

Piroxicam:

0.25g Piroxicam raw drug powder from Spectrum chemical (part number P1198, Lot # VF1070) was added to 50.00g Humco LipoBase Heavy (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 0.5% 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, and Humco PLO 20 Flowable (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 0.5% w/w, stability-indicating HPLC analysis found less than 2% Piroxicam loss in Humco LipoBase Heavy at 90 days.

Compounded at 1.0% w/w, stability-indicating HPLC analysis found negligible Ketoprofen loss in Humco PLO 20 at 90 days.

Compounded at 2.0% w/w, stability-indicating HPLC analysis found less than 10% Ketoprofen loss in Humco PLO 20 Flowable at 60 days.

Attached are 6 chromatographs of Humco LipoBase Heavy showing in order: Initial Standard, Initial Sample, 56-Day Standard, 56-Day Sample, 90-Day Standard, and 90-Day Sample.

Attached are 8 chromatographs of Humco PLO 20 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 PLO 20 Flowable showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, and 60-Day Sample.

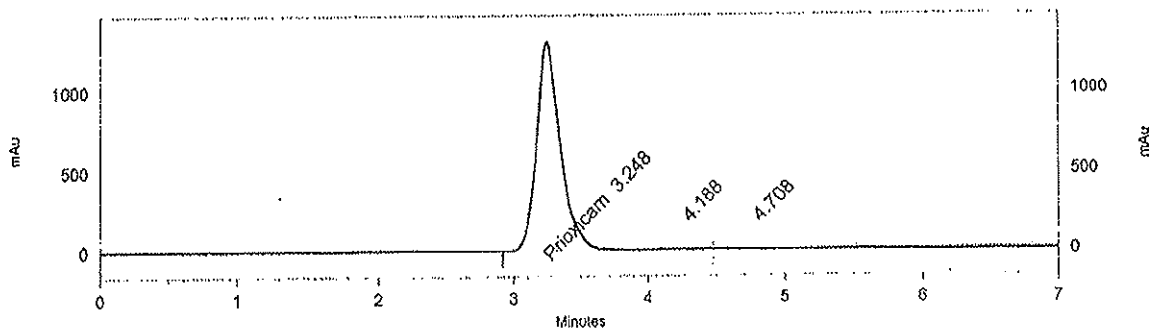
HUMCO HOLDING GROUP

Sample: Piroxicam Standard 5

Method: C:\CLASS-VP\Methods\Compounding\Piroxicam in Bases Final Method.met

Integration Method: C:\CLASS-VP\Methods\Compounding\Piroxicam in Bases  
Final Method.met

Vial: #61



1: 350 nm, 4 nm

Results

| Name      | Retention Time | Area     | % w/w     |
|-----------|----------------|----------|-----------|
| Piroxicam | 3.248          | 16204774 | 1.010 CAL |

HUMCO HOLDING GROUP

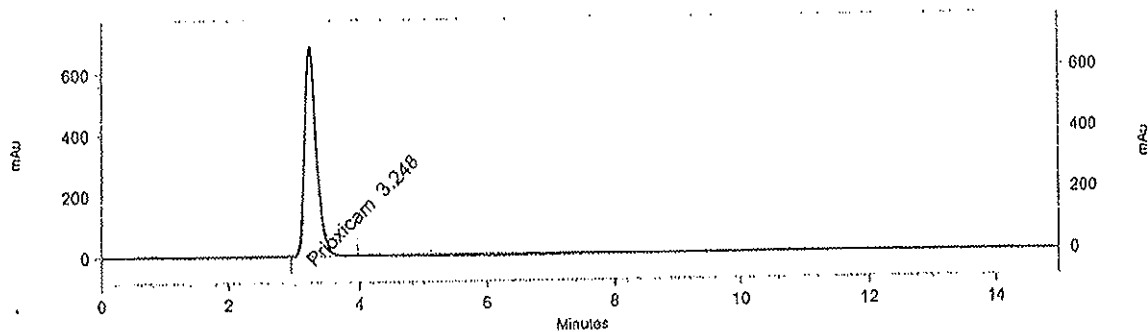
Sample: Piroxicam Lipo Closed

Method: C:\CLASS-VP\Methods\Compounding\Piroxicam in Bases Final Method.met

Integration Method: C:\CLASS-VP\Methods\Compounding\Piroxicam in Bases

Final Method.met

Vial: #62



1: 350 nm, 4 nm

Results

| Name      | Retention Time | Area    | % w/w |
|-----------|----------------|---------|-------|
| Piroxicam | 3.248          | 8686579 | 0.494 |

