



Scientific Study

**B4512, Durabase Advanced Cream
(Gabapentin 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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Gabapentin:

6.40g Gabapentin raw drug powder from Shanghai Chemical (part number SY005403, Lot # E021-103-21A) 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 6.0% w/w. This emulsion was then stored at room temperature in the same Unguator container.

Similar steps were used in preparing the following combination compounds:

Compound 1 (2% Baclofen + 1% Bupivacaine HCl + 2% Cyclobenzaprine HCl + 5% Diclofenac Na + 6% Gabapentin + 3% Ibuprofen + 10% Ketamine HCl + 3% Pentoxifylline) Compound 2 (2% Baclofen + 0.2% Clonidine HCl + 10% Gabapentin + 5% Ketamine 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.

60-Day Summary:

Compounded at 6.0% w/w in Compound 1 (2% Baclofen + 1% Bupivacaine HCl + 2% Cyclobenzaprine HCl + 5% Diclofenac Na + 6% Gabapentin + 3% Ibuprofen + 10% Ketamine HCl + 3% Pentoxifylline), stability-indicating HPLC analysis found less than 10% (Gabapentin + Gabapentin RC) loss in Spectrum Chemical Mfg. Corp. Durabase Advanced at 60 days.

90-Day Summary:

Compounded at 10.0% w/w in Compound 2 (2% Baclofen + 0.2% Clonidine HCl + 10% Gabapentin + 5% Ketamine HCl), stability-indicating HPLC analysis found less than 2% (Gabapentin + Gabapentin RC) loss in Spectrum Chemical Mfg. Corp. Durabase Advanced at 90 days.

Attached are 4 chromatographs of Spectrum Chemical Mfg. Corp. Durabase Advanced showing 90-Day Standard, and 90-Day Sample of both combination compounds.

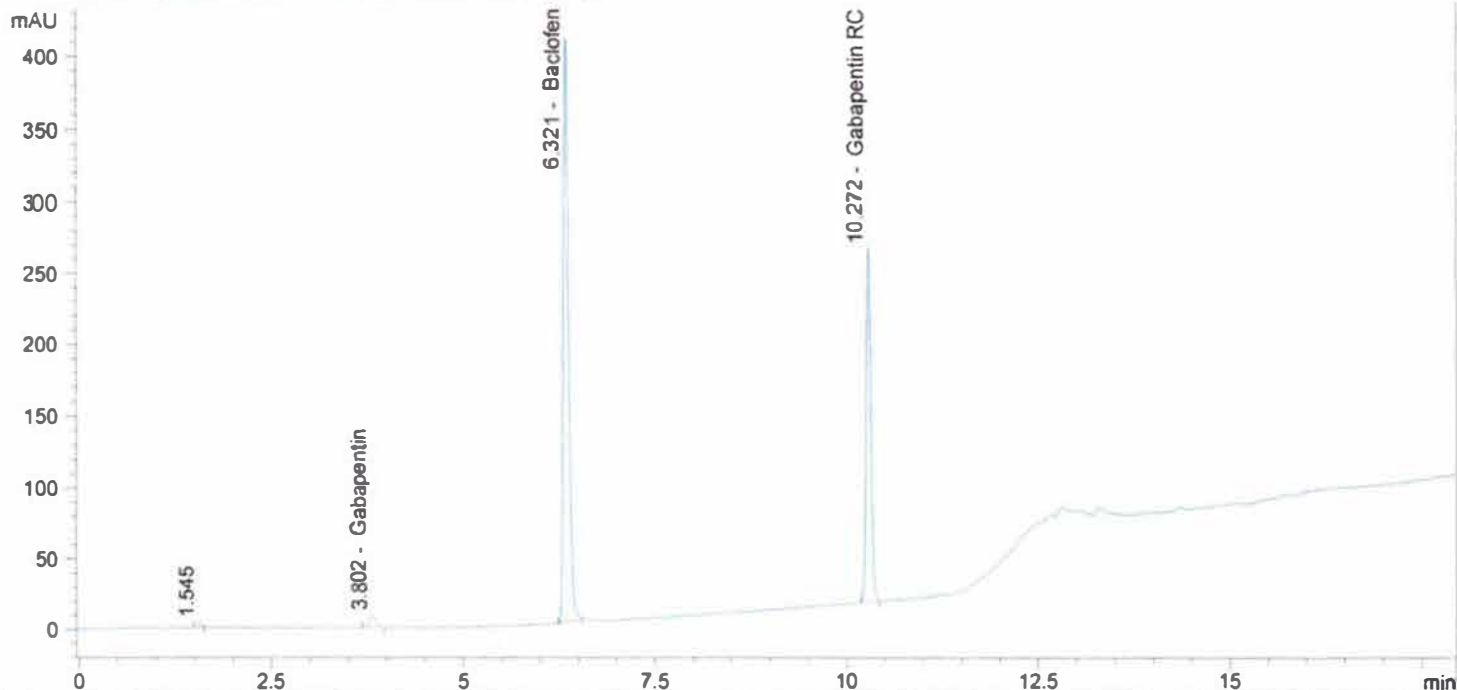
GAB, BAC AND GAB RCA STD
 XbridgeC18150x4.6x3.5,1ml/min,30C Buf5mMNa2B4O7,ACN,MEO
 H, 80Buf20MEOH HOLD TO2MIN,58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min,46Buf14ACN40MEOH@10MIN,5 buff
 47.5ACN/MEOH@16min TILL18 min

