



Scientific Study

**B4512, Durabase Advanced Cream
(Lidocaine HCl 2 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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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 + 2% Cyclobenzaprine HCl + 20% Ketoprofen + 5% Lidocaine HCl

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:

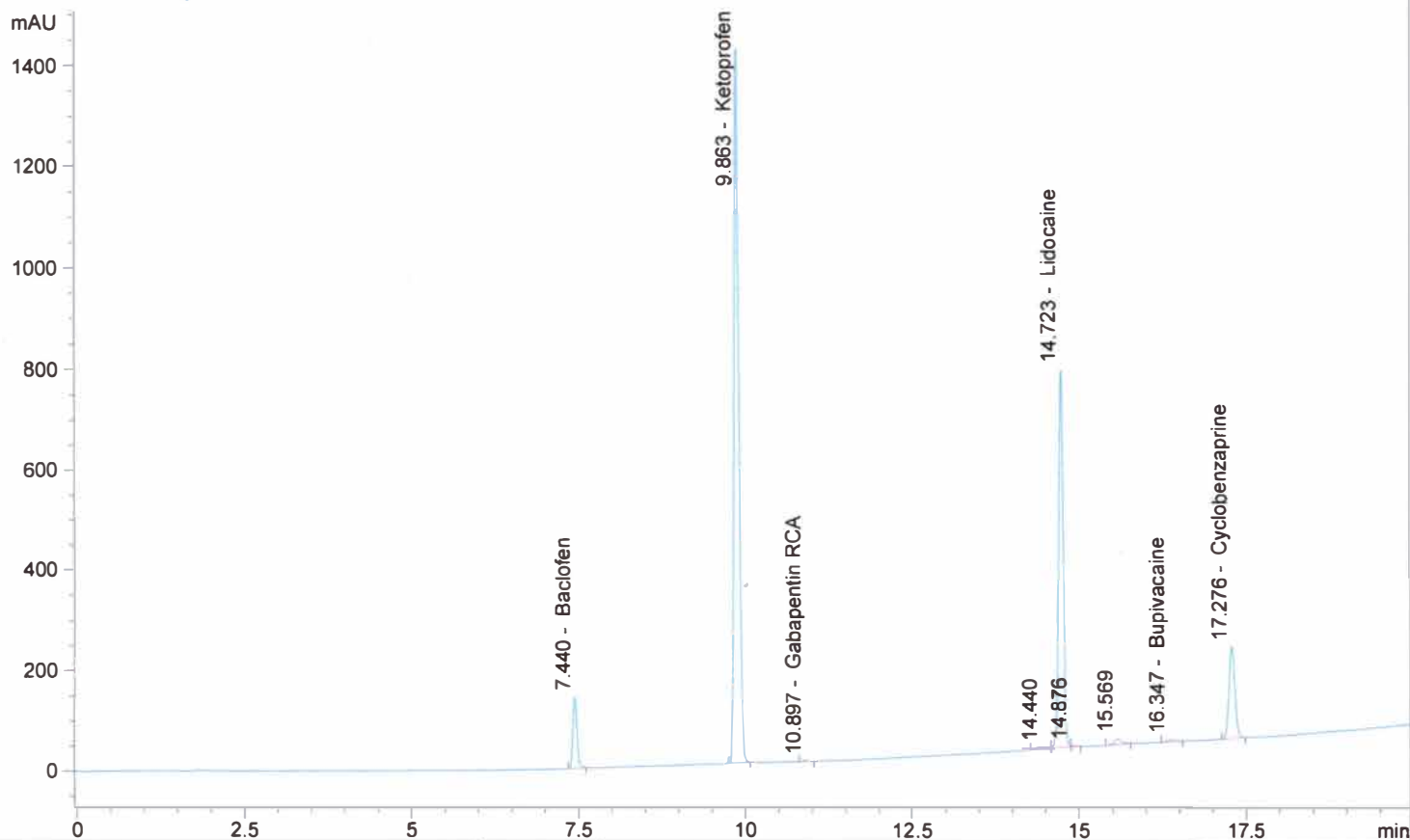
Compounded at 5.0% w/w in (2% Baclofen + 2% Cyclobenzaprine HCl + 20% Ketoprofen + 5% Lidocaine HCl), stability-indicating HPLC analysis found less than 4% Lidocaine Hydrochloride loss in Spectrum Chemical Mfg. Corp. Durabase Advanced at 90 days.

