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Scientific Study

B4514, Durabase Cream
(Amitriptyline 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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Amitriptyline Hydrochloride:

1.00g Amitriptyline Hydrochloride raw drug powder from Spectrum Chemical (part number A1322, Lot # VD0701) was added to 49.00g Spectrum Chemical Mfg. Corp. Durabase and levigated with an electronic mortar and pestle, resulting in a final concentration of 2.0% w/w. This 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.

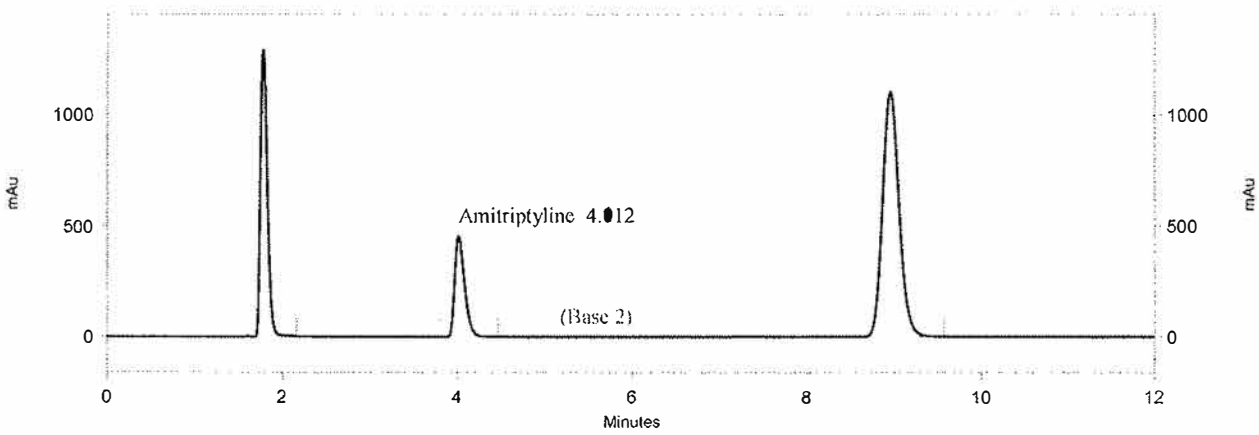
90-Day Summary:

Compounded at 2.0% w/w, stability-indicating HPLC analysis found less than 10% Amitriptyline Hydrochloride loss in Spectrum Chemical Mfg. Corp. Durabase.

Attached are 8 chromatographs 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.

Sample: Amitriptyline Standard Chek
Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met

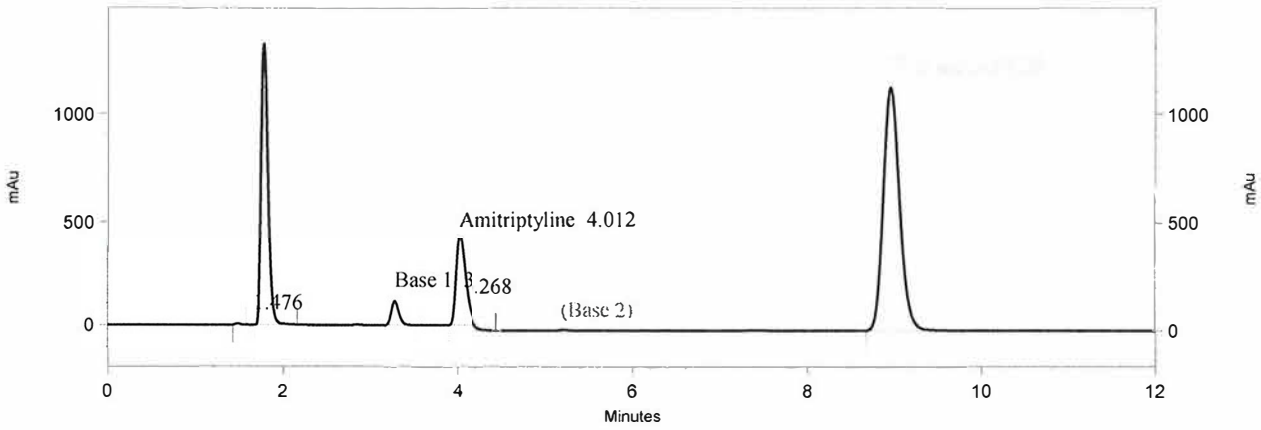
Integration Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met
Vial: #3



