

Testosterone:

1.00g Testosterone raw drug powder from Sigma-Aldrich (part number T1500, Lot # 070M1626V) was added to 50.00g Humco HRT Heavy (Humco Holding Group, Texarkana, Texas) 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.

Similar steps were used in preparing samples in Humco MultiBase (Humco Holding Group, Texarkana, Texas)

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:

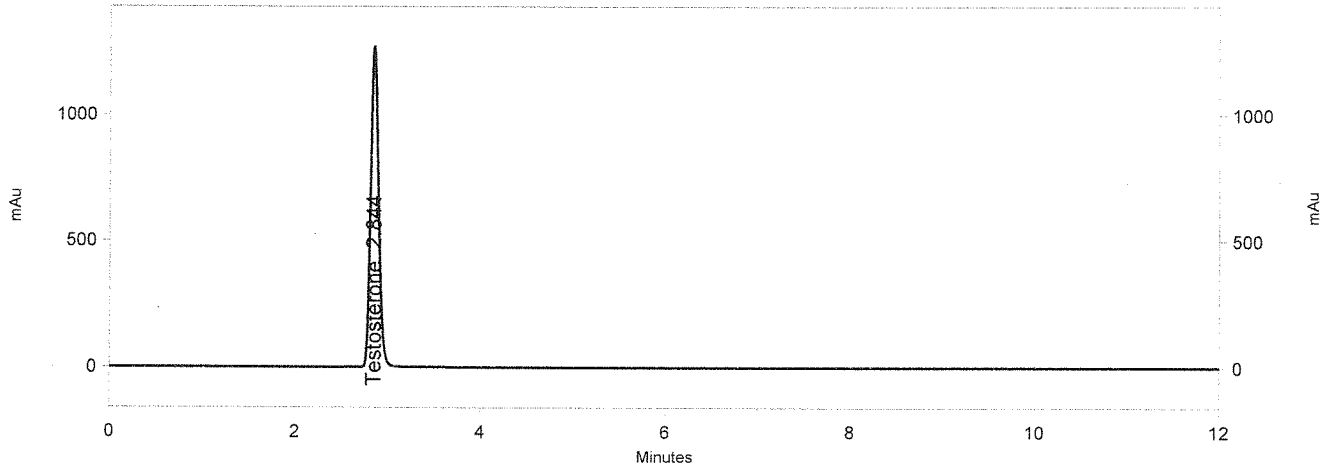
Compounded at 2.0% w/w, stability-indicating HPLC analysis found negligible Testosterone loss in Humco HRT Heavy at 180 days.

Compounded at 2.0% w/w, stability-indicating HPLC analysis found negligible Testosterone loss in Humco MultiBase at 180 days.

Attached are 14 chromatographs of Humco HRT Heavy 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.

Attached are 14 chromatographs of Humco MultiBase 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.

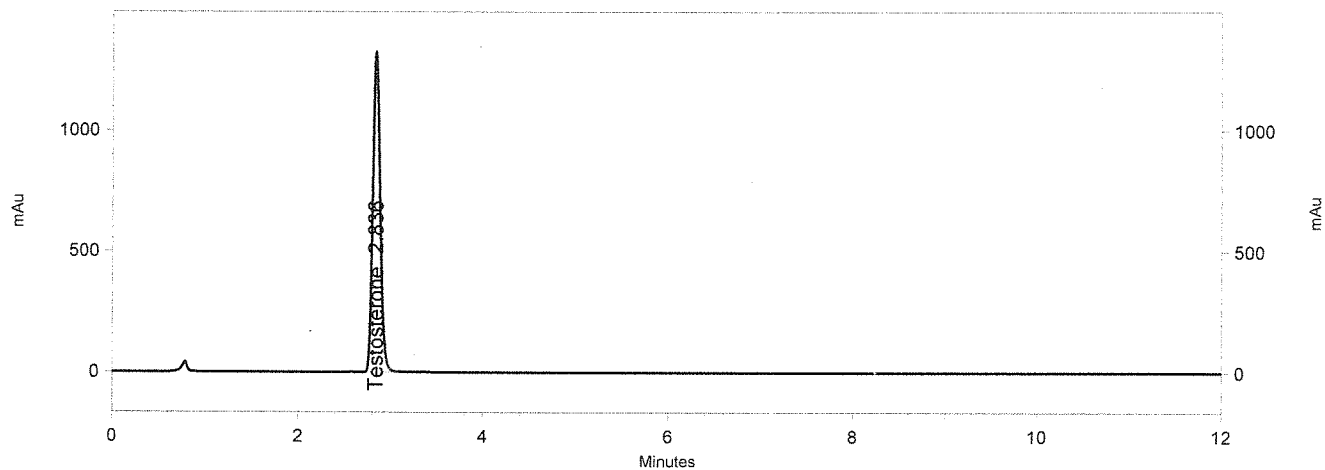
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\April\HPLC 3\Testosterone
 2% HRT Heavy April 12-11.seq
 4/12/2011 3:22:21 PM 1
 4/12/2011 3:22:22 PM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	2.844	7516464	0.08 CAL	1.25921	0.00000	5373

Testosterone 1
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\April\HPLC 3\Testosterone
 2% Multi Base April 11-11.seq
 4/12/2011 9:19:05 AM 1
 4/12/2011 9:19:06 AM
 45

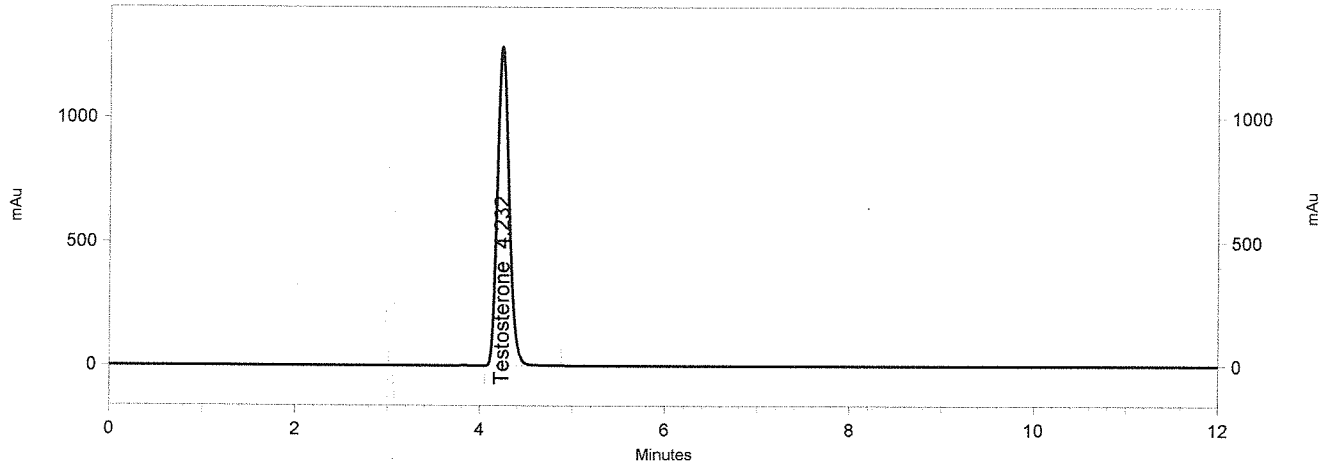


1: 241
 nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	2.836	7338034	1.95	1.24492	0.00000	6117

