

Clomipramine Hydrochloride:

2.50g Clomipramine Hydrochloride raw drug powder from Spectrum chemical (part number C1376, Lot # XA0670) was added to 50.00g Humco Salt-Stable LO (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 5.0% w/w. This emulsion was then stored at room temperature in the same 50/70 mL Unguator container.

Similar steps were used in preparing samples in Humco PenCream (Humco Holding Group, Texarkana, Texas).

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 2% Clomipramine Hydrochloride loss in Humco Salt-Stable LO at 90 days.

Compounded at 7.5% w/w, stability-indicating HPLC analysis found negligible Clomipramine Hydrochloride loss in Humco PenCream at 90 days.

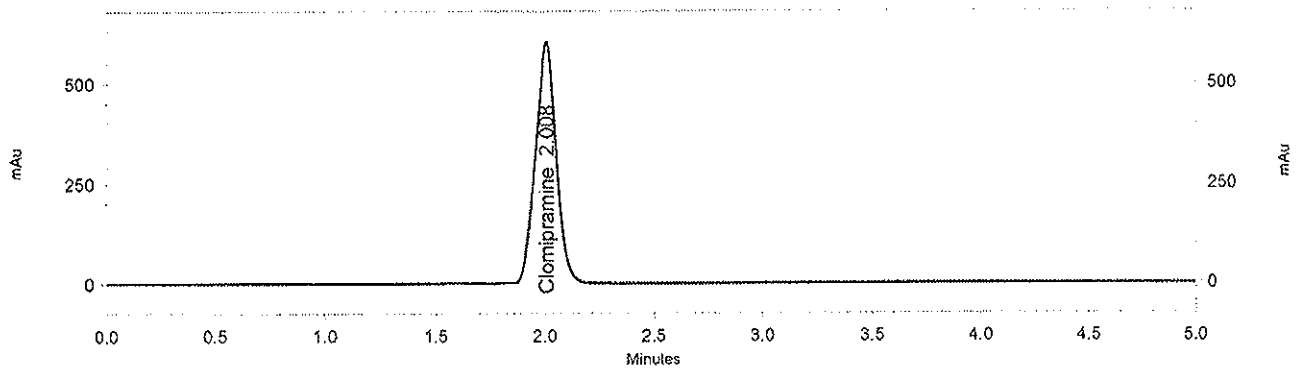
Attached are 8 chromatographs of Humco Salt-Stable LO showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

Attached are 8 chromatographs of Humco PenCream 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.

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2008\December 2008\HPLC 3\December 03-08
Clomipramine Linearity.seq

Name Standard 1
Time 12/4/2008 8:38:47 AM
Vial 2
Injection Vol 25



1: 254
nm, 4
nm

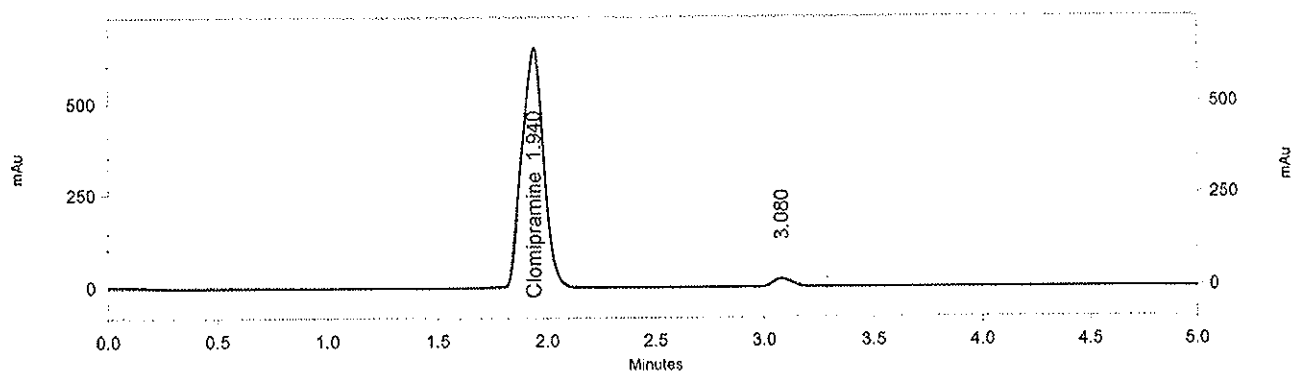
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry	Peak purity
Clomipramine	2.008	3938096	0.10000 CAL	2046	0.00000	1.00627	0.537224

