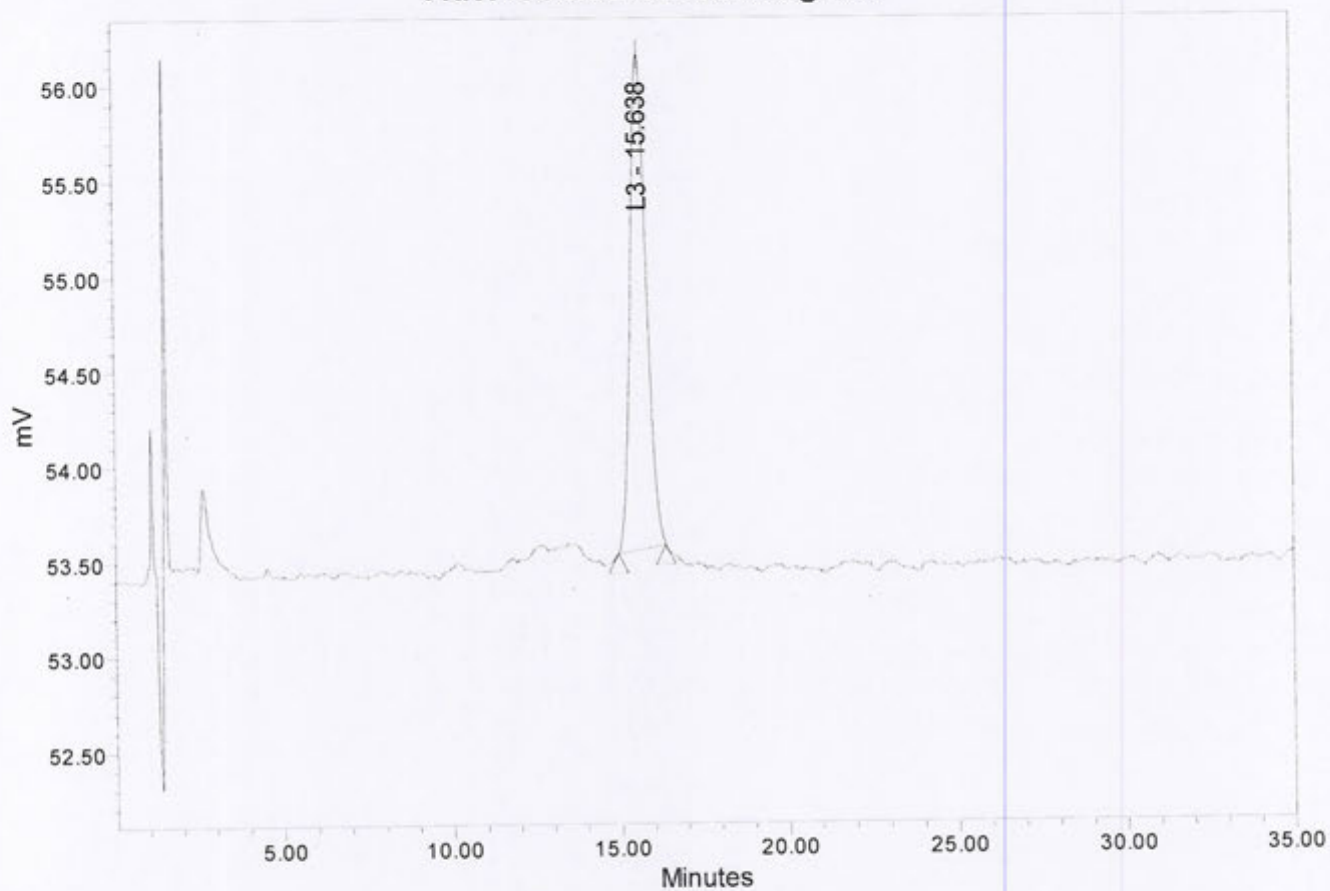
Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	L3 1.00 ug/mL	15.633	1320	44393	2	100.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:48:57 PM
Date Acquired: 2/12/2015 6:23:58 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: L3 2.00 ug/mL
Injection Id: 4780

