



Scientific Study

B4522, Omnibase
(Testosterone 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

777 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300

Testosterone:

1.00g Testosterone raw drug powder from Sigma-Aldrich (part number T1 500, Lot # 070M1626V) was added to 50.00g Spectrum Chemical Mfg. Corp. Omnibase and levigated with an electronic mortar and pestle, resulting in a final concentration of 2.0% w/w. This emulsion 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.

180-Day Summary:

Compounded at 2.0% w/w, stability-indicating HPLC analysis found negligible Testosterone loss in Spectrum Chemical Mfg. Corp. Omnibase at 180 days.

Attached are 14 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, 90-Day Sample, 120-Day Standard, 120-Day Sample, 150-Day Standard, 150-Day Sample, 180-Day Standard, and 180-Day Sample.

Testosterone std

C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final Method.met

C:\CLASS-VP\Sequence\Sequence\2011\April\HPLC

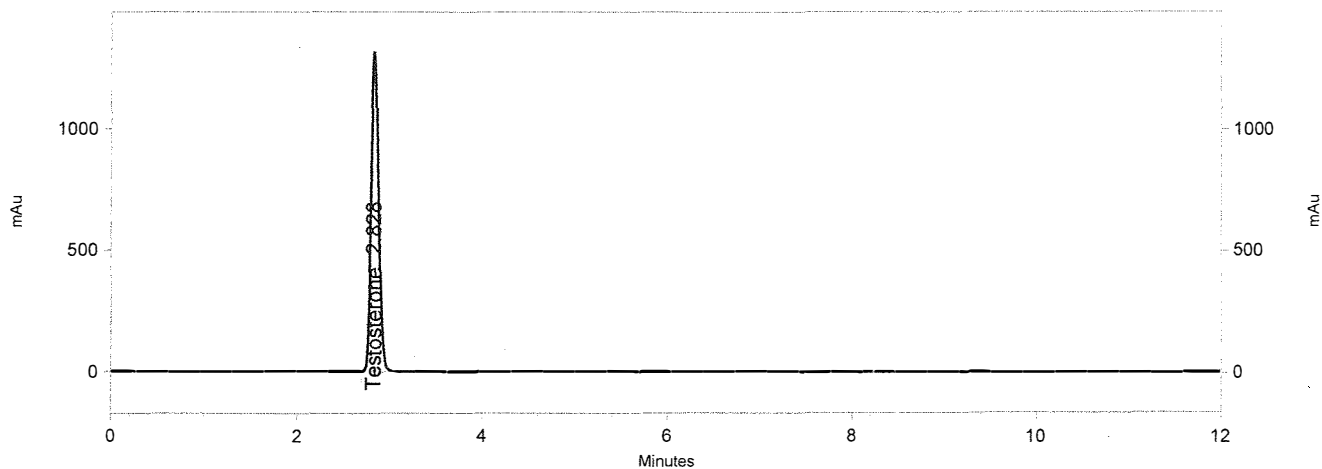
3\Testosterone 2% Spectrum Chemical Mfg. Corp. Omnibase April

11-11.seq

4/12/2011 9:18:46 AM 1

4/12/2011 9:18:47 AM

45



1: 241

nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|---------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 2.828 | 7382282 | 0.08 CAL | 1.25228 | 0.00000 | 5883 |