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2008\December 2008\HPLC 3\December 04-08
Clomipramine Precision.seq

Name Precision 1
Time 12/4/2008 2:36:39 PM
Vial 5
Injection Vol 25



1: 254
nm, 4
nm

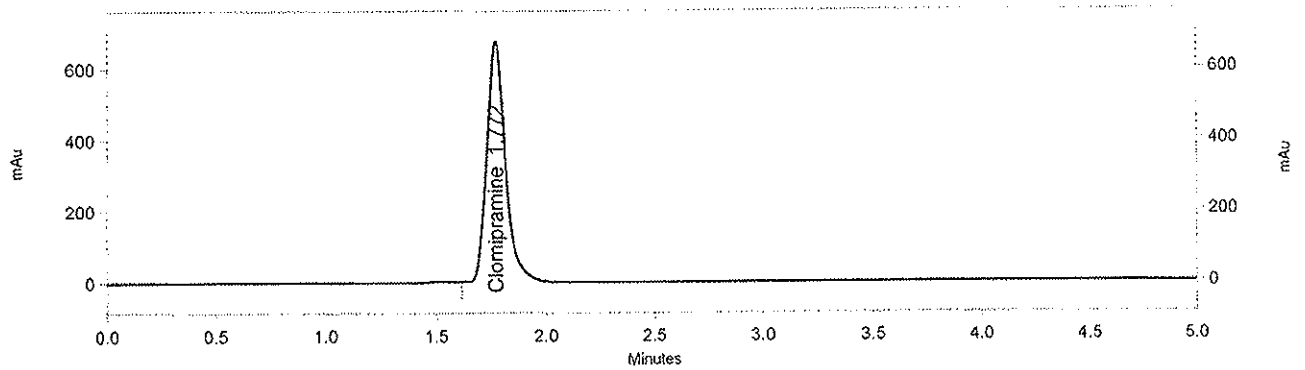
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry	Peak purity
Clomipramine	1.940	4426180	4.95478	1724	0.00000	1.02681	0.601547

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\January\HPLC3\January 19-09 Clomipramine Stability.seq

Name Standard 1
Time 1/19/2009 11:40:03 AM
Vial 2
Injection Vol 25



1: 254
nm, 4
nm

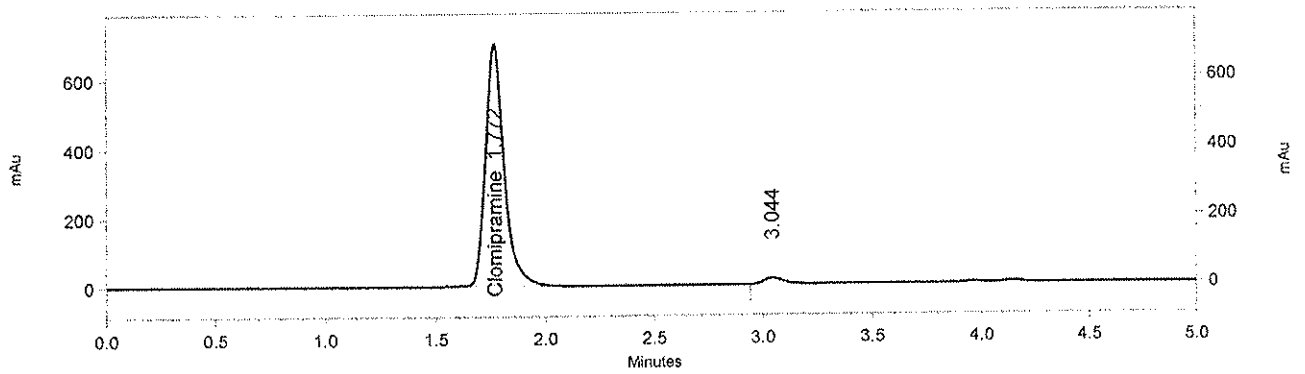
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry	Peak purity
Clomipramine	1.772	3972500	0.10000 CAL	2187	0.00000	1.25793	0.617181

Method C:\CLASS-VP-Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\January\HPLC3\January 19-09 Clomipramine Stability.seq

