



# Scientific Study

**B4520**, Lipocream Base  
(Diclofenac Study)

Not appropriate for regulatory submission.  
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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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#### Diclofenac:

2.00g Diclofenac raw drug powder from Spectrum Chemical (part number D1151, Lot # YR3052) was added to 48.00g Spectrum Chemical Mfg. Corp. Lipocream and levigated with an electronic mortar and pestle, resulting in a final concentration of 4.0% 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.

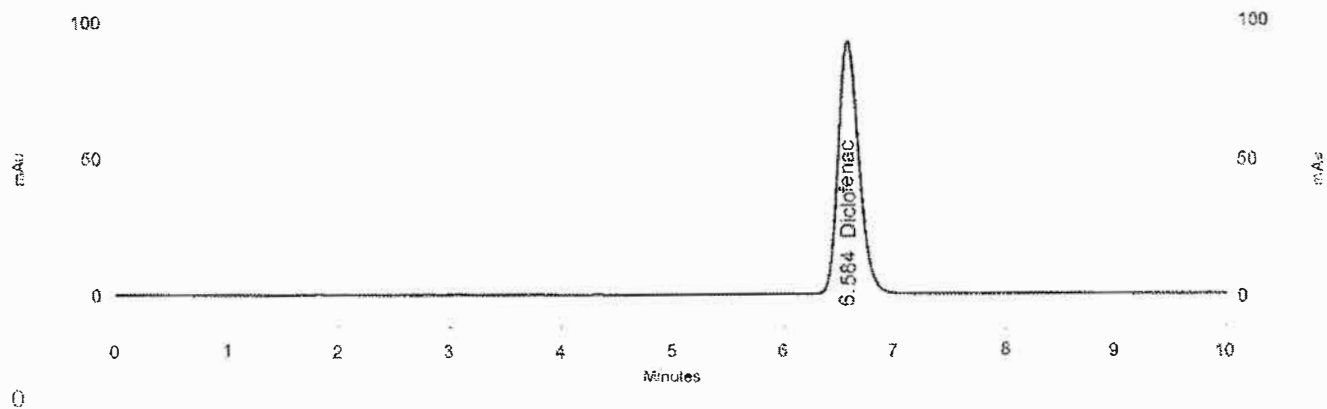
Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations, initial interval, and latest passing interval to illustrate no co-elution or baseline interference, as well as degradation products.

#### 90-Day Summary:

Compounded at 4.0% w/w, stability-indicating HPLC analysis found negligible Diclofenac 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\Sequence\2010\November\Nov 4-10 Diclofenac precision 10  
 Sample ID: Diclofenac Std 1  
 C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 3\Diclofenac precision  
 validation 11-4-10.seq  
 C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met  
 Vial: 2  
 Sample amount: 1

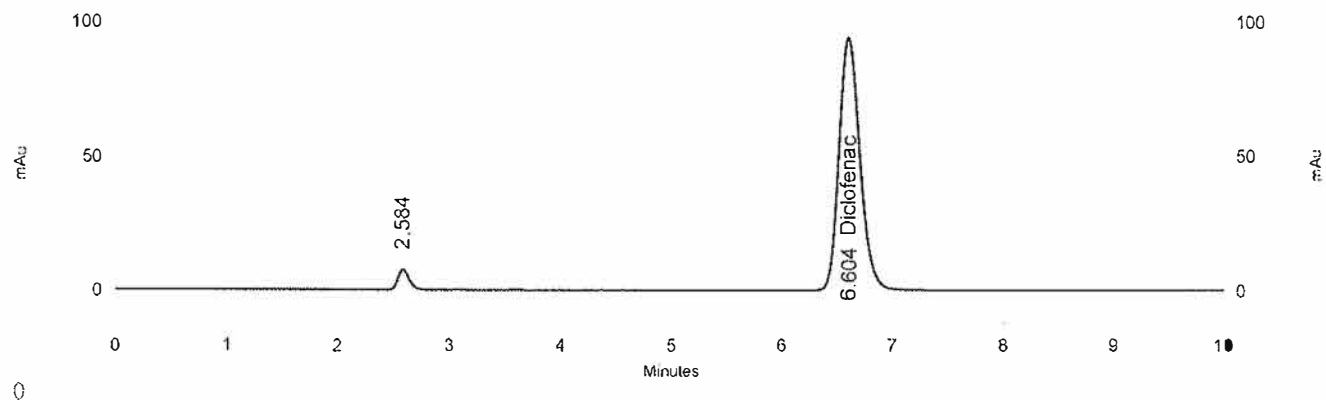


1: 254 nm, 4

nm Results

Name	Retention Time	Area	%w/w	Resolution	Asymmetry
Diclofenac	6.584	1129005	0.100 CAL	0.09600 (USP)	1.17222

