	12809
PK Assessment	Lacosamide and SPM 12809 in plasma Cmax, Cmax,norm and CTrough and normalized
Safety Assessment	Laboratory tests, adverse events, ECGs
PD Assessment	None

Pharmacokinetic Results:

Pharmacokinetics of lacosamide in plasma:

Descriptive statistics for C_{trough} (predose) and C_{max} (end of infusion) LCM plasma concentration on Day 2 (am and pm) by actual daily dose are presented in the following tables.

**APPEARS THIS WAY
ON ORIGINAL**

Descriptive statistics for C_{trough} (predose) and C_{max} (end of infusion) LCM plasma concentration on Day 2 by actual daily dose and time point
Population: Pharmacokinetic Set

Actual daily dose/ Infusion duration/ Time point	Concentration in μg/mL					
	n	n>LOQ	Mean (SD)	Median	Min	Max
LCM 200mg/day						
30-minute						
Day 2 am predose (C_{trough} iv)	4	4	2.3563 (0.59347)	2.3650	1.700	2.995
Day 2 am postdose (C_{max} iv)	4	4	5.0813 (0.91183)	5.2250	3.895	5.980
Day 2 pm predose (C_{trough} iv)	5	5	2.6300 (1.10937)	2.5850	1.570	4.390
Day 2 pm postdose (C_{max} iv)	3	3	5.3933 (1.48359)	4.7500	4.340	7.090
15-minute						
Day 2 am predose (C_{trough} iv)	16	16	2.7538 (0.87086)	2.6625	1.650	4.600
Day 2 am postdose (C_{max} iv)	14	14	5.5186 (1.16874)	5.5400	3.870	7.380
Day 2 pm predose (C_{trough} iv)	15	15	2.6333 (0.78026)	2.5000	1.510	4.045
Day 2 pm postdose (C_{max} iv)	16	16	5.8066 (2.60599)	5.5700	2.250	14.285
10-minute						
Day 2 am predose (C_{trough} iv)	2	2	1.7925 (0.61165)	1.7925	1.360	2.225
Day 2 am postdose (C_{max} iv)	2	2	5.5225 (2.71175)	5.5225	3.605	7.440
Day 2 pm predose (C_{trough} iv)	2	2	1.6050 (0.50912)	1.6050	1.245	1.965
Day 2 pm postdose (C_{max} iv)	2	2	5.0725 (1.94808)	5.0725	3.695	6.450

Descriptive statistics for C_{trough} (predose) and C_{max} (end of infusion) LCM plasma concentration on Day 2 by actual daily dose and time point
Population: Pharmacokinetic Set

Actual daily dose/ Infusion duration/ Time point	Concentration in µg/mL					
	n	n>LOQ	Mean (SD)	Median	Min	Max
LCM 300mg/day						
30-minute						
Day 2 am predose (C_{trough} iv)	3	3	3.1650 (0.80261)	3.1500	2.370	3.975
Day 2 am postdose (C_{max} iv)	2	2	7.3025 (0.32173)	7.3025	7.075	7.530
Day 2 pm predose (C_{trough} iv)	2	2	3.4000 (0.42426)	3.4000	3.100	3.700
Day 2 pm postdose (C_{max} iv)	2	2	6.9800 (1.11723)	6.9800	6.190	7.770
15-minute						
Day 2 am predose (C_{trough} iv)	18	18	3.6533 (0.96793)	3.3675	1.900	6.015
Day 2 am postdose (C_{max} iv)	17	17	7.7153 (1.95741)	7.1100	5.465	12.395
Day 2 pm predose (C_{trough} iv)	16	16	3.3406 (0.96508)	3.1100	1.685	5.990
Day 2 pm postdose (C_{max} iv)	15	15	7.3913 (1.72096)	7.0250	4.980	11.290
10-minute						
Day 2 am predose (C_{trough} iv)	4	4	2.7350 (0.74001)	2.8275	1.775	3.510
Day 2 am postdose (C_{max} iv)	4	4	7.6813 (1.70842)	8.4800	5.125	8.640
Day 2 pm predose (C_{trough} iv)	4	4	2.5075 (0.77327)	2.5350	1.710	3.250
Day 2 pm postdose (C_{max} iv)	4	4	6.6575 (1.61383)	6.8125	4.870	8.135

