



# Scientific Study

**B4514, Durabase Cream**  
(Methimazole Study)

Not appropriate for regulatory submission.  
Please visit [www.SpectrumRx.com](http://www.SpectrumRx.com) or  
contact Tech Services for the most up-to-  
date information contained in this  
information package.

## **Spectrum Pharmacy Products**

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Methimazole:

2.50g Methimazole raw drug powder from Spectrum Chemical was added to 47.50g Spectrum Chemical Mfg. Corp. Durabase and levigated with an electronic mortar and pestle, resulting in a final concentration of 5.0% 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.

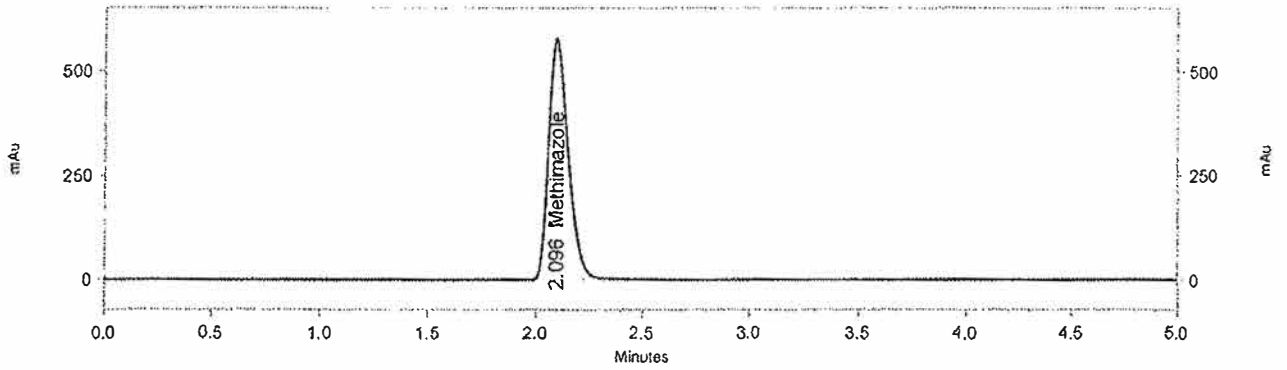
Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations,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

90-Day Summary:

Compounded at 5.0% w/w, stability-indicating HPLC analysis found negligible Methimazole loss in Spectrum Chemical Mfg. Corp. Durabase at 90 days.

Attached are 5 chromatographs of Spectrum Chemical Mfg. Corp. Durabase showing in order: Initial Standard, Initial Sample, 30-Day Sample, 60-Day Sample, and 90-Day Sample.

C:\CLASS-VP\Enterprise\Projects\Default\Data\February 05-07 Methimazole  
 Time.0 02  
 Sample ID: Methimazole Std Check  
 C:\CLASS-VP\Sequence\2008\February 2008\HPLC 3\February 05-08 Time 0  
 Methimazole.seq  
 C:\CLASS-VP\Methods\Compounding\Methimazole Final Method.met  
 Vial: 3  
 Sample amount: 0.1002