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 Method Inj vol 5ul
 Actual inj vol 5ul

Injection date and Time 8/27/2013 4:19:57 PM

Vial 50 Inj # 1

DAD1 B, Sig=210.5 Ref=360.100 (130801\BUD00074.D)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.545	0.052	3	0.612	0.00000	0.00000	11	0.35
2.0	Gabapentin	3.802	0.098	8	0.888	6.41818e-3	0.33600	52	1.67
3.0	Baclofen	6.321	0.077	409	0.669	9.80622e-5	0.19600	1999	63.89
4.0	Pentoxifylline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
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	Gabapentin RC	10.272	0.068	249	0.889	3.55723e-4	0.37926	1066	34.08
8.0	Flurbiprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0	Ibuprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
10.0	Diclofenac	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
11.0	Ketamine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
12.0	Triclosan	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
13.0	Lidocaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
14.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
15.0	Bupivacaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
16.0	Cyclobenzaprine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
17.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							0.91126	3128	100.00

03192013@135 302.6MG/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 7:02:37 PM Vial 54 Inj # 2
Method Inj vol 5ul
Actual inj vol 5ul

DAD1 B, Sig=210.5 Ref=360,100 (130801\BUD00081.D)

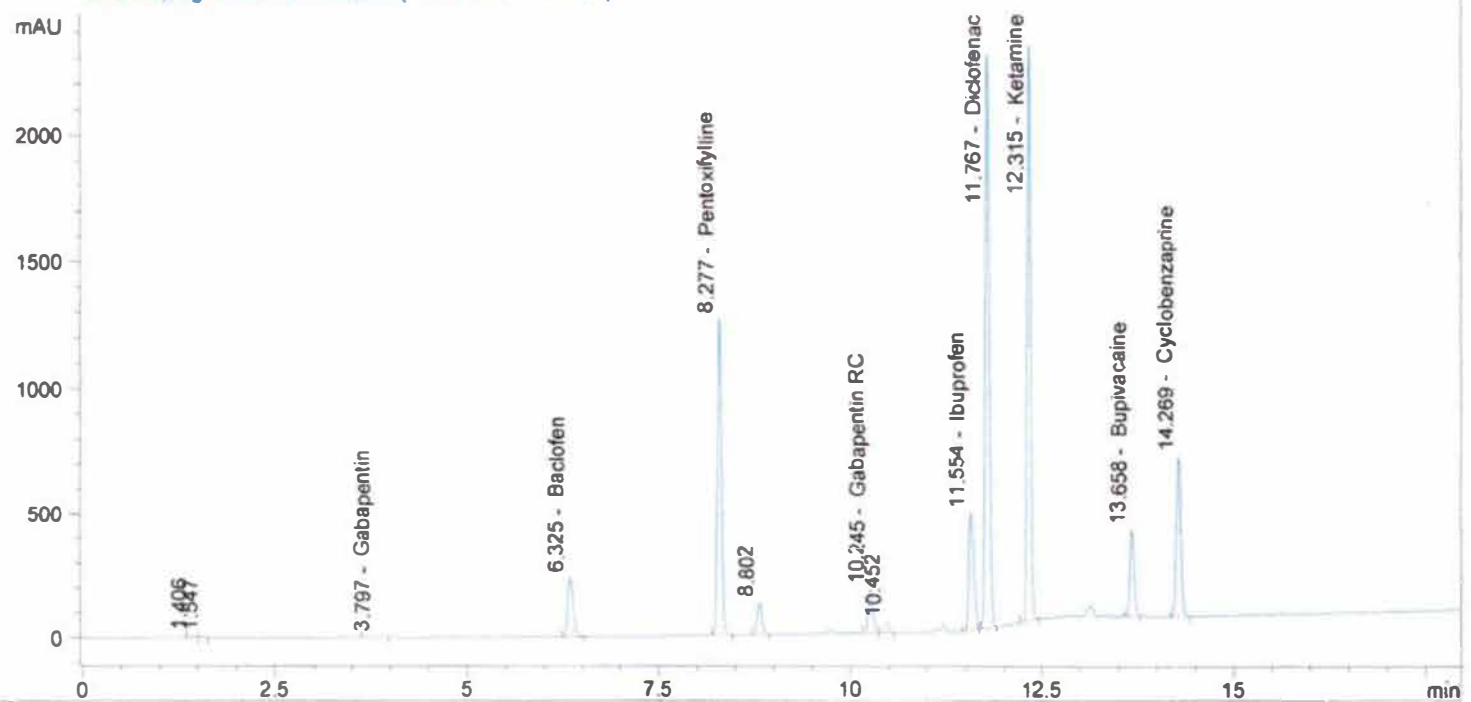


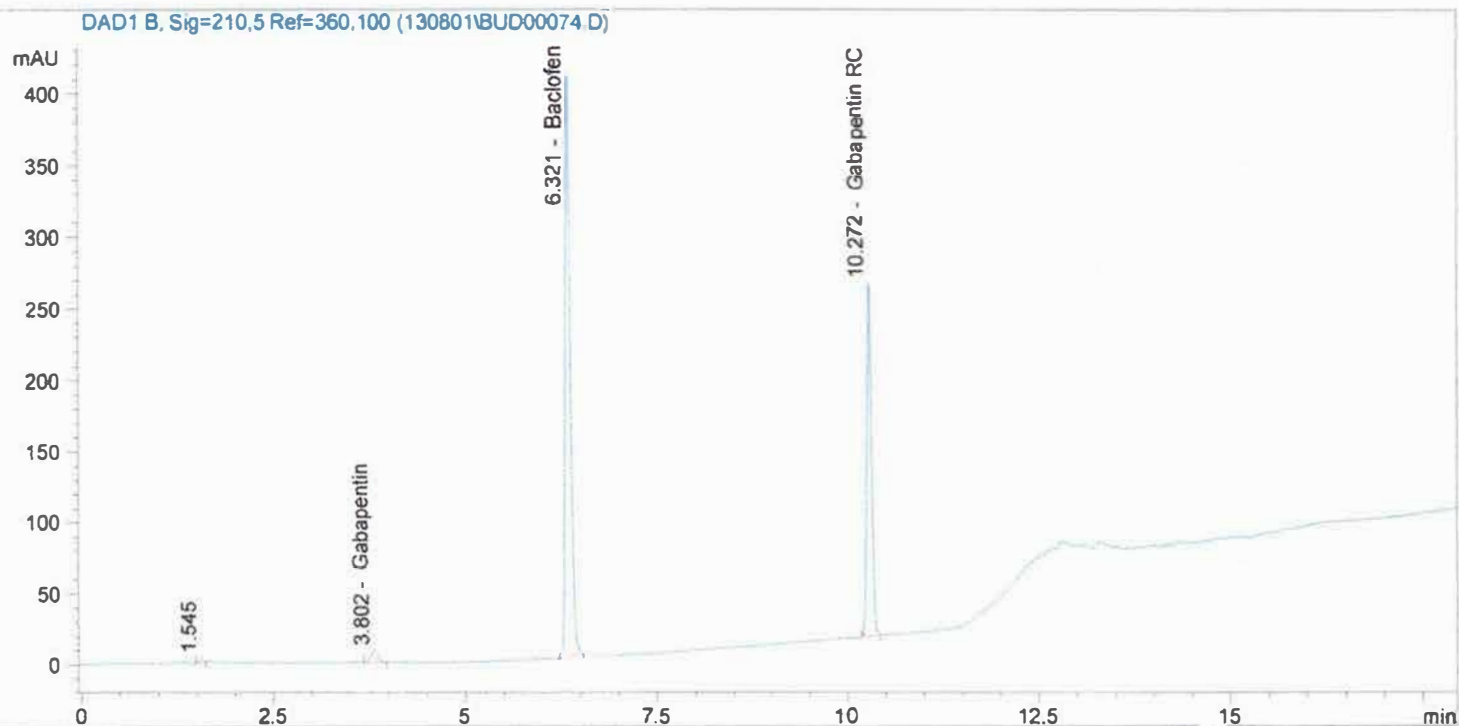
Table with 11 columns: #, Compound Name, Meas. R, Width, Height, Symmetr, Response Fact, Amount, Area, Area %. Contains 20 rows of peak data and a total row.

GAB, BAC AND GAB RCA STD
 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

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 Method Inj vol 5ul
 Actual inj vol 5ul

