

Hydroquinone:

2.50g Hydroquinone raw drug powder from Spectrum chemical (part number HY113, Lot # WA1662) was added to 47.50g Humco VaniBase (PD006/55) and levigated with an electronic mortar and pestle, resulting in a final concentration of 5.0% w/w. This cream was then stored at room temperature in the same 50/70 mL Unguator container.

Similar steps were used in preparing samples in Humco LipoBase Heavy (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.

90-Day Summary:

Compounded at 5.0% w/w, stability-indicating HPLC analysis found less than 6% Hydroquinone loss in Humco VaniBase at 90 days.

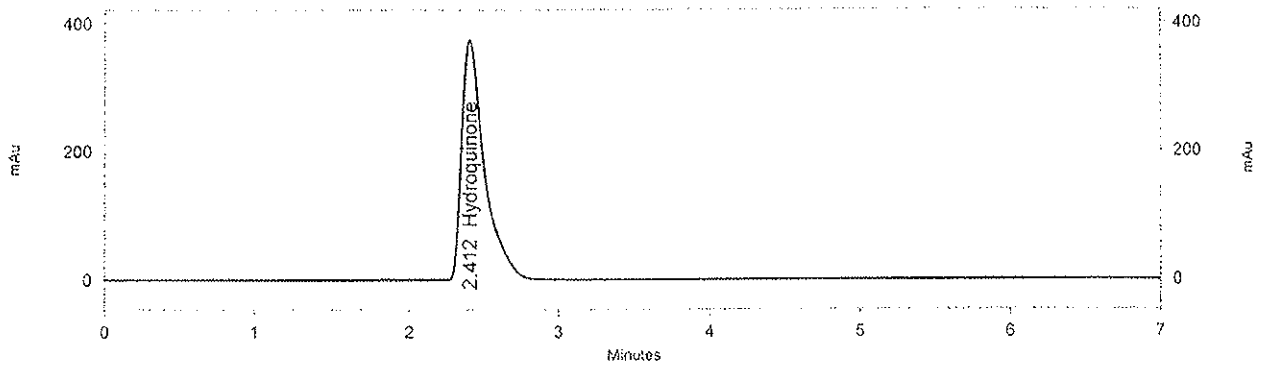
Compounded at 5.0% w/w, stability-indicating HPLC analysis found less than 4% Hydroquinone loss in Humco LipoBase Heavy at 90 days.

Attached are 6 chromatographs of Humco VaniBase showing in order: 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

Attached are 8 chromatographs of Humco LipoBase Heavy 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.

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\March 11-08
Hydroquinone Stability 1 Month 102
Sample ID: *Hydroquinone Std check*
C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\March 11-08
Hydroquinone Stability.seq
C:\CLASS-VP\Methods\Compounding\Hydroquinone Final Method.met
Vial: 3
Sample amount: 0.30012



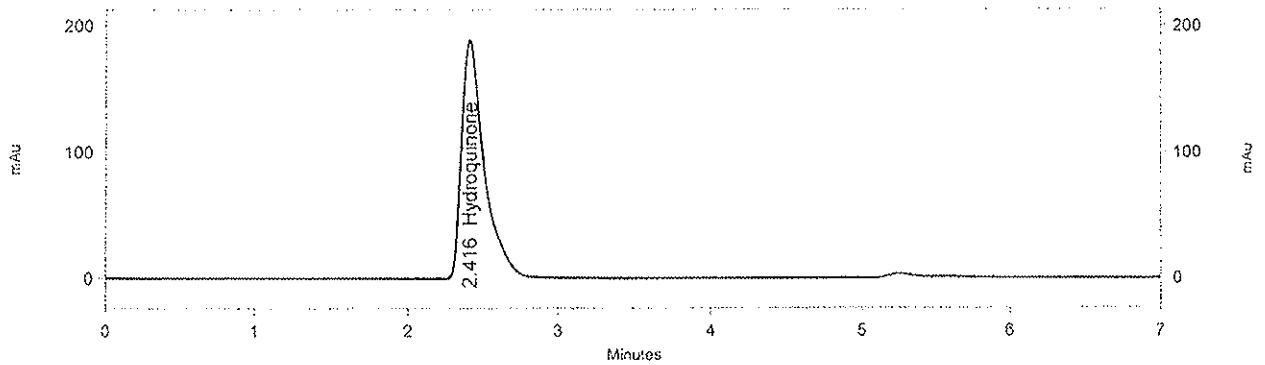
1: 280 nm, 4
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	2.412	3897802	100.025	0.00000	1.86566