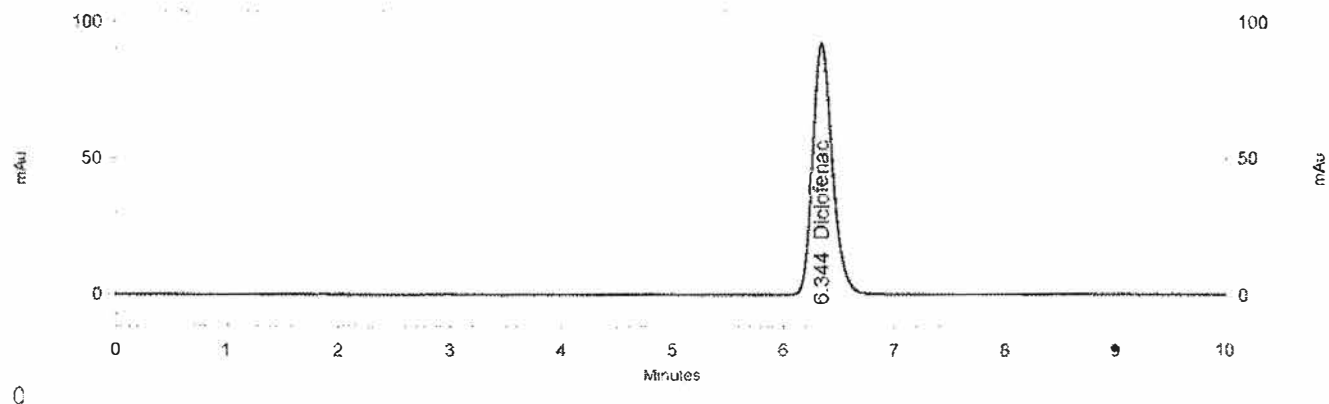
C:\CLASS-VP\Sequence\2010\November\Nov 4-10 Diclofenac precision 04  
 Sample ID: Diclofenac p-1  
 C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 3\Diclofenac precision  
 validation 11-4-10.seq  
 C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met  
 Vial: 11  
 Sample amount: 0.2631



1: 254 nm, 4  
 nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Diclofenac	6.604	1215784	3.902	15.17559	1.16852

C:\CLASS-VP\Sequence\2010\November\Dec 8-10 Diclofenac 30days Stability  
 101-Rep1  
 Sample ID: Diclofenac std  
 C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Diclofenac 30days  
 Stability 12-7-10.seq  
 C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met  
 Vial: 2  
 Sample amount: 1



1: 254 nm, 4  
 nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Diclofenac	6.344	1141648	0.100 CAL	0.00000	1.20458

C:\CLASS-VP\Sequence\2010\November\Dec 8-10 Diclofenac 30days Stability 103

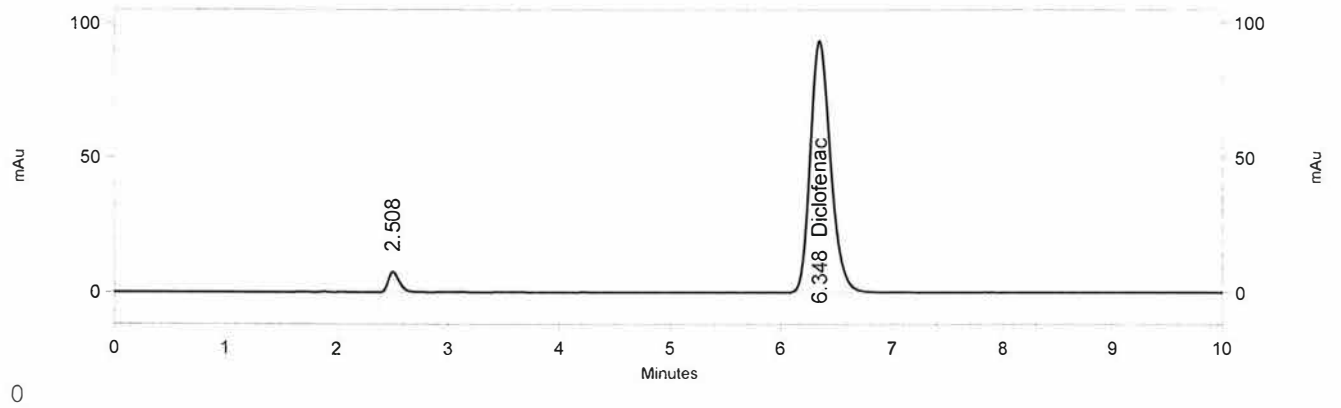
Sample ID: Diclofenac 30days stability

C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Diclofenac 30days  
Stability 12-7-10.seq

