

Baclofen:

2.00g Baclofen raw drug powder from TCI chemical (part number B3343, Lot # UWJKK-LO) was added to 100.00g Humco Salt-Stable LS Advanced (Humco Holding Group, Texarkana, Texas) 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 compounds:

Compound 1 (2% Baclofen + 10% Flurbiprofen + 5% Lidocaine HCl + 3% Pentoxifylline)

Compound 2 (2% Baclofen + 0.2% Clonidine HCl + 10% Gabapentin + 5% Ketamine HCl)

Compound 3 (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.

45-Day Summary:

Compounded at 2.0% w/w in Compound 1 (2% Baclofen + 10% Flurbiprofen + 5% Lidocaine HCl + 3% Pentoxifylline), stability-indicating HPLC analysis found less than 10% Baclofen loss in Humco Salt-Stable LS Advanced at 45 days.

90-Day Summary:

Compounded at 2.0% w/w in Compound 2 (2% Baclofen + 0.2% Clonidine HCl + 10% Gabapentin + 5% Ketamine HCl), stability-indicating HPLC analysis found negligible Baclofen loss in Humco Salt-Stable LS Advanced at 90 days.

Compounded at 2.0% w/w in Compound 3 (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 5% Baclofen loss in Humco Salt-Stable LS Advanced at 90 days.

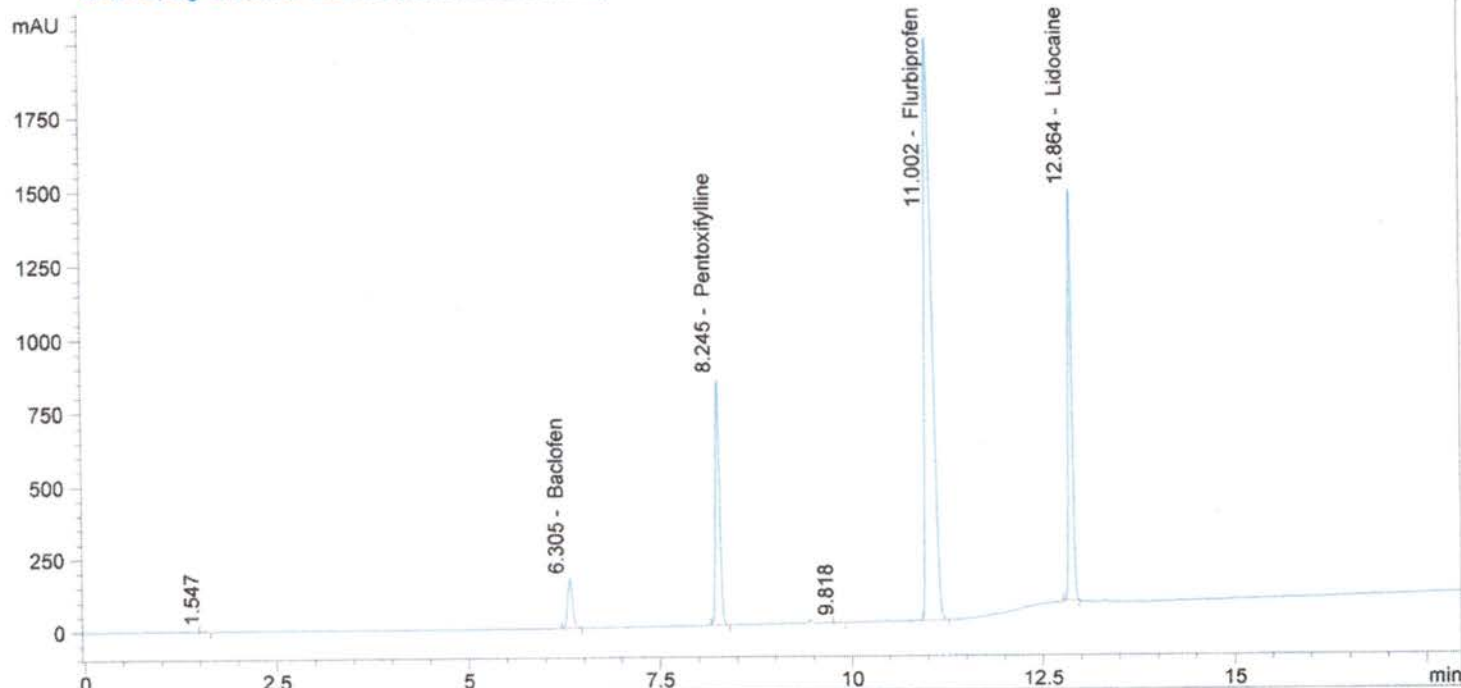
Attached are 6 chromatographs of Humco Salt-Stable LS Advanced showing 90-Day Standard, and 90-Day Sample of all 3 combination compounds.

