Tetracaine Hydrochloride:

2.00g Tetracaine Hydrochloride raw drug powder from Spectrum chemical 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 4.0% 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 30 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 30 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 30 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.

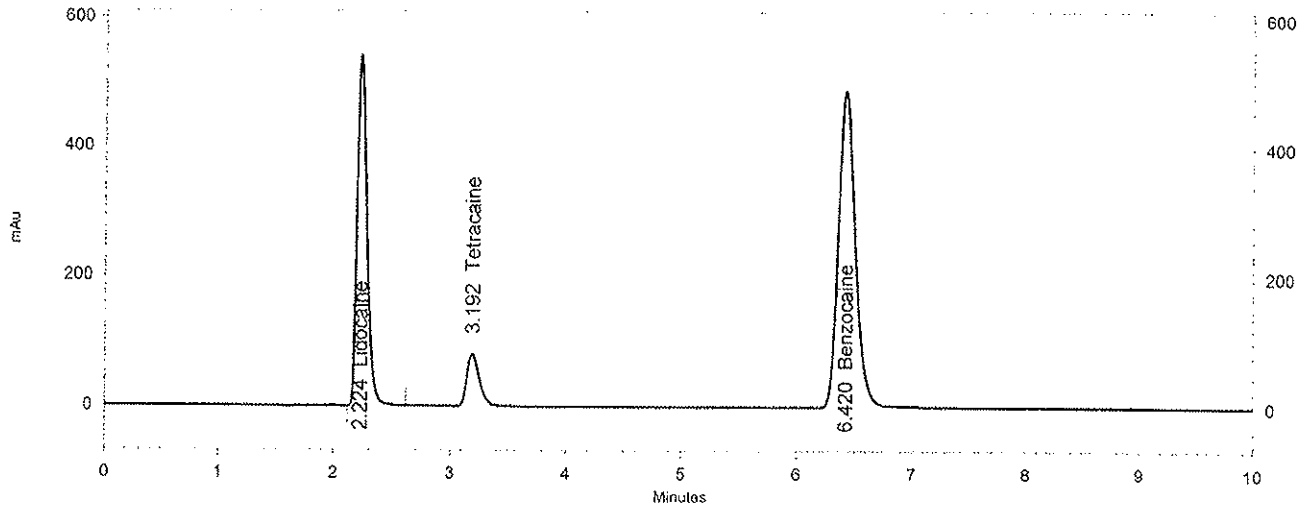
90-Day Summary:

Compounded at 4.0% w/w, stability-indicating HPLC analysis found negligible Tetracaine Hydrochloride loss in Humco Salt-Stable LO at 90 days.
Compounded at 2.0% w/w, stability-indicating HPLC analysis found negligible Tetracaine 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.

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April 23-08 Linearity 31
Sample ID: Std 1
C:\CLASS-VP\Sequence\2008\April 2008\HPLC 3\April 23-08 Lidobenzotetracaine Linearity.seq
C:\CLASS-VP\Methods\Compounding\LidoBenzoTetracaine.met
Vial: 2
Sample amount: 1

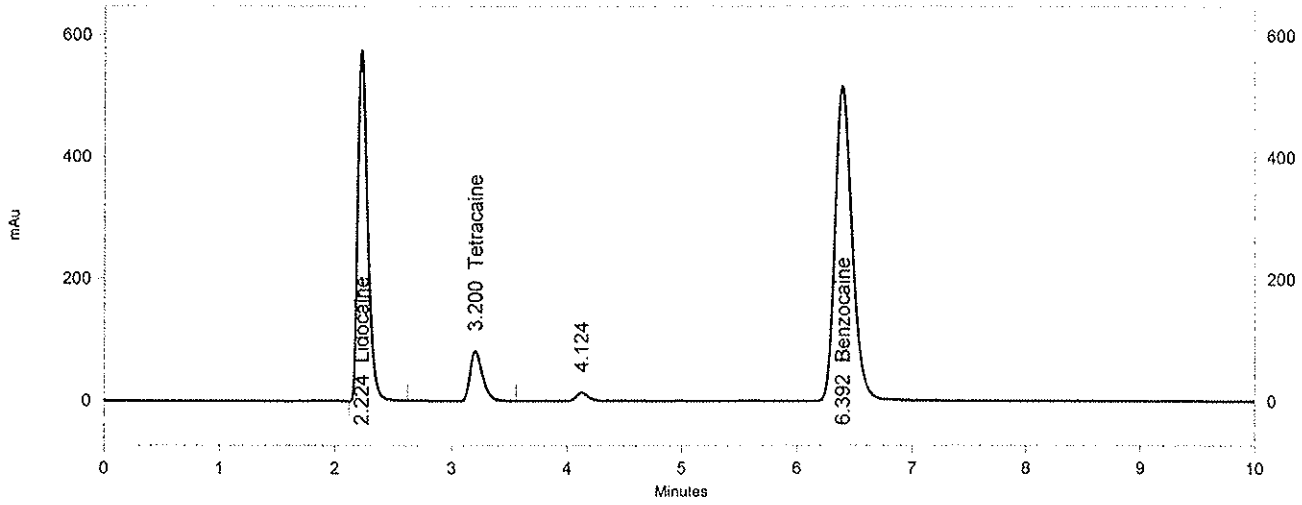


2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.224	3117450	0.100 CAL	1.55201	0.00000
Tetracaine	3.192	584733	0.040 CAL	1.39731	5.64222
Benzocaine	6.420	4952536	0.200 CAL	1.26060	14.06373