HUMCO HOLDING GROUP

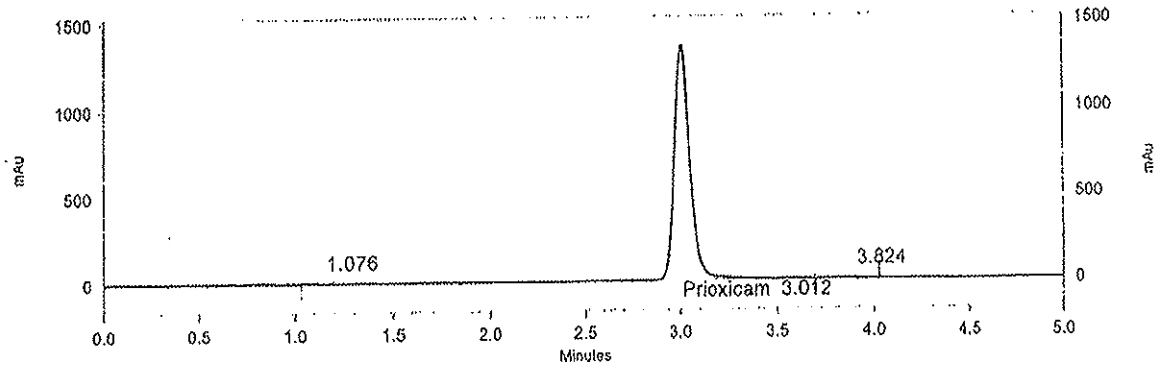
Sample: Piroxicam Standards 1-4

Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards Method.met

Integration Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards

Method.met

Vial: #16



5: 350 nm, 4 nm

Results  
Name

Retention Time

Area

ESTD  
concentration

Piroxicam

3.012

7708480

1.045 CAL

HUMCO HOLDING GROUP

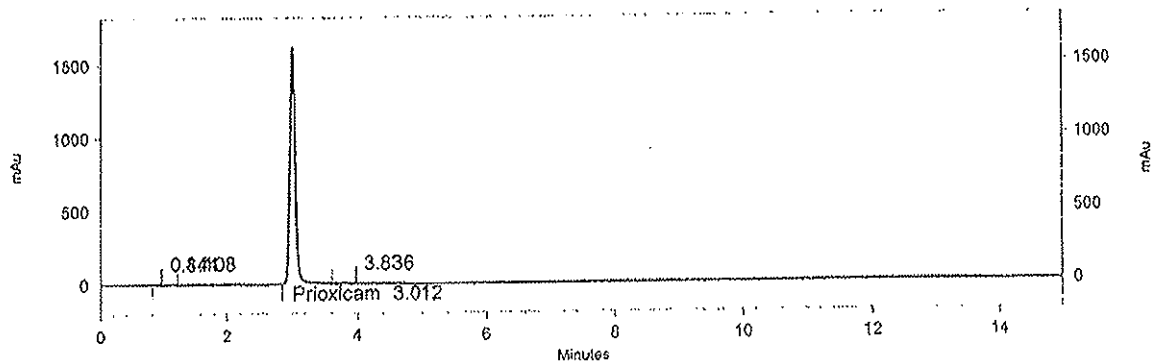
Sample: Piroxicam Lipo

Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards Method.met

Integration Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards

Method.met

Vial: #18



5: 350 nm, 4 nm

Results

Name

Retention Time

Area

ESTD  
concentration

Piroxicam

3.012

9449848

0.470

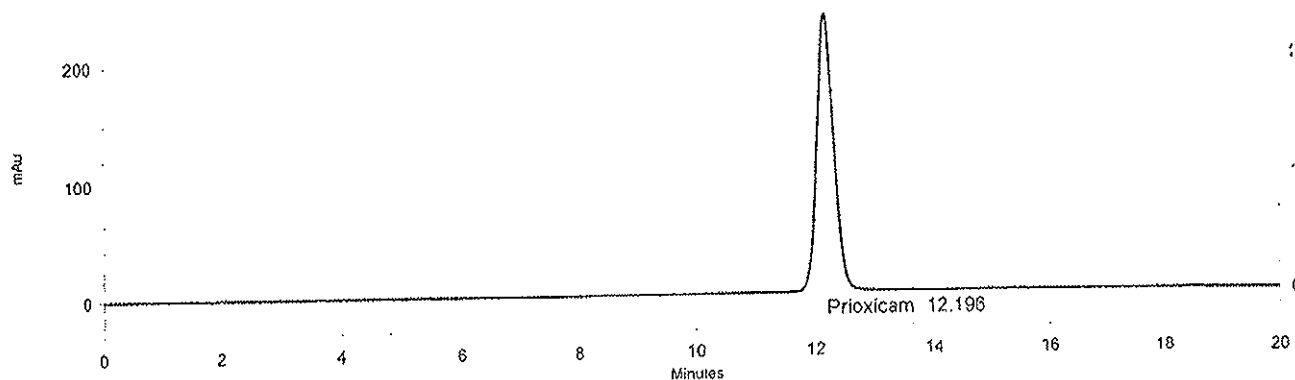
HUMCO HOLDING GROUP

Sample: Piroxicam

Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards Method.met

Integration Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards Method.met

Vial: #2



5: 350 nm, 4

nm Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) |
|-----------|----------------|---------|--------------------|------------------|
| Piroxicam | 12.196         | 4662464 | 1.000 CAL          | 0.00000          |

