



Scientific Study

B4512, Durabase Advanced Cream
(Verapamil 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

777 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300

Verapamil Hydrochloride:

11.00g Verapamil Hydrochloride raw drug powder from TRC Chemical (part number V125000, Lot # 11-XJ2-55-1) was added to 100.00g Spectrum Chemical Mfg. Corp. Durabase Advanced Base and levigated with an electronic mortar and pestle, resulting in a final concentration of 10.0% 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:
5% Diclofenac Na + 3% Ibuprofen + 3% Pentoxifylline + 10% Verapamil 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 10.0% w/w in (5% Diclofenac Na + 3% Ibuprofen + 3% Pentoxifylline + 10% Verapamil HCl), stability-indicating HPLC analysis found less than 8% Verapamil Hydrochloride loss in Spectrum Chemical Mfg. Corp. Durabase Advanced Base at 90 days.

Attached are 2 chromatographs of Spectrum Chemical Mfg. Corp. Durabase Advanced Base 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

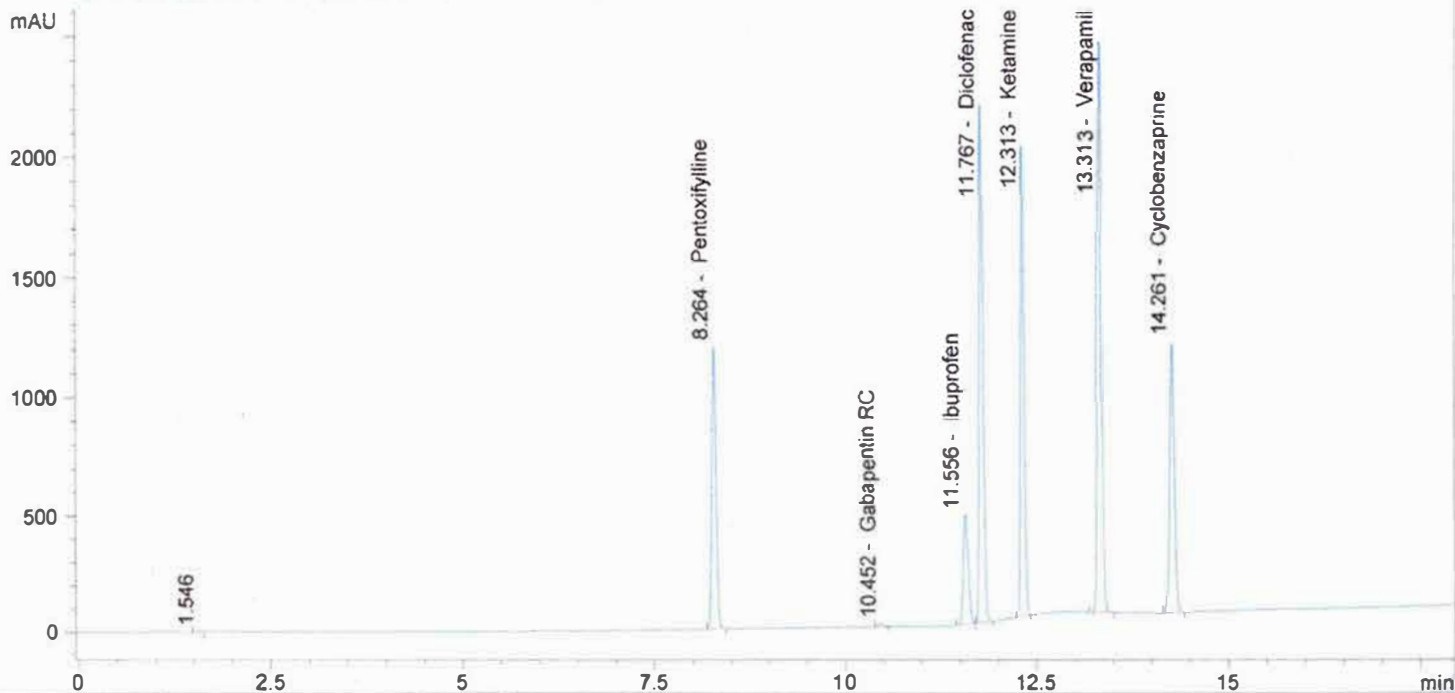
->

Method Inj vol 5ul
 Actual inj vol 5ul

Injection date and Time 8/27/2013 6:16:06 PM

Vial 43 Inj # 2

DAD1 B, Sig=210,5 Ref=360,100 (130801\BUD00079.D)



