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Scientific Study

B4514, Durabase Cream (Cyclobenzaprine 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.

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Cyclobenzaprine Hydrochloride:

1.00g Cyclobenzaprine Hydrochloride raw drug powder from Spectrum Chemical (part number C1570, Lot # XG0806) was added to 50.00g Spectrum Chemical Mfg. Corp. Durabase and levigated with an electronic mortar and pestle, resulting in a final concentration of 2.0% 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.

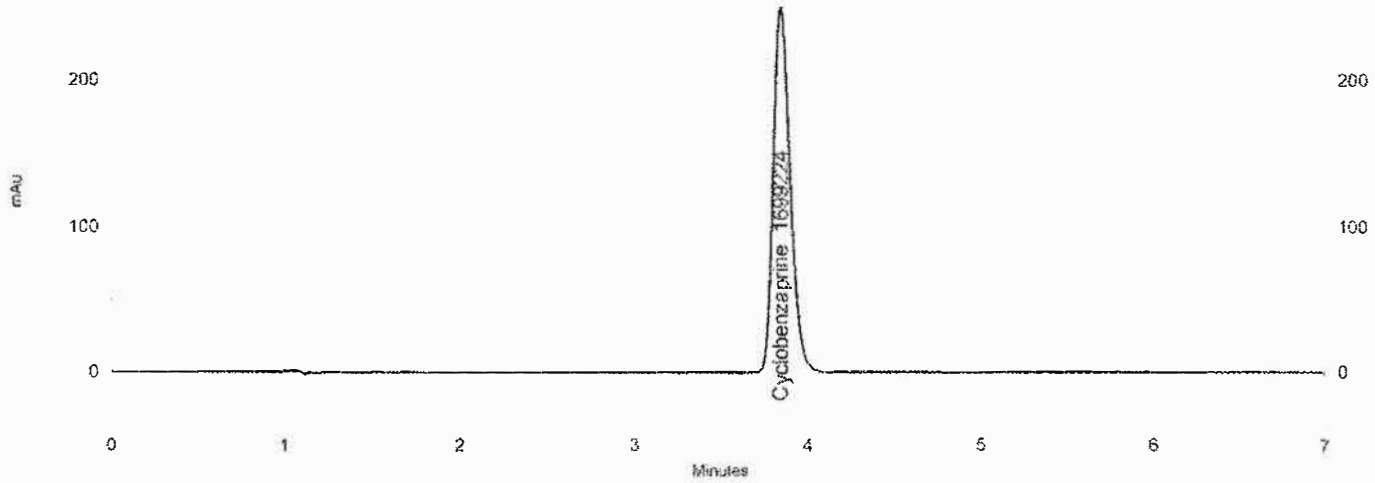
Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations,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

90-Day Summary:

Compounded at 2.0% w/w, stability-indicating HPLC analysis found less than 1% Cyclobenzaprine Hydrochloride loss in Spectrum Chemical Mfg. Corp. Durabase at 90 days.

Attached are 8 chromatographs of Spectrum Chemical Mfg. Corp. Durabase 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.