flur, bac, lido, pent in MeOH and H2O 9:1
 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 11:18:27 PM Vial 51 Inj # 1

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

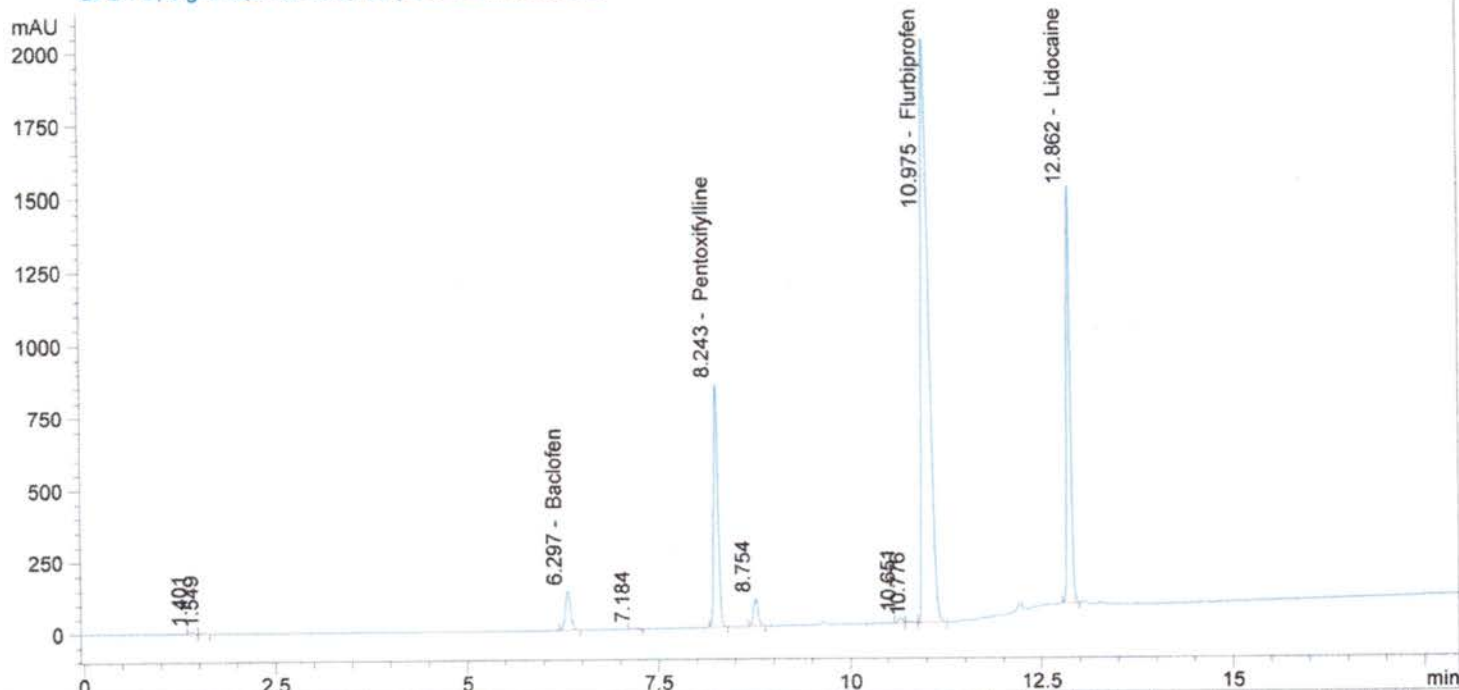
Hum base 03192013@139 216.0mg/50ml MeOH
 XbridgeC18150x4.6x3.5, 1ml/min, 30C Buf5mMNa2B4O7, ACN, MEO
 H, 80Buf20MEOH HOLD TO2MIN, 58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min, 46Buf14ACN40MEOH@10MIN, 5 buff
 47.5ACN/MEOH@16min TILL18 min

