

Ibuprofen:

5.00g Ibuprofen raw drug powder from Spectrum chemical (part number IB100, Lot # XD1118) was QS to 50.00g with Humco PLO 20 (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 10.0% w/w. This gel was then stored at room temperature in the same 50/70 mL Unguator container.

Similar steps were used in preparing samples in Humco PLO 20 Flowable and Humco PenCream (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 10.0% w/w, stability-indicating HPLC analysis found less than 3% Ibuprofen loss in Humco PLO 20 at 90 days.

Compounded at 20.0% w/w, stability-indicating HPLC analysis found less than 2% Ibuprofen loss in Humco PLO 20 Flowable at 90 days.

Compounded at 10.0% w/w, stability-indicating HPLC analysis found negligible Ibuprofen loss in Humco PenCream at 90 days.

Attached are 6 chromatographs of Humco PLO 20 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 PLO 20 Flowable 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.

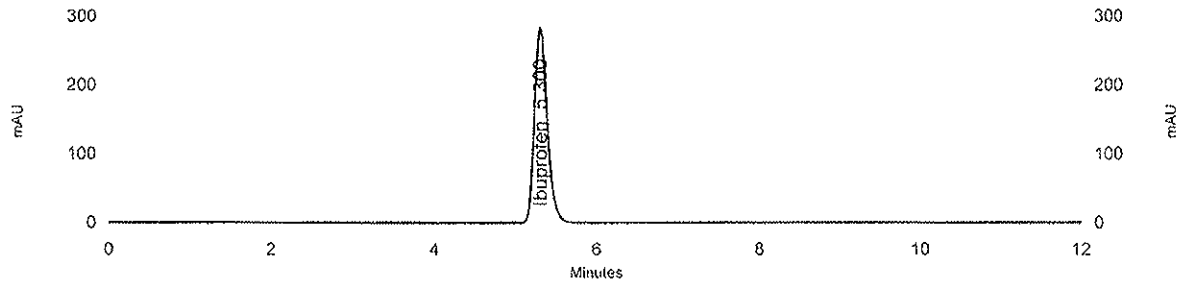
Attached are 6 chromatographs of Humco PenCream showing in order: 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\September 07-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 07-10 Ibuprofen 002-Rep1
Acquired: 9/7/2010 1:04:47 PM
Printed: 9/7/2010 3:26:12 PM
Vial: 3



SPD-20AV
Ch1-230nm

Results

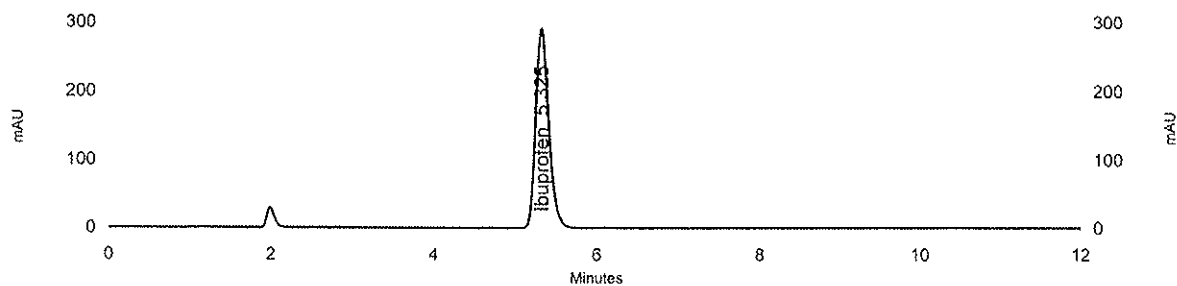
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		282454	3111586	0.010 CAL

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

30 days stability sample

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\September 07-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 07-10 ibuprofen 004
Acquired: 9/7/2010 2:20:42 PM
Printed: 9/7/2010 3:26:36 PM
Vial: 5



SPD-20AV
Ch1-230nm
Results

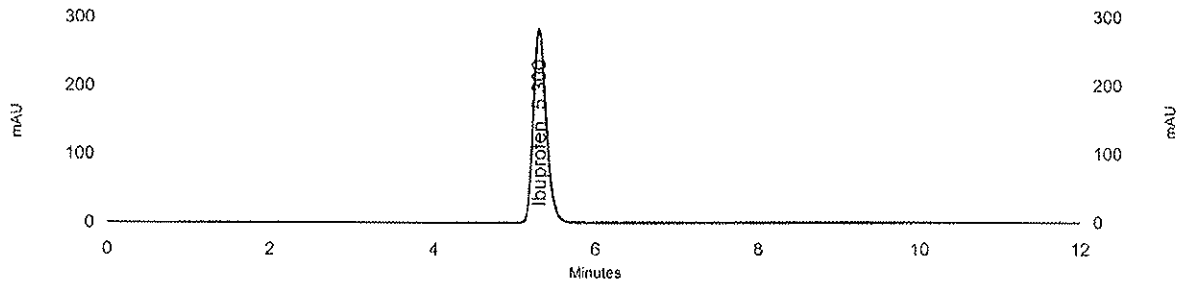
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		290531	3218481	10.252