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April 23-08 Linearity 11
Sample ID: Precision 1
C:\CLASS-VP\Sequence\2008\April 2008\HPLC 3\April 23-08 Lidobenzotetracaine Linearity.seq
C:\CLASS-VP\Methods\Compounding\LidoBenzoTetracaine.met
Vial: 9
Sample amount: 0.107



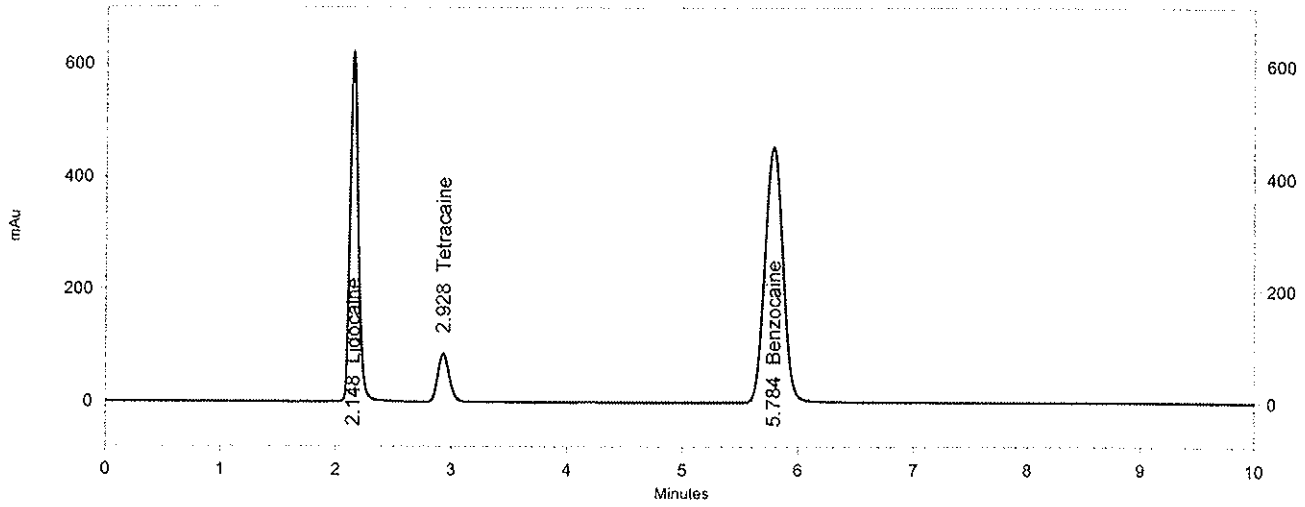
2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.224	3320650	9.991	1.51364	0.00000
Tetracaine	3.200	595957	3.818	1.40598	5.64284
Benzocaine	6.392	5228755	19.767	1.24392	9.91827

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May 19-08 Stability 1 month 02

Sample ID: STDTetracaine Check
C:\CLASS-VP\Sequence\2008\April 2008\HPLC 3\May-19-08 Lidobenzotetracaine Stability 1 month.seq
C:\CLASS-VP\Methods\Enterprise\Compounding\LidoBenzoTetracaine.met
Vial: 3
Sample amount: 0.04004



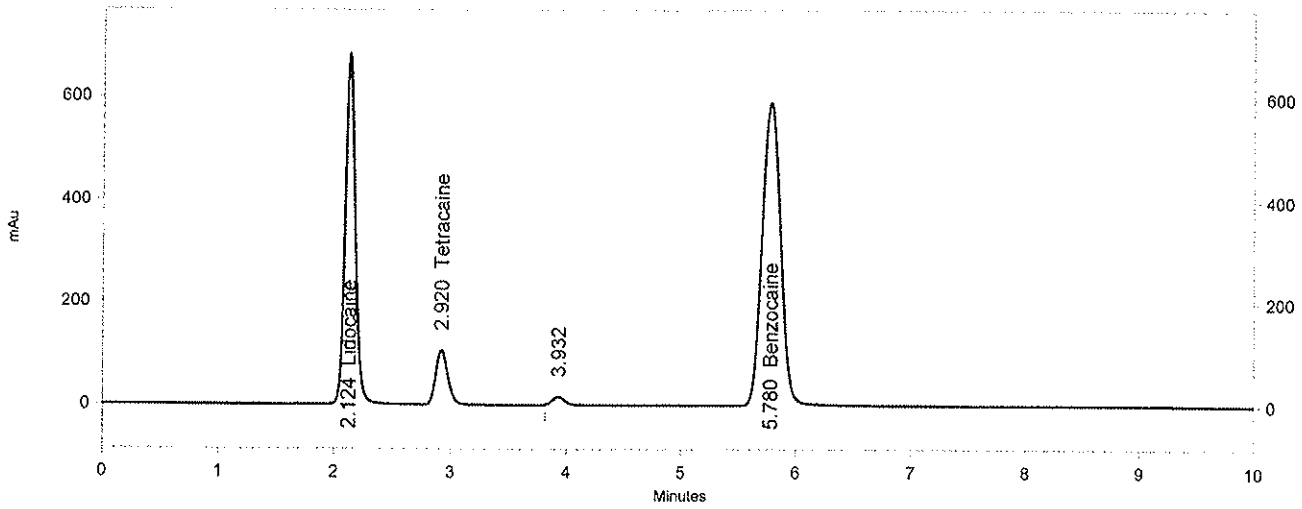
2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.148	3059698	250.334	1.32807	0.00000
Tetracaine	2.928	587895	100.380	1.18552	5.03784
Benzocaine	5.784	4946333	499.959	1.07081	12.14795