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)

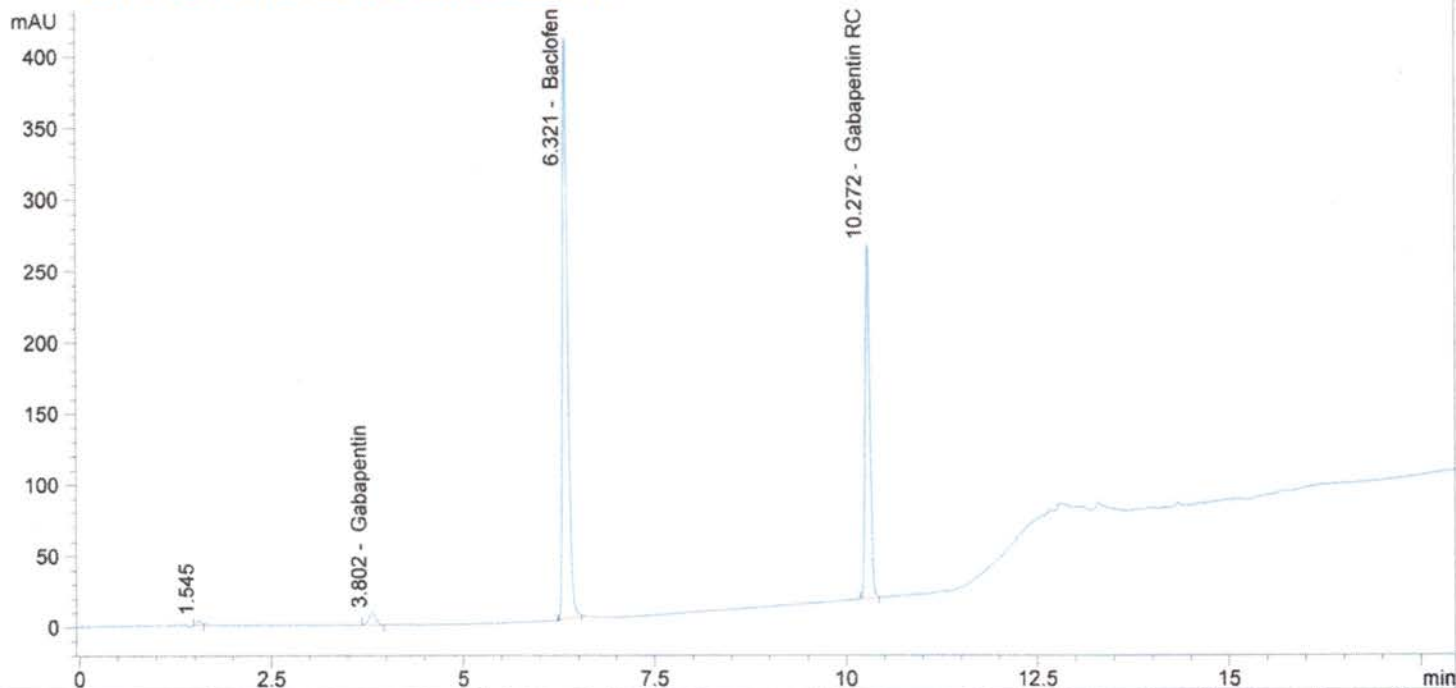


#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.401	0.049	6	0.912	0.00000	0.00000	20	0.09
2.0		1.549	0.059	3	0.563	0.00000	0.00000	12	0.05
3.0	Gabapentin	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
4.0	Baclofen	6.297	0.076	138	0.835	1.00479e-4	1.59891	687	2.99
5.0		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	2.91892	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	13703	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

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

Injection date and Time 8/27/2013 4:19:57 PM Vial 50 Inj # 1
 Method Inj vol 5ul
 Actual inj vol 5ul

DAD1 B, Sig=210,5 Ref=360,100 (130801\BUD00074.D)