Testosterone 1

C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
Method.met

C:\CLASS-VP\Sequence\Sequence\2011\April\HPLC 3

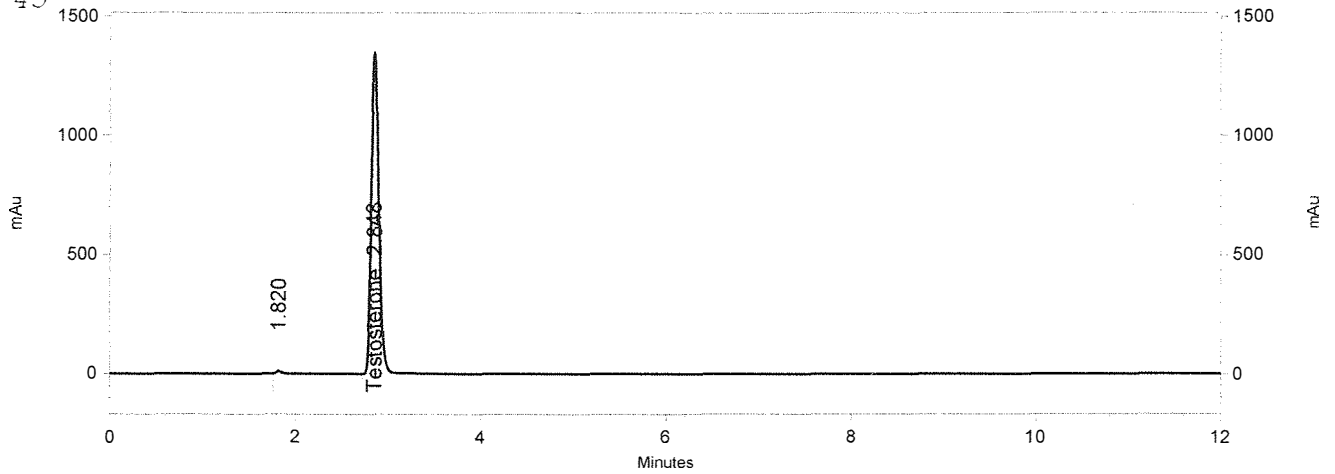
\Testosterone 2% Spectrum Chemical Mfg. Corp. Omnibase

April 12-11.seq

4/12/2011 3:22:39 PM 1

4/12/2011 3:22:40 PM

45



1: 241
nm, 4 nm
Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|---------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 2.848 | 7559583 | 1.99 | 1.27608 | 7.97088 | 6071 |

Testosterone std

C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final

Method.met

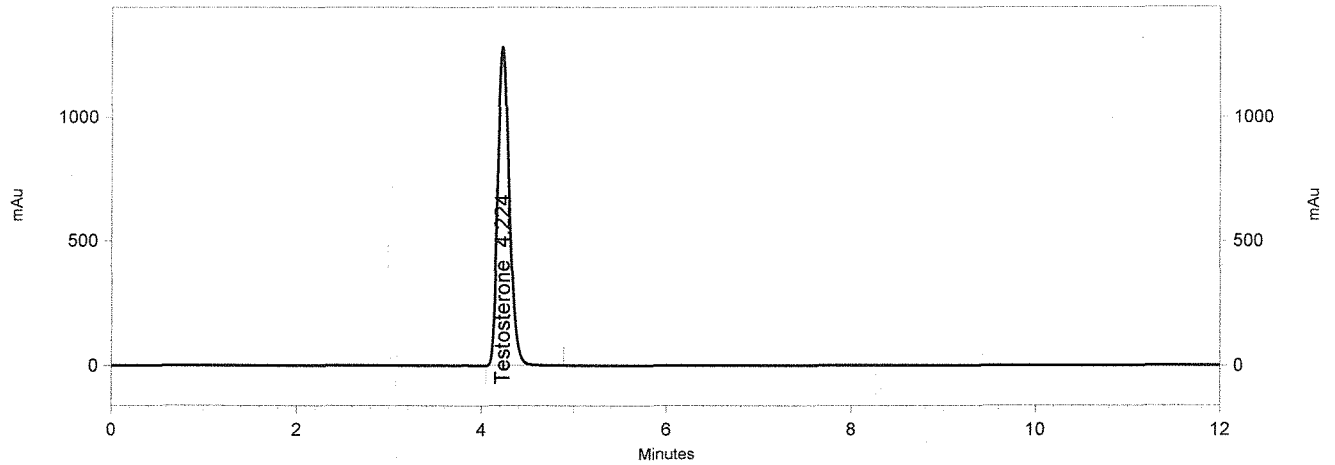
C:\CLASS-VP\Sequence\Sequence\2011\May\HPLC-3\Testosterone 2%

May 10-11.seq

5/11/2011 10:38:38 AM 1

5/11/2011 10:38:39 AM

45



1: 241

nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.224 | 11284631 | 0.08 CAL | 1.30637 | 0.00000 | 5305 |

Testosterone Spectrum Chemical Mfg. Corp. Omnibase 30days
 stability C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone
 Final

