



Scientific Study

B4520, Lipocream Base
(Dexamethasone 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

Dexamethasone:

0.75g Dexamethasone raw drug powder from Spectrum Chemical (part number DE121, Lot # VC0773) was added to 50.00g with Spectrum Chemical Mfg. Corp. Lipocream and levigated with an electronic mortar and pestle, resulting in a final concentration of 1.5% 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 1.5% w/w, stability-indicating HPLC analysis found negligible Dexamethasone 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.

C:\CLASS-VP\Enterprise\Projects\Default\Data\April-15 Dexamethasone Precision 101-Rep1

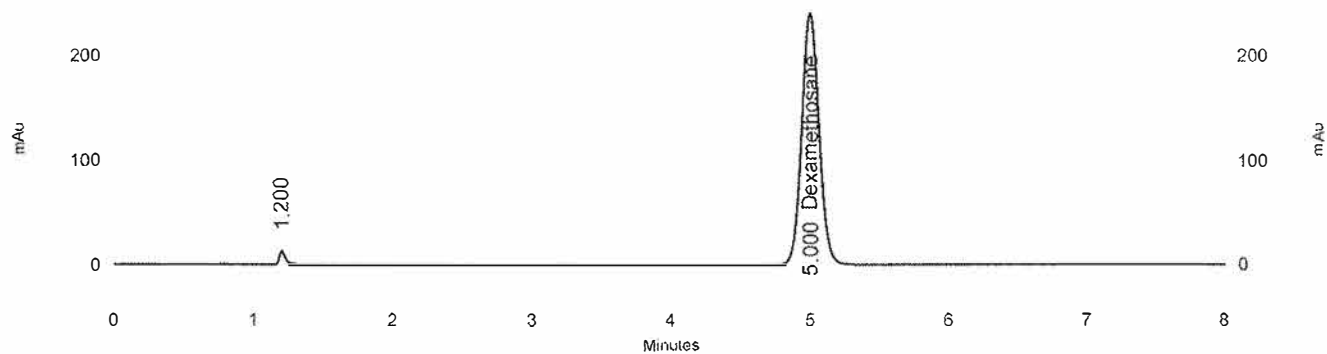
Sample ID: Dexamethasone Standards

C:\CLASS-VP\Sequence\2009\April\HPLC 3\April 15-09 Dexamethasone Precision .seq

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

Vial: 2

Sample amount: 1



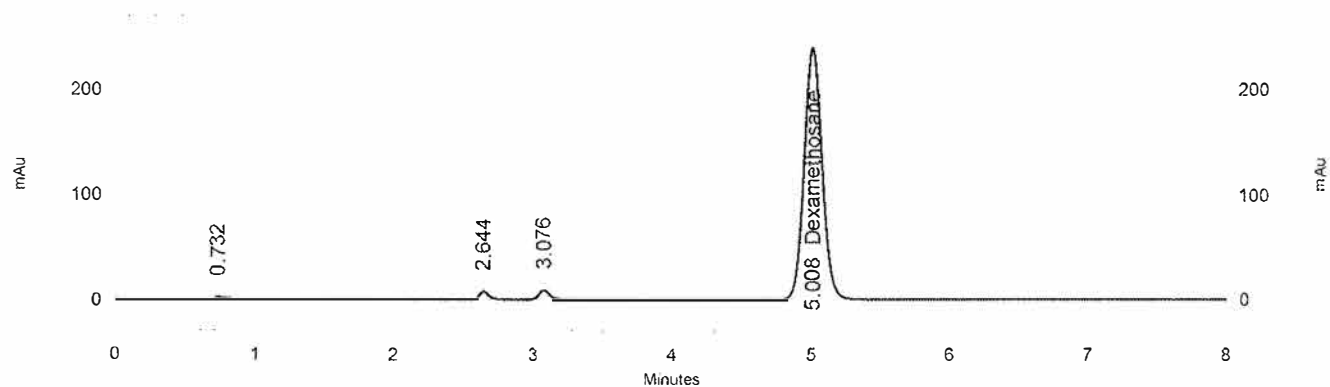
3: 254

nm, 4 nm

Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethasone	5.000	2062739	0.10 CAL	1.05970	77018.98	24.81013