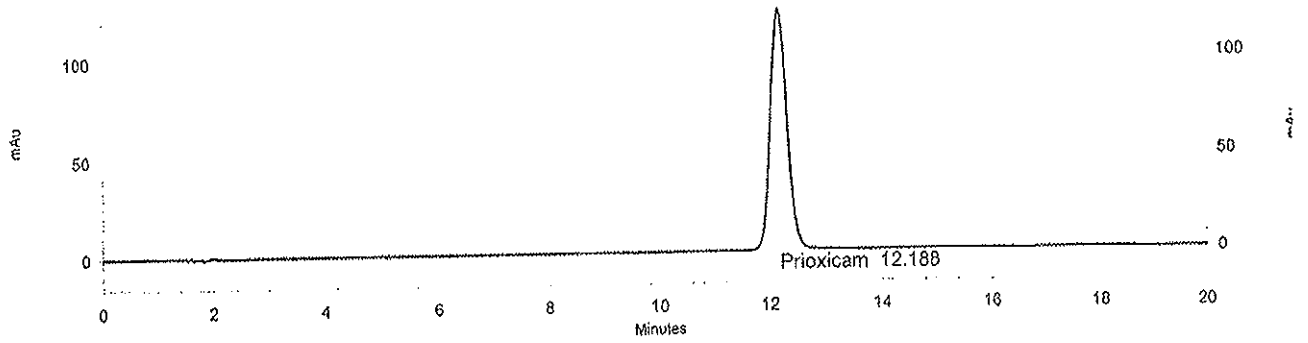
HUMCO HOLDING GROUP

Sample: Piroxicam Sp 06/07/07 (0.5%)

Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards Method.met

Integration Method: C:\CLASS-VP\Methods\Compounding\Piroxicam Standards Method.met

Vial: #4



5: 350 nm, 4

nm Results  
Name

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) |
|-----------|----------------|---------|--------------------|------------------|
| Piroxicam | 12.188         | 2540162 | 0.489              | 0.00000          |

HUMCO HOLDING GROUP

Sample: Piroxicam

Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

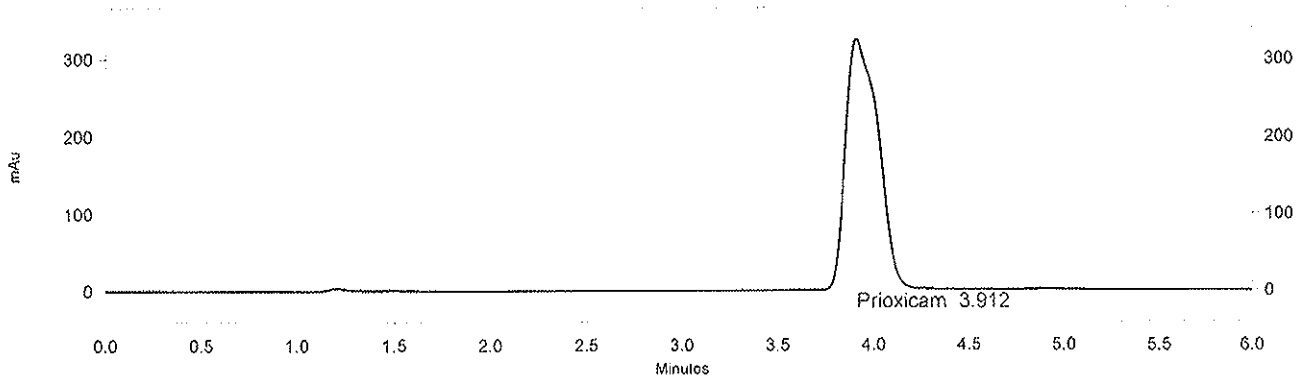
Standards Method.met

Integration Method:

C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

Standards Method.met

Vial: #2



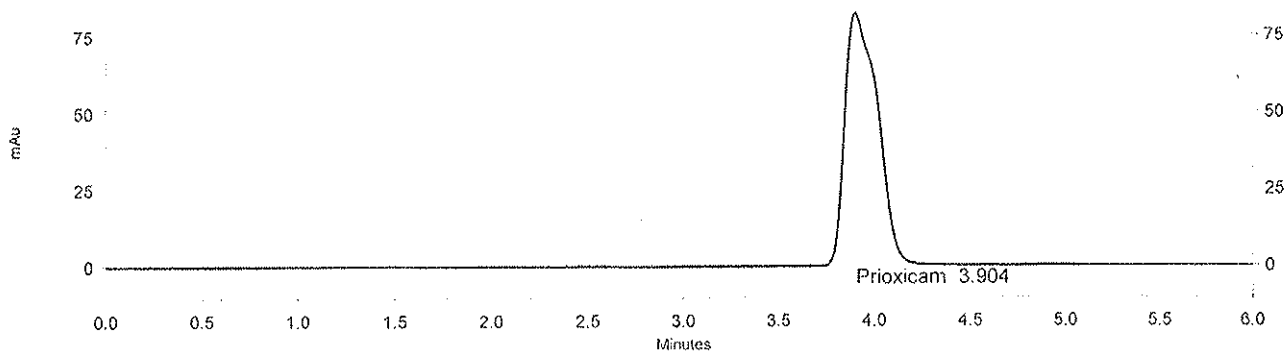
5: 350 nm, 4

nm Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) |
|-----------|----------------|---------|--------------------|------------------|
| Piroxicam | 3.912          | 3845806 | 0.100 CAL          | 0.00000          |



