

Table 38: Reasons for Study Termination from MDAP by treatment (3 cycles combined); N49-00-06-130

Reason for Withdrawal	Placebo (N=79)	Celecoxib (N=94)	Naproxen Na (N=107)
Took rescue medication	6 (8%)	13 (14%)	10 (10%)
Lost to follow-up	0 (0%)	0 (0%)	0 (0%)
Protocol violation	0 (0%)	0 (0%)	0 (0%)
Protocol noncompliance	4 (5%)	2 (2%)	2 (2%)
Adverse sign	0 (0%)	0 (0%)	0 (0%)
Withdrawn	10 (13%)	15 (16%)	12 (11%)
Completed treatment cycle	69 (87%)	79 (84%)	95 (89%)

Table 39: Patient Demographics; N49-00-06-130

		Seq 1	Seq 2	Seq3	Seq 4	Seq 5	Seq 6	P-value
Age	N	26	26	24	25	26	27	0.043
	Mean	34.1	33.2	29.9	28.3	31.7	33.3	
	Std dev	8.27	7.22	6.89	6.85	8.38	6.74	
Race	Caucasian	20	23	19	16	22	24	0.731
	Black	1	2	2	3	1	1	
	Asian	2	0	0	1	0	0	
	Hispanic	3	1	3	4	3	2	
	Other	0	0	0	1	0	0	
Height	N	26	26	24	25	26	27	0.357
	Mean	162.15	164.95	165.10	165.13	166.22	163.87	
	Std dev	7.711	5.404	6.354	8.316	6.127	6.342	
Weight	N	26	26	24	25	26	27	0.028
	Mean	70.06	71.74	72.01	86.72	78.99	69.16	
	Std dev	23.916	15.948	14.719	25.330	28.726	15.591	

a. seq 1 = A B C, seq 2 = C A B, seq 3 = B C A, seq4 = A C B, seq 5 = C B A, seq 6 = B A C
 where A = Celecoxib, B=Naproxen Na, C=Placebo

Table 40: Baseline Menstrual Cramping Pain by Treatment; N49-00-06-130

Baseline Pain Intensity	Placebo (N=129)	Celecoxib (N=124)	Naproxen Na (N=123)	P-value
Moderate	80 (62%)	80 (65%)	76 (62%)	0.885
Severe	49 (38%)	44 (35%)	47 (38%)	
Total	129	124	123	

Table 41: Pain Intensity Difference (PID, Categorical Scale, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.10 (0.39)	0.06 (0.40)	0.05 (0.38)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.18 (0.60)	0.27 (0.65)	0.35 (0.69)
	LSD comparison	B	AB	A
0.75	Mean (Std dev)	0.41 (0.74)	0.49 (0.78)	0.61 (0.82)
	LSD comparison	B	B	A
1.00	Mean (Std dev)	0.58 (0.85)	0.69 (0.87)	0.93 (0.92)
	LSD comparison	B	B	A
1.50	Mean (Std dev)	0.72 (1.00)	1.00 (0.97)	1.30 (0.96)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	0.77 (1.04)	1.24 (0.99)	1.47 (0.97)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	0.84 (1.06)	1.44 (1.03)	1.71 (1.03)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	0.92 (1.10)	1.49 (1.05)	1.74 (0.99)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	0.88 (1.10)	1.51 (1.11)	1.74 (0.99)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	0.89 (1.17)	1.51 (1.11)	1.66 (1.01)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	0.76 (0.76)	1.48 (1.12)	1.56 (0.98)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	0.71 (1.15)	1.45 (1.13)	1.45 (1.03)
	LSD comparison	B	A	A
SPID8	Mean (Std dev)	5.96 (7.19)	10.06 (7.09)	11.48 (6.42)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	0.71 (1.16)	1.38 (1.11)	1.39 (1.10)
	LSD comparison	B	A	A
10.00	Mean (Std dev)	0.70 (1.18)	1.35 (1.12)	1.39 (1.10)
	LSD comparison	B	A	A
11.00	Mean (Std dev)	0.70 (1.17)	1.30 (1.14)	1.33 (1.09)
	LSD comparison	B	A	A
12.00	Mean (Std dev)	0.65 (1.16)	1.23 (1.14)	1.26 (1.14)
	LSD comparison	B	A	A
SPID12	Mean (Std dev)	8.75 (11.30)	15.43 (11.04)	16.94 (9.86)
	LSD comparison	B	A	A

Table 42: Pain Relief (PR, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.23 (0.58)	0.20 (0.60)	0.20 (0.60)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.52 (0.89)	0.55 (0.90)	0.70 (1.02)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.94 (1.12)	1.01 (1.13)	1.14 (1.22)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	1.26 (1.24)	1.45 (1.40)	1.59 (1.36)
	LSD comparison	A	A	A
1.50	Mean (Std dev)	1.60 (1.41)	1.91 (1.44)	2.31 (1.45)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	1.69 (1.50)	2.35 (1.48)	2.74 (1.37)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	1.77 (1.53)	2.63 (1.50)	3.06 (1.40)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	1.89 (1.59)	2.67 (1.54)	3.05 (1.42)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	1.84 (1.61)	2.66 (1.58)	3.01 (1.44)
	LSD comparison	B	A	A
6.00	Mean (Std dev)	1.87 (1.66)	2.67 (1.56)	3.00 (1.51)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	1.70 (1.61)	2.66 (1.58)	2.79 (1.47)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	1.58 (1.68)	2.57 (1.61)	2.70 (1.49)
	LSD comparison	B	A	A
TOTPAR8	Mean (Std dev)	12.82 (10.23)	18.28 (10.21)	20.59 (9.18)
	LSD comparison	B	A	A
9.00	Mean (Std dev)	1.53 (1.68)	2.45 (1.61)	2.62 (1.58)
	LSD comparison	B	A	A
10.00	Mean (Std dev)	1.54 (1.71)	2.41 (1.61)	2.60 (1.58)
	LSD comparison	B	A	A
11.00	Mean (Std dev)	1.49 (1.72)	2.30 (1.65)	2.49 (1.58)
	LSD comparison	B	A	A
12.00	Mean (Std dev)	1.43 (1.68)	2.20 (1.73)	2.42 (1.59)
	LSD comparison	B	A	A
TOTPAR 12	Mean (Std dev)	18.89 (16.23)	27.82 (15.82)	30.85 (14.25)
	LSD comparison	B	A	A

Table 43: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - LOCF: N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.33 (0.90)	0.26 (0.92)	0.25 (0.89)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.70 (1.40)	0.82 (1.48)	1.05 (1.64)
	LSD comparison	B	AB	A
0.75	Mean (Std dev)	1.35 (1.78)	1.50 (1.83)	1.75 (1.96)
	LSD comparison	B	AB	A
1.00	Mean (Std dev)	1.84 (2.00)	2.14 (2.21)	2.52 (2.21)
	LSD comparison	B	AB	A
1.50	Mean (Std dev)	2.33 (2.33)	2.92 (2.33)	3.60 (2.33)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	2.46 (2.46)	3.59 (2.40)	4.21 (2.21)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	2.61 (2.51)	4.07 (2.45)	4.77 (2.35)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	2.80 (2.61)	4.17 (2.52)	4.79 (2.32)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	2.71 (2.62)	4.16 (2.61)	4.75 (2.34)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	2.75 (2.76)	4.19 (2.59)	4.66 (2.44)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	2.46 (2.67)	4.14 (2.63)	4.36 (2.34)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	2.29 (2.76)	4.02 (2.66)	4.15 (2.44)
	LSD comparison	B	A	A
SPRID8	Mean (Std dev)	18.78 (16.92)	28.34 (16.82)	32.06 (15.01)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	2.24 (2.77)	3.83 (2.63)	4.01 (2.59)
	LSD comparison	B	A	A
10.00	Mean (Std dev)	2.25 (2.82)	3.76 (2.63)	3.98 (2.60)
	LSD comparison	B	A	A
11.00	Mean (Std dev)	2.19 (2.81)	3.59 (2.70)	3.82 (2.55)
	LSD comparison	B	A	A
12.00	Mean (Std dev)	2.07 (2.76)	3.43 (2.78)	3.68 (2.63)
	LSD comparison	B	A	A
SPRID12	Mean (Std dev)	27.64 (26.79)	43.24 (26.06)	47.79 (23.23)
	LSD comparison	B	A	A

Table 44: Pain Intensity Difference (PID, Categorical Scale, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.02 (0.38)	0.06 (0.23)	0.02 (0.30)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.13 (0.58)	0.17 (0.53)	0.16 (0.48)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.21 (0.66)	0.31 (0.63)	0.40 (0.70)
	LSD comparison	B	AB	A
1.00	Mean (Std dev)	0.41 (0.77)	0.55 (0.77)	0.76 (0.89)
	LSD comparison	B	B	A
1.50	Mean (Std dev)	0.63 (0.84)	0.84 (0.90)	1.17 (0.94)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	0.73 (0.89)	1.15 (0.95)	1.47 (0.91)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	0.90 (1.02)	1.33 (0.97)	1.64 (0.88)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	0.99 (1.06)	1.51 (1.00)	1.78 (0.86)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	1.03 (1.08)	1.50 (1.01)	1.79 (0.87)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	0.96 (1.14)	1.50 (1.03)	1.78 (0.89)
	LSD comparison	C	B	A
7.00	Mean (Std dev)	0.96 (1.16)	1.43 (1.04)	1.75 (0.93)
	LSD comparison	C	B	A
8.00	Mean (Std dev)	0.93 (1.20)	1.40 (1.05)	1.71 (0.94)
	LSD comparison	C	B	A
SPID8	Mean (Std dev)	6.41 (6.82)	9.60 (6.34)	11.71 (5.63)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	0.93 (1.20)	1.38 (1.10)	1.68 (0.96)
	LSD comparison	C	B	A
10.00	Mean (Std dev)	0.89 (1.19)	1.24 (1.12)	1.60 (1.03)
	LSD comparison	C	B	A
11.00	Mean (Std dev)	0.87 (1.18)	1.18 (1.10)	1.52 (1.06)
	LSD comparison	C	B	A
12.00	Mean (Std dev)	0.88 (1.18)	1.12 (1.14)	1.46 (1.06)
	LSD comparison	C	B	A
SPID12	Mean (Std dev)	10.01 (11.01)	14.66 (10.04)	18.10 (8.86)
	LSD comparison	C	B	A

Table 45: Pain Relief (PR, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.17 (0.60)	0.16 (0.47)	0.17 (0.52)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.39 (0.87)	0.44 (0.94)	0.46 (0.83)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.65 (1.09)	0.80 (1.06)	0.98 (1.15)
	LSD comparison	B	AB	A
1.00	Mean (Std dev)	0.96 (1.25)	1.23 (1.24)	1.54 (1.30)
	LSD comparison	C	B	A
1.50	Mean (Std dev)	1.37 (1.34)	1.70 (1.36)	2.26 (1.39)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	1.56 (1.56)	2.20 (1.45)	2.70 (1.32)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	1.83 (1.50)	2.51 (1.48)	2.98 (1.24)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	1.94 (1.60)	2.73 (1.49)	3.17 (1.22)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	1.99 (1.65)	2.72 (1.53)	3.22 (1.24)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	1.92 (1.68)	2.70 (1.55)	3.17 (1.28)
	LSD comparison	C	B	A
7.00	Mean (Std dev)	1.87 (1.87)	2.69 (1.52)	3.10 (1.34)
	LSD comparison	C	B	A
8.00	Mean (Std dev)	1.81 (1.81)	2.64 (1.54)	3.01 (1.38)
	LSD comparison	C	B	A
TOTPAR8	Mean (Std dev)	12.98 (10.20)	17.98 (9.49)	21.27 (7.80)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	1.81 (1.74)	2.55 (1.60)	2.93 (1.45)
	LSD comparison	C	B	A
10.00	Mean (Std dev)	1.78 (1.73)	2.40 (1.62)	2.83 (1.49)
	LSD comparison	C	B	A
11.00	Mean (Std dev)	1.74 (1.75)	2.28 (1.65)	2.75 (1.52)
	LSD comparison	C	B	A
12.00	Mean (Std dev)	1.78 (1.77)	2.18 (1.72)	2.64 (1.56)
	LSD comparison	C	B	A
TOTPAR	Mean (Std dev)	20.10 (16.29)	27.62 (14.69)	32.62 (12.45)
12	LSD comparison	C	B	A

Table 46: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.20 (0.91)	0.21 (0.66)	0.19 (0.72)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.52 (1.39)	0.62 (1.38)	0.62 (1.21)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.86 (1.67)	1.10 (1.61)	1.38 (1.77)
	LSD comparison	B	AB	A
1.00	Mean (Std dev)	1.37 (1.95)	1.78 (1.92)	2.30 (2.11)
	LSD comparison	C	B	A
1.50	Mean (Std dev)	2.00 (2.11)	2.54 (2.17)	3.44 (2.24)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	2.29 (2.19)	3.35 (2.33)	4.17 (2.15)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	2.74 (2.44)	3.84 (2.37)	4.62 (2.03)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	2.93 (2.59)	4.24 (2.42)	4.95 (1.99)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	3.02 (2.65)	4.22 (2.47)	5.01 (2.03)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	2.88 (2.75)	4.20 (2.52)	4.94 (2.08)
	LSD comparison	C	B	A
7.00	Mean (Std dev)	2.83 (2.77)	4.12 (2.49)	4.85 (2.19)
	LSD comparison	C	B	A
8.00	Mean (Std dev)	2.74 (2.84)	4.04 (2.51)	4.72 (2.23)
	LSD comparison	C	B	A
SPRID8	Mean (Std dev)	19.39 (16.55)	27.58 (15.33)	32.98 (12.84)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	2.74 (2.88)	3.93 (2.63)	4.61 (2.31)
	LSD comparison	C	B	A
10.00	Mean (Std dev)	2.67 (2.84)	3.64 (2.66)	4.44 (2.42)
	LSD comparison	C	B	A
11.00	Mean (Std dev)	2.61 (2.87)	3.46 (2.68)	4.27 (2.50)
	LSD comparison	C	B	A
12.00	Mean (Std dev)	2.66 (2.88)	3.30 (2.78)	4.11 (2.53)
	LSD comparison	C	B	A
SPRID12	Mean (Std dev)	30.11 (26.62)	42.28 (23.97)	50.72 (20.38)
	LSD comparison	C	B	A

Additional analyses

Table 47: Summary of the primary efficacy analysis results - Corrected ITT, LOCF

Study	Variable	LSMean (Std Dev)			P-value Celecoxib vs. Placebo
		Placebo	Celecoxib 400mg/ 200mg q12hr prn	Naproxen Na 550mg q12hr prn	
029	SPID(8)	6.46 (7.34)	10.10 (7.08)	11.52 (6.38)	< 0.001
	TOTPAR(8)	13.49 (10.40)	18.38 (10.19)	20.62 (9.17)	< 0.001
030	SPID(8)	6.75 (6.86)	9.65 (6.33)	11.62 (5.76)	< 0.001
	TOTPAR(8)	13.35 (10.11)	17.89 (9.39)	20.94 (7.97)	< 0.001

Table 48: Summary of the secondary efficacy analysis results - Corrected ITT, LOCF

	Time															
	0:15	0:30	0:45	1:00	1:30	2:00	3:00	4:00	5:00	6:00	7:00	8:00	9:00	10:00	11:00	12:00
N49-98-02-129																
PID					*	*	*	*	*	*	*	*	*	*	*	*
PR					*	*	*	*	*	*	*	*	*	*	*	*
PRID					*	*	*	*	*	*	*	*	*	*	*	*
Duration	*															
N49-98-02-130																
PID					*	*	*	*	*	*	*	*	*	*	*	*
PR				*	*	*	*	*	*	*	*	*	*	*	*	*
PRID				*	*	*	*	*	*	*	*	*	*	*	*	*
Duration ²	*															

* = Significantly different between SC-58635 and placebo treatment periods

² Time to Rescue Medication

Table 49: Pain Intensity Difference (PID, Categorical Scale, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - Corrected ITT, LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.11 (0.39)	0.08 (0.40)	0.07 (0.39)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.22 (0.61)	0.29 (0.65)	0.38 (0.68)
	LSD comparison	B	AB	A
0.75	Mean (Std dev)	0.45 (0.73)	0.53 (0.77)	0.64 (0.79)
	LSD comparison	B	B	A
1.00	Mean (Std dev)	0.65 (0.85)	0.74 (0.86)	0.90 (0.90)
	LSD comparison	B	B	A
1.50	Mean (Std dev)	0.80 (1.00)	1.04 (0.95)	1.32 (0.94)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	0.86 (1.06)	1.27 (0.98)	1.49 (0.96)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	0.90 (1.08)	1.43 (1.03)	1.70 (1.02)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	0.98 (1.12)	1.49 (1.06)	1.73 (0.98)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	0.95 (1.13)	1.51 (1.11)	1.74 (0.98)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	0.94 (1.20)	1.50 (1.13)	1.66 (1.02)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	0.83 (1.16)	1.48 (1.14)	1.57 (0.99)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	0.76 (1.16)	1.43 (1.14)	1.44 (1.03)
	LSD comparison	B	A	A
SPID8	Mean (Std dev)	6.46 (6.38)	10.10 (7.08)	11.52 (6.38)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	0.75 (1.17)	1.35 (1.17)	1.39 (1.09)
	LSD comparison	B	A	A
10.00	Mean (Std dev)	0.74 (1.18)	1.31 (1.18)	1.36 (1.09)
	LSD comparison	B	A	A
11.00	Mean (Std dev)	0.72 (1.17)	1.25 (1.17)	1.31 (1.09)
	LSD comparison	B	A	A
12.00	Mean (Std dev)	0.68 (1.17)	1.21 (1.17)	1.25 (1.13)
	LSD comparison	B	A	A
SPID12	Mean (Std dev)	9.39 (11.44)	15.32 (11.04)	16.93 (9.80)
	LSD comparison	C	B	A