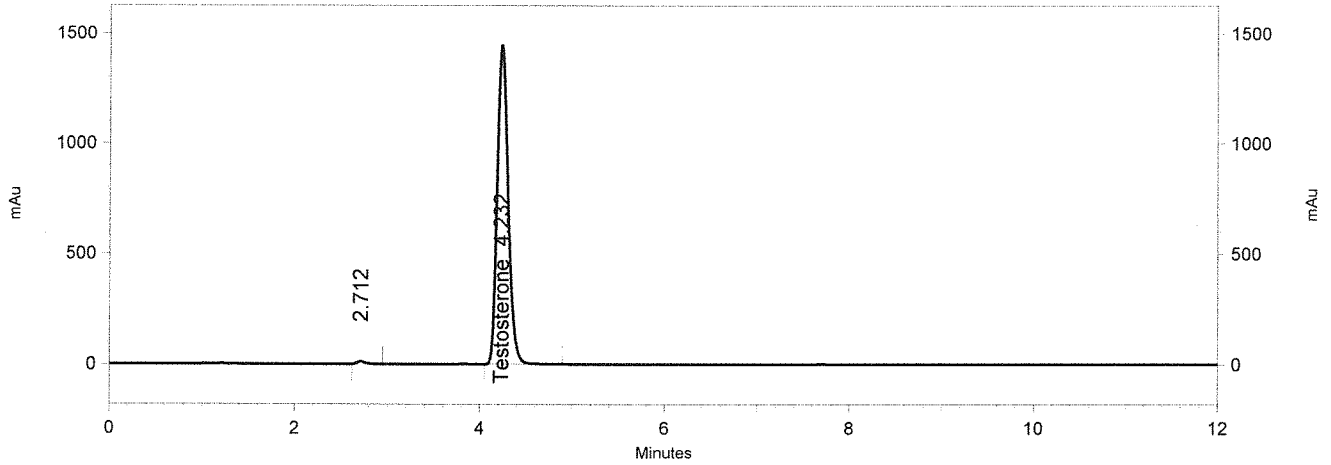
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\May\HPLC-3\Testosterone 2%
 May 10-11.seq
 5/11/2011 10:38:35 AM 1
 5/11/2011 10:38:36 AM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.232	11308153	0.08 CAL	1.29240	0.00000	5300

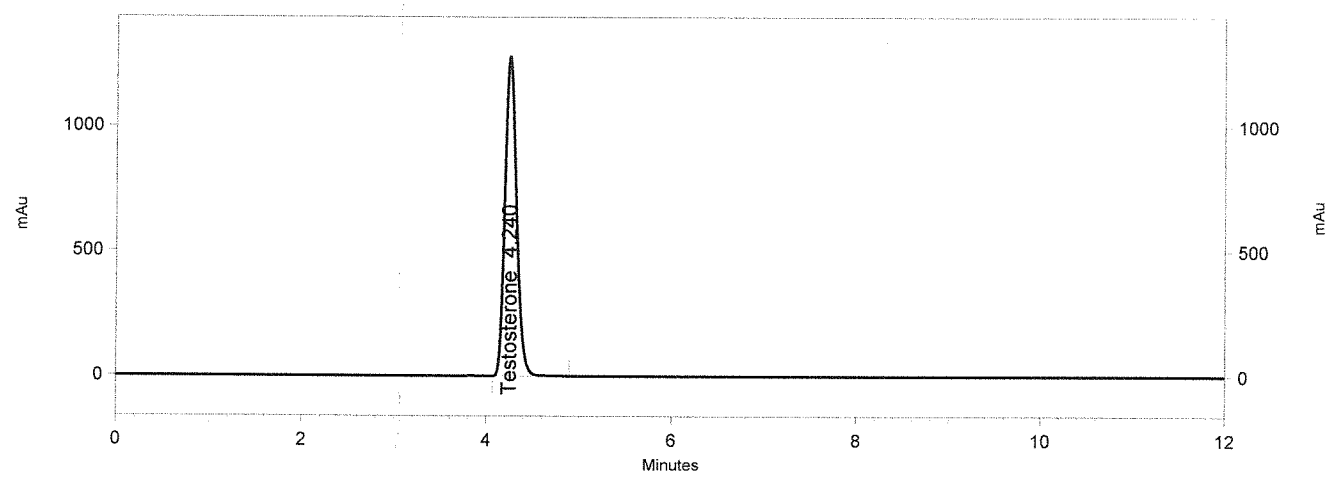
Testosterone HRT Heavy 30days stability
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\May\HPLC-3\Testosterone 2%
 May 10-11.seq
 5/11/2011 10:38:50 AM 1
 5/11/2011 10:38:51 AM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.232	11840829	2.07	1.31290	8.04800	6243

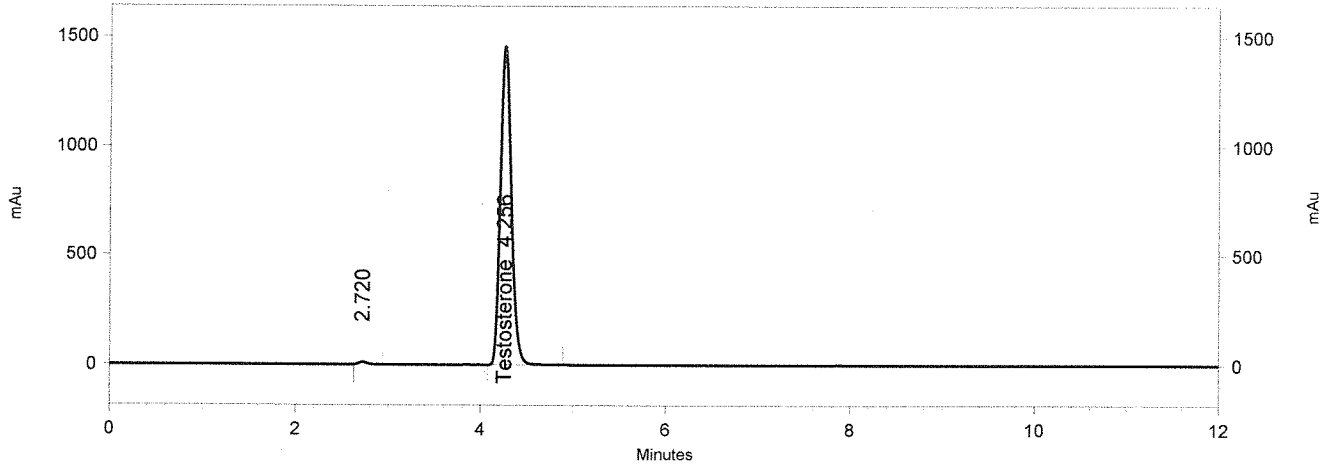
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\June\HPLC-3\Testosterone 2%
 60days stability 6-13-11.seq
 6/14/2011 10:08:27 AM 1
 6/14/2011 10:08:28 AM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.240	11211062	0.08 CAL	1.31830	0.00000	5400

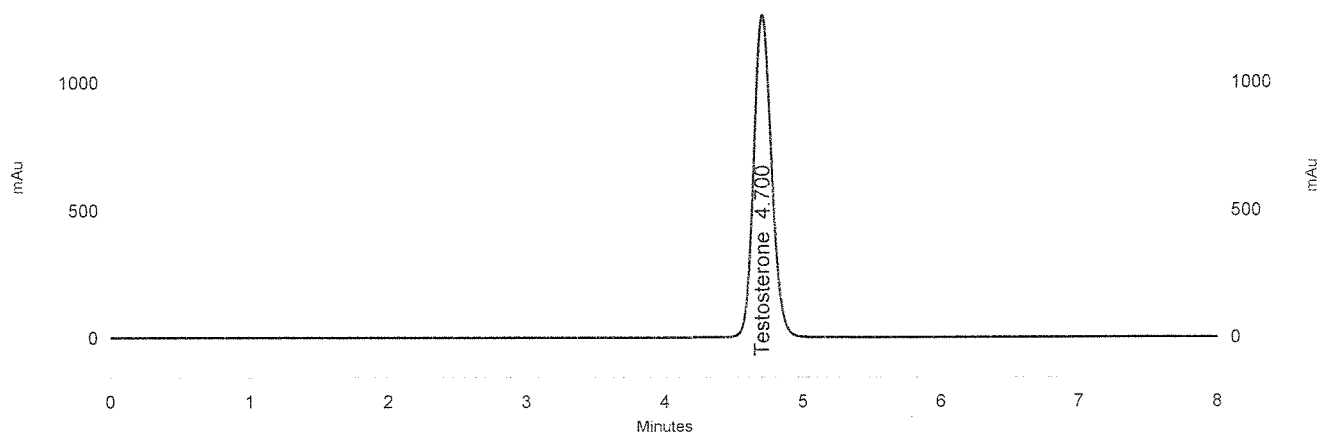
Testosterone HRT Heavy 60days stability
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\June\HPLC-3\Testosterone 2%
 60days stability 6-13-11.seq
 6/14/2011 10:08:43 AM 1
 6/14/2011 10:08:44 AM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.256	11969577	1.97	1.31792	8.07431	6214

