



Scientific Study

**B4512, Durabase Advanced Cream
(Lidocaine HCL 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.

Spectrum Pharmacy Products

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New Brunswick, NJ 08901
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Lidocaine Hydrochloride:

5.30g Lidocaine Hydrochloride raw drug powder from MP Chemical (part number 193917, Lot # M3821) was added to 100.00g Spectrum Chemical Mfg. Corp. Durabase Advanced 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 Unguator container.

Similar steps were used in preparing the following combination compound:
2% Baclofen + 10% Flurbiprofen + 5% Lidocaine HCl + 3% Pentoxifylline

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 products.

90-Day Summary:

Compounded at 5.0% w/w in (2% Baclofen + 10% Flurbiprofen + 5% Lidocaine HCl + 3% Pentoxifylline), stability-indicating HPLC analysis found negligible Lidocaine Hydrochloride loss in Spectrum Chemical Mfg. Corp. Durabase Advanced at 90 days.

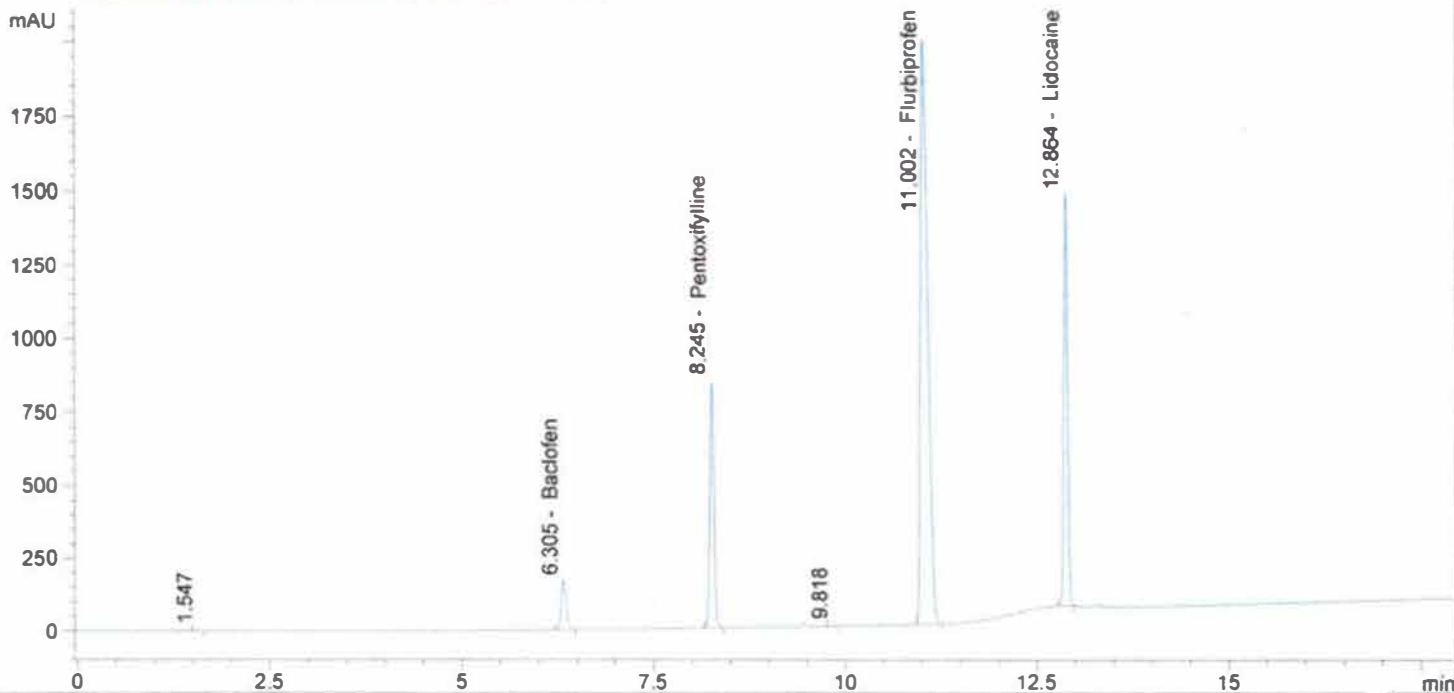
Attached are 2 chromatographs of Spectrum Chemical Mfg. Corp. Durabase Advanced showing 90-Day Standard, and 90-Day Sample of the combination compound.

flur, bac, lido, pent in MeOH and H2O 9:1
 XbridgeCl18150x4.6x3.5, 1ml/min, 30C Buf5mMNa2B4O7, ACN, MEO
 H, 80Buf20MEOH HOLD TO2MIN, 58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min, 46Buf14ACN40MEOH@10MIN, 5 buff
 47.5ACN/MEOH@16min TILL18 min

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Injection date and Time 8/27/2013 11:18:27 PM Vial 51 Inj # 1 Method Inj vol 5ul
 Actual inj vol 5ul

DAD1 B. Sig=210.5 Ref=360.100 (130801\BUD00092.D)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.547	0.055	3	0.555	0.00000	0.00000	11	0.05
2.0	Gabapentin	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
3.0	Baclofen	6.305	0.072	169	0.768	1.00876e-4	0.07938	787	3.59
4.0	Pentoxifylline	8.245	0.059	845	0.893	3.96374e-5	0.12400	3128	14.28
5.0	Clonidine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
6.0	ketoprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
7.0		9.818	0.055	3	0.980	0.00000	0.00000	11	0.05
8.0	Gabapentin RC	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0	Flurbiprofen	11.002	0.106	1986	0.460	3.13387e-5	0.41552	13259	60.51
10.0	Ibuprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
11.0	Diclofenac	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
12.0	Ketamine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
13.0	Triclosan	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
14.0	Lidocaine	12.864	0.055	1418	0.913	4.57033e-5	0.21549	4715	21.52
15.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
16.0	Bupivacaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
17.0	Cyclobenzaprine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
18.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							0.83438	21911	100.00