1: 200 nm, 4 nm Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	4.012	3604654	99.833	12.61999	1.49132

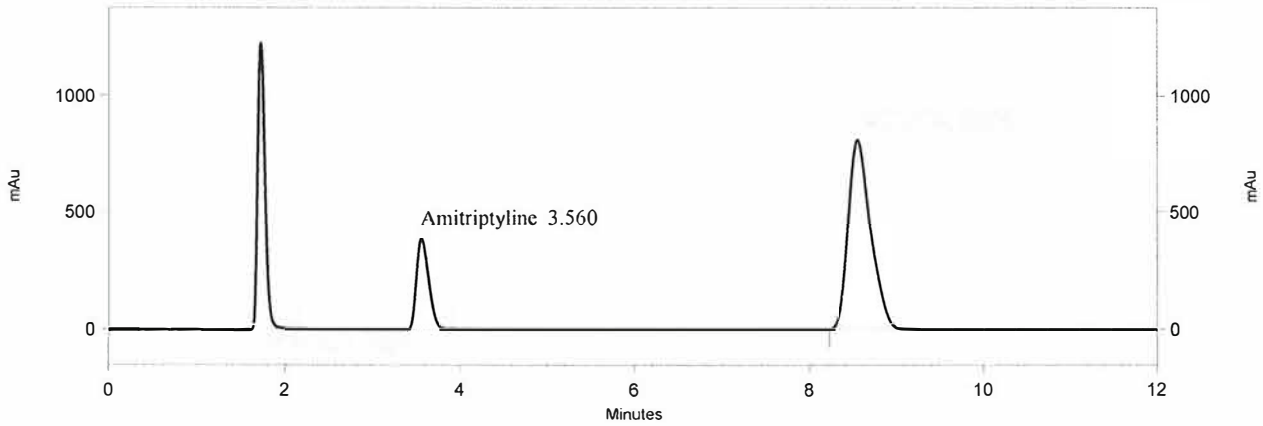
Sample: Precision 1
Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met Integration Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met
Vial: #4



1: 200 nm, 4 nm Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	4.012	3299781	1.789	4.03857	1.44818

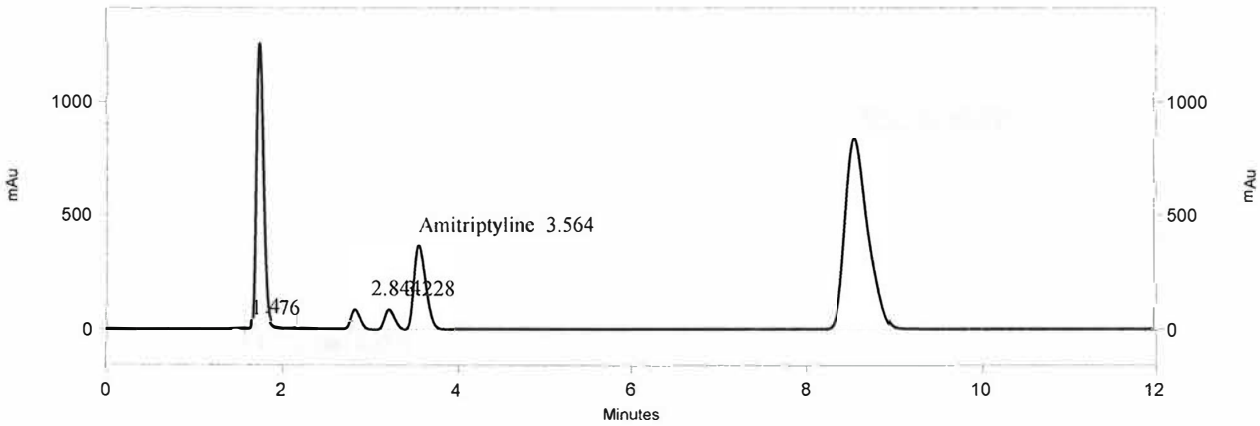
Sample: Amitriptyline Standard Chek
Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met Integration Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met
Vial: #3



1: 200 nm, 4 nm Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	3.560	3582973	99.859	9.08223	1.29558