HUMCO HOLDING GROUP  
 Sample: Piroxicam Sp 1%  
 Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Integration Method:  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Vial: #4



5: 350 nm, 4

nm Results

| Name      | Retention Time | Area   | ESTD concentration | Resolution (USP) |
|-----------|----------------|--------|--------------------|------------------|
| Piroxicam | 3.904          | 983931 | 1.012              | 0.00000          |

HUMCO HOLDING GROUP

Sample: Piroxicam

Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

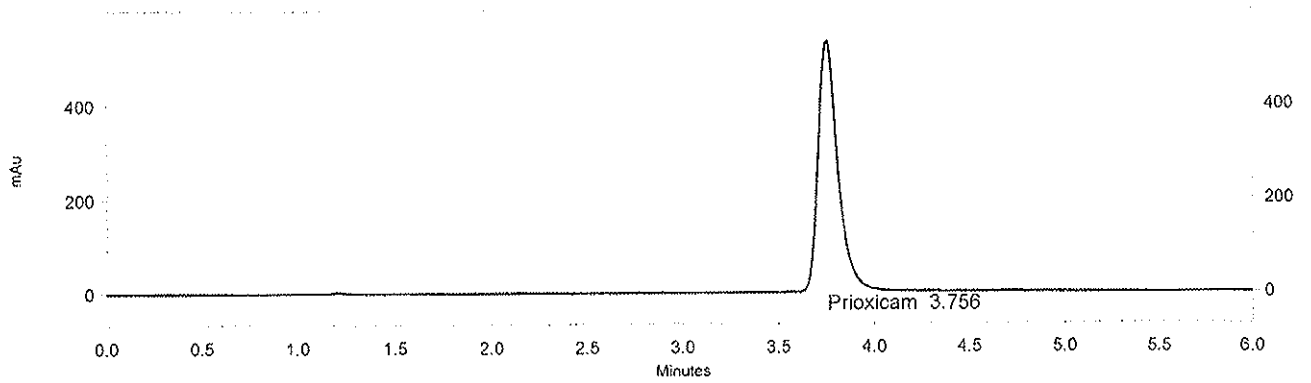
Standards Method.met

Integration Method:

C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

Standards Method.met

Vial: #2



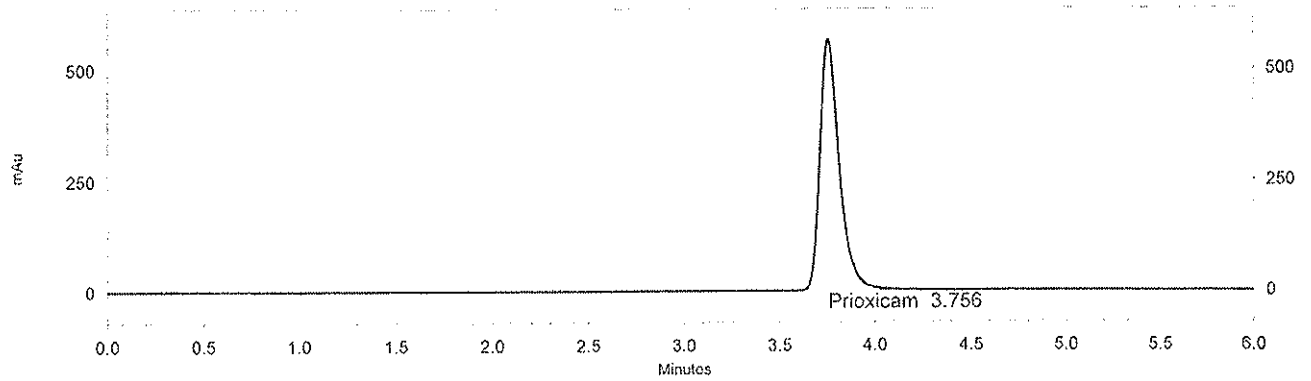
5: 350

nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 3.756          | 3846049 | 0.100 CAL          | 0.00000          | 1.368     |

HUMCO HOLDING GROUP  
 Sample: Piroxicam Sp 13  
 Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Integration Method:  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Vial: #4

