



Scientific Study

B4514, Durabase Cream
(Promethazine Study)

Not appropriate for regulatory submission.
Please visit 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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Promethazine:

2.50g Promethazine Hydrochloride raw drug powder from Spectrum Chemical (part number PR123, Lot # VG0217) 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.

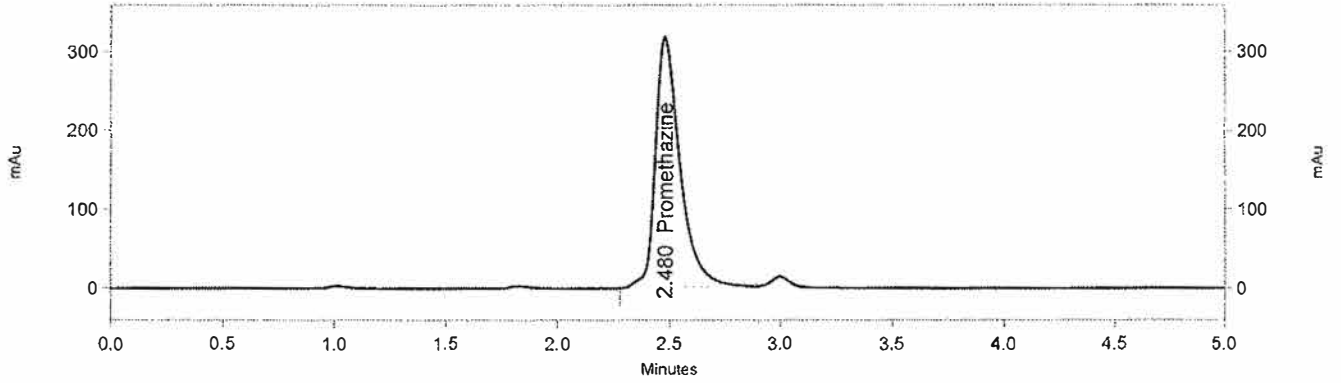
Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations, 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 less than 6% Promethazine loss in Spectrum Chemical Mfg. Corp. Durabase at 90 days.

Attached are 5 chromatographs of Spectrum 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 05-08 0 Time
 Promethazine 02
 Sample ID: Promethazine Std Check
 C:\CLASS-VP\Sequence\2008\February 2008\HPLC 3\February 05-08 0 Time
 Promethazine.seq
 C:\CLASS-VP\Methods\Compounding\Promethazine Final Method.met
 Vial: 3
 Sample amount: 0.1002

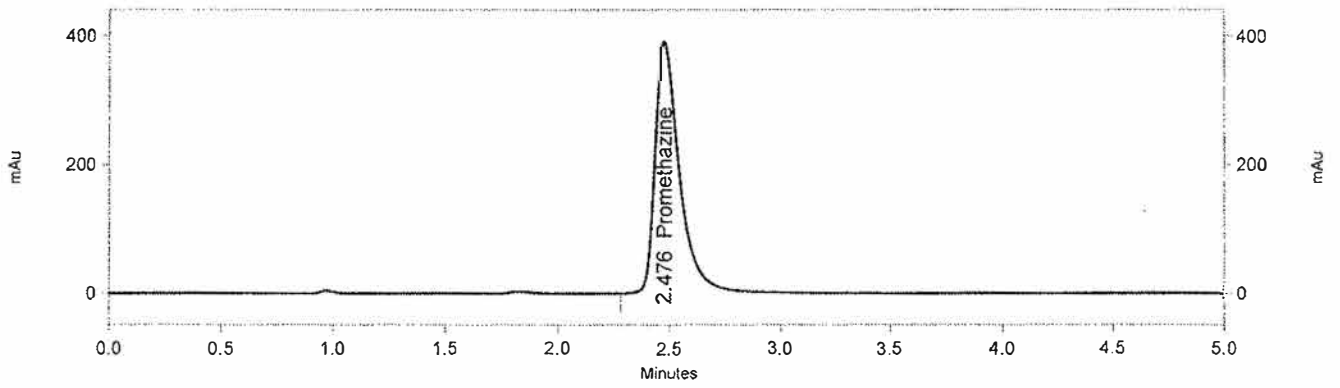


2: 250 nm,
4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Promethazin e	2.480	2408448	99.605	0.00000	1.49412

C:\CLASS-VP\Enterprise\Projects\Default\Data\February 05-08 0 Time
 Promethazine 03
 Sample ID: Promethazine Stabillity) Time
 C:\CLASS-VP\Sequence\2008\February 2008\HPLC 3\February 05-08 0 Time
 Promethazine.seq
 C:\CLASS-VP\Methods\Compounding\Promethazine Final Method.met
 Vial: 4
 Sample amount: 0.1182

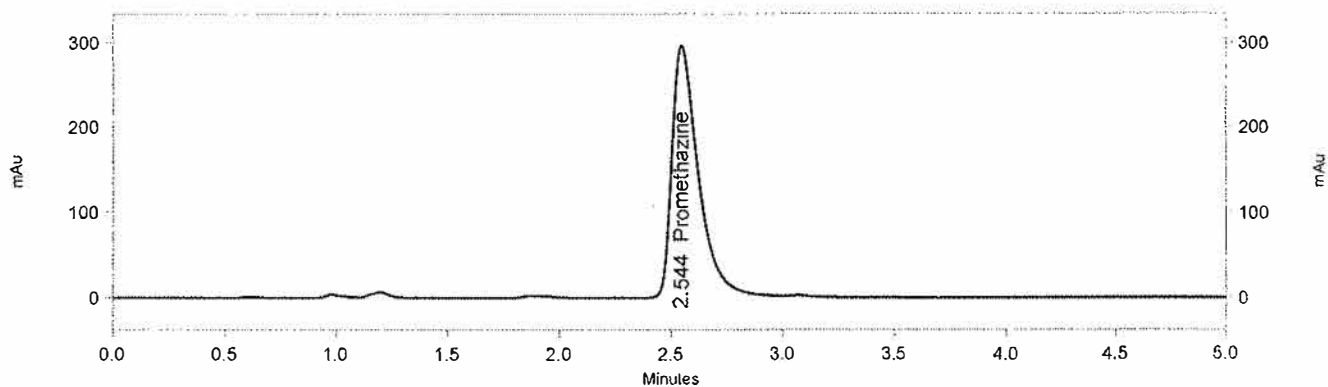


2: 250 nm,
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Promethazine	2.476	2914862	5.110	0.00000	1.63663