Auto-Scaled Chromatogram



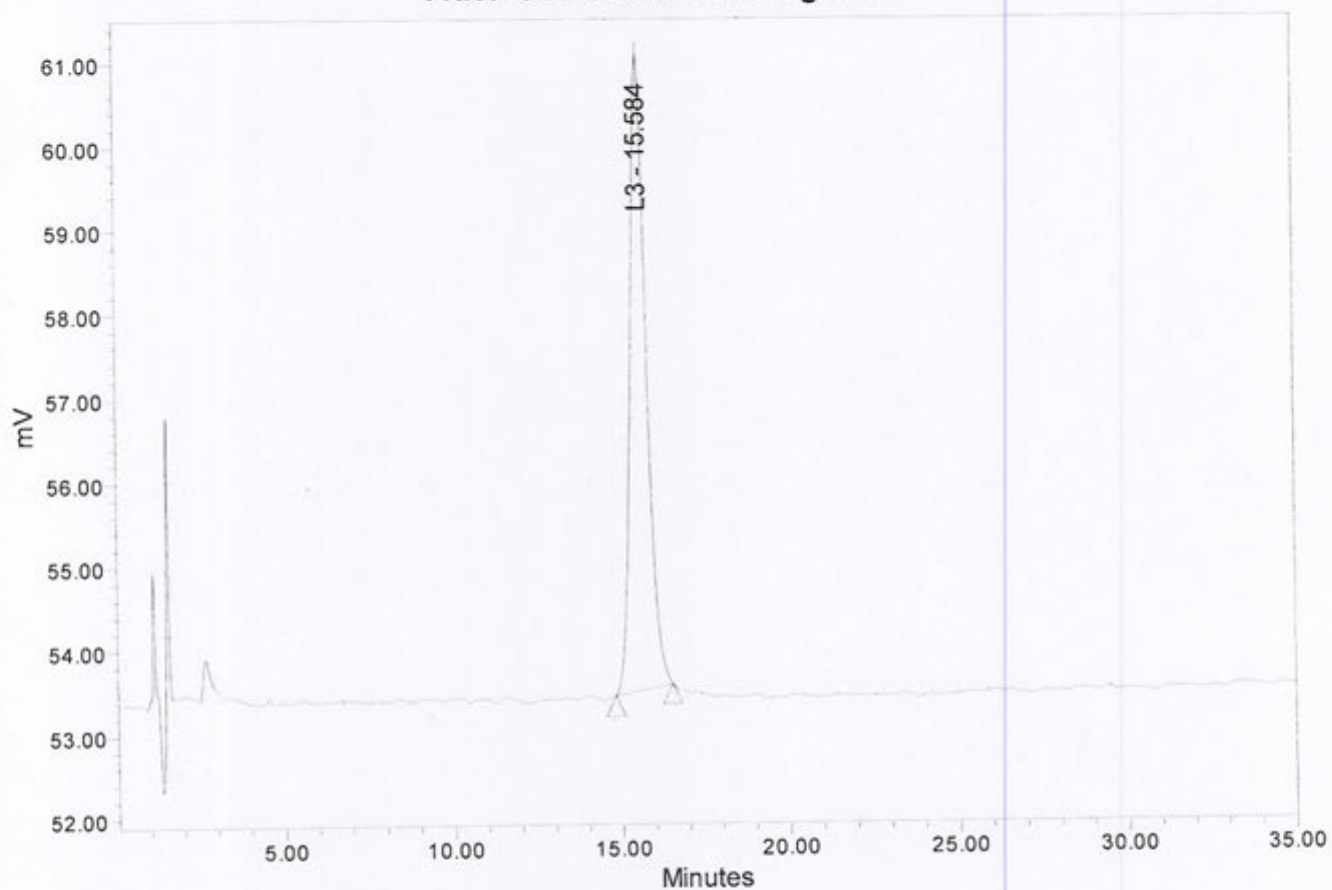
Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	L3 2.00 ug/mL	15.638	2609	86981	3	100.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:48:59 PM
Date Acquired: 2/12/2015 6:59:46 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: L3 5.00 ug/mL
Injection Id: 4783