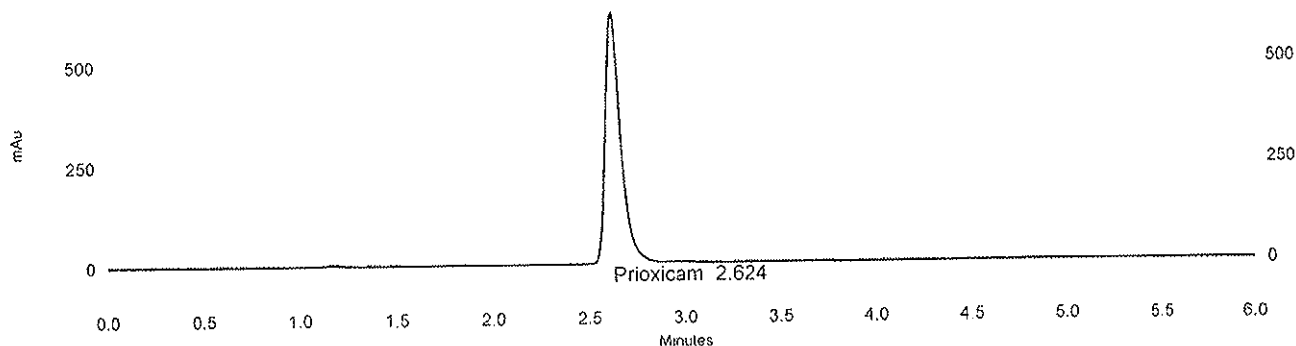


5: 350  
 nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 3.756          | 4053815 | 1.048              | 0.00000          | 1.403     |

HUMCO HOLDING GROUP  
 Sample: Piroxicam  
 Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Integration Method:  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Vial: #2



S: 350  
 nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 2.624          | 3480171 | 0.100 CAL          | 0.00000          | 1.433     |

HUMCO HOLDING GROUP

Sample: Piroxicam Sp 1% 60 days

Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

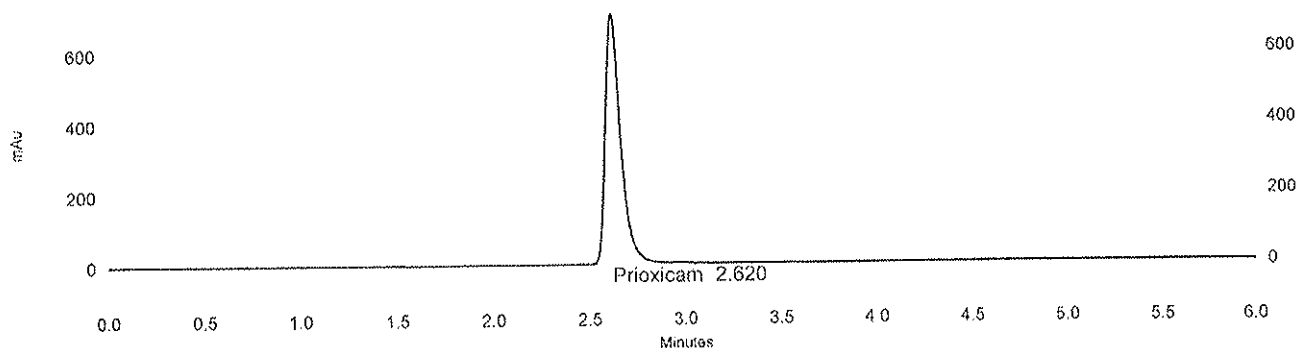
Standards Method.met

Integration Method:

C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

Standards Method.met

Vial: #4



5: 350  
nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 2.620          | 3936058 | 1.051              | 0.00000          | 1.477     |

HUMCO HOLDING GROUP

Sample: Piroxicam

Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

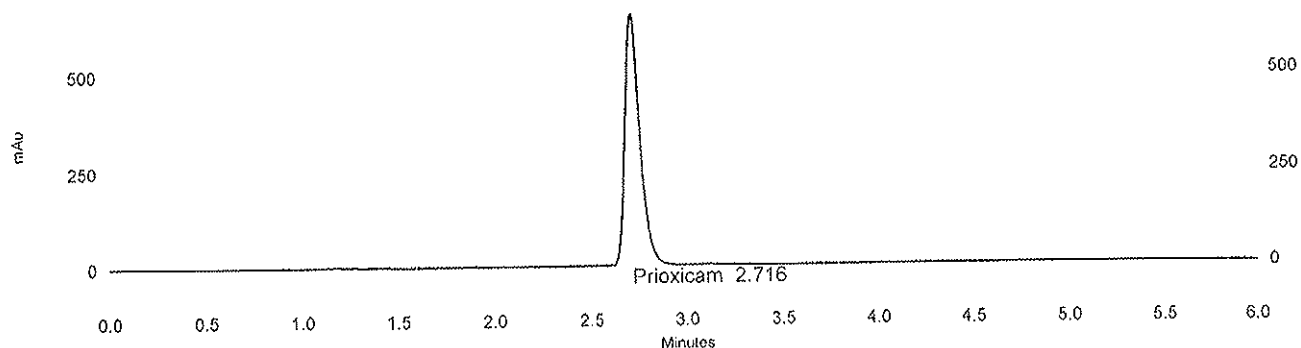
Standards Method.met

Integration Method:

C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

Standards Method.met

Vial: #2



5: 350  
nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 2.716          | 3501601 | 0.100 CAL          | 0.00000          | 1.340     |

HUMCO HOLDING GROUP

Sample: Piroxicam Sp 1% 90 days

Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

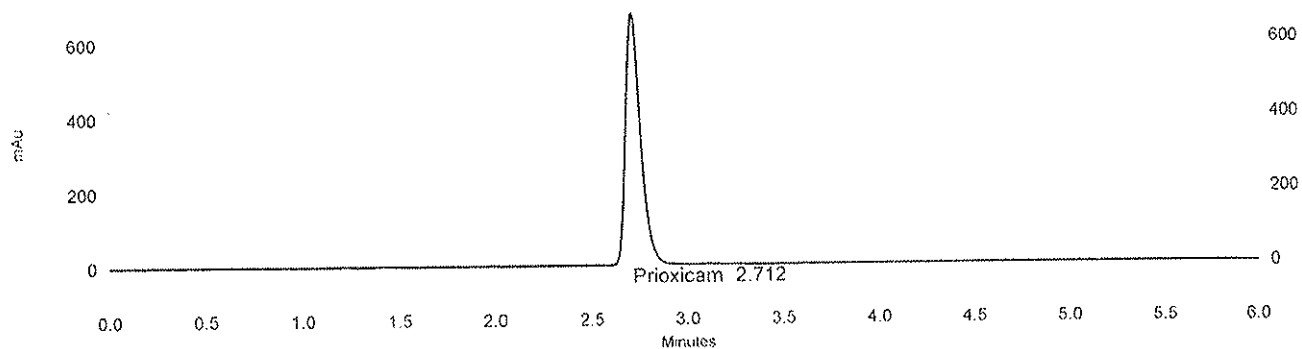
Standards Method.met

Integration Method:

C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam

Standards Method.met

Vial: #4

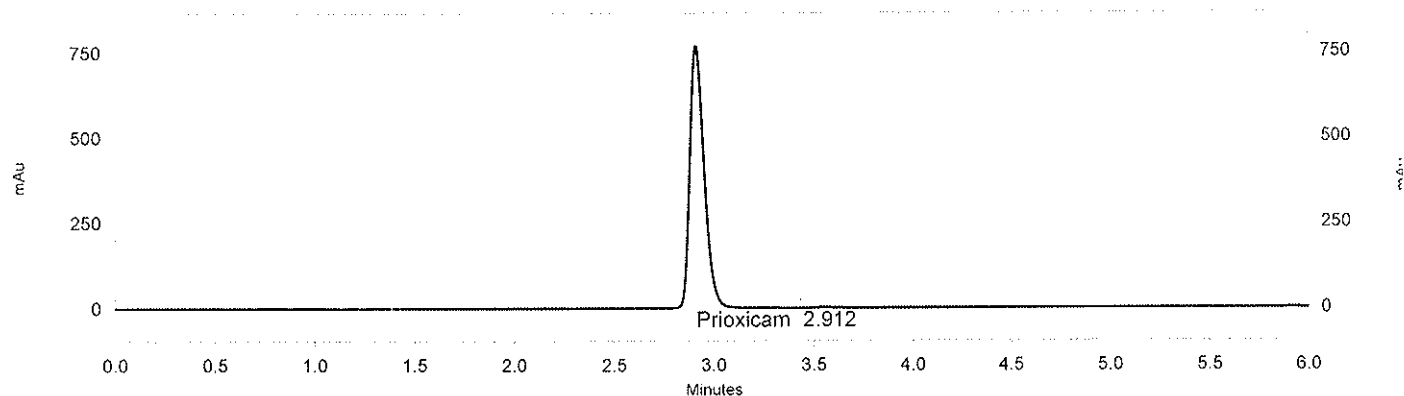


5: 350  
nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 2.712          | 3623575 | 0.953              | 0.00000          | 1.398     |

HUMCO HOLDING GROUP  
 Sample: Piroxicam  
 Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Integration Method:  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Vial: #2