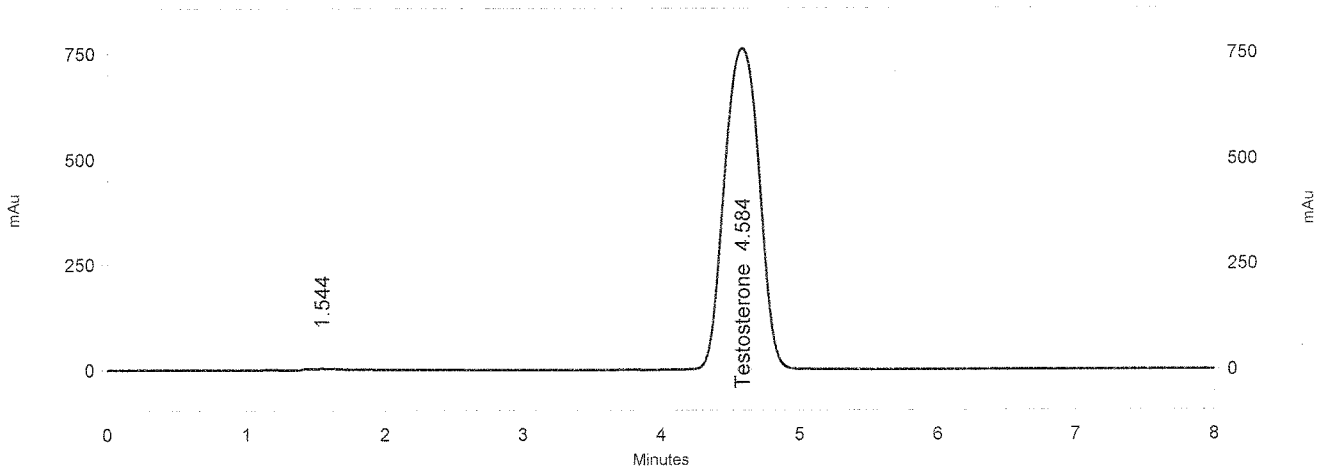
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\July\HPLC 3\July 19-11
 Testosterone 90 Days.seq
 7/19/2011 12:44:02 PM 1
 7/19/2011 12:44:03 PM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.700	11282439	0.08 CAL	1.15244	0.00000	6345

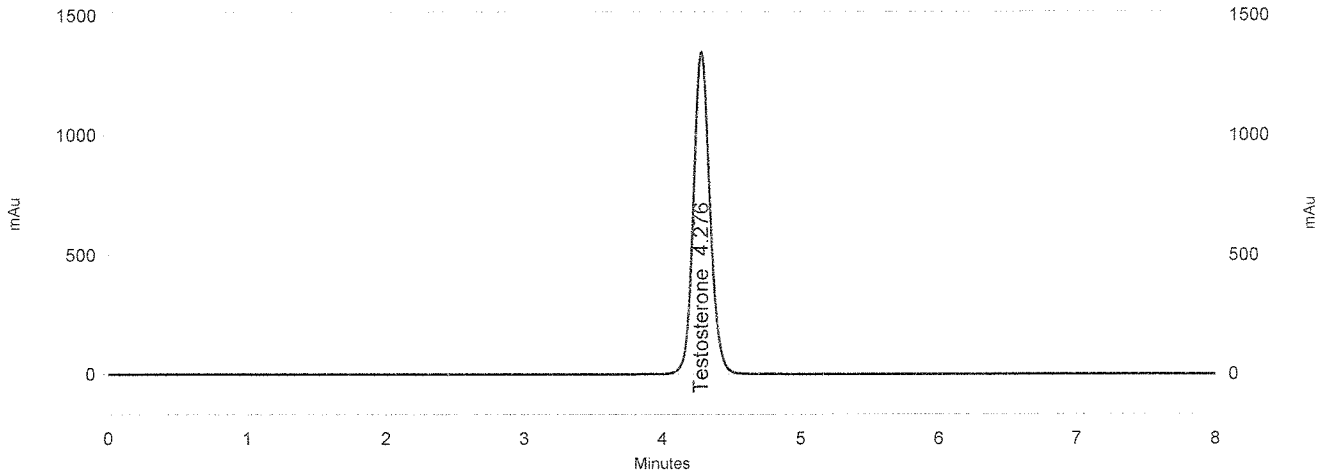
Testosterone HRT Heavy 60days stability
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\July\HPLC 3\July 19-11
 Testosterone 90 Days.seq
 7/19/2011 12:47:30 PM 1
 7/19/2011 12:47:30 PM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.584	13265886	2.08	1.00978	0.00000	1645

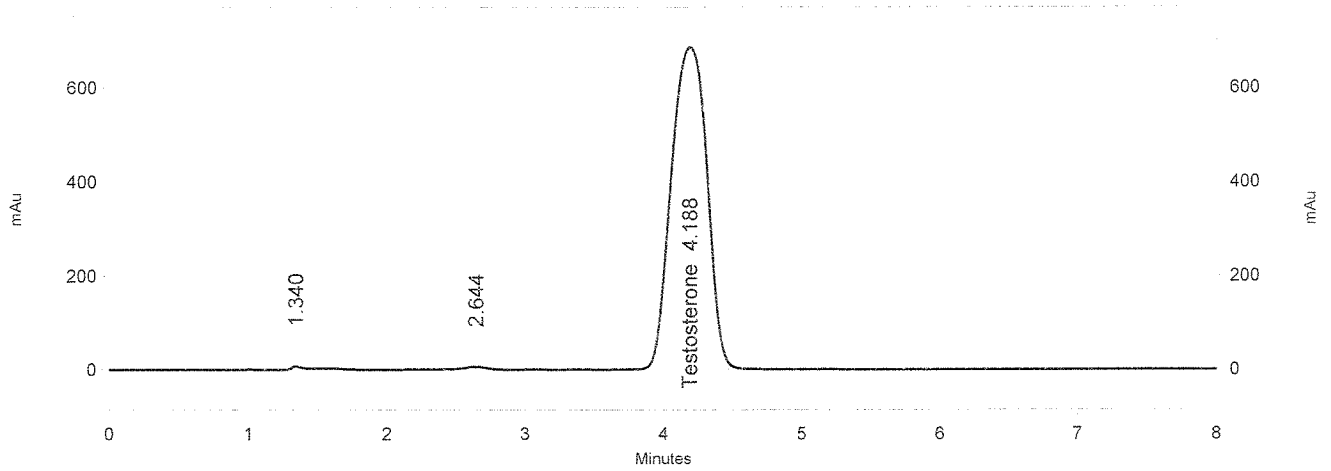
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\August\HPLC 3\August 15-11
 Testosterone Stability 120 days.seq
 8/15/2011 4:44:39 PM 1
 8/15/2011 4:44:40 PM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.276	11246548	0.08 CAL	1.14962	0.00000	6212

