

Diclofenac:

2.00g Diclofenac raw drug powder from Spectrum chemical (part number D1151, Lot # YR3052) was added to 48.00g Humco LipoBase Heavy (Humco Holding Group, Texarkana, Texas) 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 Humco LipoBase Heavy at 90 days.

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\Sequence\2010\November\Nov 4-10 Diclofenac precision 10

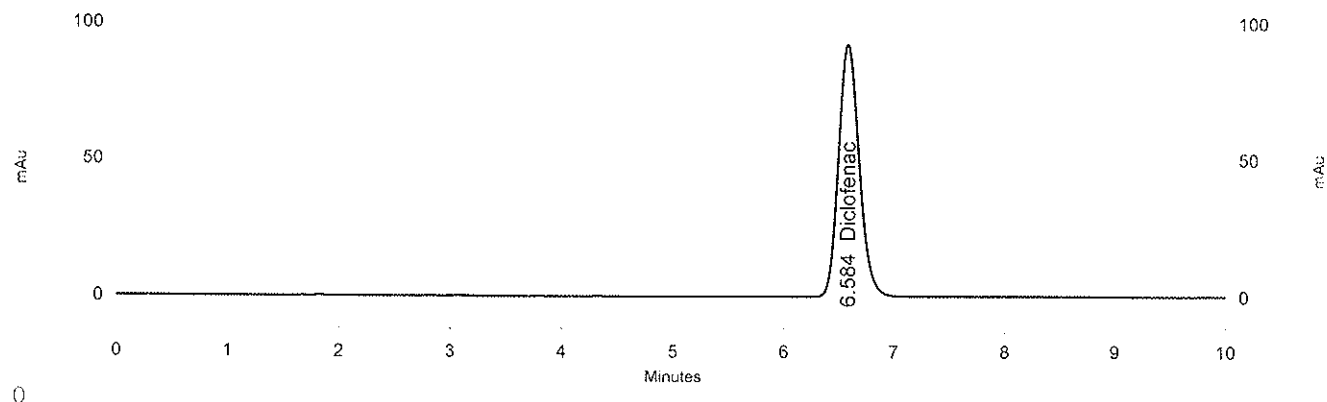
Sample ID: Diclofena Std 1

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 (USP)	Asymmetry
Diclofenac	6.584	1189005	0.100 CAL	0.00000	1.17222

HUMCO QUALITY CONTROL LABORATORY

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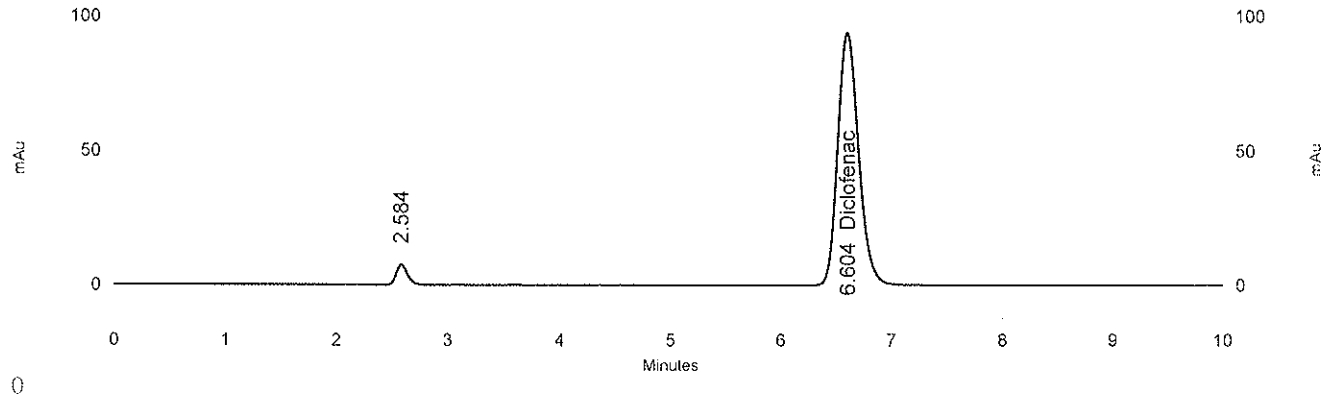
Sample ID: Diclofena p-1