Auto-Scaled Chromatogram



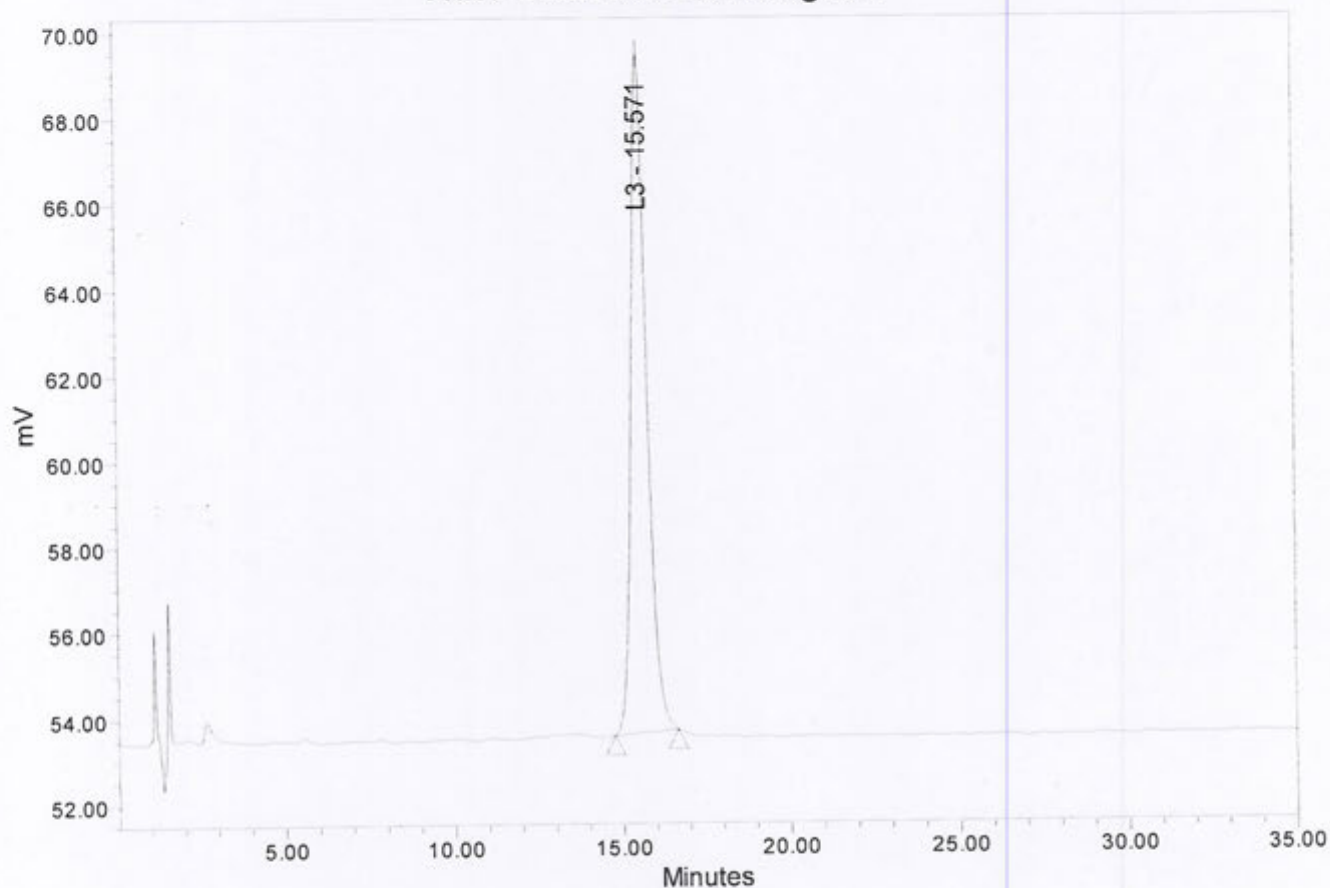
Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	L3 5.00 ug/mL	15.584	7584	254202	4	100.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:49:05 PM
Date Acquired: 2/12/2015 7:35:34 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: L3 10.0 ug/mL
Injection Id: 4786

