



Scientific Study

B4520, Lipocream Base
(Hydroquinone 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
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Hydroquinone:

2.50g Hydroquinone raw drug powder from Spectrum Chemical (part number HY113, Lot # WA1662) was added to 47.50g Spectrum Chemical Mfg. Corp. Lipocream 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.

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.

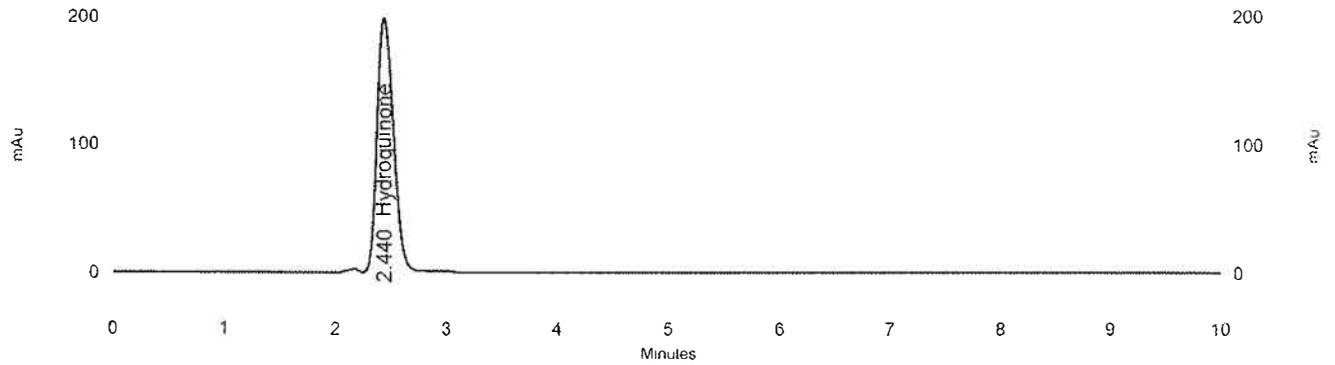
Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations, 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 4% Hydroquinone loss in Spectrum Chemical Mfg. Corp. Lipocream at 90 days.

Attached are 8 chromatographs of Spectrum Chemical Mfg. Corp. Lipocream 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.

