



Scientific Study

B4522, Omnibase
(Lactic Acid Study)

Not appropriate for regulatory submission.
Please visit www.SpectrumRx.com or
contact Tech Services for the most up-to-
date information contained in this
information package.

Spectrum Pharmacy Products

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Lactic Acid:

4.65g Lactic Acid raw drug powder from Spectrum Chemical (part number L1010, Lot # YL0734) was added to 50.00g Spectrum Mfg. Corp. Omnibase and levigated with an electronic mortar and pestle, resulting in a final concentration of 8.5% w/w. This gel was then stored at room temperature in the same 50/70 mL Unguator container.

Samples were prepared every 14 days by a 5.00 g accurately weighed sample being transferred to a 50.0 ml volumetric flask. The contents of the flask were diluted to volume with matrix matched mobile phase for HPLC determination.

Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations, initial interval, and latest passing interval to illustrate no co-elution or baseline interference, as well as degradation products.

90-Day Summary:

Compounded at 8.50% w/w, stability-indicating HPLC analysis found less than 2% Lactic Acid loss in Spectrum Mfg. Corp. Omnibase at 90 days.

Attached are 8 chromatographs of Spectrum Mfg. Corp. Omnibase showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90- Day Standard, and 90-Day Sample.

Lactic Acid Std 1

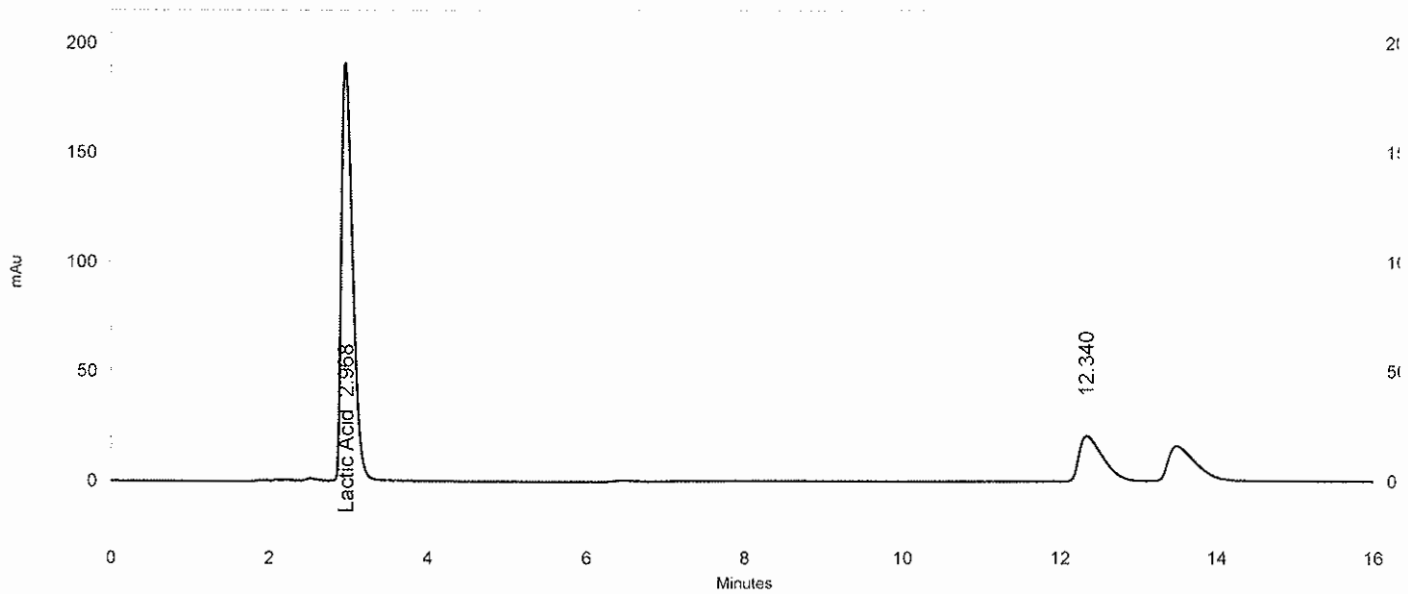
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A.met

C:\CLASS-VP\Sequence\2010\February\HPLC 3\February 19-10
Lactic Acid Precision.seq