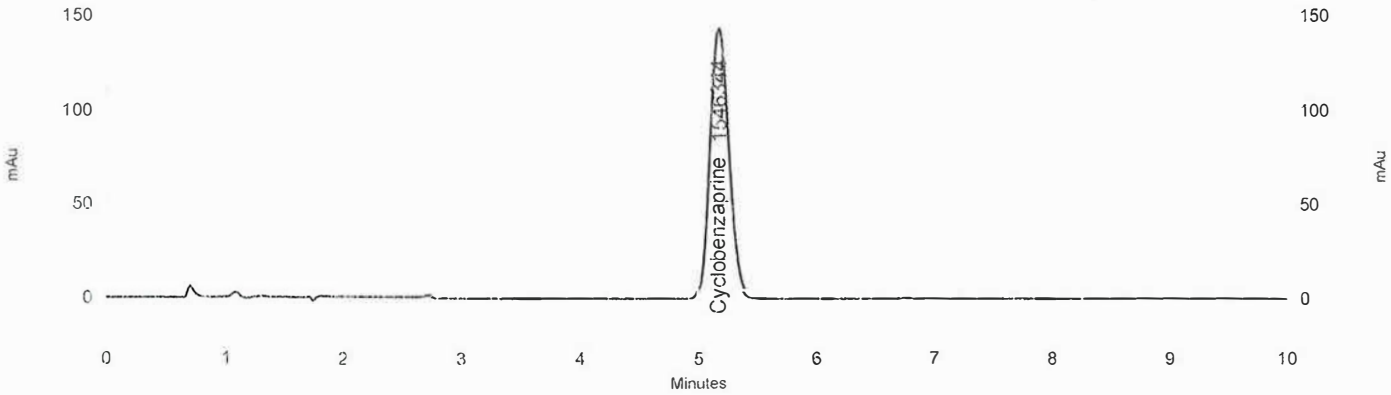
C:\CLASS-VP\Enterprise\Projects\Default\Data\April-13 Cyclobenzaprine Linearity 101-Rep1
Sample ID: Cyclobenzaprine Standards
C:\CLASS-VP\Sequence\2009\April\HPLC 3\April 13-09 Cyclobenzaprine Linearity.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 2
Sample amount: 1



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Cyclobenzaprine	3.848	1699224	0.05 CAL	1.29119	0.00000	7343

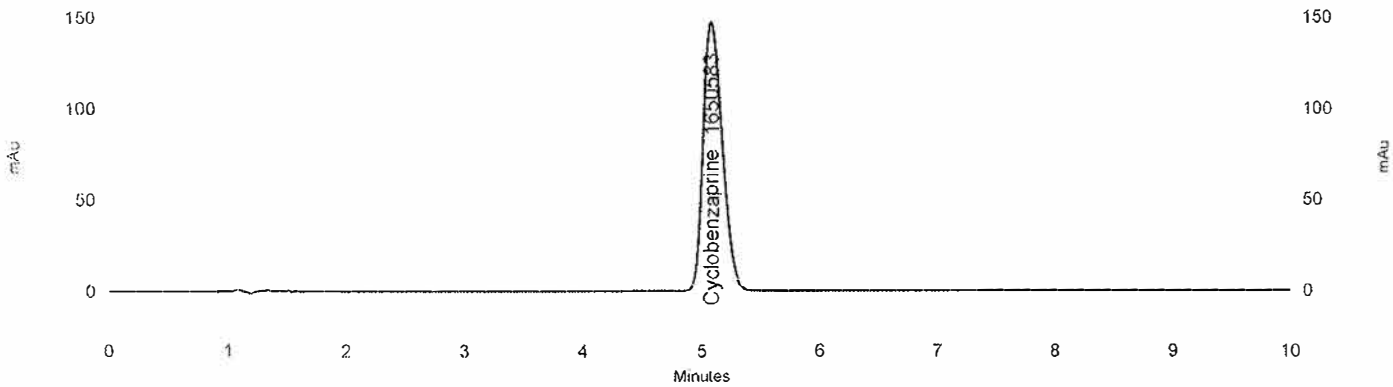
C:\CLASS-VP\Enterprise\Projects\Default\Data\April-19-10 Cyclobenzaprine Presicion 103
Sample ID: Cyclobenzaprine Presicion 1
C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 19-10 Cyclobenzaprine Stability time zero.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 4
Sample amount: 0.2328



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Area Percent	Theoretical plates (USP)
Cyclobenzaprine	5.160	1546344	2.01	1.104	0.000	100.000	4988

