

Bupivacaine Hydrochloride:

1.00g Bupivacaine Hydrochloride raw drug powder from MP chemical (part number 154904, Lot # 7845H) 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 1.0% 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.

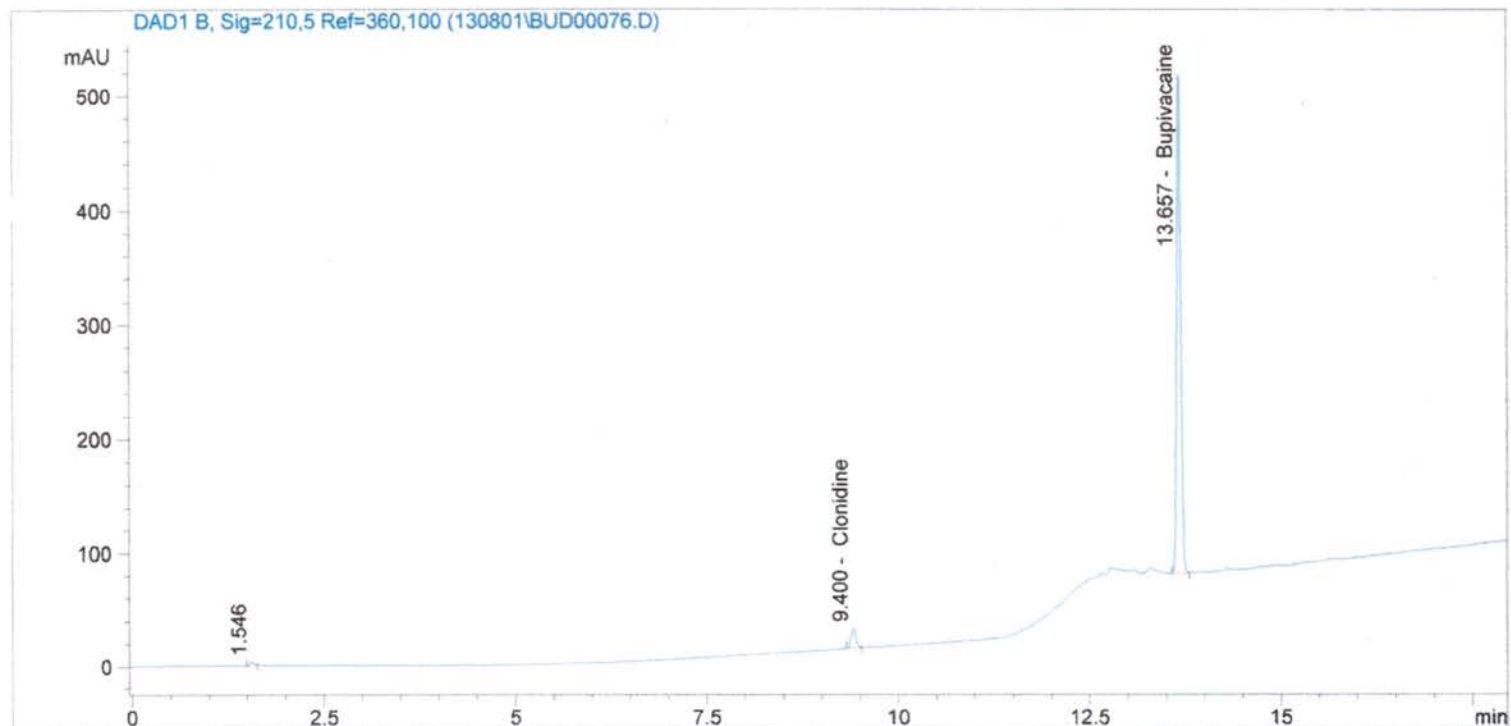
90-Day Summary:

Compounded at 1.0% 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 negligible Bupivacaine Hydrochloride loss in Humco Salt-Stable LS Advanced at 90 days.

Attached are 2 chromatographs of Humco Salt-Stable LS Advanced showing 90-Day Standard, and 90-Day Sample of the combination compound.

