



# Scientific Study

**B4522, Omnibase**  
(Phenytoin 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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## Phenytoin:

4.30g Phenytoin raw drug powder from Spectrum Chemical (part number PH161, Lot # YT3036) was added to 50.00g Spectrum Mfg. Corp. Omnibase and levigated with an electronic mortar and pestle, resulting in a final concentration of 8.0% w/w. This emulsion 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.

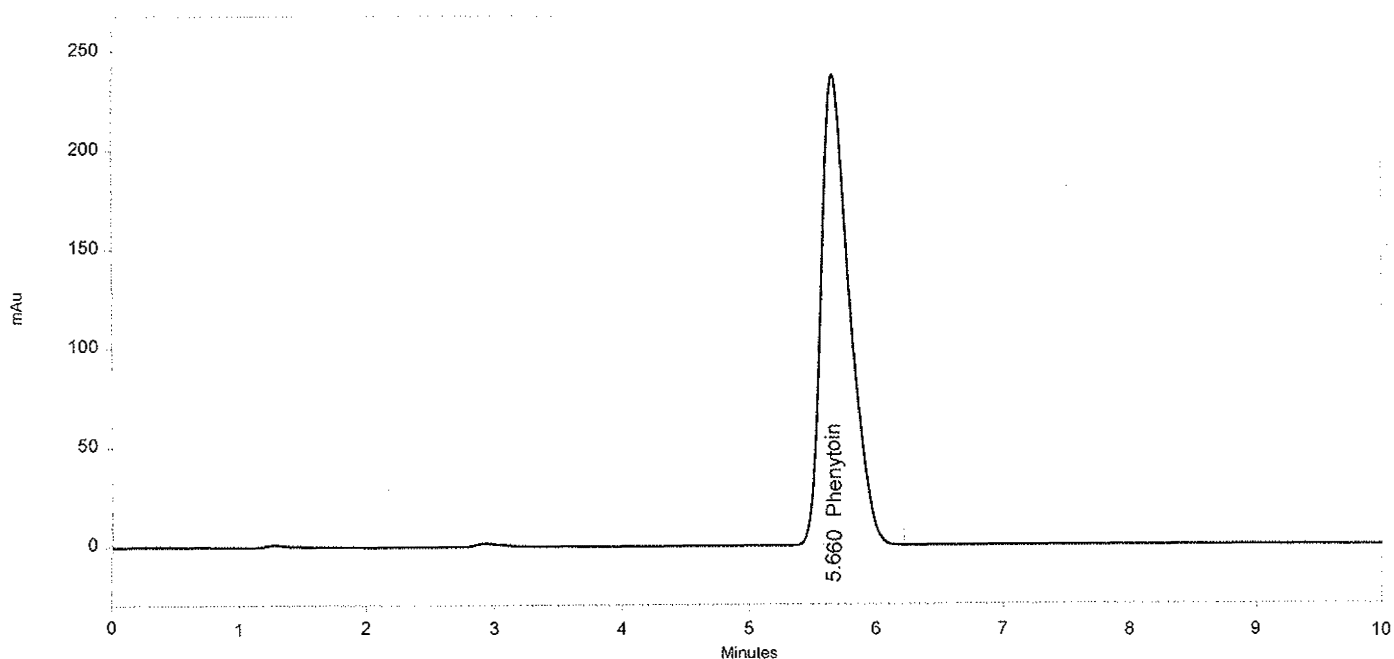
Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations,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

## 90-Day Summary:

Compounded at 8.0% w/w, stability-indicating HPLC analysis found less than 4% Phenytoin loss in Spectrum Mfg. Corp. Omnibase at 90 days.

Attached are 8 chromatographs of Spectrum Mfg. Corp. Omnibase 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.