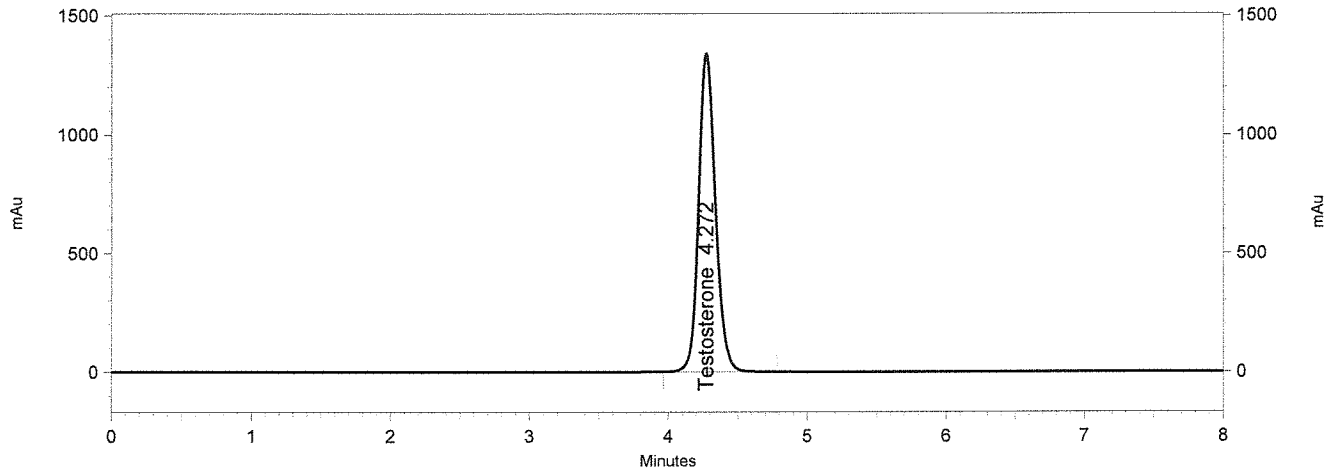
Testosterone HRT Heavy 120 days stability
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\August\HPLC 3\August 15-11
 Testosterone Stability 120 days.seq
 8/15/2011 4:44:52 PM 1
 8/15/2011 4:44:52 PM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.188	12258011	2.08	0.98741	4.11357	1331

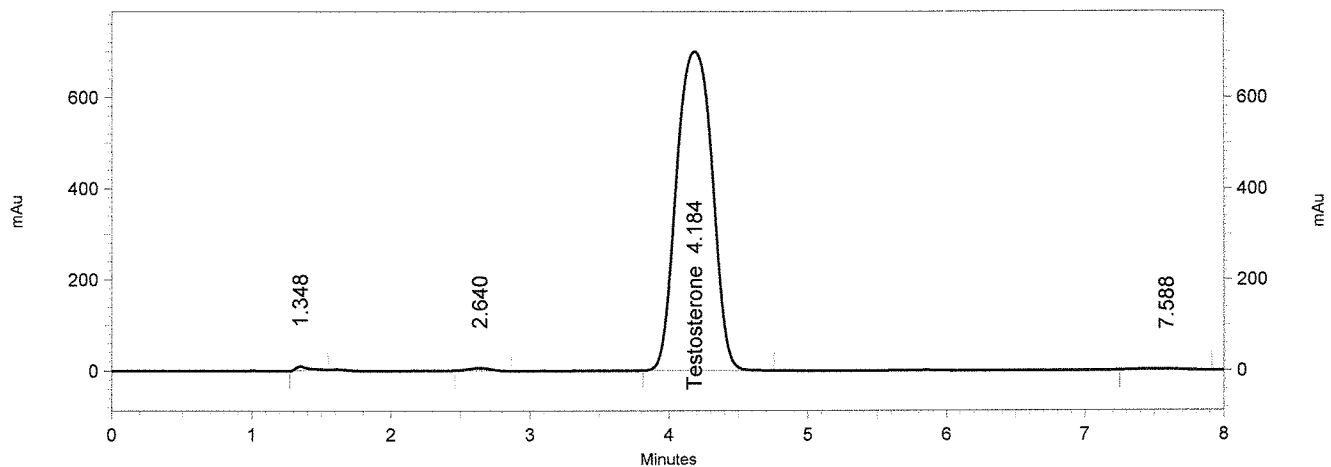
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\September\HPLC3\September
 19-11 Testosterone 150 Days Stability.seq
 9/19/2011 11:27:35 AM 1
 9/19/2011 11:27:36 AM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.272	11172919	0.08 CAL	1.16889	0.00000	6275

Testosterone HRT Heavy 120 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 11:27:48 AM 1
 9/19/2011 11:27:48 AM
 45

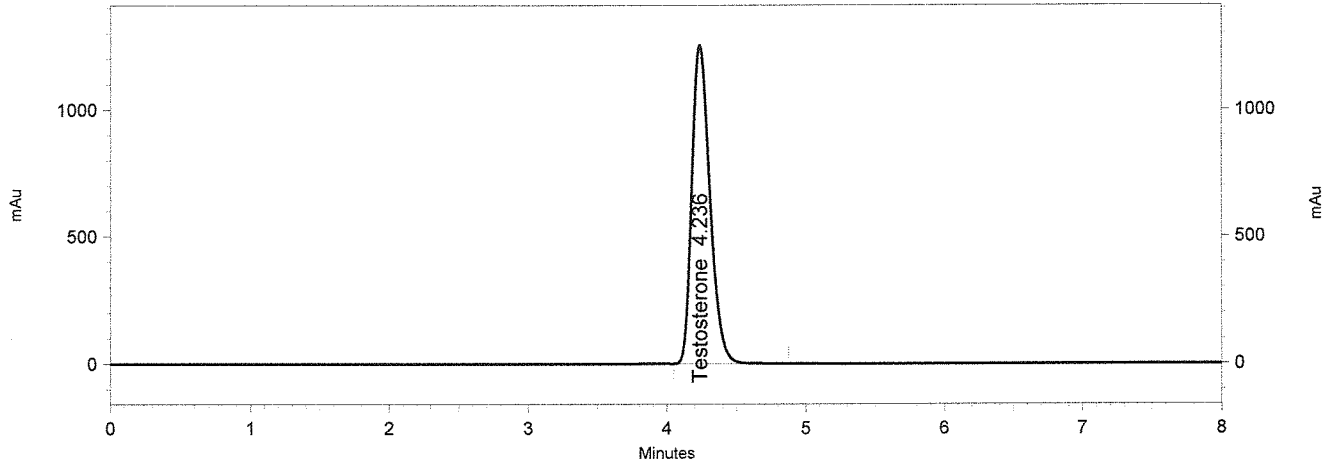


1: 241
nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.184	12519953	2.09	1.01844	4.13852	1357

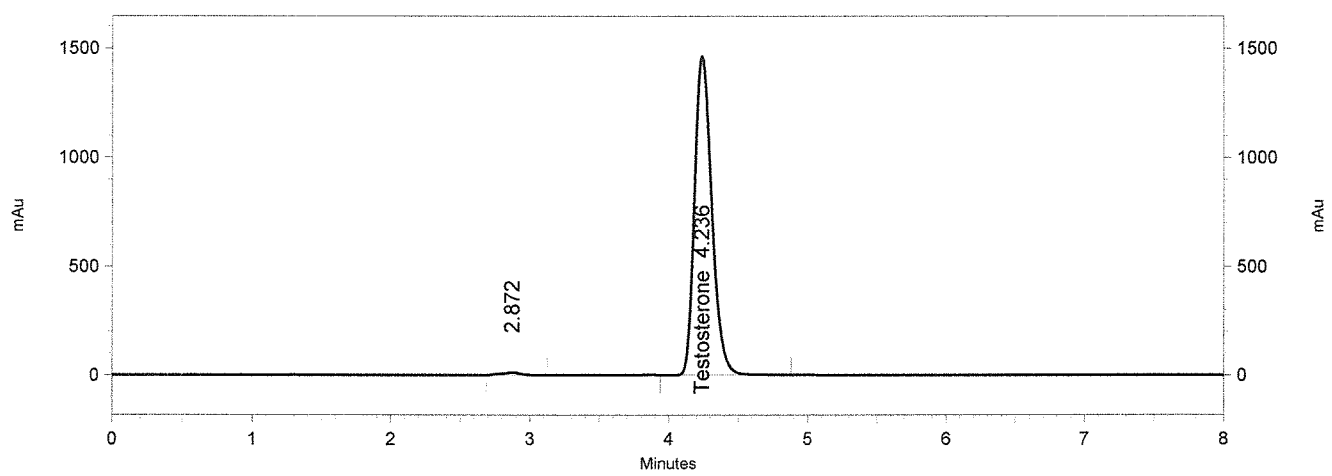
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\October\HPLC 3\October
 17-11 Testosterone 180 days Stability.seq
 10/17/2011 12:38:02 PM 1
 10/17/2011 12:38:02 PM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.236	11322816	0.08 CAL	1.28431	0.00000	5042