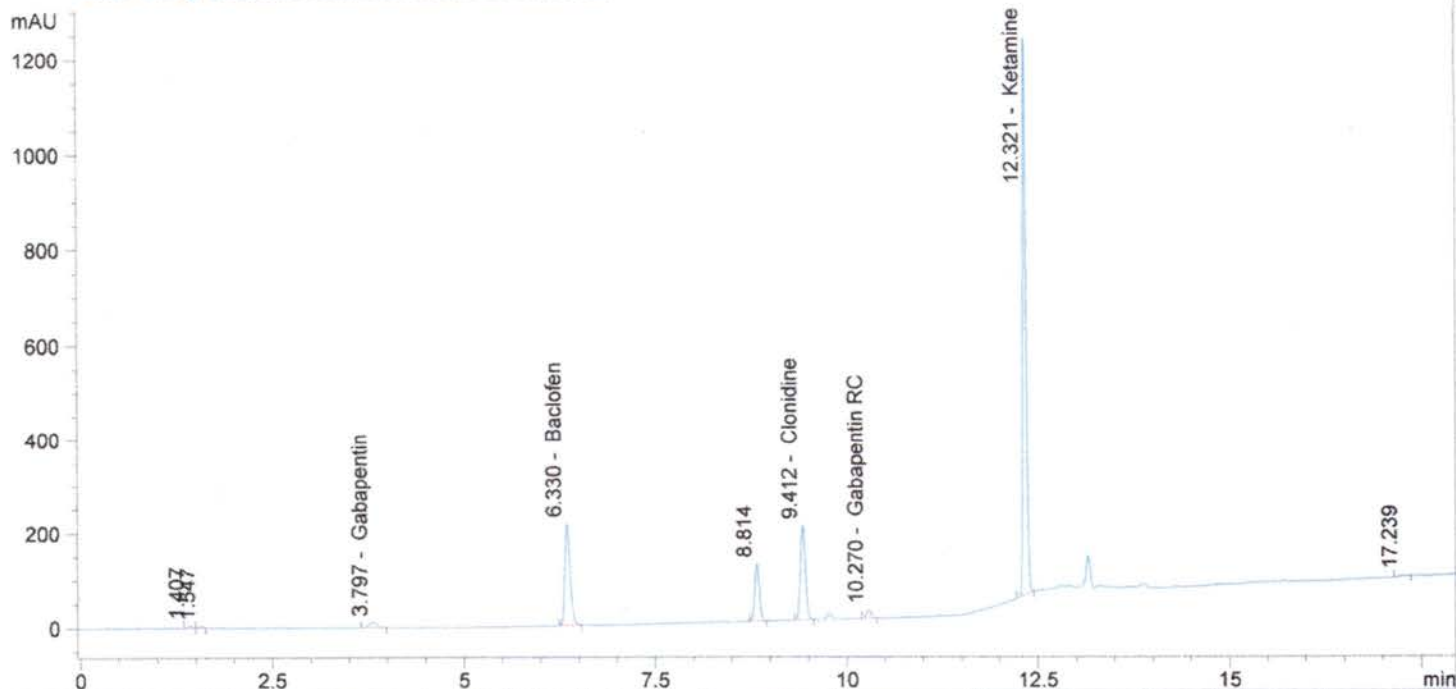


#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.545	0.052	3	0.612	0.00000	0.00000	11	0.35
2.0	Gabapentin	3.802	0.098	8	0.888	6.41818e-3	0.33600	52	1.67
3.0	Baclofen	6.321	0.077	409	0.669	9.80622e-5	0.19600	1999	63.89
4.0	Pentoxifylline	0.000	0.000	0	0.000	0.00000	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

HUMCO 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

Injection date and Time 8/27/2013 8:35:35 PM Vial 56 Inj # 2
 Method Inj vol 5ul
 Actual inj vol 5ul

DAD1 B, Sig=210,5 Ref=360,100 (130801\BUD00085.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