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

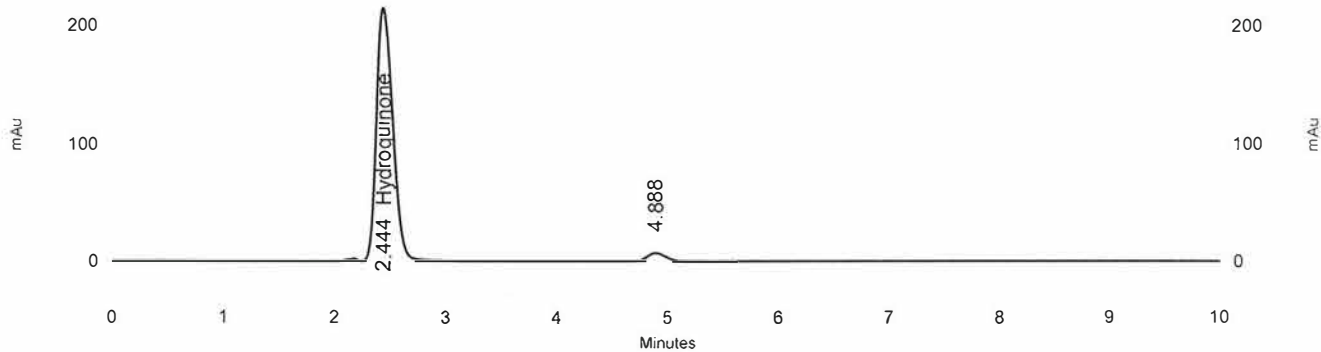


39

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

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



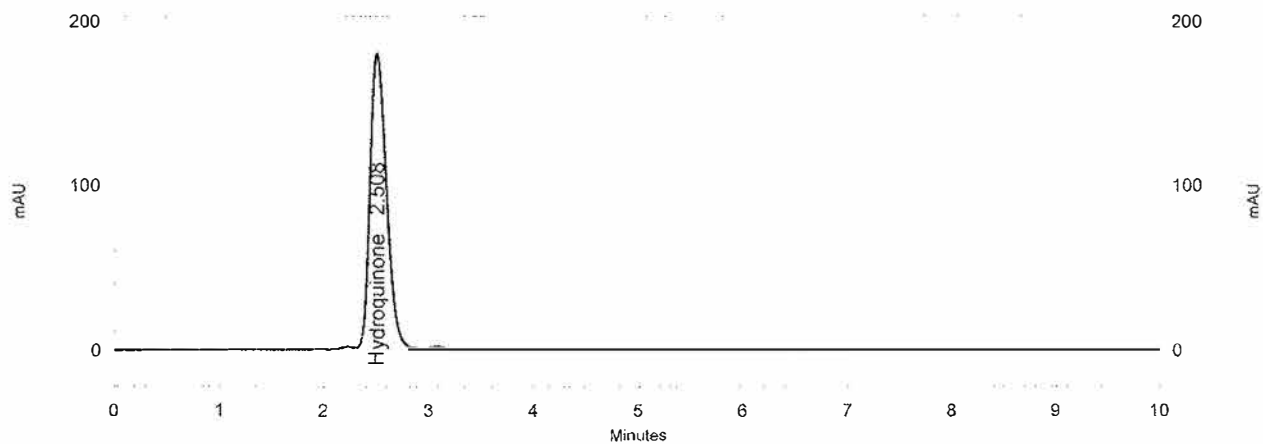
39

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

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
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Printed: 12/7/2010 1:07:34 PM
Vial: 2



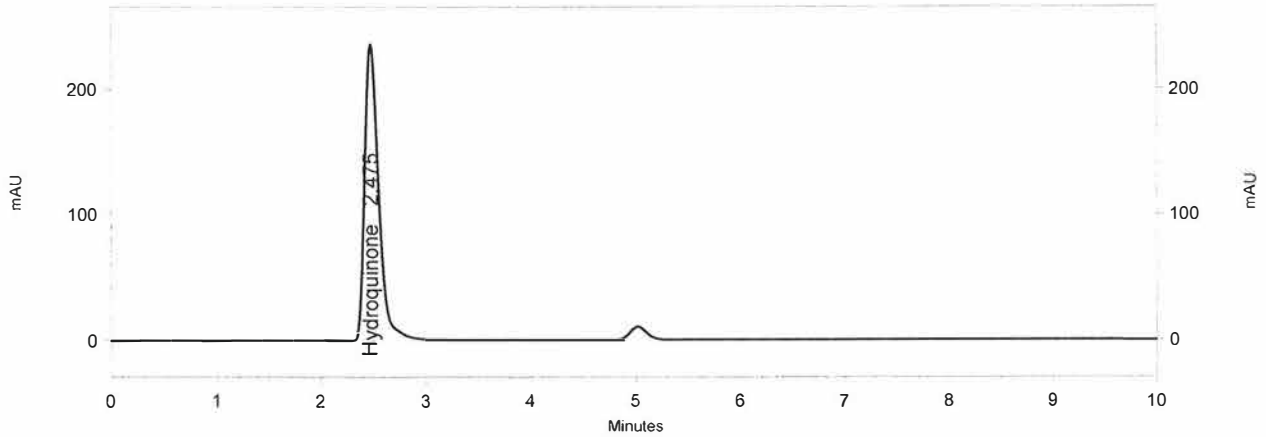
SPD-20AV
Ch1-280nm

Results

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

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

Results

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

Hydroquinone std

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

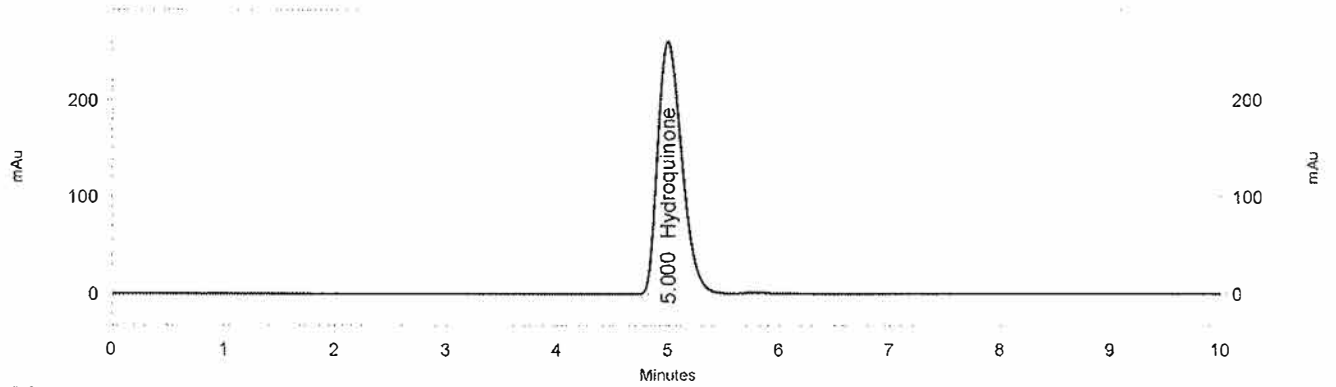
C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Dec 30 -10 Hydroquinone