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May 19-08 Stability 1 month 03

Sample ID: Stability Sample 1 month
C:\CLASS-VP\Sequence\2008\April 2008\HPLC 3\May-19-08 Lidobenzotetracaine Stability 1 month.seq
C:\CLASS-VP\Methods\Enterprise\Compounding\LidoBenzoTetracaine.met
Vial: 4
Sample amount: 0.1276

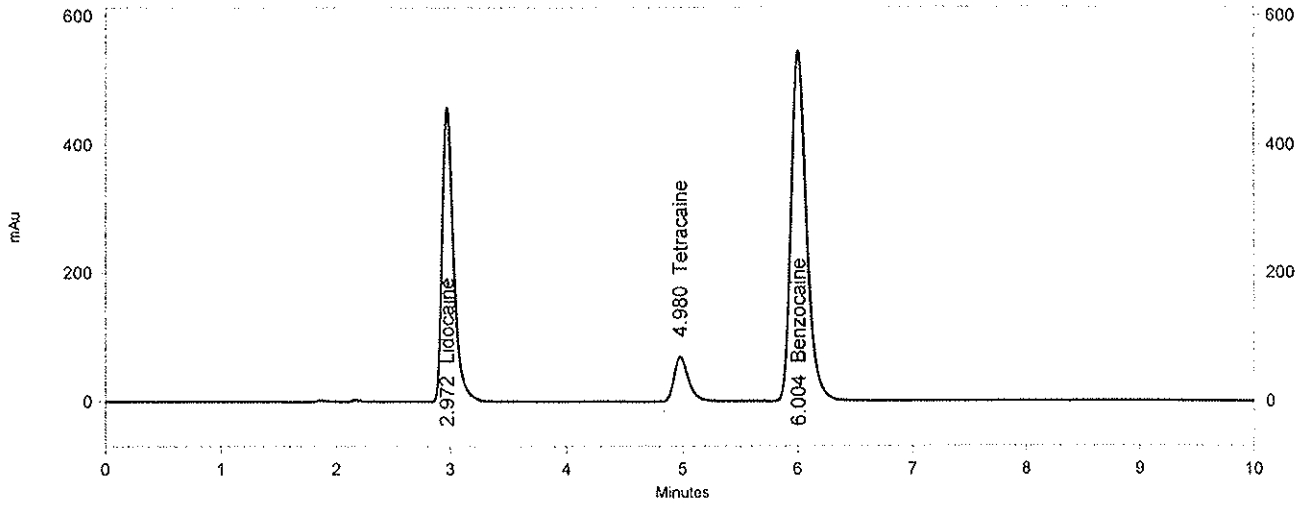


2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.124	4008614	10.292	1.26076	0.00000
Tetracaine	2.920	764455	4.096	1.19123	4.64187
Benzocaine	5.780	6474736	20.536	1.08189	7.46310

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June 20-08 Stability 2 month 02
Sample ID: Tetracaine STD Check
C:\CLASS-VP\Sequence\2008\May 2008\HPLC 3\June-20-08 Lidobenzotetracaine Stability 2 month.seq
C:\CLASS-VP\Methods\Enterprise\Compounding\LidoBenzoTetracaine.met
Vial: 3
Sample amount: 0.04004