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\September 07-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 07-10 Ibuprofen 002-Rep1
Acquired: 9/7/2010 1:04:47 PM
Printed: 9/7/2010 4:07:40 PM
Vial: 3



SPD-20AV
Ch1-230nm
Results

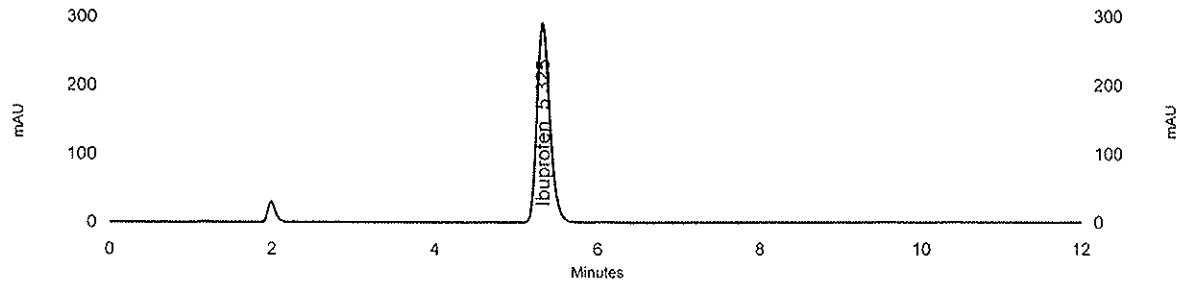
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		282454	3111586	0.103 CAL

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

30 days stability sample

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\September 07-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 07-10 Ibuprofen 004
Acquired: 9/7/2010 2:20:42 PM
Printed: 9/7/2010 4:07:45 PM
Vial: 5



SPD-20AV
Ch1-230nm
Results

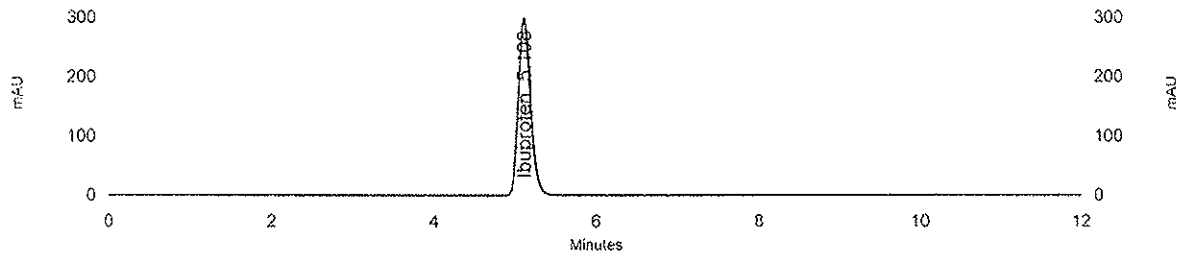
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		290531	3218481	10.252

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\October\HPLC 4\October 13-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 13-10 Ibuprofen 001-Rep1
Acquired: 10/13/2010 1:16:36 PM
Printed: 10/13/2010 4:06:25 PM
Vial: 2



SPD-20AV
Ch1-230nm
Results

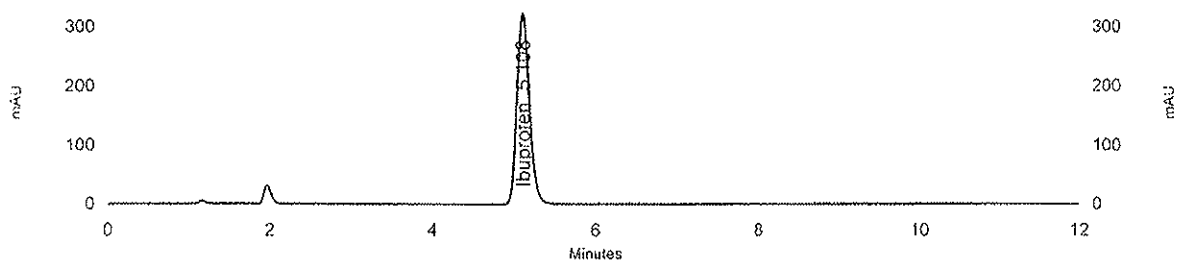
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		298134	3126599	0.103 CAL

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

60 days stability sample

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\October\HPLC 4\October 13-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 13-10 Ibuprofen 003
Acquired: 10/13/2010 2:32:35 PM
Printed: 10/13/2010 4:06:40 PM
Vial: 4