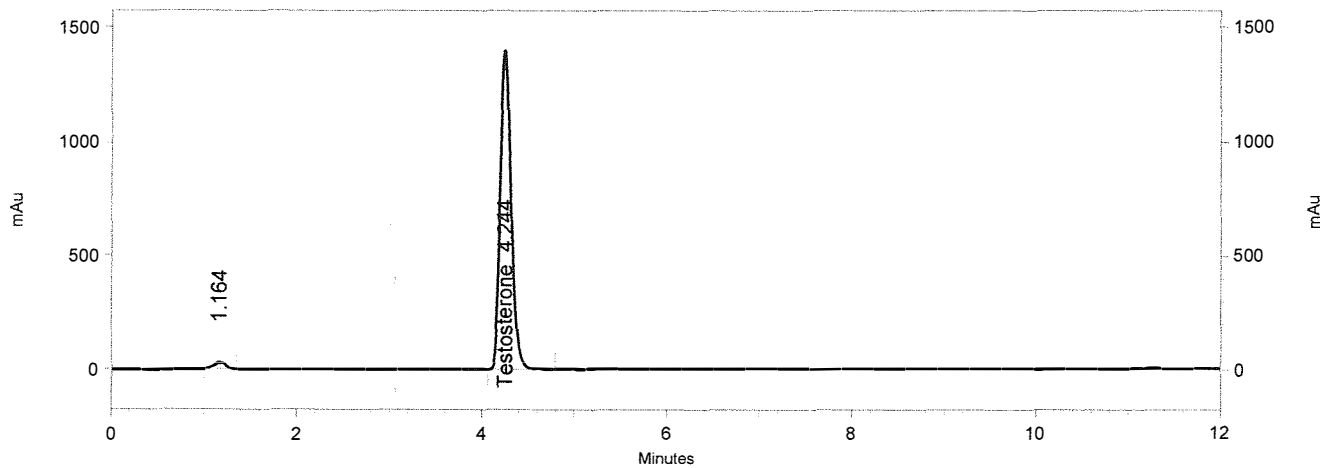
Method.met

C:\CLASS-VP\Sequence\Sequence\2011\May\HPLC-3\Testosterone 2%
 May 10-11.seq

5/11/2011 10:38:52 AM 1

5/11/2011 10:38:53 AM

45

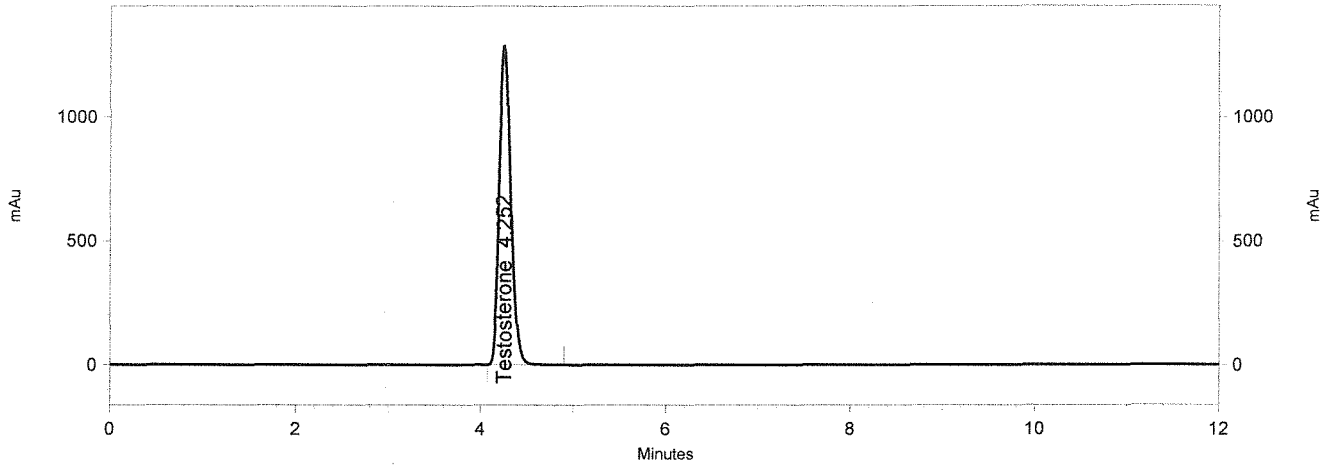


1: 241
 nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.244 | 11470928 | 1.97 | 1.29176 | 13.96936 | 6204 |

Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\June\HPLC-3\Testosterone 2%
 60days stability 6-13-11.seq
 6/14/2011 10:08:30 AM 1
 6/14/2011 10:08:31 AM
 45



1: 241
 nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.252 | 11217913 | 0.08 CAL | 1.27528 | 0.00000 | 5440 |