Table 50: Pain Relief (PR, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Corrected ITT, LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.24 (0.57)	0.21 (0.59)	0.21 (0.59)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.56 (0.90)	0.59 (0.91)	0.73 (1.01)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	1.00 (1.12)	1.06 (1.12)	1.18 (1.19)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	1.35 (1.25)	1.51 (1.39)	1.67 (1.36)
	LSD comparison	B	AB	A
1.50	Mean (Std dev)	1.70 (1.42)	1.98 (1.42)	2.35 (1.43)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	1.81 (1.53)	2.40 (1.48)	2.76 (1.36)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	1.84 (1.55)	2.61 (1.51)	3.01 (1.42)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	1.97 (1.61)	2.68 (1.54)	3.05 (1.42)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	1.90 (1.64)	2.64 (1.60)	2.99 (1.46)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	1.96 (1.69)	2.69 (1.58)	3.01 (1.52)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	1.80 (1.66)	2.67 (1.60)	2.82 (1.49)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	1.68 (1.71)	2.57 (1.62)	2.72 (1.51)
	LSD comparison	B	A	A
TOTPAR8	Mean (Std dev)	13.49 (10.40)	18.38 (10.19)	20.62 (9.17)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	1.64 (1.72)	2.45 (1.62)	2.64 (1.59)
	LSD comparison	B	A	A
10.00	Mean (Std dev)	1.63 (1.73)	2.39 (1.61)	2.60 (1.58)
	LSD comparison	B	A	A
11.00	Mean (Std dev)	1.57 (1.73)	2.28 (1.65)	2.50 (1.57)
	LSD comparison	B	A	A
12.00	Mean (Std dev)	1.54 (1.72)	2.22 (1.73)	2.45 (1.59)
	LSD comparison	B	A	A
TOTPAR 12	Mean (Std dev)	19.94 (16.52)	27.89 (15.82)	30.94 (14.30)
	LSD comparison	B	A	A

Table 51: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Corrected ITT, LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.34 (0.89)	0.29 (0.91)	0.28 (0.89)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.78 (1.43)	0.88 (1.49)	1.11 (1.63)
	LSD comparison	B	AB	A
0.75	Mean (Std dev)	1.45 (1.77)	1.58 (1.81)	1.82 (1.91)
	LSD comparison	B	AB	A
1.00	Mean (Std dev)	1.99 (2.02)	2.25 (2.18)	2.63 (2.19)
	LSD comparison	B	B	A
1.50	Mean (Std dev)	2.50 (2.33)	3.02 (2.29)	3.66 (2.28)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	2.67 (2.51)	3.67 (2.38)	4.25 (2.20)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	2.74 (2.55)	4.04 (2.47)	4.71 (2.35)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	2.95 (2.65)	4.16 (2.53)	4.78 (2.32)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	2.85 (2.67)	4.15 (2.63)	4.73 (2.36)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	2.90 (2.82)	4.19 (2.64)	4.66 (2.46)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	2.63 (2.75)	4.14 (2.68)	4.38 (2.38)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	2.44 (2.81)	4.00 (2.69)	4.16 (2.46)
	LSD comparison	B	A	A
9.00	Mean (Std dev)	2.39 (2.82)	3.80 (2.66)	4.03 (2.59)
	LSD comparison	B	A	A
10.00	Mean (Std dev)	2.36 (2.83)	3.70 (2.65)	3.96 (2.59)
	LSD comparison	B	A	A
11.00	Mean (Std dev)	2.29 (2.83)	3.53 (2.71)	3.81 (2.56)
	LSD comparison	B	A	A
12.00	Mean (Std dev)	2.22 (2.80)	3.42 (2.79)	3.70 (2.62)
	LSD comparison	B	A	A

Table 52: Pain Intensity Difference (PID, Categorical Scale, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - Corrected ITT, LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.02 (0.36)	0.05 (0.22)	0.02 (0.29)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.14 (0.57)	0.18 (0.52)	0.17 (0.48)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.23 (0.66)	0.32 (0.63)	0.41 (0.71)
	LSD comparison	B	AB	A
1.00	Mean (Std dev)	0.42 (0.77)	0.55 (0.77)	0.76 (0.89)
	LSD comparison	B	B	A
1.50	Mean (Std dev)	0.66 (0.84)	0.86 (0.89)	1.17 (0.93)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	0.77 (0.89)	1.16 (0.93)	1.45 (0.90)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	0.96 (1.03)	1.35 (0.96)	1.65 (0.88)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	1.05 (1.06)	1.52 (0.99)	1.77 (0.87)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	1.07 (1.07)	1.50 (1.00)	1.77 (0.89)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	1.01 (1.14)	1.50 (1.03)	1.76 (0.91)
	LSD comparison	C	B	A
7.00	Mean (Std dev)	1.01 (1.18)	1.44 (1.05)	1.73 (0.96)
	LSD comparison	C	B	A
8.00	Mean (Std dev)	0.98 (1.22)	1.41 (1.07)	1.68 (0.98)
	LSD comparison	C	B	A
SPID8	Mean (Std dev)	6.75 (6.86)	9.65 (6.33)	11.62 (5.76)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	0.97 (1.23)	1.38 (1.13)	1.65 (1.01)
	LSD comparison	C	B	A
10.00	Mean (Std dev)	0.95 (1.22)	1.26 (1.15)	1.60 (1.07)
	LSD comparison	C	B	A
11.00	Mean (Std dev)	0.92 (1.22)	1.21 (1.14)	1.53 (1.10)
	LSD comparison	C	B	A
12.00	Mean (Std dev)	0.92 (1.20)	1.47 (1.16)	1.47 (1.09)
	LSD comparison	C	B	A
SPID12	Mean (Std dev)	10.55 (11.13)	14.76 (10.13)	17.97 (9.16)
	LSD comparison	C	B	A

Table 53: Pain Relief (PR, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Corrected ITT, LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.16 (0.58)	0.14 (0.45)	0.16 (0.51)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.39 (0.85)	0.44 (0.92)	0.47 (0.82)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.67 (1.10)	0.80 (1.07)	0.99 (1.16)
	LSD comparison	B	B	A
1.00	Mean (Std dev)	0.98 (1.25)	1.23 (1.23)	1.52 (1.29)
	LSD comparison	C	B	A
1.50	Mean (Std dev)	1.42 (1.34)	1.72 (1.35)	2.25 (1.38)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	1.62 (1.38)	2.21 (1.43)	2.67 (1.33)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	1.89 (1.49)	2.50 (1.46)	2.93 (1.25)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	2.00 (1.58)	2.71 (1.47)	3.12 (1.24)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	2.03 (1.63)	2.69 (1.52)	3.16 (1.28)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	1.96 (1.66)	2.68 (1.54)	3.11 (1.31)
	LSD comparison	C	B	A
7.00	Mean (Std dev)	1.93 (1.67)	2.67 (1.53)	3.05 (1.38)
	LSD comparison	C	B	A
8.00	Mean (Std dev)	1.87 (1.71)	2.62 (1.55)	2.95 (1.40)
	LSD comparison	C	B	A
TOTPAR8	Mean (Std dev)	13.35 (10.11)	17.89 (9.39)	20.94 (7.97)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	1.86 (1.74)	2.53 (1.61)	2.88 (1.48)
	LSD comparison	C	B	A
10.00	Mean (Std dev)	1.84 (1.74)	2.41 (1.63)	2.81 (1.51)
	LSD comparison	C	B	A
11.00	Mean (Std dev)	1.81 (1.76)	2.30 (1.66)	2.74 (1.55)
	LSD comparison	C	B	A
12.00	Mean (Std dev)	1.82 (1.77)	2.19 (1.72)	2.62 (1.58)
	LSD comparison	C	B	A
TOTPAR	Mean (Std dev)	20.70 (16.10)	27.54 (14.51)	32.16 (12.62)
12	LSD comparison	C	B	A

Table 54: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Corrected ITT, LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.18 (0.87)	0.20 (0.63)	0.18 (0.69)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.53 (1.36)	0.62 (1.35)	0.65 (1.21)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.89 (1.67)	1.12 (1.62)	1.41 (1.79)
	LSD comparison	B	B	A
1.00	Mean (Std dev)	1.41 (1.93)	1.79 (1.91)	2.27 (2.10)
	LSD comparison	C	B	A
1.50	Mean (Std dev)	2.09 (2.10)	2.58 (2.13)	3.41 (2.22)
	LSD comparison	C	B	A
2.00	Mean (Std dev)	2.39 (2.19)	3.37 (2.29)	4.12 (2.15)
	LSD comparison	C	B	A
3.00	Mean (Std dev)	2.85 (2.43)	3.86 (2.33)	4.58 (2.04)
	LSD comparison	C	B	A
4.00	Mean (Std dev)	3.05 (2.56)	4.23 (2.38)	4.89 (2.01)
	LSD comparison	C	B	A
5.00	Mean (Std dev)	3.10 (2.62)	4.20 (2.45)	4.92 (2.08)
	LSD comparison	C	B	A
6.00	Mean (Std dev)	2.97 (2.73)	4.17 (2.50)	4.86 (2.13)
	LSD comparison	C	B	A
7.00	Mean (Std dev)	2.94 (2.78)	4.11 (2.51)	4.77 (2.25)
	LSD comparison	C	B	A
8.00	Mean (Std dev)	2.85 (2.86)	4.03 (2.55)	4.63 (2.30)
	LSD comparison	C	B	A
9.00	Mean (Std dev)	2.83 (2.90)	3.92 (2.66)	4.53 (2.39)
	LSD comparison	C	B	A
10.00	Mean (Std dev)	2.79 (2.90)	3.67 (2.70)	4.41 (2.50)
	LSD comparison	C	B	A
11.00	Mean (Std dev)	2.74 (2.91)	3.51 (2.72)	4.26 (2.56)
	LSD comparison	C	B	A
12.00	Mean (Std dev)	2.74 (2.90)	3.32 (2.80)	4.09 (2.59)
	LSD comparison	C	B	A

Table 55: Summary of the primary efficacy analysis results – Cycle 1 only, LOCF

Study	Variable	LSMean (Std Dev)			P-value Celecoxib vs. Placebo
		Placebo	Celecoxib 400mg/ 200mg q12hr prn	Naproxen Na 550mg q12hr prn	
029	SPID(8)	6.74 (7.23)	11.42 (5.95)	11.20 (6.27)	< 0.001
	TOTPAR(8)	13.95 (10.92)	20.87 (9.11)	20.36 (9.23)	0.001
030	SPID(8)	6.70 (6.14)	9.18 (6.16)	12.11 (6.01)	0.037
	TOTPAR(8)	13.71 (9.63)	18.79 (8.86)	20.84 (7.59)	0.008

Table 56: Summary of the secondary efficacy analysis results – Cycle 1 only, LOCF

	Time															
	0:15	0:30	0:45	1:00	1:30	2:00	3:00	4:00	5:00	6:00	7:00	8:00	9:00	10:00	11:00	12:00
N49-98-02-129																
PID	*			*	*	*	*	*	*	*	*	*	*			
PR				*	*	*	*	*	*	*	*	*	*			
PRID	*			*	*	*	*	*	*	*	*	*	*			
Duration	*															
Onset	*															
N49-98-02-130																
PID	*						*	*	*	*	*	*	*			
PR							*	*	*	*	*	*	*			
PRID							*	*	*	*	*	*	*			
Duration ^a	*															
Onset ^b	*															

* = Significantly different between SC-58635 and placebo treatment periods

^a Time to Rescue Medication

^b Time to Onset Perceptible Pain Relief

Table 57: Pain Intensity Difference (PID, Categorical Scale, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Cycle 1 only, LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.12 (0.32)	0.16 (0.42)	0.06 (0.38)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.16 (0.42)	0.52 (0.62)	0.41 (0.67)
	LSD comparison	B	A	A
0.75	Mean (Std dev)	0.48 (0.67)	0.78 (0.71)	0.66 (0.73)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	0.68 (0.81)	0.99 (0.84)	1.05 (0.81)
	LSD comparison	A	A	A
1.50	Mean (Std dev)	0.79 (0.95)	1.39 (0.79)	1.48 (0.77)
	LSD comparison	B	A	A
2.00	Mean (Std dev)	0.88 (1.07)	1.53 (0.81)	1.53 (0.93)
	LSD comparison	B	A	A
3.00	Mean (Std dev)	0.95 (1.05)	1.62 (0.88)	1.66 (0.94)
	LSD comparison	B	A	A
4.00	Mean (Std dev)	1.00 (1.08)	1.67 (0.90)	1.66 (0.98)
	LSD comparison	B	A	A
5.00	Mean (Std dev)	0.98 (1.11)	1.64 (0.91)	1.66 (1.01)
	LSD comparison	B	A	A
6.00	Mean (Std dev)	1.00 (1.14)	1.58 (0.96)	1.57 (1.06)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	0.89 (1.09)	1.57 (1.01)	1.48 (1.00)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	0.83 (1.05)	1.52 (1.04)	1.22 (1.09)
	LSD comparison	B	A	AB
9.00	Mean (Std dev)	0.81 (1.04)	1.43 (1.07)	1.13 (1.19)
	LSD comparison	B	A	AB
10.00	Mean (Std dev)	0.87 (1.06)	1.32 (1.02)	1.06 (1.17)
	LSD comparison	A	A	A
11.00	Mean (Std dev)	0.85 (1.06)	1.21 (1.07)	1.00 (1.12)
	LSD comparison	A	A	A
12.00	Mean (Std dev)	0.79 (1.04)	1.10 (1.06)	0.94 (1.15)
	LSD comparison	A	A	A

Table 58: Pain Relief (PR, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Cycle 1 only, LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.28 (0.53)	0.28 (0.67)	0.31 (0.69)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.56 (0.69)	0.90 (0.98)	0.86 (1.05)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	1.15 (1.12)	1.38 (1.11)	1.26 (1.15)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	1.46 (1.28)	1.91 (1.42)	1.81 (1.41)
	LSD comparison	A	A	A
1.50	Mean (Std dev)	1.74 (1.36)	2.53 (1.19)	2.50 (1.37)
	LSD comparison	B	A	A
2.00	Mean (Std dev)	1.80 (1.53)	2.88 (1.23)	2.81 (1.31)
	LSD comparison	B	A	A
3.00	Mean (Std dev)	1.93 (1.57)	2.96 (1.31)	2.96 (1.41)
	LSD comparison	B	A	A
4.00	Mean (Std dev)	2.04 (1.67)	3.05 (1.32)	3.01 (1.43)
	LSD comparison	B	A	A
5.00	Mean (Std dev)	1.89 (1.67)	2.93 (1.42)	2.96 (1.50)
	LSD comparison	B	A	A
6.00	Mean (Std dev)	2.02 (1.76)	2.89 (1.45)	2.99 (1.67)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	1.89 (1.73)	2.88 (1.46)	2.57 (1.59)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	1.81 (1.79)	2.76 (1.51)	2.46 (1.58)
	LSD comparison	B	A	AB
9.00	Mean (Std dev)	1.72 (1.77)	2.65 (1.51)	2.30 (1.68)
	LSD comparison	B	A	AB
10.00	Mean (Std dev)	1.81 (1.79)	2.49 (1.49)	2.19 (1.61)
	LSD comparison	A	A	A
11.00	Mean (Std dev)	1.72 (1.81)	2.31 (1.58)	2.13 (1.58)
	LSD comparison	A	A	A
12.00	Mean (Std dev)	1.68 (1.77)	2.22 (1.67)	2.13 (1.57)
	LSD comparison	A	A	A

Table 59: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Cycle 1 only, LOCF; N49-98-02-129

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.40 (0.77)	0.43 (1.04)	0.37 (0.94)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.72 (0.99)	1.42 (1.53)	1.26 (1.63)
	LSD comparison	B	A	A
0.75	Mean (Std dev)	1.63 (1.72)	2.16 (1.74)	1.91 (1.77)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	2.15 (2.03)	2.90 (2.18)	2.86 (2.15)
	LSD comparison	A	A	A
1.50	Mean (Std dev)	2.53 (2.24)	3.92 (1.90)	3.98 (2.05)
	LSD comparison	B	A	A
2.00	Mean (Std dev)	2.68 (2.54)	4.41 (1.95)	4.34 (2.05)
	LSD comparison	B	A	A
3.00	Mean (Std dev)	2.87 (2.56)	4.58 (2.10)	4.62 (2.25)
	LSD comparison	B	A	A
4.00	Mean (Std dev)	3.04 (2.68)	4.72 (2.15)	4.67 (2.35)
	LSD comparison	B	A	A
5.00	Mean (Std dev)	2.87 (2.68)	4.57 (2.25)	4.62 (2.42)
	LSD comparison	B	A	A
6.00	Mean (Std dev)	30.2 (2.85)	4.47 (2.35)	4.57 (2.63)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	2.79 (2.77)	4.44 (2.41)	4.04 (2.42)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	2.64 (2.78)	4.28 (2.50)	3.68 (2.59)
	LSD comparison	B	A	AB
9.00	Mean (Std dev)	2.53 (2.73)	4.08 (2.49)	3.43 (2.79)
	LSD comparison	B	A	AB
10.00	Mean (Std dev)	2.68 (2.77)	3.80 (2.43)	3.26 (2.68)
	LSD comparison	A	A	A
11.00	Mean (Std dev)	2.57 (2.80)	3.52 (2.57)	3.13 (2.61)
	LSD comparison	A	A	A
12.00	Mean (Std dev)	2.47 (2.72)	3.32 (2.65)	3.06 (2.61)
	LSD comparison	A	A	A

Table 60: Pain Intensity Difference (PID, Categorical Scale, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons - Corrected ITT, LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.00 (0.30)	0.17 (0.38)	0.02 (0.26)
	LSD comparison	B	A	B
0.50	Mean (Std dev)	0.24 (0.57)	0.19 (0.55)	0.20 (0.50)
	LSD comparison	A	A	AA
0.75	Mean (Std dev)	0.39 (0.65)	0.36 (0.73)	0.47 (0.69)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	0.55 (0.73)	0.60 (0.77)	0.80 (0.97)
	LSD comparison	A	A	A
1.50	Mean (Std dev)	0.79 (0.79)	0.79 (0.81)	1.18 (1.01)
	LSD comparison	A	A	A
2.00	Mean (Std dev)	0.89 (0.80)	1.12 (0.92)	1.50 (0.95)
	LSD comparison	B	AB	A
3.00	Mean (Std dev)	0.98 (0.88)	1.26 (0.94)	1.76 (0.91)
	LSD comparison	B	B	A
4.00	Mean (Std dev)	1.07 (0.98)	1.43 (0.97)	1.87 (0.89)
	LSD comparison	B	A	A
5.00	Mean (Std dev)	1.05 (1.01)	1.43 (1.04)	1.80 (0.94)
	LSD comparison	B	A	A
6.00	Mean (Std dev)	0.89 (1.10)	1.43 (1.06)	1.84 (0.93)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	0.87 (1.13)	1.36 (1.06)	1.80 (0.94)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	0.85 (1.15)	1.24 (1.10)	1.71 (0.92)
	LSD comparison	B	AB	A
9.00	Mean (Std dev)	0.83 (1.20)	1.17 (1.21)	1.67 (1.02)
	LSD comparison	B	AB	A
10.00	Mean (Std dev)	0.91 (1.24)	0.90 (1.16)	1.64 (1.05)
	LSD comparison	B	B	A
11.00	Mean (Std dev)	0.93 (1.22)	0.83 (1.15)	1.53 (1.10)
	LSD comparison	B	B	A
12.00	Mean (Std dev)	0.96 (1.21)	0.76 (1.21)	1.47 (1.08)
	LSD comparison	AB	B	A