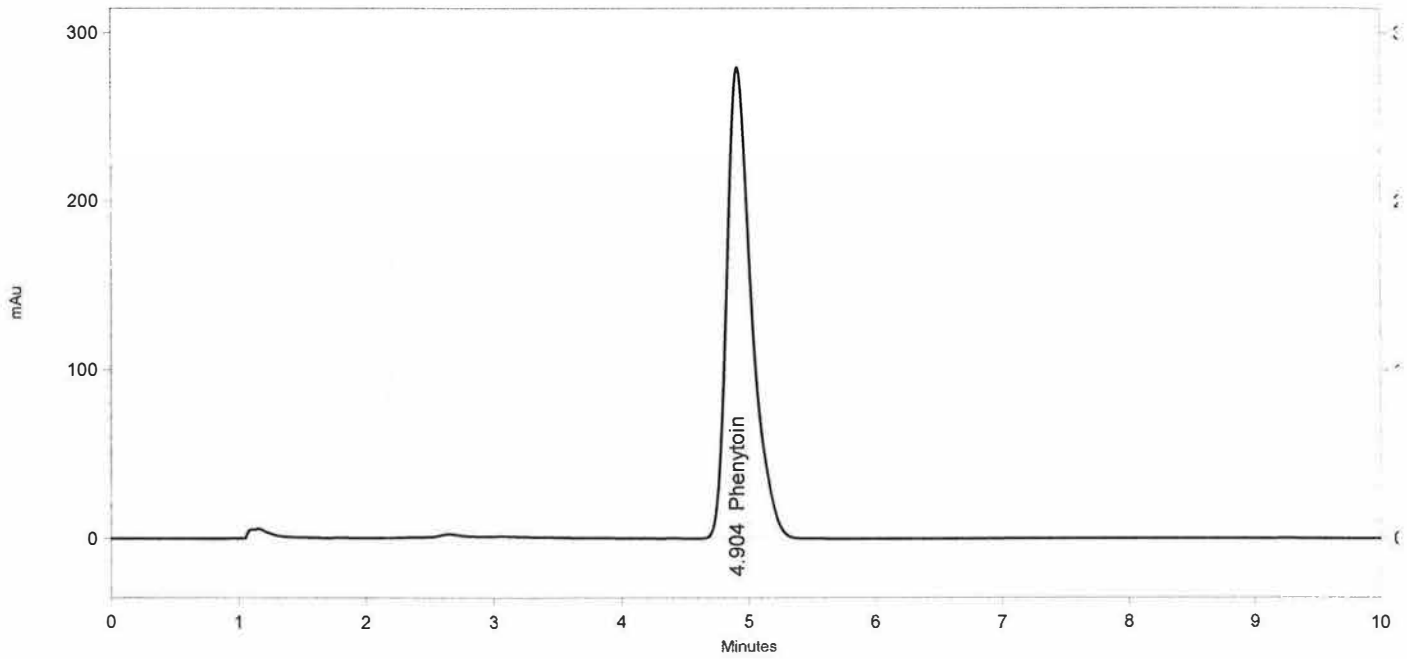
C:\CLASS-VP\Data\2009\July\HPLC 4\January 13-10 Phenytoin stability  
 01-Rep1  
 Sample ID: Phenytoin St  
 C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 13-10 Phenytoin 8% 0  
 time.seq  
 C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
 Vial: 2  
 Sample amount: 1