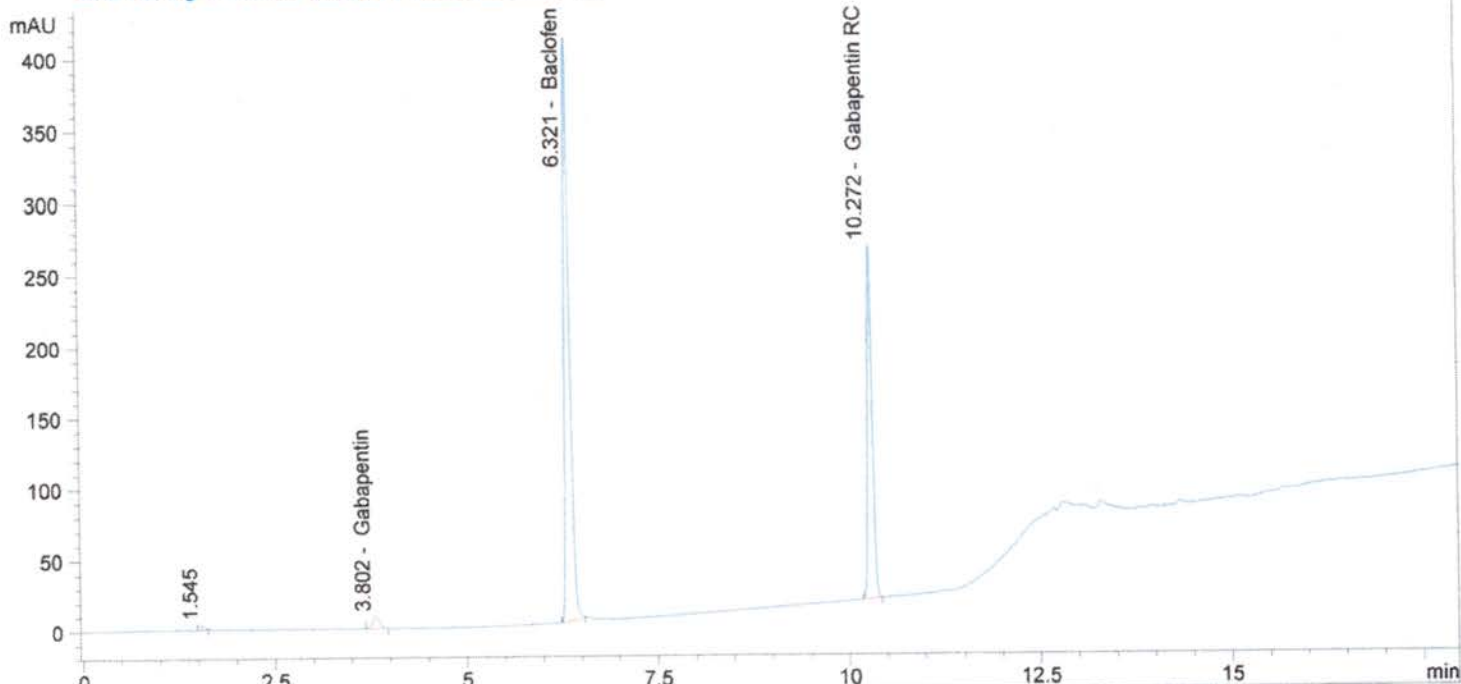
GAB, BAC AND GAB RCA STD
 XbridgeC18150x4.6x3.5, 1ml/min, 30C Buf5mMNa2B4O7, ACN, MEO
 H, 80Buf20MEOH HOLD TO2MIN, 58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min, 46Buf14ACN40MEOH@10MIN, 5 buff
 47.5ACN/MEOH@16min TILL18 min

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

Vial 50 Inj # 1

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 Method Inj vol 5ul
 Actual inj vol 5ul

DAD1 B, Sig=210,5 Ref=360,100 (130801\BUD00074.D)