Table 61: Pain Relief (PR, Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Corrected ITT, LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.20 (0.54)	0.31 (0.64)	0.18 (0.58)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.59 (0.91)	0.60 (1.13)	0.51 (0.89)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	0.97 (1.20)	0.99 (1.23)	1.01 (1.14)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	-1.24 (1.25)	1.50 (1.29)	1.58 (1.31)
	LSD comparison	A	A	A
1.50	Mean (Std dev)	1.68 (1.29)	1.79 (1.30)	2.13 (1.36)
	LSD comparison	A	A	A
2.00	Mean (Std dev)	1.91 (1.30)	2.32 (1.41)	2.59 (1.35)
	LSD comparison	A	A	A
3.00	Mean (Std dev)	2.00 (1.40)	2.57 (1.40)	2.96 (1.23)
	LSD comparison	B	A	A
4.00	Mean (Std dev)	2.07 (1.51)	2.83 (1.36)	3.17 (1.15)
	LSD comparison	B	A	A
5.00	Mean (Std dev)	1.94 (1.62)	2.86 (1.46)	3.13 (1.18)
	LSD comparison	B	A	A
6.00	Mean (Std dev)	1.85 (1.67)	2.81 (1.45)	3.13 (1.22)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	1.82 (1.66)	2.74 (1.47)	3.00 (1.26)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	1.74 (1.64)	2.62 (1.53)	2.84 (1.31)
	LSD comparison	B	A	A
9.00	Mean (Std dev)	1.70 (1.72)	2.43 (1.61)	2.78 (1.41)
	LSD comparison	B	A	A
10.00	Mean (Std dev)	1.80 (1.77)	2.07 (1.58)	2.69 (1.44)
	LSD comparison	B	AB	A
11.00	Mean (Std dev)	1.83 (1.78)	1.93 (.61)	2.64 (1.49)
	LSD comparison	B	B	A
12.00	Mean (Std dev)	1.85 (1.80)	1.83 (1.70)	2.53 (1.55)
	LSD comparison	A	A	A

Table 62: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated) Means, (Std Dev), and Fisher's Protected LSD Comparisons – Corrected ITT, LOCF; N49-98-02-130

Time	Description	Placebo	Celecoxib	Naproxen Na
0.25	Mean (Std dev)	0.20 (0.75)	0.48 (0.99)	0.20 (0.76)
	LSD comparison	A	A	A
0.50	Mean (Std dev)	0.83 (1.40)	0.79 (1.62)	0.71 (1.34)
	LSD comparison	A	A	A
0.75	Mean (Std dev)	1.36 (1.77)	1.34 (1.90)	1.48 (1.78)
	LSD comparison	A	A	A
1.00	Mean (Std dev)	1.79 (1.88)	2.10 (2.10)	2.38 (2.19)
	LSD comparison	A	A	A
1.50	Mean (Std dev)	2.47 (1.99)	2.57 (2.57)	3.31 (2.28)
	LSD comparison	A	A	A
2.00	Mean (Std dev)	2.80 (2.02)	3.44 (3.44)	4.09 (2.21)
	LSD comparison	B	AB	A
3.00	Mean (Std dev)	2.98 (2.21)	3.83 (2.26)	4.71 (2.05)
	LSD comparison	B	AB	A
4.00	Mean (Std dev)	3.13 (2.40)	4.26 (2.25)	5.03 (1.95)
	LSD comparison	B	A	A
5.00	Mean (Std dev)	2.98 (2.55)	4.29 (2.43)	4.93 (2.03)
	LSD comparison	B	A	A
6.00	Mean (Std dev)	2.74 (2.71)	4.24 (2.46)	4.98 (2.04)
	LSD comparison	B	A	A
7.00	Mean (Std dev)	2.68 (2.72)	4.10 (2.45)	4.80 (2.12)
	LSD comparison	B	A	A
8.00	Mean (Std dev)	2.59 (2.71)	3.86 (2.57)	4.56 (2.15)
	LSD comparison	B	A	A
9.00	Mean (Std dev)	2.52 (2.85)	3.60 (2.76)	4.44 (2.33)
	LSD comparison	B	AB	A
10.00	Mean (Std dev)	2.72 (2.96)	2.98 (2.68)	4.33 (2.38)
	LSD comparison	B	B	A
11.00	Mean (Std dev)	2.76 (2.95)	2.78 (2.69)	4.18 (2.50)
	LSD comparison	B	B	A
12.00	Mean (Std dev)	2.80 (2.95)	2.60 (2.83)	4.00 (2.53)
	LSD comparison	A	A	A

Figures

Post-Surgical Studies

Figure 1: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); LOCF, N49-98-02-082

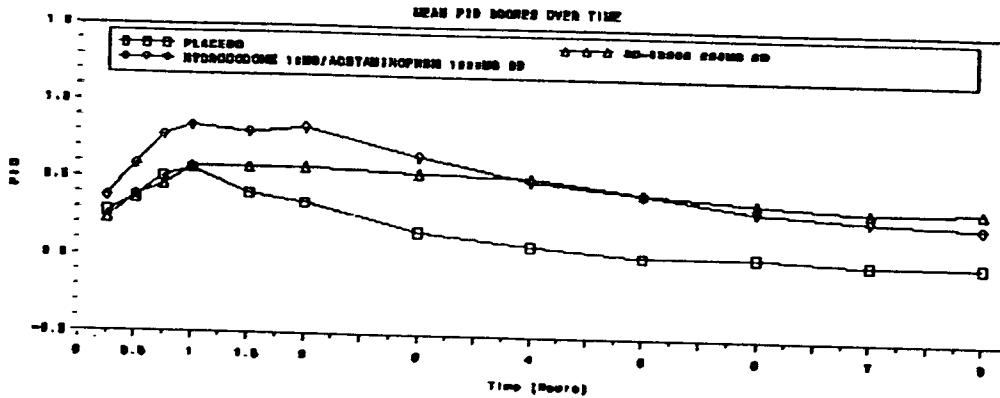


Figure 2: Pain Relief (PR, Extrapolated) Means, (Std Dev); LOCF, N49-98-02-082

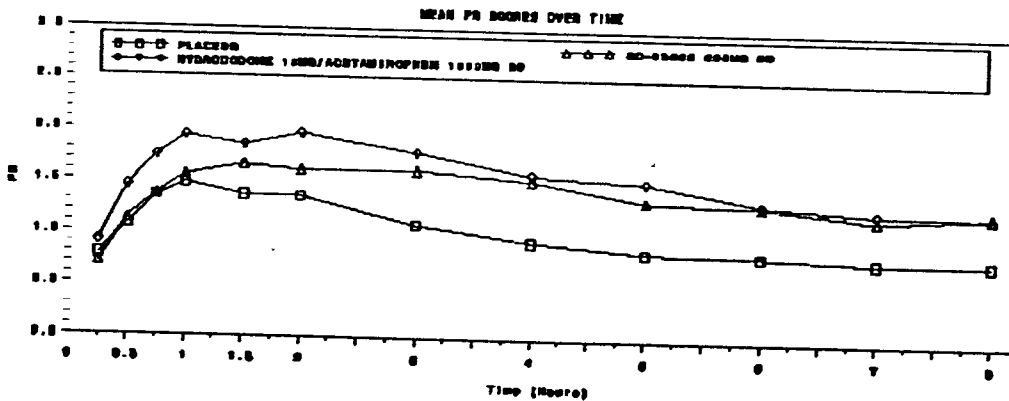


Figure 3: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); LOCF, N49-98-02-082

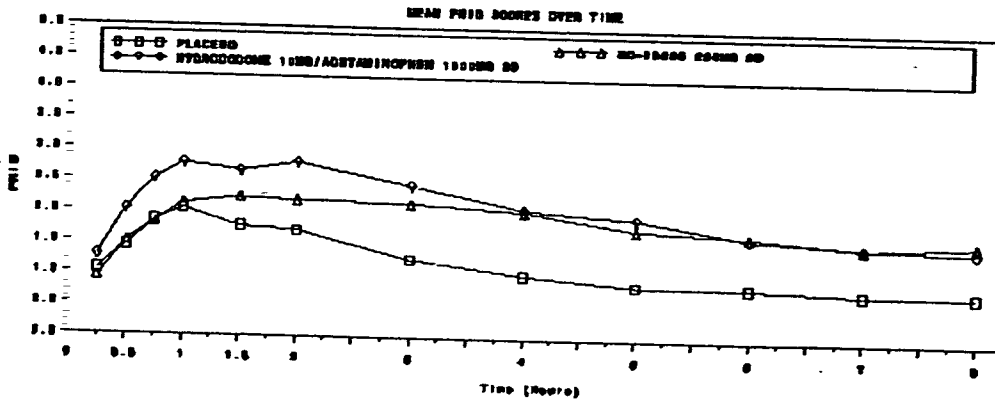


Figure 4: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); BOCF, N49-98-02-082

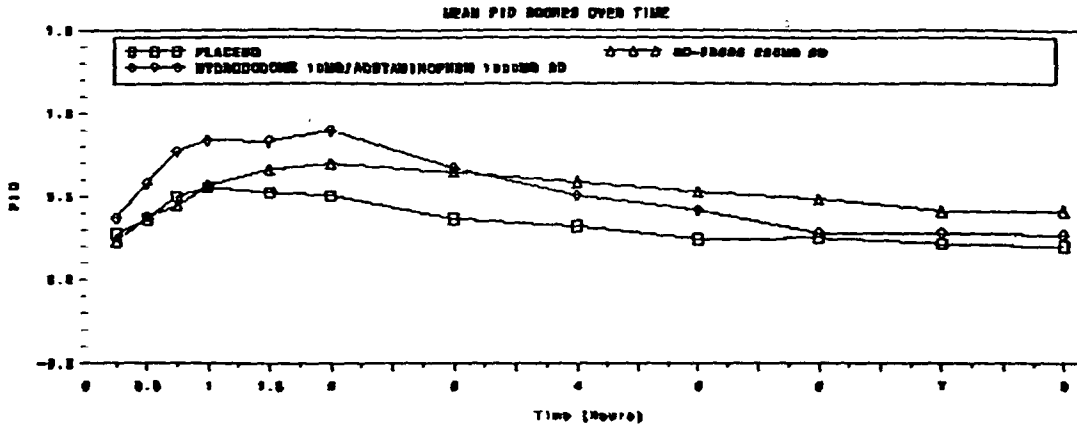


Figure 5: Pain Relief (PR, Extrapolated) Means, (Std Dev); BOCF, N49-98-02-082

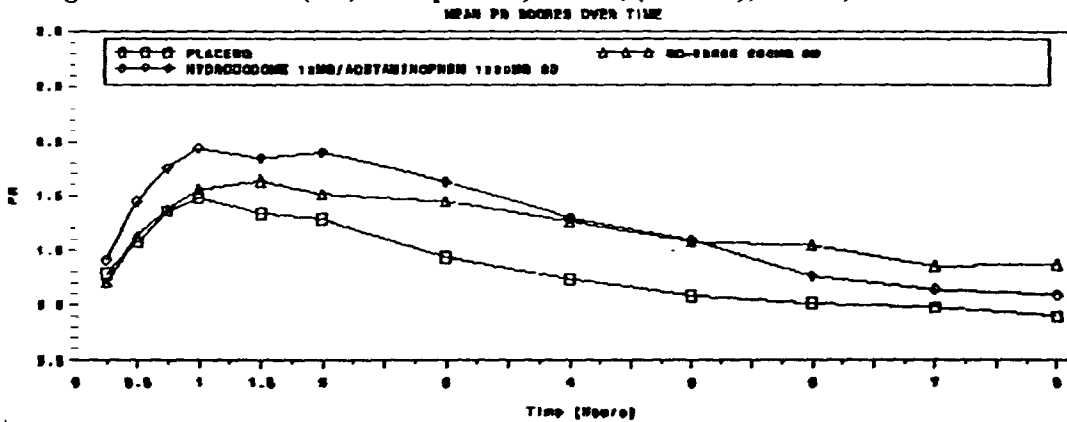


Figure 6: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); BOCF, N49-98-02-082

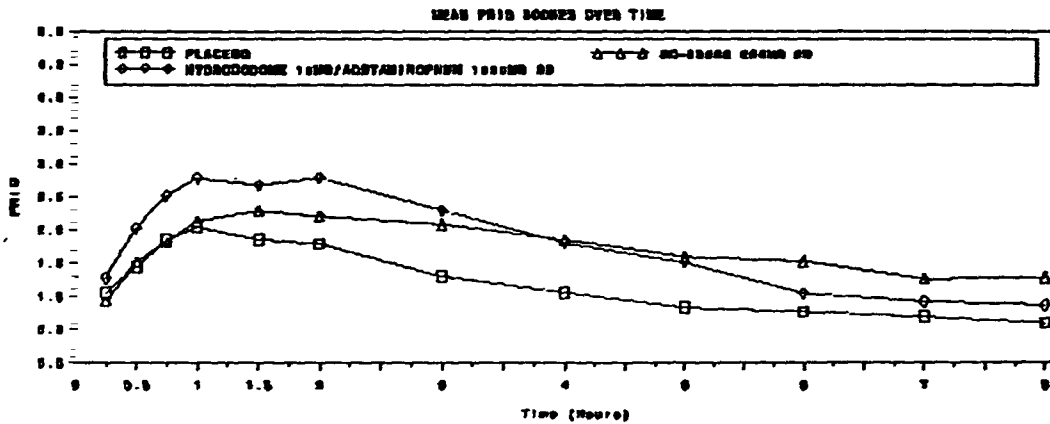


Figure 7: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); LOCF, N49-98-02-083

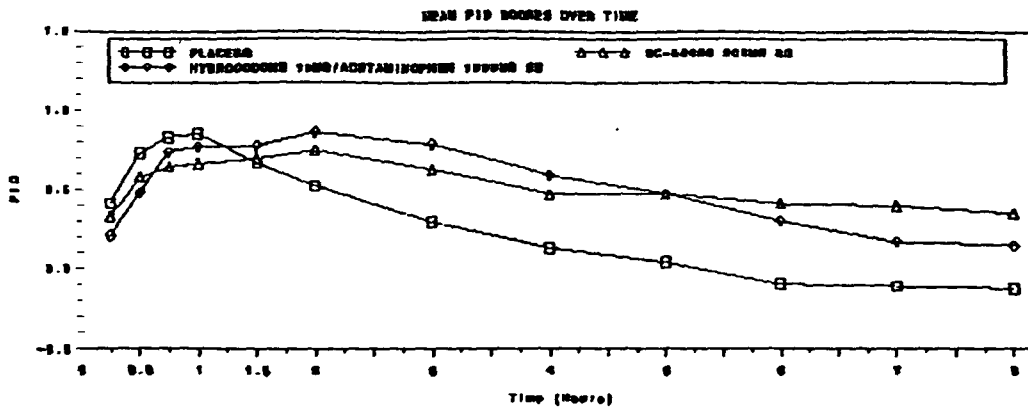


Figure 8: Pain Relief (PR, Extrapolated) Means, (Std Dev); LOCF, N49-98-02-083

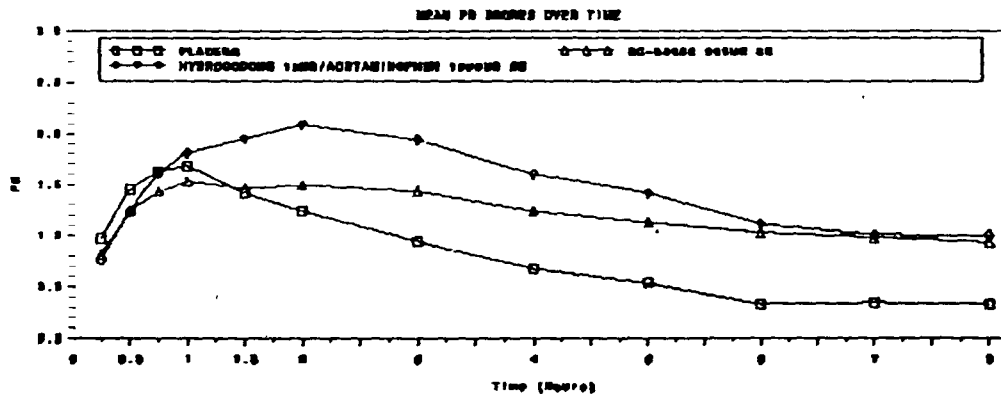


Figure 9: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); LOCF, N49-98-02-083

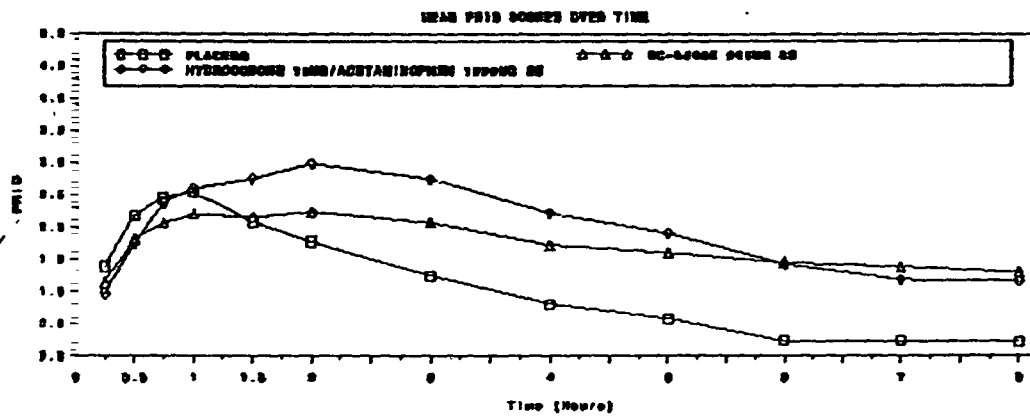


Figure 10: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); BOCF, N49-98-02-083

