Table 58: Summary of Flushing Episode Duration, MFSS

Summary of flushing episode duration, MFSS

	ASA placebo BID (N=81)	ASA 75 mg QAM (N=80)	ASA 150 mg BID (N=80)
Number of Subjects Randomized	81	80	80
Weeks 1 – 4 Combined			
Number of Subjects evaluable	73 (90.1%)	75 (93.8%)	77 (96.3%)
Duration of side effect episode (hours)[1]			
N	73	75	77
Mean	0.69	0.8	1.11
SD	0.44	0.59	1.16
Median	0.65	0.66	0.83
Min, Max	0.05, 2.08	0.04, 3.17	0.03, 6.1
Mean Difference (95% CI)*		-0.145 (-0.414, 0.125)	-0.392 (-0.656, -0.128)
Mean Difference (95% CI)*			-0.247 (-0.507, 0.012)
Weeks 5 – 8 Combined			
Number of Subjects evaluable	57 (70.4%)	58 (72.5%)	59 (73.8%)
Duration of side effect episode (hours)[1]			
N	57	58	59
Mean	1.06	0.73	1.08
SD	2.12	0.52	1.18
Median	0.57	0.63	0.77
Min, Max	0.03, 12.5	0.03, 2.73	0, 6.36
Mean Difference (95% CI)*		0.376 (-0.193, 0.945)	0.069 (-0.498, 0.635)
Mean Difference (95% CI)*			-0.308 (-0.867, 0.251)
Weeks 9 – 12 Combined			
Number of Subjects evaluable	45 (55.6%)	45 (56.3%)	51 (63.8%)
Duration of side effect episode (hours)[1]			
N	45	45	51
Mean	0.66	0.69	0.79
SD	0.52	0.59	0.94
Median	0.57	0.6	0.6
Min, Max	0, 2.27	0.09, 3.78	0.05, 6.49
Mean Difference (95% CI)*		0.024 (-0.308, 0.355)	-0.06 (-0.374, 0.254)
Mean Difference (95% CI)*			-0.084 (-0.4, 0.232)

[1] For subjects with more than 1 flushing event during a visit interval, the average duration for the visit interval were used.
*: Analysis of variance model (ANCOVA) model was used with treatment, center as effects and baseline char ates.
Baseline characteristics included: age, sex, alcohol consumption (Yes or No) and Tobacco use (Yes or No).