Injection date and Time 8/27/2013 4:19:57 PM

Vial 50 Inj # 1



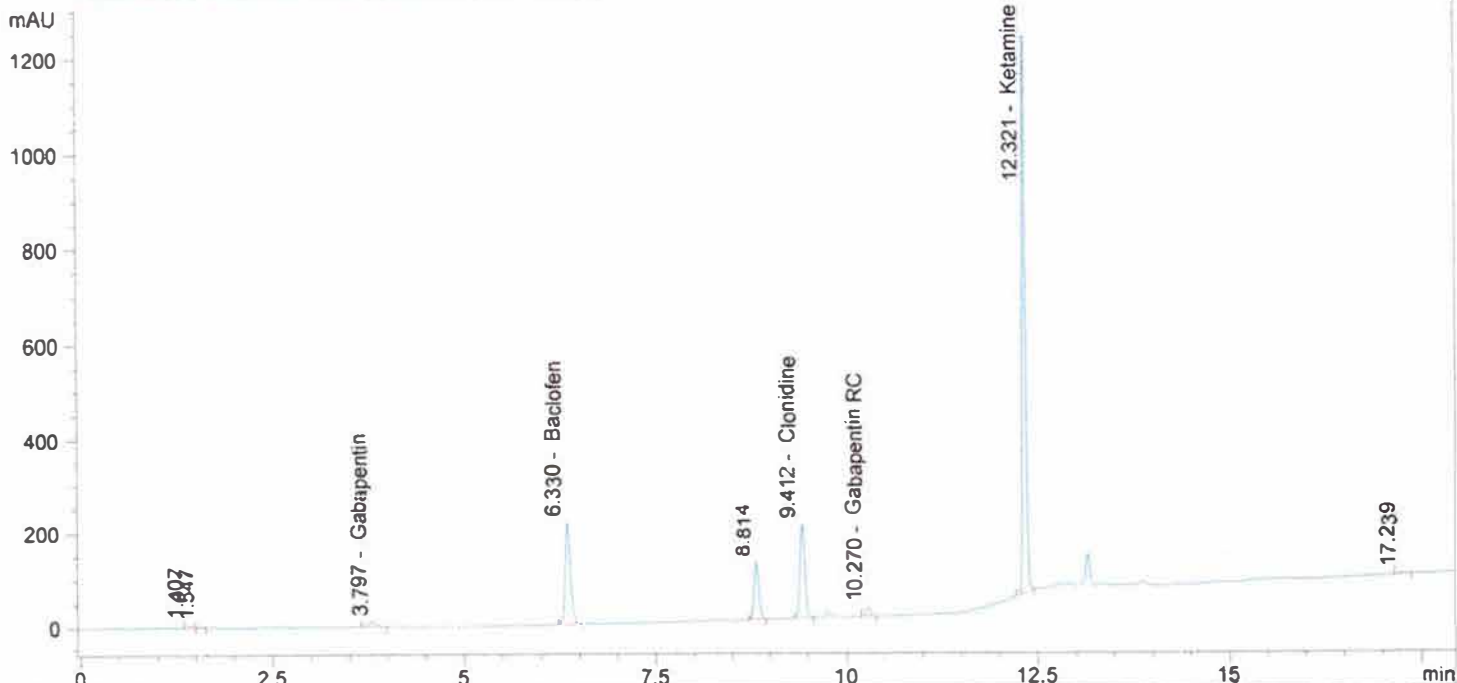
#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.545	0.052	3	0.612	0.00000	0.00000	11	0.35
2.0	Gabapentin	3.802	0.098	8	0.888	6.41818e-3	0.33600	52	1.67
3.0	Baclofen	6.321	0.077	409	0.669	9.80622e-5	0.19600	1999	63.89
4.0	Pentoxifylline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
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	Gabapentin RC	10.272	0.068	249	0.889	3.55723e-4	0.37926	1066	34.08
8.0	Flurbiprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0	Ibuprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
10.0	Diclofenac	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
11.0	Ketamine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
12.0	Triclosan	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
13.0	Lidocaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
14.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
15.0	Bupivacaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
16.0	Cyclobenzaprine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
17.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							0.91126	3128	100.00

03192013@144 264.3MG/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

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 Method Inj vol 5ul