Testosterone HRT Heavy 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 12:38:14 PM 1
 10/17/2011 12:38:14 PM
 45

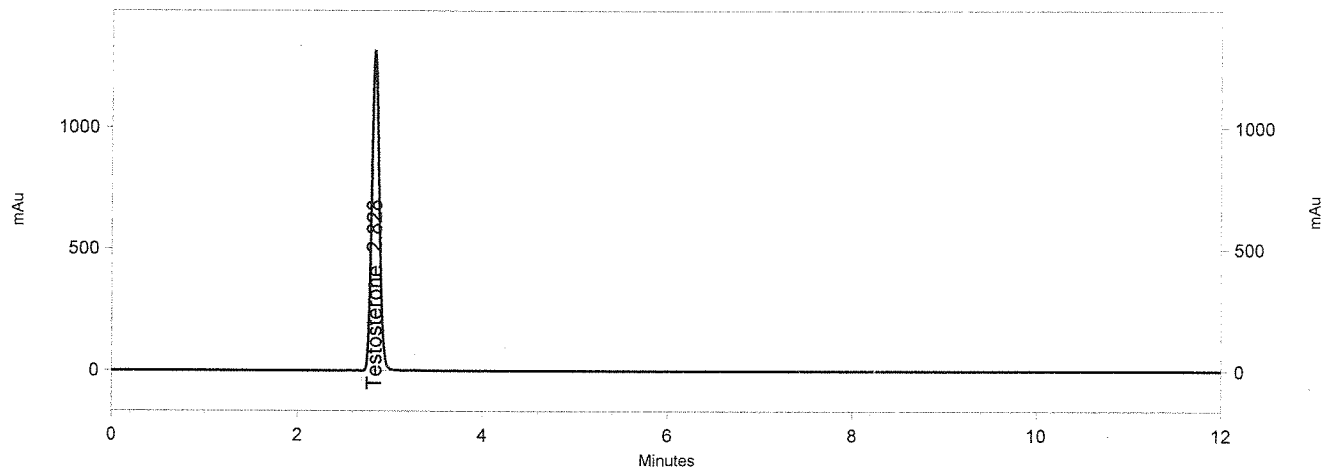


1: 241
 nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.236	12675308	2.11	1.30450	6.04323	5579

Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\April\HPLC 3\Testosterone
 2% Multi Base 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

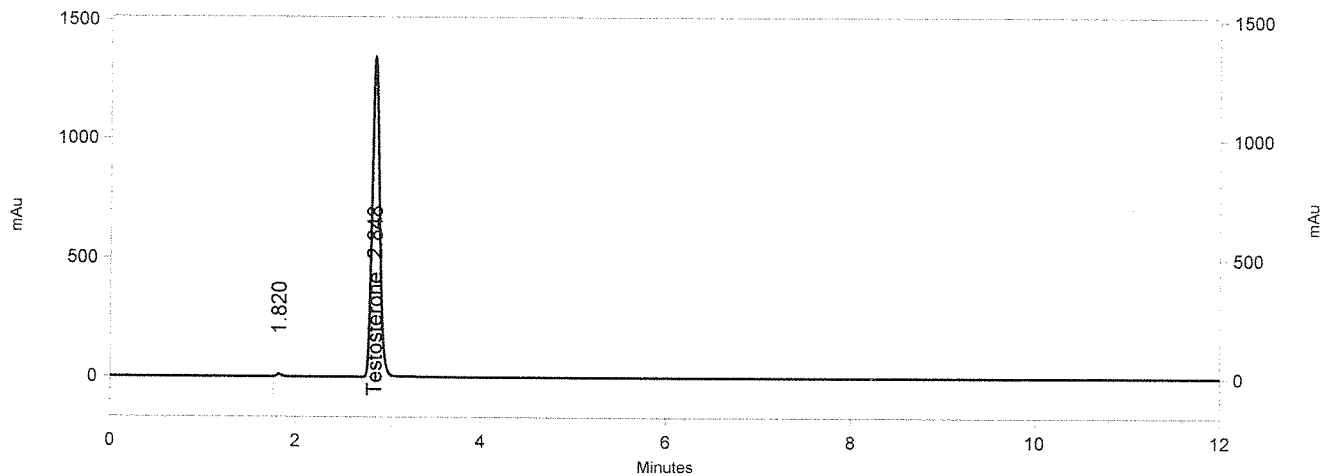
C:\CLASS-VP\Sequence\Sequence\2011\April\HPLC 3\Testosterone

2% HRT Heavy 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

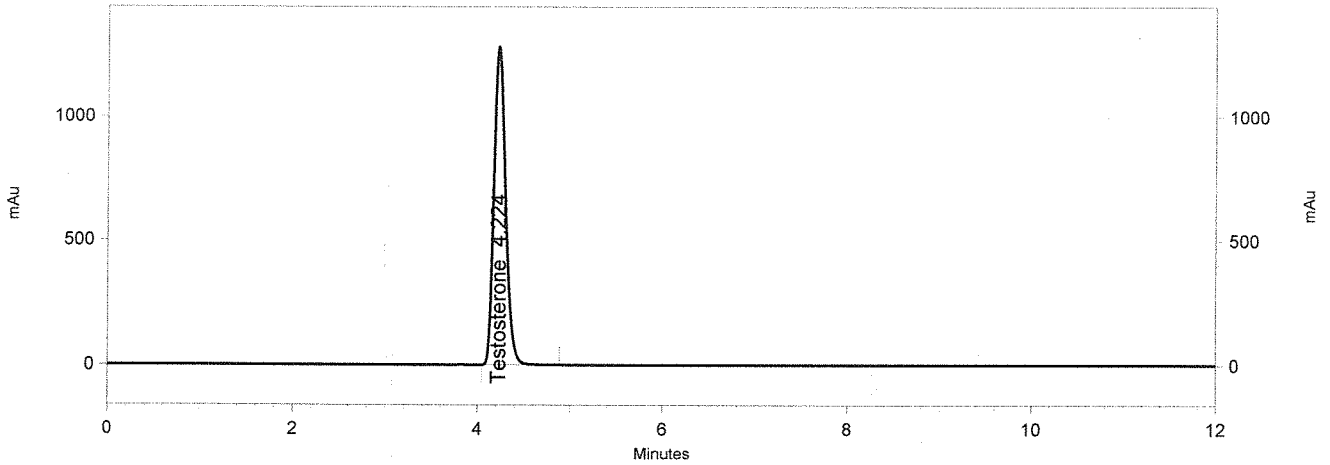
C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
Method.met