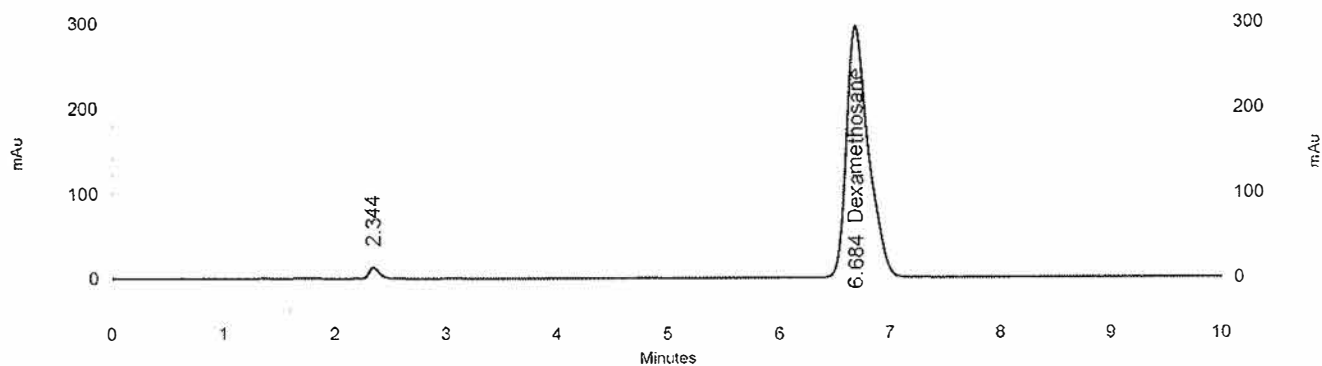
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Precision 104
Sample ID: Dexamethasone Precision 1
C:\CLASS-VP\Sequence\2009\April\HPLC 3\April 15-09 Dexamethasone Precision
.seq
C:\CLASS-VP\Methods\HPLC3\Dexamethasone.met
Vial: 5
Sample amount: 0.1855



3: 254
nm, 4 nm
Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethasone	5.008	2112108	1.38	1.07987	72876.27	10.39373

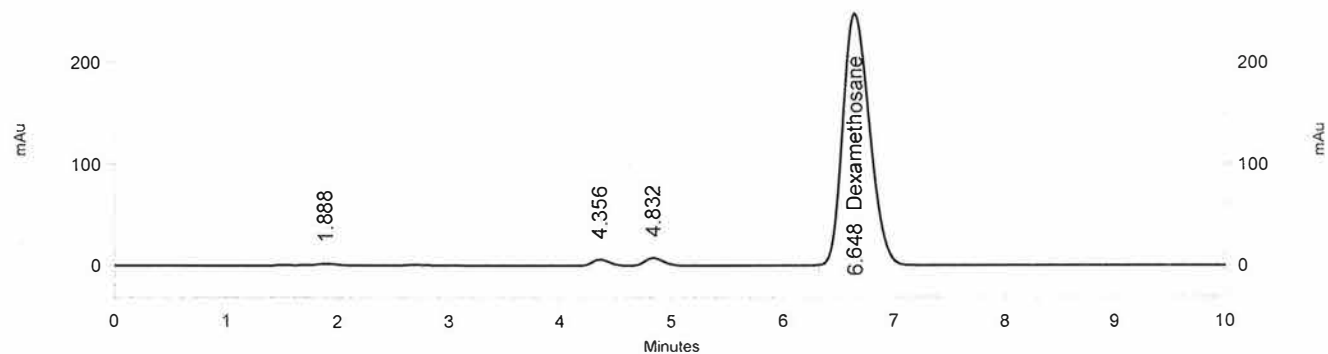
C:\CLASS-VP\Enterprise\Projects\Default\Data\May-14 Dexamethasone
 Stability 30 days 01-Rep1
 Sample ID: Dexamethasone Standards
 C:\CLASS-VP\Sequence\2009\April\HPLC 3\May 14-09 Dexamethasone Stability 30
 Days .seq
 C:\CLASS-VP\Methods\HPLC3\Dexamethasone.met
 Vial: 2
 Sample amount: 1



3: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethasone	6.684	4016384	0.10 CAL	1.34505	56151.44	16.51814

