

#### Phenytoin:

2.00g Phenytoin raw drug powder from Spectrum Chemical (part number PH161, Lot # YT3036) was added to 50.00g Humco Vanishing Base II (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 4.0% w/w. This emulsion was then stored at room temperature in the same 50/70 mL Unguator container.

Similar steps were used in preparing samples in Humco MultiBase (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 4.0% w/w, stability-indicating HPLC analysis found less than 2% Phenytoin loss in Humco Vanishing Base II at 90 days.

Compounded at 8.0% w/w, stability-indicating HPLC analysis found less than 4% Phenytoin loss in Humco MultiBase at 90 days.

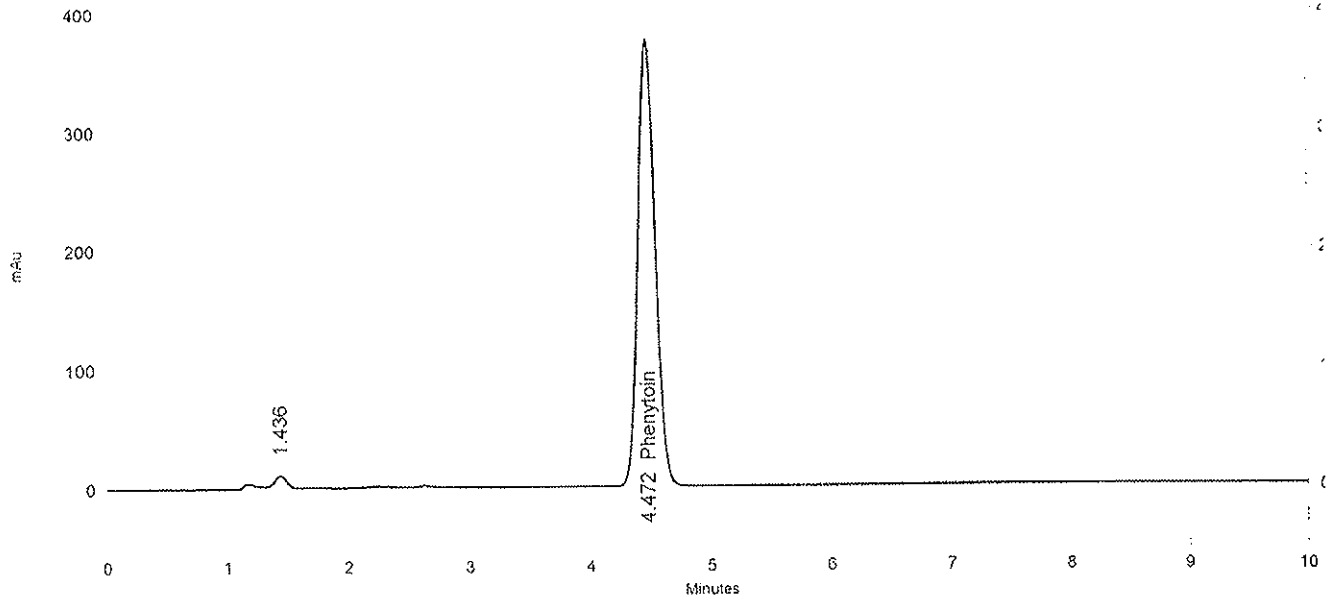
Attached are 8 chromatographs of Humco Vanishing Base II showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

Attached are 8 chromatographs of Humco MultiBase 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\Data\2009\July\HPLC 4\October15-09 Phenytoin Presicion 01-Rep1

Sample ID: Phenytoin St  
C:\CLASS-VP\Sequence\2009\October\HPLC 3\October 15-09 Phenytoin  
Precision.seq  
C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
Vial: 2  
Sample amount: 1



3: 220 nm,  
4 nm

Results

| Name      | Retention Time | Area    | mg / ml   | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|-----------|-----------|------------------|
| Phenytoin | 4.472          | 3677212 | 0.100 CAL | 1.04593   | 13.44989         |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\October15-09 Phenytoin Precision 08

Sample ID: Phenytoin Linearity 6

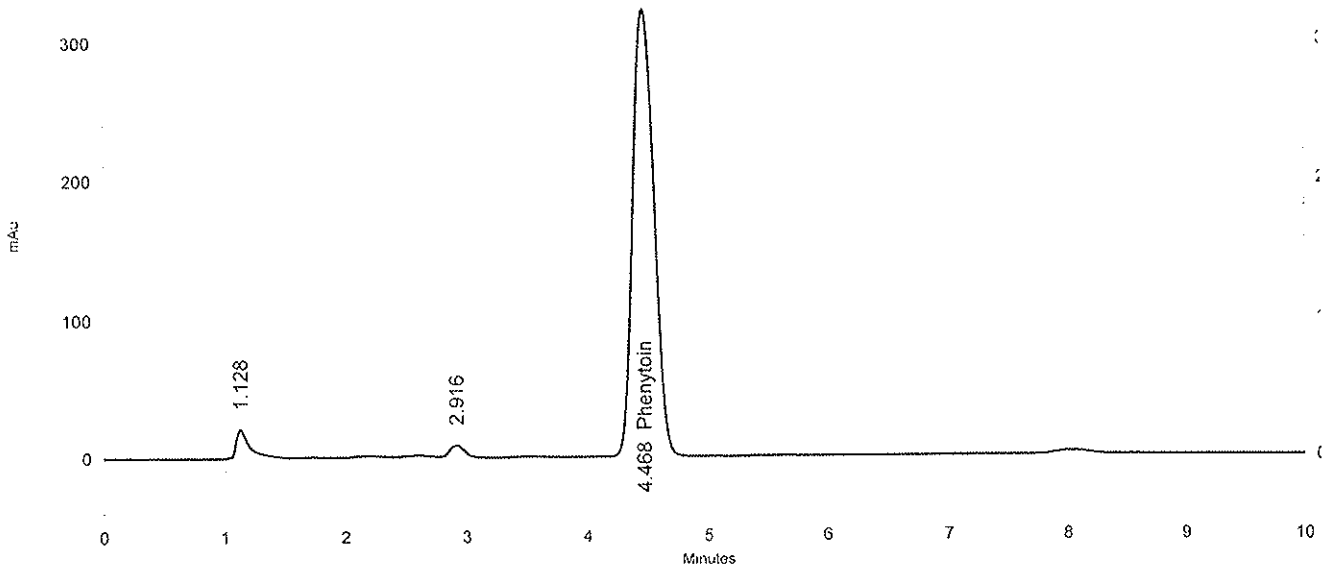
C:\CLASS-VP\Sequence\2009\October\HPLC 3\October 15-09 Phenytoin