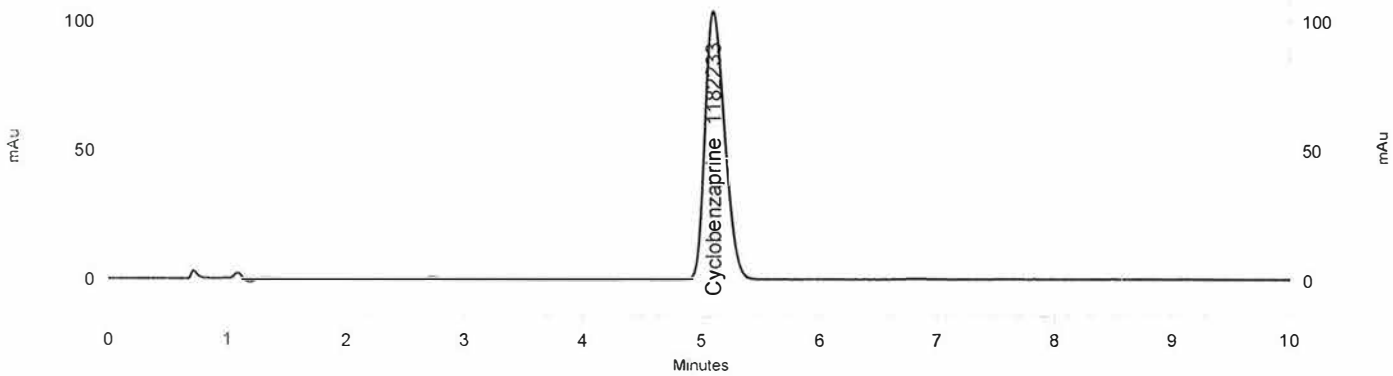
C:\CLASS-VP\Enterprise\Projects\Default\Data\May-19-10 Cyclobenzaprine Stability 30 Days 101-Rep1
Sample ID: Cyclobenzaprine Standards
C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 19-10 Cyclobenzaprine 2% 30 days Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 2
Sample amount: 1



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Area Percent	Theoretical plates (USP)
Cyclobenzaprine	5.080	1650583	0.05 CAL	1.233	0.000	100.000	4509

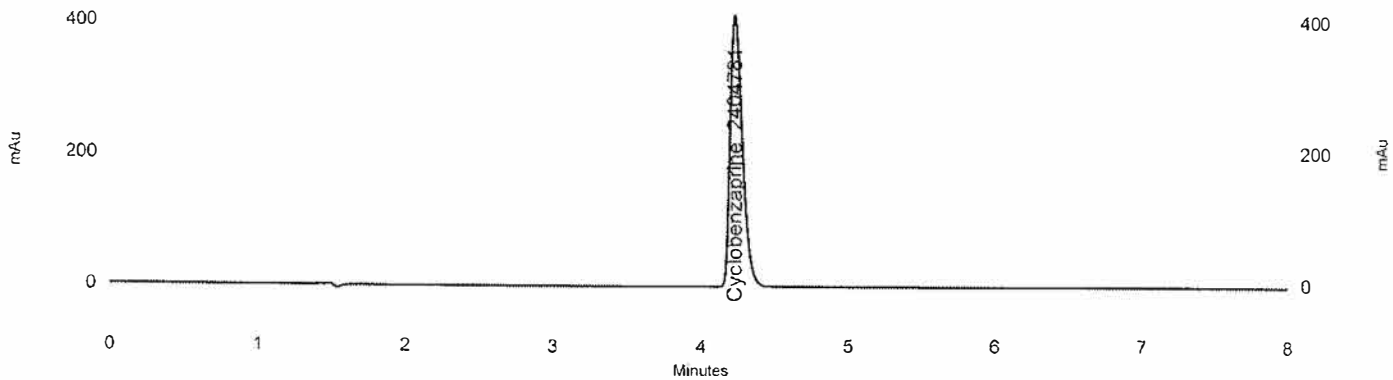
C:\CLASS-VP\Enterprise\Projects\Default\Data\May-19-10 Cyclobenzaprine Stability 30 Days 103
Sample ID: Cyclobenzaprine Presicion 1
C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 19-10 Cyclobenzaprine 2% 30 days Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 4
Sample amount: 0.1801