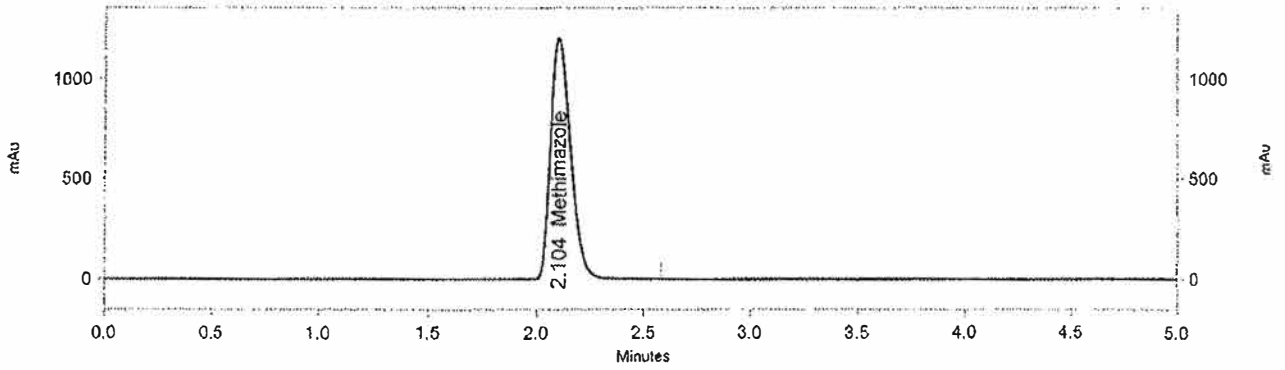


2: 250 nm,  
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Methimazole	2.096	3754768	99.916	0.00000	1.36957

C:\CLASS-VP\Enterprise\Projects\Default\Data\February 05-07 Methimazole  
 Time 0 03  
 Sample ID: Methimazole Sp1 (5.0%) Time 0  
 C:\CLASS-VP\Sequence\2008\February 2008\HPLC 3\February 05-08 Time 0  
 Methimazole.seq  
 C:\CLASS-VP\Methods\Compounding\Methimazole Final Method.met  
 Vial: 4  
 Sample amount: 0.2149

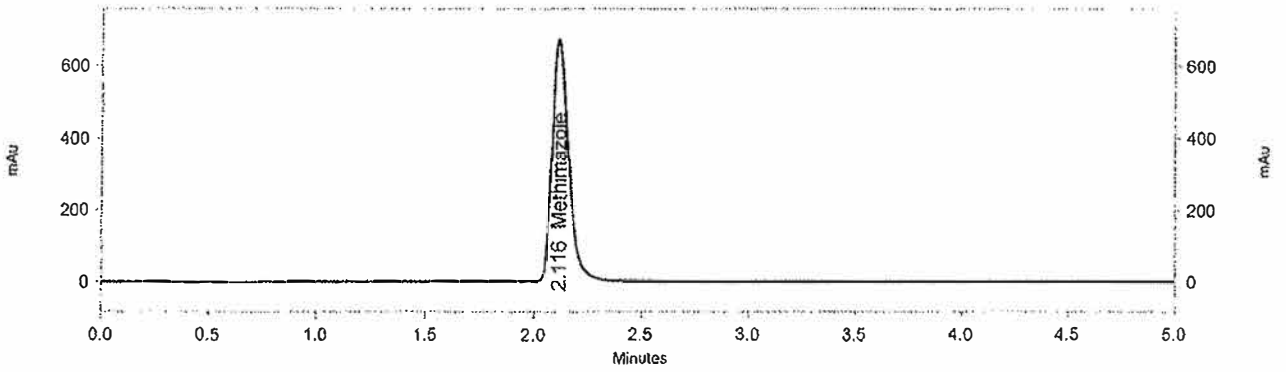


2: 250 nm,  
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Methimazole	2.104	7756437	4.812	0.00000	1.32895

C:\CLASS-VP\Enterprise\Projects\Default\Data\March 10-08 Methimazole  
 Stability Sp 05  
 Sample ID: Methimazole Sp1 (5.0%) 1 Month Dif Base  
 C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\March 10-08 Methimazole  
 Stability.seq  
 C:\CLASS-VP\Methods\Compounding\Methimazole Final Method.met  
 Vial: 6  
 Sample amount: 0.2005