98-102%
PL 03/11/08

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\March 11-08
Hydroquinone Stability 1 Month 103
Sample ID: *Hydroquinone stability sample*
C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\March 11-08
Hydroquinone Stability.seq
C:\CLASS-VP\Methods\Compounding\Hydroquinone Final Method.met
Vial: 4
Sample amount: 0.302

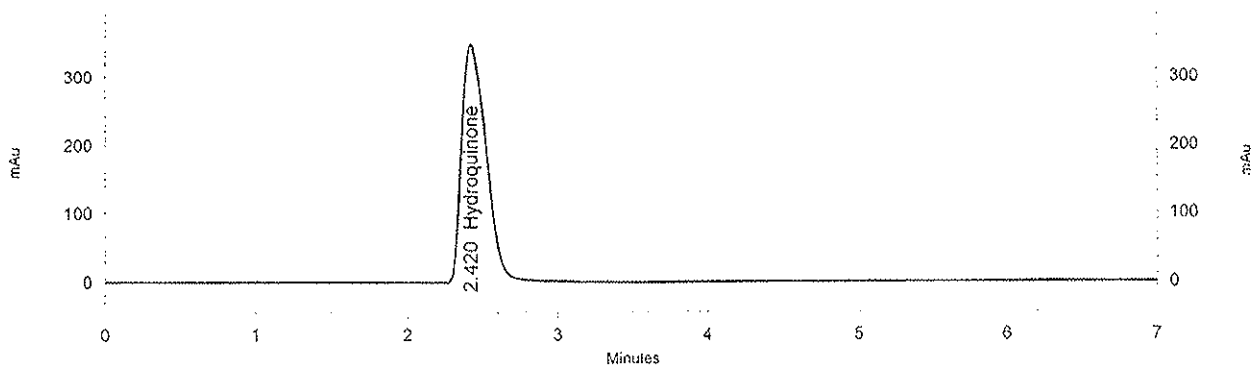


1: 280 nm, 4
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	2.416	1944307	4.958	0.00000	1.82569

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April 04-08
Hydroquinone Stability 2 Month 02
Sample ID: *Hydroquinone Std check*
C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\March 11-08
Hydroquinone Stability.seq
C:\CLASS-VP\Methods\Compounding\Hydroquinone Final Method.met
Vial: 3
Sample amount: 0.30012