#	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

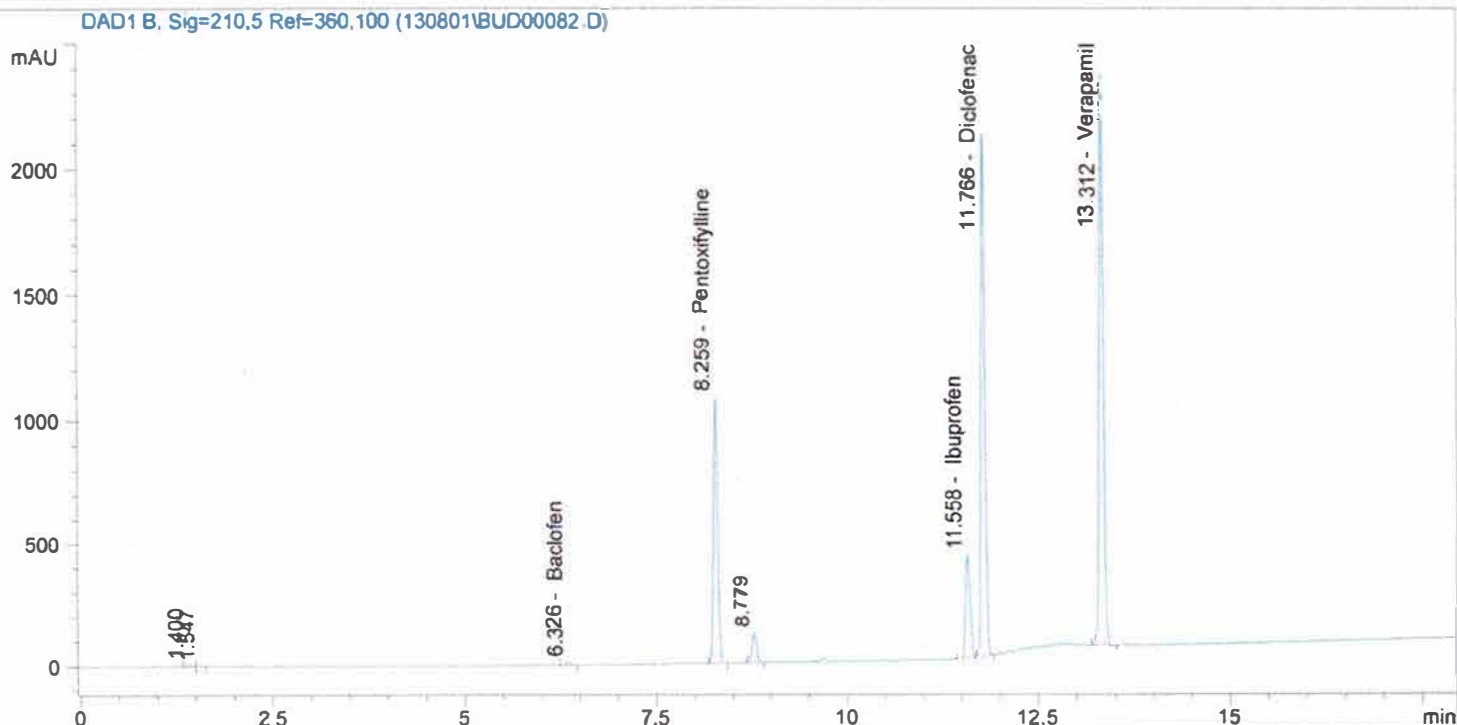
total 1.79556 34849 100.00

03192013@143 265.1MG/50ML MEQH
 XbridgeC18150x4.6x3.5,1ml/min,30C Buf5mMNa2B407,ACN,MEO
 H, 80Buf20MEOH HOLD TO2MIN,58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min,46Buf14ACN40MEOH@10MIN,5 buff
 47.5ACN/MEQH@16min TILL18 min

Injection date and Time 8/27/2013 7:25:53 PM

Vial 55 Inj # 1

->
 Method Inj vol 5ul
 Actual inj vol 5ul



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.400	0.055	7	1.042	0.00000	0.00000	25	0.11
2.0		1.547	0.054	3	0.566	0.00000	0.00000	13	0.06
3.0	Gabapentin	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
4.0	Baclofen	6.326	0.071	13	0.916	0.00000	0.00000	59	0.26
5.0	Pentoxifylline	8.259	0.057	1084	0.915	4.05347e-5	3.06163	4006	17.71
6.0		8.779	0.065	121	0.904	0.00000	0.00000	513	2.27
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	Gabapentin RC	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
10.0	Flurbiprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
11.0	Ibuprofen	11.558	0.068	418	0.695	8.61798e-5	2.93374	1806	7.98
12.0	Diclofenac	11.766	0.058	2119	0.831	3.31767e-5	4.64431	7425	32.82
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	Lidocaine	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
16.0	Verapamil	13.312	0.061	2296	0.889	5.53591e-5	9.15748	8774	38.79
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
total							19.79716	22620	100.00