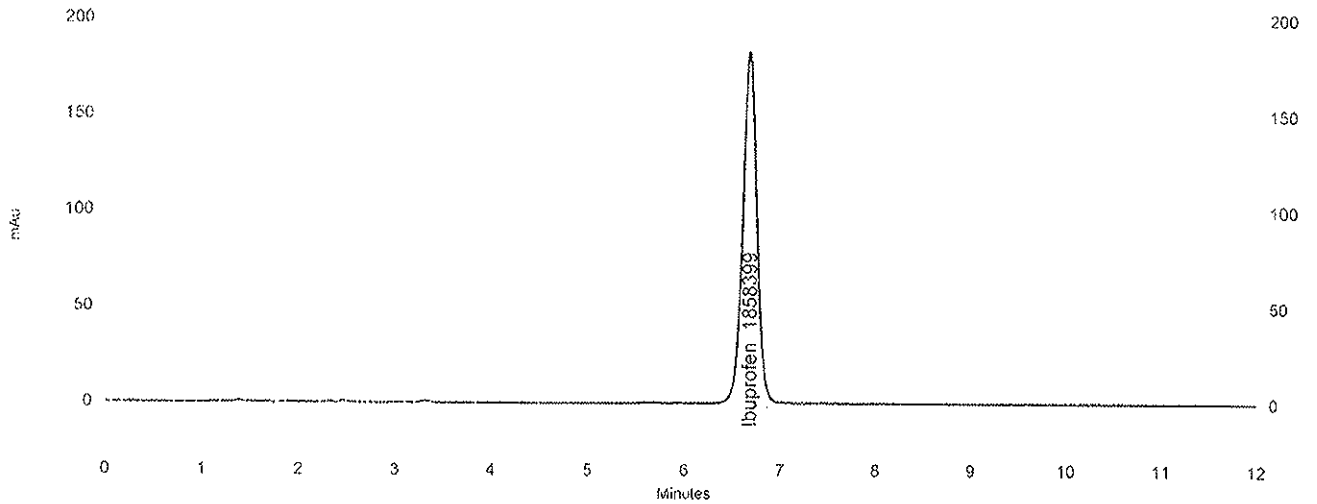


SFD-20AV
Ch1-230nm
Results

Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		321247	3376367	10.824

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April 27-10 Ibuprofen
Stability Zero time days 101-Rep1
Sample ID: Ibuprofen Standards
C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 27-10 Ibuprofen stability Zero
time.seq
C:\CLASS-VP\Methods\HPLC3\Ibuprofen.met
Vial: 2
Sample amount: 1



1: 230 nm,

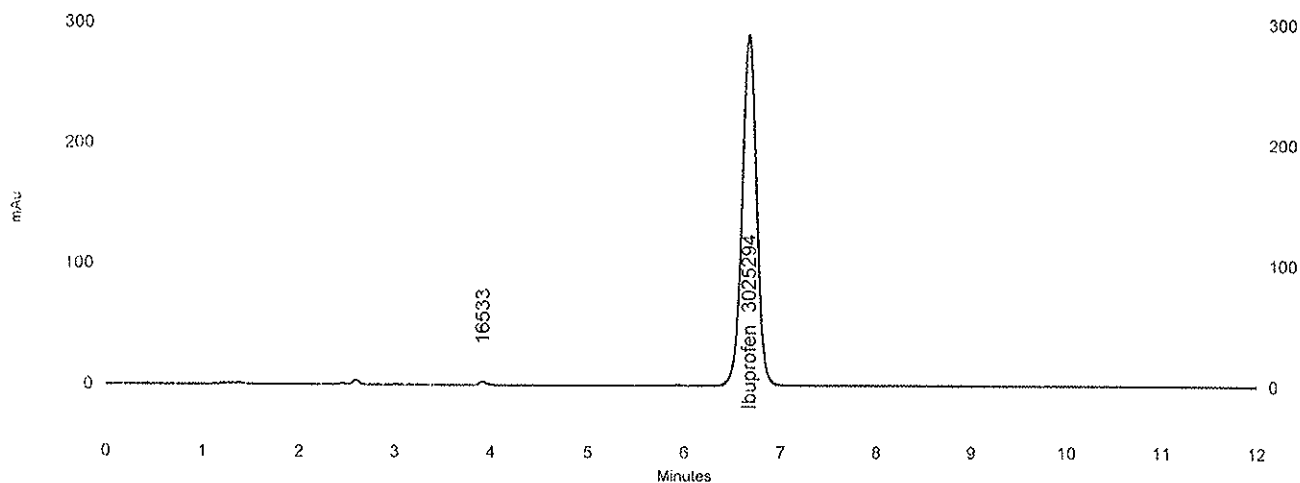
4 nr

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	6.68	1858399	0.1001 CAL	1.02	0.00

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April 27-10 Ibuprofen
Stability Zero time days 103
Sample ID: Ibuprofen 20 % Stability Zero time
C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 27-10 Ibuprofen stability Zero
time.seq
C:\CLASS-VP\Methods\HPLC3\Ibuprofen.met
Vial: 4
Sample amount: 0.1353



1: 230 nm,
4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	6.65	3025294	20.0414	1.02	12.22

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\MAY 26-10 Ibuprofen Stability
30 days 101-Repl