Name Precision Stability 30 days
Time 1/19/2009 11:40:14 AM
Vial 4
Injection Vol 25



1: 254
nm, 4
nm

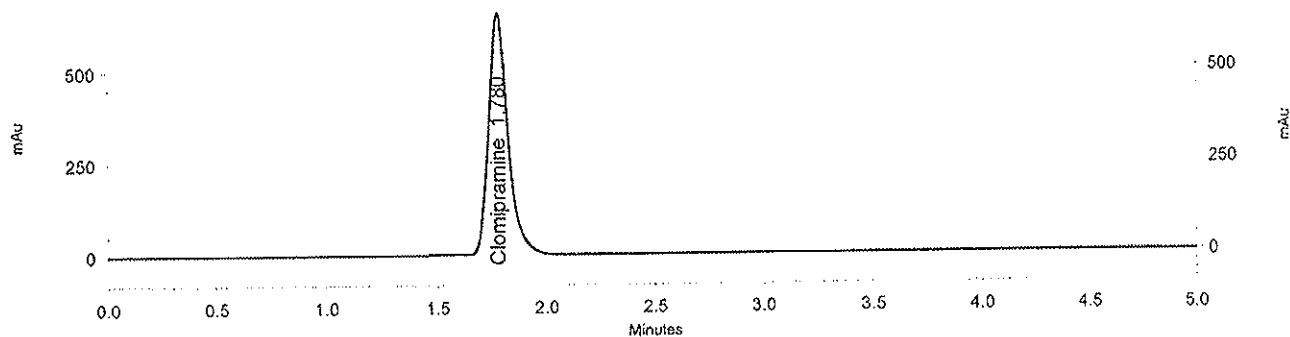
Results

Results Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry	Peak purity
Clomipramine	1.772	4152316	5.08379	2161	0.00000	1.25788	0.613070

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\February\HPLC 3\February10-09
Clomipramine Stability 60 days.seq

Name Standard 1
Time 2/10/2009 12:54:49 PM
Vial 32
Injection Vol 25



1: 254
nm, 4
nm

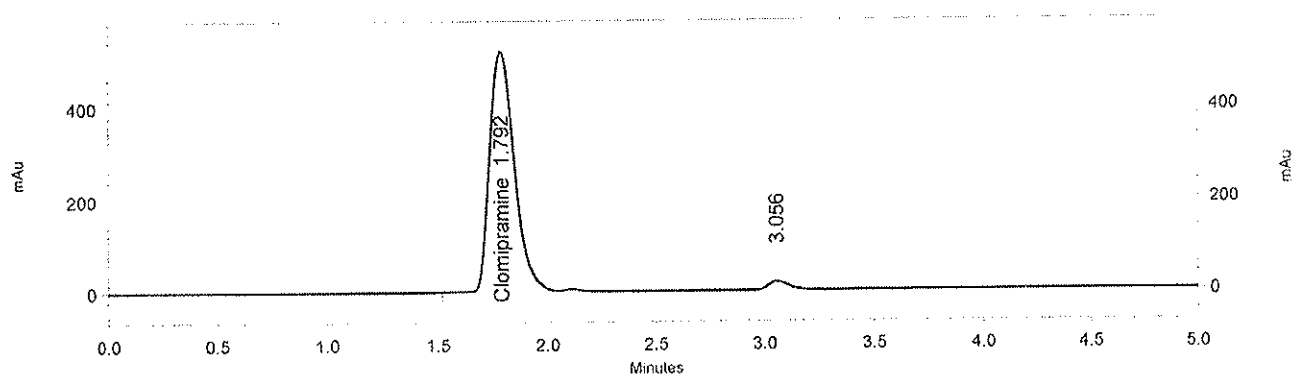
Results
Name

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry	Peak purity
Clomipramine	1.780	4017623	0.10000 CAL	2051	0.00000	1.27058	0.626526

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\February\HPLC 3\February10-09
Clomipramine Stability 60 days.seq

Name Precision Stability 60 days
Time 2/10/2009 12:55:12 PM
Vial 34
Injection Vol 25