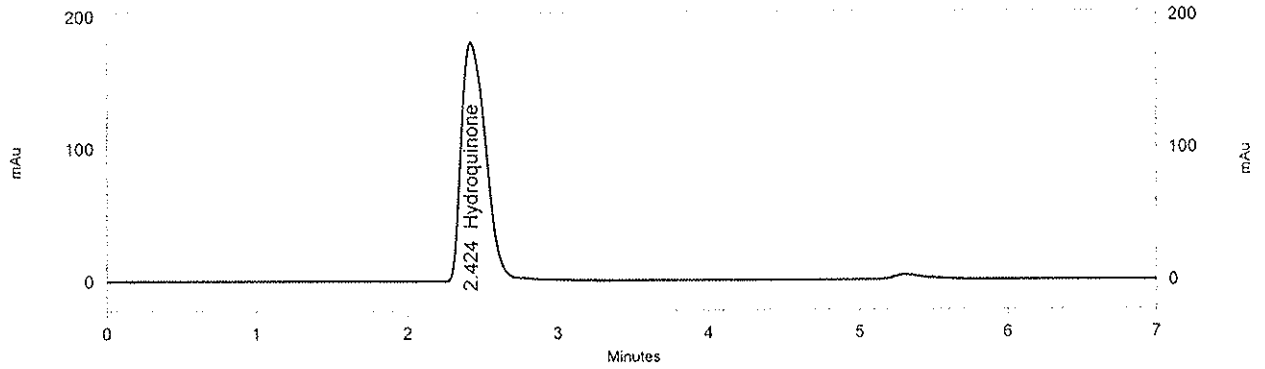


1: 280 nm, 4
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	2.420	3872703	99.857	0.00000	1.50333

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April 04-08
Hydroquinone Stability 2 Month 03
Sample ID: *Hydrocoquinone stability sample*
C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\March 11-08
Hydroquinone Stability.seq
C:\CLASS-VP\Methods\Compounding\Hydroquinone Final Method.met
Vial: 4
Sample amount: 0.3154

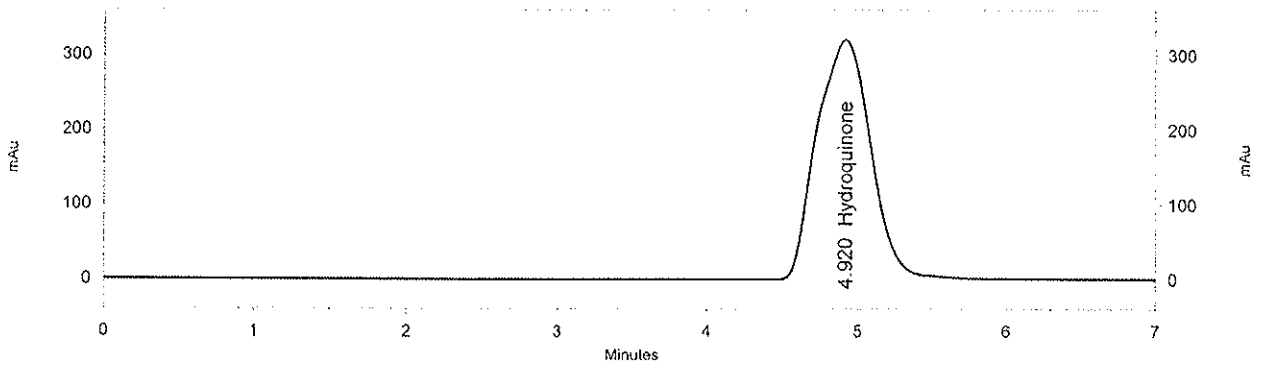


1: 280 nm, 4
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	2.424	1964782	4.921	0.00000	1.41636

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May-06-08
Hydroquinone Stability 3 Month 02
Sample ID: *Hydroquinone Std check*
C:\CLASS-VP\Sequence\2008\May 2008\HPLC 3\May-06-08
Hydroquinone Stability 3 months.seq
C:\CLASS-VP\Methods\Compounding\Hydroquinone Final Method.met
Vial: 33
Sample amount: 0.30012