Auto-Scaled Chromatogram



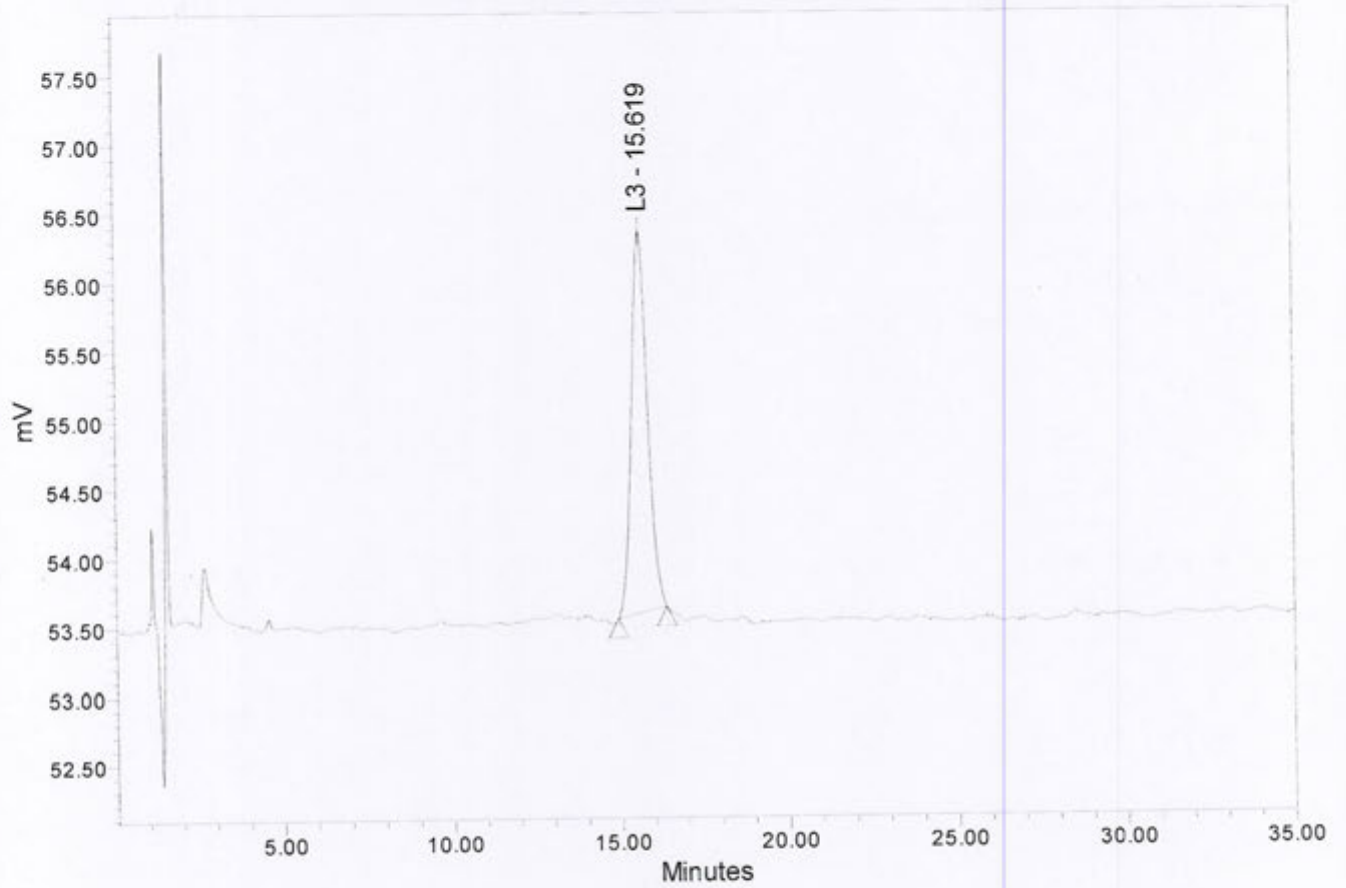
Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	L3 10.0 ug/mL	15.571	15853	516185	5	100.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:49:08 PM
Date Acquired: 2/12/2015 8:11:25 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: S 2.00 ug/mL
Injection Id: 4789