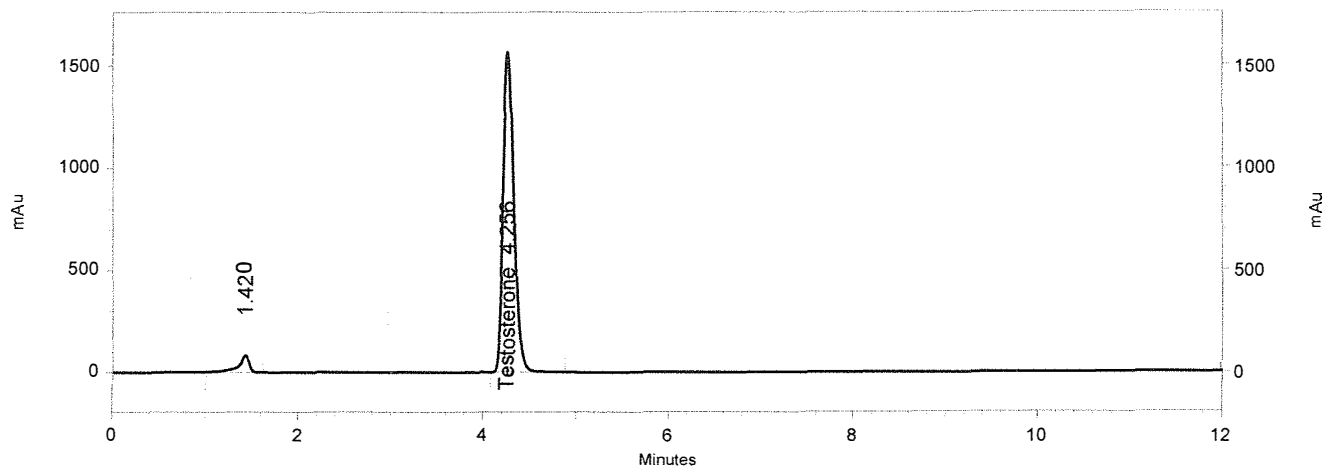
Testosterone Spectrum Chemical Mfg. Corp. Omnibase
 60days stability
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met

C:\CLASS-VP\Sequence\Sequence\2011\June\HPLC-3\Testosterone
 2%60days stability 6-13-11.seq

6/14/2011 10:08:45 AM 1

6/14/2011 10:08:46 AM

45



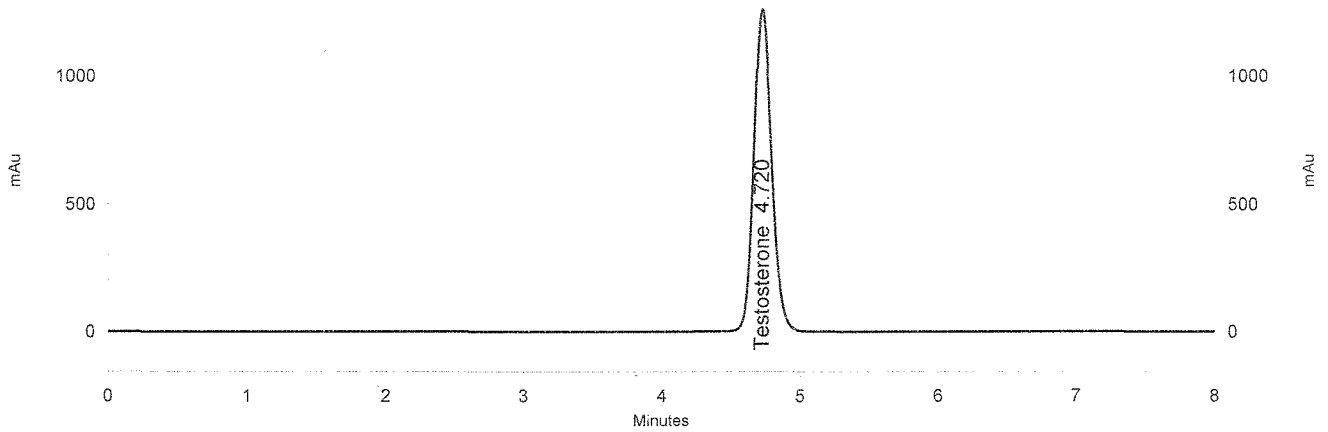
1: 241

nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.256 | 12692181 | 1.99 | 1.30730 | 14.60956 | 6465 |

Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\July\HPLC 3\July 19-11
 Testosterone 90 Days.seq
 7/19/2011 12:47:19 PM 1
 7/19/2011 12:47:20 PM
 45



1: 241
 nm, 4 nm
 Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.720 | 11261144 | 0.08 CAL | 1.17597 | 0.00000 | 6412 |

Testosterone Spectrum Chemical Mfg. Corp. Omnibase 90days
stability

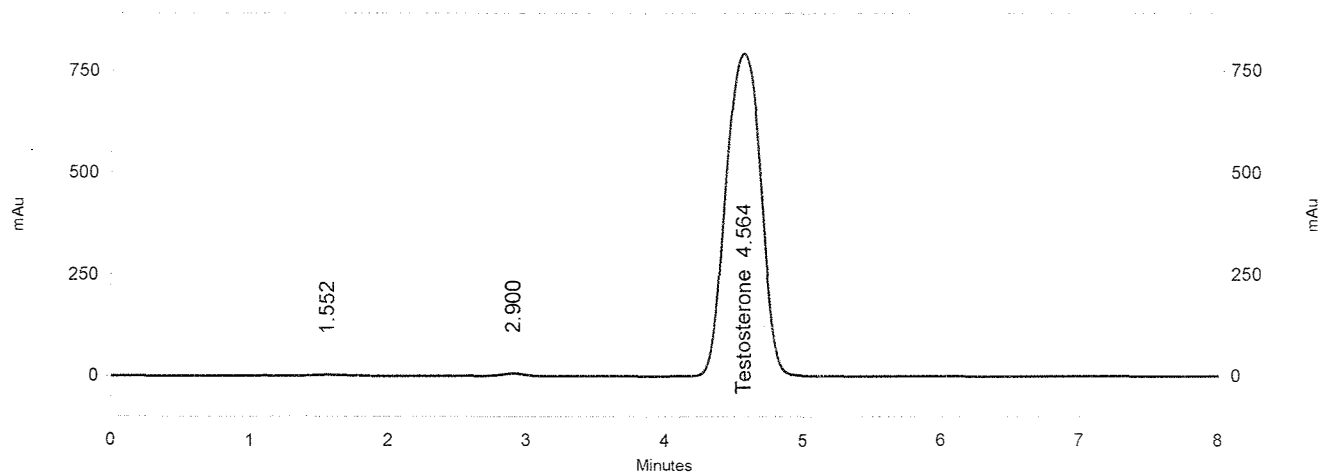
C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
Method.met

C:\CLASS-VP\Sequence\Sequence\2011\July\HPLC 3\July 19-11
Testosterone 90 Days.seq

7/19/2011 12:47:31 PM 1

7/19/2011 12:47:32 PM

45

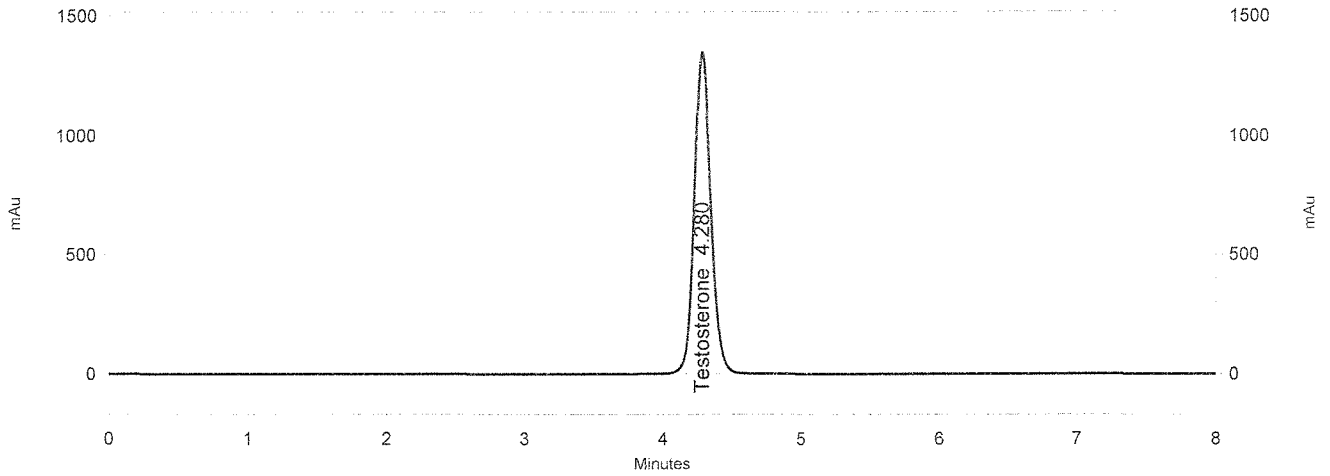


1: 241
nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.564 | 13845552 | 2.16 | 1.00123 | 4.40187 | 1624 |

Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\August\HPLC 3\August 15-11
 Testosterone Stability 120 days.seq
 8/15/2011 4:44:41 PM 1
 8/15/2011 4:44:42 PM
 45



1: 241
 nm, 4 nm
 Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.280 | 11242548 | 0.08 CAL | 1.14625 | 0.00000 | 6246 |

Testosterone Spectrum Chemical Mfg. Corp. Omnibase 120 days stability

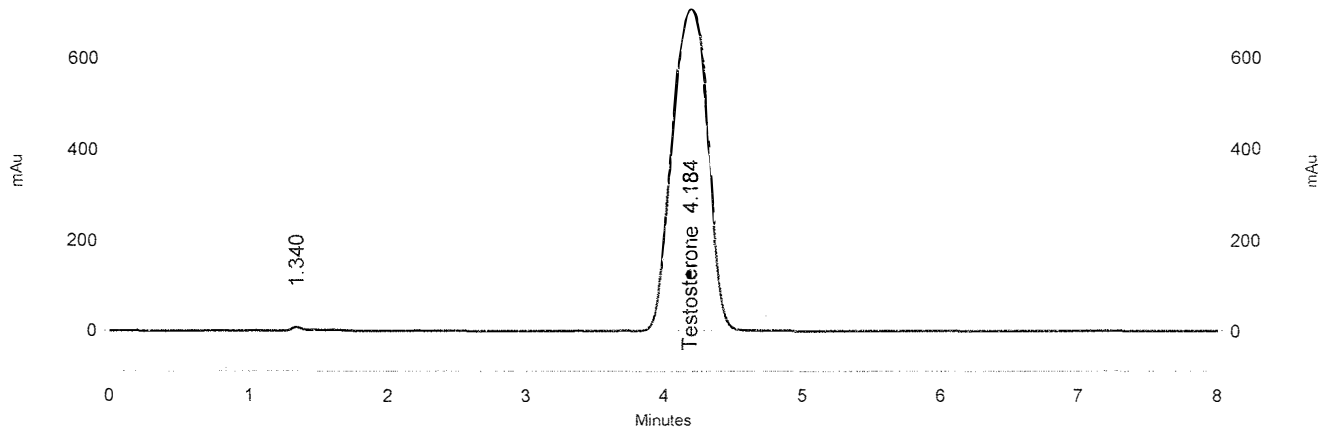
C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final Method.met

C:\CLASS-VP\Sequence\Sequence\2011\August\HPLC 3\August 15-11 Testosterone Stability 120 days.seq

8/15/2011 4:44:53 PM 1

8/15/2011 4:44:54 PM

45



1: 241
nm, 4 nm
Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.184 | 12674683 | 2.11 | 0.99207 | 9.73744 | 1321 |