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

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

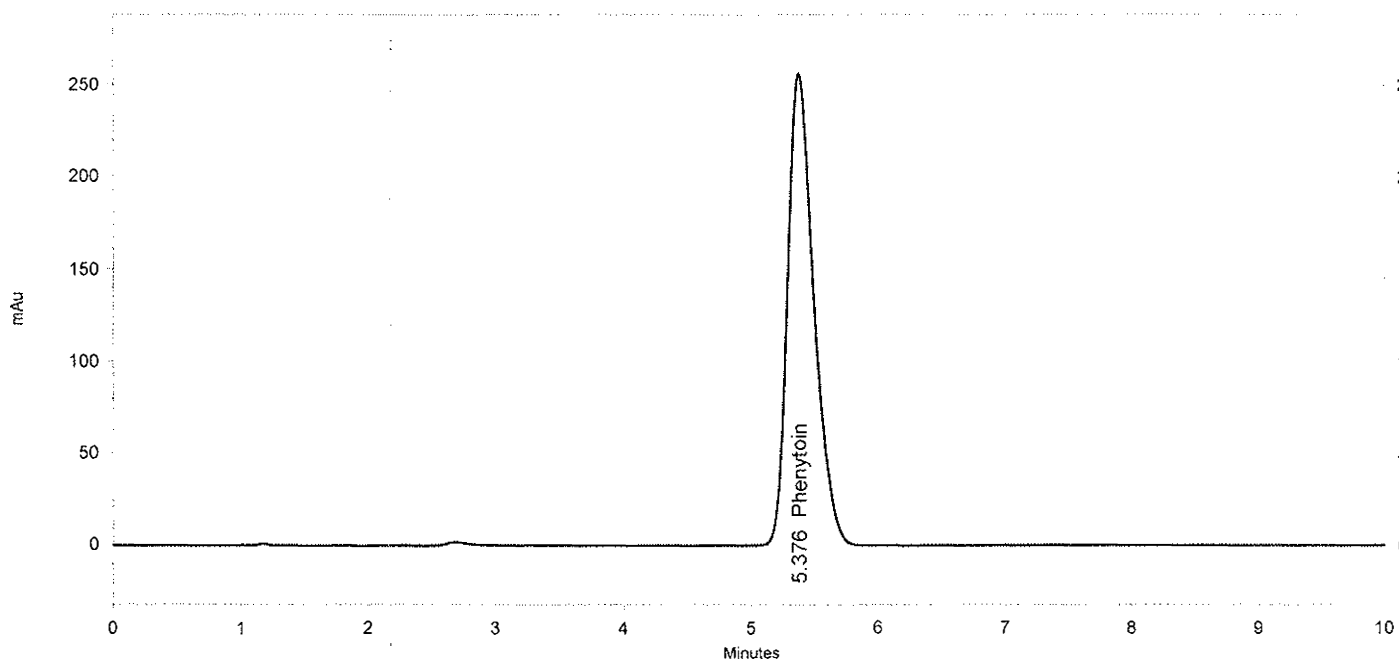


3: 220 nm,  
 4 nm

Results

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

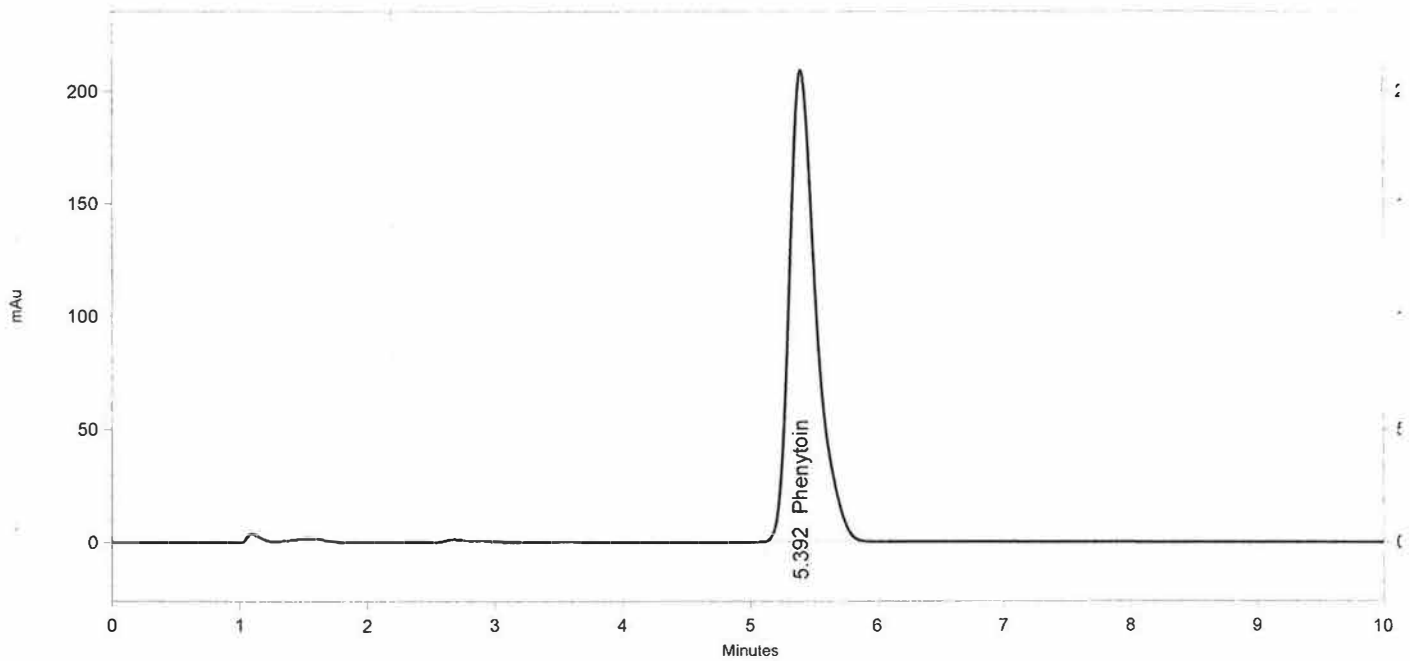
C:\CLASS-VP\Data\2009\July\HPLC 4\February 12-10 Phenytoin 30 days  
 stability 01-Rep1  
 Sample ID: Phenytoin St  
 C:\CLASS-VP\Sequence\2010\February\HPLC 3\February 12-10 Phenytoin 8% 30  
 days Stability.seq  
 C:\CLASS-VP\Methods\HPLC3\Phenytoin.met  
 Vial: 2  
 Sample amount: 1



