



# Scientific Study

**B4522, Omnibase**  
(Lidocaine Study)

Not appropriate for regulatory submission.  
Please visit [www.SpectrumRx.com](http://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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Lidocaine:

4.40g Lidocaine raw drug powder from Spectrum Chemical (part number LI102, Lot # UL1239) was added to 50.00g Spectrum Mfg. Corp. Omnibase and levigated with an electronic mortar and pestle, resulting in a final concentration of 8.0% w/w. This gel 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 8.0% w/w, stability-indicating HPLC analysis found negligible Lidocaine loss in Spectrum Mfg. Corp. Omnibase at 90 days.

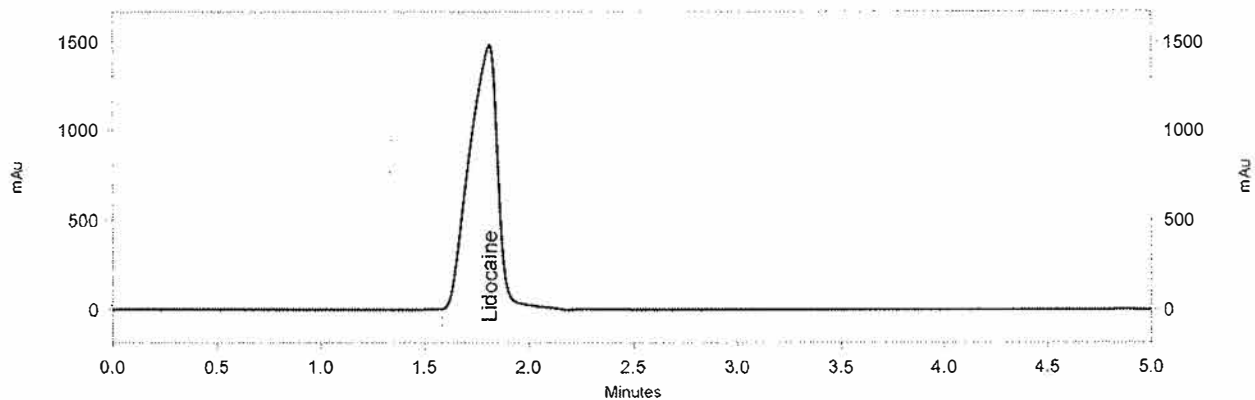
Attached are 8 chromatographs of 8.0% w/w Lidocaine in Spectrum Mfg. Corp. Omnibase showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

Sample ID: Lidocaine Standard  
C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 08-10 Lidocaine 8% 0 Time.seq

C:\CLASS-VP\Enterprise\Projects\Default\Method\Lidocaine HCL.met

Vial: 2

Sample amount: 1



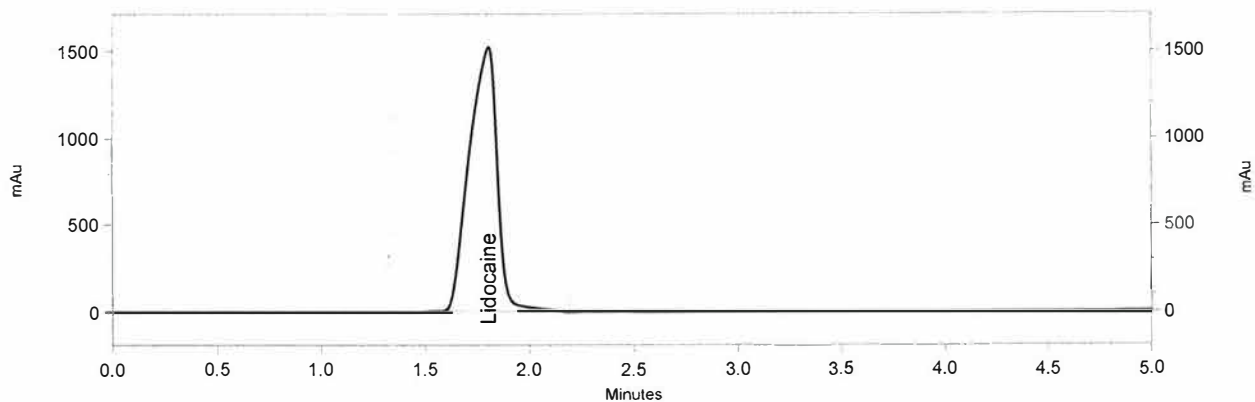
2: 203 nm,

4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	1.812	14089285	0.100 CAL	0.763	0.000