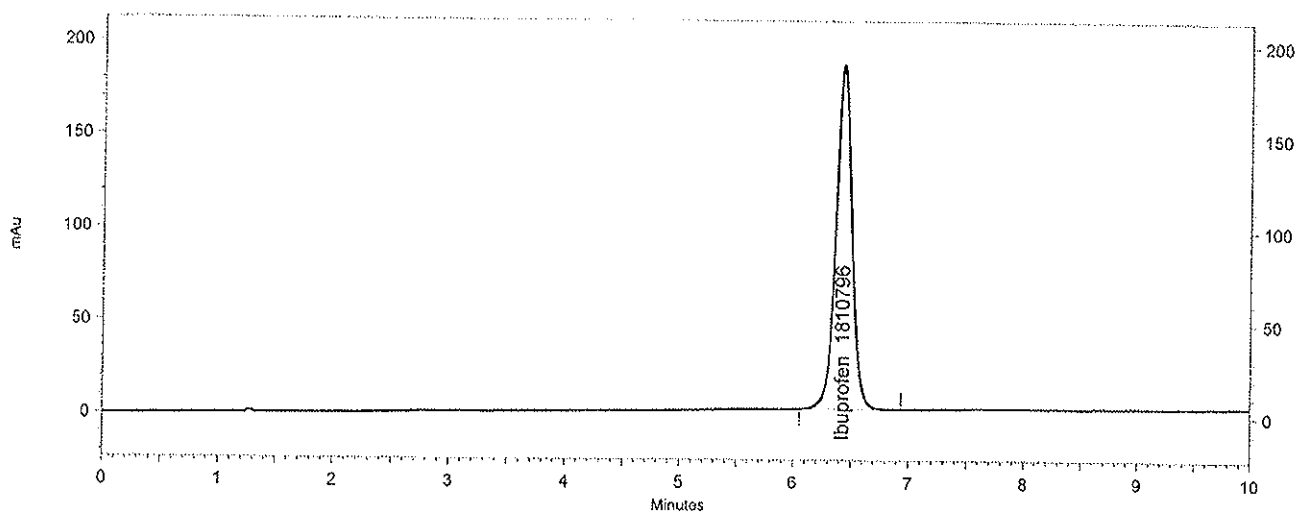
Sample ID: Ibuprofen Standards

C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 26-10 Ibuprofen 30 days
Stability.seq

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

Vial: 2

Sample amount: 1



1: 230 nm,
4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	6.42	1810796	0.1001 CAL	1.07	0.00

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\MAY 26-10 Ibuprofen Stability
30 days 103

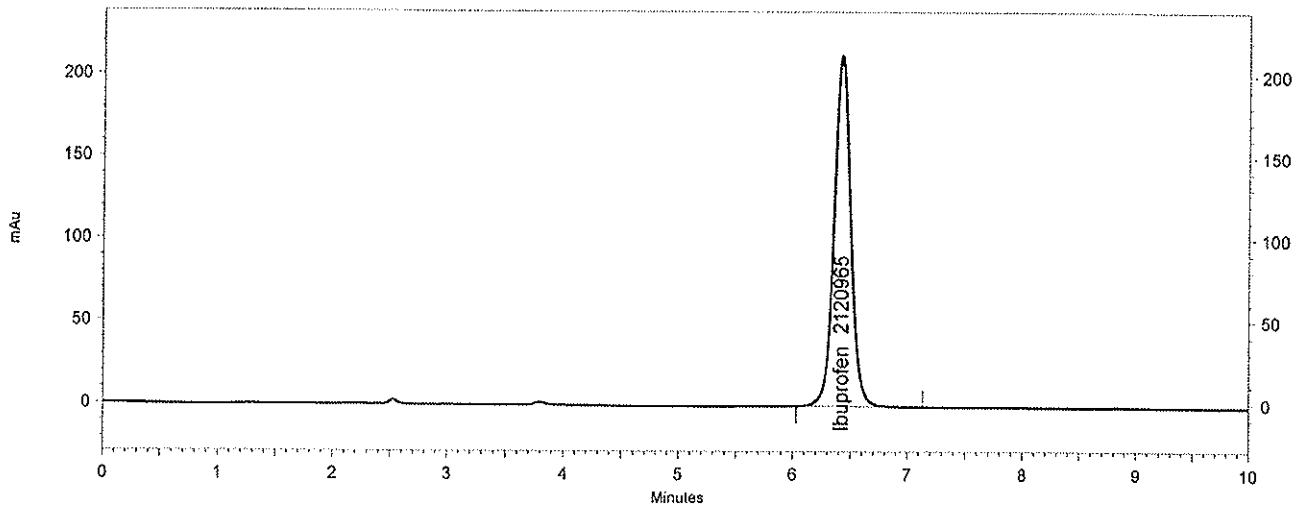
Sample ID: Ibuprofen 20 % Stability Zero time

C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 26-10 Ibuprofen 30 days
Stability.seq

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

Vial: 4

Sample amount: 0.1013



1: 230 nm,

4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	6.42	2120965	20.1353	1.10	0.00

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June 24-10 Ibuprofen Stability
60 days 101-Repl