Precision.seq

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

Vial: 9

Sample amount: 0.2583



3: 220 nm,

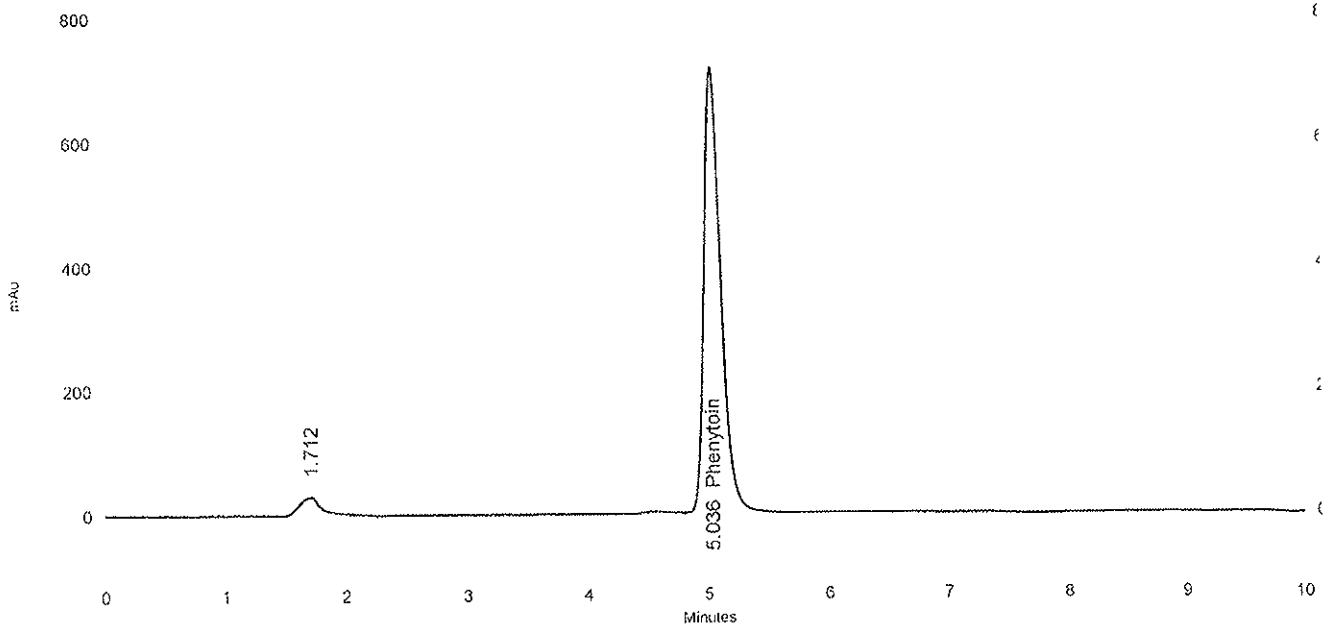
4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 4.468          | 3884284 | 4.096   | 1.07116   | 5.76608          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\November 16-09 Phenytoin 30 days  
stability 01-Rep1  
Sample ID: Phenytoin St  
C:\CLASS-VP\Sequence\2009\November\HPLC 3\November 16 Phenytoin 30 Days  
Stability.seq  
C:\CLASS-VP-Methods\HPLC3\Phenytoin.met  
Vial: 2  
Sample amount: 1



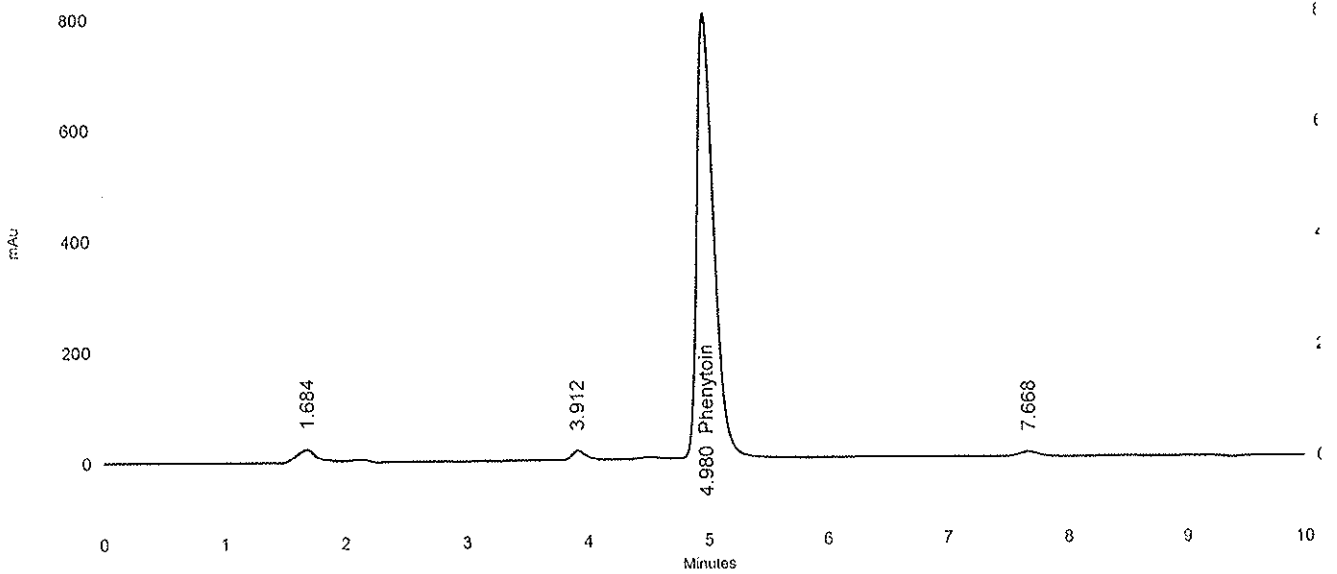
3: 220 nm,  
4 nm

## Results

| Name      | Retention Time | Area    | mg / ml   | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|-----------|-----------|------------------|
| Phenytoin | 5.036          | 7021240 | 0.100 CAL | 1.27624   | 11.50988         |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\November 16-09 Phenytoin 30 days  
stability 03  
Sample ID: Phenytoin 30 days Stability  
C:\CLASS-VP\Sequence\2009\November\HPLC 3\November 16 Phenytoin 30 Days  
Stability.seq  
C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
Vial: 4  
Sample amount: 0.139



3: 220 nm,  
4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 4.980          | 7838902 | 4.024   | 1.27320   | 4.61106          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\December 14-09 Phenytoin 60 days  
stability 01-Repl