1: 254
nm, 4
nm

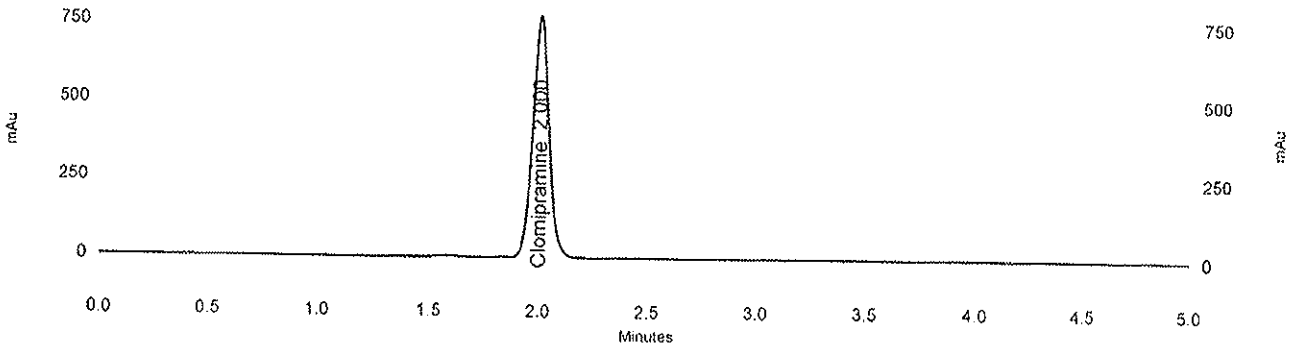
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry	Peak purity
Clomipramine	1.792	4081916	4.92785	1239	0.00000	1.29724	0.715023

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\March\HPLC 3\March 09-09 Clomipramine
Stability 90 days.seq

Name Standard 1
Time 3/9/2009 11:09:45 AM
Vial 2
Injection Vol 25



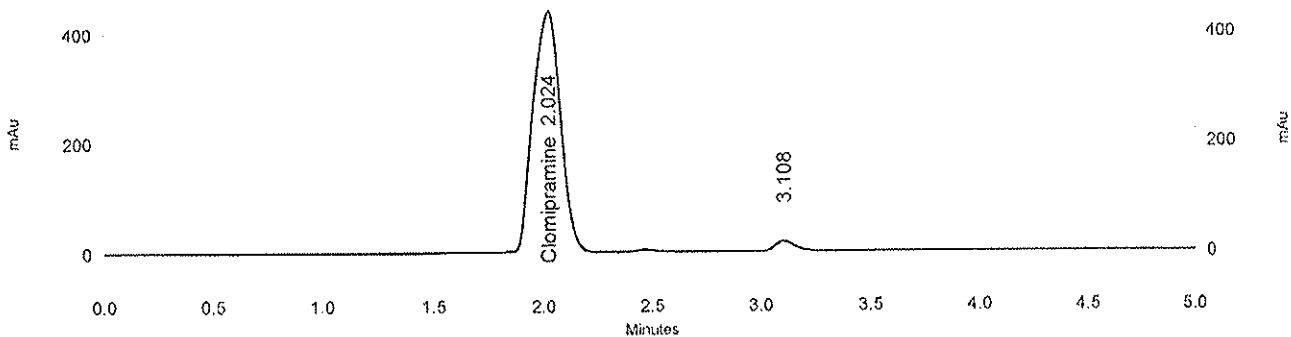
1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry
Clomipramine	2.000	3948242	0.1000 CAL	3576	0.00000	1.13596

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\March\HPLC 3\March 09-09 Clomipramine
Stability 90 days.seq

Name Precision Stability 60 days
Time 3/9/2009 11:09:56 AM
Vial 4
Injection Vol 25