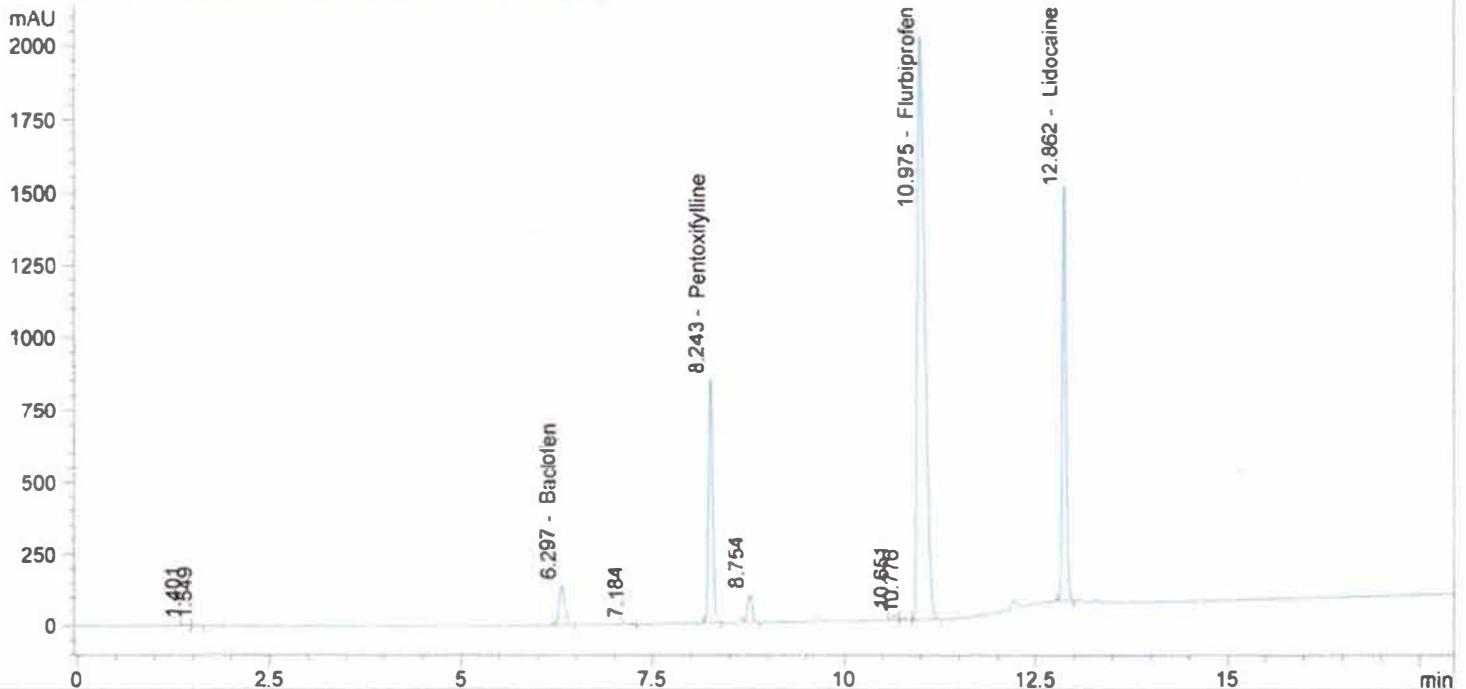
03192013@139 216.0mg/50ml MeOH
 XbridgeC18150x4.6x3.5,1ml/min,30C Buf5mMNa2B4O7,ACN,MEO
 H, 80Buf20MEOH HOLD TO2MIN,58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min,46Buf14ACN40MEOH@10MIN,5 buff
 47.5ACN/MEOH@16min TILL18 min

Injection date and Time 8/27/2013 12:05:06 AM

Vial 52 Inj # 1

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 Method Inj vol 5ul
 Actual inj vol 5ul

DAD1 B, Sig=210.5 Ref=360.100 (130801\BUD00094.D)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %	
1.0		1.401	0.049	6	0.912	0.00000	0.00000	20	0.09	
2.0		1.549	0.059	3	0.563	0.00000	0.00000	12	0.05	
3.0	Gabapentin	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
4.0	Baclofen	6.297	0.076	138	0.835	1.00479e-4	1.59891	687	2.99	
5.0		7.184	0.061	2	0.976	0.00000	0.00000	8	0.03	
6.0	Pentoxifylline	8.243	0.060	844	0.902	3.94534e-5	7.91892	3196	13.90	
7.0		8.754	0.066	98	0.885	0.00000	0.00000	423	1.84	
8.0	Clonidine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
9.0	ketoprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
10.0	Gabapentin RC	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
11.0		10.651	0.059	18	0.901	0.00000	0.00000	71	0.31	
12.0		10.776	0.071	5	0.859	0.00000	0.00000	25	0.11	
13.0	Flurbiprofen	10.975	0.107	2015	0.447	3.12331e-5	9.90680	83703	59.59	
14.0	Ibuprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
15.0	Diclofenac	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
16.0	Ketamine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
17.0	Triclosan	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
18.0	Lidocaine	12.862	0.056	1449	0.904	4.55329e-5	5.11157	4850	21.09	
19.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
20.0	Bupivacaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
21.0	Cyclobenzaprine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
22.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00	
total								19.53620	22995	100.00