2/22/2010 8:39:20 AM 1

2/22/2010 8:39:20 AM

100



1: 220
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.968	1845243	0.904 CAL	1.53380	0.00000	2138

Lactic Acid 8.5% Precision 1

C:\CLASS-VP\Enterprise\Projects\Default\Method\Lactic Acid
A.met

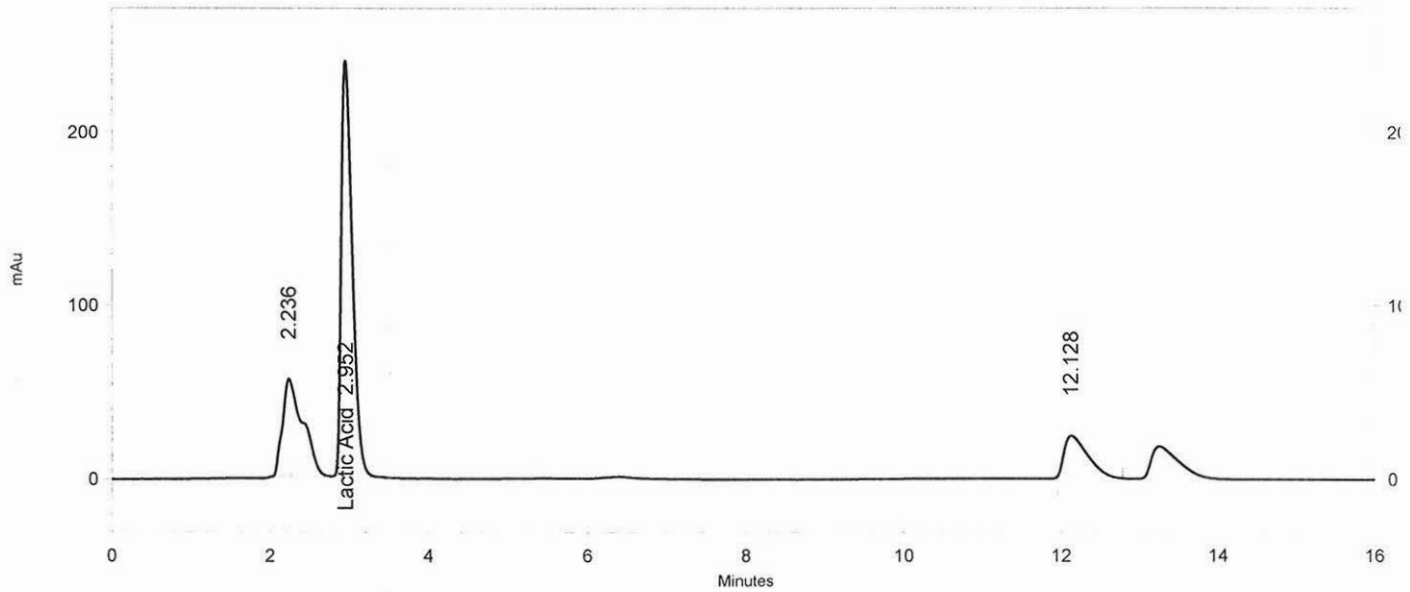
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Lactic Acid Precision.seq

2/22/2010 8:39:47 AM 1

2/22/2010 8:39:47 AM

100



1: 220
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.952	2274548	8.771	1.57693	2.06089	2205