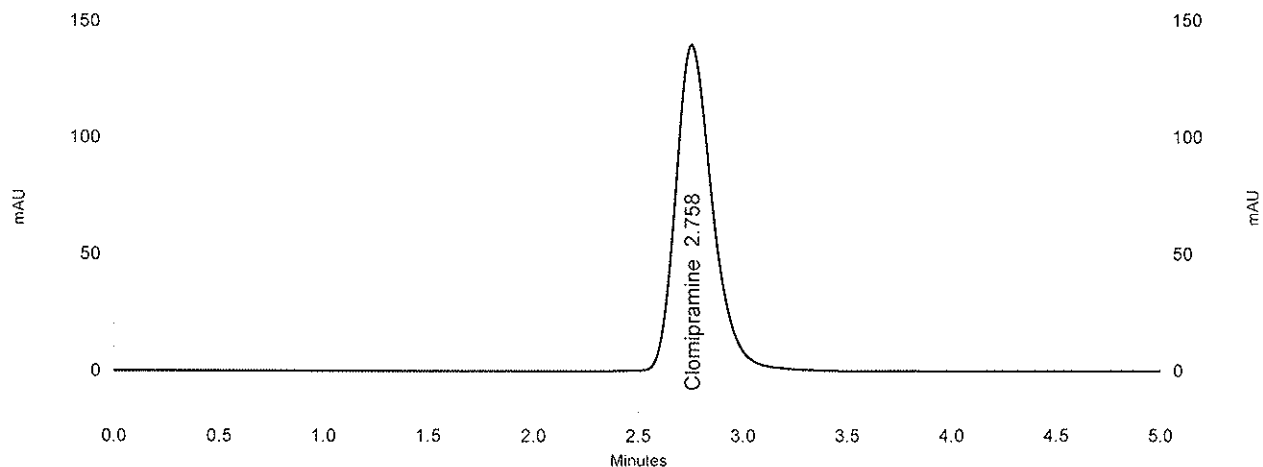
1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry
Clomipramine	2.024	3881963	4.90025	1185	0.00000	1.00648

HUMCO QUALITY CONTROL LABORATORY

Sample ID: Clomipramine St

Method Name: C:\CLASS-VP\Methods\HPLC4\Clomipramine.met
Sequence: C:\CLASS-VP\Sequence\2009\July\HPLC 3\July 16-09 Clomipramine 7.5 % In PEN Cream.seq
Filename: C:\CLASS-VP\Data\2009\July\HPLC 4\July 16-09 Clomipramine 0 Time 01-Rep1
Acquired: 7/16/2009 3:42:59 PM
Printed: 7/16/2009 4:36:28 PM
Vial: 2



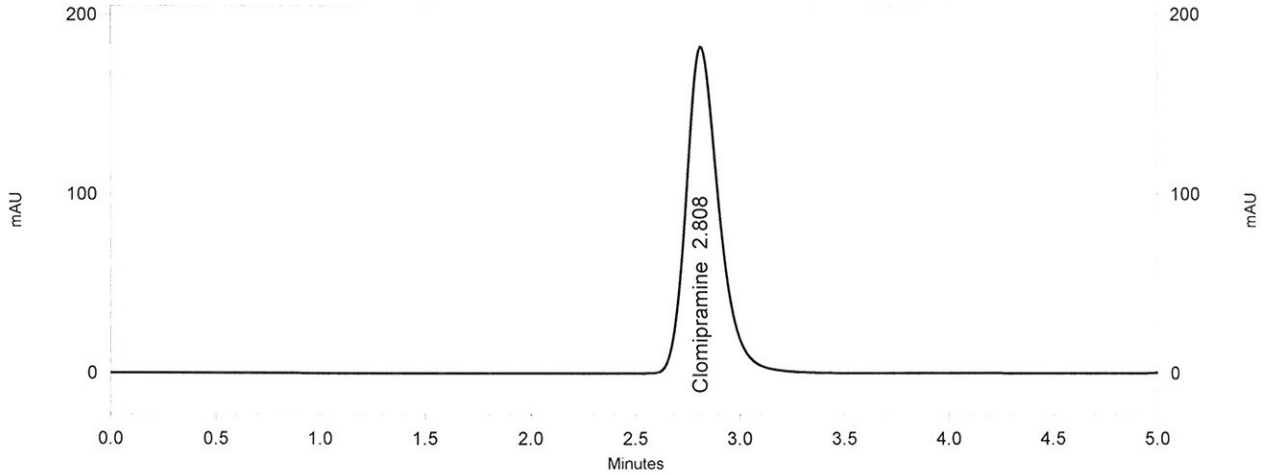
SPD-20AV
Ch1-254nm
Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Clomipramine	2.758	1723147	0.1003 CAL	0.00000	1.26093