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

Cycl, bac, keto, lido std 1 Diluted 15/20 in Methanol
 Gemini C18 150x4.5x5, 5520-142, 1ml/min, 30C, 10mMNa2B4O7,
 ACN, MeOH
 90B10MeOH-2m, 58B14ACN28MeOH@5.5M, 43B24ACN33MeOH@9m, 22B4
 0ACN38MeOH@12M, 5B47.5ACN/MeOH@18M till 20M.

Injection date and Time 11/14/2013 5:38:35 PM Vial 54 Inj # 1 Method Inj vol 5ul
 Actual inj vol 5ul

DAD1 B, Sig=210,5 Ref=360,100 (131104\CC000054.D)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0	Gabapentin	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
2.0	Baclofen	7.440	0.066	144	0.846	9.48597e-5	0.05880	620	4.89
3.0	Methyl Paraban	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
4.0	Pentoxifylline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
5.0	Ketoprofen	9.863	0.078	1423	0.733	4.16590e-5	0.29620	7110	56.07
6.0	Phenoxyethanol	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
7.0	Propyl Paraban	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
8.0	Clonidine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0	Gabapentin RCA	10.897	0.073	2	1.026	5.44805e-3	0.04851	9	0.07
10.0	Flurbiprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
11.0	Ibuprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
12.0	Diclofenac	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
13.0	Ketamine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
14.0	Triclosan	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
15.0		14.440	0.204	5	0.000	0.00000	0.00000	58	0.46
16.0	Lidocaine	14.723	0.080	755	0.940	4.07011e-5	0.14780	3631	28.64
17.0		14.876	0.065	3	0.000	0.00000	0.00000	12	0.09
18.0		14.941	0.000	5	0.000	0.00000	0.00000	0	0.00
19.0		15.569	0.113	11	0.793	0.00000	0.00000	89	0.70
20.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
21.0	Bupivacaine	16.347	0.092	4	0.975	0.00000	0.00000	26	0.20
22.0	Cyclobenzaprine	17.276	0.096	183	0.885	4.03675e-5	0.04544	1126	8.88
23.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							0.59675	12680	100.00