C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met

Vial: 4

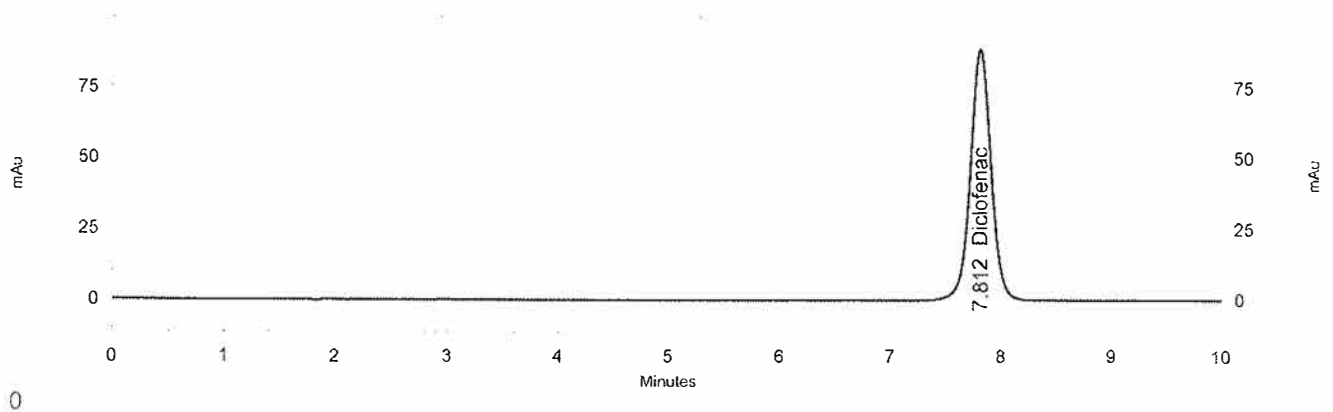
Sample amount: 0.254



1: 254 nm, 4  
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Diclofenac	6.348	1162716	4.027	15.08292	1.20547

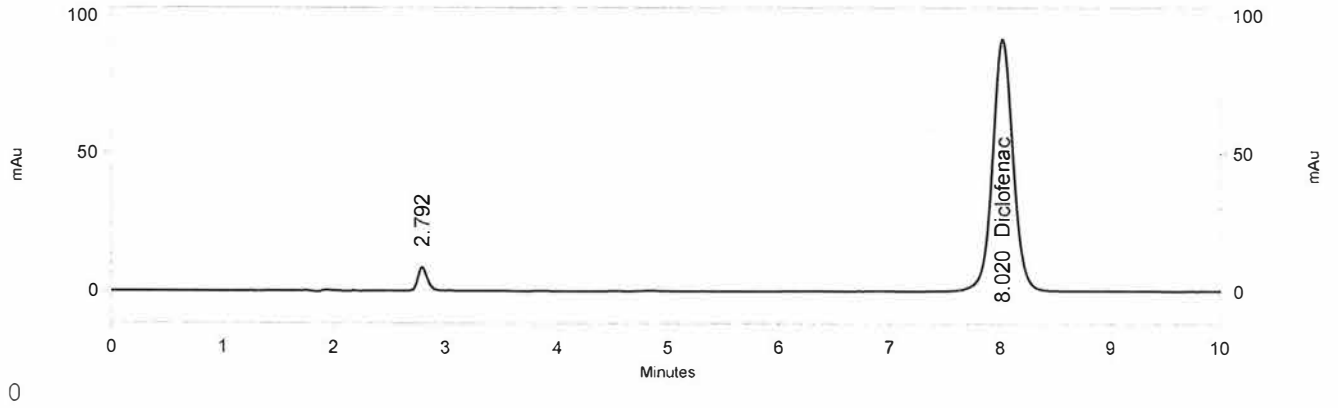
C:\CLASS-VP\Sequence\2010\November\Dec 31-10 Diclofenac 60days Stability  
 101-Rep1  
 Sample ID: Diclofenac std  
 C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Diclofenac 60days  
 Stability 12-31-10.seq  
 C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met  
 Vial: 1  
 Sample amount: 1



1: 254 nm, 4  
 nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Diclofenac	7.812	1135954	0.100 CAL	0.00000	1.02527

C:\CLASS-VP\Sequence\2010\November\Dec 31-10 Diclofenac 60days Stability  
 103  
 Sample ID: Diclofenac 60days stability  
 C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Diclofenac 60days  
 Stability 12-31-10.seq  
 C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met  
 Vial: 3  
 Sample amount: 0.2526