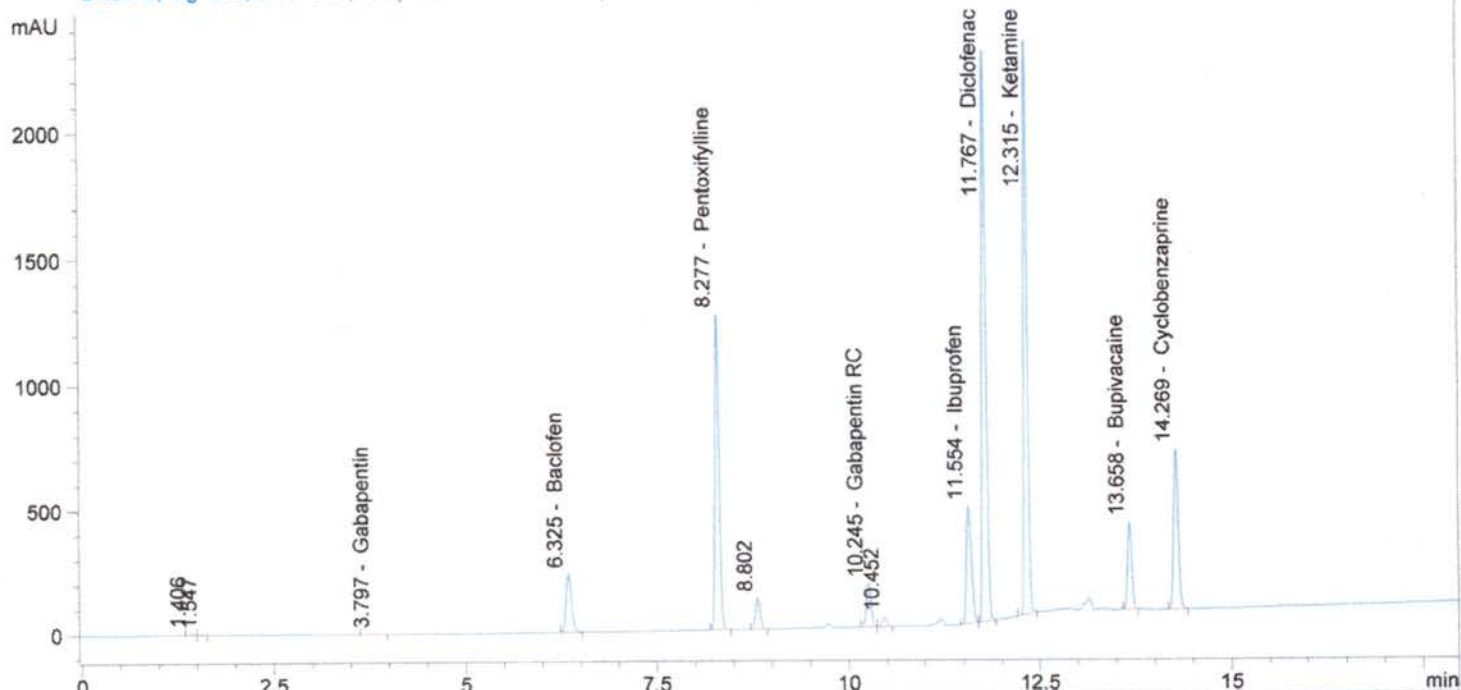


#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.545	0.052	3	0.612	0.00000	0.00000	11	0.35
2.0	Gabapentin	3.802	0.098	8	0.888	6.41818e-3	0.33600	52	1.67
3.0	Baclofen	6.321	0.077	409	0.669	9.80622e-5	0.19600	1999	63.89
4.0	Pentoxifylline	0.000	0.000	0	0.000	0.00000	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

HUMCO 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)



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.406	0.052	7	0.859	0.00000	0.00000	23	0.08
2.0		1.547	0.055	3	0.559	0.00000	0.00000	12	0.04
3.0	Gabapentin	3.797	0.119	1	0.977	6.41228e-3	0.65415	6	0.02
4.0	Baclofen	6.325	0.077	236	0.741	9.80405e-5	1.87864	1160	3.98
5.0	Pentoxifylline	8.277	0.059	1265	0.900	0.00000	0.00000	4667	16.00
6.0		8.802	0.067	126	0.912	0.00000	0.00000	530	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	Gabapentin RC	10.245	0.066	177	0.885	3.55422e-4	4.43375	755	2.59
10.0		10.452	0.065	40	0.934	0.00000	0.00000	168	0.57
11.0	Flurbiprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
12.0	Ibuprofen	11.554	0.073	473	0.656	0.00000	0.00000	2149	7.37
13.0	Diclofenac	11.767	0.056	2280	0.799	0.00000	0.00000	8178	28.04
14.0	Ketamine	12.315	0.053	2285	0.885	0.00000	0.00000	7584	26.00
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	13.658	0.059	351	0.924	0.00000	0.00000	1303	4.47
19.0	Cyclobenzaprine	14.269	0.063	648	0.895	0.00000	0.00000	2635	9.03
20.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							6.96655	29170	100.00