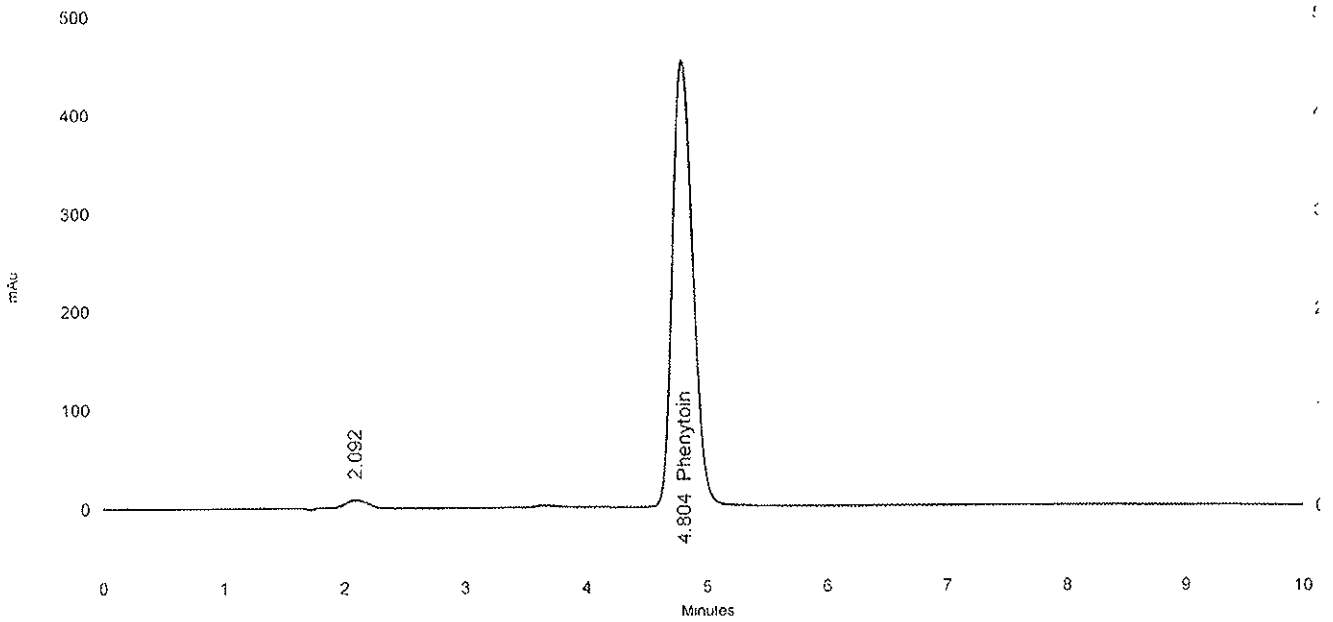
Sample ID: Phenytoin St

C:\CLASS-VP\Sequence\2009\December\HPLC 3\December 14-09 Phenytoin 60 days  
Stability.seq

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

Vial: 2

Sample amount: 1



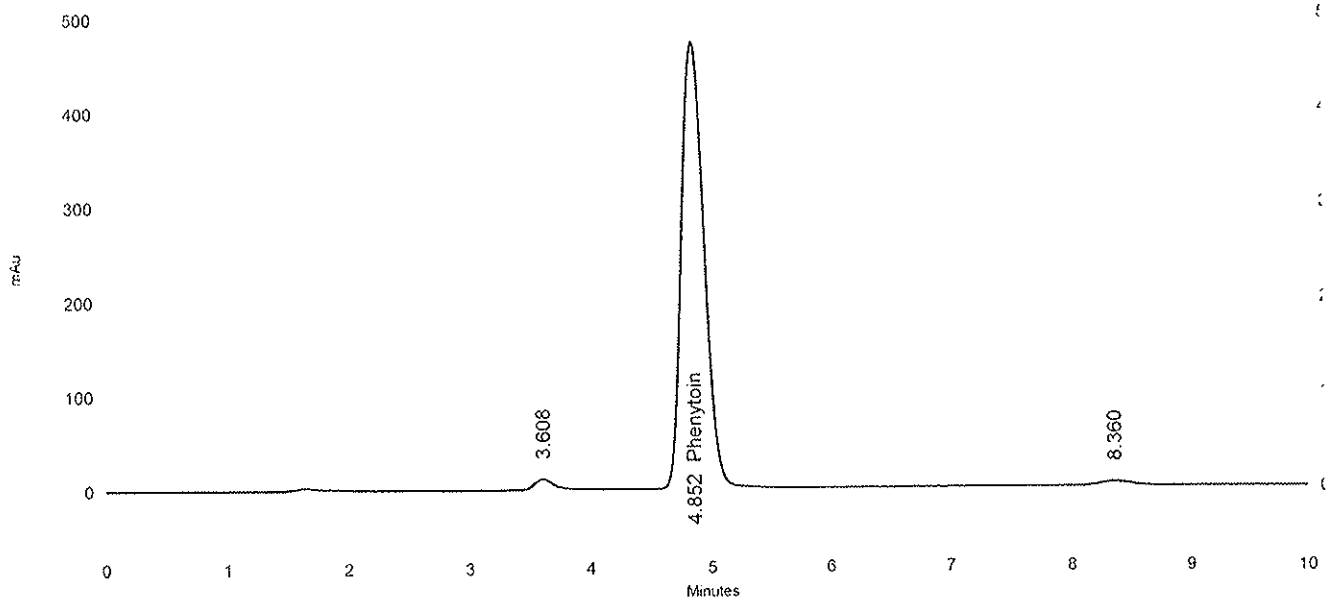
3: 220 nm,  
4 nm

Results

| Name      | Retention<br>Time | Area    | mg / ml   | Asymmetry | Resolution<br>(USP) |
|-----------|-------------------|---------|-----------|-----------|---------------------|
| Phenytoin | 4.804             | 5457385 | 0.100 CAL | 1.07303   | 7.88363             |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\December 14-09 Phenytoin 60 days  
stability 03  
Sample ID: Phenytoin 60 days Stability  
C:\CLASS-VP\Sequence\2009\December\HPLC 3\December 14-09 Phenytoin 60 days  
Stability.seq  
C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
Vial: 4  
Sample amount: 0.1386