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



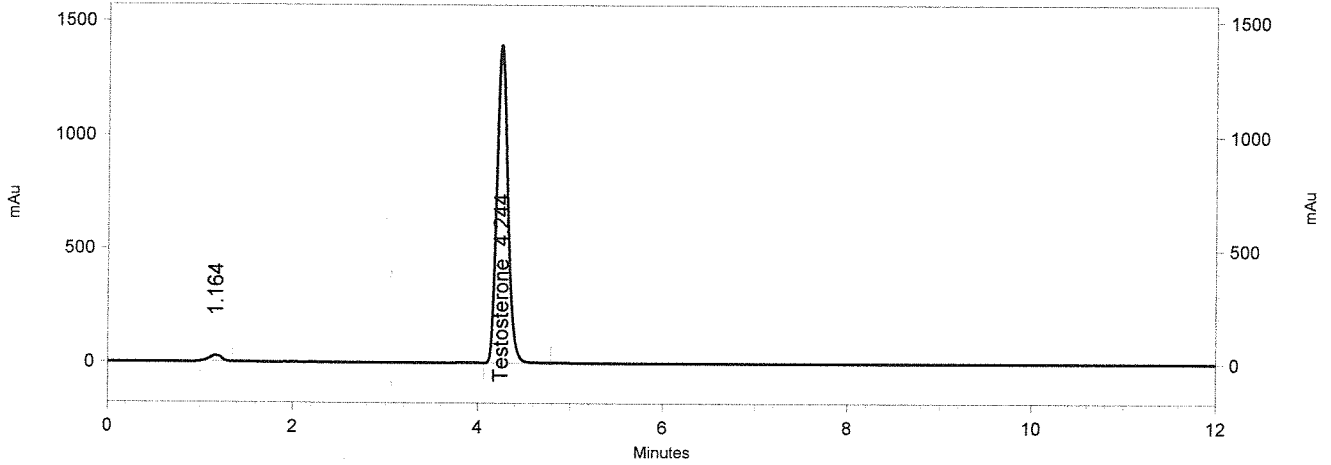
1: 241

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 Multi Base 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

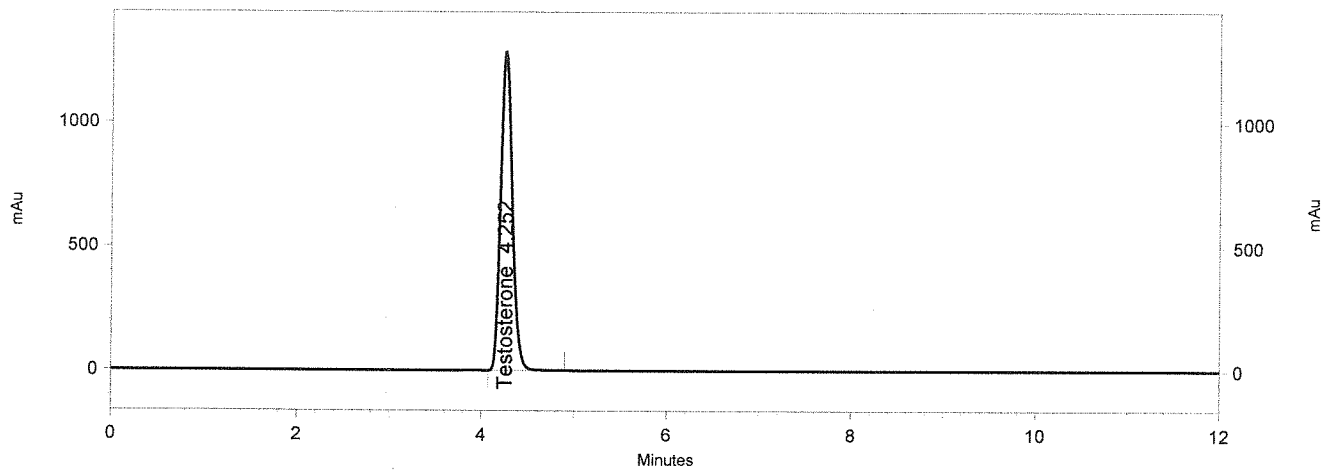
C:\CLASS-VP\Sequence\Sequence\2011\June\HPLC-3\Testosterone 2%

60days stability 6-13-11.seq

6/14/2011 10:08:30 AM 1

6/14/2011 10:08:31 AM

45



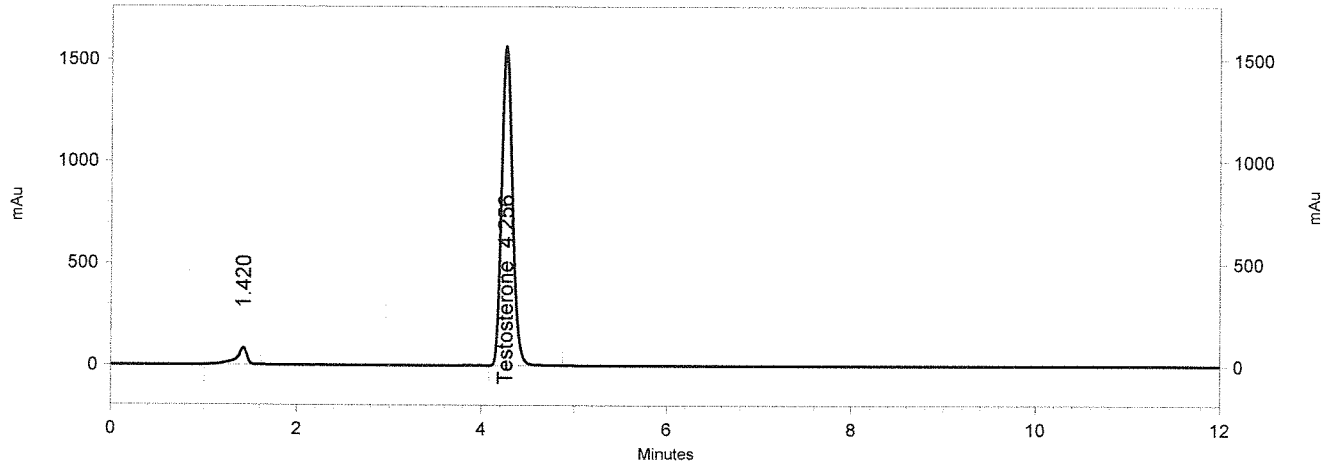
1: 241

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 Multi Base 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

