



Scientific Study

B4522, Omnibase
(Progesterone 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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New Brunswick, NJ 08901
Phone 732.214.1300

Progesterone:

5.50g Progesterone raw drug powder from Spectrum Chemical (part number P1834, Lot # VG1290) was added to 50.00g Spectrum Chemical Mfg. Corp. Omnibase and levigated with an electronic mortar and pestle, resulting in a final concentration of 10.0% 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 10.0% w/w, stability-indicating HPLC analysis found negligible Progesterone loss in Spectrum Chemical Mfg. Corp. Omnibase at 90 days.

Attached are 8 chromatographs of Spectrum Chemical 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.

Progesterone Standards

C:\CLASS-VP\Methods\HPLC3\Progesterone.met

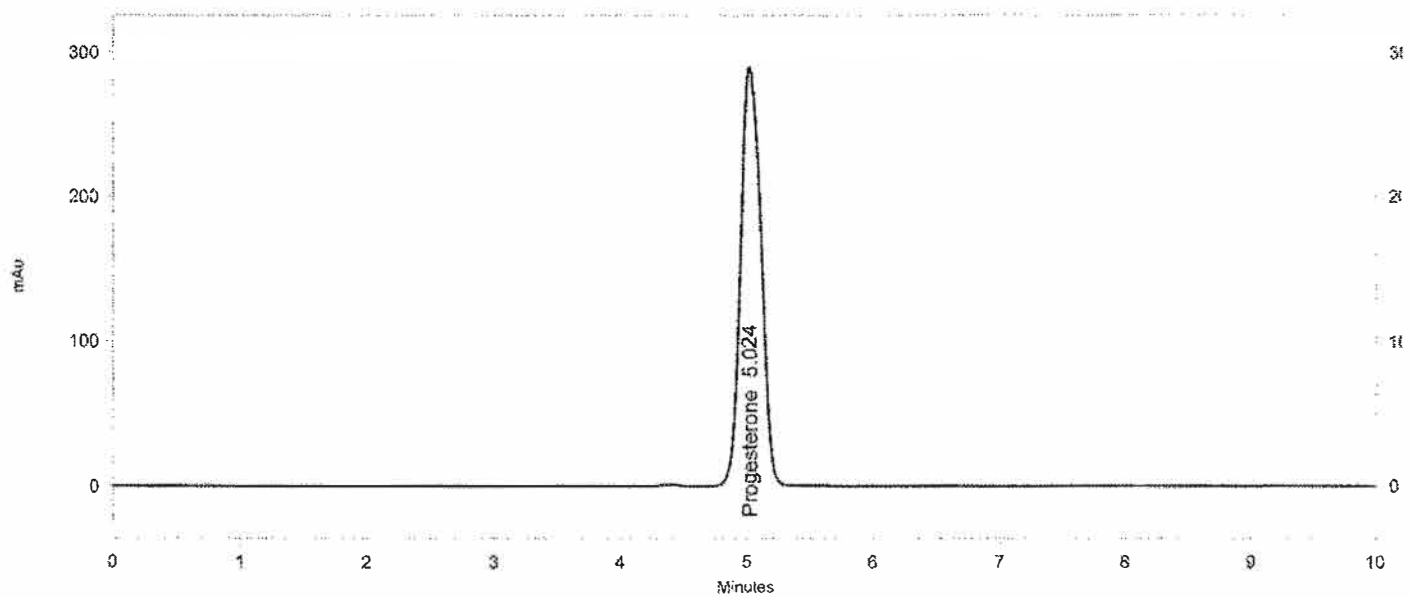
C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 18-10