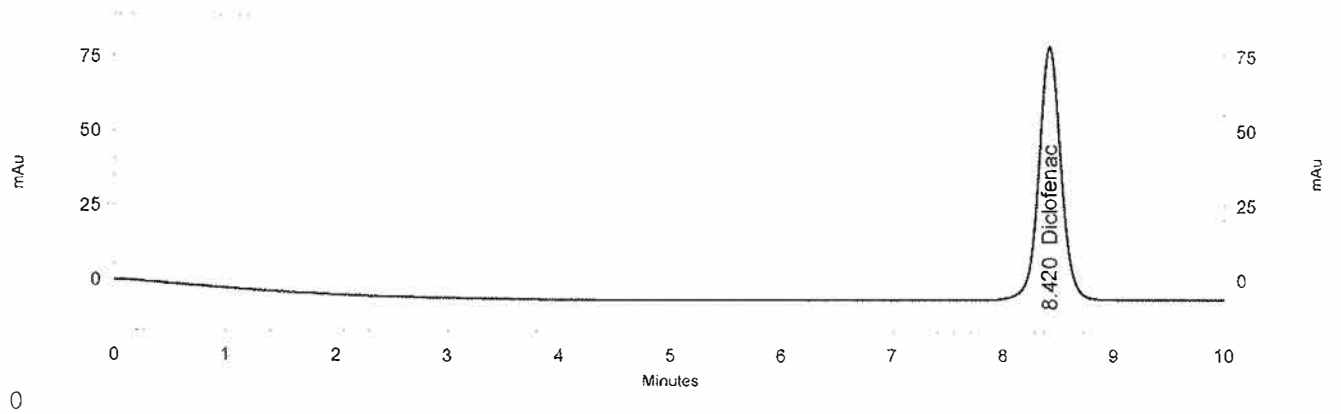


1: 254 nm, 4  
 nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Diclofenac	8.020	1167486	4.082	21.45406	1.02552



C:\CLASS-VP\Sequence\2010\November\Jan 28-11 Diclofenac 90days Stability  
 01-Rep1  
 Sample ID: Diclofenac std  
 C:\CLASS-VP\Sequence\Sequence\2011\Jan\HPLC-3\Diclofenac 90days Stability  
 1-28-11.seq  
 C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met  
 Vial: 16  
 Sample amount: 1



1: 254 nm, 4 nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Diclofenac	8.420	1157661	0.100 CAL	0.00000	1.02144

C:\CLASS-VP\Sequence\2010\November\Jan 28-11 Diclofenac 90days Stability 03

Sample ID: Diclofenac 90days stability

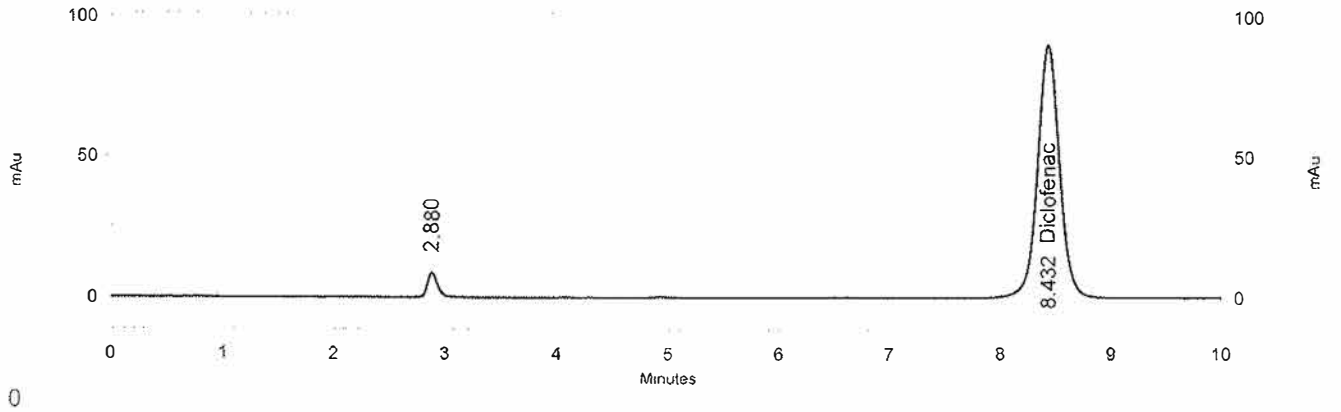
C:\CLASS-VP\Sequence\Sequence\2011\Jan\HPLC-3\Diclofenac 90days Stability

1-28-11.seq

C:\CLASS-VP\Methods\Methods\HPLC3\Diclofenac development met..met

Vial: 18

Sample amount: 0.2523



1: 254 nm, 4  
nm Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Diclofenac	8.432	1231674	4.228	21.49392	1.01673