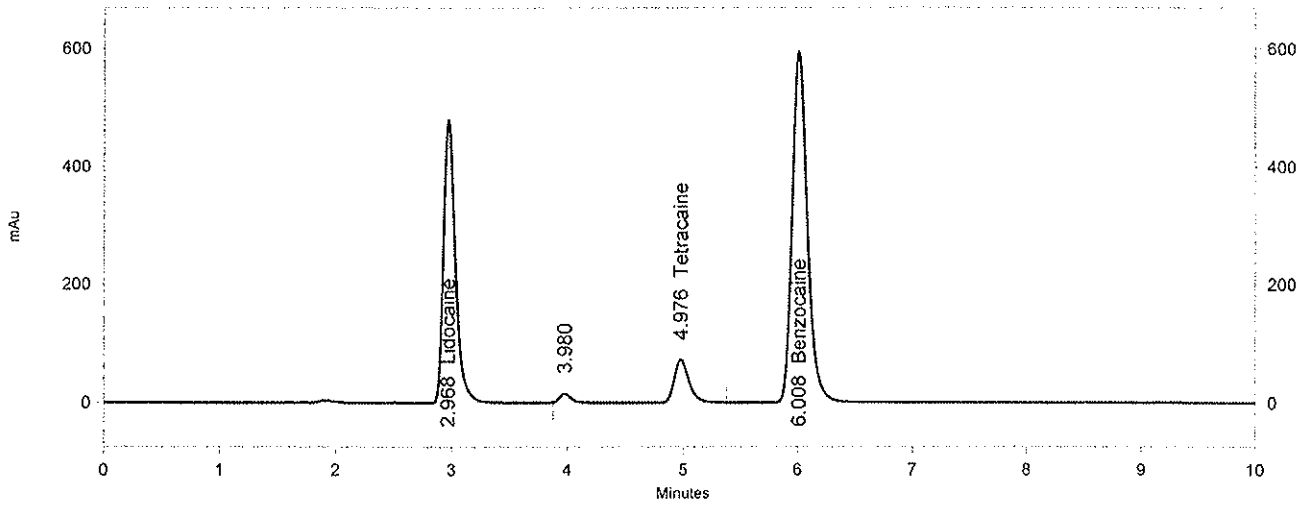


2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.972	3121257	250.384	1.43443	0.00000
Tetracaine	4.980	579039	99.887	1.34707	10.12489
Benzocaine	6.004	4927830	499.955	1.25792	4.47428

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June 20-08 Stability 2 month 05
Sample ID: Stability Sample 2 month
C:\CLASS-VP\Sequence\2008\May 2008\HPLC 3\June-20-08 Lidobenzotetracaine Stability 2 month.seq
C:\CLASS-VP\Methods\Enterprise\Compounding\LidoBenzoTetracaine.met
Vial: 4
Sample amount: 0.1094

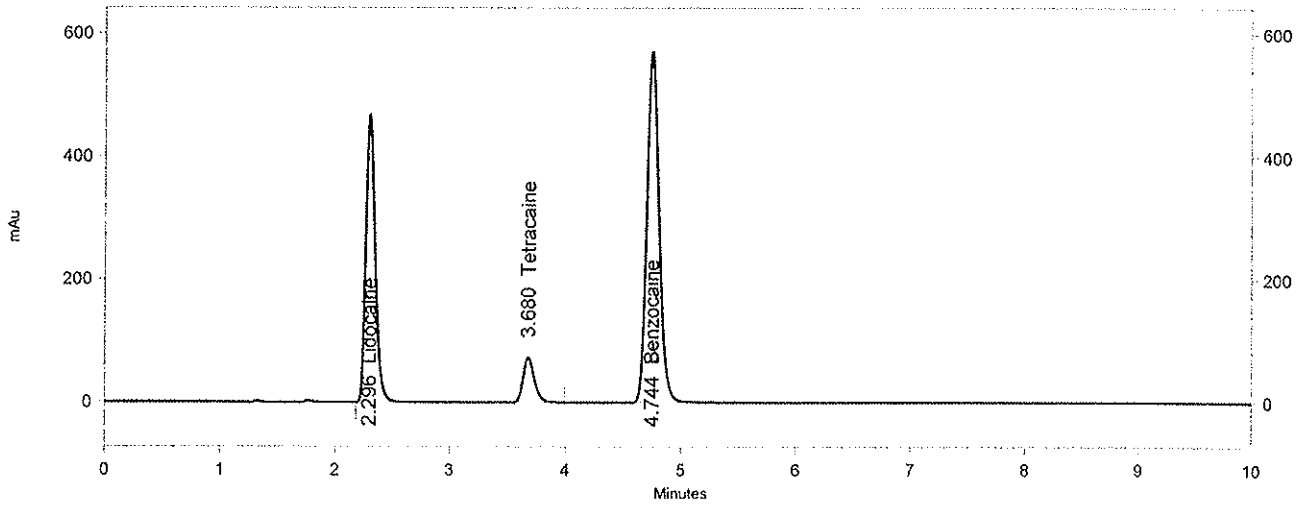


2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.968	3439490	10.098	1.47314	0.00000
Tetracaine	4.976	629126	3.972	1.34219	4.85952
Benzocaine	6.008	5488397	20.380	1.26270	4.37987

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\September 02-08 Stability 3 month 02
Sample ID: Tetracaine St check
C:\CLASS-VP\Sequence\2008\July 2008\HPLC 3\September 02-08 Lidobenzotetracaine Stability.seq
C:\CLASS-VP\Methods\Enterprise\Compounding\LidoBenzoTetracaine.met
Vial: 3
Sample amount: 0.0404