Progesterone 10% 0 time.seq

1/18/2010 3:09:58 PM 1

1/18/2010 3:09:58 PM

25



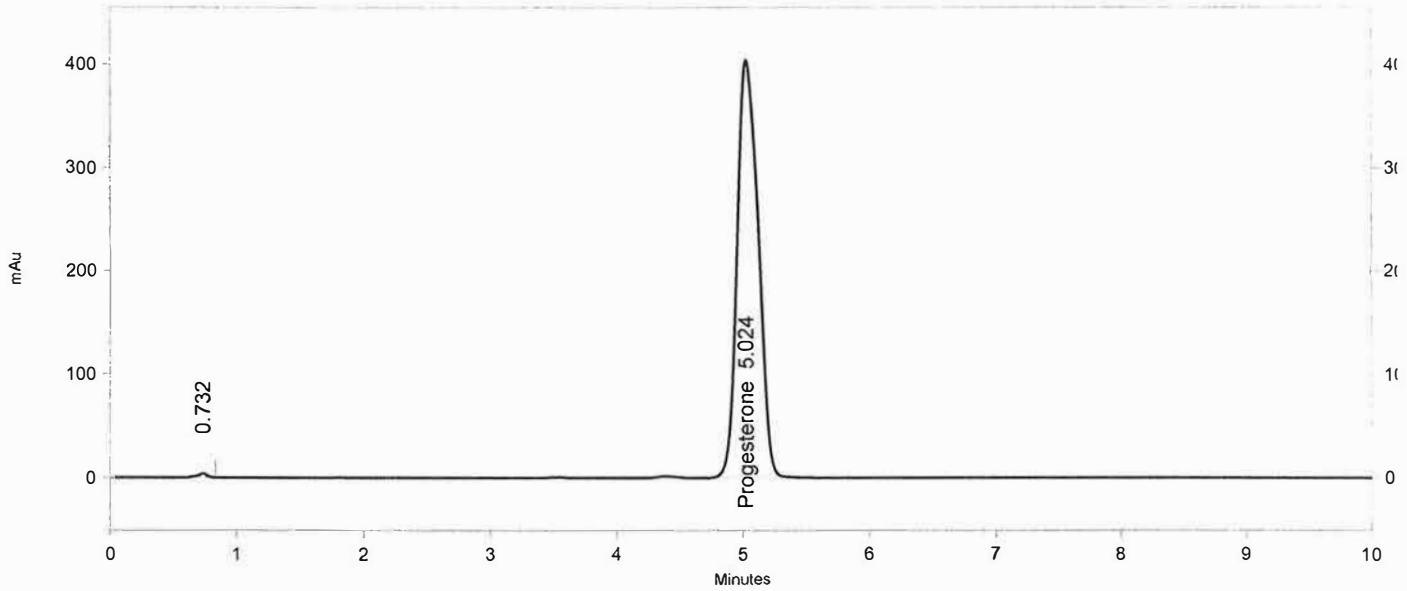
1: 254

nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	5.024	3250000	0.100 CAL	1.08592	0.00000	4632

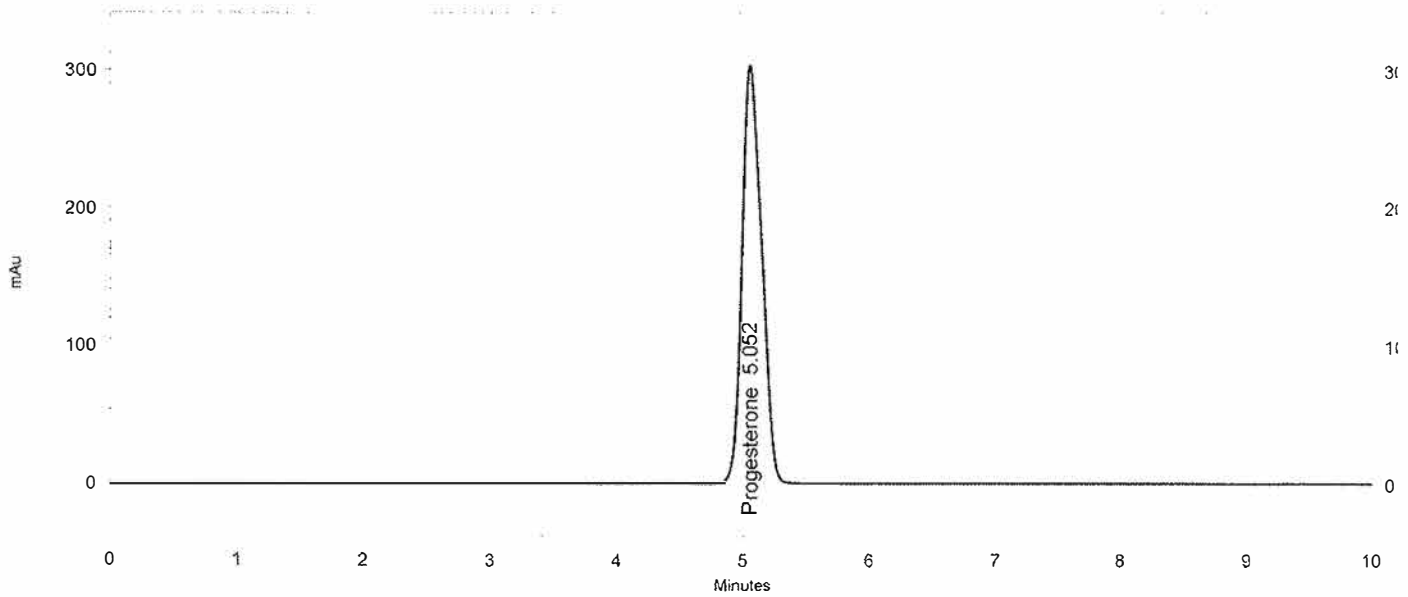
Progesterone 10% in Spectrum Mfg. Corp. Omnibase
 ZeroTime C:\CLASS-VP\Methods\HPLC3\Progesterone.met
 C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 18-10
 Progesterone 10% 0 time.seq
 1/18/2010 3:10:09 PM 1
 1/18/2010 3:10:10 PM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	5.024	4605843	10.111	1.14493	20.47528	4374