Sample ID: 8% Lidocaine 0 Time in Spectrum Mfg. Corp. Omnibase Base  
 C:\CLASS-VP\Sequence\2010\January\HPLC 3\January 08-10 Lidocaine 8% 0 Time.seq  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Lidocaine HCL.met  
 Vial: 5  
 Sample amount: 0.1254

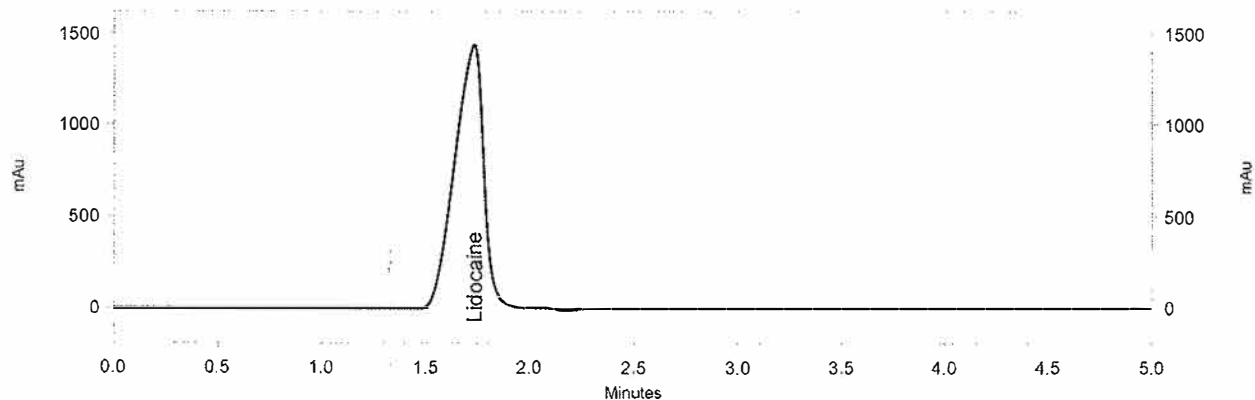


2: 203 nm,  
4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	1.808	14189230	8.021	0.774	0.000

Sample ID: Lidocaine Standard  
 C:\CLASS-VP\Sequence\2010\February\HPLC 3\February 09-10 Lidocaine 30 days  
 stability.seq  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Lidocaine HCL.met  
 Vial: 2  
 Sample amount: 1

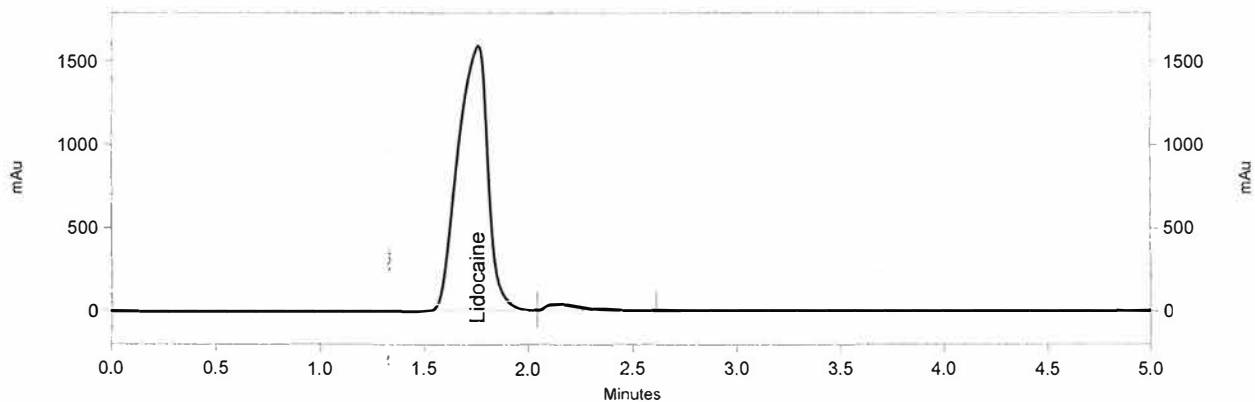


2: 203 nm,  
 4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	1.736	13925873	0.100 CAL	0.784	0.000

