



Scientific Study

**B4512, Durabase Advanced Cream
(Cyclobenzaprine 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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Cyclobenzaprine Hydrochloride:

2.00g Cyclobenzaprine Hydrochloride raw drug powder from AK Chemical (part number Q517, Lot # LC24561) 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 2.0% 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 + 1% Bupivacaine HCl + 2% Cyclobenzaprine HCl + 5% Diclofenac Na + 6% Gabapentin + 3% Ibuprofen + 10% Ketamine 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.

60-Day Summary:

Compounded at 2.0% w/w in (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% Cyclobenzaprine Hydrochloride loss in Spectrum Chemical Mfg. Corp. Durabase Advanced at 60 days.

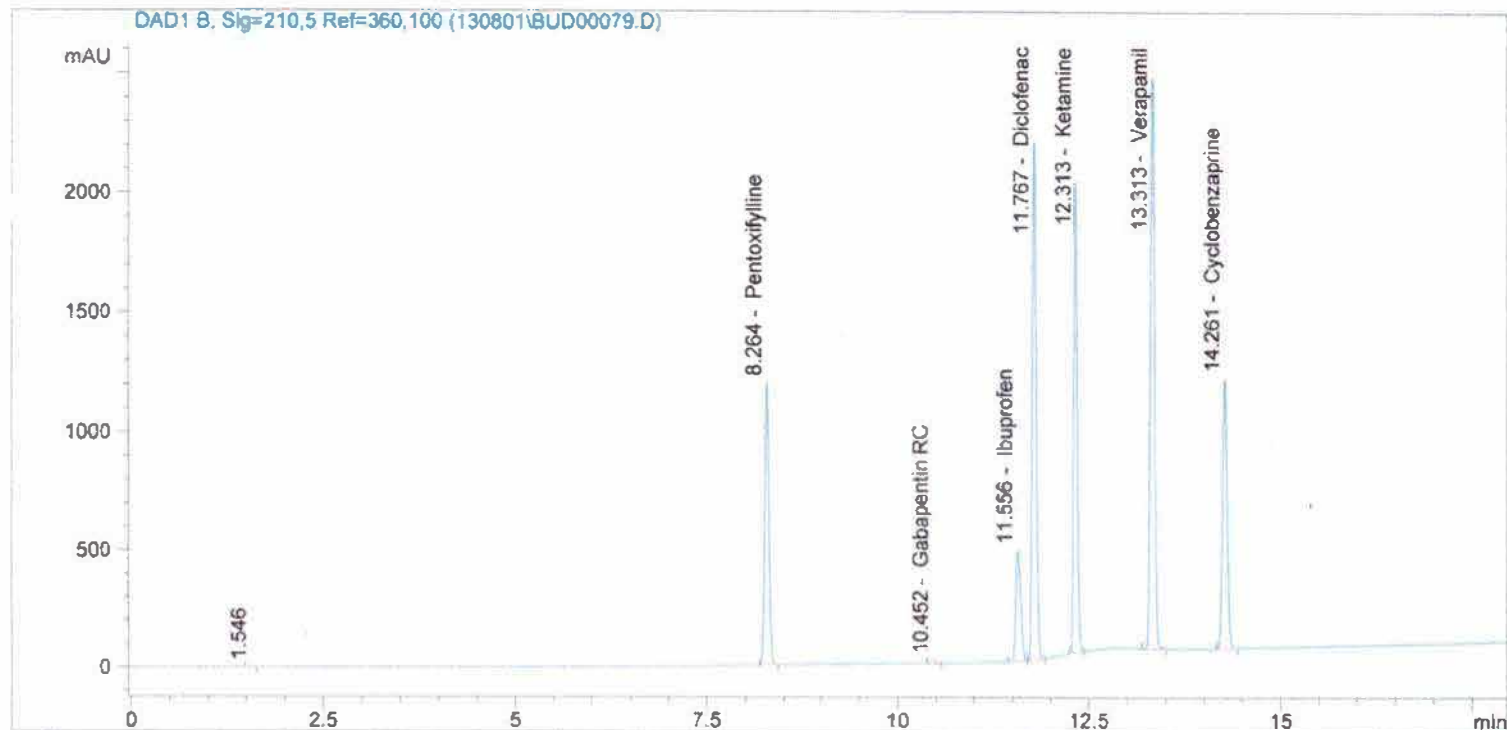
Attached are 2 chromatographs of Spectrum Chemical Mfg. Corp. Durabase Advanced showing 90-Day Standard, and 90-Day Sample of the combination compound.

PENT, DICL, KET, VER, CYC, IBU STD IN 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 6:16:06 PM

Vial 43 Inj # 2

Method Inj vol 5ul
 Actual inj vol 5ul



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.546	0.049	3	0.652	0.00000	0.00000	10	0.03
2.0	Gabapentin	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
3.0	Baclofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
4.0	Pentoxifylline	8.264	0.057	1202	0.910	4.05347e-5	0.17934	4424	12.70
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	10.452	0.064	15	0.913	0.00000	0.00000	64	0.18
8.0	Flurbiprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0	Ibuprofen	11.556	0.070	474	0.665	8.61798e-5	0.18351	2129	6.11
10.0	Diclofenac	11.767	0.057	2201	0.804	3.31767e-5	0.25831	7786	22.34
11.0	Ketamine	12.313	0.054	2014	0.909	7.39912e-5	0.47976	6484	18.61
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	13.313	0.061	2417	0.890	5.53591e-5	0.51370	9279	26.63
15.0	Bupivacaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
16.0	Cyclobenzaprine	14.261	0.063	1150	0.897	3.87244e-5	0.18093	4672	13.41
17.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							1.79556	34849	100.00