Progesterone Standards
 C:\CLASS-VP\Methods\HPLC3\Progesterone.met
 C:\CLASS-VP\Sequence\2010\February\HPLC 3\February 16-10
 Progesterone 10% 30 days Stability.seq
 2/16/2010 12:46:43 PM 1
 2/16/2010 12:46:44 PM
 25



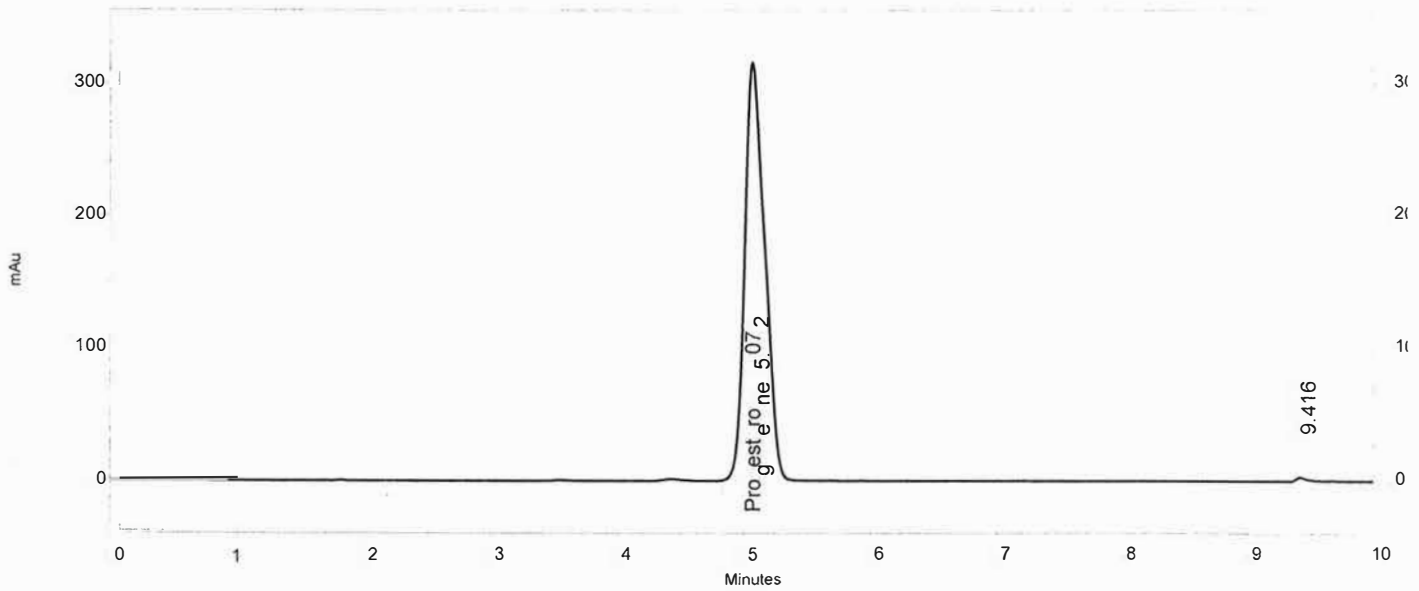
1: 254
 nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	5.052	3263807	0.100 CAL	1.20416	0.00000	4472