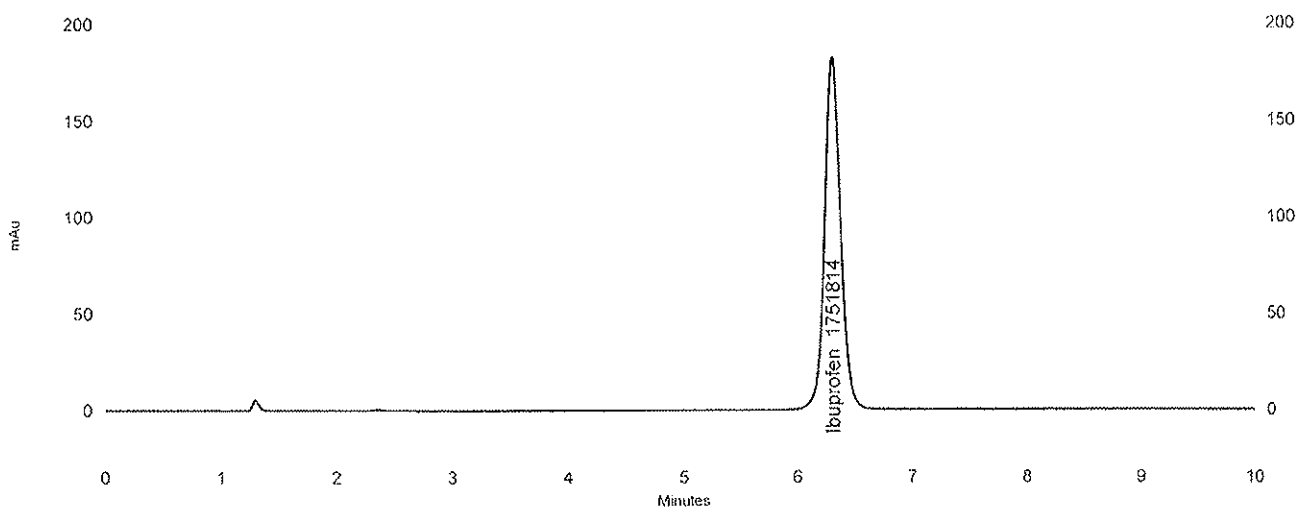
Sample ID: Ibuprofen Standards

C:\CLASS-VP\Sequence\2010\June\HPLC 3\June 24-10 Ibuprofen 60 days.seq

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

Vial: 2

Sample amount: 1



1: 230 nm,

4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	6.30	1751814	0.1001 CAL	1.06	0.00

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June 24-10 Ibuprofen Stability
60 days 103

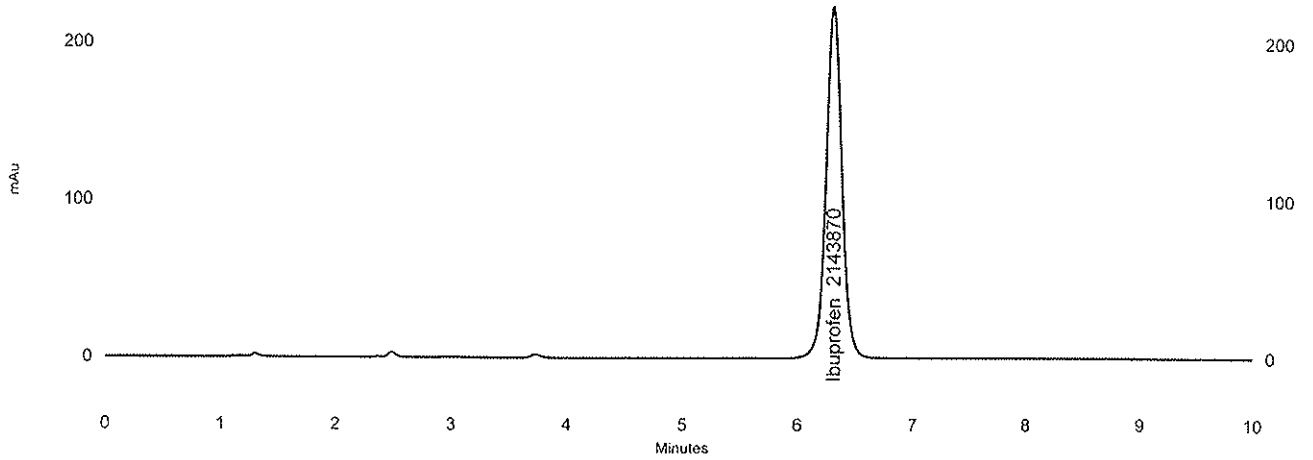
Sample ID: Ibuprofen 20 % Stability 60 days

C:\CLASS-VP\Sequence\2010\June\HPLC 3\June 24-10 Ibuprofen 60 days.seq

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

Vial: 4

Sample amount: 0.1069



1: 230 nm,
4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	6.31	2143870	19.9175	1.06	0.00

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\July 30-10 Ibuprofen Stability
90 days 101-Rep1