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

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Sequence\2010\November\Dec 8-10 Diclofenac 30days Stability
101-Rep1

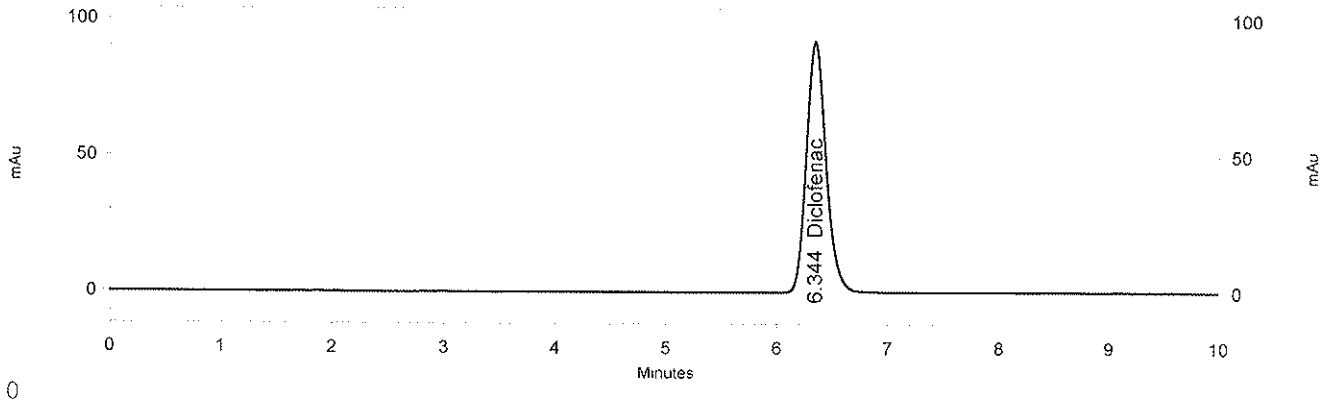
Sample ID: Diclofena std

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

HUMCO QUALITY CONTROL LABORATORY

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

Sample ID: Diclofena 30days stability

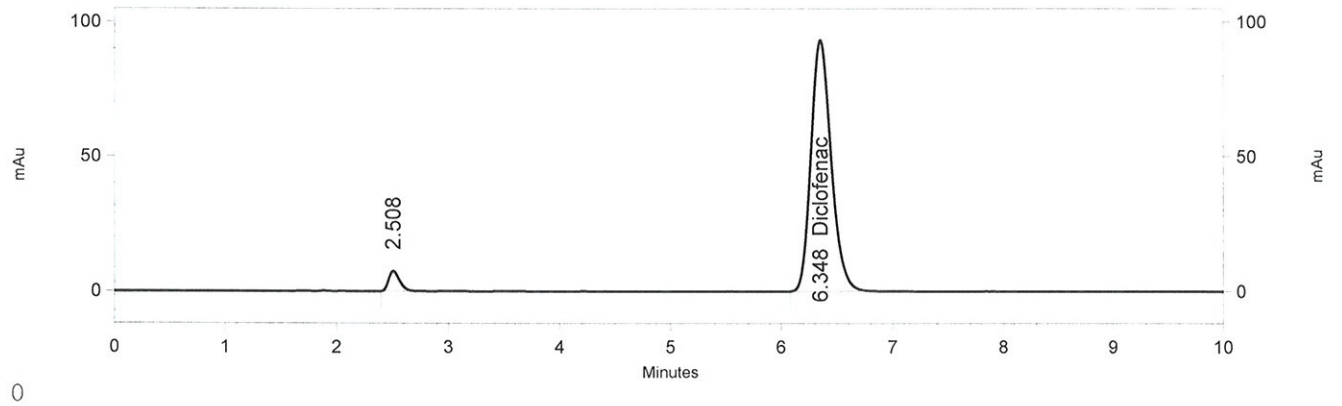
C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 3\Diclofenac 30days