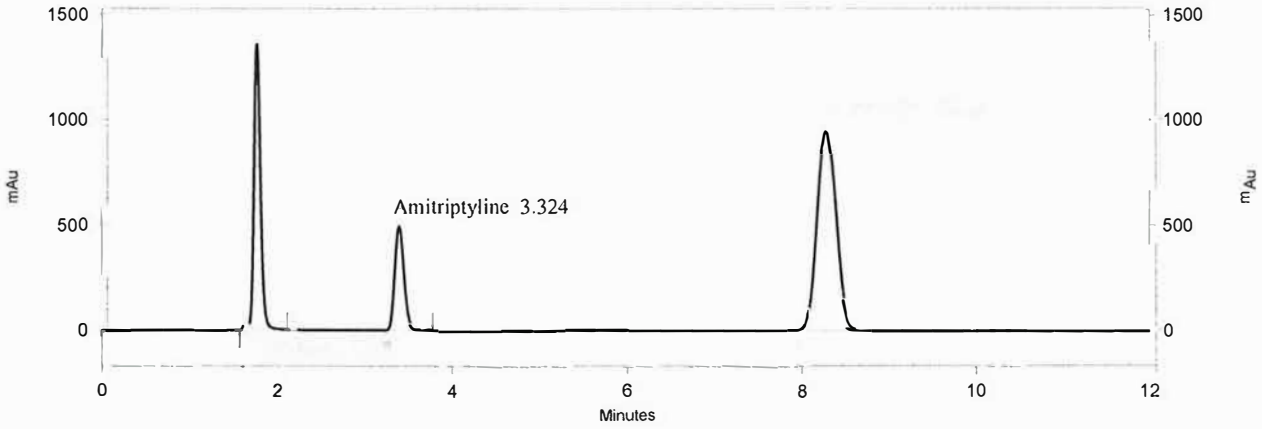
Sample: Sample Stability 1 month
Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met Integration Method: C:\CLASS-VP\Methods\Compounding\Amitriptyline Final Method.met
Vial: #4



1: 200 nm, 4 nm Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	3.564	3427021	1.878	1.44534	1.28891

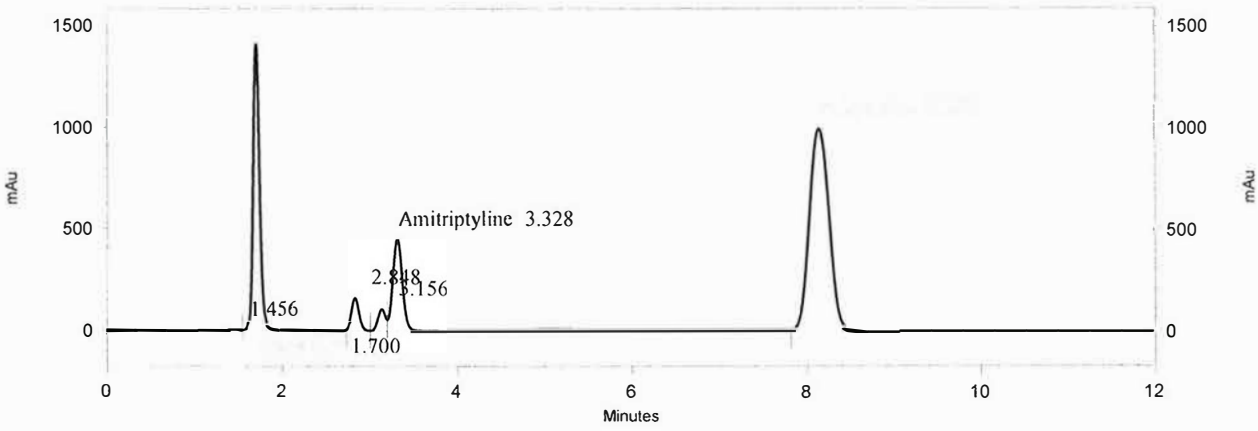
Sample: Amitriptyline Standards Check
Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Integration Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Vial: #3



1: 200 nm, 4 nm Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	3.324	3619786	99.509	9.91992	1.15027