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Area Percent	Theoretical plates (USP)
Cyclobenzaprine	5.104	1182233	1.99	1.239	0.000	100.000	4385

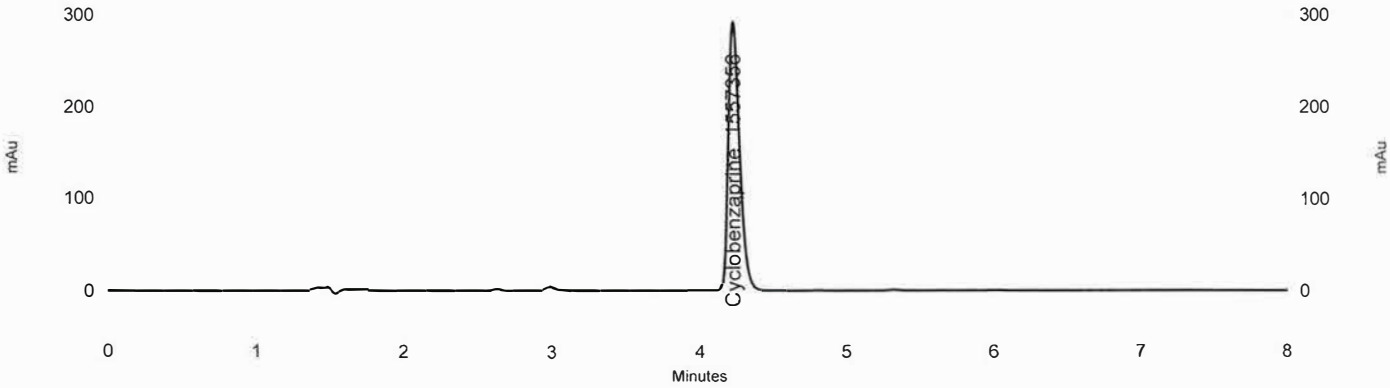
C:\CLASS-VP\Enterprise\Projects\Default\Data\June-16-10 Cyclobenzaprine Stability 60 Days 101-Rep1
Sample ID: Cyclobenzaprine Standards
C:\CLASS-VP\Sequence\2010\June\HPLC 3\Jun 16 Cyclobenzaprine 60 days Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 47
Sample amount: 1



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Area Percent	Theoretical plates (USP)
Cyclobenzaprine	4.224	2404781	0.05 CAL	1.573	0.000	100.000	11871

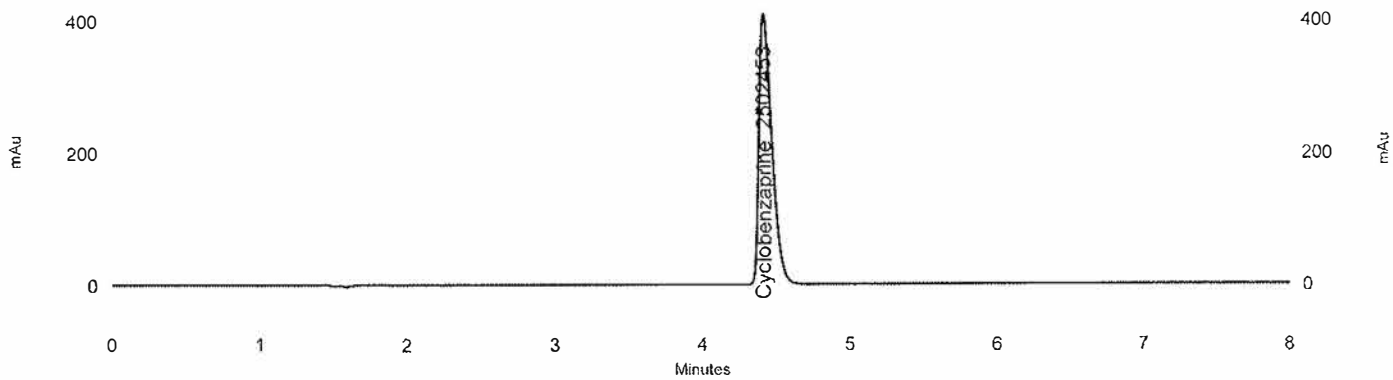
C:\CLASS-VP\Enterprise\Projects\Default\Data\June-16-10 Cyclobenzaprine Stability 60 Days 103
Sample ID: Cyclobenzaprine 60 days Stability
C:\CLASS-VP\Sequence\2010\June\HPLC 3\Jun 16 Cyclobenzaprine 60 days Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 49
Sample amount: 0.1651