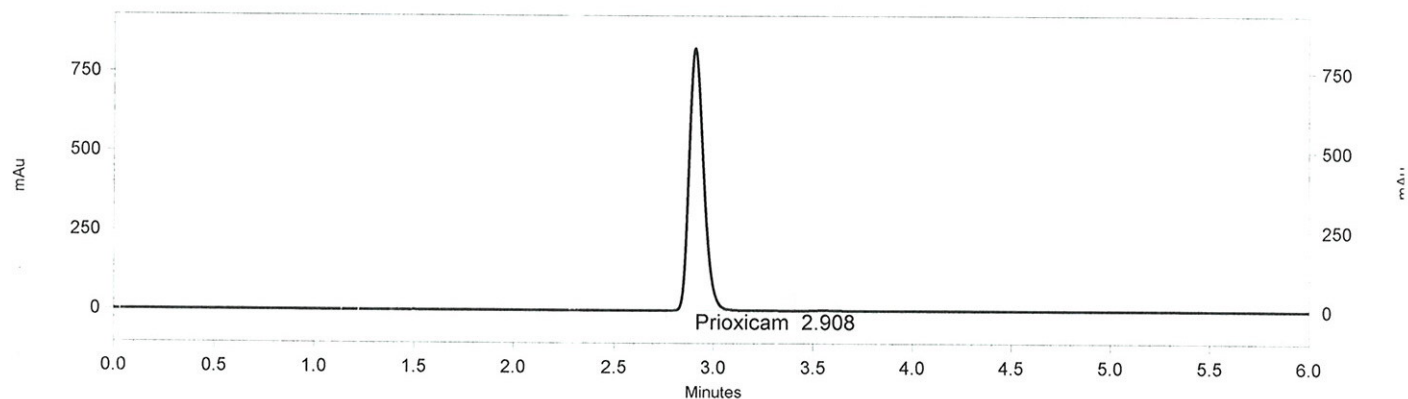


5: 350  
 nm, 4 nm  
 Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 2.912          | 3837852 | 0.100 CAL          | 0.00000          | 1.332     |



HUMCO HOLDING GROUP  
 Sample: Piroxicam Sp 1  
 Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Integration Method:  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Vial: #4



5: 350  
 nm, 4 nm  
 Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 2.908          | 4245590 | 2.106              | 0.00000          | 1.274     |

HUMCO HOLDING GROUP

Sample: Piroxicam Standard

Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Prioxicam

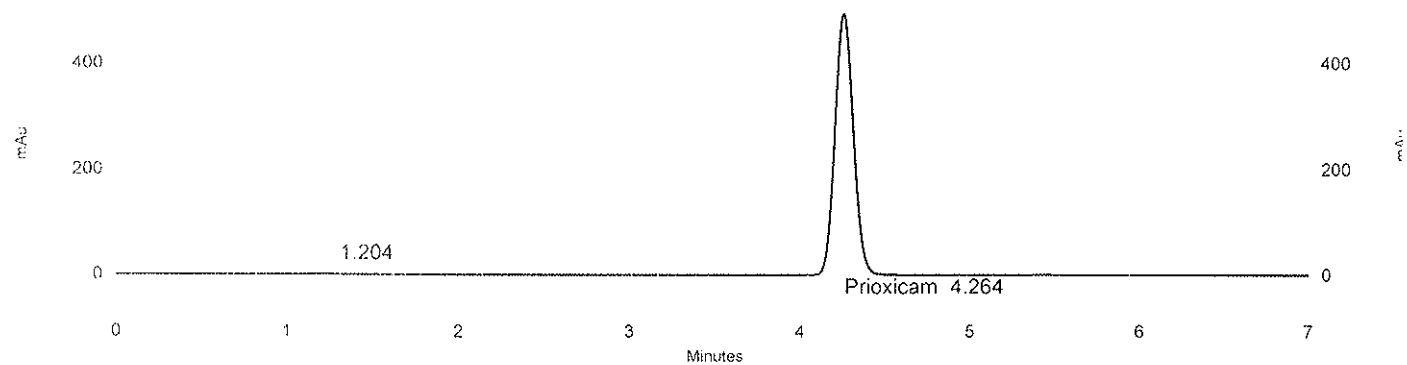
Standards Method.met

Integration Method:

C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Prioxicam

Standards Method.met

Vial: #2



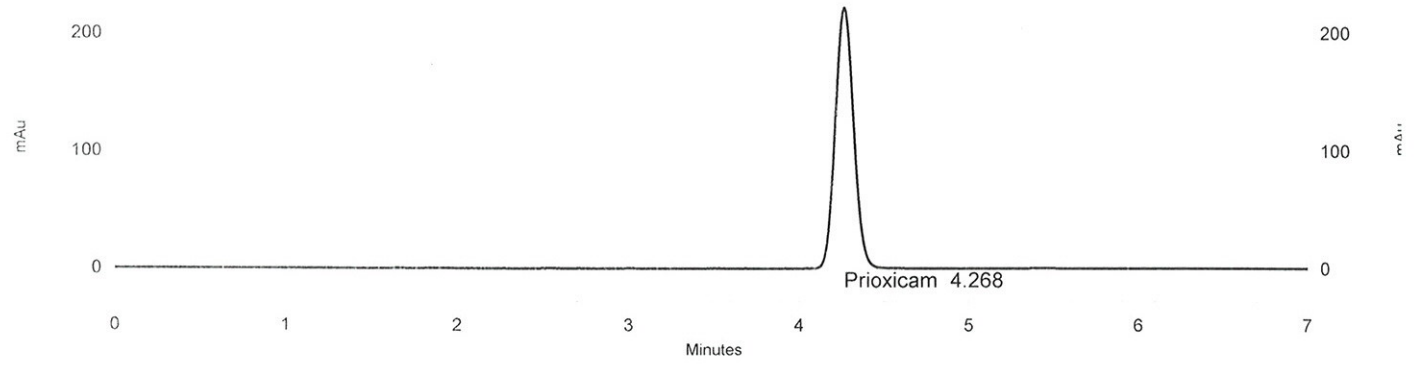
5: 350

nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Prioxicam | 4.264          | 3725662 | 0.100 CAL          | 15.08241         | 1.060     |