Descriptive statistics for C$_{trough}$ (predose) and C$_{max}$ (end of infusion) LCM plasma concentration on Day 2 by actual daily dose and time point
Population: Pharmacokinetic Set

Actual daily dose/ Infusion duration/ Time point	Concentration in µg/mL					
	n	n>LOQ	Mean (SD)	Median	Min	Max
LCM 400mg/day						
30-minute						
Day 2 am predose (C$_{trough}$ iv)	12	12	4.7842 (1.49153)	4.4625	2.935	7.655
Day 2 am postdose (C$_{max}$ iv)	11	11	9.8236 (2.46334)	10.5750	5.590	13.440
Day 2 pm predose (C$_{trough}$ iv)	11	11	4.5809 (1.51039)	4.3850	2.450	7.500
Day 2 pm postdose (C$_{max}$ iv)	11	11	9.4273 (2.13709)	9.8350	5.245	12.570
15-minute						
Day 2 am predose (C$_{trough}$ iv)	26	26	4.9600 (1.74908)	4.7125	2.725	10.725
Day 2 am postdose (C$_{max}$ iv)	25	25	10.4720 (2.51337)	10.1800	7.275	18.135
Day 2 pm predose (C$_{trough}$ iv)	26	26	4.6715 (1.43918)	4.3550	2.620	8.330
Day 2 pm postdose (C$_{max}$ iv)	26	26	9.9687 (2.93351)	9.5075	3.990	15.565
10-minute						
Day 2 am predose (C$_{trough}$ iv)	7	7	4.2664 (1.40990)	4.3450	2.730	6.895
Day 2 am postdose (C$_{max}$ iv)	6	6	12.7883 (2.79038)	12.2400	9.780	16.650
Day 2 pm predose (C$_{trough}$ iv)	7	7	3.9557 (1.79375)	3.4400	2.335	7.570
Day 2 pm postdose (C$_{max}$ iv)	7	7	10.7521 (3.54318)	10.1450	6.900	17.130

Descriptive statistics for C$_{trough}$ (predose) and C$_{max}$ (end of infusion) LCM plasma concentration on Day 2 by actual daily dose and time point
Population: Pharmacokinetic Set

Actual daily dose/ Infusion duration/ Time point	Concentration in µg/mL					
	n	n>LOQ	Mean (SD)	Median	Min	Max
LCM 500mg/day						
30-minute						
Day 2 am predose (C$_{trough}$ iv)	5	5	9.6600 (4.33103)	9.0150	6.200	16.825
Day 2 am postdose (C$_{max}$ iv)	5	5	16.3320 (3.31565)	17.3250	11.300	19.935
Day 2 pm predose (C$_{trough}$ iv)	5	5	8.4830 (3.36541)	8.7350	5.170	13.590
Day 2 pm postdose (C$_{max}$ iv)	5	5	15.0200 (3.78553)	14.8450	10.245	19.770
15-minute						
Day 2 am predose (C$_{trough}$ iv)	8	8	6.2494 (1.65881)	5.8100	4.185	9.110
Day 2 am postdose (C$_{max}$ iv)	8	8	11.9425 (1.65198)	11.8875	9.530	15.140
Day 2 pm predose (C$_{trough}$ iv)	8	8	5.1869 (1.53381)	4.8125	3.305	8.535
Day 2 pm postdose (C$_{max}$ iv)	8	8	11.3131 (2.94770)	10.6125	7.930	15.685
10-minute						
Day 2 am predose (C$_{trough}$ iv)	4	4	6.4213 (1.94006)	6.5575	3.925	8.645
Day 2 am postdose (C$_{max}$ iv)	4	4	14.7113 (1.63288)	14.2975	13.220	17.030
Day 2 pm predose (C$_{trough}$ iv)	4	4	6.3563 (2.55900)	5.9350	3.805	9.750
Day 2 pm postdose (C$_{max}$ iv)	3	3	12.0567 (1.55644)	12.2200	10.425	13.525

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