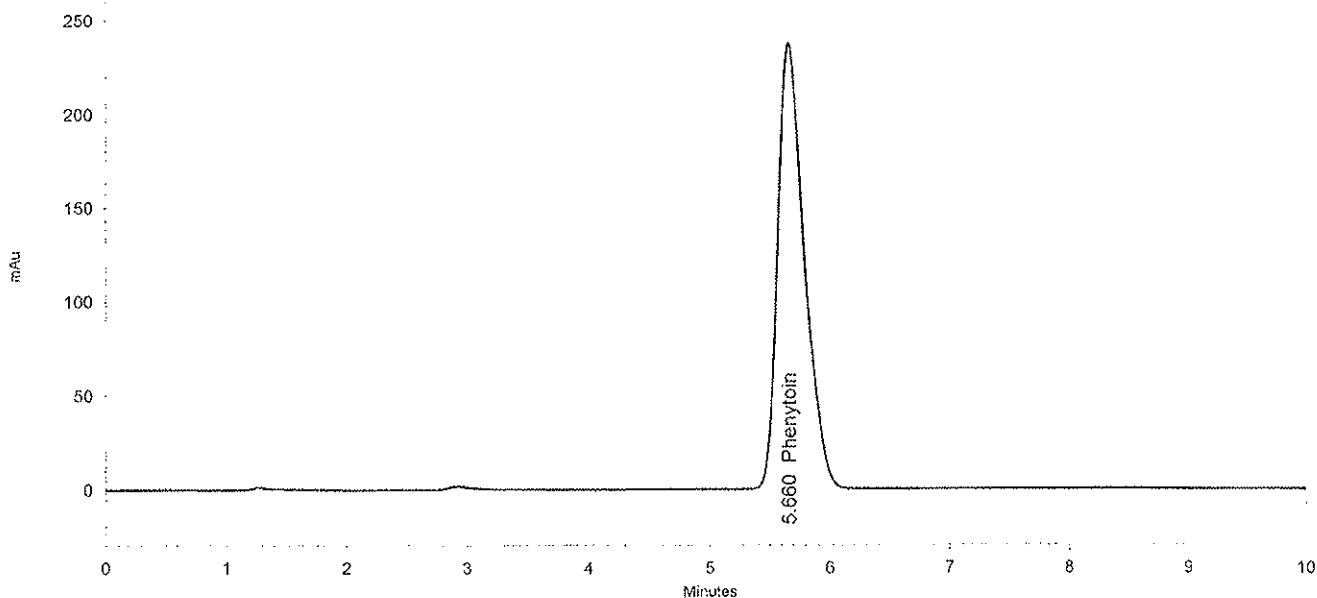
3: 220 nm,  
4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 4.852          | 6164853 | 4.081   | 1.11647   | 3.95184          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\January 13-10 Phenytoin stability  
01-Rep1  
Sample ID: Phenytoin St  
C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 13-10 Phenytoin 8% 0  
time.seq  
C:\CLASS-VP-Methods\HPLC3\Phenytoin.met  
Vial: 2  
Sample amount: 1



3: 220 nm,  
4 nm

Results

| Name      | Retention Time | Area    | mg / ml   | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|-----------|-----------|------------------|
| Phenytoin | 5.660          | 3643917 | 0.100 CAL | 1.32835   | 0.00000          |



# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\January 13-10 Phenytoin stability 03

Sample ID: Phenytoin 4% 90 days Stability

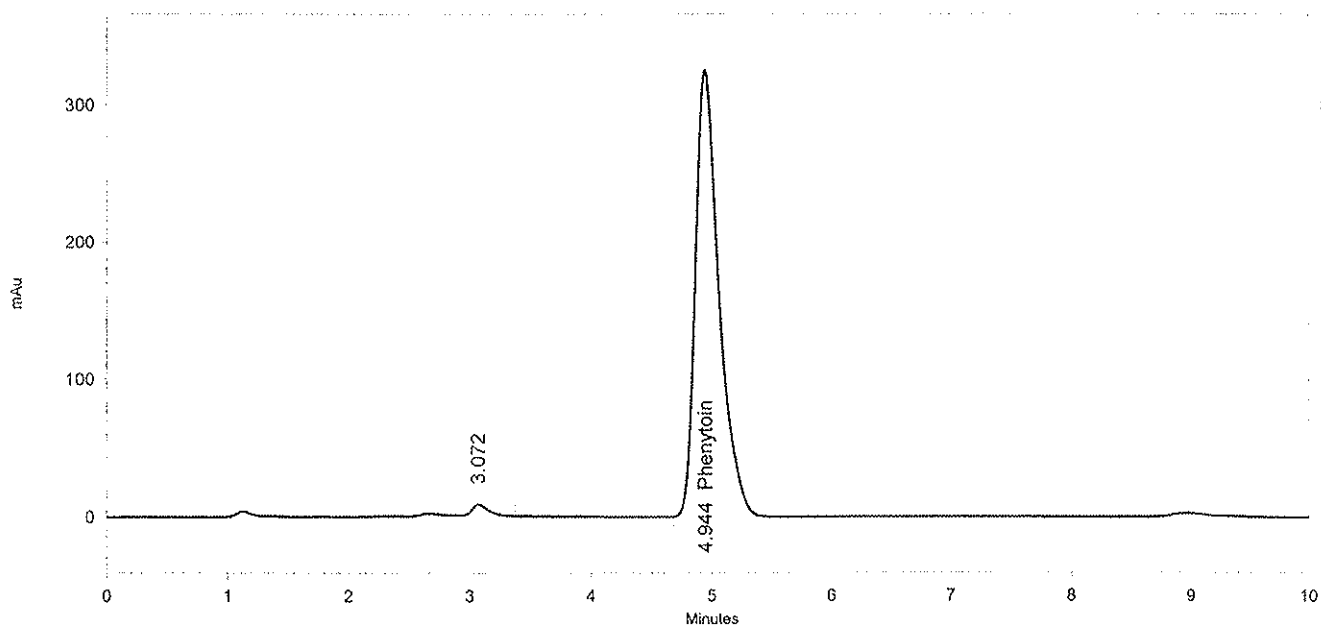
C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 13-10 Phenytoin 8% 0