Progesterone 10% in Spectrum Chemical Mfg. Corp. Omnibase 30 Days

C:\CLASS-VP\Methods\HPLC3\Progesterone.met
 C:\CLASS-VP\Sequence\2010\February\HPLC 3\February
 16-10
 Progesterone 10% 30 days Stability.seq
 2/16/2010 1:07:38 PM 1
 2/16/2010 1:07:39 PM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	5.072	3418515	10.108	1.21904	0.00000	4378

Progesterone Standards

C:\CLASS-VP\Methods\HPLC3\Progesterone.met

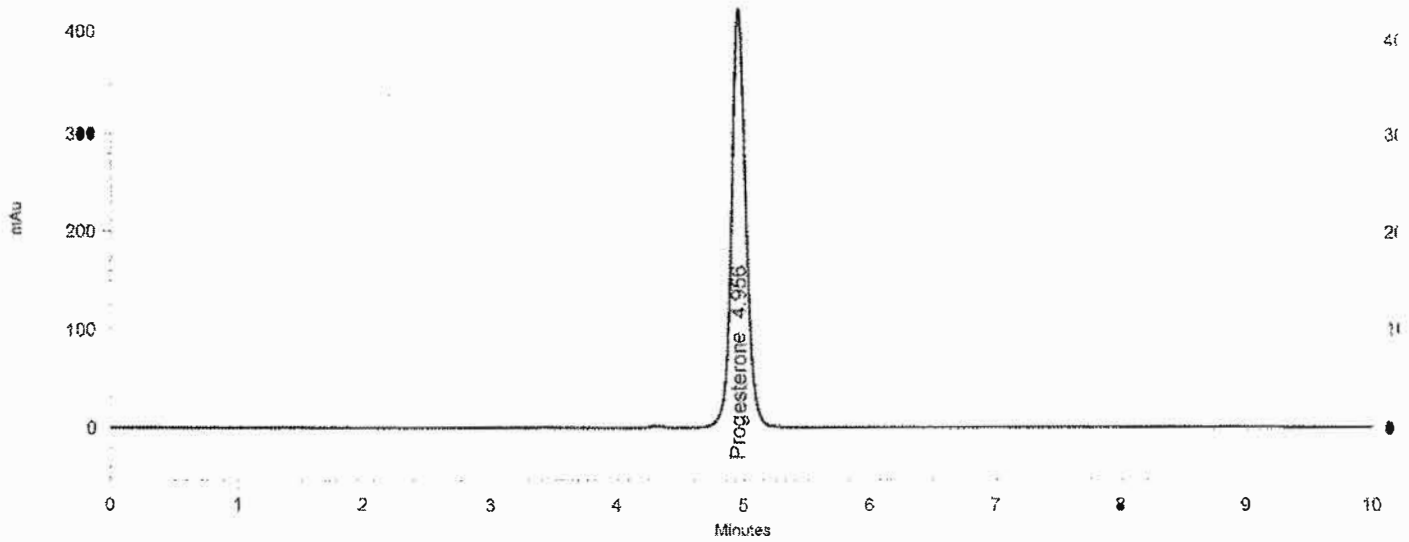
C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 16-10

Progesterone 10% 60 days stability.seq

3/17/2010 8:10:23 AM 1

3/17/2010 8:10:24 AM

25



1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	4.956	3331953	0.100 CAL	1.06249	0.00000	9617

Progesterone 10% in Spectrum Chemical Mfg. Corp.