Sample ID: 8% Lidocaine 30 days in Spectrum Mfg. Corp. Omnibase  
 C:\CLASS-VP\Sequence\2010\February\HPLC 3\February 09-10 Lidocaine 30 days  
 stability.seq  
 C:\CLASS-VP\Enterprise\Projects\Default\Method\Lidocaine HCL.met  
 Vial: 4  
 Sample amount: 0.142



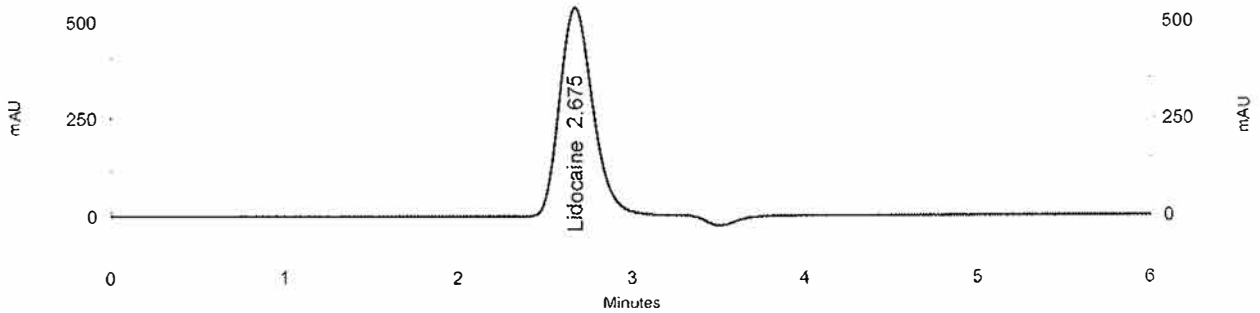
2: 203 nm,  
 4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	1.756	15912970	8.062	0.866	0.000

Sample ID: Lidocaine Std 1

Method Name: C:\CLASS-VP\Methods\HPLC4\Lidocaine R&D.met  
Sequence: C:\CLASS-VP\Sequence\2010\March\HPLC 4\March 09 10 Lidocaine 60 days StabilityA .seq  
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\Lidocaine Stability 60 days 101-Rep1  
Acquired: 3/9/2010 3:38:59 PM  
Printed: 3/9/2010 4:59:03 PM

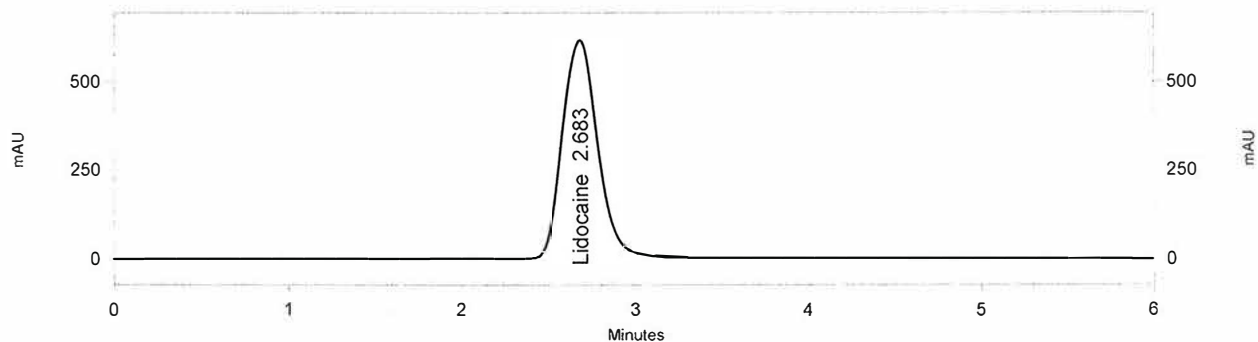


SPD-20AV  
Ch1-203nm  
Results

Name	Retention Time	Height	Area	ESTD concentration
Lidocaine	2.675	535530	7088571	0.1002 CAL

Sample ID: 8% Lidocaine Spectrum Mfg. Corp. Omnibase

Method Name: C:\CLASS-VP\Methods\HPLC4\Lidocaine R&D.met  
Sequence: C:\CLASS-VP\Sequence\2010\March\HPLC 4\March 09 10 Lidocaine 60 days StabilityA .seq  
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\Lidocaine Stability 60 days 103  
Acquired: 3/9/2010 4:18:46 PM  
Printed: 3/9/2010 4:59:08 PM