time.seq

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

Vial: 4

Sample amount: 0.1488



3: 220 nm,

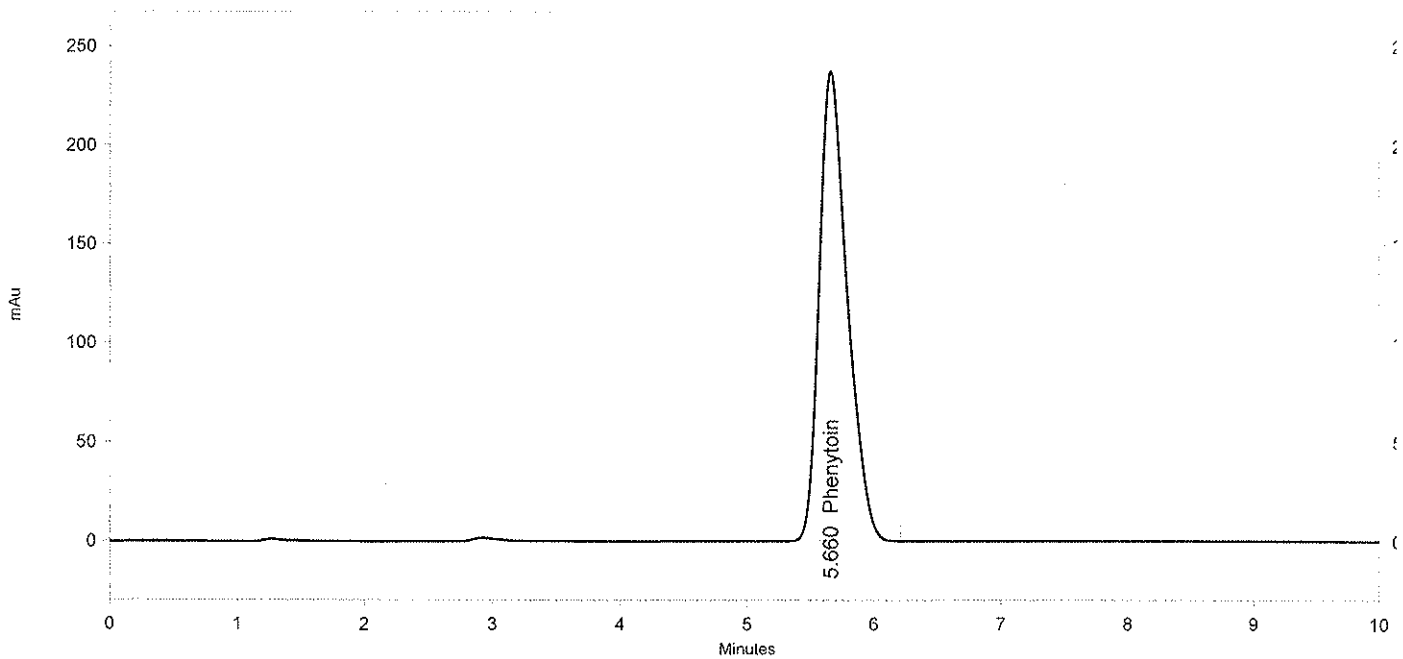
4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 4.944          | 4442491 | 4.073   | 1.42802   | 6.37671          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\January 13-10 Phenytoin stability  
01-Rep1  
Sample ID: Phenytoin St  
C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 13-10 Phenytoin 8% 0  
time.seq  
C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
Vial: 2  
Sample amount: 1



3: 220 nm,  
4 nm  
Results

| Name      | Retention Time | Area    | mg / ml   | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|-----------|-----------|------------------|
| Phenytoin | 5.660          | 3643917 | 0.100 CAL | 1.32835   | 0.00000          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\January 13-10 Phenytoin stability 04

Sample ID: Phenytoin 8% Zero time Stability

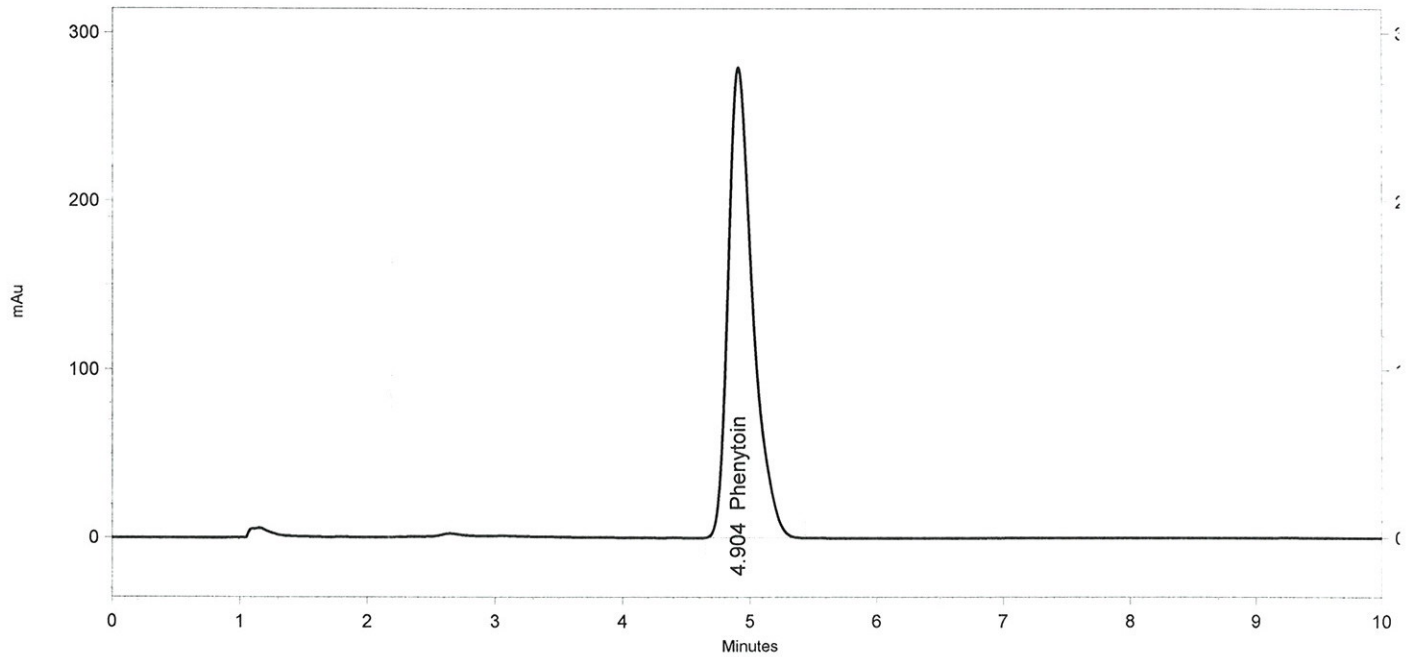
C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 13-10 Phenytoin 8% 0