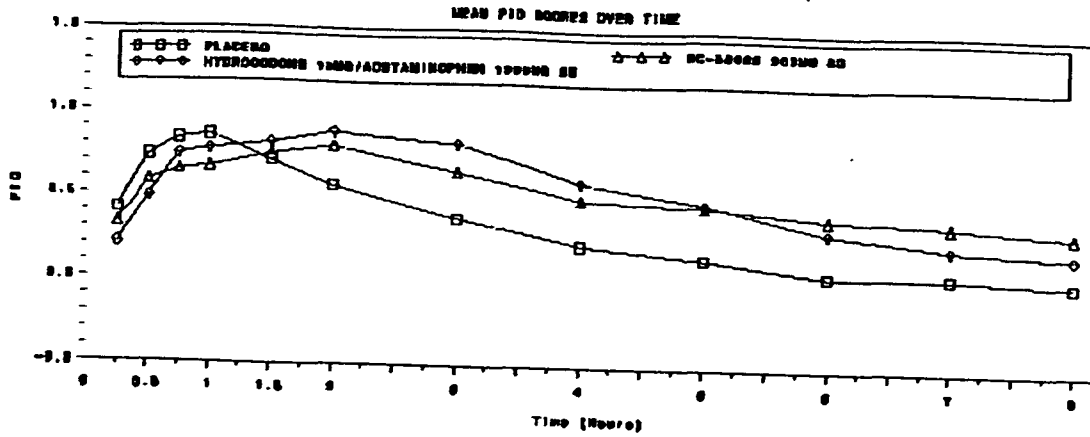


Figure 11: Pain Relief (PR, Extrapolated) Means, (Std Dev); BOCF, N49-98-02-083

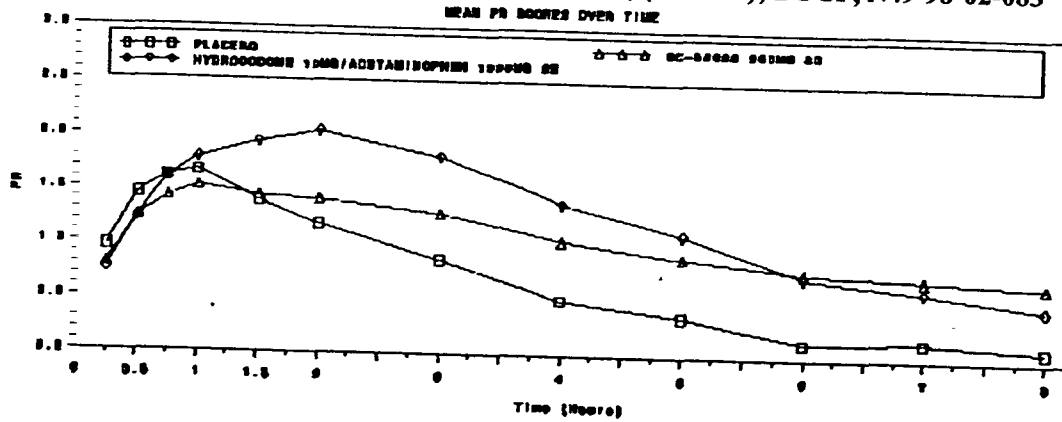


Figure 12: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); BOCF, N49-98-02-083

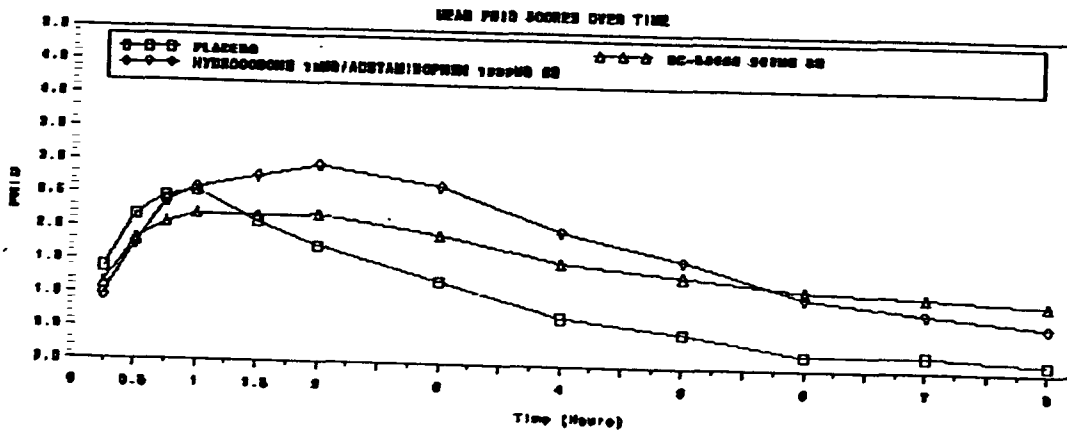


Figure 13: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); N49-98-02-085

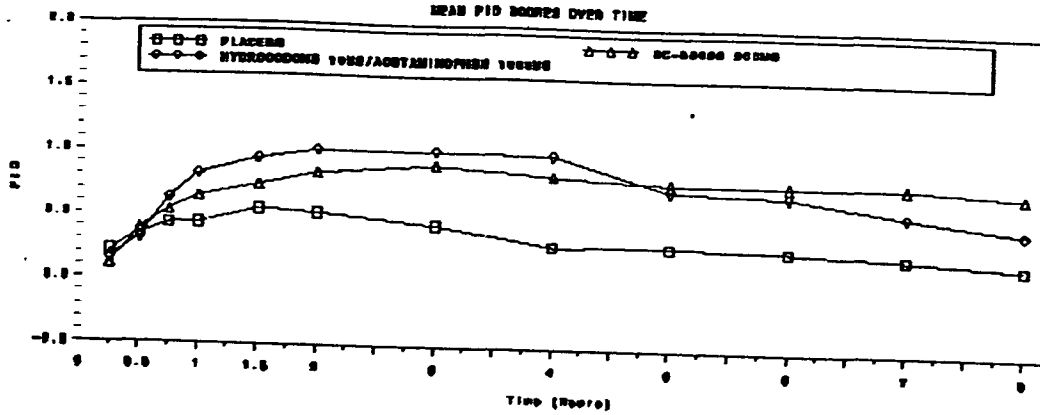


Figure 14: Pain Relief (PR, Extrapolated) Means, (Std Dev); N49-98-02-085

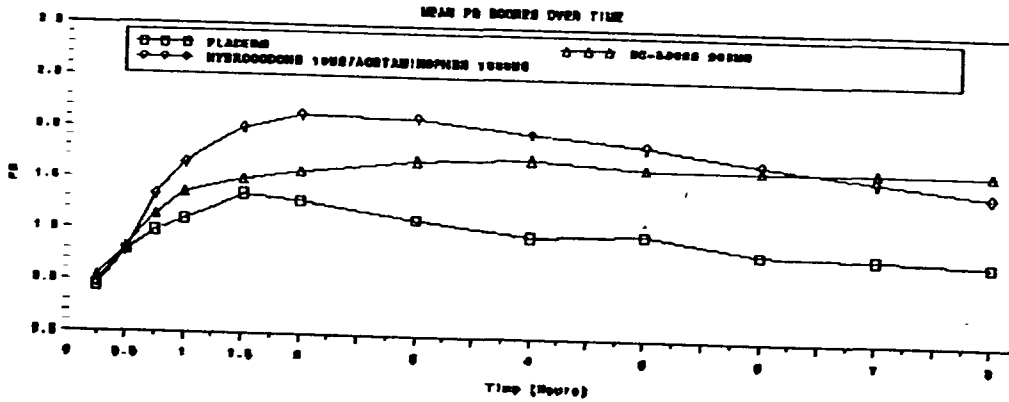


Figure 15: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); N49-98-02-085

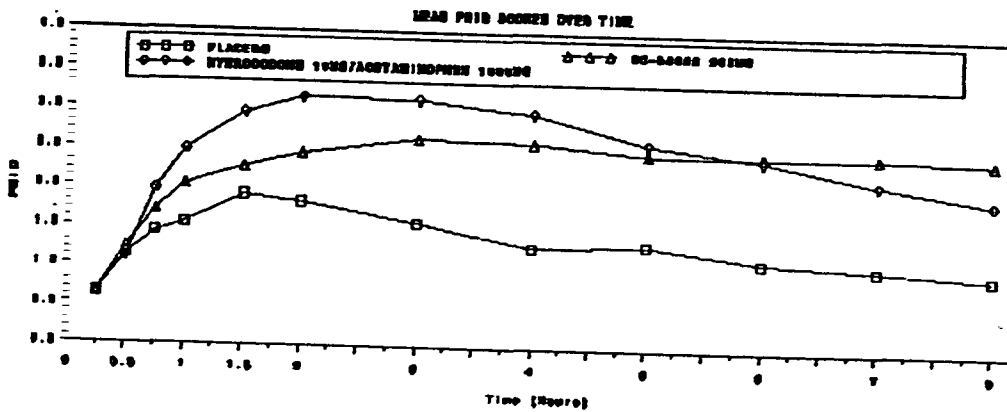


Figure 16: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); BOCF, N49-98-02-085

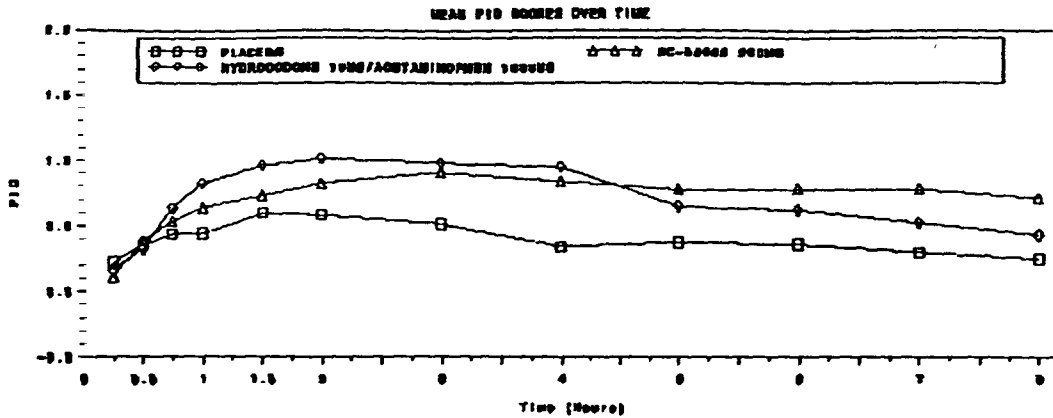


Figure 17: Pain Relief (PR, Extrapolated) Means, (Std Dev); BOCF, N49-98-02-085

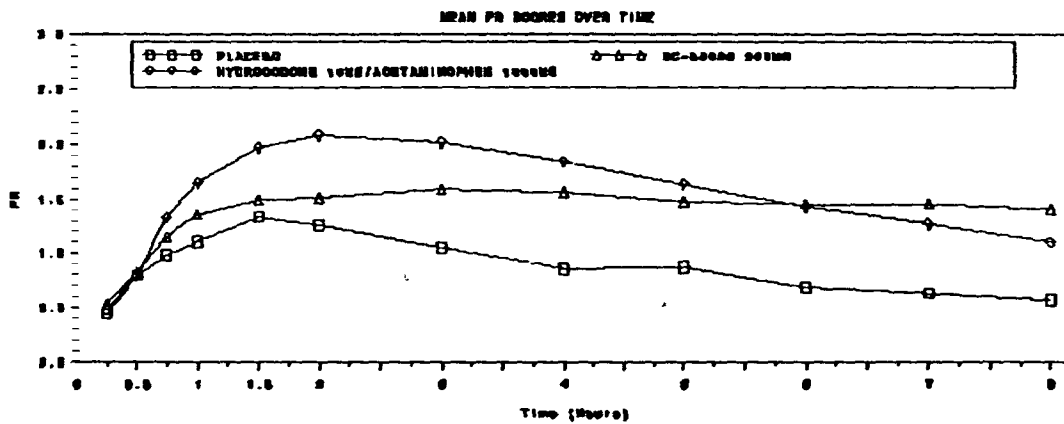


Figure 18: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); BOCF, N49-98-02-085

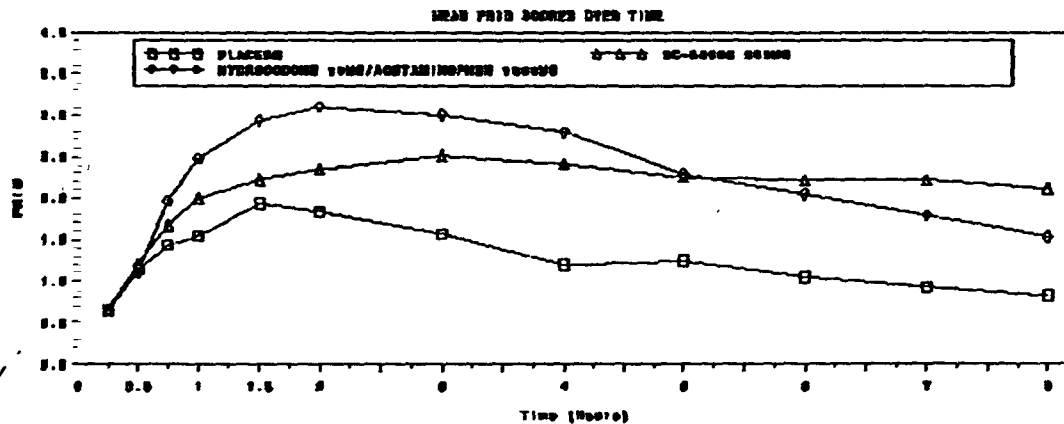


Figure 19: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); N49-98-02-086

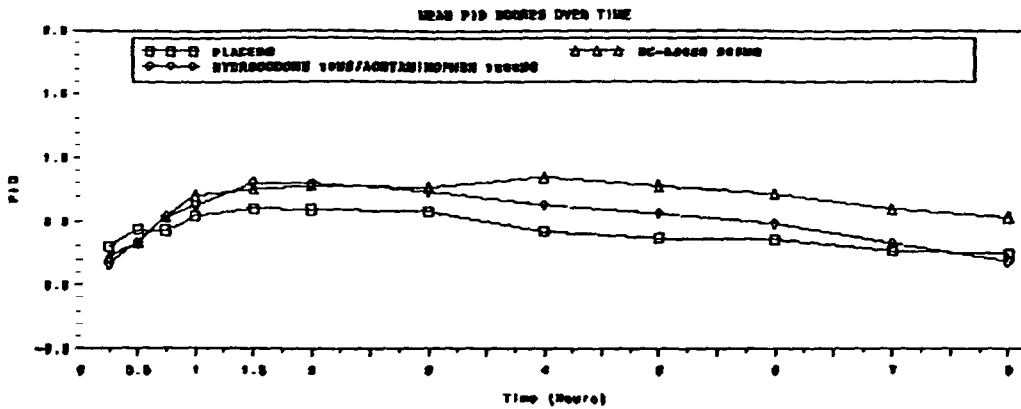


Figure 20: Pain Relief (PR, Extrapolated) Means, (Std Dev); N49-98-02-086

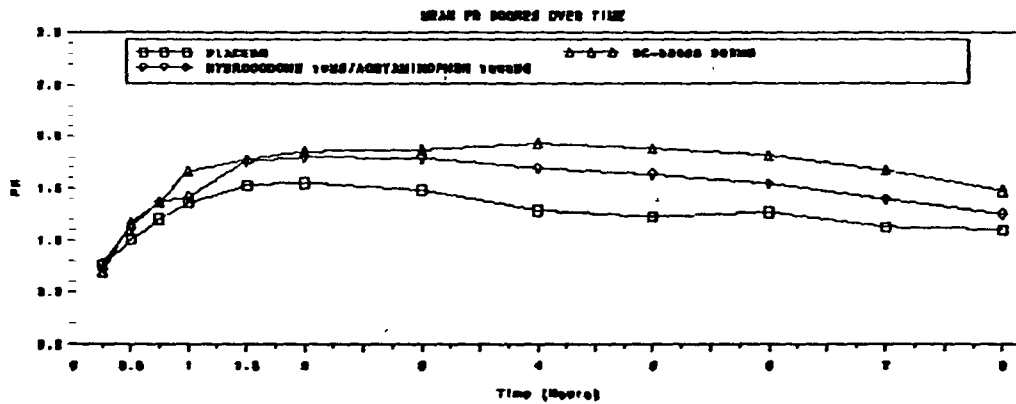


Figure 21: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); N49-98-02-086

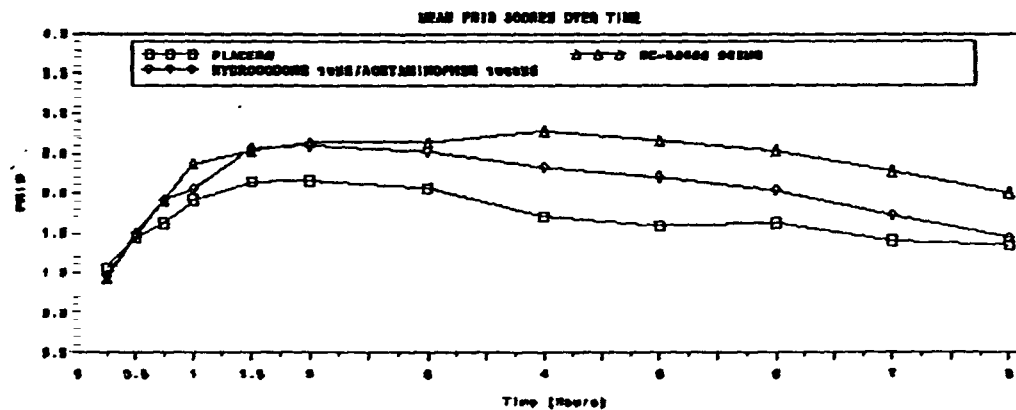


Figure 22: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); BOCF, N49-98-02-086