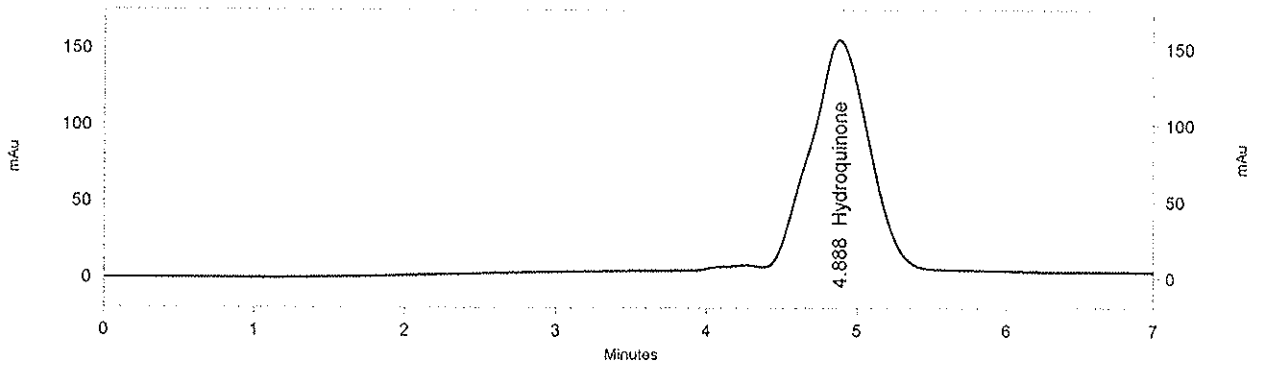


1: 280 nm, 4
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	4.920	7690065	100.113	0.00000	1.04919

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May-06-08
Hydroquinone Stability 3 Month 03
Sample ID: *Hydroquinone Stability 3 month*
C:\CLASS-VP\Sequence\2008\May 2008\HPLC 3\May-06-08
Hydroquinone Stability 3 months.seq
C:\CLASS-VP\Methods\Compounding\Hydroquinone Final Method.met
Vial: 34
Sample amount: 0.314

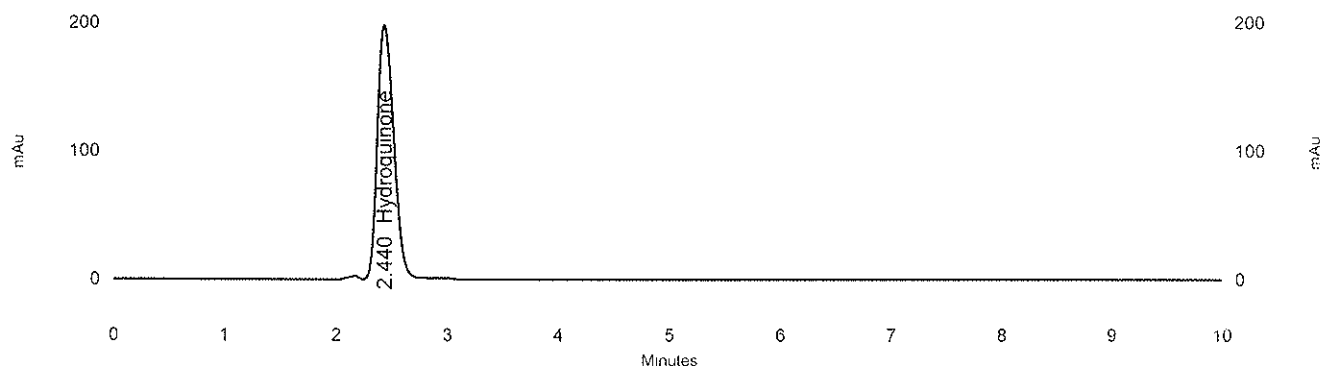


1: 280 nm, 4
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	4.888	3896746	4.849	0.00000	1.02837

HUMCO QUALITY CONTROL LABORATORY

Hydroquinone std
C:\CLASS-VP\Methods\Methods\HPLC3\186 Hydroquinone met.met
C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 3\Hydroquinone
stability-Zero day 5%.seq
10/21/2010 4:12:47 PM
10/21/2010 4:12:47 PM
3