time.seq

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

Vial: 5

Sample amount: 0.126



3: 220 nm,

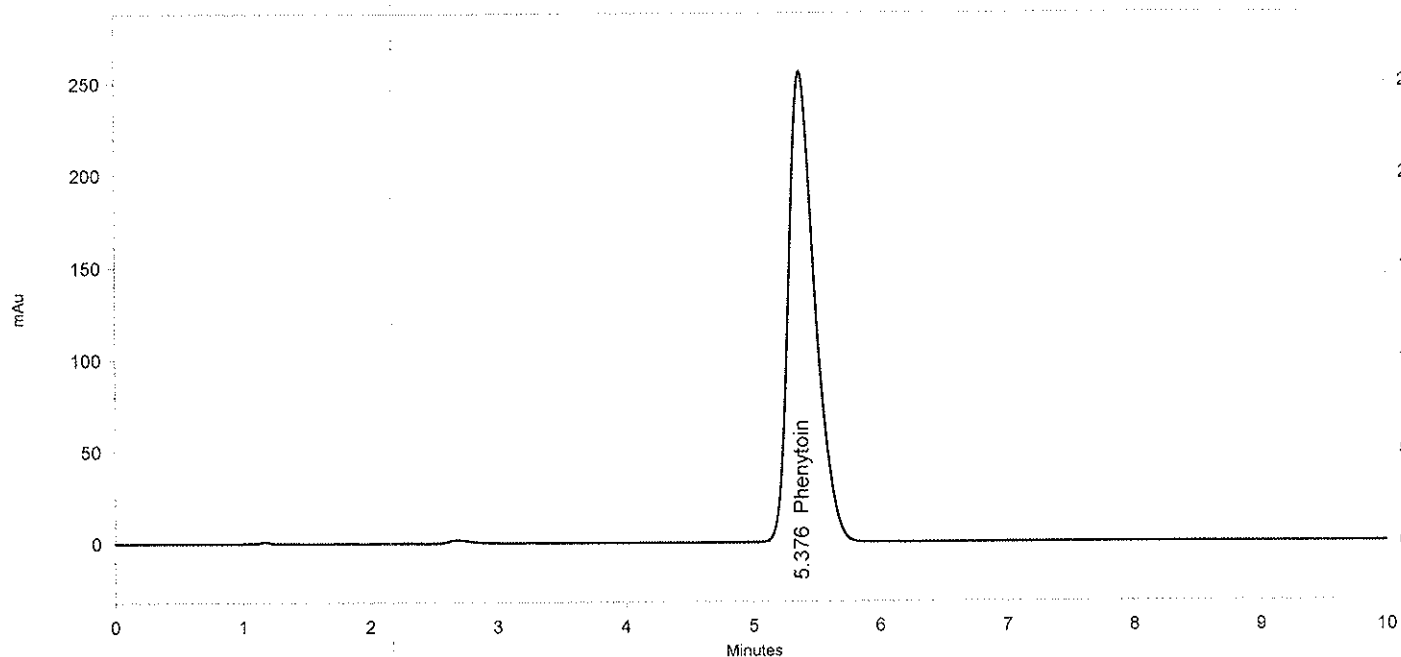
4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 4.904          | 3752411 | 8.126   | 1.43667   | 0.00000          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\February 12-10 Phenytoin 30 days  
stability 01-Rep1  
Sample ID: Phenytoin St  
C:\CLASS-VP\Sequence\2010\February\HPLC 3\February 12-10 Phenytoin 8% 30  
days Stability.seq  
C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
Vial: 2  
Sample amount: 1



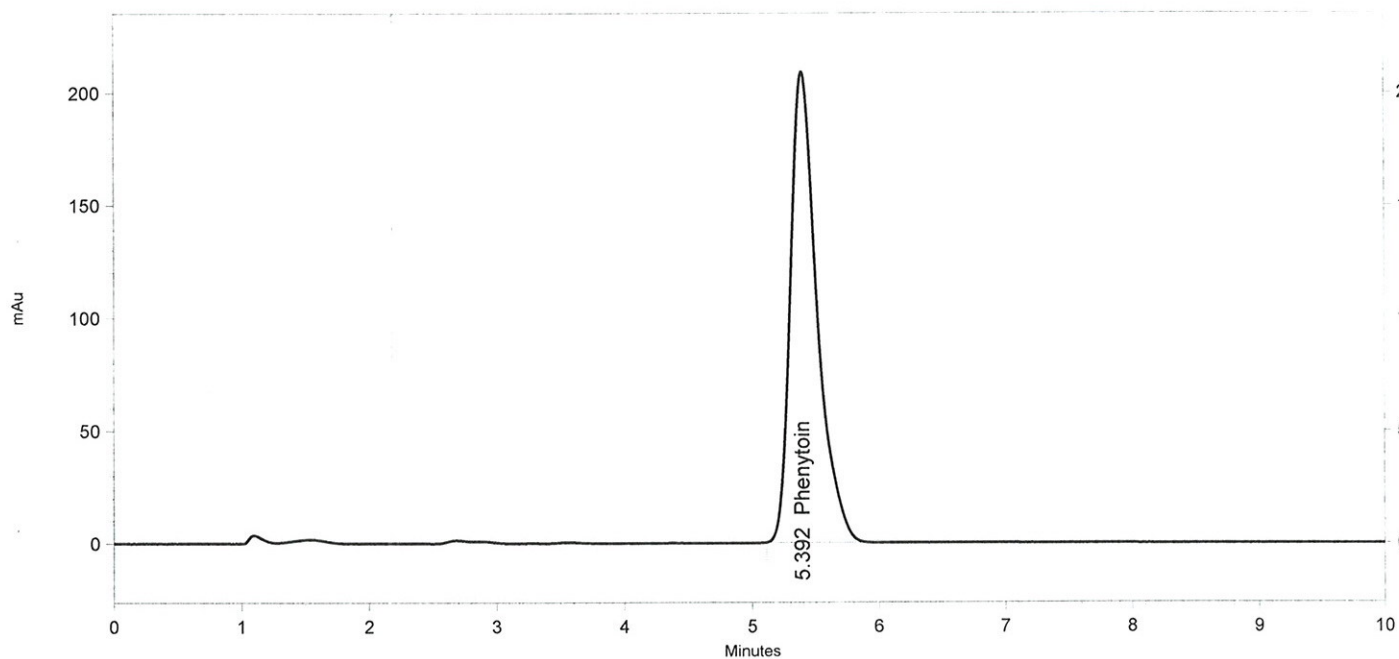
3: 220 nm,  
4 nm

Results

| Name      | Retention Time | Area    | mg / ml   | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|-----------|-----------|------------------|
| Phenytoin | 5.376          | 3699874 | 0.100 CAL | 1.28068   | 0.00000          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\February 12-10 Phenytoin 30 days  
stability 03  
Sample ID: Phenytoin 8% 30 days Stability  
C:\CLASS-VP\Sequence\2010\February\HPLC 3\February 12-10 Phenytoin 8% 30  
days Stability.seq  
C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
Vial: 4  
Sample amount: 0.1025



3: 220 nm,  
4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 5.392          | 3042569 | 8.037   | 1.41187   | 0.00000          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\March 16-10 Phenytoin 60 days stability  
01-Rep1