60days stability.seq

12/31/2010 7:00:48 AM

12/31/2010 7:00:49 AM

1



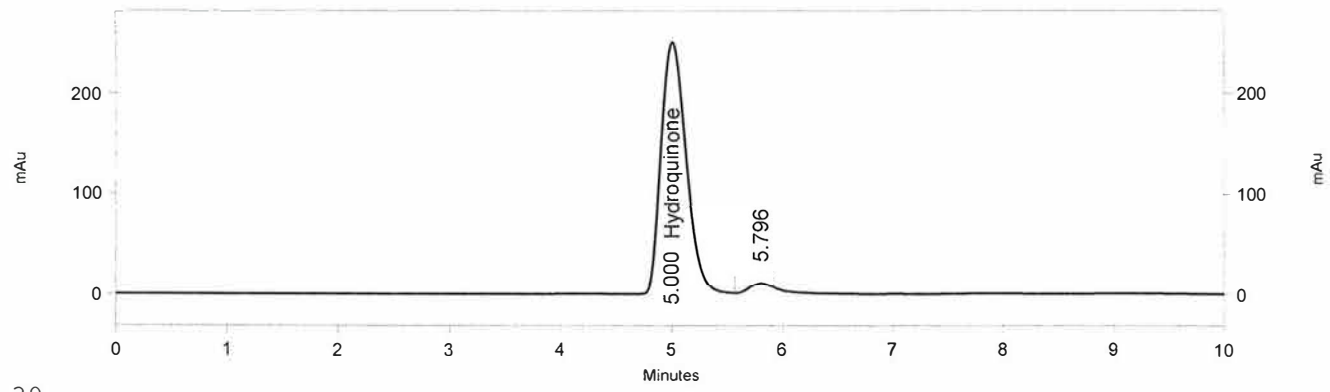
39

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

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



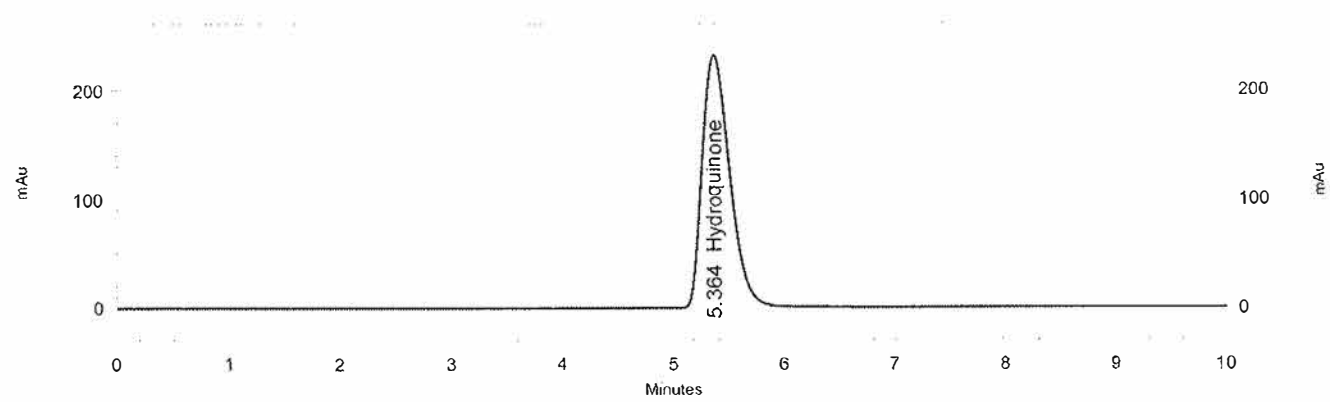
39

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

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
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 1/24/2011 10:16:53 AM
 1



39

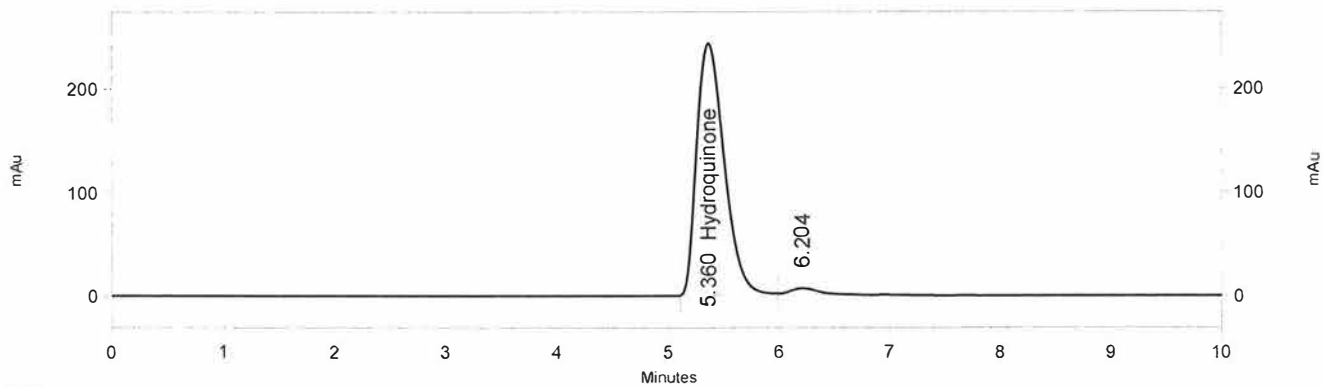
1: 280
 nm, 4 nm

Results

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

STABILITY -90days

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
Results

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