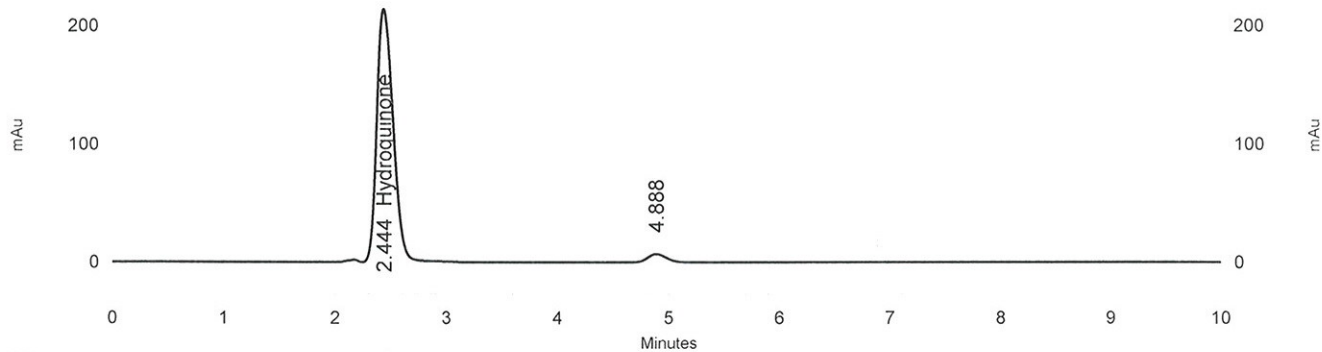
39

1: 280
nm, 4 nm
Results

Name	Retention Time	Height	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	2.440	197137	1983344	0.151 CAL	0.00	1.22

HUMCO QUALITY CONTROL LABORATORY

stability -zero day
C:\CLASS-VP\Methods\Methods\HPLC3\186 Hydroquinone met.met
C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 3\Hydroquinone
stability-Zero day 5%.seq
10/21/2010 4:13:26 PM
10/21/2010 4:13:27 PM
5



39

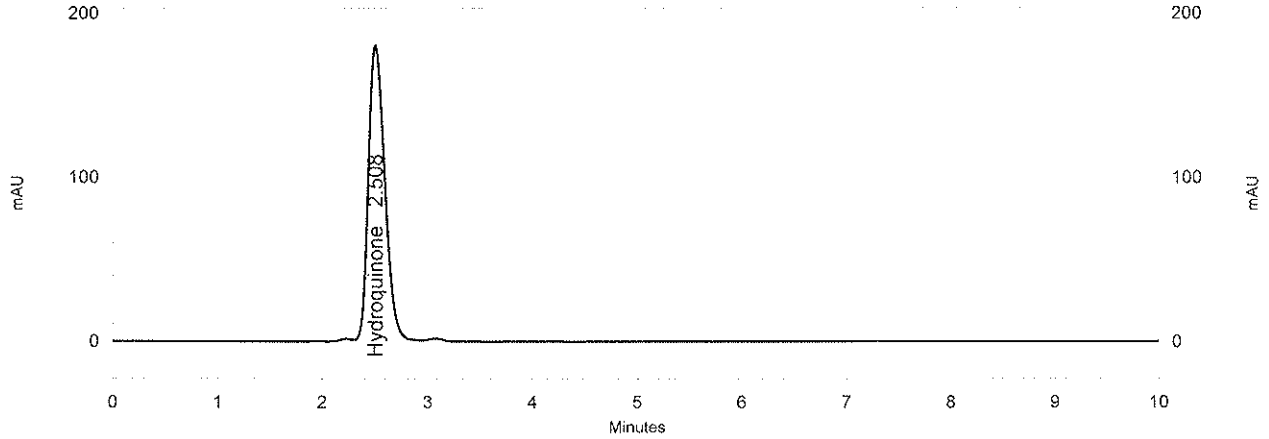
1: 280
nm, 4 nm
Results

Name	Retention Time	Height	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	2.444	213819	2166091	5.198	0.00	1.21