Auto-Scaled Chromatogram



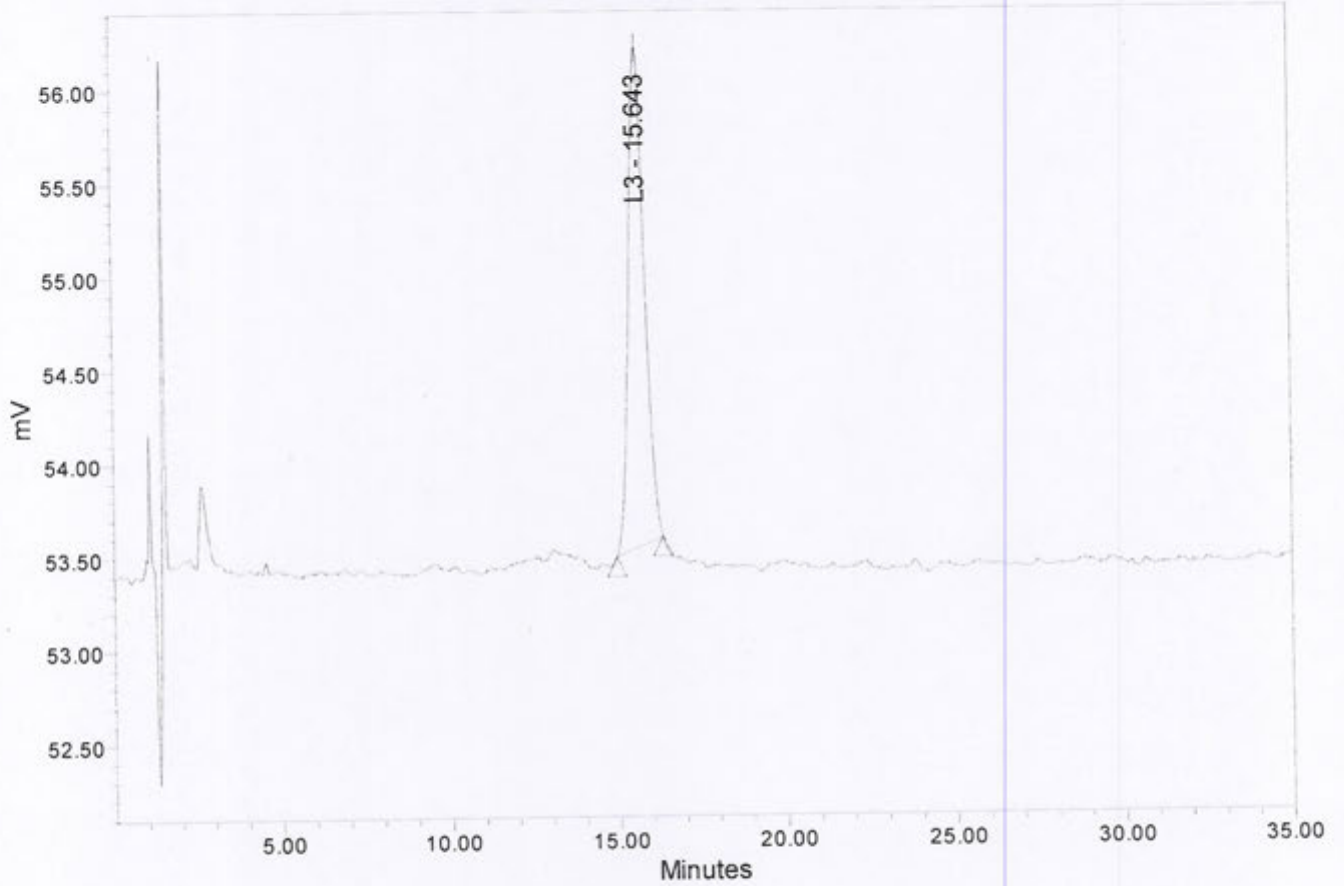
Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	S 2.00 ug/mL	15.619	2778	92637	6	100.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:49:11 PM
Date Acquired: 2/12/2015 8:47:13 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: S 2.00 ug/mL
Injection Id: 4792