Lactic Acid Std 1

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A.met

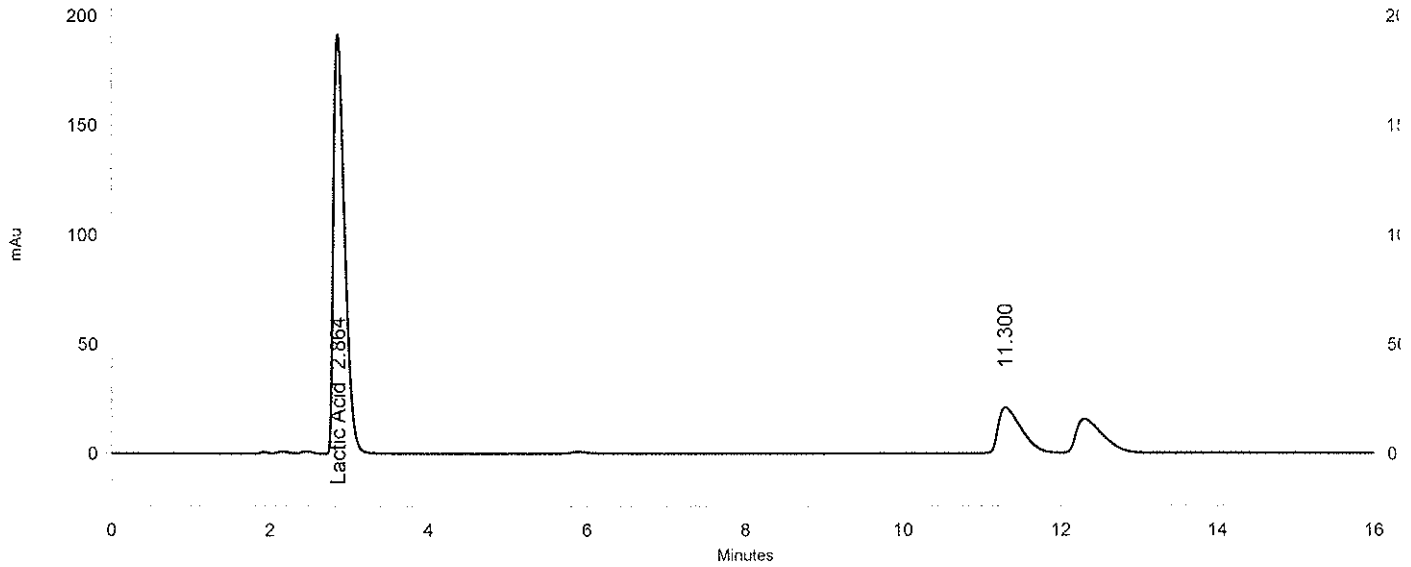
C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 18-10 Lactic Acid

30 days Stability.seq

3/18/2010 2:05:53 PM 1

3/18/2010 2:05:54 PM

100



1: 220
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.864	1850738	0.909 CAL	1.54781	0.00000	1991

Lactic Acid 8.5% Stability 30 days

C:\CLASS-VP\Enterprise\Projects\Default\Method\Lactic Acid

A.met

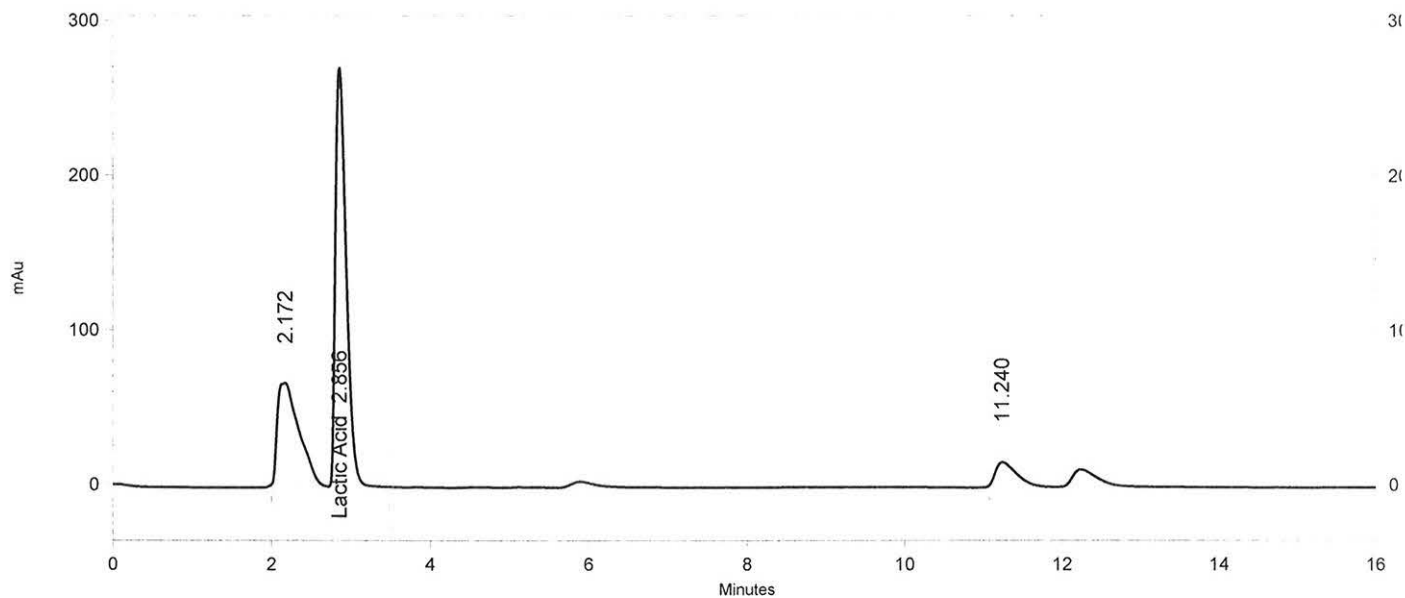
C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 18-10 Lactic Acid