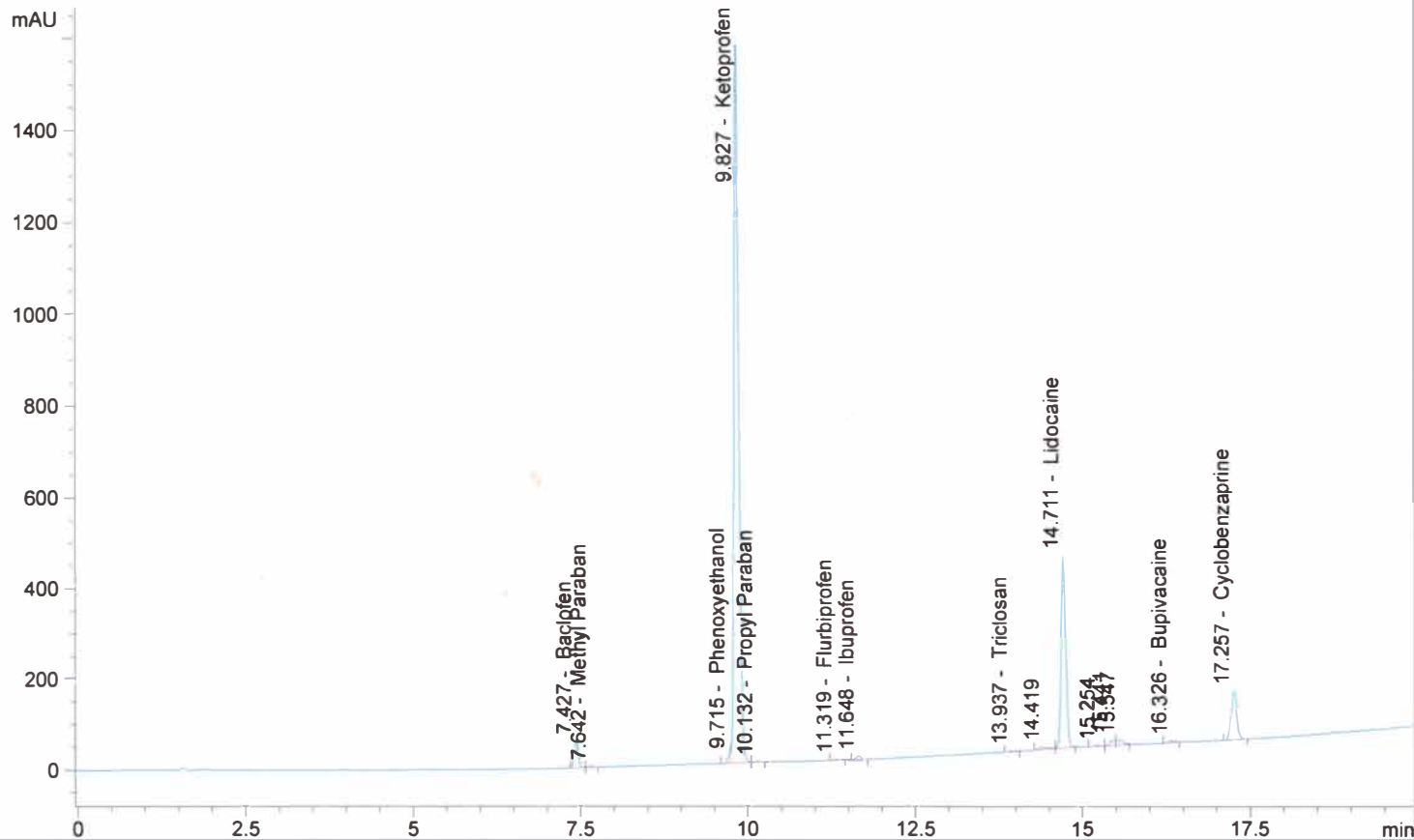
CC 08152013@17BCLK smp 2

Gemini C18 150x4.5x5, 5520-142, 1ml/min, 30C, 10mMNa2B4O7, ACN, MeOH

90B10MeOH-2m, 58B14ACN28MeOH@5.5M, 43B24ACN33MeOH@9m, 22B40ACN38MeOH@12M, 5B47.5ACN/MeOH@18M till 20M.

Injection date and Time 11/14/2013 6:54:15 PM Vial 55 Inj # 2 Method Inj vol 5ul Actual inj vol 5ul

DAD1 B, Sig=210,5 Ref=360,100 (131104\CC000057.D)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0	Gabapentin	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
2.0	Baclofen	7.427	0.066	61	0.863	9.35907e-5	1.50340	262	2.33
3.0	Methyl Paraban	7.642	0.064	3	1.061	0.00000	0.00000	13	0.12
4.0	Pentoxifylline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
5.0	Phenoxyethanol	9.715	0.044	19	1.463	0.00000	0.00000	58	0.52
6.0	Ketoprofen	9.827	0.077	1572	0.725	4.11353e-5	20.02681	7950	70.68
7.0	Propyl Paraban	10.132	0.089	3	0.945	0.00000	0.00000	15	0.14
8.0	Clonidine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0	Gabapentin RCA	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
10.0	Flurbiprofen	11.319	0.081	2	0.916	0.00000	0.00000	9	0.08
11.0	Ibuprofen	11.648	0.080	7	0.928	6.45357e-3	14.78130	37	0.33
12.0	Diclofenac	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
13.0	Ketamine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
14.0	Triclosan	13.937	0.070	2	1.438	0.00000	0.00000	8	0.07
15.0	Lidocaine	14.419	0.200	4	0.000	0.00000	0.00000	49	0.44
16.0	Lidocaine	14.711	0.079	424	0.942	4.02317e-5	4.97772	2020	17.96
17.0		15.254	0.117	1	3.301	0.00000	0.00000	12	0.11
18.0		15.441	0.074	12	1.055	0.00000	0.00000	59	0.52
19.0		15.547	0.096	11	0.757	0.00000	0.00000	70	0.62
20.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
21.0	Bupivacaine	16.326	0.097	5	0.888	0.00000	0.00000	29	0.26
22.0	Cyclobenzaprine	17.257	0.096	107	0.887	3.98358e-5	1.59812	655	5.82
23.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00

total 42.88735 11249 100.00