Testosterone std

C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final

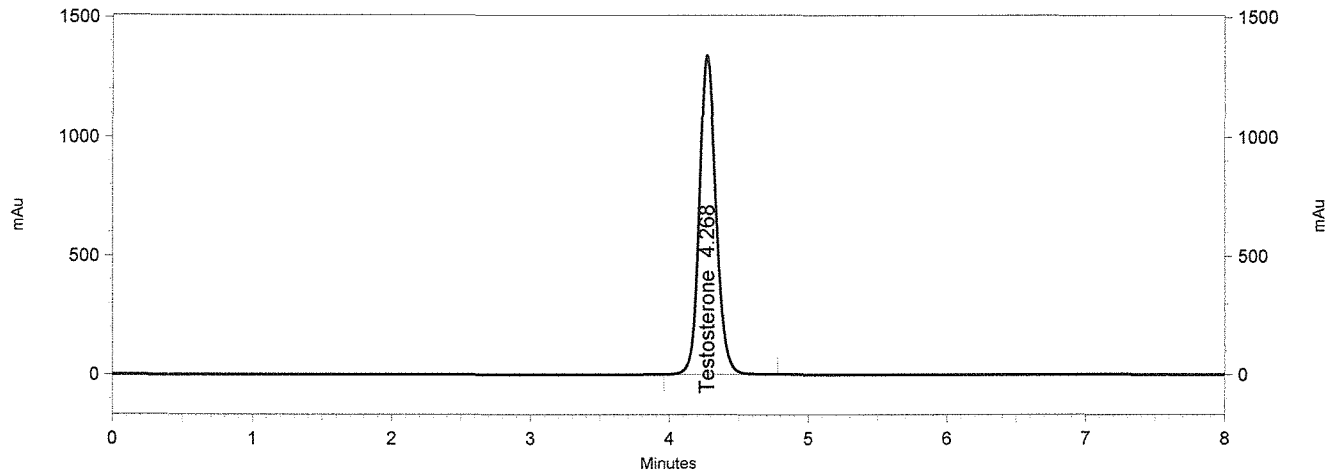
Method.met

C:\CLASS-VP\Sequence\Sequence\2011\September\HPLC3\September
19-11 Testosterone 150 Days Stability.seq

9/19/2011 11:27:37 AM 1

9/19/2011 11:27:38 AM

45



1: 241

nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.268 | 11169475 | 0.08 CAL | 1.16432 | 0.00000 | 6251 |

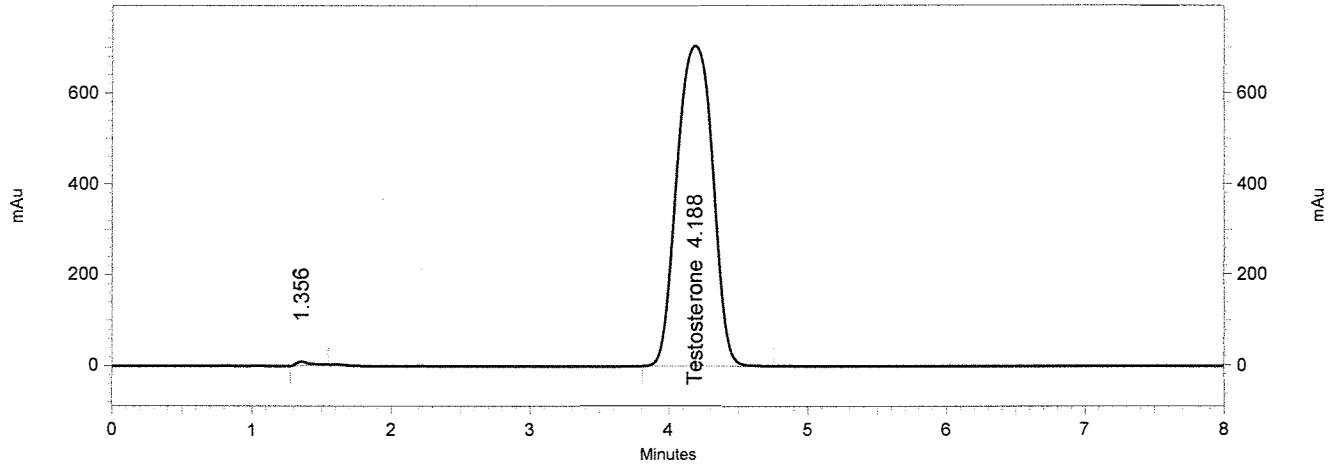
Testosterone Spectrum Chemical Mfg. Corp. Omnibase 150 days
 stability C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met

C:\CLASS-VP\Sequence\Sequence\2011\September\HPLC3\September
 19-11 Testosterone 150 Days Stability.seq