30 days Stability.seq

3/18/2010 2:06:07 PM 1

3/18/2010 2:06:08 PM

100



1: 220
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.856	2567146	8.579	1.61783	1.84178	2065

Lactic Acid Std 1

C:\CLASS-VP\Enterprise\Projects\Default\Method\Lactic Acid

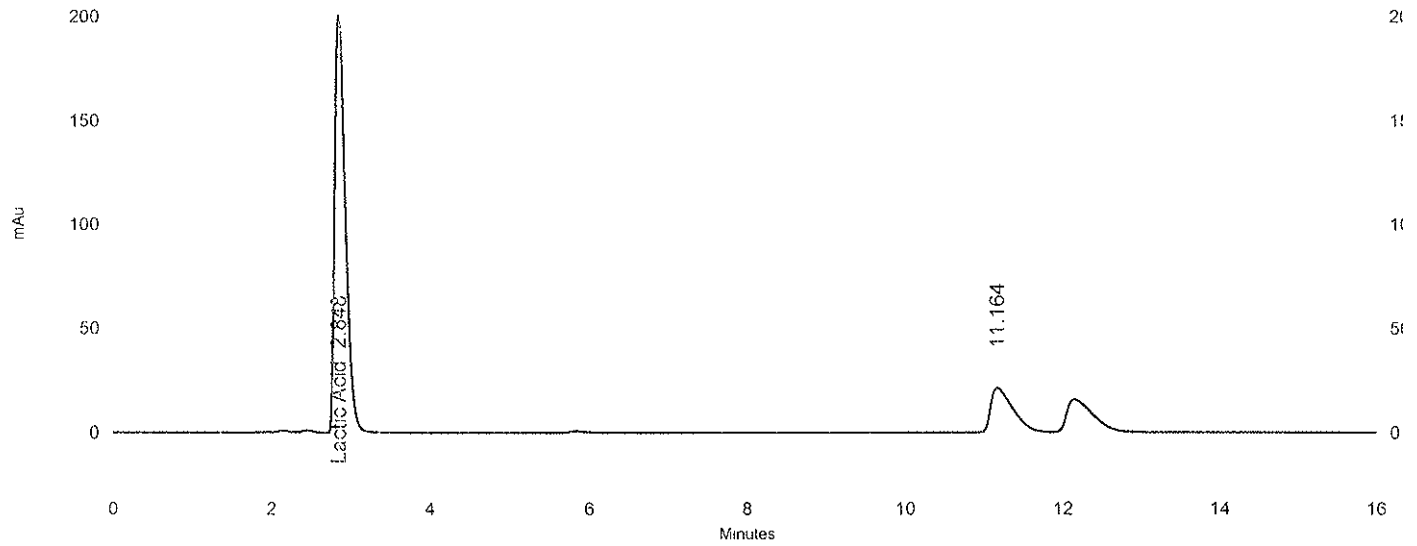
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C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 13-10 Lactic Acid
60 days stability.seq

4/13/2010 3:40:54 PM 1

4/13/2010 3:40:54 PM

100



1: 220
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.848	1855154	0.909 CAL	1.61353	0.00000	2155