HUMCO QUALITY CONTROL LABORATORY

Sample ID: Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Hydroquinone met.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 4\Dec 7-10 Hydroquinone 30days stability.seq
Filename: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Dec 7-10 Hydroquinone 30days 01-Rep1
Acquired: 12/7/2010 11:29:36 AM
Printed: 12/7/2010 1:07:34 PM
Vial: 2



SPD-20AV
Ch1-280nm

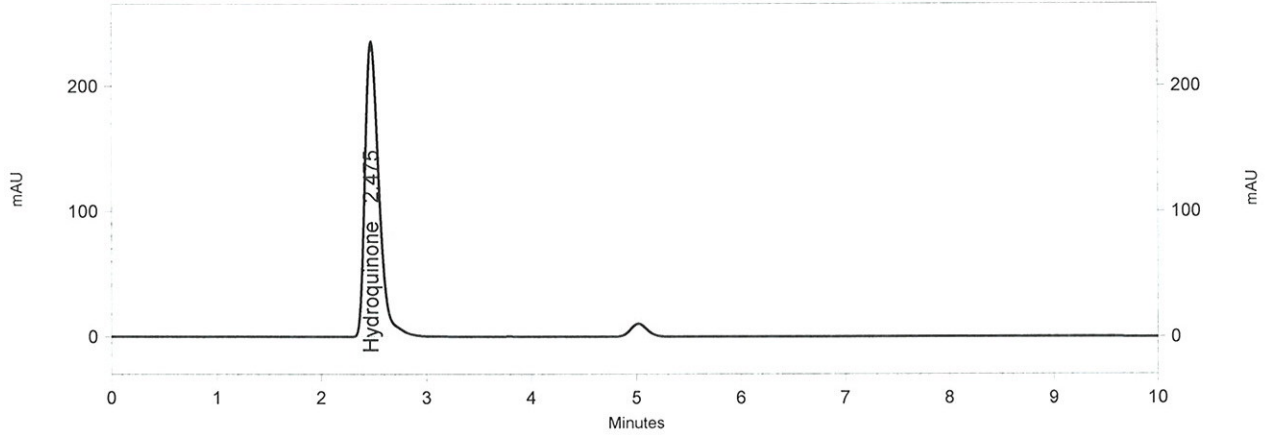
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Hydroquinone	2.508	179855	1954030	0.15 CAL	1.26

HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Hydroquinone sample 30days Stability*

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Hydroquinone met.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 4\Dec 7-10 Hydroquinone 30days stability.seq
Filename: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Dec 7-10 Hydroquinone 30days 03
Acquired: 12/7/2010 12:33:32 PM
Printed: 12/7/2010 1:08:53 PM
Vial: 4



SPD-20AV
Ch1-280nm

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Hydroquinone	2.475	235540	2144798	5.30	1.38

HUMCO QUALITY CONTROL LABORATORY

Hydroquinone std

C:\CLASS-VP\Methods\Methods\HPLC3\186 Hydroquinone met.met

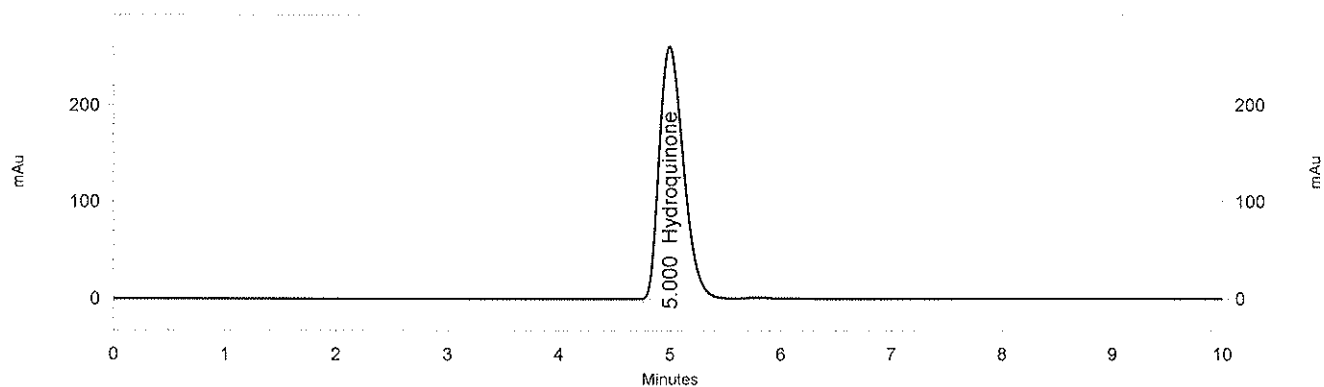
C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Dec 30 -10 Hydroquinone