Sample ID: Ibuprofen Standards

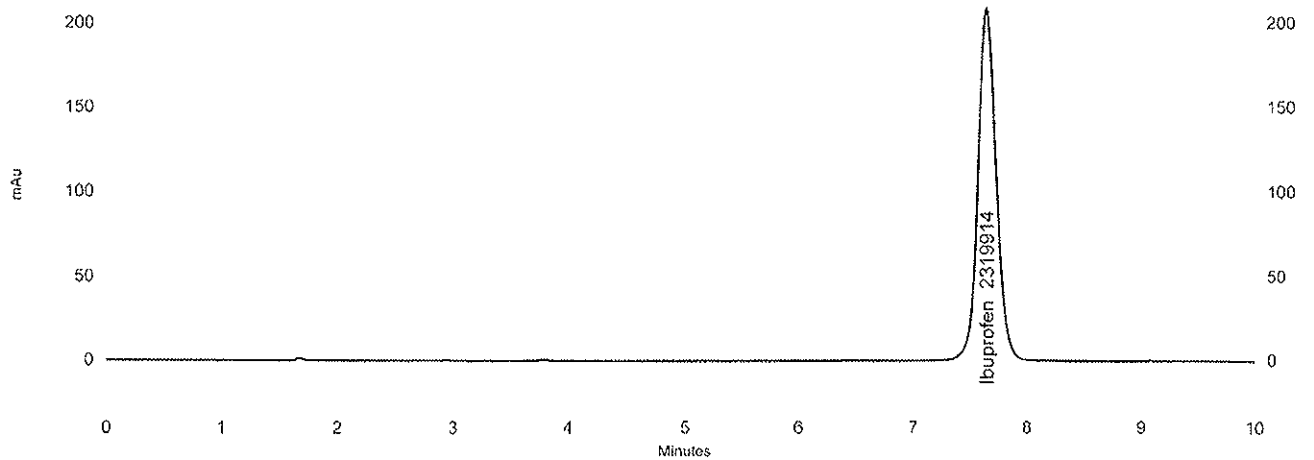
C:\CLASS-VP\Sequence\2010\July\HPLC 3\July 30-10 Ibuprofen 90 Days

Stability.seq

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

Vial: 2

Sample amount: 1



1: 230 nm,

4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	7.65	2319914	0.1001 CAL	1.06	0.00

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\July 30-10 Ibuprofen Stability
90 days 103

Sample ID: Ibuprofen 20 % Stability 90 days

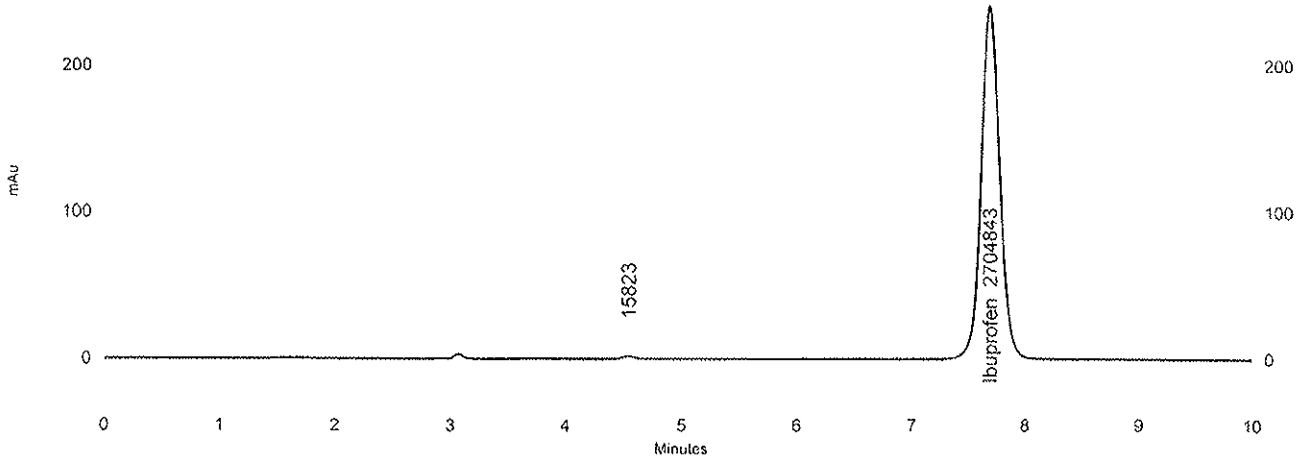
C:\CLASS-VP\Sequence\2010\July\HPLC 3\July 30-10 Ibuprofen 90 Days

Stability.seq

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

Vial: 4

Sample amount: 0.118



1: 230 nm,

4 nm

Results

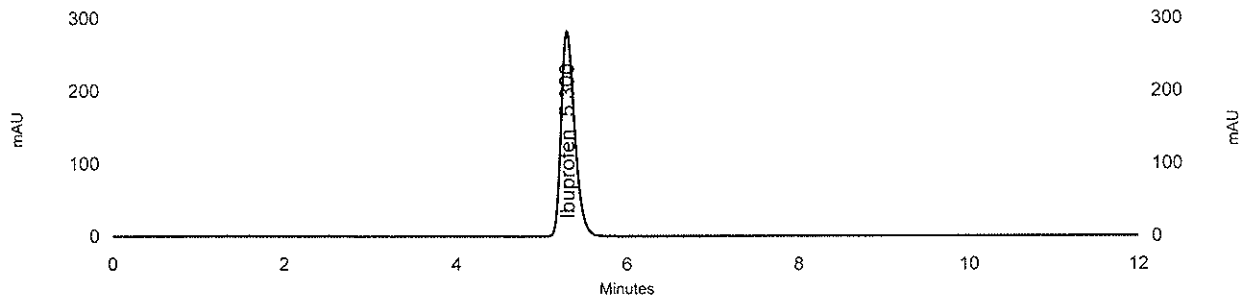
Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	7.69	2704843	19.7082	1.06	12.99