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

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

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

Sample ID: Phenytoin St

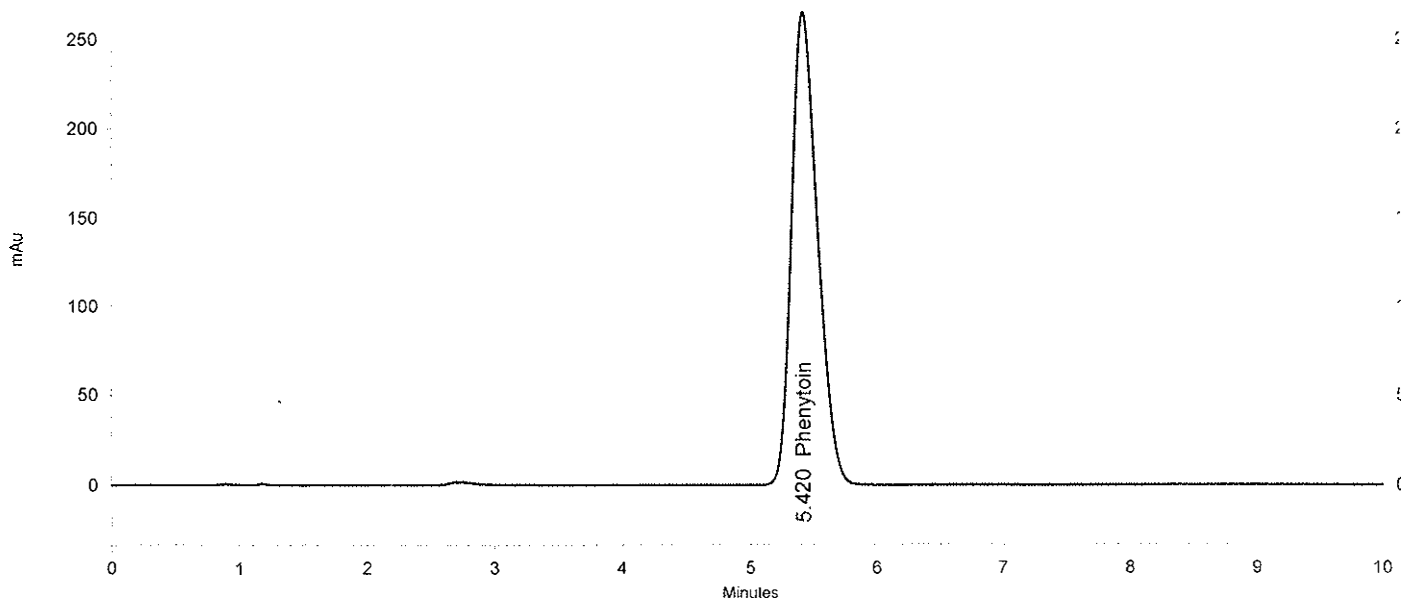
C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 16-10 Phenytoin 60 days