Auto-Scaled Chromatogram



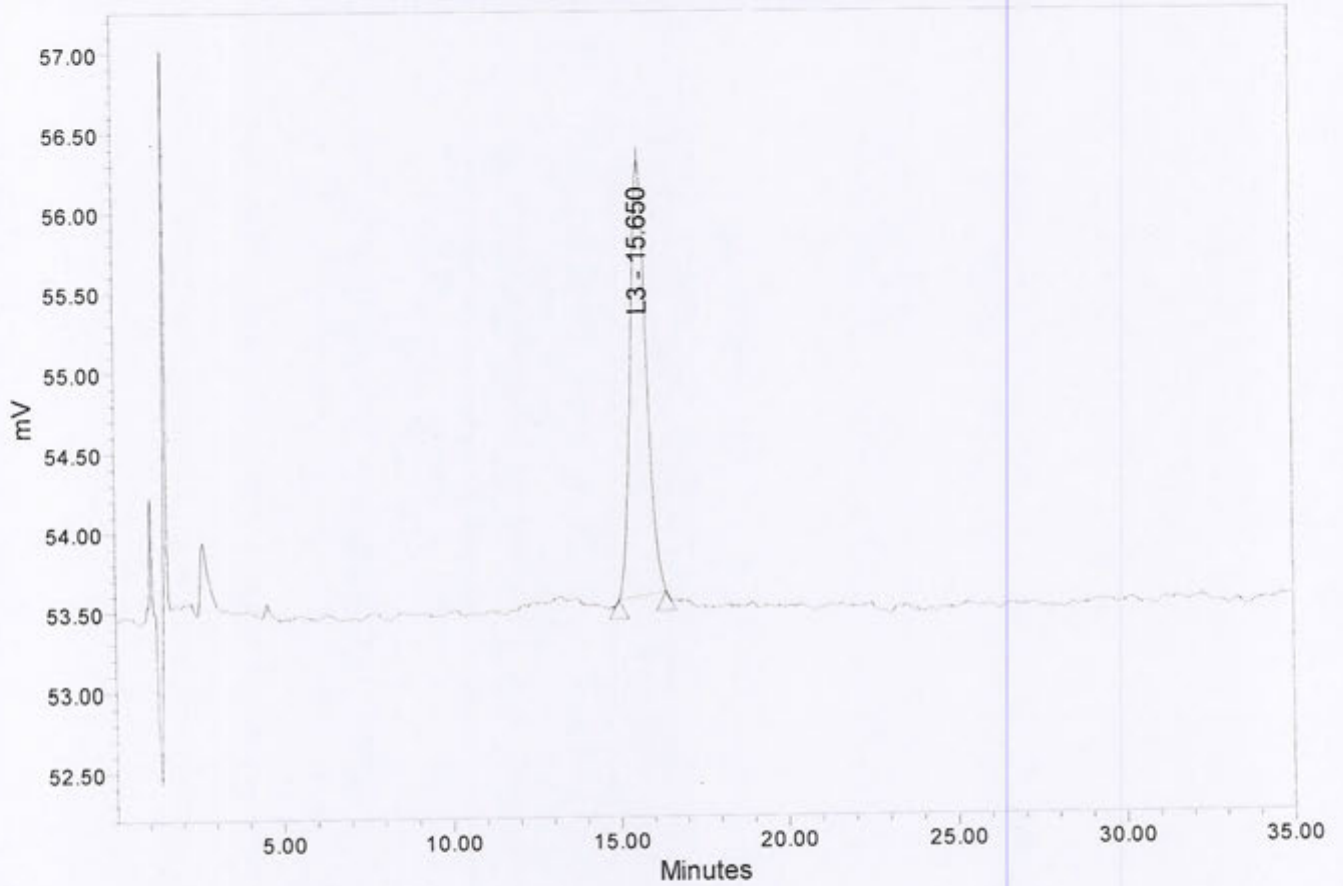
Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	S 2.00 ug/mL	15.643	2684	89374	7	100.00

Project: PF15F0014
Compound: L3

Current Date: 2/15/2015
Current Time: 1:49:14 PM
Date Acquired: 2/12/2015 9:23:01 PM
Date Calibrated: 2/13/2015 11:13:26

Analytical Run: AR13 L3
Text: S 2.00ug/mL
Injection Id: 4795

Auto-Scaled Chromatogram



Name	SampleName	RT	Height	Area	Vial	% Area	
1	L3	S 2.00ug/mL	15.650	2741	91185	8	100.00

AR13 Liothyronine Sodium

HPLC Condition

Solvent A: Water

Solvent B: Methanol

Mobile Phase: Solvent A:Solvent B (50:50, v/v)

Flow Rate (mL/min): 1.20

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	1.99	1.96	2.00	98.0
S1-2	1.92			
S1-3	1.96			