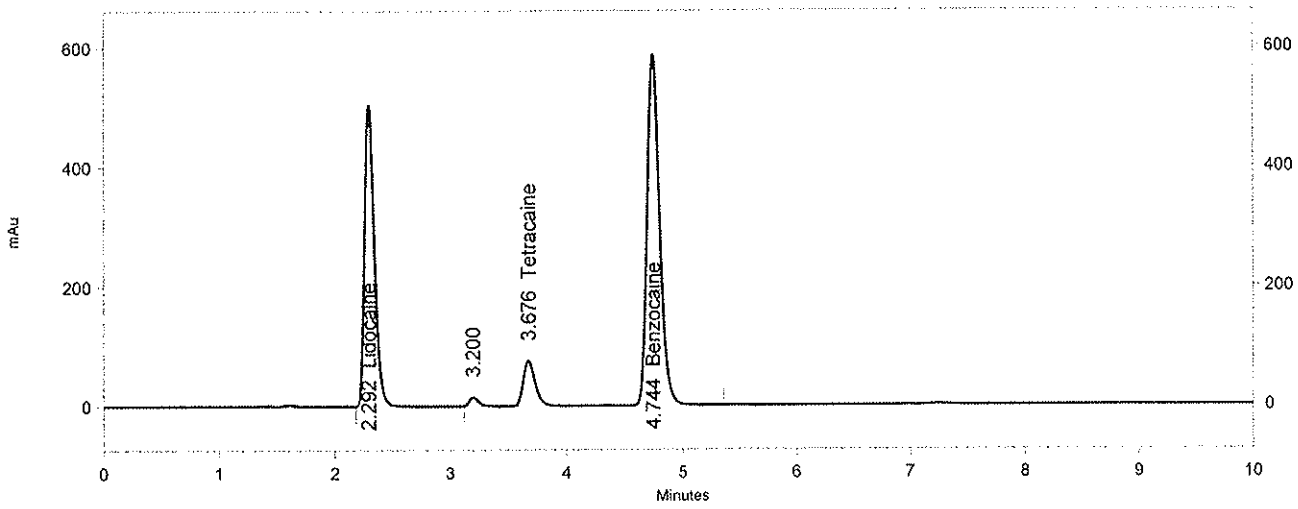


2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.296	2617143	247.534	1.38858	0.00000
Tetracaine	3.680	488573	98.999	1.28748	8.55039
Benzocaine	4.744	4167812	495.462	1.24568	5.75382

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\September 02-08 Stability 3 month 05
Sample ID: Stability Sample 3 month
C:\CLASS-VP\Sequence\2008\July 2008\HPLC 3\September 02-08 Lidobenzotetracaine Stability.seq
C:\CLASS-VP\Methods\Enterprise\Compounding\LidoBenzoTetracaine.met
Vial: 4
Sample amount: 0.107



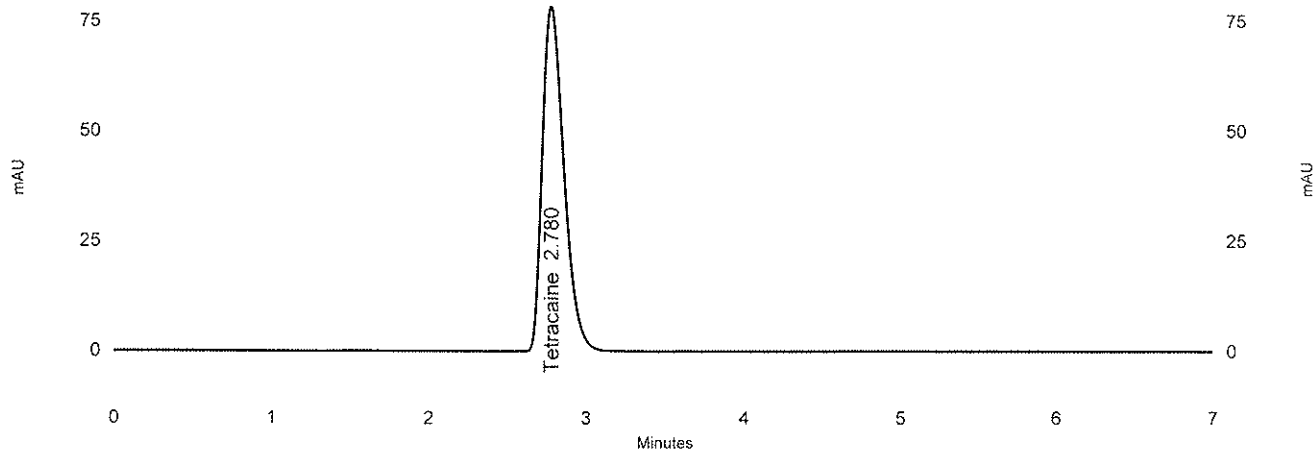
2: 203 nm,
4 nm
Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	2.292	2904275	10.372	1.39644	0.00000
Tetracaine	3.676	528947	4.047	1.27875	2.84082
Benzocaine	4.744	4375498	19.639	1.22380	5.63595

HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Standard*

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Tetracain Method.met
Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 23-10 Tetracaine stability Zero day.seq
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\August 23-10 Tetracaine stability 02-Rep1
Acquired: 8/23/2010 12:54:03 PM
Printed: 8/23/2010 2:07:28 PM
Vial: 3



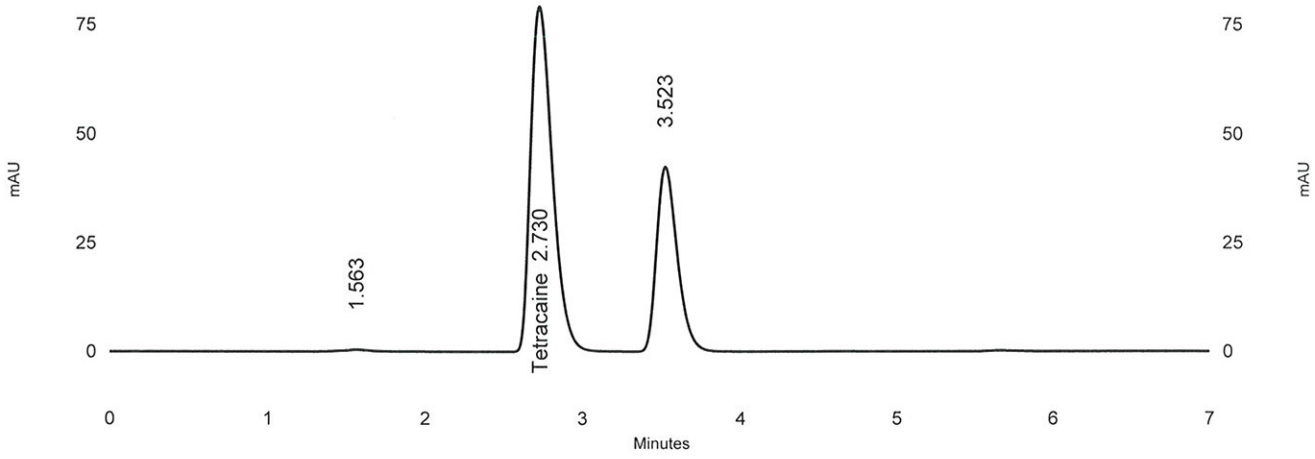
SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	*Asymmetry*
Tetracaine	2.780	78363	750102	0.201 CAL	*1.40307*

HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Tetracaine*
sample

Method Name:	C:\CLASS-VP\Enterprise\Projects\Default\Method\Tetracain Method.met
Sequence:	C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 23-10 Tetracaine stability Zero day.seq
Filename:	C:\CLASS-VP\Data\2010\August\HPLC 4\August 23-10 Tetracaine stability 04
Acquired:	8/23/2010 1:39:46 PM
Printed:	8/23/2010 2:07:56 PM
Vial:	5



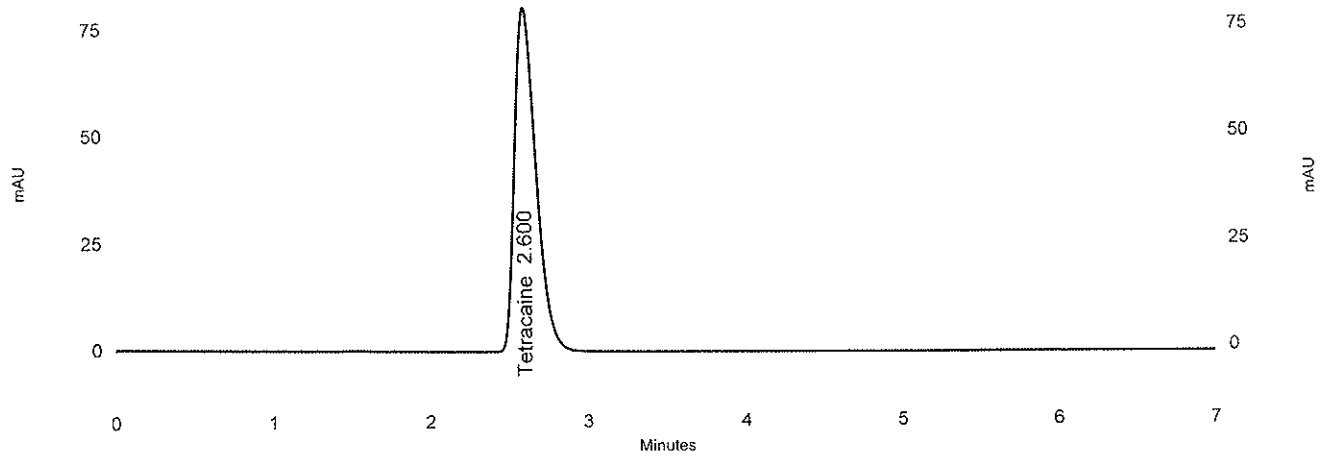
SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	*Asymmetry*
	1.563	429	4690	0.000	*0.94006*
Tetracaine	2.730	79127	751217	1.988	*1.40206*
	3.523	42444	385261	0.000	*1.33584*

HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Standard*

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Tetracain Method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\Tetracaine 30 days stability 9-27-10.seq
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\Sept 27-10 Tetracaine 30days stability 01-Rep1
Acquired: 9/27/2010 10:28:12 AM
Printed: 9/27/2010 12:00:23 PM
Vial: 2



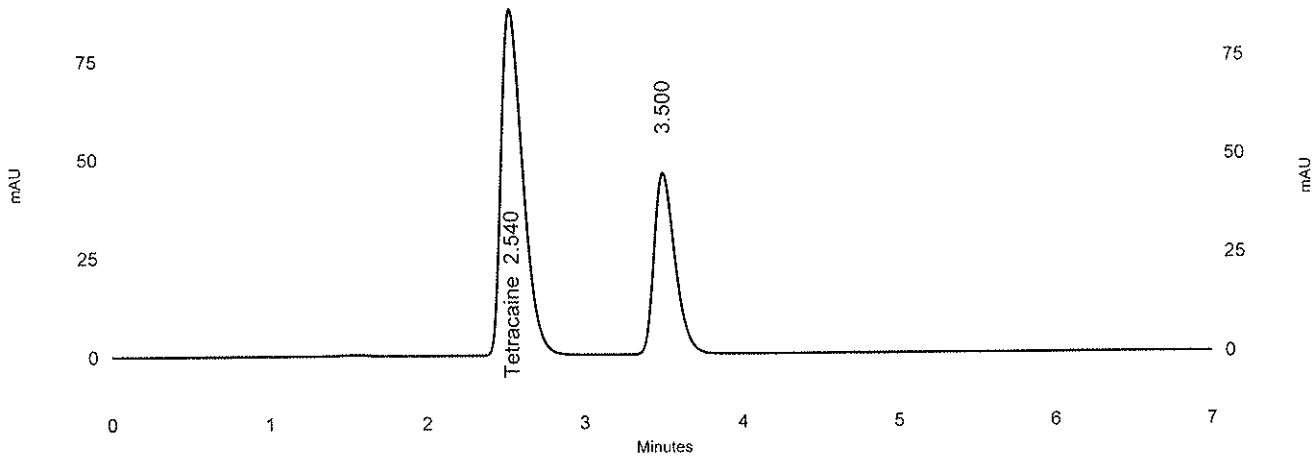
SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	*Asymmetry*
Tetracaine	2.600	80395	763844	0.201 CAL	*1.36162*

HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Tetracaine*
sample

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Tetracain Method.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\Tetracaine 30 days stability 9-27-10.seq
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\Sept 27-10 Tetracaine 30days stability 03
Acquired: 9/27/2010 11:13:52 AM
Printed: 9/27/2010 12:00:36 PM
Vial: 4



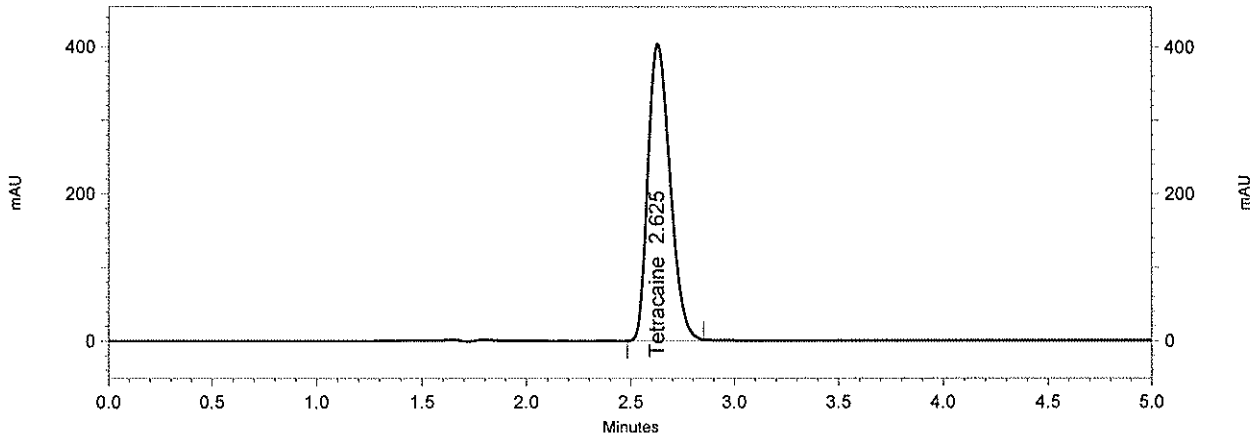
SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	*Asymmetry*
Tetracaine	2.540	87764	829059	2.023	*1.36754*
	3.500	45779	423198	0.000	*1.28930*

HUMCO QUALITY CONTROL LABORATORY

Sample ID: Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Tetracaine met.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 4\Tetracaine stability 11-3-10.seq
Filename: C:\CLASS-VP\Data\Data\2010\November\HPLC 4\Nov- 3-10 Tetracaine stability 01-Rep1
Acquired: 11/3/2010 1:39:03 PM
Printed: 11/3/2010 2:39:05 PM
Vial: 2



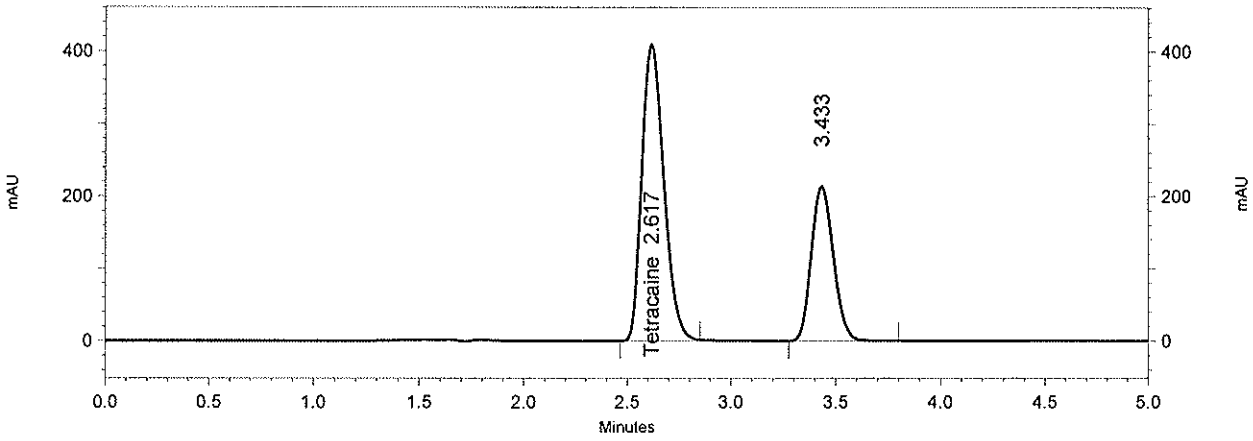
SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Tetracaine	2.625	403951	3009493	0.20 CAL	1.34

