

Table 14.4.4.2
Summary of QTcF Interval by Dose Level and Visit
(Safety Analysis Set)

Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Baseline				
n	15			15
Mean (SD)	414.56 (15.544)			414.56 (15.544)
Median	412.74			412.74
Min, Max	391.32, 442.96			391.32, 442.96
Week 1				
n	15			15
Mean (SD)	409.91 (15.075)			409.91 (15.075)
Median	412.52			412.52
Min, Max	384.81, 432.57			384.81, 432.57
Change from Baseline to Week 1				
n	15			15
Mean (SD)	-4.66 (10.552)			-4.66 (10.552)
Median	-3.10			-3.10
Min, Max	-33.80, 10.19			-33.80, 10.19

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Week 2				
n	15			15
Mean (SD)	411.19 (17.276)			411.19 (17.276)
Median	409.04			409.04
Min, Max	386.92, 442.59			386.92, 442.59
Change from Baseline to Week 2				
n	15			15
Mean (SD)	-3.37 (9.607)			-3.37 (9.607)
Median	-5.09			-5.09
Min, Max	-18.23, 16.04			-18.23, 16.04
Week 4				
n	2	13		15
Mean (SD)	434.17 (4.349)	410.34 (15.190)		413.52 (16.413)
Median	434.17	410.53		411.11
Min, Max	431.09, 437.24	389.17, 440.60		389.17, 440.60
Change from Baseline to Week 4				
n	2	13		15
Mean (SD)	15.69 (15.754)	-3.62 (10.756)		-1.04 (12.769)
Median	15.69	-2.21		-1.22
Min, Max	4.55, 26.83	-24.47, 16.35		-24.47, 26.83

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Week 6				
n	3	5	7	15
Mean (SD)	419.86 (19.203)	410.25 (12.672)	411.78 (10.631)	412.88 (12.670)
Median	430.92	409.33	415.89	415.77
Min, Max	397.69, 430.98	391.47, 426.22	399.45, 425.78	391.47, 430.98
Change from Baseline to Week 6				
n	3	5	7	15
Mean (SD)	-6.77 (5.168)	2.50 (7.409)	-2.48 (13.051)	-1.68 (10.228)
Median	-6.57	3.03	-6.12	-4.55
Min, Max	-12.04, -1.71	-5.49, 10.30	-18.21, 19.51	-18.21, 19.51
Week 8				
n	3	2	10	15
Mean (SD)	426.29 (25.175)	397.56 (3.635)	418.00 (13.042)	416.94 (16.554)
Median	436.16	397.56	417.15	417.02
Min, Max	397.68, 445.04	394.99, 400.13	392.36, 433.88	392.36, 445.04
Change from Baseline to Week 8				
n	3	2	10	15
Mean (SD)	-0.34 (5.446)	-0.52 (6.541)	3.77 (9.612)	2.37 (8.417)
Median	2.08	-0.52	1.91	2.08
Min, Max	-6.58, 3.47	-5.14, 4.11	-10.25, 21.34	-10.25, 21.34

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Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 12				
n	3	2	8	13
Mean (SD)	435.84 (21.978)	397.59 (8.549)	414.04 (17.359)	416.54 (20.483)
Median	442.82	397.59	413.38	411.22
Min, Max	411.22, 453.48	391.54, 403.63	386.77, 438.80	386.77, 453.48
Change from Baseline to Week 12				
n	3	2	8	13
Mean (SD)	4.31 (14.767)	-0.49 (5.643)	0.20 (14.024)	1.04 (12.540)
Median	-0.14	-0.49	-0.95	-0.14
Min, Max	-7.72, 20.79	-4.48, 3.50	-19.00, 25.10	-19.00, 25.10
Week 16				
n	3	3	7	13
Mean (SD)	437.69 (7.199)	407.62 (35.143)	411.81 (14.270)	416.81 (21.471)
Median	439.88	397.53	412.57	418.83
Min, Max	429.65, 443.54	378.62, 446.70	397.04, 435.05	378.62, 446.70
Change from Baseline to Week 16				
n	3	3	7	13
Mean (SD)	6.16 (5.143)	-1.67 (16.215)	0.52 (14.580)	1.32 (12.766)
Median	7.19	-2.60	-1.11	0.58
Min, Max	0.58, 10.71	-17.40, 14.99	-14.70, 28.78	-17.40, 28.78