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\September 07-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 07-10 Ibuprofen 002-Rep1
Acquired: 9/7/2010 1:04:47 PM
Printed: 9/7/2010 3:26:12 PM
Vial: 3



SPD-20AV
Ch1-230nm
Results

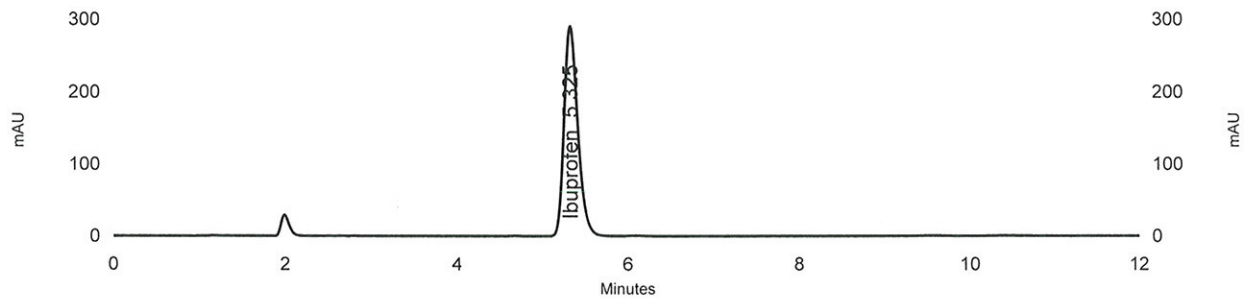
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		282454	3111586	0.010 CAL

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

30 days stability sample

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\September 07-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 07-10 Ibuprofen 004
Acquired: 9/7/2010 2:20:42 PM
Printed: 9/7/2010 3:26:36 PM
Vial: 5



SPD-20AV
Ch1-230nm
Results

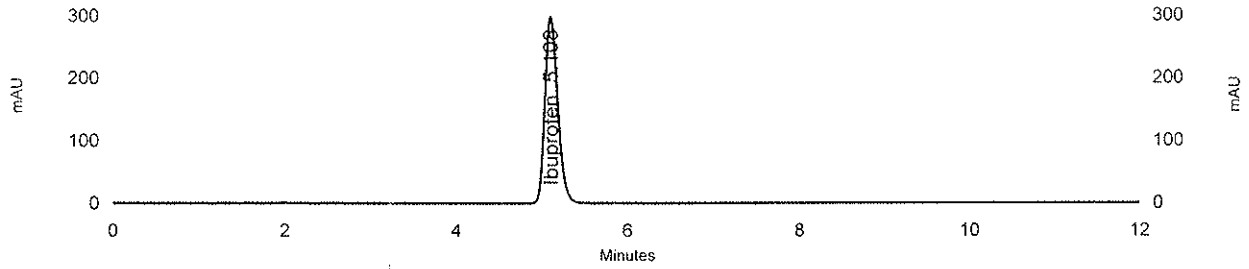
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		290531	3218481	10.252

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\October\HPLC 4\October 13-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 13-10 Ibuprofen 001-Rep1
Acquired: 10/13/2010 1:16:36 PM
Printed: 10/13/2010 4:06:25 PM
Vial: 2



SPD-20AV
Ch1-230nm
Results

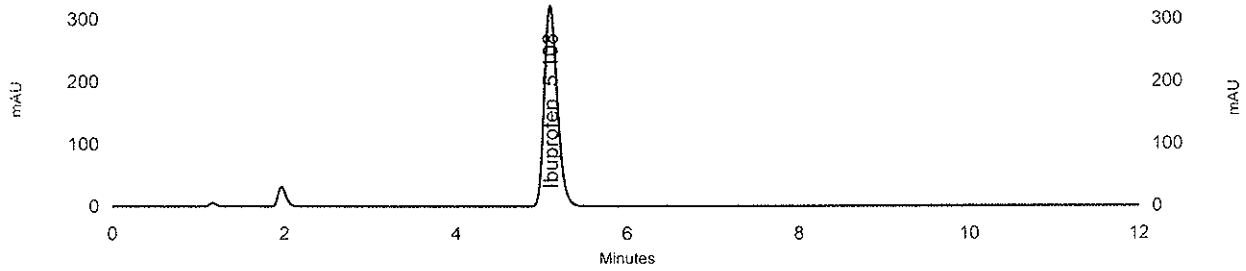
Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		298134	3126599	0.103 CAL

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

60 days stability sample

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Ibuprofen method.met
Sequence: C:\CLASS-VP\Sequence\2010\October\HPLC 4\October 13-10 ibuprofen.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\September 13-10 Ibuprofen 003
Acquired: 10/13/2010 2:32:35 PM
Printed: 10/13/2010 4:06:40 PM
Vial: 4



SPD-20AV
Ch1-230nm
Results

Name	Retention Time	Height	Area	ESTD concentration
Ibuprofen		321247	3376367	10.824

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\Nov 15-10 Ibuprofen Stability
90 days 01-Repl