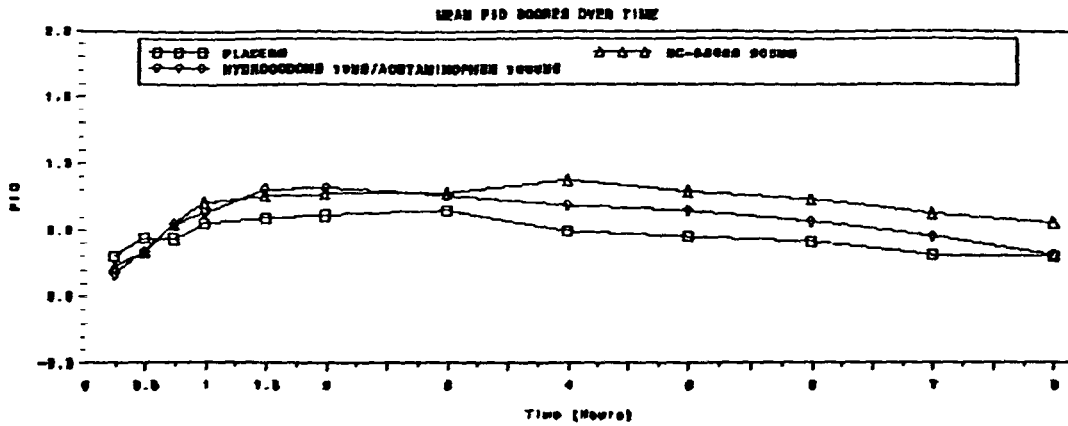


Figure 23: Pain Relief (PR, Extrapolated) Means, (Std Dev); BOCF, N49-98-02-086

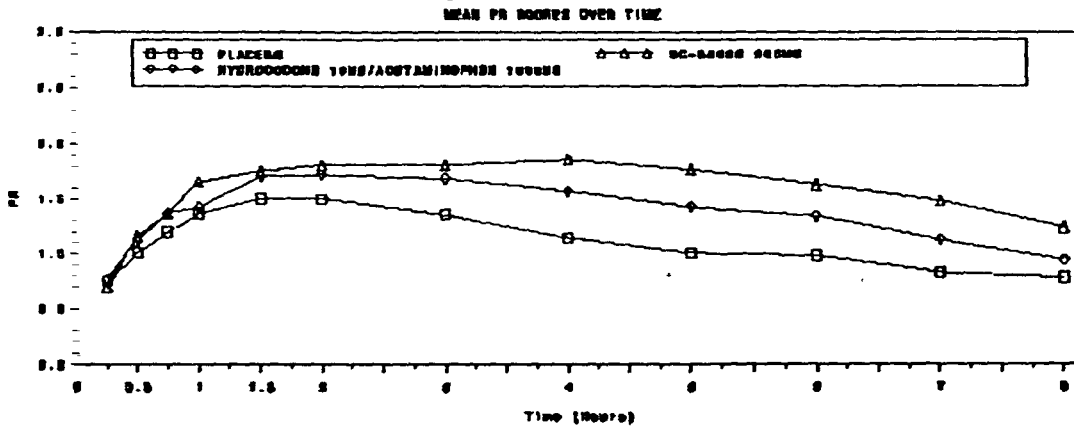


Figure 24: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); BOCF, N49-98-02-086

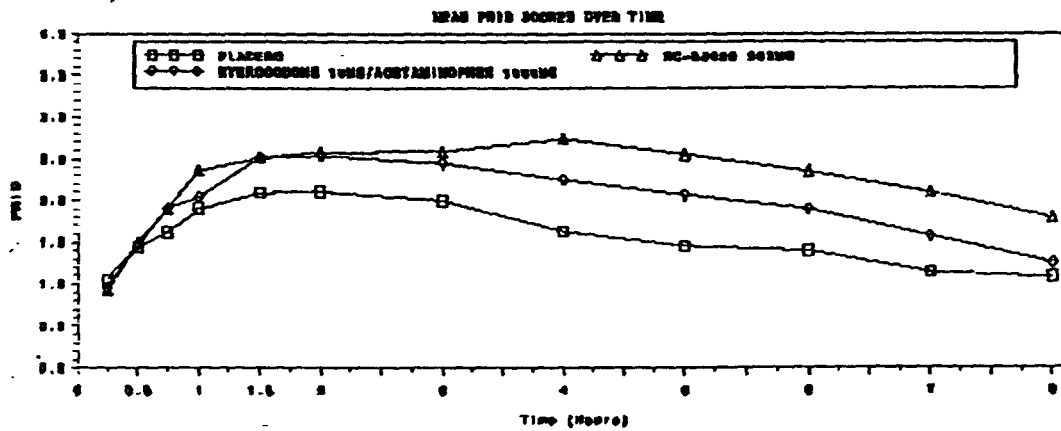


Figure 25: Time to Rescue Medication; N49-98-02-082

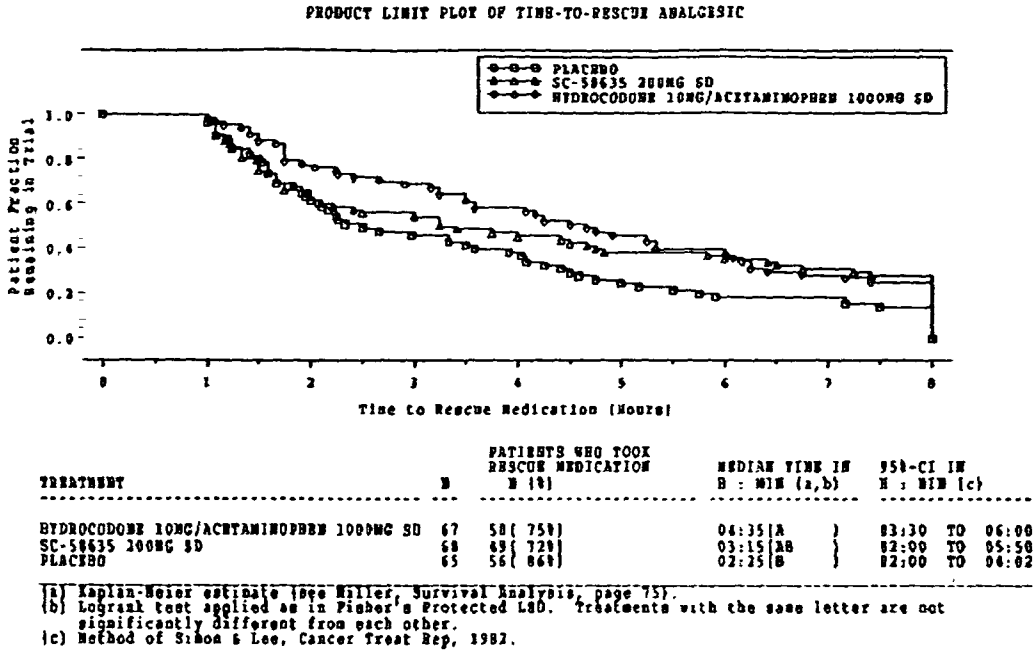


Figure 26: Time to Onset of Analgesia; N49-98-02-082

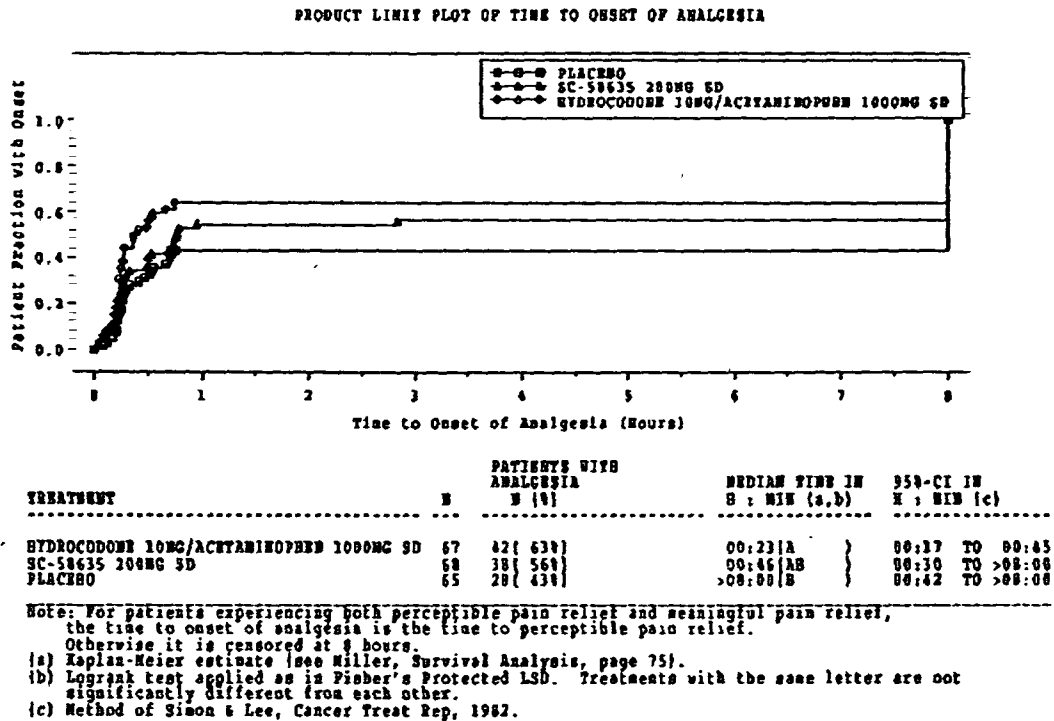


Figure 27: Time to Rescue Medication; N49-98-02-083

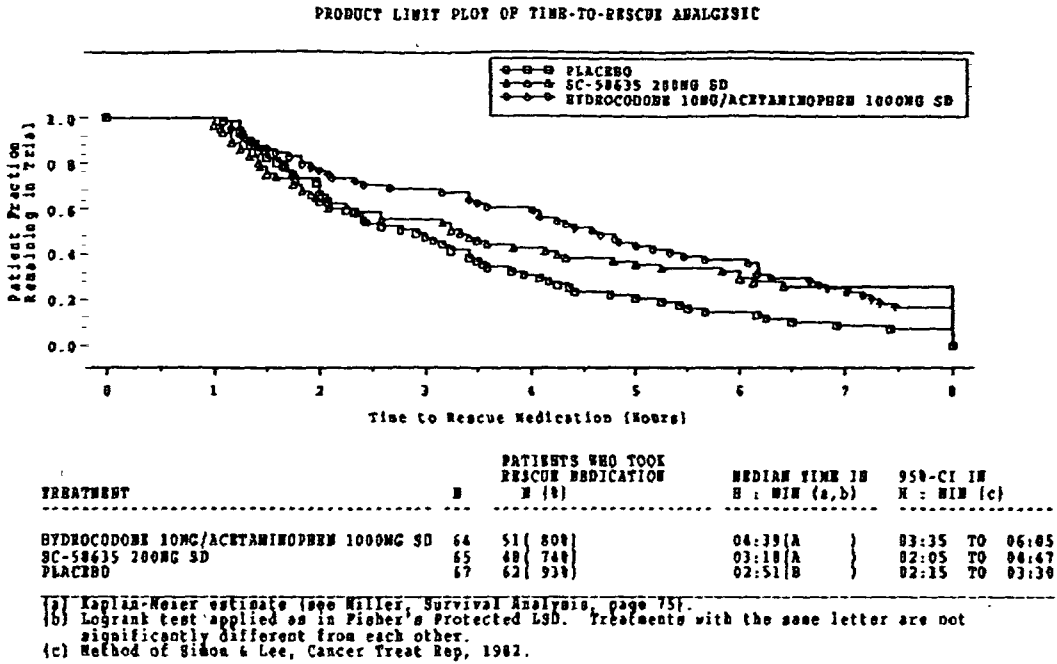


Figure 28: Time to Onset of Analgesia; N49-98-02-083

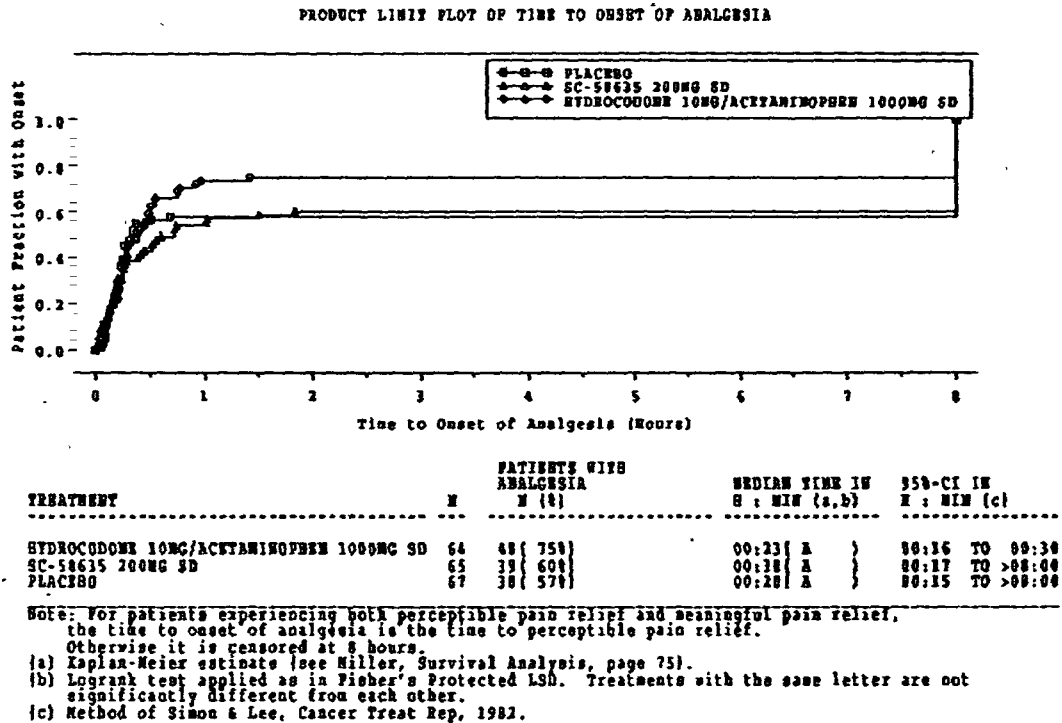


Figure 29: Time to Rescue Medication; N49-98-02-085

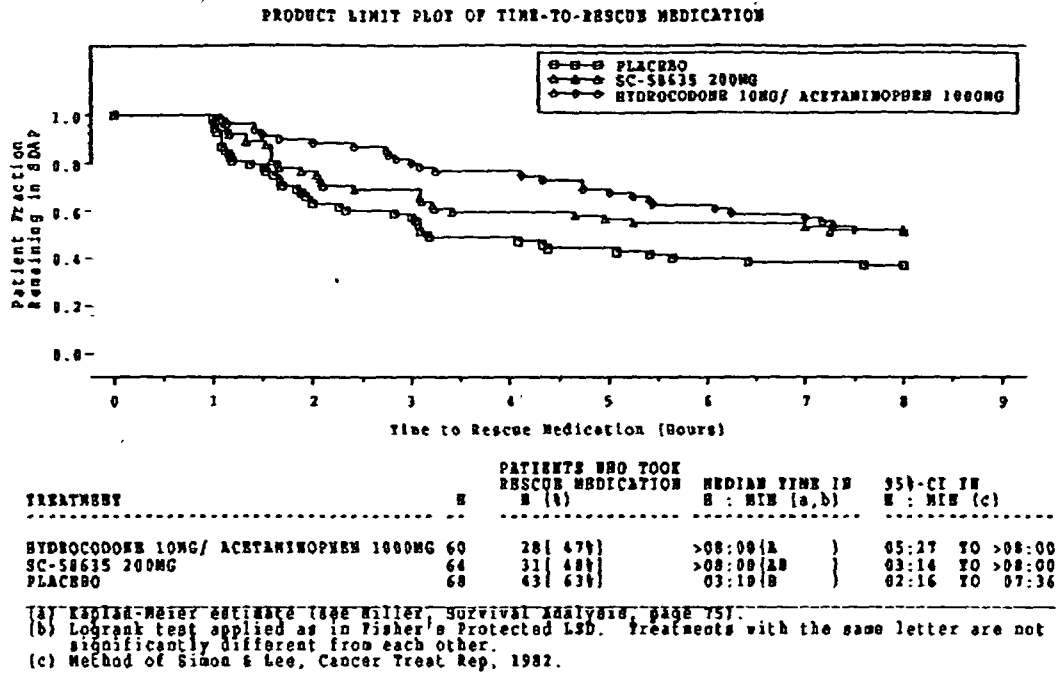


Figure 30: Time to Onset of Analgesia; N49-98-02-085

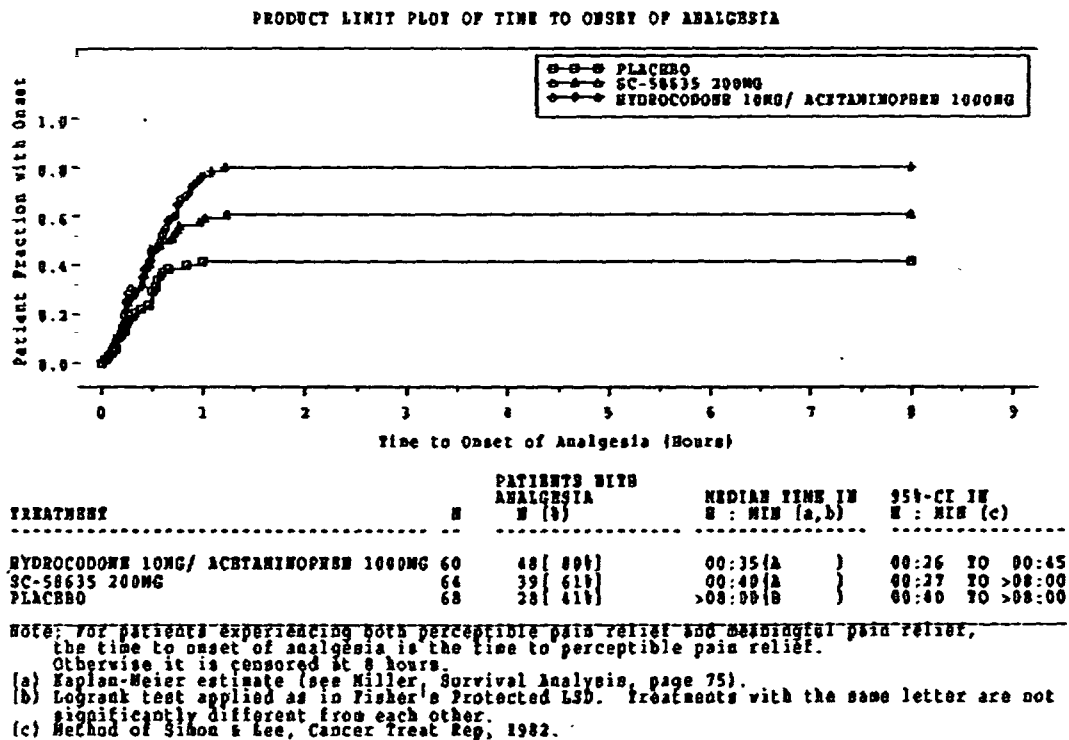
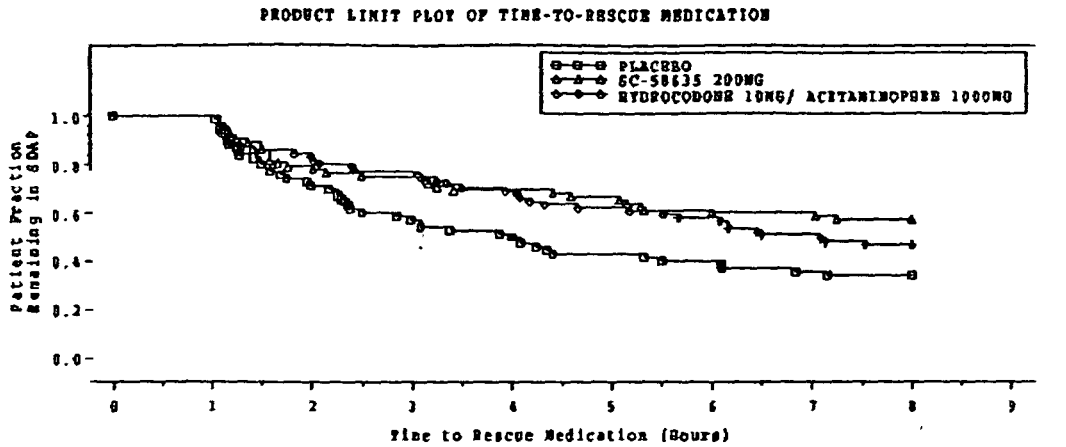