Sample ID: Phenytoin St

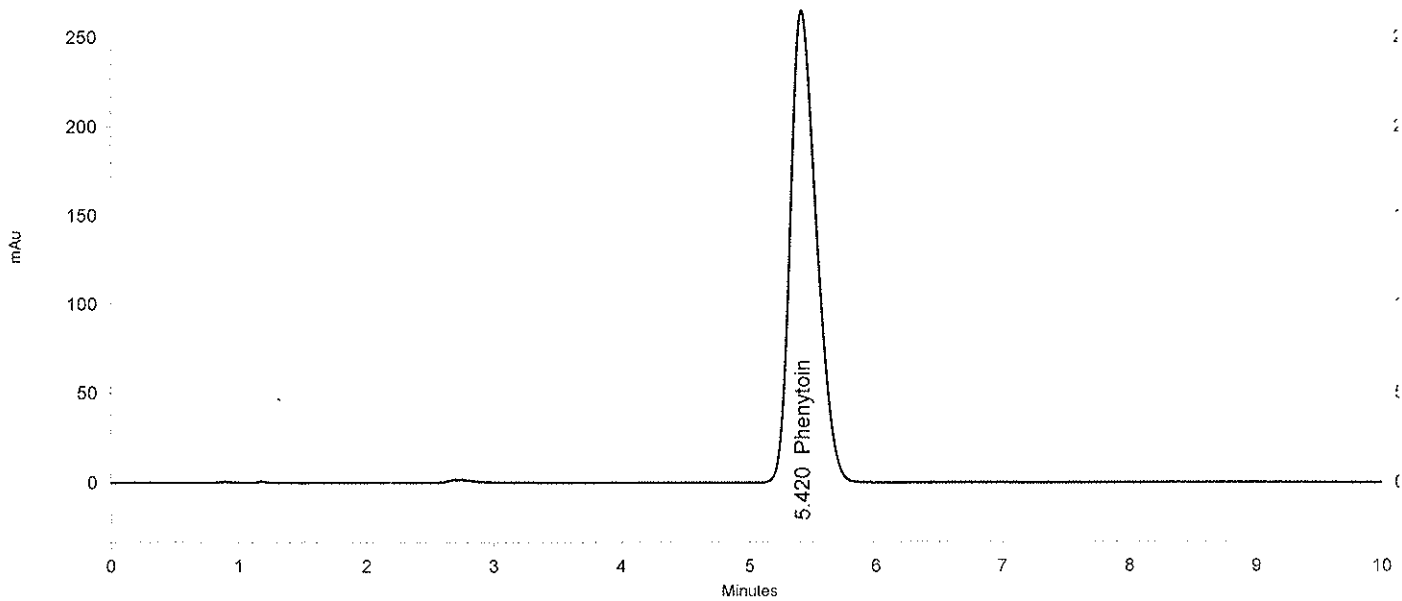
C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 16-10 Phenytoin 60 days

Stability.seq

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

Vial: 2

Sample amount: 1



3: 220 nm,

4 nm

Results

| Name      | Retention Time | Area    | mg / ml   | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|-----------|-----------|------------------|
| Phenytoin | 5.420          | 3725138 | 0.100 CAL | 1.22267   | 0.00000          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\March 16-10 Phenytoin 60 days stability  
03

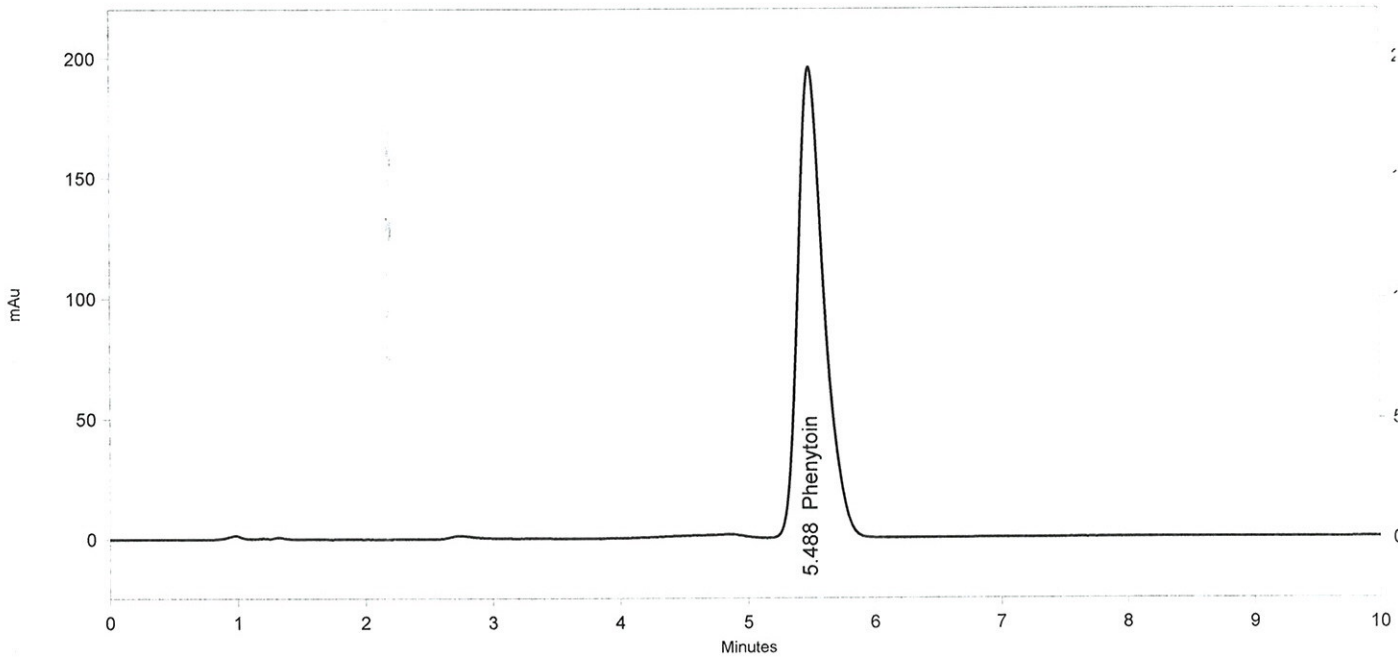
Sample ID: Phenytoin 8% 60 days Stability

C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 16-10 Phenytoin 60 days  
Stability.seq