HUMCO QUALITY CONTROL LABORATORY

Sample ID: Clomipramine 7.5% in PEN Cream 0 Time

Method Name: C:\CLASS-VP\Methods\HPLC4\Clomipramine.met
Sequence: C:\CLASS-VP\Sequence\2009\July\HPLC 3\July 16-09 Clomipramine 7.5 % In PEN Cream.seq
Filename: C:\CLASS-VP\Data\2009\July\HPLC 4\July 16-09 Clomipramine 0 Time 03
Acquired: 7/16/2009 4:16:50 PM
Printed: 7/16/2009 4:36:33 PM
Vial: 4



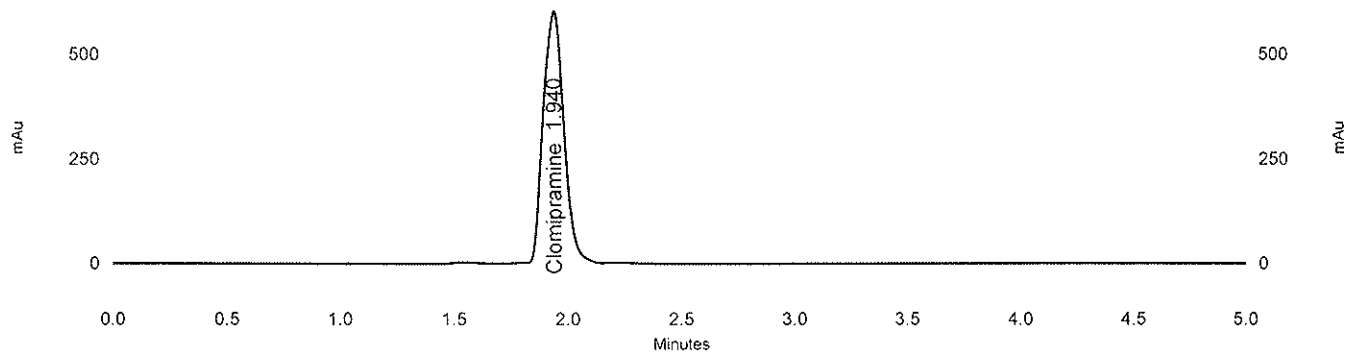
SPD-20AV
Ch1-254nm
Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Clomipramine	2.808	2013199	7.8645	0.00000	1.29185

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\August\HPLC 3\August 17-09 Clomipramine
30 days Stability.seq

Name Standard 1
Time 8/17/2009 2:11:06 PM
Vial 2
Injection Vol 25



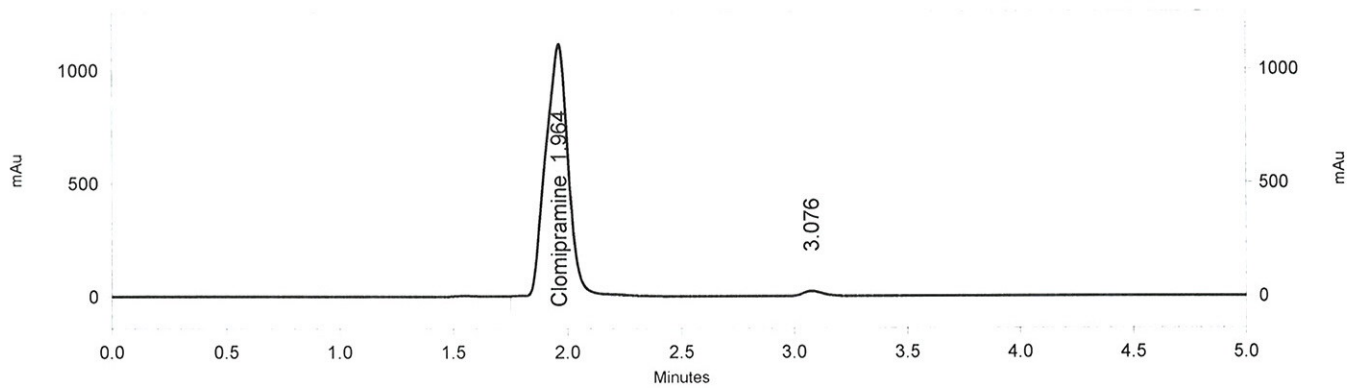
1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry
Clomipramine	1.940	3806910	0.10000 CAL	2170	0.00000	1.10804

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\August\HPLC 3\August 17-09 Clomipramine 30 days Stability.seq

Name Clomipramine Stability 30 days
Time 8/17/2009 2:19:26 PM
Vial 4
Injection Vol 25