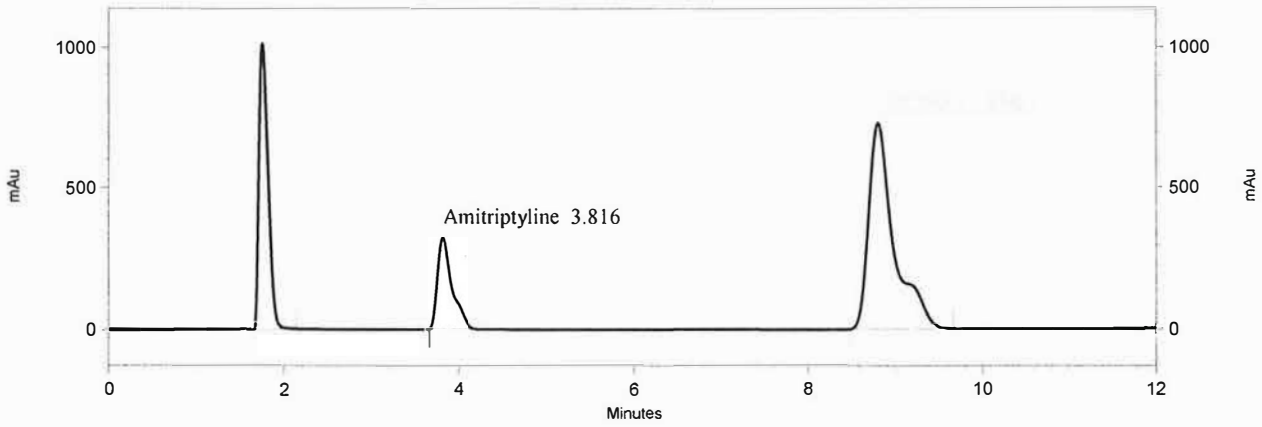
Sample: Amitriptyline 6 pl 2 month Stability
Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Integration Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Vial: #6



1: 200 nm, 4 nm Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	3.328	3428031	1.790	0.89564	0.00000

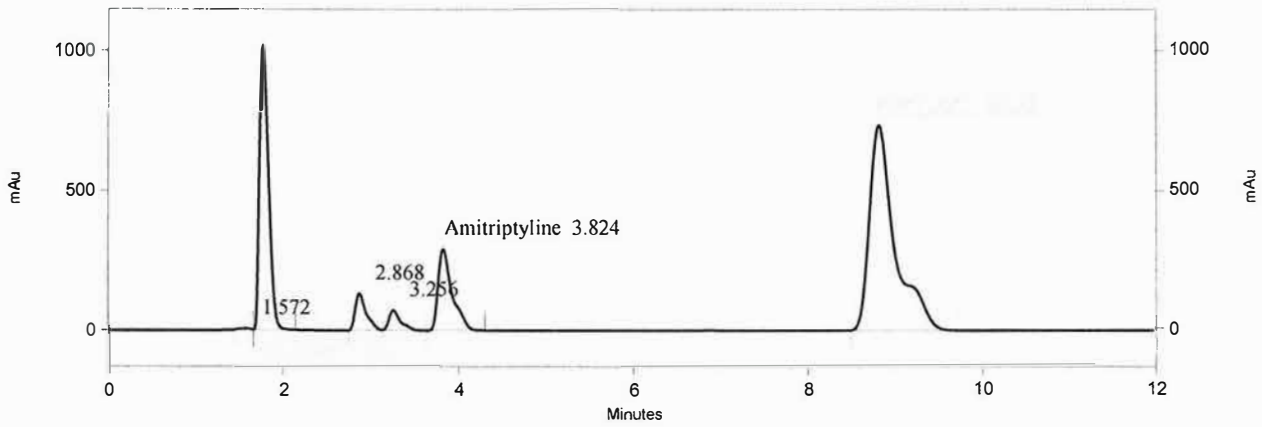
Sample: Amitriptyline Standards Std Chek
Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Integration Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Vial: #3



1: 200 nm, 4 nm Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	3.816	3626181	100.018	8.60750	1.70567

Sample: Sample Stability 2 month
Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Integration Method: C:\CLASS-VP\Methods\Enterprise\Compounding\Amitriptyline Final Method.met
Vial: #4



1: 200 nm, 4 nm
Results

Name	Retention Time	Area	% w/w	Resolution (USP)	Asymmetry
Amitriptyline	3.824	3264851	1.789	2.28035	1.71763