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

Vial: 4

Sample amount: 0.0926



3: 220 nm,

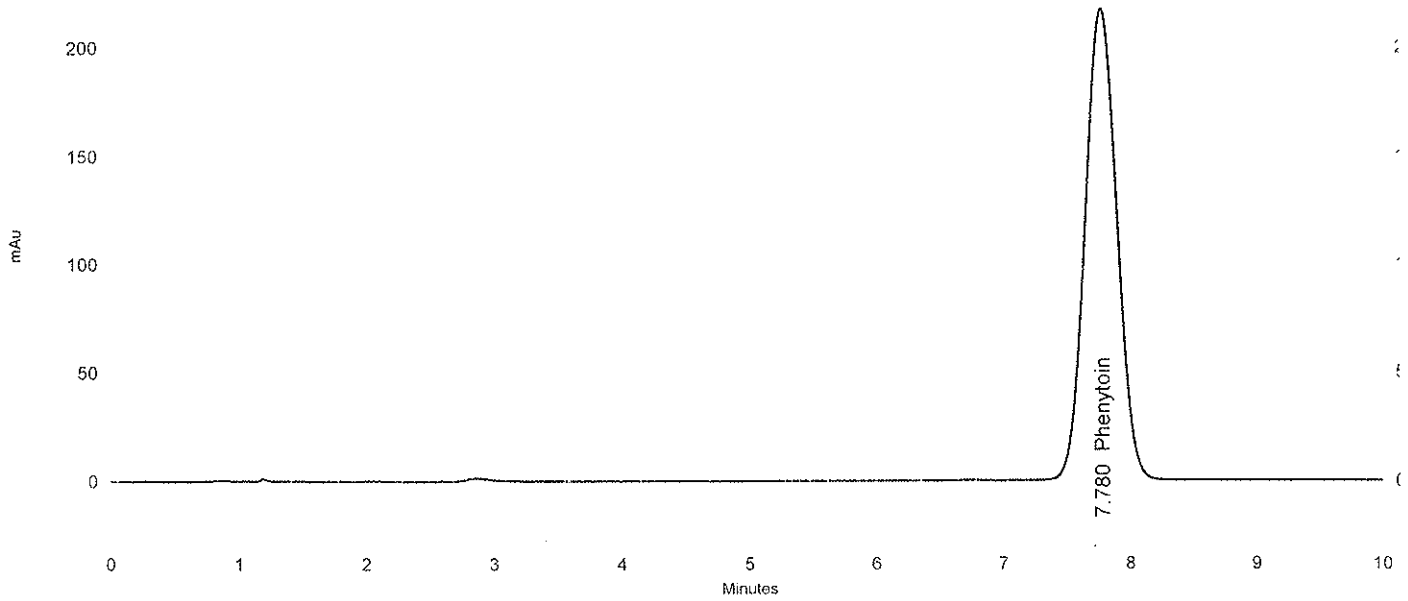
4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 5.488          | 2766729 | 8.011   | 1.28566   | 0.00000          |

# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\March 16-10 Phenytoin 90 days stability  
01-Rep1  
Sample ID: Phenytoin St  
C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 11-10 Phenytoin 90 days  
stability.seq  
C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
Vial: 2  
Sample amount: 1



3: 220 nm,  
4 nm

Results

| Name      | Retention Time | Area    | mg / ml   | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|-----------|-----------|------------------|
| Phenytoin | 7.780          | 3752234 | 0.100 CAL | 0.99906   | 0.00000          |



# HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Data\2009\July\HPLC 4\March 16-10 Phenytoin 90 days stability  
03

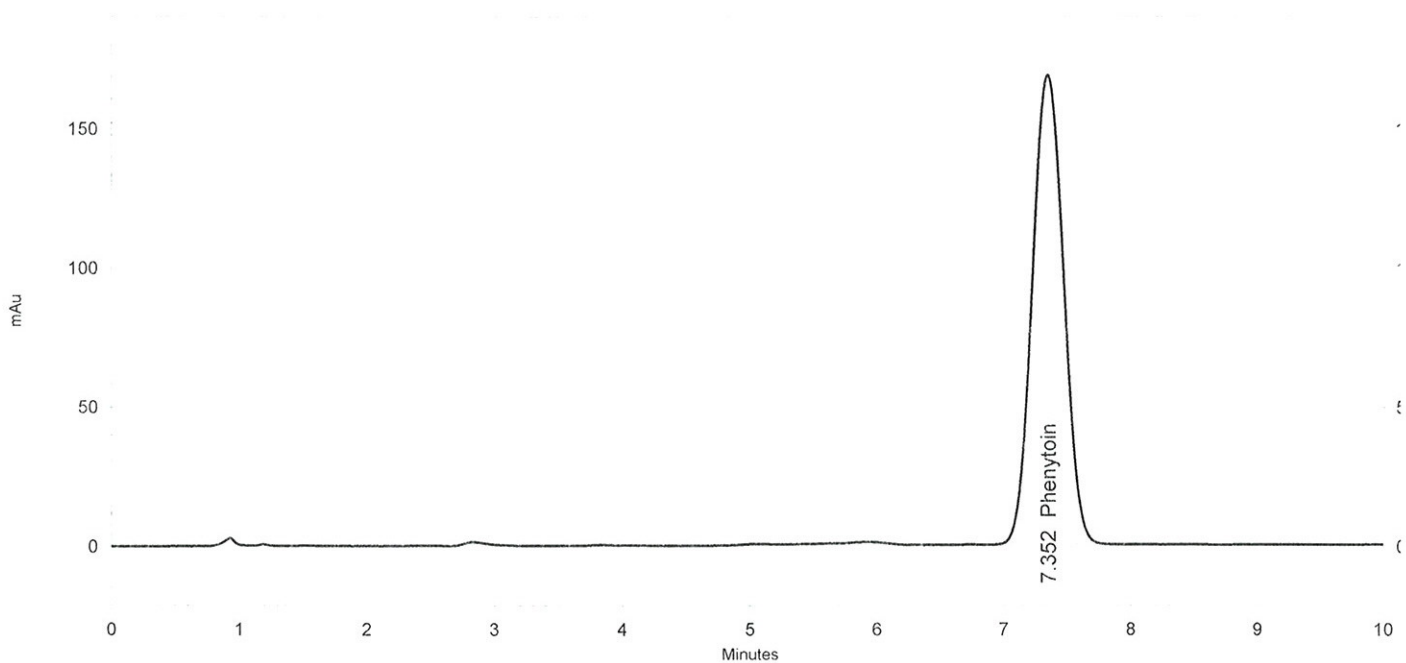
Sample ID: Phenytoin 8% 90 days Stability

C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 11-10 Phenytoin 90 days  
stability.seq

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

Vial: 4

Sample amount: 0.098



3: 220 nm,

4 nm

Results

| Name      | Retention Time | Area    | mg / ml | Asymmetry | Resolution (USP) |
|-----------|----------------|---------|---------|-----------|------------------|
| Phenytoin | 7.352          | 2869505 | 7.819   | 1.02364   | 0.00000          |