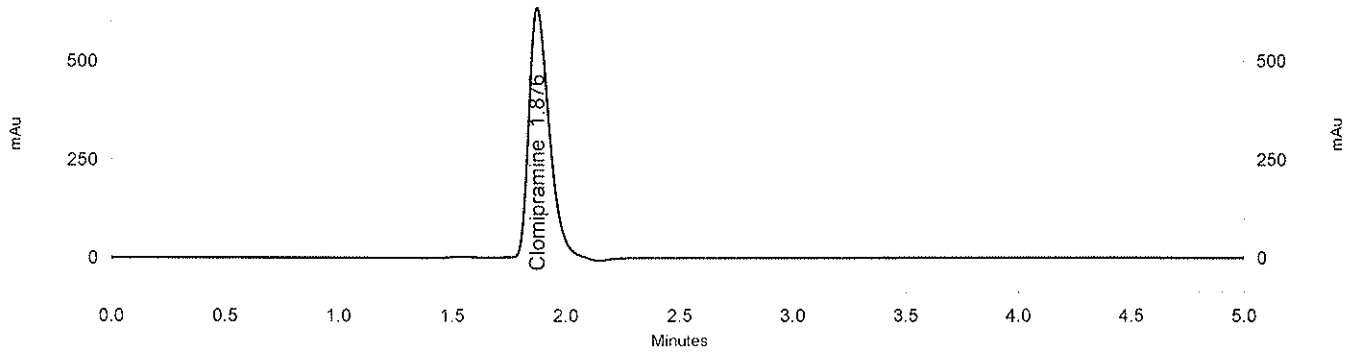
1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry
Clomipramine	1.964	7518943	7.67587	1786	0.00000	0.95454

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\September\HPLC 3\September 17-09
Clomipramine Stability 60 days.seq

Name Standard 1
Time 9/17/2009 12:41:53 PM
Vial 2
Injection Vol 25



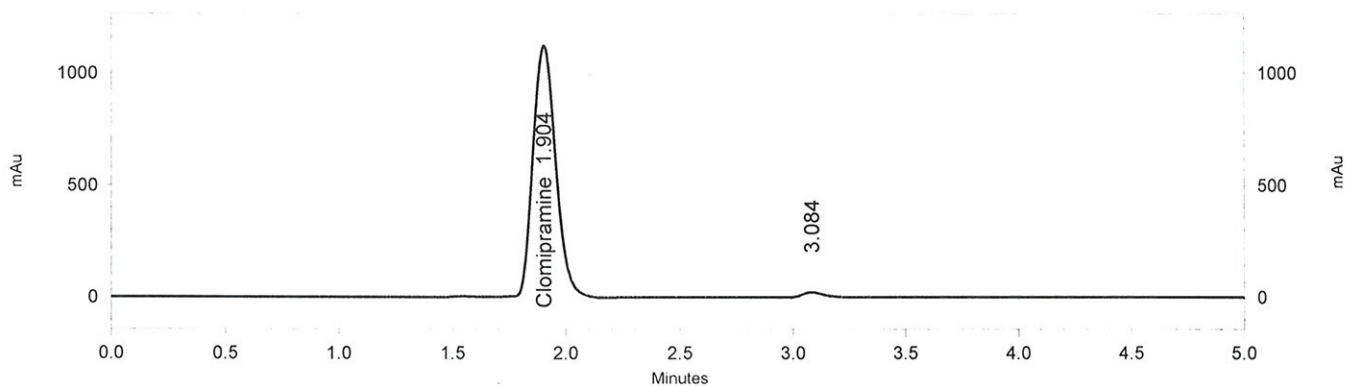
1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry
Clomipramine	1.876	3941383	0.10000 CAL	2129	0.00000	1.43597

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\September\HPLC 3\September 17-09
Clomipramine Stability 60 days.seq

Name Clomipramine Stability 60 days
Time 9/17/2009 12:42:02 PM
Vial 4
Injection Vol 25