CLO, BUPIV 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 5:06:29 PM Vial 53 Inj # 1 Method Inj vol 5ul
 Actual inj vol 5ul



#	Compound Name	Meas. R	Width	Height	Symmetr	Response Fact	Amount	Area	Area %
1.0		1.546	0.054	3	0.571	0.00000	0.00000	13	0.73
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	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
5.0	Clonidine	9.400	0.069	18	0.896	2.16790e-5	0.00168	78	4.49
6.0	ketoprofen	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
7.0	Gabapentin RC	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
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	13.657	0.060	440	0.911	5.47016e-5	0.08967	1639	94.78
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							0.09135	1730	100.00

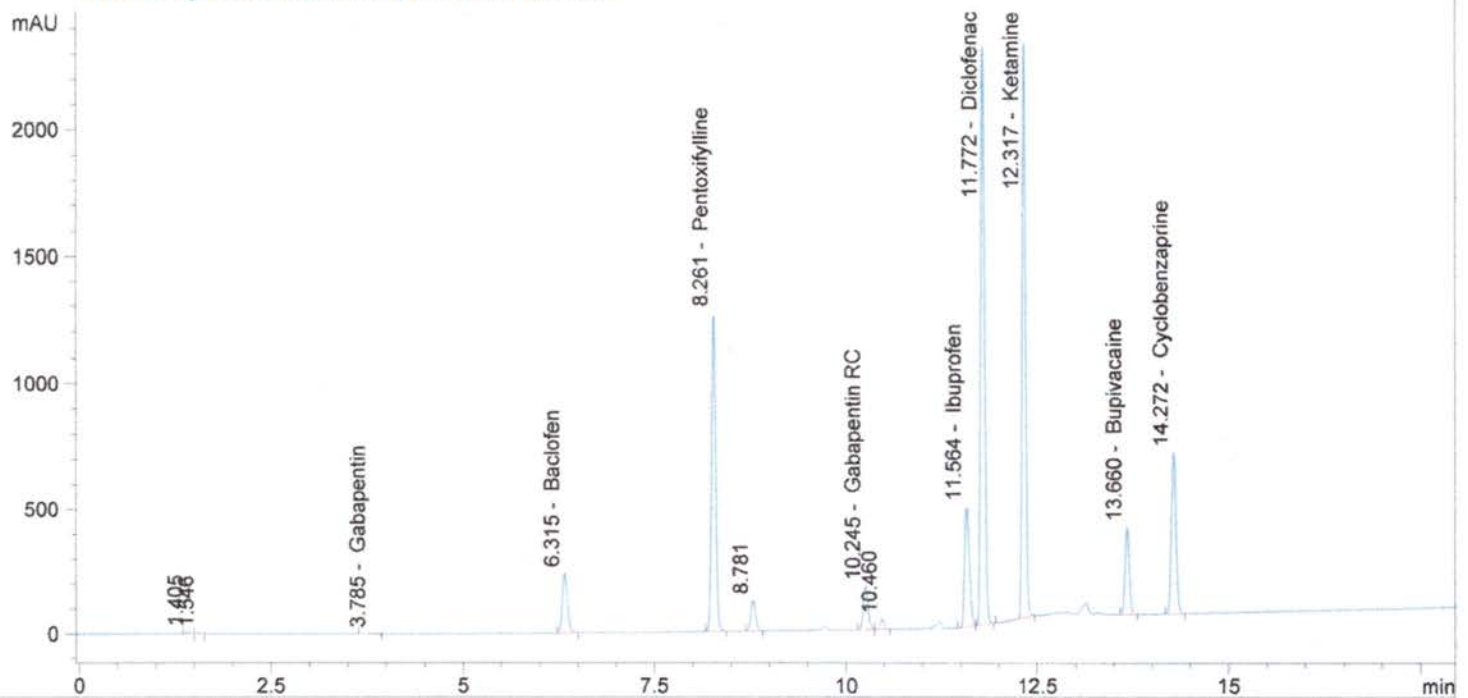
HUMCO 03192013@135 302.6MG/50ML MEOH
 XbridgeC18150x4.6x3.5, 1ml/min, 30C Buf5mMNa2B4O7, ACN, MEO
 H, 80Buf20MEOH HOLD TO2MIN, 58Buf14ACN28MeOH@5.5min to 4
 3Buf24ACN33MEOH@9min, 46Buf14ACN40MEOH@10MIN, 5 buff
 47.5ACN/MEOH@16min TILL18 min

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

Vial 54 Inj # 1

->
 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	0.109	1	1.065	0.00000	0.00000	5	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	0.00000	0.00000	4644	15.98
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	Gabapentin RC	10.245	0.068	175	0.891	0.00000	0.00000	753	2.59
10.0		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	0.00000	0.00000	2141	7.37
13.0	Diclofenac	11.772	0.055	2298	0.808	0.00000	0.00000	8139	28.01
14.0	Ketamine	12.317	0.053	2288	0.886	0.00000	0.00000	7555	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	13.660	0.057	349	0.930	5.46957e-5	1.05551	1298	4.47
19.0	Cyclobenzaprine	14.272	0.063	649	0.901	0.00000	0.00000	2633	9.06
20.0	Amitriptyline	0.000	0.000	0	0.000	0.00000	0.00000	0	0.00
total							1.05551	29052	100.00