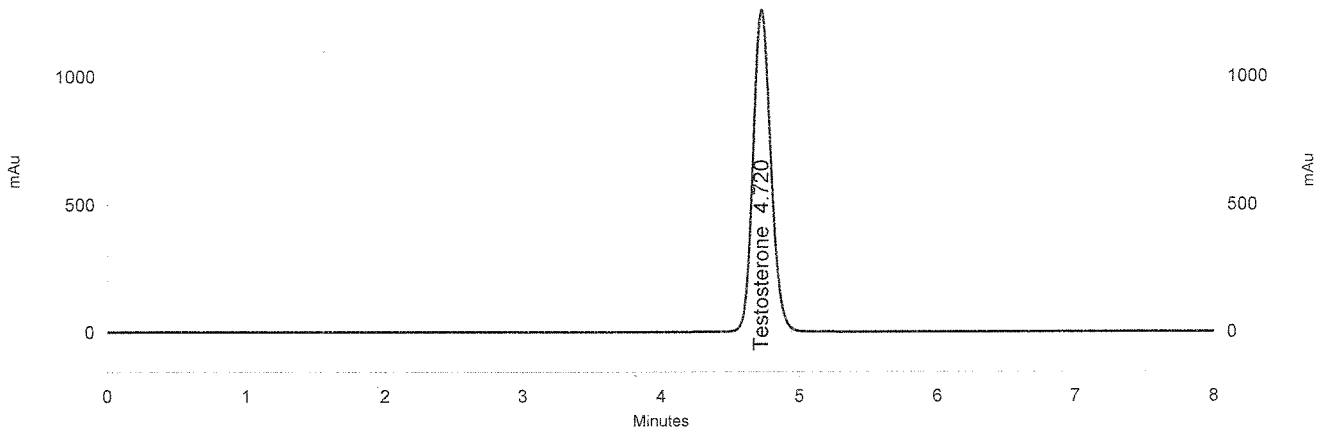


1: 241
 nm, 4 nm

Results

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

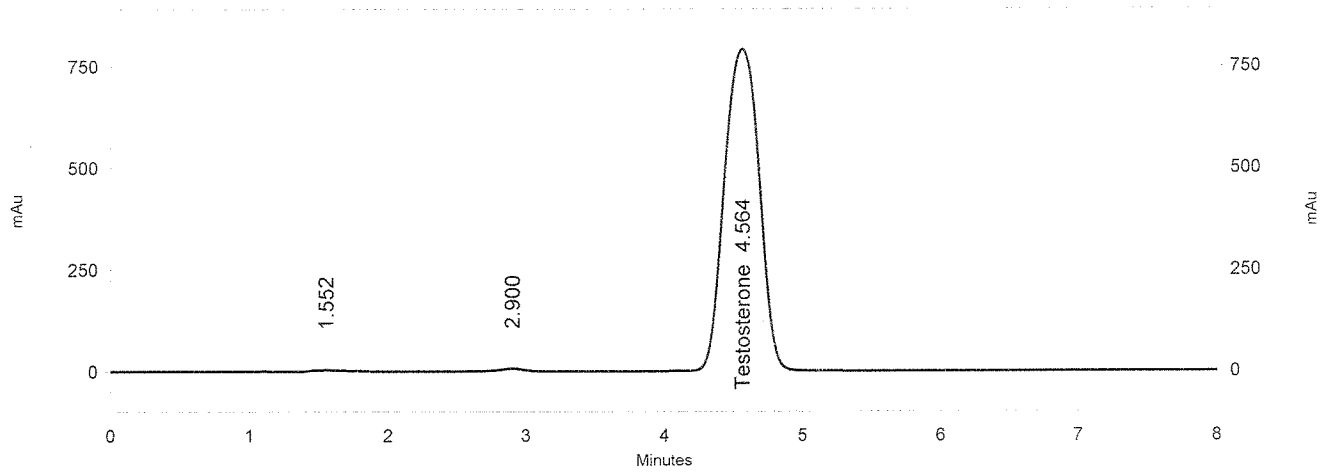
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\July\HPLC 3\July 19-11
 Testosterone 90 Days.seq
 7/19/2011 12:47:19 PM 1
 7/19/2011 12:47:20 PM
 45



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 Multi Base 60days 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

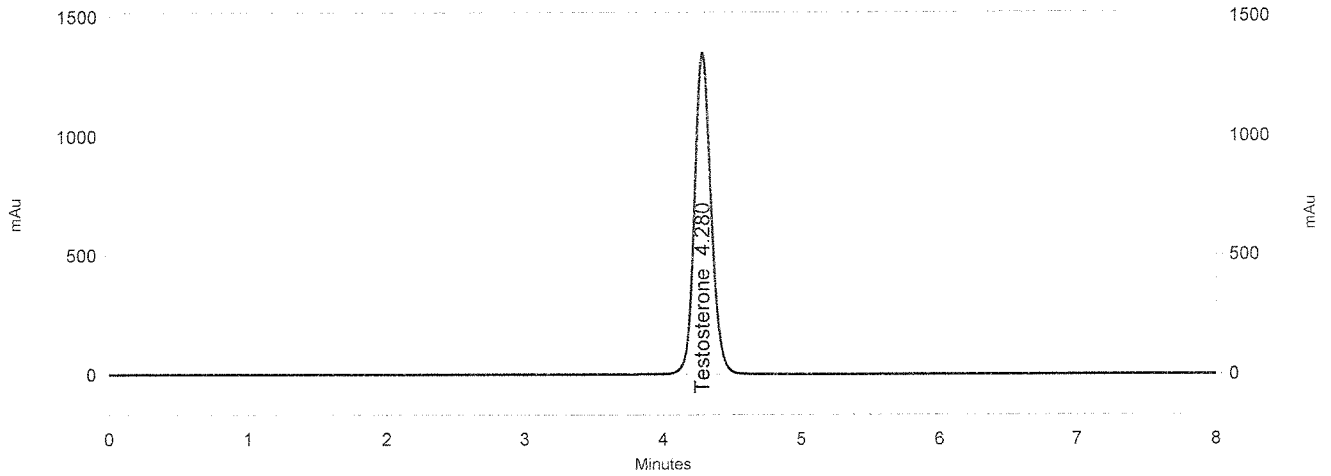


1: 241
 nm, 4 nm

Results

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

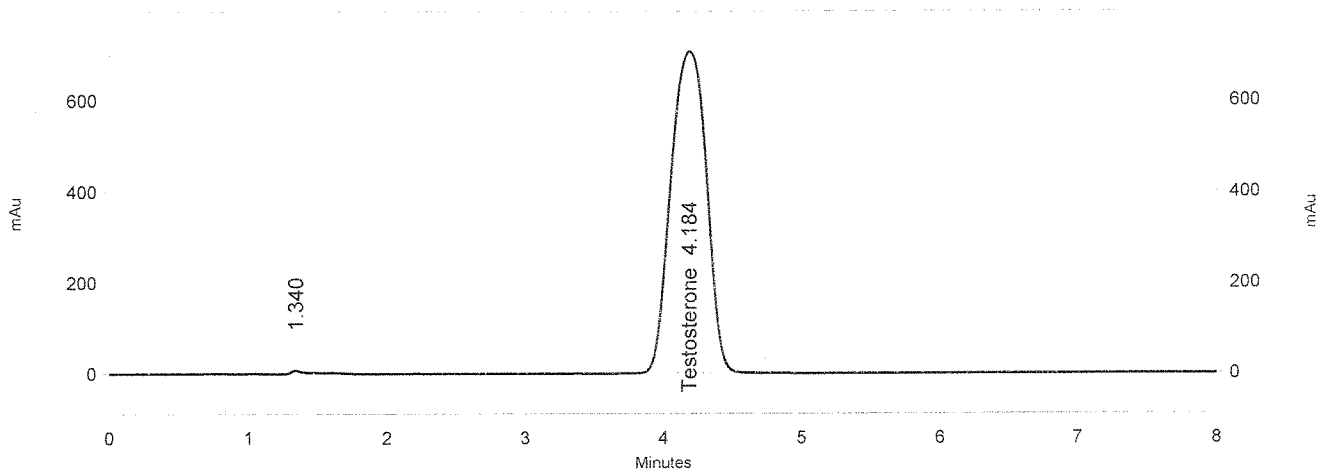
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\August\HPLC 3\August 15-11
 Testosterone Stability 120 days.seq
 8/15/2011 4:44:41 PM 1
 8/15/2011 4:44:42 PM
 45



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

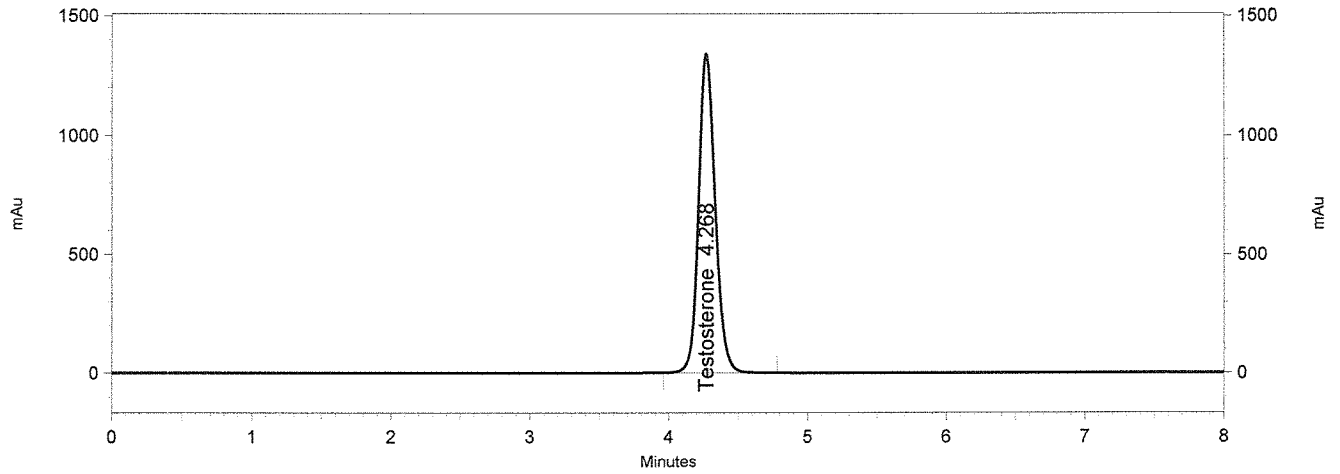
Testosterone Multi Base 120 days stability
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\August\HPLC 3\August 15-11
 Testosterone Stability 120 days.seq
 8/15/2011 4:44:53 PM 1
 8/15/2011 4:44:54 PM
 45