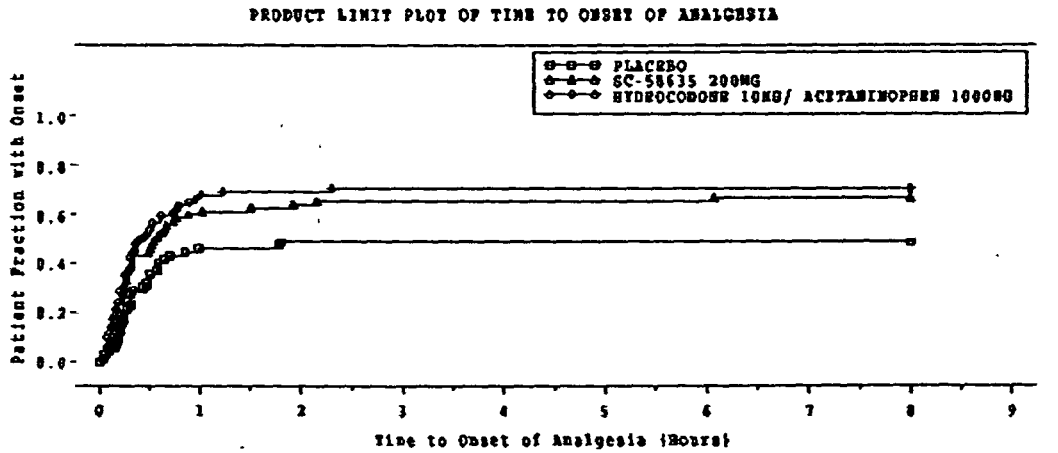
Figure 31: Time to Rescue Medication; N49-98-02-086



TREATMENT	N	PATIENTS WHO TOOK RESCUE MEDICATION n (%)	MEDIAN TIME IN H : MIN (a,b)	95%-CI IN H : MIN (c)
HYDROCODONE 10MG/ ACETAMINOPHEN 1000MG	71	38 (54%)	06:48 (AB)	05:11 TO >08:00
SC-58635 200MG	72	31 (43%)	>08:00 (A)	05:20 TO >08:00
PLACEBO	70	46 (66%)	04:00 (B)	02:23 TO 06:06

(a) Kaplan-Meier estimate (see Miller, Survival Analysis, page 75).
 (b) Logrank test applied as in Fisher's Protected LSD. Treatments with the same letter are not significantly different from each other.
 (c) Method of Simon & Lee, Cancer Treat Rep, 1982.

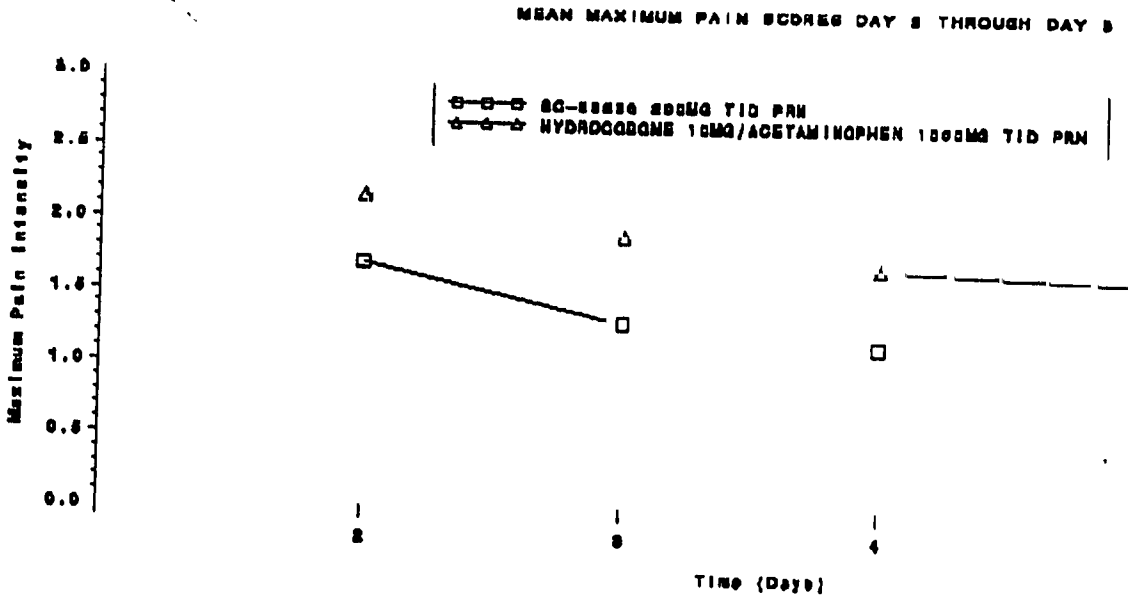
Figure 32: Time to Onset of Analgesia; N49-98-02-086



TREATMENT	N	PATIENTS WITH ANALGESIA n (%)	MEDIAN TIME IN H : MIN (a,b)	95%-CI IN H : MIN (c)
HYDROCODONE 10MG/ ACETAMINOPHEN 1000MG	71	50 (70%)	00:26 (A)	00:21 TO 00:46
SC-58635 200MG	72	48 (67%)	00:34 (A)	00:18 TO 01:30
PLACEBO	70	34 (49%)	>08:00 (B)	00:35 TO >08:00

NOTE: FOR patients experiencing both perceptible pain relief and meaningful pain relief, the time to onset of analgesia is the time to perceptible pain relief. Otherwise it is censored at 8 hours.
 (a) Kaplan-Meier estimate (see Miller, Survival Analysis, page 75).
 (b) Logrank test applied as in Fisher's Protected LSD. Treatments with the same letter are not significantly different from each other.
 (c) Method of Simon & Lee, Cancer Treat Rep, 1982.

Figure 33: Maximum Pain Intensity (MDAP, LOCF) Means (Std Dev), Sample Size without Extrapolation and Fisher's Protected LSD Comparisons: N49-98-02-085



TREATMENT	ASSESSMENTS			
	Day 2	Day 3	Day 4	Day 5
HYDROCODONE 10MG/ ACETAMINOPHEN 1000MG	2.17 (0.80) 24 (A)	1.80 (0.78) 24 (A)	1.59 (0.85) 24 (A)	1.42 (1.05) 24 (A)
HC-88888 880MG	1.70 (0.81) 28 (A)	1.30 (0.82) 27 (A)	1.14 (0.88) 28 (A)	0.87 (0.89) 24 (A)
TREATMENT p-VALUE (b)	<0.001	<0.001	<0.001	<0.001

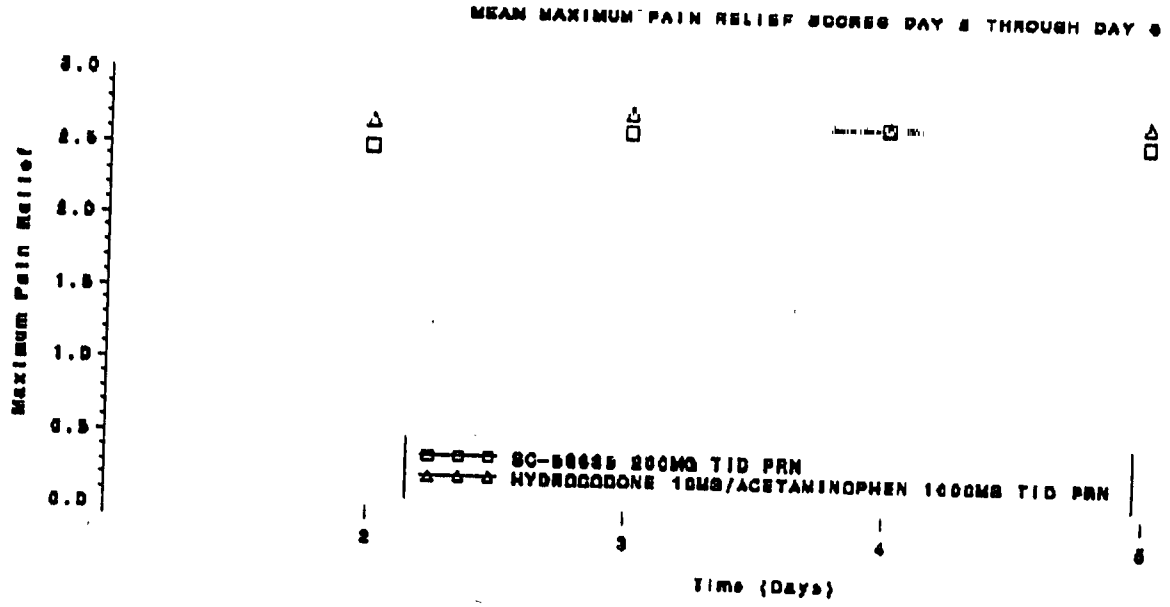
Note: Only those patients who entered the Multiple Day Assessment Period were included in the analysis. The last available analgesic score was assigned to all subsequent assessment time points for patients who were early terminated for any reason.

(a) Sample size is not extrapolated.

(b) Model: Maximum Pain Intensity = $\mu + \tau + \text{error}$ + original randomization + error.

(c) Used as model (b) means. Treatments with the same letter are not significantly different from each other.

Figure 34: Maximum Pain Relief (MDAP, LOCF) Means (Std Dev), Sample Size without Extrapolation and Fisher's Protected LSD Comparisons: N49-98-02-085

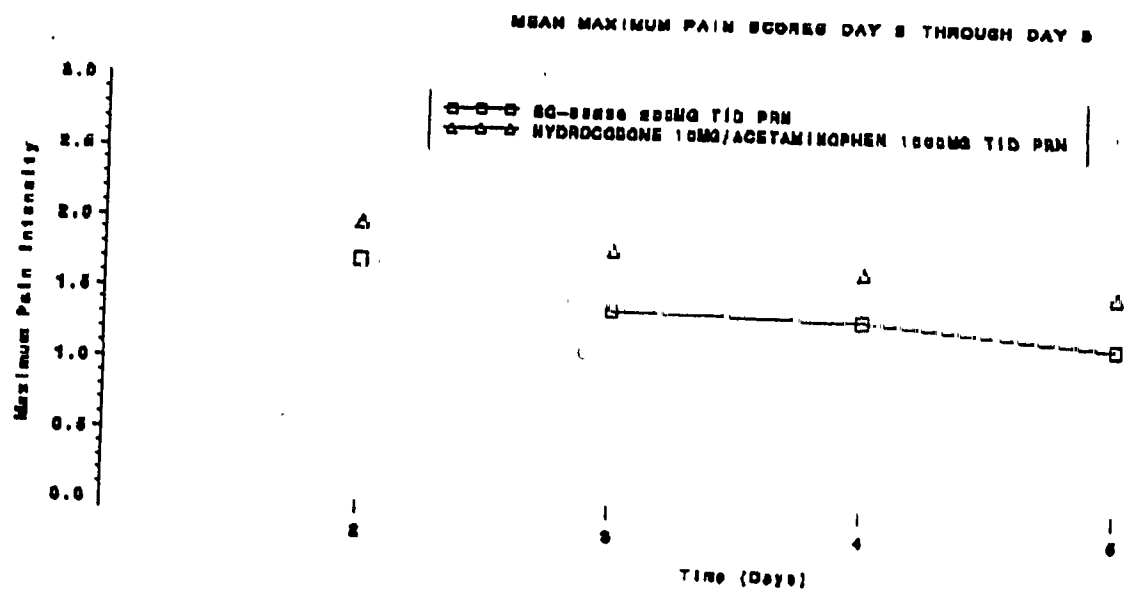


TREATMENT	ASSESSMENTS			
	Day 2	Day 3	Day 4	Day 6
HYDROCODONE 10MG/ ACETAMINOPHEN 1000MG	2.45 (0.56)	2.50 (0.57)	2.55 (1.05)	2.45 (1.11)
SC-5555 200MG	2.45 (1.11)	2.55 (1.10)	2.55 (1.25)	2.55 (1.44)
TREATMENT p-VALUE (b)	0.855	0.815	0.811	0.445

Note: Only those patients who entered the Multiple Day Assessment Period were included in the analysis. The last available analysis score was assigned to all subsequent assessment time points for patients who early terminated for any reason.

(a) Sample size is not extrapolated.
 Model: Maximum Pain = $\mu + \tau_i + \text{center} + \text{original randomization} + \text{error}$
 Based on model (a) Least Squares. Treatments with the same letter are not significantly different from each other.

Figure 35: Maximum Pain Intensity (MDAP, LOCF) Means (Std Dev), Sample Size without Extrapolation and Fisher's Protected LSD Comparisons: N49-98-02-086

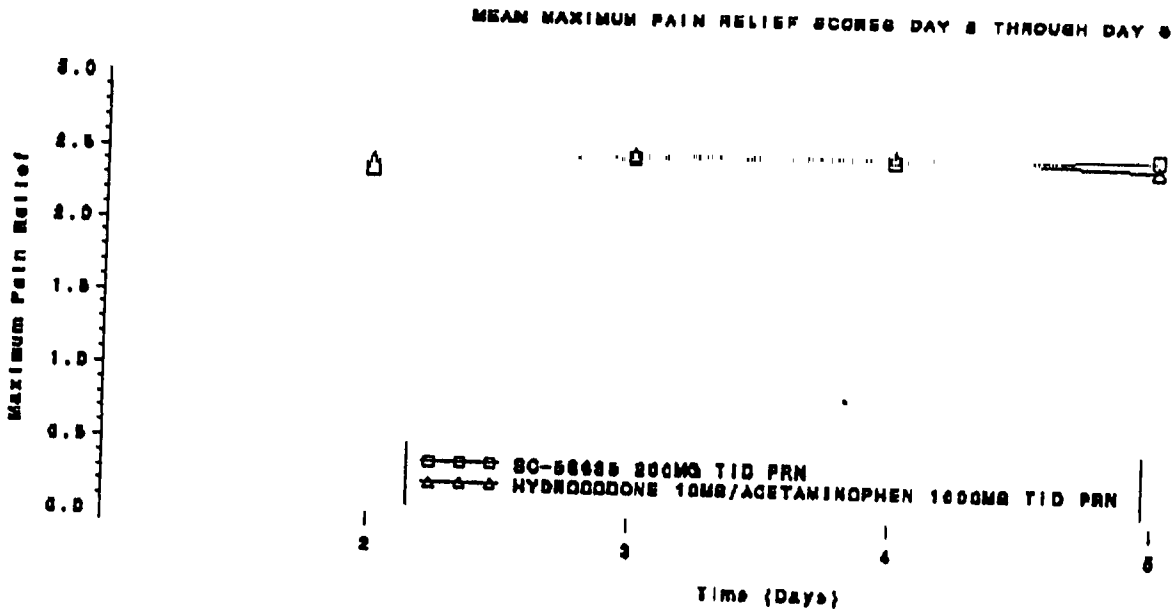


TREATMENT	ASSESSMENTS			
	Day 2	Day 3	Day 4	Day 5
HYDROCODONE 10MG/ ACETAMINOPHEN 1000MG	1.65 (0.82) 42 (n) 2 (z)	1.72 (0.64) 38	1.52 (0.64) 34	1.35 (0.61) 31
SC-33333 300MG	1.72 (0.82) 47	1.48 (1.00) 35	1.22 (1.02) 31	1.00 (1.00) 28
TREATMENT P-VALUE (b)	0.052	0.002	0.012	0.002

Note: Only those patients who entered the Multiple Day Assessment Period were included in the analysis. The last available analgesic score was assigned to all subsequent assessment time points for patients who early terminated for any reason.

(a) Sample size is not extrapolated
 (b) Model: Maximum Pain = $\mu + \tau_i + \text{center} + \text{original randomization} + \text{error}$
 (c) Based on model (b) Leastwise. Treatments with the same letter are not significantly different from each other.