Lactic Acid 8.5% Stability 60 days

C:\CLASS-VP\Enterprise\Projects\Default\Method\Lactic Acid

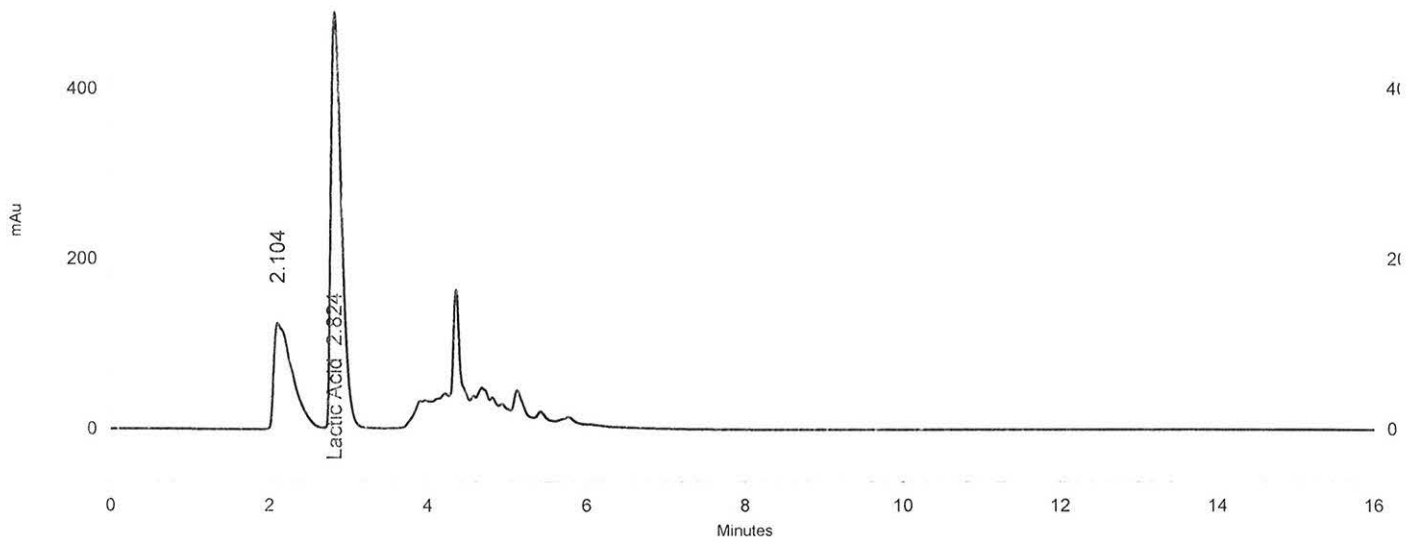
A.met

C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 13-10 Lactic Acid
60 days stability.seq

4/13/2010 3:41:12 PM 1

4/13/2010 3:41:13 PM

100



1: 220
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.824	4481586	8.504	1.80968	2.15548	2134

Lactic Acid Std 2

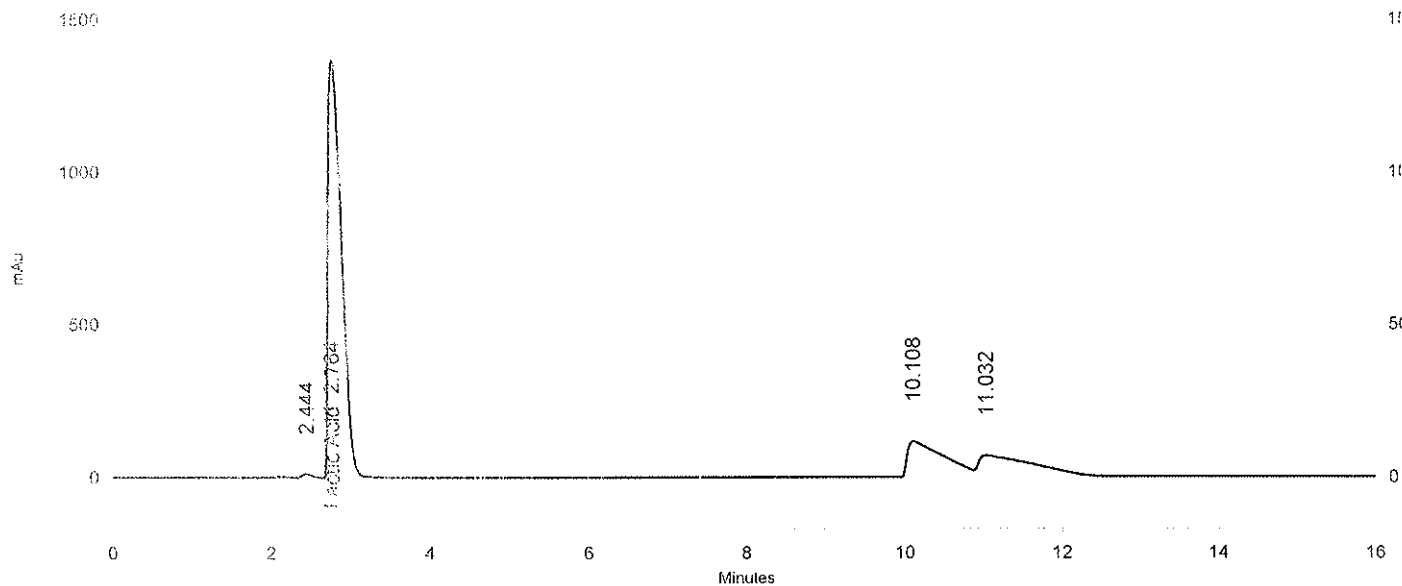
C:\CLASS-VP\Enterprise\Projects\Default\Method\Lactic Acid
A.met