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

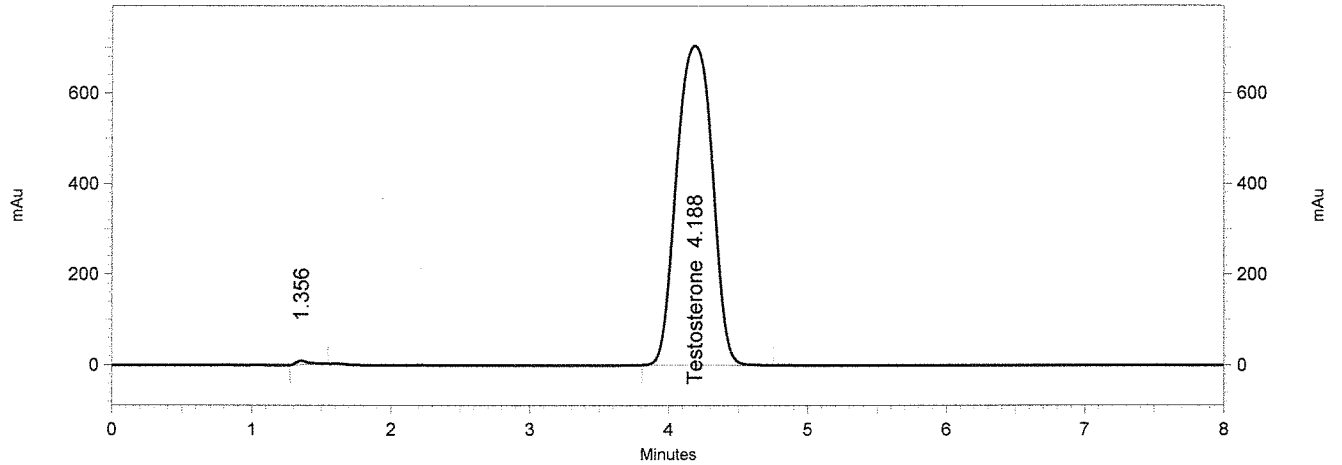
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\September\HPLC3\September
 19-11 Testosterone 150 Days Stability.seq
 9/19/2011 11:27:37 AM 1
 9/19/2011 11:27:38 AM
 45



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

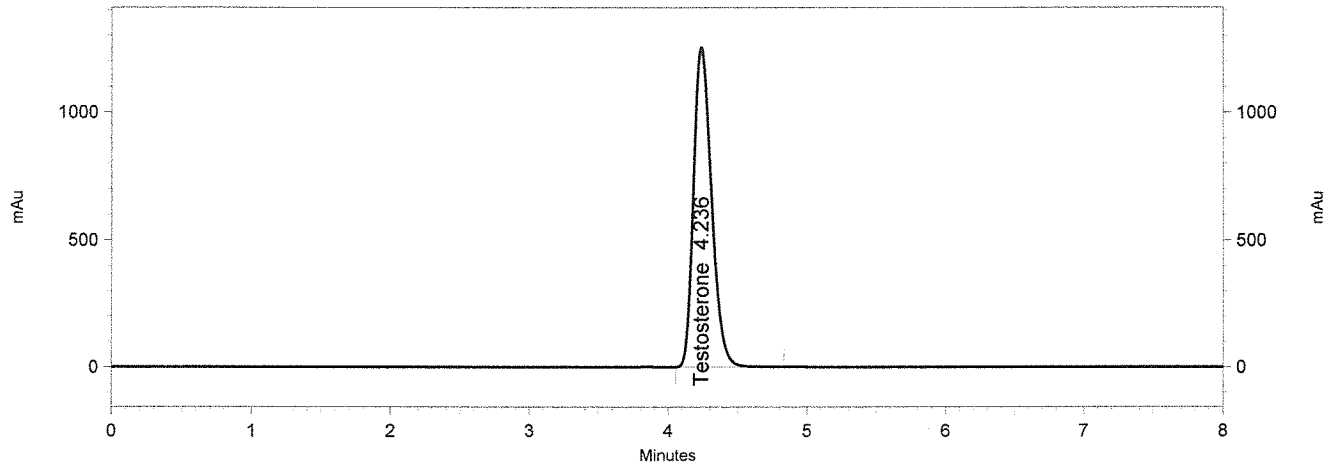
Testosterone Multi Base 120 days stability
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\September\HPLC3\September
 19-11 Testosterone 150 Days Stability.seq
 9/19/2011 11:27:49 AM 1
 9/19/2011 11:27:50 AM
 45



1: 241
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Testosterone	4.188	12620061	2.15	1.00723	9.27818	1356

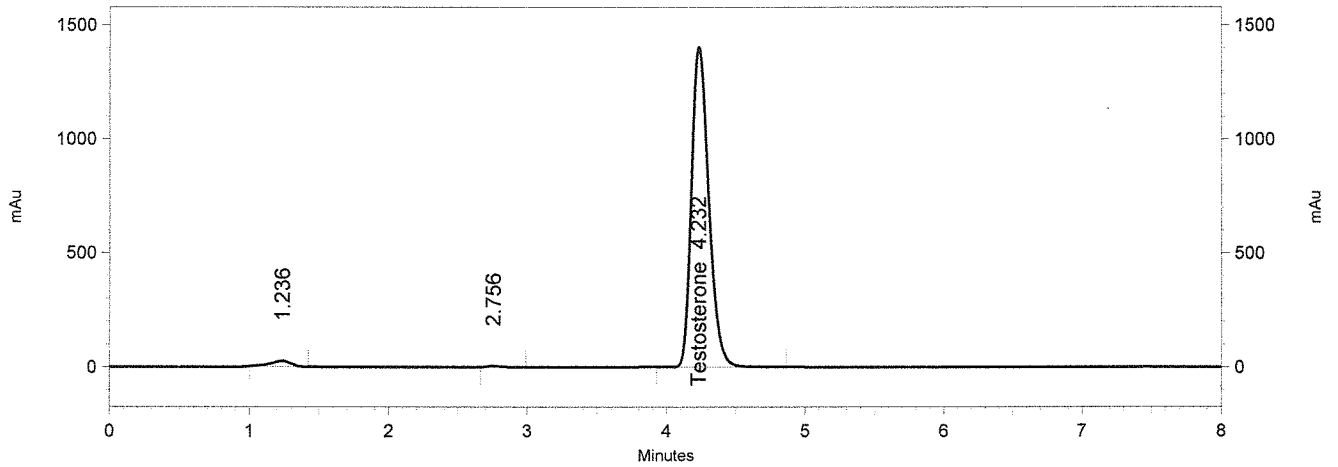
Testosterone std
 C:\CLASS-VP\Methods\Methods\HPLC3\Testosterone Final
 Method.met
 C:\CLASS-VP\Sequence\Sequence\2011\October\HPLC 3\October
 17-11 Testosterone 180 days Stability.seq
 10/17/2011 12:38:03 PM 1
 10/17/2011 12:38:04 PM
 45



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 Multi Base 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