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

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Sequence\2010\November\Dec 31-10 Diclofenac 60days Stability
101-Rep1

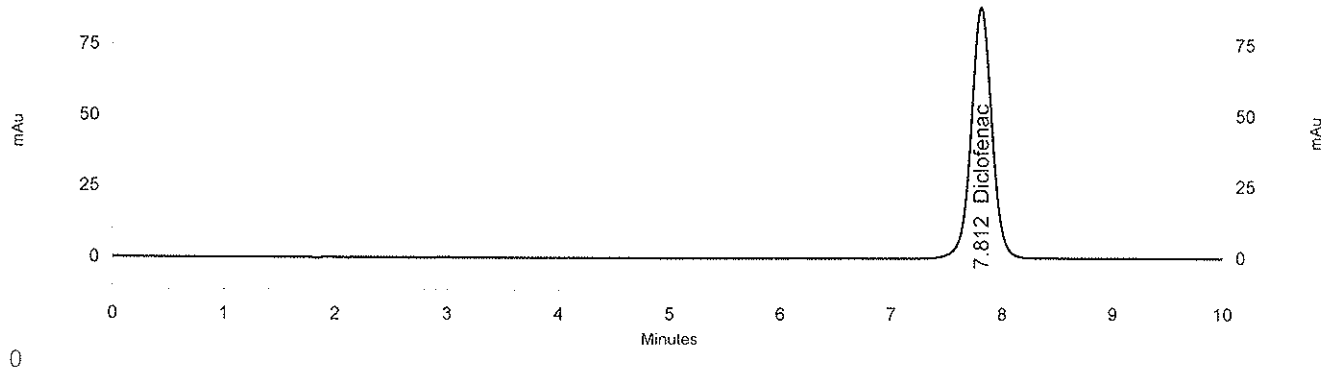
Sample ID: Diclofena std

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

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Sequence\2010\November\Dec 31-10 Diclofenac 60days Stability
103