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	0.0000

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

Sample ID: Phenytoin 8% 60 days Stability

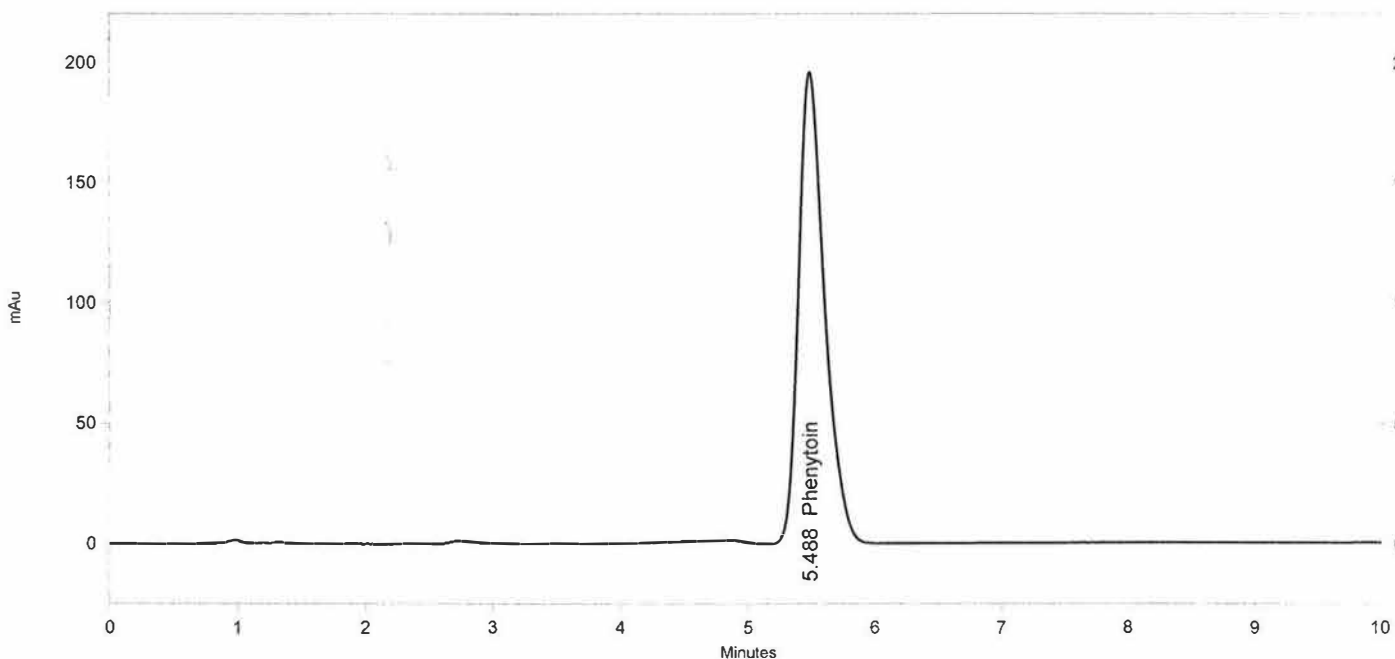
C:\CLASS-VP\Sequence\2010\March\HPLC 3\March 16-10 Phenytoin 60 days