C:\CLASS-VP\Enterprise\Projects\Default\Data\March 010-08 2 month
 Promethazine 04
 Sample ID: Promethazine Stabillity 1 month
 C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\March 10-08 Promethazine
 Stability.seq
 C:\CLASS-VP\Methods\Compounding\Promethazine Final Method.met
 Vial: 5
 Sample amount: 0.1116

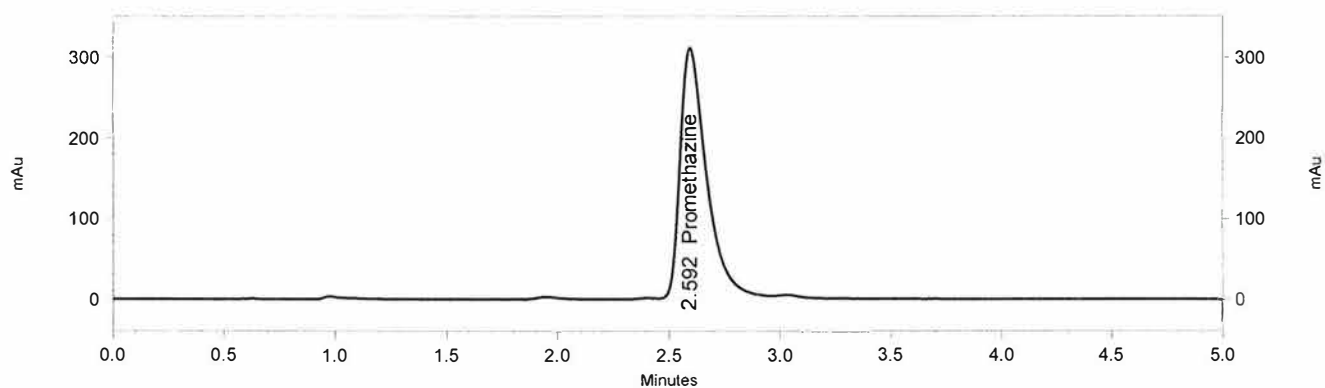


2: 250 nm,
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Promethazine	2.544	2399314	4.727	0.00000	1.72842

C:\CLASS-VP\Enterprise\Projects\Default\Data\April 04-08 2 months
 Promethazine 03
 Sample ID: Promethazine Stability 2 month
 C:\CLASS-VP\Sequence\2008\March 2008\HPLC 3\April 04-08 Promethazine
 Stability.seq
 C:\CLASS-VP\Methods\Compounding\Promethazine Final Method.met
 Vial: 4
 Sample amount: 0.1074

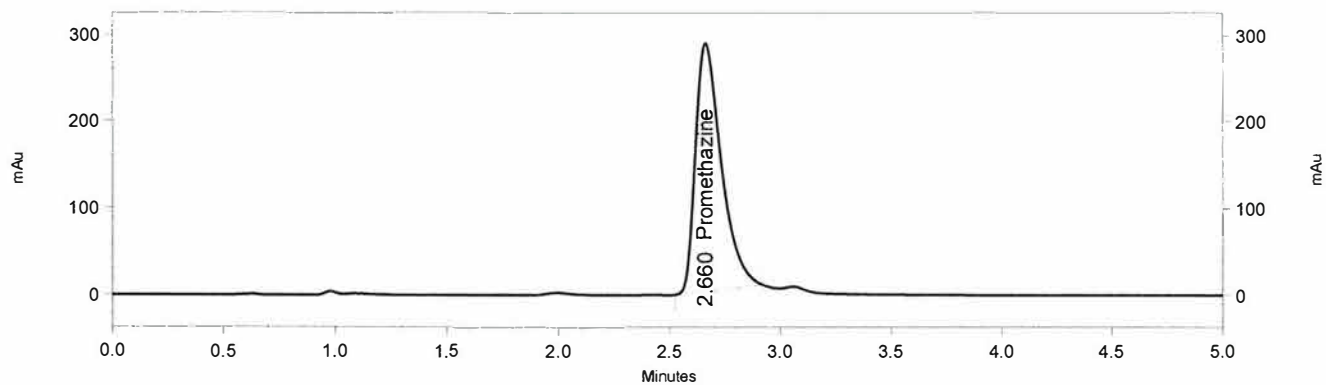


2: 250 nm,
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Promethazine	2.592	2520448	4.958	0.00000	1.64239

C:\CLASS-VP\Enterprise\Projects\Default\Data\May 05-08 3 months
 Promethazine 03
 Sample ID: Promethazine Stability 3 month
 C:\CLASS-VP\Sequence\2008\May 2008\HPLC 3\May-05-08 Promethazine Stability
 3 months.seq
 C:\CLASS-VP\Methods\Compounding\Promethazine Final Method.met
 Vial: 4
 Sample amount: 0.1125



2: 250 nm,
 4 nm

Results

Name	Retention Time	Area	%w/w	Resolution (USP)	Asymmetry
Promethazine	2.660	2297992	4.840	0.00000	1.60305