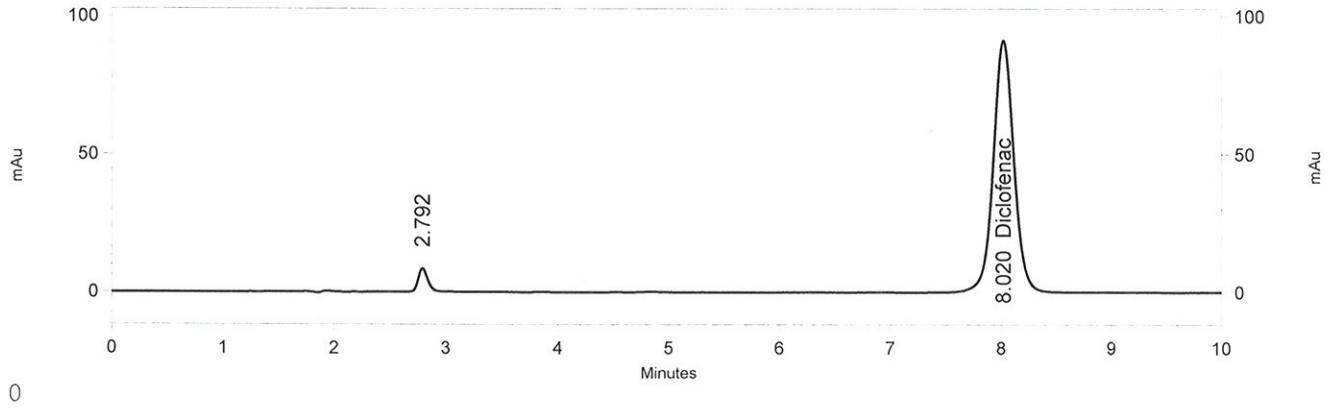
Sample ID: Diclofena 60days stability

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

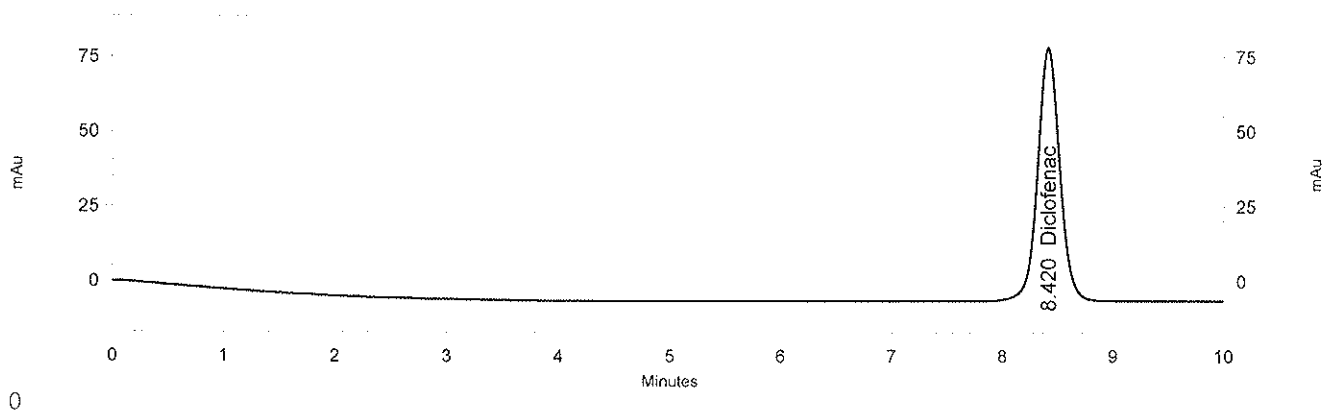


1: 254 nm, 4
nm Results

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

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Sequence\2010\November\Jan 28-11 Diclofenac 90days Stability
01-Rep1
Sample ID: Diclofena 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

HUMCO QUALITY CONTROL LABORATORY

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

Sample ID: Diclofena 90days stability

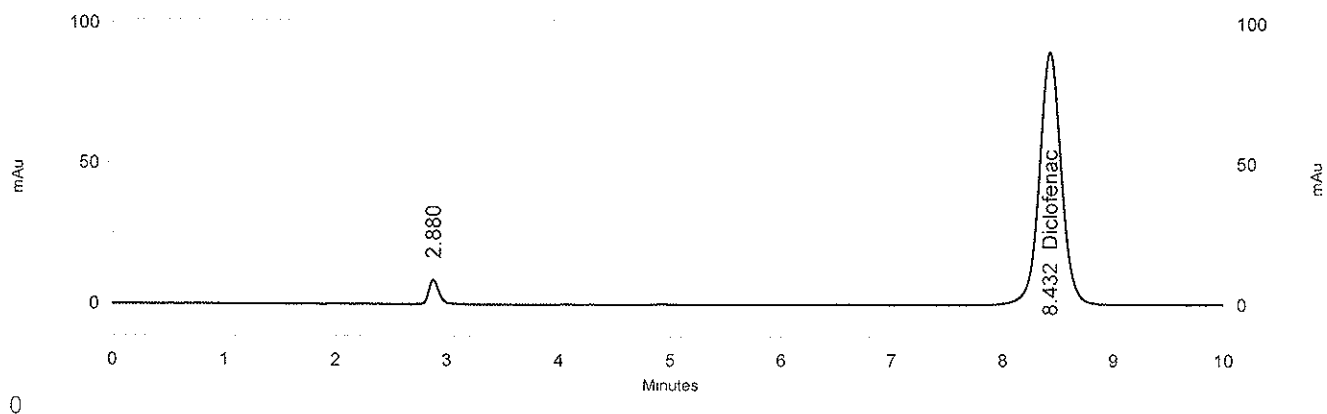
C:\CLASS-VP\Sequence\Sequence\2011\Jan\HPLC-3\Diclofenac 90days Stability

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