HUMCO HOLDING GROUP  
 Sample: Piroxicam Stability 30 days  
 Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Integration Method:  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Vial: #4

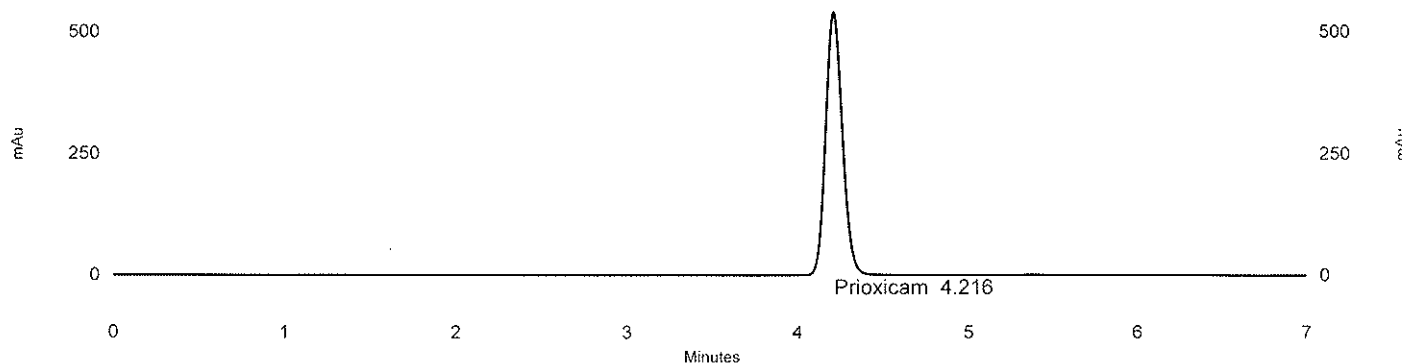


5: 350  
 nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 4.268          | 1668569 | 2.074              | 0.00000          | 1.088     |

HUMCO HOLDING GROUP  
 Sample: Piroxicam Standard  
 Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Integration Method:  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
 Standards Method.met  
 Vial: #2



5: 350  
 nm, 4 nm  
 Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 4.216          | 3683705 | 0.100 CAL          | 0.00000          | 1.093     |

HUMCO HOLDING GROUP

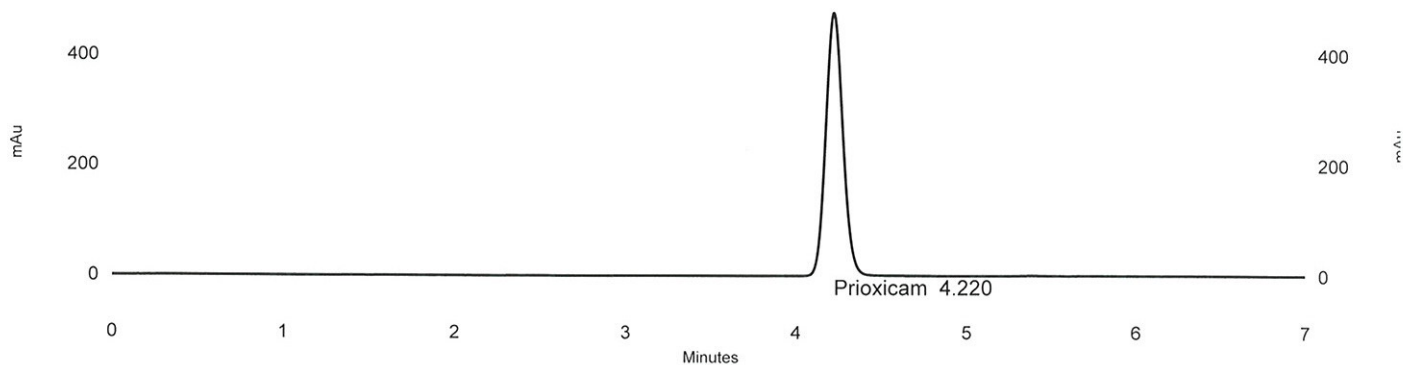
Sample: Piroxicam Stability 30 days

Method: C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
Standards Method.met

Integration Method:

C:\CLASS-VP\Enterprise\Projects\Default\Method\Compounding\Piroxicam  
Standards Method.met

Vial: #6



5: 350  
nm, 4 nm

Results

| Name      | Retention Time | Area    | ESTD concentration | Resolution (USP) | Asymmetry |
|-----------|----------------|---------|--------------------|------------------|-----------|
| Piroxicam | 4.220          | 3340122 | 1.895              | 0.00000          | 1.118     |