 Actual inj vol 5ul

Injection date and Time 8/27/2013 8:35:35 PM Vial 56 Inj # 2

DAD1 B, Sig=210.5 Ref=360,100 (130801BUD00085.D)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.407	0.056	6	0.901	0.00000	0.00000	22	0.33
2.0		1.547	0.056	3	0.574	0.00000	0.00000	13	0.19
3.0	Gabapentin	3.797	0.109	11	0.938	6.41228e-3	9.32099	77	1.18
4.0	Baclofen	6.330	0.077	216	0.699	9.80405e-5	2.02832	1094	16.80
5.0	Pentoxifylline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
6.0		8.814	0.066	122	0.904	0.00000	0.00000	519	7.98
7.0	Clonidine	9.412	0.070	200	0.879	0.00000	0.00000	894	13.74
8.0	ketoprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0	Gabapentin RC	10.270	0.066	18	0.911	3.55422e-4	0.51816	77	1.18
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	12.321	0.049	1189	0.887	0.00000	0.00000	3802	58.43
14.0	Triclosan	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
15.0	Lidocaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
16.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
17.0	Bupivacaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
18.0	Cyclobenzaprine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
19.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
20.0		17.239	0.064	2	1.370	0.00000	0.00000	10	0.15
total							11.86748	6508	100.00