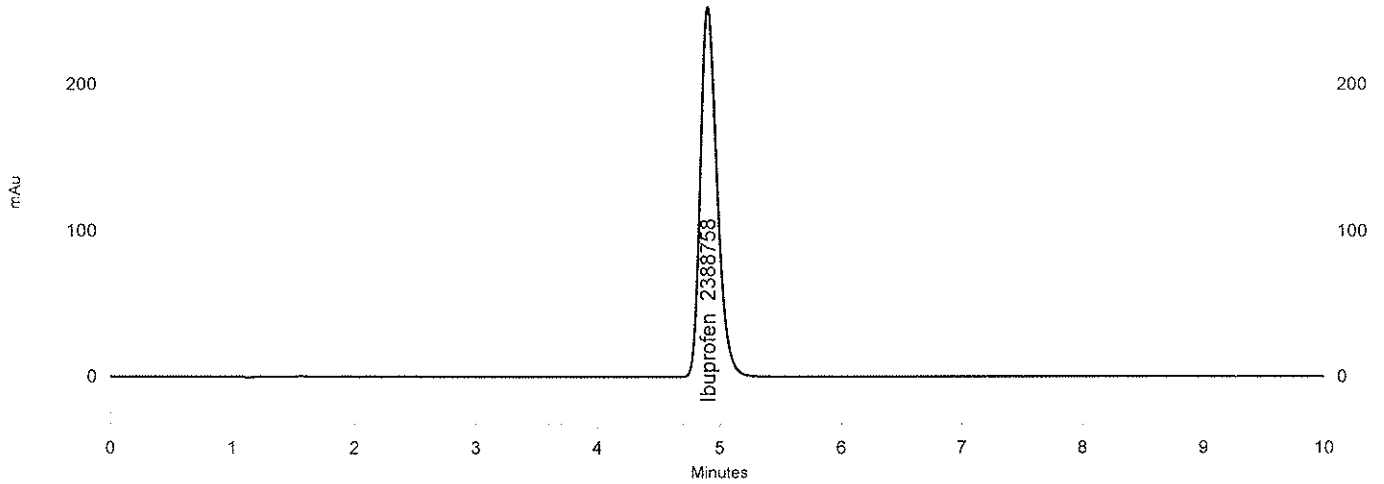
Sample ID: Ibuprofen Standards

C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 3\Nov 15-10 Ibuprofen
90days stability.seq

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

Vial: 2

Sample amount: 1



1: 230 nm,
4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	4.91	2388758	0.1001 CAL	1.25	0.00

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\Nov 15-10 Ibuprofen Stability
90 days 03

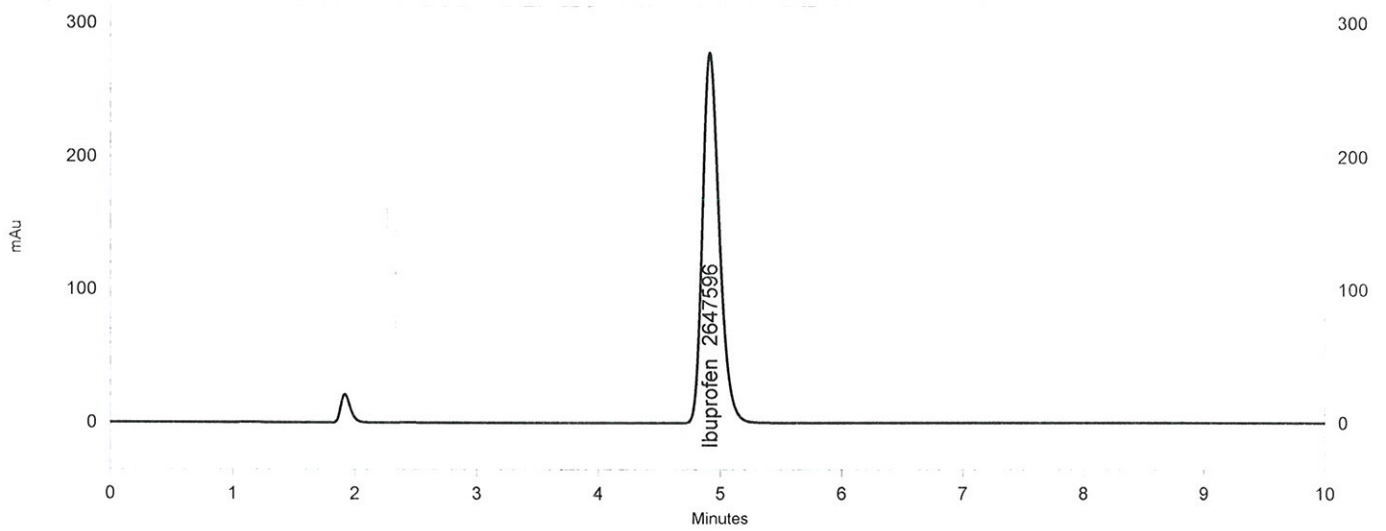
Sample ID: Ibuprofen 10% Stability 90 days

C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 3\Nov 15-10 Ibuprofen
90days stability.seq

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

Vial: 4

Sample amount: 0.1114



1: 230 nm,

4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Ibuprofen	4.92	2647596	9.9526	1.27	0.00