HUMCO QUALITY CONTROL LABORATORY

Sample ID: Tetracaine sample

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Tetracaine met.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 4\Tetracaine stability 11-3-10.seq
Filename: C:\CLASS-VP\Data\Data\2010\November\HPLC 4\Nov- 3-10 Tetracaine stability 03
Acquired: 11/3/2010 2:12:53 PM
Printed: 11/3/2010 2:39:16 PM
Vial: 4



SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Tetracaine	2.617	409211	3050954	2.04	1.28

HUMCO QUALITY CONTROL LABORATORY

Sample ID: Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Tetracaine met.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 4\Tetracaine 90 days stability A 12-1-10.seq
Filename: C:\CLASS-VP\Data\Data\2010\December\HPLC 4\Nov 1-10 Tetracaine 90 days stability 101-Rep1
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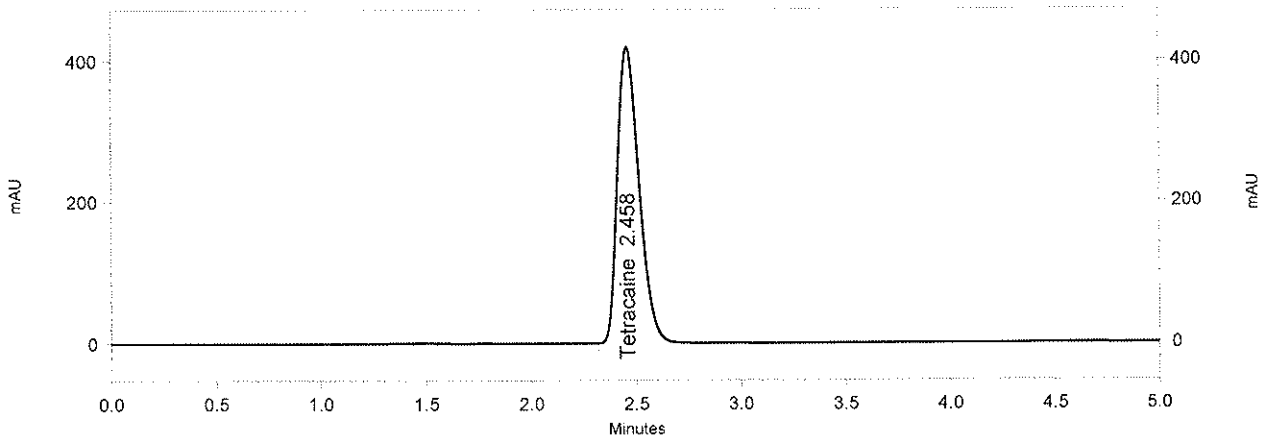
Printed: 12/1/2010 3:26:33 PM
Vial: 2



SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Tetracaine	2.458	419467	3014111	0.20 CAL	1.29

HUMCO QUALITY CONTROL LABORATORY

Sample ID: Tetracaine sample

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Tetracaine met.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 4\Tetracaine 90 days stability A 12-1-10.seq
Filename: C:\CLASS-VP\Data\Data\2010\December\HPLC 4\Nov 1-10 Tetracaine 90 days stability 103
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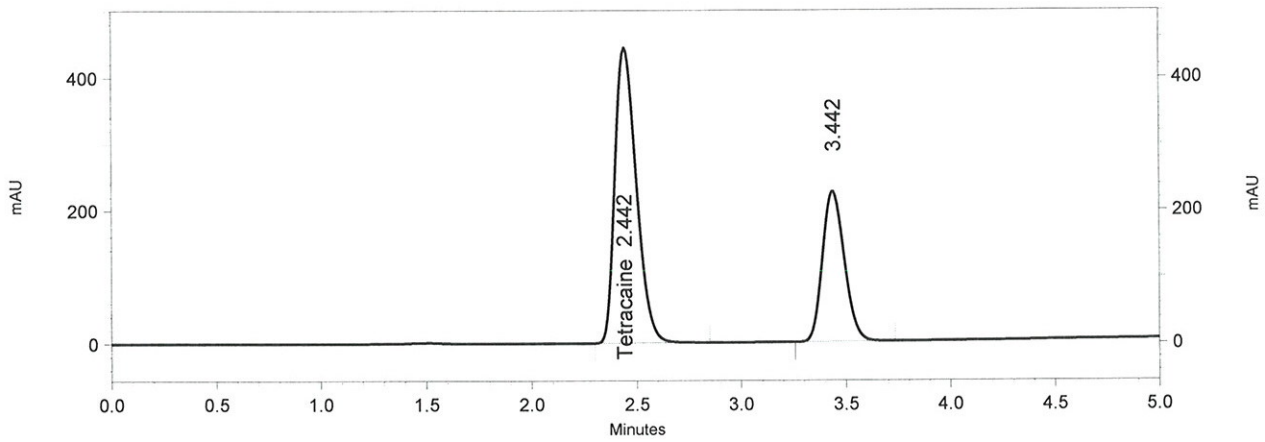
Printed: 12/1/2010 3:26:51 PM
Vial: 4



SPD-20AV
Ch1-203nm
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Tetracaine	2.442	443817	3170115	2.04	1.30