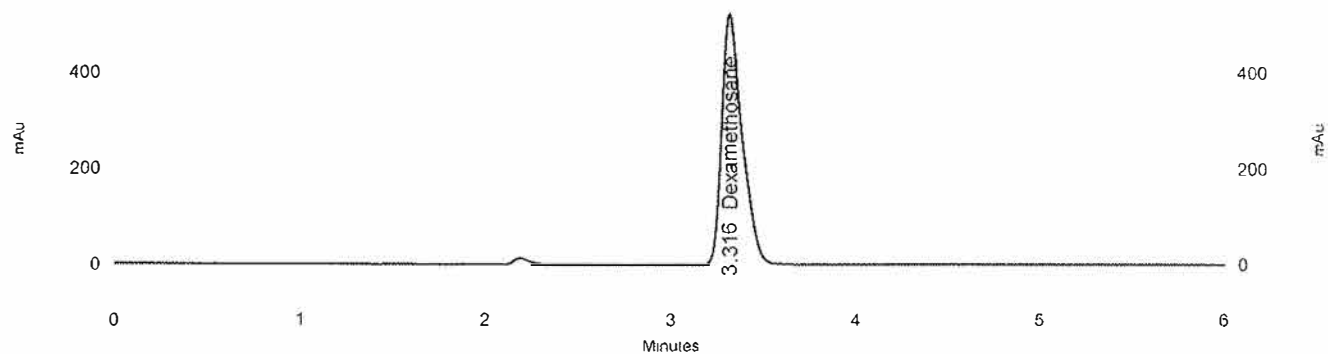
C:\CLASS-VP\Enterprise\Projects\Default\Data\May-14 Dexamethasone
 30 days
 Sample ID: Dexamethasone Precision 1
 C:\CLASS-VP\Sequence\2009\April\HPLC 3\May 14-09 Dexamethasone Stability 30
 Days .seq
 C:\CLASS-VP\Methods\HPLC3
 \Dexamethasone.met Vial: 4
 Sample amount: 0.3519



3: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethasone	6.648	41071.62	1.45	1.17797	35127.41	4.69840

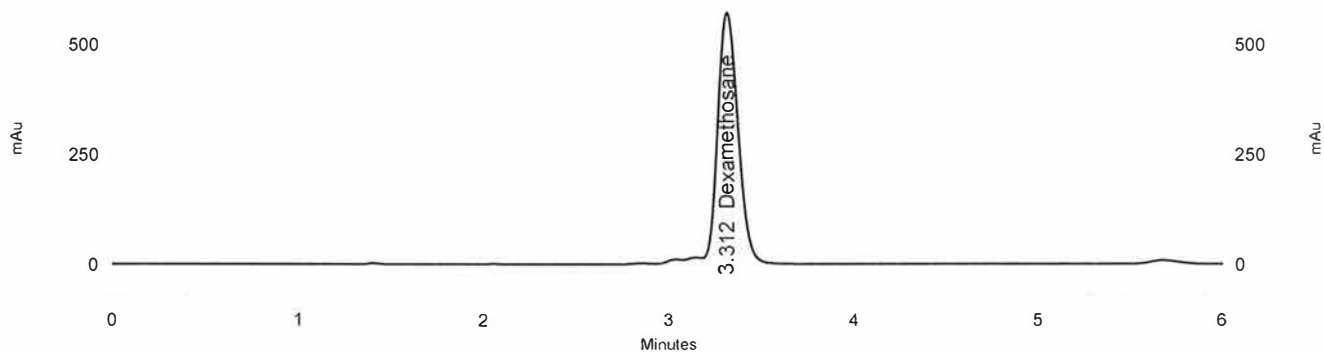
C:\CLASS-VP\Enterprise\Projects\Default\Data\June 15 09 Dexamthasone
 Stability 60 days 01-Rep1
 Sample ID: Dexamethasone Standards
 C:\CLASS-VP\Sequence\2009\June\HPLC 3\June 15 09 Dexamethasone stability
 60 days.seq
 C:\CLASS-VP\Methods\HPLC3\Dexamethasone.met
 Vial: 2
 Sample amount: 1



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethasone	3.316	3912008	0.10 CAL	1.39781	45692.38	0.00000

C:\CLASS-VP\Enterprise\Projects\Default\Data\June 15 09 Dexamthasone
 Stability 60 days 03
 Sample ID: Dexamethasone 60 days Stability
 C:\CLASS-VP\Sequence\2009\June\HPLC 3\June 15 09 Dexamethasone stability
 60 days.seq
 C:\CLASS-VP\Methods\HPLC3
 \Dexamethasone.met Vial: 4
 Sample amount: 0.3903