Omnibase 60 days C:\CLASS-VP\Methods\HPLC3

\Progesterone.met

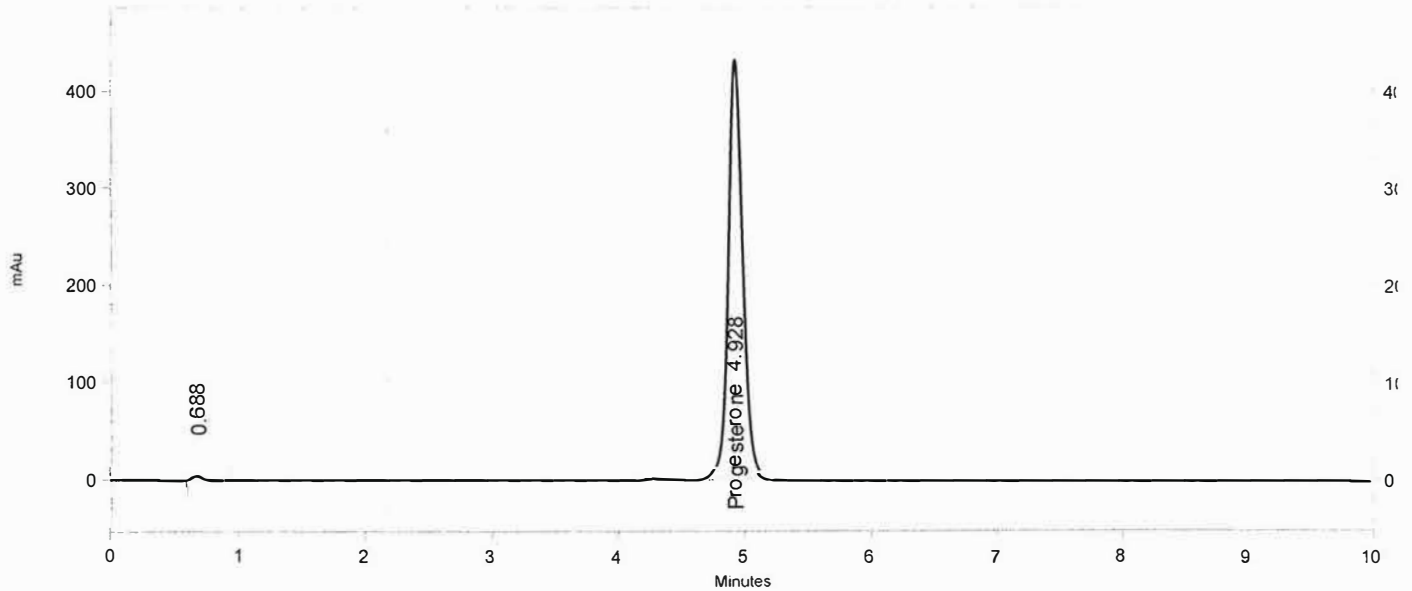
C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 16-10

Progesterone 10% 60 days stability.seq

3/17/2010 8:22:50 AM 1

3/17/2010 8:22:51 AM

25



1: 254

nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	4.928	3397688	10.030	1.06347	23.13385	9312

Progesterone Standards

C:\CLASS-VP\Methods\HPLC3\Progesterone.met

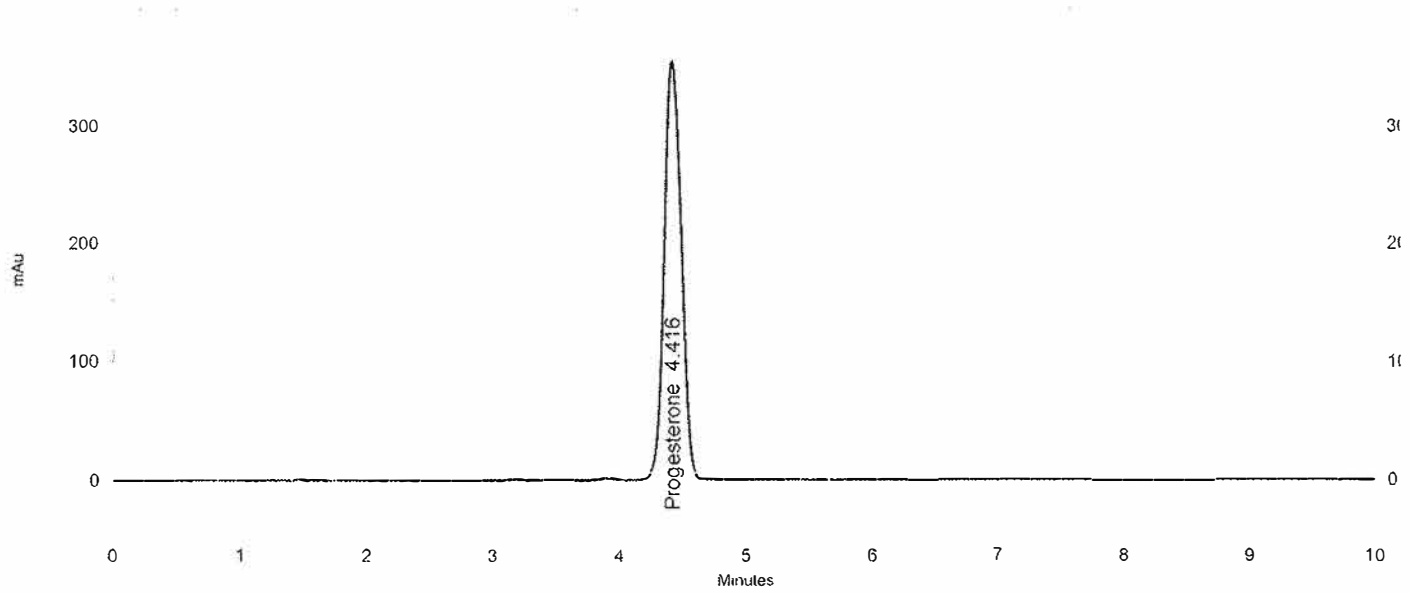
C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 13-10