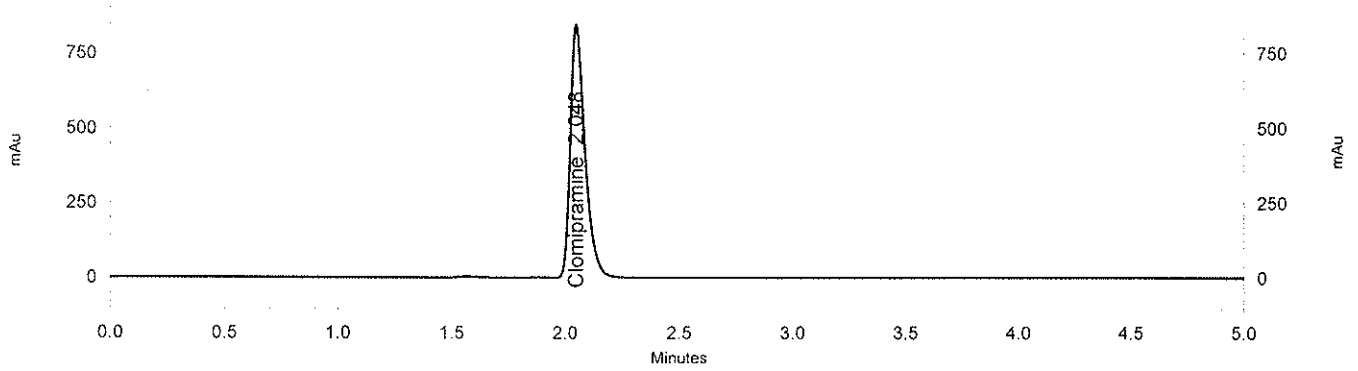
1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Theoretical plates (USP)	Resolution (USP)	Asymmetry
Clomipramine	1.904	7865142	7.94433	1687	0.00000	1.17177

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

Sequence C:\CLASS-VP\Sequence\2009\October\HPLC 3\October 16-09 Clomipramine
90 Days Stability.seq

Name Standard 1
Time 10/16/2009 1:02:22 PM
Vial 2
Injection Vol 25



1: 254
nm, 4 nm
Results

Name	Retention Time	Area	ESTD concentration	Theoretic al plates (USP)	Resolutio n (USP)	Asymmetry
Clomipramine	2.048	3790996	0.10000 CAL	5008	0.00000	1.46496

Method C:\CLASS-VP\Methods\HPLC3\Clomipramine.met

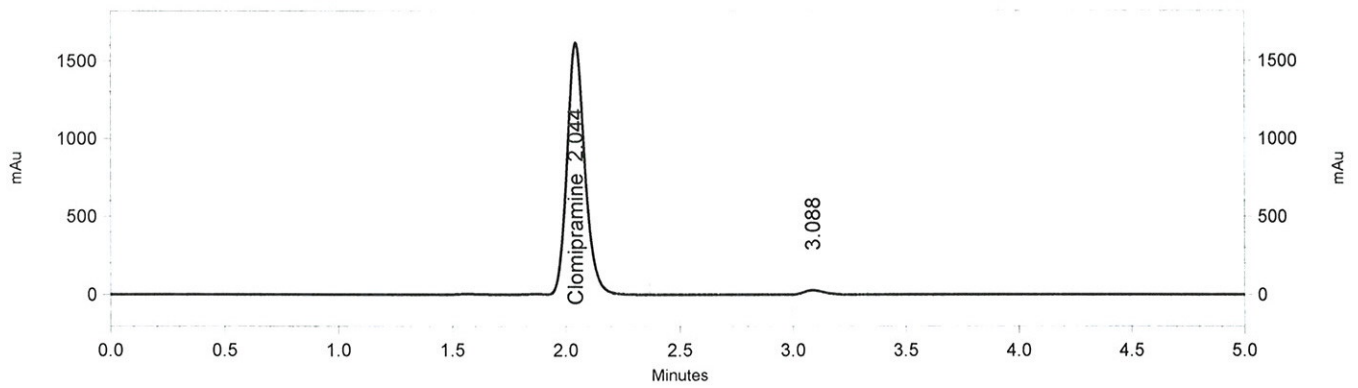
Sequence C:\CLASS-VP\Sequence\2009\October\HPLC 3\October 16-09 Clomipramine 90 Days Stability.seq

Name Clomipramine Stability 90 days

Time 10/16/2009 1:02:39 PM

Vial 4

Injection Vol 25



1: 254

nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Theoretic al plates (USP)	Resolutio n (USP)	Asymmetry
Clomipramine	2.044	8792322	7.50367	3341	0.00000	1.15714