60days stability.seq

12/31/2010 7:00:48 AM

12/31/2010 7:00:49 AM

1



39

1: 280

nm, 4 nm

Results

Name	Retention Time	Height	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	5.000	260253	3917854	0.150 CAL	0.00	1.31

HUMCO QUALITY CONTROL LABORATORY

stability -60days

C:\CLASS-VP\Methods\Methods\HPLC3\186 Hydroquinone met.met

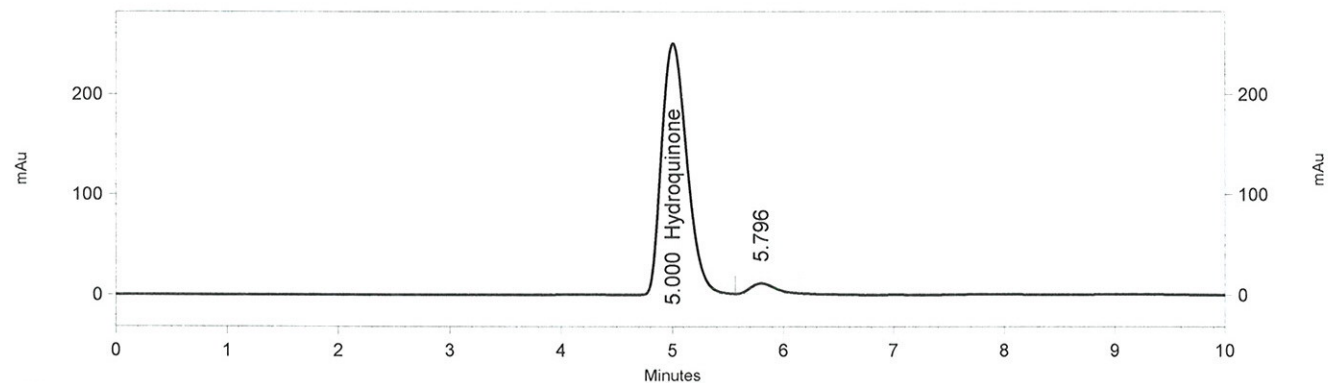
C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Dec 30 -10 Hydroquinone

60days stability.seq

12/31/2010 7:01:02 AM

12/31/2010 7:01:03 AM

3



39

1: 280

nm, 4 nm

Results

Name	Retention Time	Height	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	5.000	249344	3917548	5.030	0.00	1.30