Progesterone 90 days stability.seq

4/13/2010 11:27:35 AM 1

4/13/2010 11:27:36 AM

25



1: 254
nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	4.416	3292840	0.100 CAL	1.03943	0.00000	5116

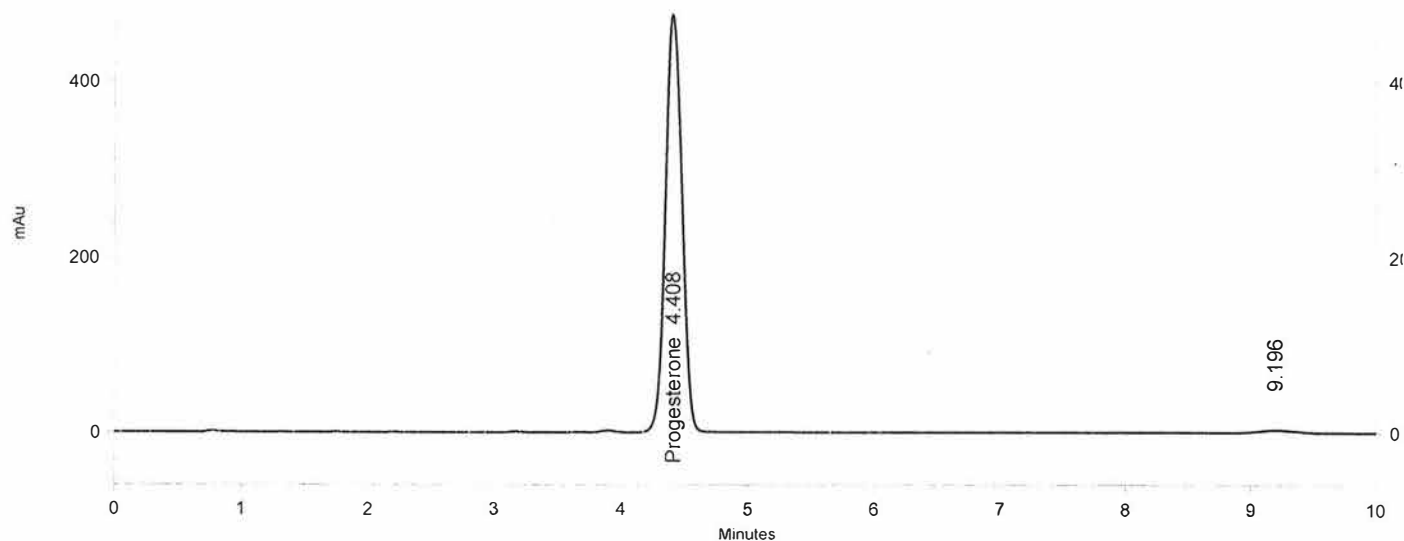
Progesterone 10% in Spectrum Chemical Mfg. Corp.
 Omnibase 90 days C:\CLASS-VP\Methods\HPLC3
 \Progesterone.met
 C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 13-10

Progesterone 90 days stability.seq

4/13/2010 11:27:49 AM 1

4/13/2010 11:27:50 AM

25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Progesterone	4.408	4342955	10.149	1.04974	0.00000	5245