Figure 36: Maximum Pain Relief (MDAP, LOCF) Means (Std Dev), Sample Size without Extrapolation and Fisher's Protected LSD Comparisons: N49-98-02-086



TREATMENT	ASSESSMENTS			
	Day 2	Day 3	Day 4	Day 6
HYDROCODONE 10MG/ ACETAMINOPHEN 1000MG	2.43 (1.06) 21	2.52 (1.08) 21	2.52 (1.10) 21	2.48 (1.27) 21
SC-58825 200MG	2.37 (1.16) 21	2.46 (1.22) 21	2.49 (1.24) 21	2.52 (1.28) 21
TREATMENT P-VALUE (b)	0.821	0.854	0.867	0.648

Note: Only those patients who entered the Multiple Base Assessment Period were included in the analysis. The last available analgesic score was assigned to all subsequent assessment time points for patients who were terminated for any reason.

(a) Sample size is not extrapolated.
 (b) Model: Maximum Pain = $\mu + \tau_i + \text{center} + \text{original randomization} + \text{error}$
 (c) Based on model (b). Letters: Treatments with the same letter are not significantly different from each other.

Primary Dysmenorrhea Studies

Figure 37: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); N49-98-02-129

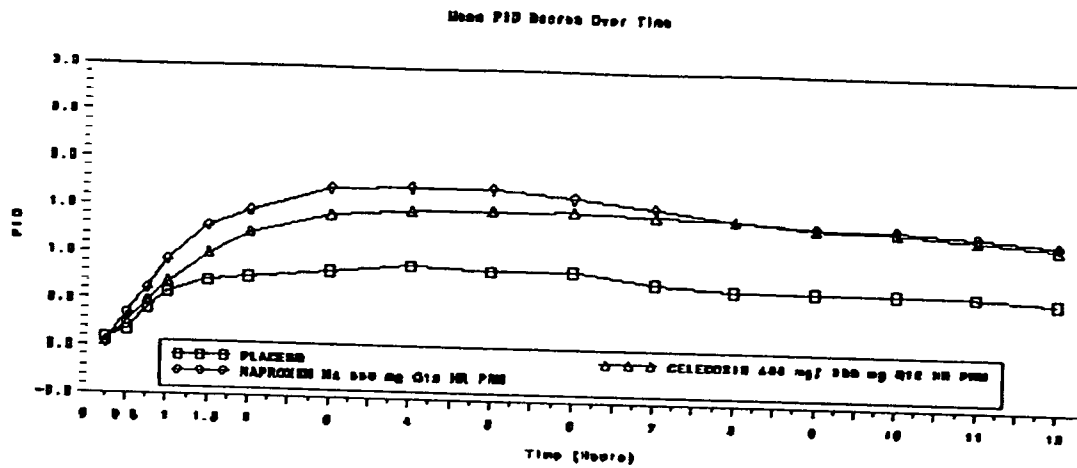


Figure 38: Pain Relief (PR, Extrapolated) Means, (Std Dev); N49-98-02-129

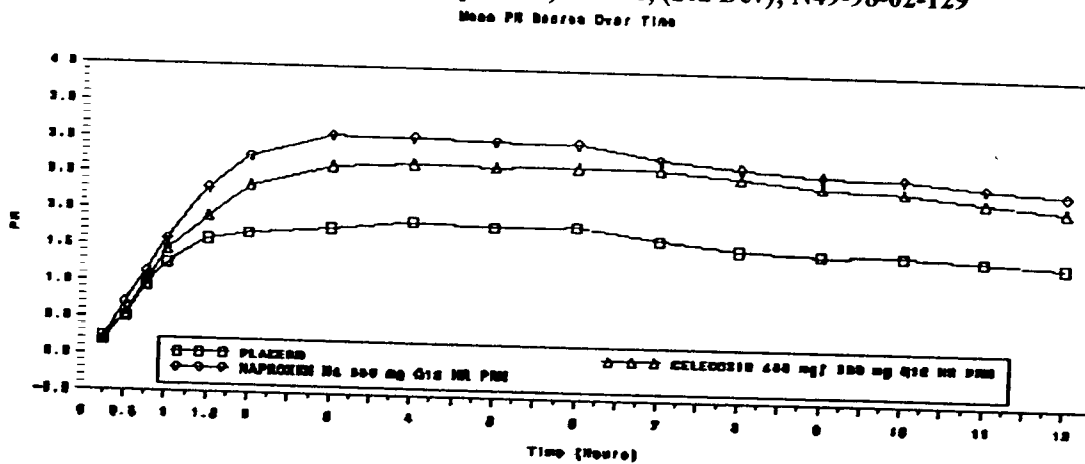


Figure 39: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); N49-98-02-129

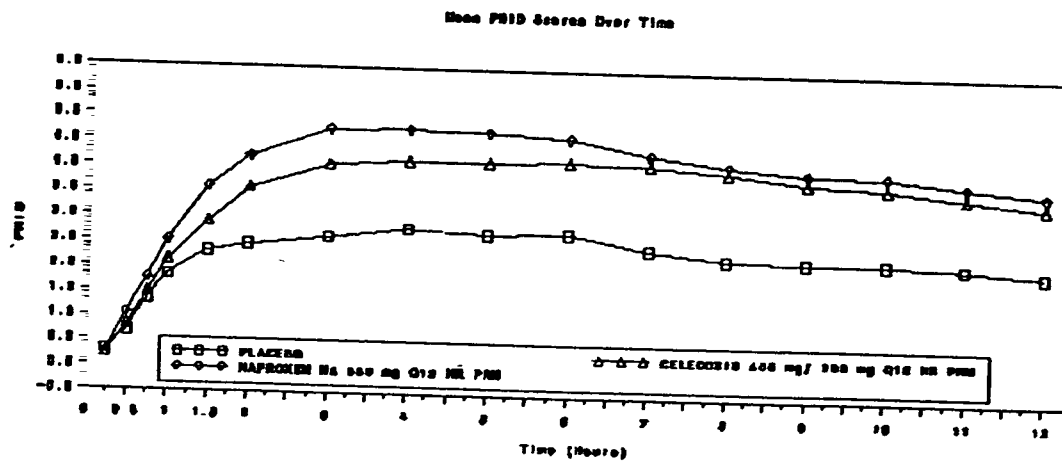


Figure 40: Pain Intensity Difference (PID, Categorical Scale, Extrapolated); N49-98-02-130

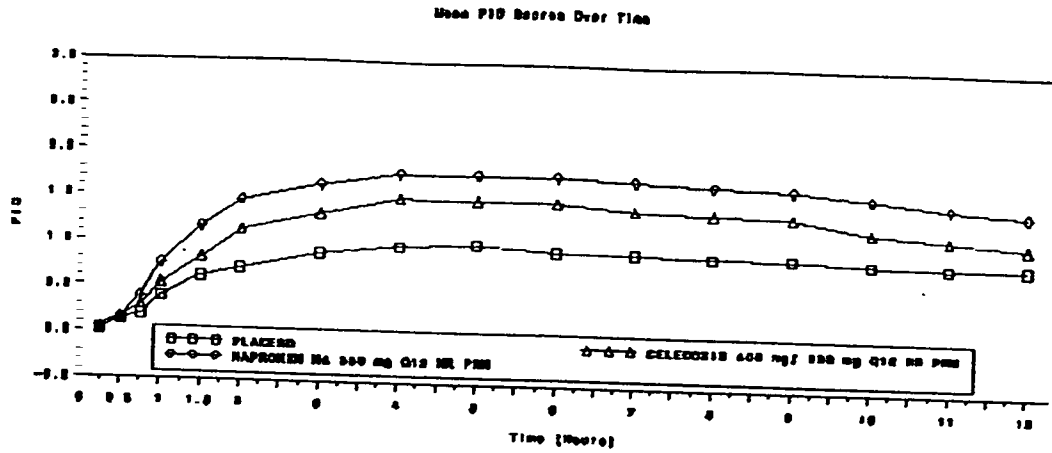


Figure 41: Pain Relief (PR, Extrapolated) Means, (Std Dev); N49-98-02-130

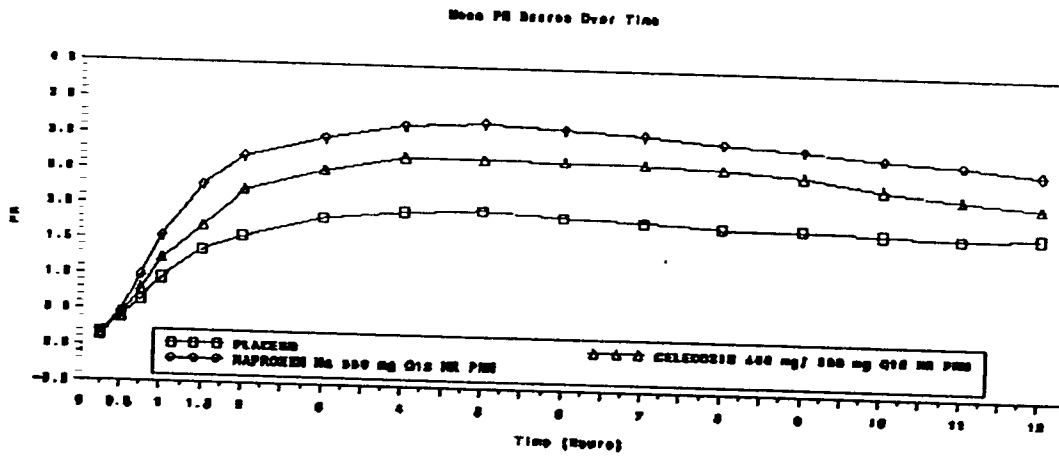


Figure 42: Pain Intensity Difference and Pain Relief (PRID, Categorical Extrapolated); N49-98-02-130

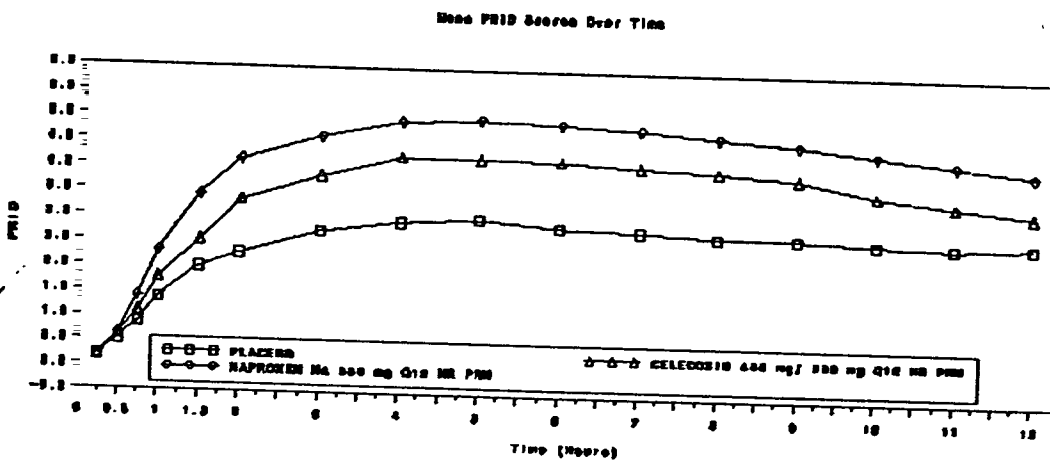
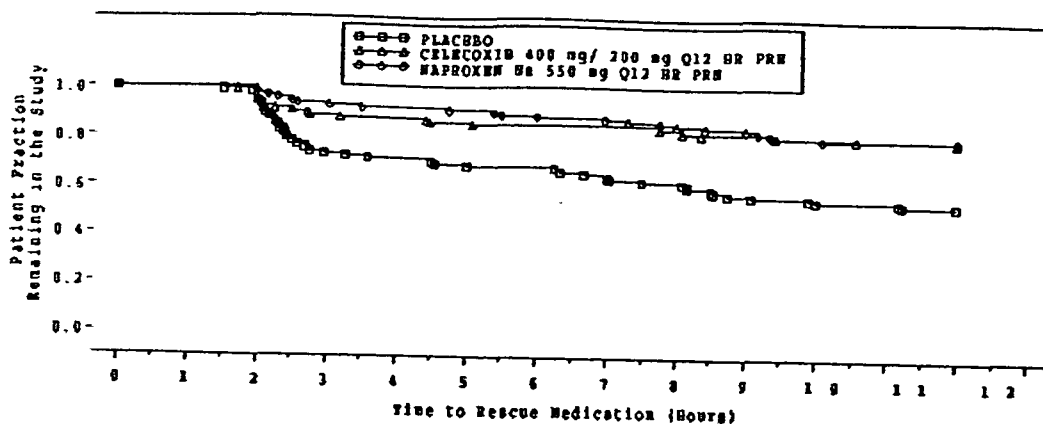


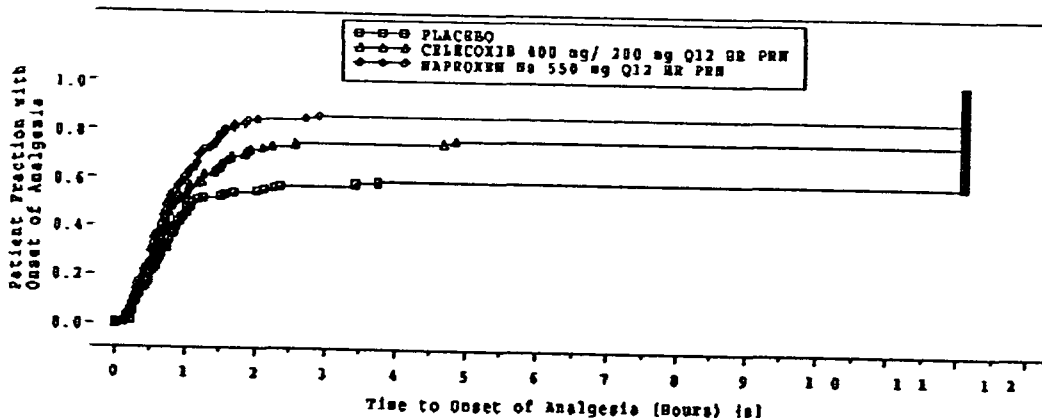
Figure 43: Time to Rescue Medication; N49-98-02-129



TREATMENT	N	PT TOOK RESCUE MEDICATION		MEDIAN TIME IN H : MIN (a,b)	95%-CI IN H : MIN (c)
		N (%)			
NAPROXEN Na 550 mg Q12 HR PRN	122	24 (20%)		>12:00(A)	
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	122	25 (20%)		>12:00(A)	
PLACEBO	122	57 (47%)		>12:00(B)	

(a) Kaplan-Meier estimate (see Miller, Survival Analysis, page 75).
 (b) Logrank test applied as in Fisher's Protected LSD. Treatments with the same letter are not significantly different from each other.
 (c) Method of Simon & Lee, Cancer Treat Rep, 1982.

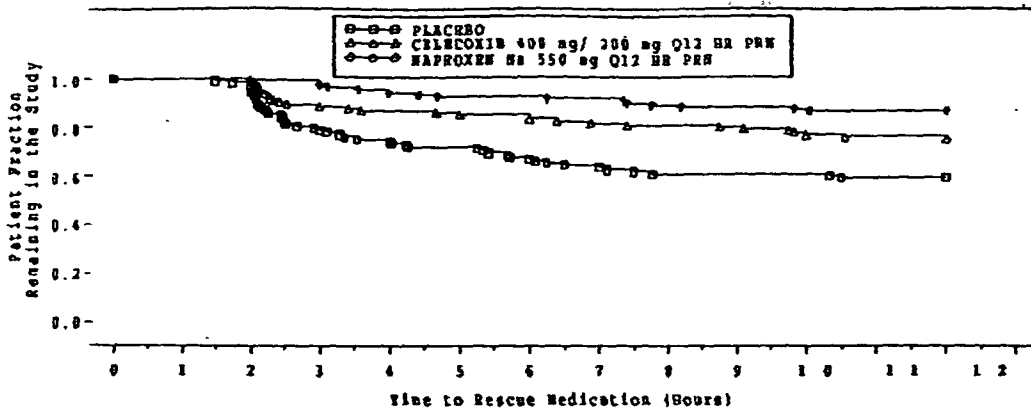
Figure 44: Time to Onset of Analgesia; N49-98-02-129



TREATMENT	N	PT EXPERIENCED ONSET OF ANALGESIA		MEDIAN TIME IN H : MIN (b,c)	95%-CI IN H : MIN (d)
		N (%)			
NAPROXEN Na 550 mg Q12 HR PRN	122	105 (86%)		00:45(A)	
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	122	93 (76%)		00:52(B)	00:40 TO 00:50
PLACEBO	122	72 (59%)		01:05(B)	00:45 TO 01:13

(a) For patients who took rescue medication before reaching onset of analgesia, the time to onset of analgesia is assigned an event time of 726 + 6 / (time first rescue medication taken - time study drug taken) (min).
 (b) Kaplan-Meier estimate (see Miller, Survival Analysis, page 75).
 (c) Logrank test applied as in Fisher's Protected LSD. Treatments with the same letter are not significantly different from each other.
 (d) Method of Simon & Lee, Cancer Treat Rep, 1982.

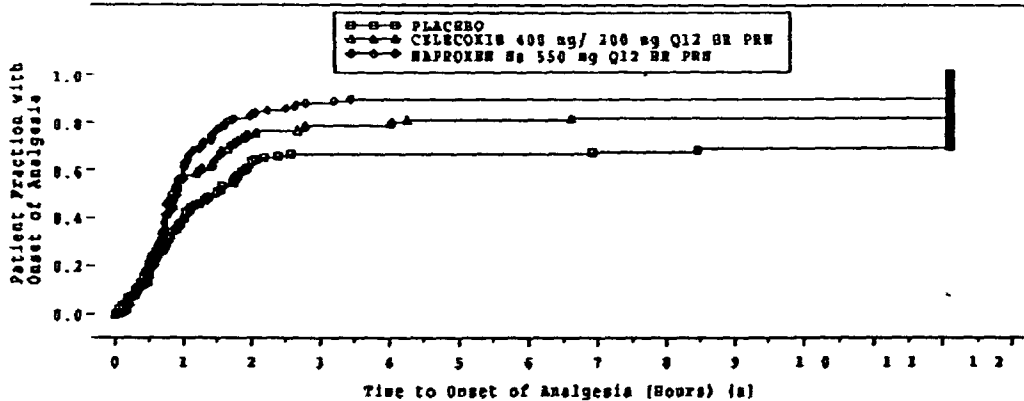
Figure 45: Time to Rescue Medication; N49-98-02-130



TREATMENT	N	PT TOOK RESCUE MEDICATION N (%)	MEDIAN TIME IN H : MIN (a,b)	95%-CI IN H : MIN (c)
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	121	16 (13%)	>12:00(A)	
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	121	30 (25%)	>12:00(B)	
PLACEBO	121	69 (57%)	>12:00(C)	

(a) Kaplan-Meier estimate (see Miller, Survival Analysis, page 75).
 (b) Logrank test applied as in Fisher's Protected LSD. Treatments with the same letter are not significantly different from each other.
 (c) Method of Simon & Lee, Cancer Treat Rep, 1982.