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Area Percent	Theoretical plates (USP)
Cyclobenzaprine	4.224	1557356	1.96	1.400	0.000	100.000	14471

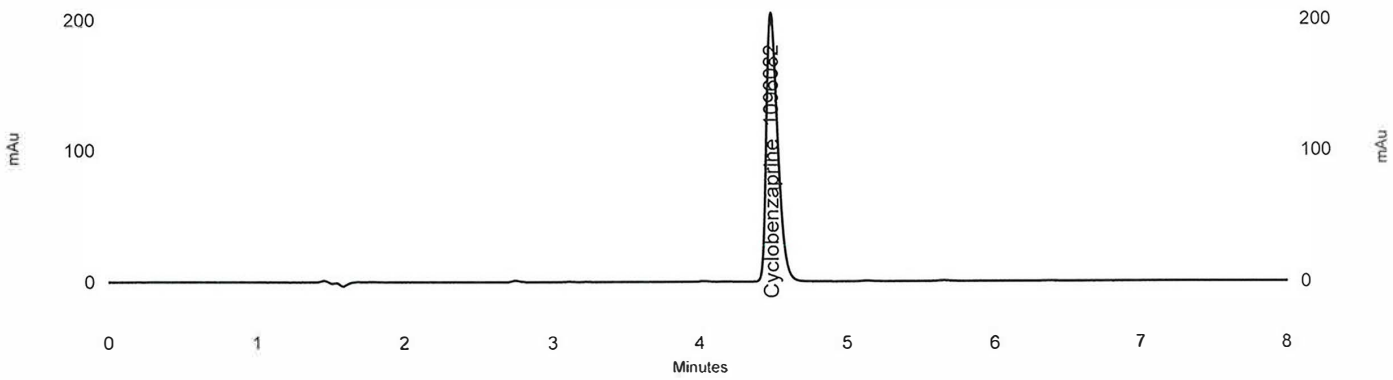
C:\CLASS-VP\Enterprise\Projects\Default\Data\July-19-10 Cyclobenzaprine Stability 90 Days 101-Rep1
Sample ID: Cyclobenzaprine Standards
C:\CLASS-VP\Sequence\2010\July\HPLC 3\July-19-10 Cyclobenzaprine 90 days Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 2
Sample amount: 1



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Area Percent	Theoretical plates (USP)
Cyclobenzaprine	4.416	2502453	0.05 CAL	1.604	0.000	100.000	11923

C:\CLASS-VP\Enterprise\Projects\Default\Data\July-19-10 Cyclobenzaprine Stability 90 Days 103
Sample ID: Cyclobenzaprine 90 days Stability
C:\CLASS-VP\Sequence\2010\July\HPLC 3\July-19-10 Cyclobenzaprine 90 days Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 4
Sample amount: 0.1102



4: 290 nm, 4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)	Area Percent	Theoretical plates (USP)
Cyclobenzaprine	4.484	1096082	1.99	1.376	0.000	100.000	16361