Stability.seq

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

Vial: 4

Sample amount: 0.0926



3: 220 nm,

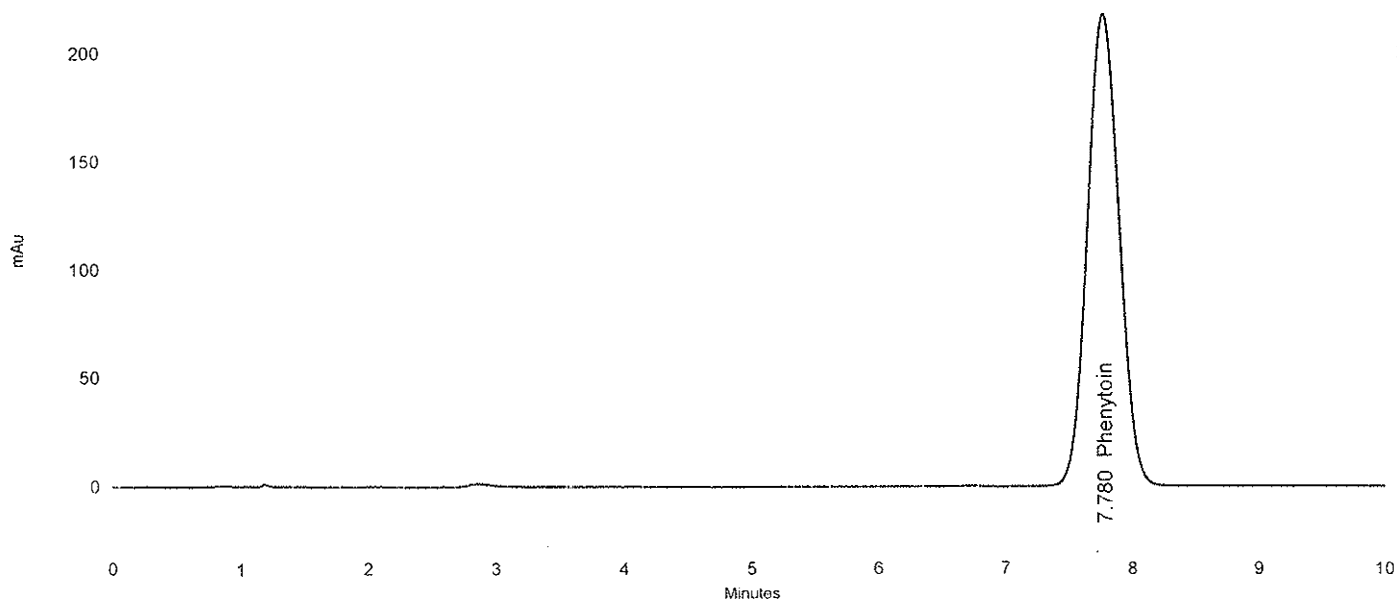
4 nm

Results

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



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

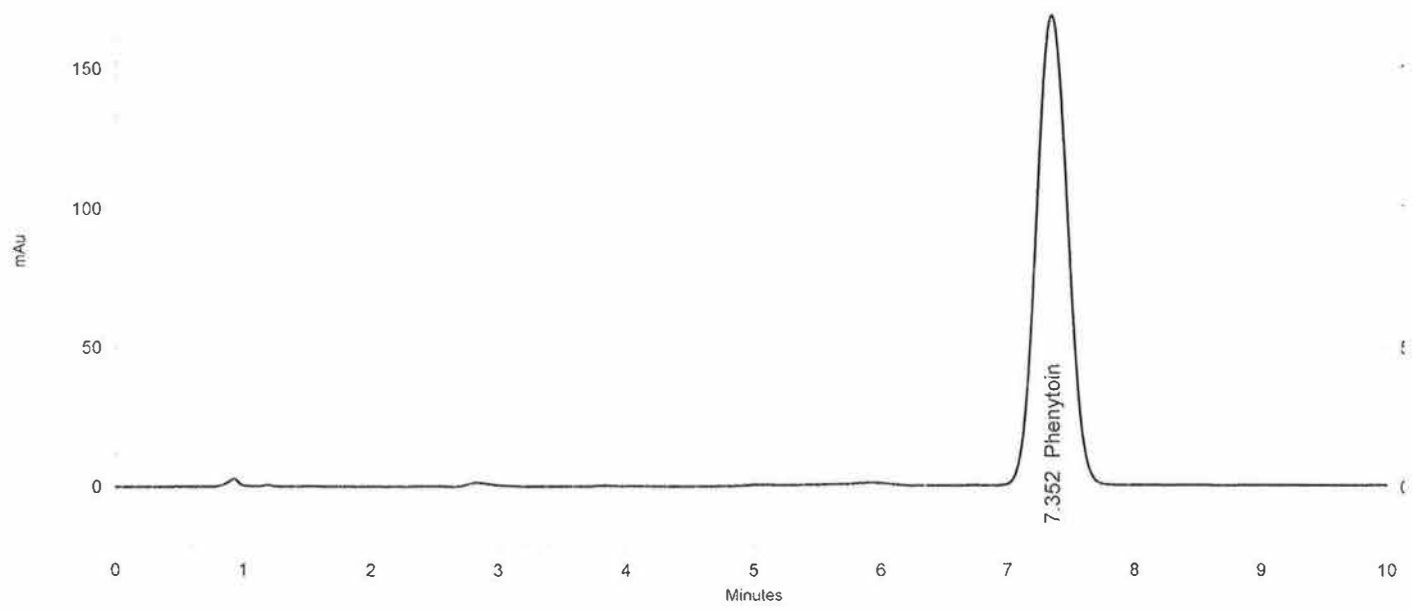


3: 220 nm,  
 4 nm

Results

Name	Retention Time	Area	mg / ml	Asymmetry	Resolution (USP)
Phenytoin	7.780	3752234	0.100 CAL	0.99906	0.0000●

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