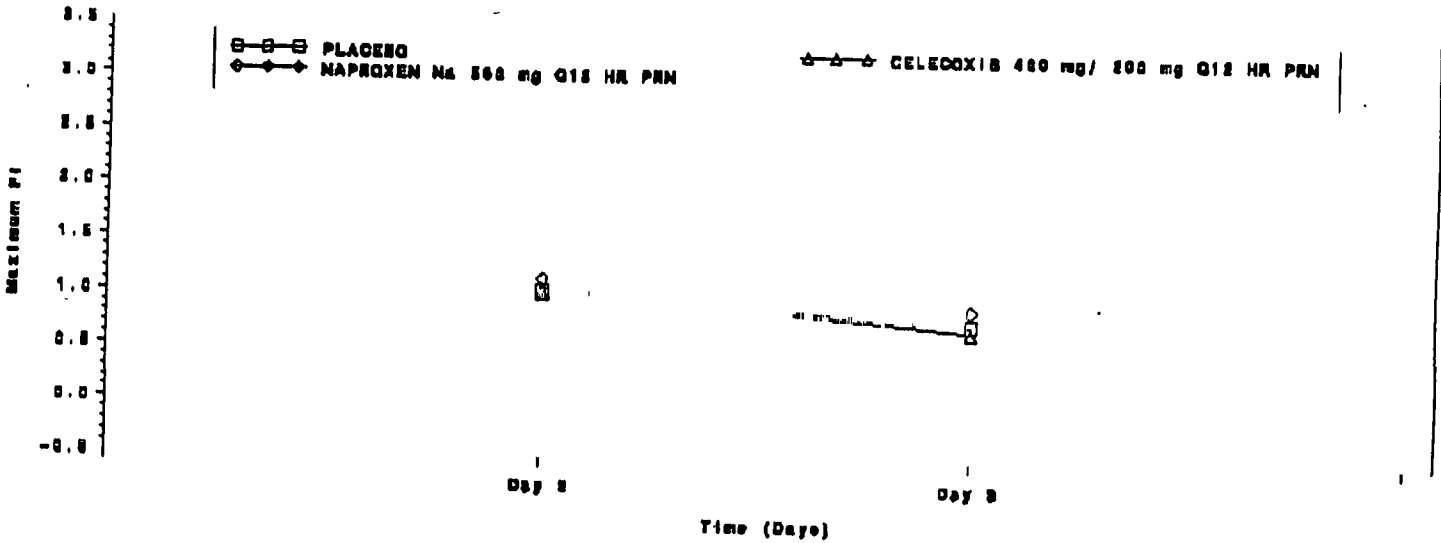
Figure 46: Time to Onset of Analgesia; N49-98-02-130



TREATMENT	N	PT EXPERIENCED ONSET OF ANALGESIA N (%)	MEDIAN TIME IN H : MIN (b,c)	95%-CI IN H : MIN (d)
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	121	109 (90%)	00:50(A)	00:44 TO 01:00
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	121	99 (82%)	00:53(B)	00:45 TO 01:12
PLACEBO	121	83 (69%)	01:27(C)	01:02 TO 01:51

(a) For patients who took rescue medication before reaching onset of analgesia, the time to onset of analgesia is assigned an event time of 720 + t / (time first rescue medication taken - time study drug taken) [min].
 (b) Kaplan-Meier estimate (see Miller, Survival Analysis, page 75).
 (c) Logrank test applied as in Fisher's Protected LSD. Treatments with the same letter are not significantly different from each other.
 (d) Method of Simon & Lee, Cancer Treat Rep, 1982.

Figure 47: Maximum Pain Intensity (PI) on Day 2 and Day 3 – MDAP, LOCF; N49-98-02-129



TREATMENT	ASSESSMENT TIME POINTS	
	Day 2	Day 3
NAPROXEN Na 500 mg Q12 HR PRN	101 (1.04)	101 (1.11)
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	102 (1.02)	102 (0.97)
PLACEBO	103 (1.02)	103 (1.02)

Note: This table is based on last observation carried forward.

Figure 48: Patient Global Evaluation of Study Medication on Day 2 and Day 3 -
 MDA, LOCF; N49-98-02-129

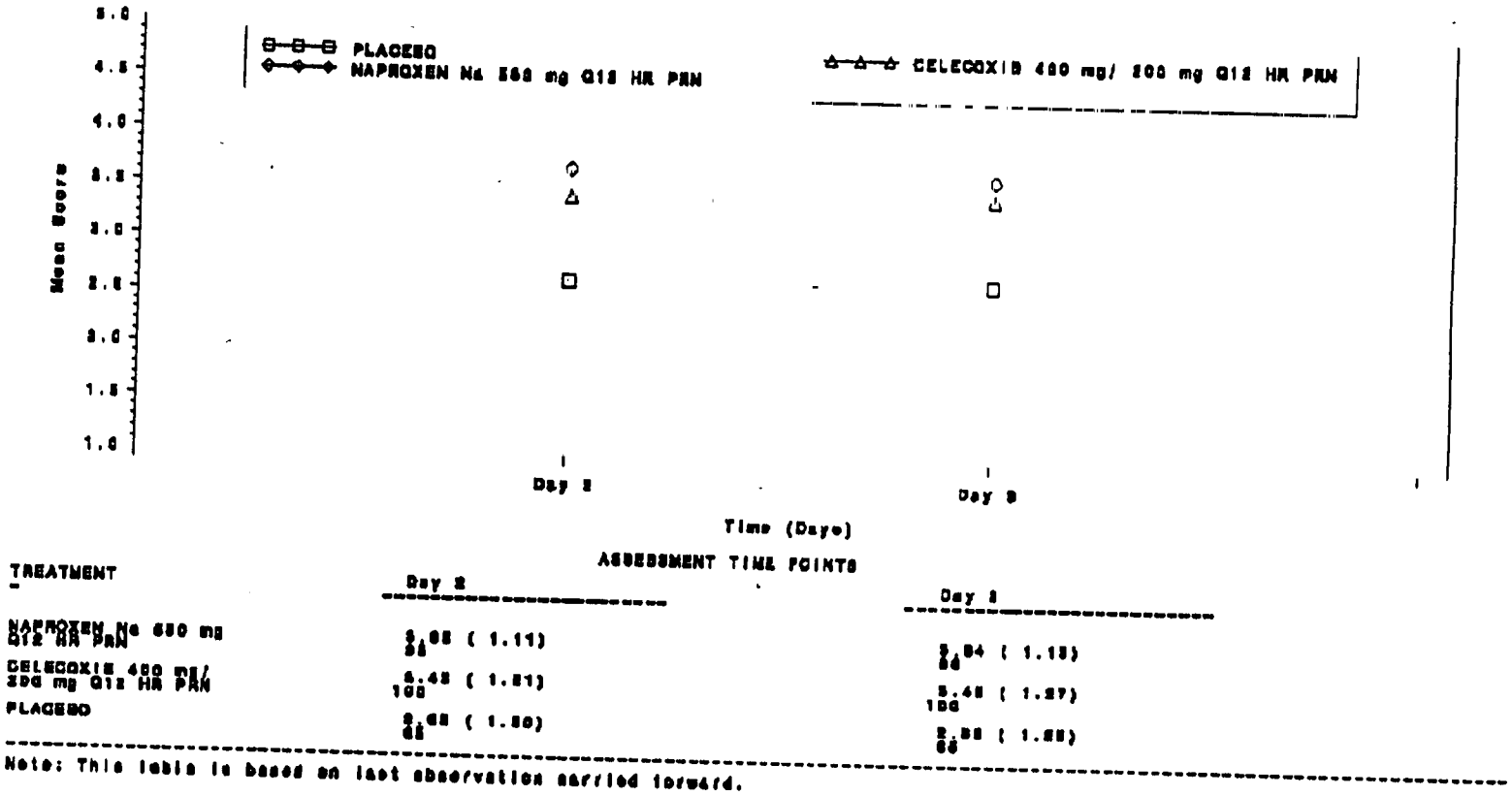
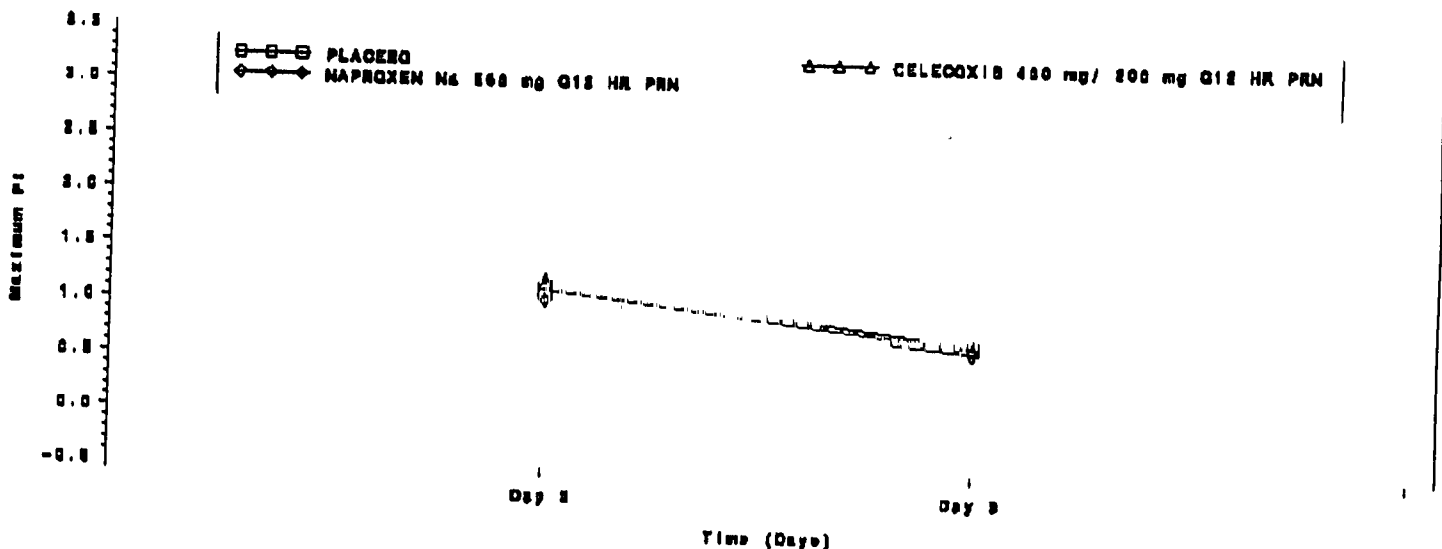


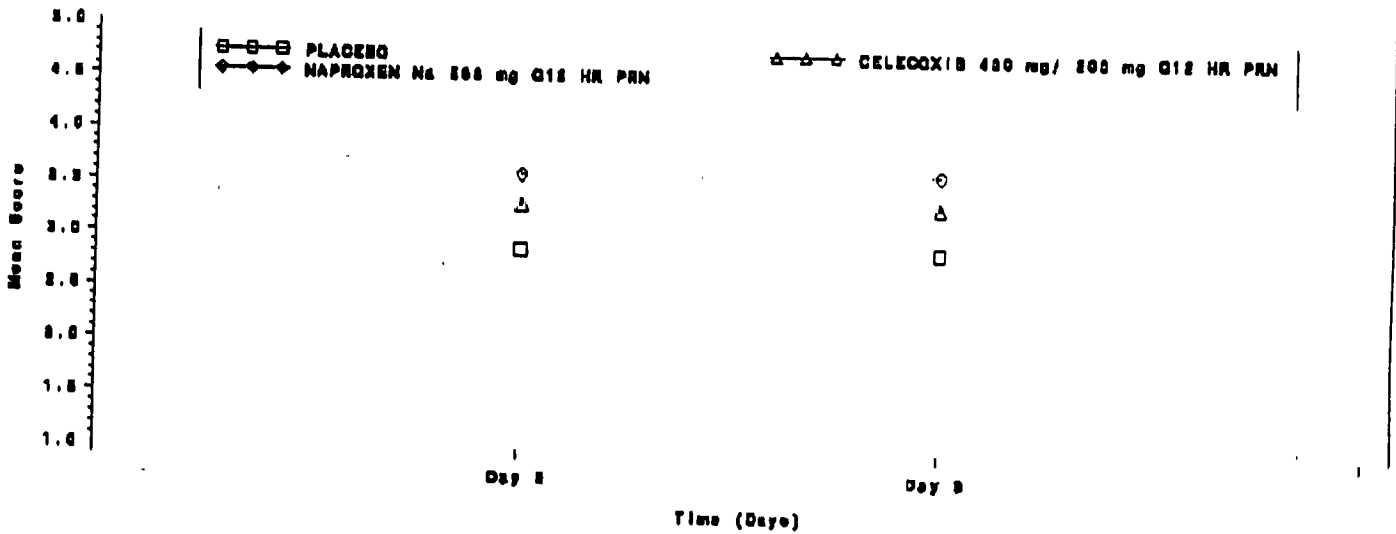
Figure 49: Maximum Pain Intensity (PI) on Day 2 and Day 3 - MDA9, LOCF, N49-98-02-130



TREATMENT	ASSESSMENT TIME POINTS	
	Day 2	Day 3
NAPROXEN 500 mg Q12 HR PRN	1.00 (0.00)	0.50 (0.01)
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	3.00 (1.00)	0.50 (0.00)
PLACEBO	1.00 (0.00)	0.50 (0.00)

Note: This table is based on last observation carried forward.

Figure 50: Patient Global Evaluation of Study Medication on Day 2 and Day 3 --
MDAP, LOCF; N49-98-02-130



TREATMENT	ASSESSMENT TIME POINTS	
	Day 2	Day 3
NAPROXEN Na 500 mg Q12 HR PRN	3.33 (1.87) 104	3.33 (1.88) 103
CELECOXIB 400 mg/ 200 mg Q12 HR PRN	3.01 (1.16) 84	3.01 (1.18) 84
PLACEBO	2.67 (1.14) 74	2.68 (1.18) 74

Note: This table is based on last observation carried forward.

Additional analyses

Figure 51: Mean of PID based on 3 cycles and 1 cycle, LOCF; N49-98-02-130

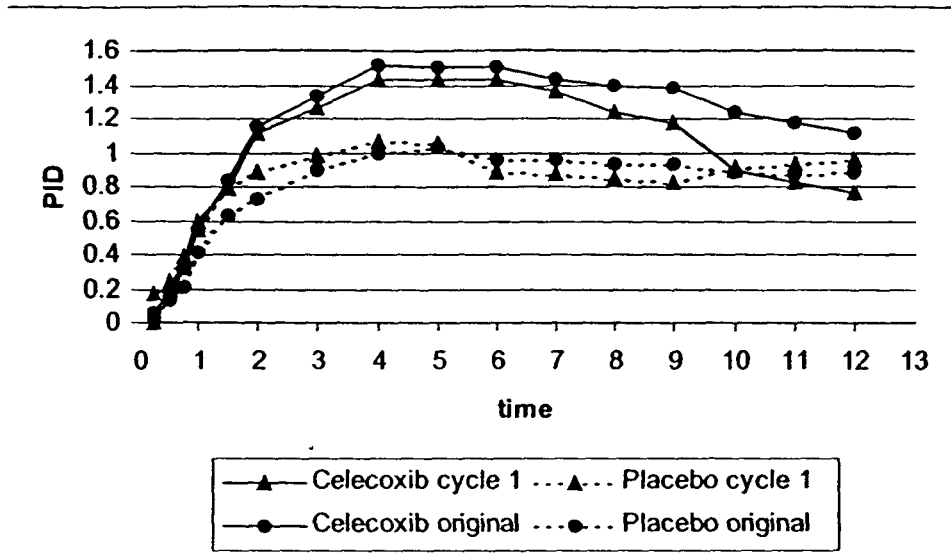
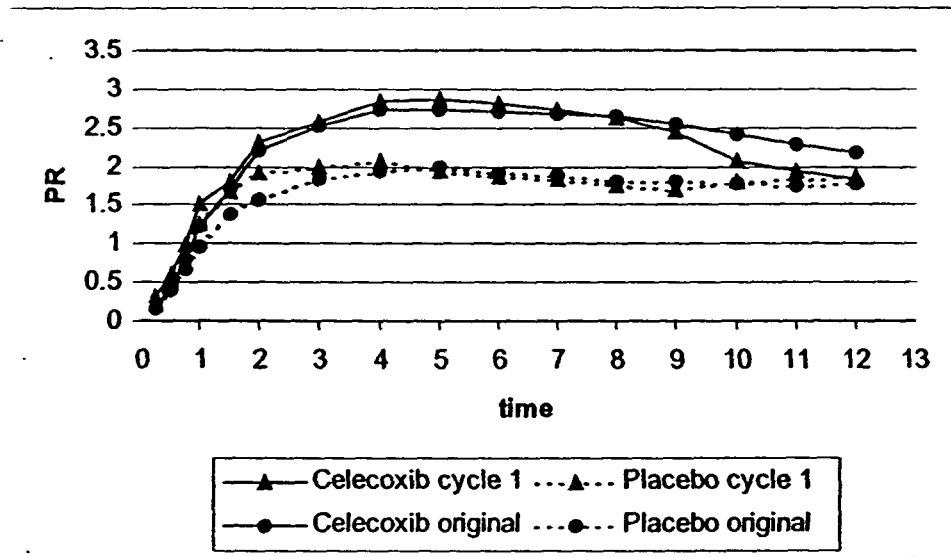


Figure 52: Mean of PR based on 3 cycles and 1 cycle, LOCF; N49-98-02-130



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