SPD-20AV  
Ch1-203nm  
Results

Name	Retention Time	Height	Area	ESTD concentration
Lidocaine	2.683	615653	8591909	8.1089



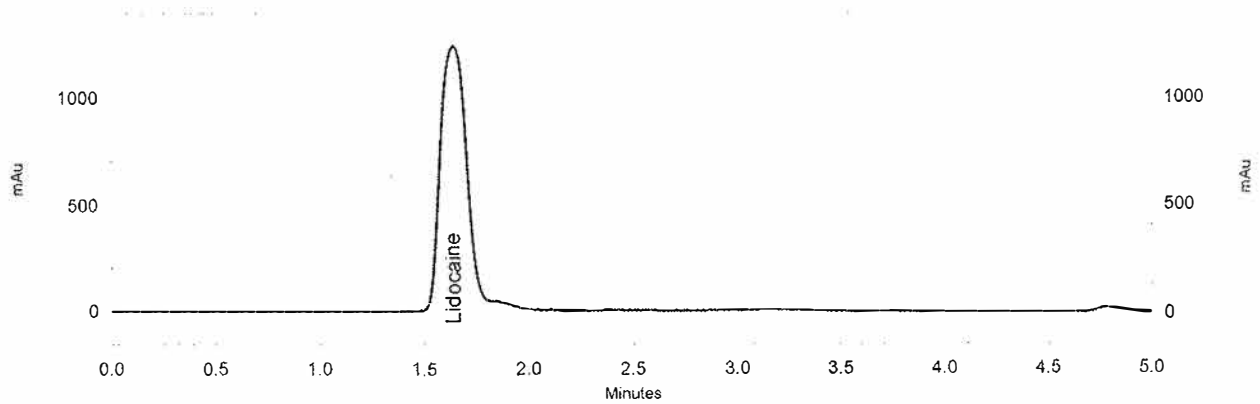
Sample ID: Lidocaine Standard

C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 09-10 Lidocaine 90 days.seq

C:\CLASS-VP\Enterprise\Projects\Default\Method\Lidocaine HCL.met

Vial: 2

Sample amount: 1



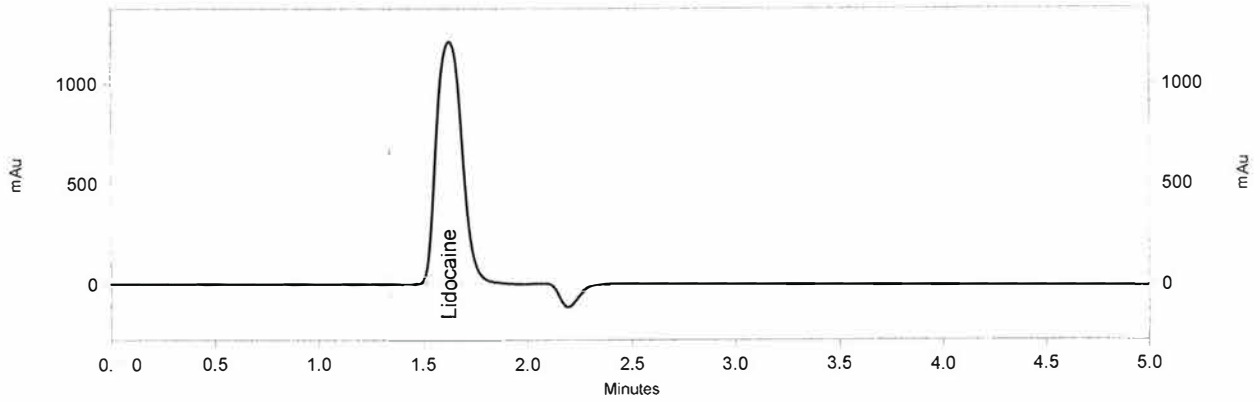
2: 203 nm,

4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	1.636	10639138	0.100 CAL	1.145	0.000

Sample ID: 8% Lidocaine 90 Days in Spectrum Mfg. Corp. Omnibase C:  
 \CLASS-VP\Sequence\2010\April\HPLC 3\April 09-10 Lidocaine 90  
 days.seq C:\CLASS-VP\Enterprise\Projects\Default\Method\Lidocaine  
 HCL.met  
 Vial: 4  
 Sample amount: 0.1198



2: 203 nm,  
 4 nm

Results

Name	Retention Time	Area	% W/W	Asymmetry	Resolution (USP)
Lidocaine	1.624	10281582	8.126	1.152	0.000