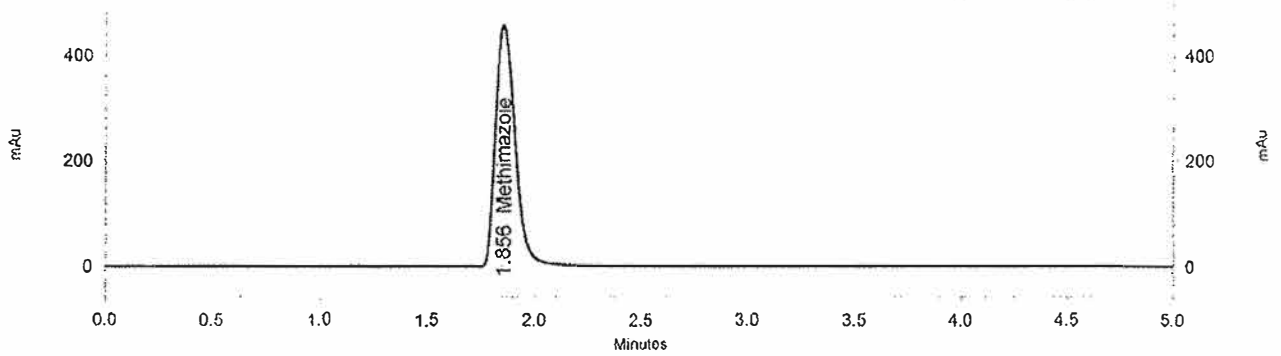
2: 250 nm,  
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Methimazole	2.116	3570764	4.890	0.00000	1.34087

C:\CLASS-VP\Enterprise\Projects\Default\Data\April-03 Methimazole Stability  
Sp103

Sample ID: Methimazole Sp1 (5.0%) 2 Month Dif Base  
C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\April-03 Methimazole  
Stability.seq  
C:\CLASS-VP\Methods\Compounding\Methimazole Final Method.met  
Vial: 4  
Sample amount: 0.198

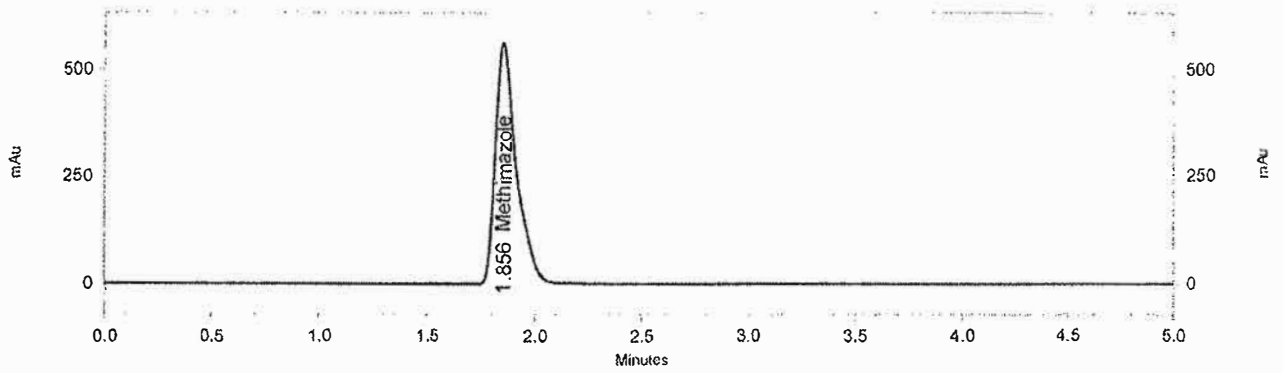


2: 250 nm,  
4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Methimazole	1.856	2920000	4.999	0.00000	1.35237

C:\CLASS-VP\Enterprise\Projects\Default\Data\May-05 Methimazole Stability  
 Sp103  
 Sample ID: Methimazole Sp1 (5.0%) 3 Month Dif Base  
 C:\CLASS-VP\Sequence\2008\May 2008\HPLC 3\May-05-08 Methimazole Stability 3  
 months.seq  
 C:\CLASS-VP\Methods\Compounding\Methimazole Final Method.met  
 Vial: 4  
 Sample amount: 0.2096



2: 250 nm,  
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Methimazole	1.856	377325	4.841	0.00000	1.53751