HUMCO QUALITY CONTROL LABORATORY

Hydroquinone std

C:\CLASS-VP\Methods\Methods\HPLC3\186 Hydroquinone met.met

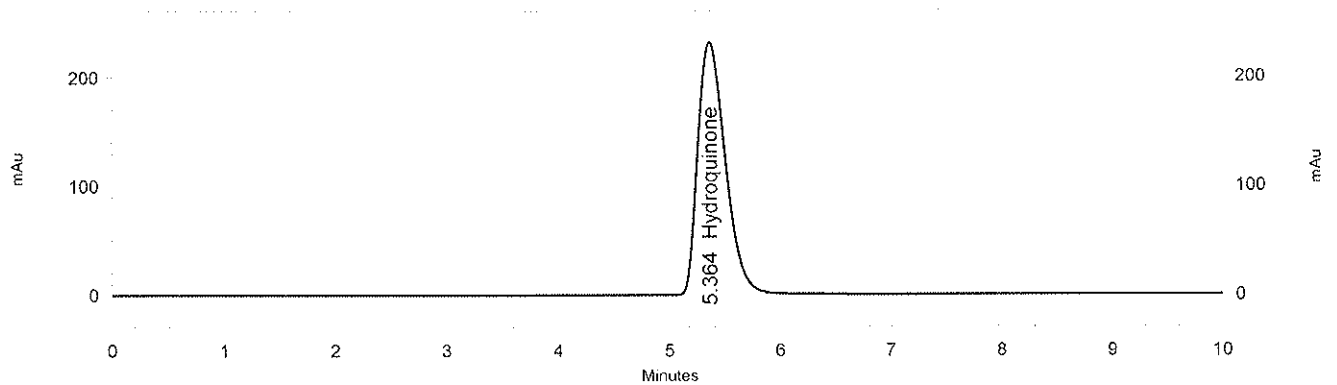
C:\CLASS-VP\Sequence\Sequence\2011\Jan\HPLC-3\Jan 21 -11 Hydroquinone

90days stability.seq

1/24/2011 10:16:51 AM

1/24/2011 10:16:53 AM

1



39

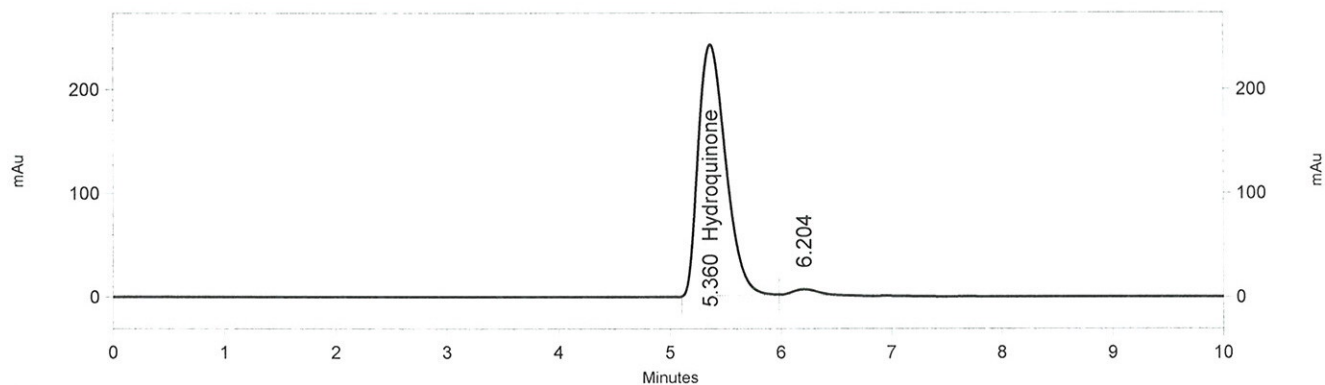
1: 280
nm, 4 nm

Results

Name	Retention Time	Height	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	5.364	231207	3958912	0.150 CAL	0.00	1.35

HUMCO QUALITY CONTROL LABORATORY

stability -90days
C:\CLASS-VP\Methods\Methods\HPLC3\186 Hydroquinone met.met
C:\CLASS-VP\Sequence\Sequence\2011\Jan\HPLC-3\Jan 21 -11 Hydroquinone
90days stability.seq
1/24/2011 10:19:48 AM
1/24/2011 10:19:49 AM
3



39

1: 280
nm, 4 nm

Name	Retention Time	Height	Area	%w/w	Resolution (USP)	Asymmetry
Hydroquinone	5.360	241854	4112514	5.045	0.00	1.37