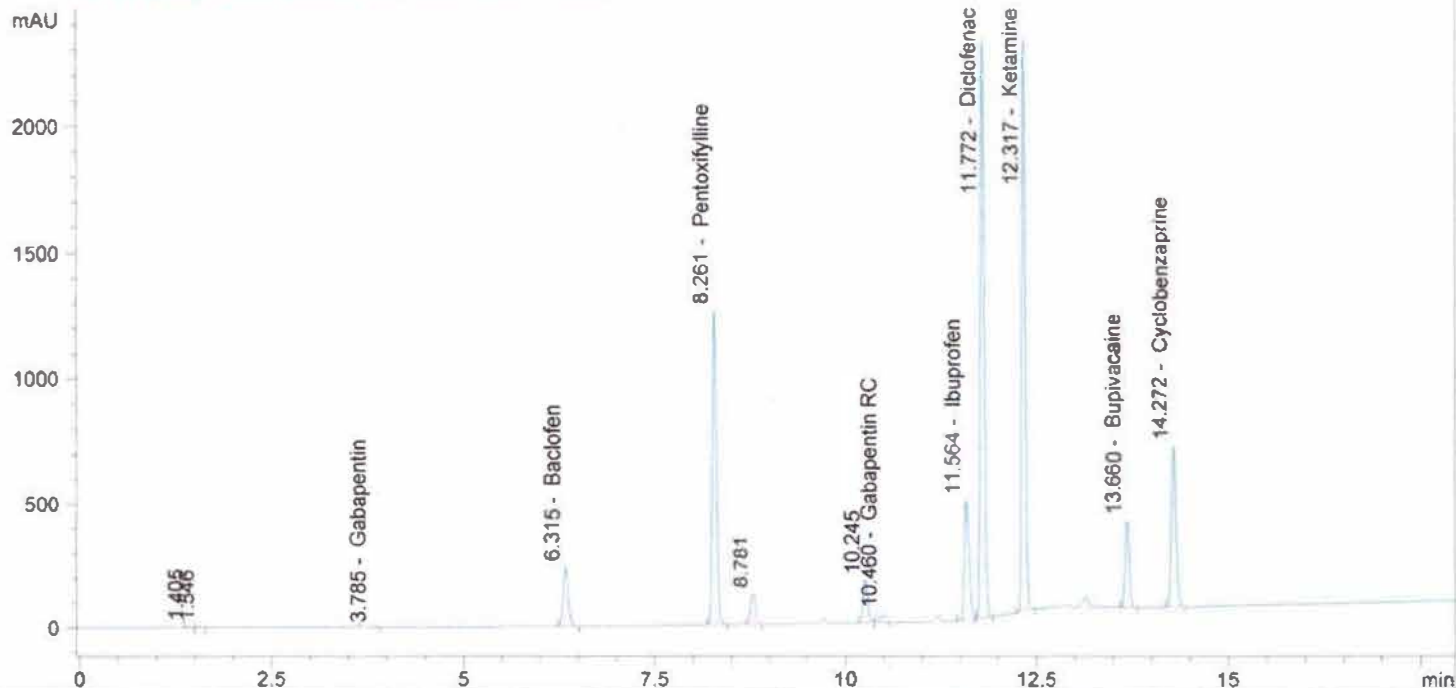
03192013@135 302.6MG/50ML MEQH
 XbridgeC18150x4.6x3.5, 1ml/min, 30C Buf5mMNa2B4O7, ACN, MEO
 H, 80Buf20MEOH HOLD TO2MIN, 58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min, 46Buf14ACN40MEOH@10MIN, 5 buff
 47.5ACN/MEOH@16min TILL18 min

Injection date and Time 8/27/2013 6:39:17 PM

Vial 54 Inj # 1

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 Method Inj vol 5ul
 Actual inj vol 5ul

DAD1 B, Sig=210,5 Ref=360,100 (130801\BUD00080.D)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.405	0.054	7	0.836	0.00000	0.00000	23	0.08
2.0		1.546	0.054	3	0.594	0.00000	0.00000	12	0.04
3.0	Gabapentin	3.785	0.115	1	1.065	0.00000	0.00000	6	0.02
4.0	Baclofen	6.315	0.076	242	0.759	0.00000	0.00000	1155	3.98
5.0	Pentoxifylline	8.261	0.059	1263	0.905	4.05347e-5	3.11033	4644	15.99
6.0		8.781	0.065	124	0.911	0.00000	0.00000	528	1.82
7.0	Clonidine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
8.0	ketoprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
9.0		10.245	0.068	175	0.891	0.00000	0.00000	753	2.59
10.0	Gabapentin RC	10.460	0.065	40	0.930	0.00000	0.00000	166	0.57
11.0	Flurbiprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
12.0	Ibuprofen	11.564	0.070	482	0.670	8.61798e-5	3.04826	2141	7.37
13.0	Diclofenac	11.772	0.055	2298	0.808	3.31767e-5	4.46159	8139	28.03
14.0	Ketamine	12.317	0.055	2295	0.910	7.39912e-5	9.21583	7538	25.96
15.0	Triclosan	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
16.0	Lidocaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
17.0	Verapamil	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
18.0	Bupivacaine	13.660	0.057	349	0.930	0.00000	0.00000	1298	4.47
19.0	Cyclobenzaprine	14.272	0.063	649	0.901	3.87244e-5	1.68494	2633	9.07
20.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							21.52094	29035	100.00