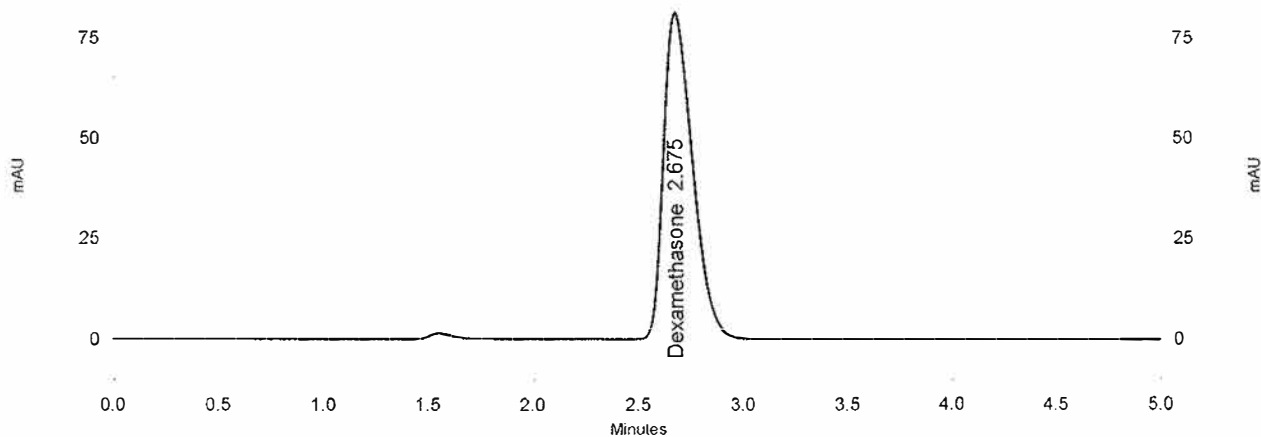


1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethasone	3.312	4440234	1.46	1.16979	44387.38	0.00000

Sample ID: Dexamethasone St

Method Name: C:\CLASS-VP\Methods\HPLC4\Dexamethasone.met
Sequence: C:\CLASS-VP\Sequence\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 Days.seq
Filename: C:\CLASS-VP\Data\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 days 01-Rep1
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Printed: 7/15/2009 2:51:53 PM
Vial: 2

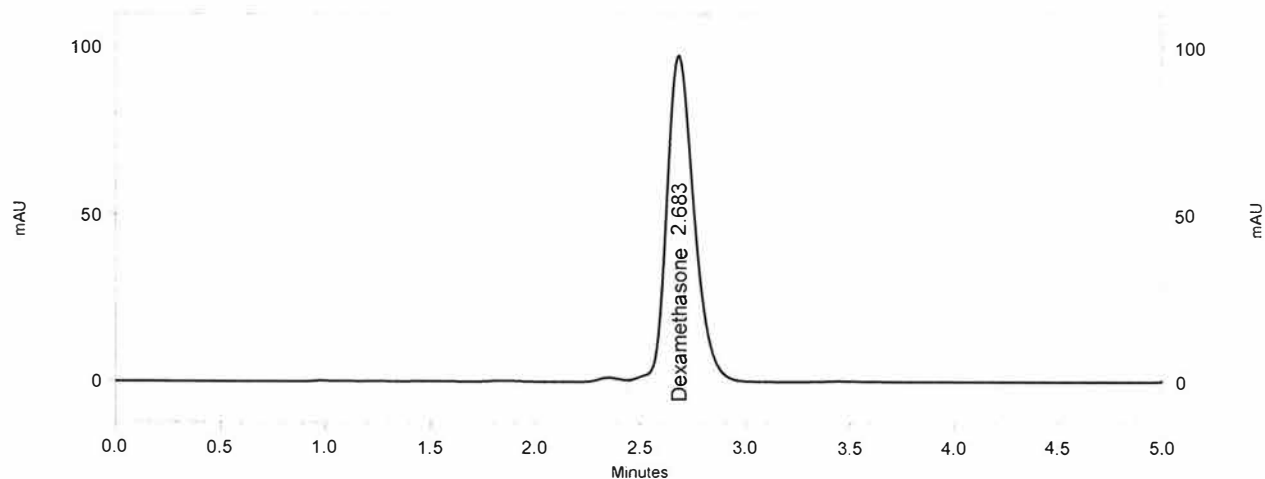


SPD-20AV
Ch1-254nm
Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Dexamethasone	2.675	774650	0.1001 CAL	0.00000	1.40230

Sample ID: Dexamethasone 1.5% Stability 90 days

Method Name: C:\CLASS-VP\Methods\HPLC4\Dexamethasone.met
Sequence: C:\CLASS-VP\Sequence\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 Days.seq
Filename: C:\CLASS-VP\Data\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 days 03
Acquired: 7/15/2009 2:30:53 PM
Printed: 7/15/2009 2:51:59 PM
Vial: 4



SPD-20AV
Ch1-254nm
Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Dexamethasone	2.683	882667	1.5065	0.00000	1.23904