C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 13-10 Lactic Acid 90
days Stability.seq

5/13/2010 4:44:10 PM 1

5/13/2010 4:44:11 PM

100



1: 220
nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.764	15831589	0.909 CAL	2.57845	1.19081	1280

Lactic Acid 8.5% Stability 90 days

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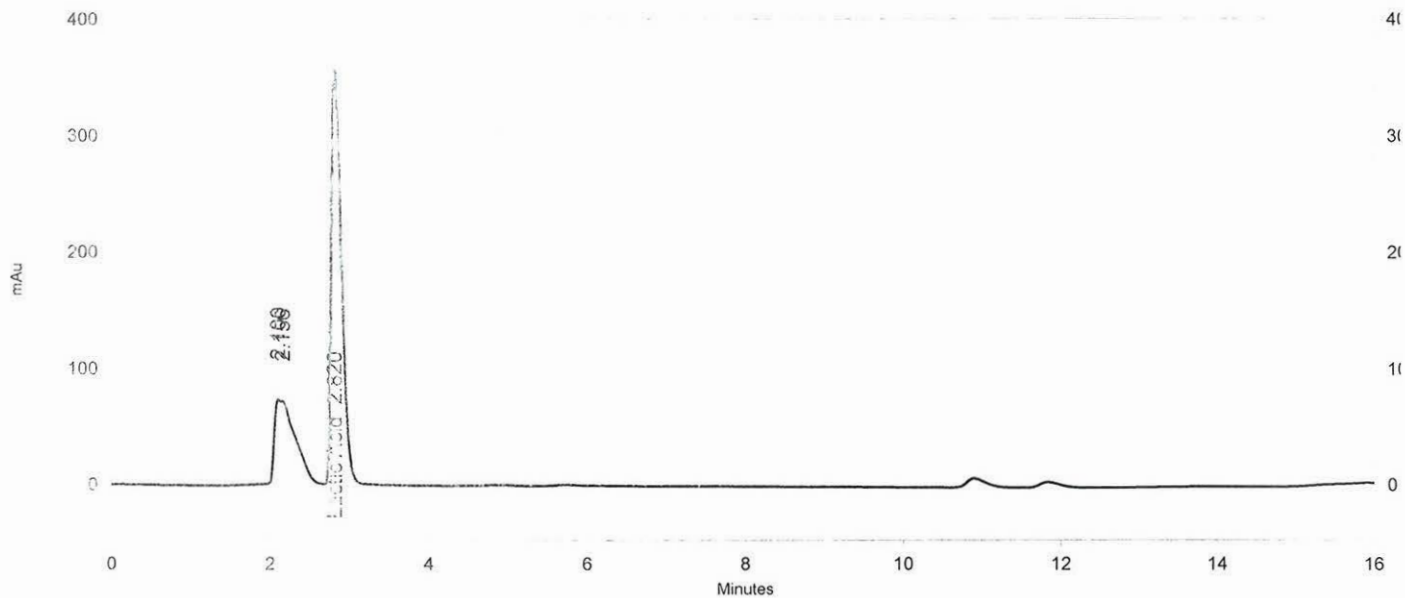
A.met

C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 13-10 Lactic Acid 90 days Stability.seq

5/13/2010 4:44:27 PM 1

5/13/2010 4:44:27 PM

100



1: 220
nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Lactic Acid	2.820	3161354	8.464	1.73474	0.00000	2255