9/19/2011 11:27:49 AM 1

9/19/2011 11:27:50 AM

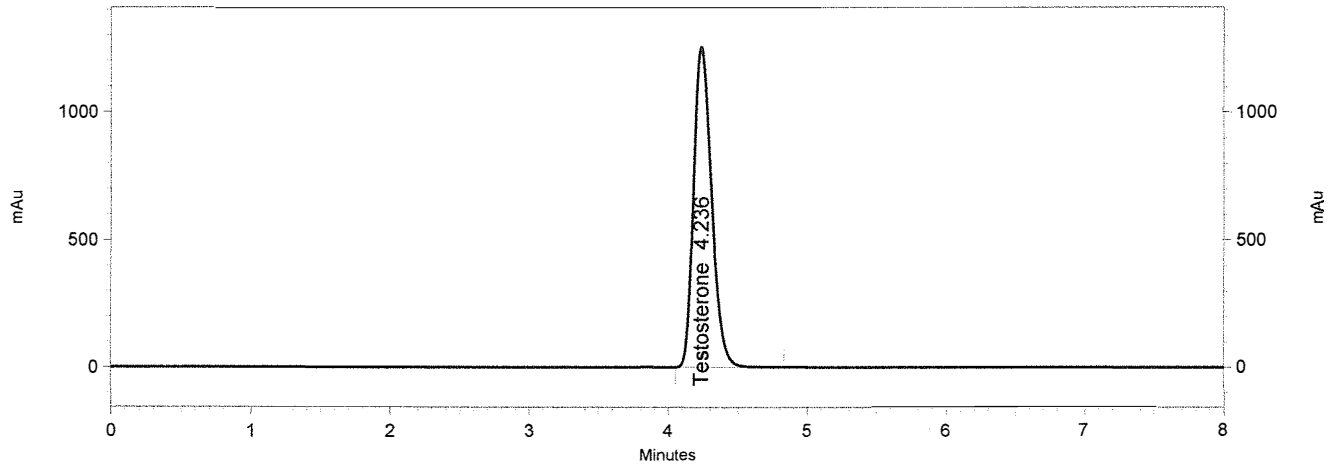
45



1: 241
 nm, 4 nm
 Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|------------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testostero ne | 4.188 | 12620061 | 2.15 | 1.00723 | 9.27818 | 1356 |

Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\October\HPLC 3\October
 17-11 Testosterone 180 days Stability.seq
 10/17/2011 12:38:03 PM 1
 10/17/2011 12:38:04 PM
 45



1: 241
 nm, 4 nm
 Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.236 | 11317233 | 0.08 CAL | 1.30154 | 0.00000 | 5059 |

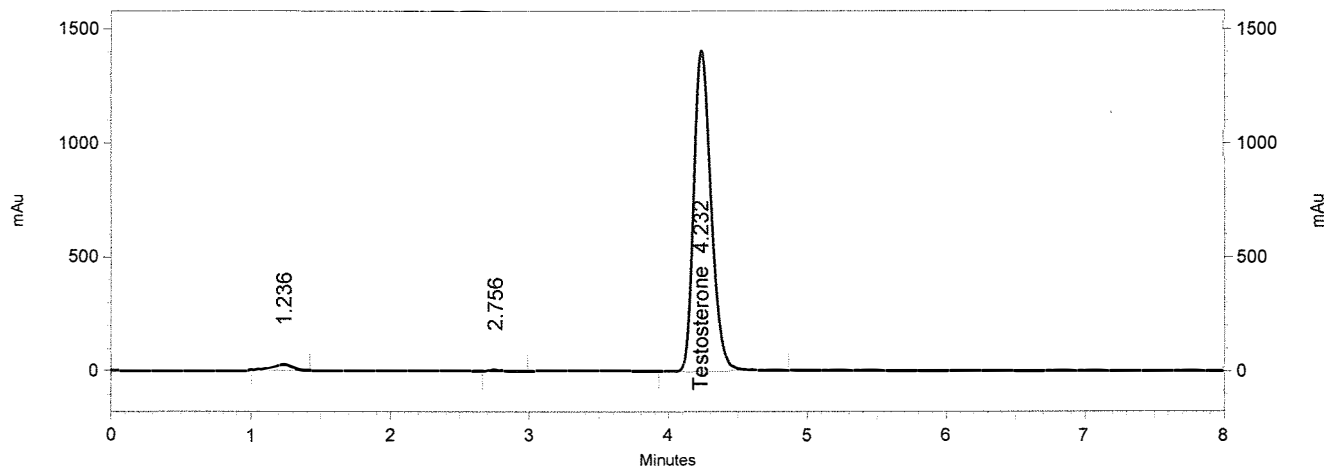
Testosterone Spectrum Chemical Mfg. Corp. Omnibase 180 days
 stability C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met

C:\CLASS-VP\Sequence\Sequence\2011\October\HPLC 3\October
 17-11 Testosterone 180 days Stability.seq

10/17/2011 12:38:16 PM 1

10/17/2011 12:38:16 PM

45



1: 241
 nm, 4 nm

Results

| Name | Retention Time | Area | ESTD concentration | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|--------------|----------------|----------|--------------------|-----------|------------------|--------------------------|
| Testosterone | 4.232 | 12126510 | 2.12 | 1.30763 | 7.50473 | 5580 |