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Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 20				
n	4	3	6	13
Mean (SD)	425.50 (8.808)	405.43 (25.884)	416.81 (13.509)	416.85 (16.268)
Median	427.75	416.82	415.86	421.70
Min, Max	413.83, 432.66	375.80, 423.66	401.72, 438.03	375.80, 438.03
Change from Baseline to Week 20				
n	4	3	6	13
Mean (SD)	-4.97 (12.117)	-3.86 (18.808)	8.19 (11.862)	1.36 (14.063)
Median	-9.72	-8.05	3.66	3.09
Min, Max	-13.44, 13.00	-20.22, 16.69	-4.73, 28.90	-20.22, 28.90
Week 24				
n	4	3	6	13
Mean (SD)	425.18 (18.079)	406.08 (21.170)	417.98 (13.372)	417.45 (16.831)
Median	427.51	415.37	420.05	415.40
Min, Max	404.60, 441.09	381.85, 421.01	398.84, 431.00	381.85, 441.09
Change from Baseline to Week 24				
n	4	3	6	13
Mean (SD)	-5.29 (12.862)	-3.21 (16.072)	9.36 (6.825)	1.95 (12.465)
Median	-3.45	-10.70	8.99	5.61
Min, Max	-22.67, 8.40	-14.17, 15.24	-0.02, 20.18	-22.67, 20.18

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Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 28				
n	5	3	7	15
Mean (SD)	431.76 (10.033)	409.36 (20.253)	414.78 (15.538)	419.36 (16.662)
Median	429.08	412.97	419.90	427.14
Min, Max	420.24, 447.12	387.54, 427.56	395.03, 431.86	387.54, 447.12
Change from Baseline to Week 28				
n	5	3	7	15
Mean (SD)	6.53 (10.244)	0.07 (11.269)	5.58 (10.518)	4.79 (10.085)
Median	10.14	-4.15	7.16	7.16
Min, Max	-8.17, 15.98	-8.48, 12.84	-6.35, 25.59	-8.48, 25.59
Week 32				
n	4	3	7	14
Mean (SD)	427.08 (16.041)	412.63 (26.794)	417.06 (11.664)	418.97 (16.251)
Median	429.11	402.68	415.39	416.54
Min, Max	409.32, 440.77	392.24, 442.98	401.92, 431.02	392.24, 442.98
Change from Baseline to Week 32				
n	4	3	7	14
Mean (SD)	2.37 (4.867)	3.35 (7.557)	7.85 (7.903)	5.32 (7.078)
Median	1.91	2.55	5.57	4.42
Min, Max	-2.19, 7.84	-3.78, 11.27	-3.22, 19.99	-3.78, 19.99

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Week 36				
n	3	3	7	13
Mean (SD)	434.86 (18.536)	403.80 (14.564)	415.13 (12.234)	417.07 (17.112)
Median	442.74	403.42	412.78	413.69
Min, Max	413.69, 448.16	389.43, 418.55	401.79, 433.52	389.43, 448.16
Change from Baseline to Week 36				
n	3	3	7	13
Mean (SD)	3.33 (10.807)	-5.49 (8.280)	5.92 (3.647)	2.69 (7.775)
Median	-0.22	-6.59	6.12	4.60
Min, Max	-5.25, 15.47	-13.16, 3.29	-0.81, 10.47	-13.16, 15.47
Week 40				
n	5	3	7	15
Mean (SD)	433.48 (14.740)	400.93 (21.591)	413.71 (12.604)	417.74 (18.811)
Median	425.78	405.74	411.73	419.71
Min, Max	419.92, 452.11	377.34, 419.71	400.17, 434.54	377.34, 452.11
Change from Baseline to Week 40				
n	5	3	7	15
Mean (SD)	8.25 (8.856)	-8.36 (12.548)	4.51 (10.313)	3.18 (11.361)
Median	4.11	-12.00	2.02	3.56
Min, Max	-1.49, 19.42	-18.68, 5.61	-8.77, 15.98	-18.68, 19.42

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Week 44				
n	5	3	7	15
Mean (SD)	428.87 (13.056)	406.27 (17.125)	412.89 (7.252)	416.90 (14.021)
Median	427.21	403.70	414.31	417.53
Min, Max	417.53, 450.72	390.57, 424.53	402.42, 422.66	390.57, 450.72
Change from Baseline to Week 44				
n	5	3	7	15
Mean (SD)	3.65 (12.118)	-3.02 (5.772)	3.69 (12.236)	2.33 (10.888)
Median	-1.41	-5.45	9.74	3.57
Min, Max	-6.94, 22.95	-7.18, 3.57	-20.93, 12.87	-20.93, 22.95
Week 48				
n	5	3	7	15
Mean (SD)	430.03 (13.667)	412.83 (16.025)	413.50 (13.838)	418.88 (15.453)
Median	428.66	408.07	410.01	413.94
Min, Max	413.94, 451.67	399.73, 430.70	398.95, 436.17	398.95, 451.67
Change from Baseline to Week 48				
n	5	3	7	15
Mean (SD)	4.80 (14.027)	3.55 (4.477)	4.29 (10.557)	4.31 (10.347)
Median	6.84	3.71	0.98	3.71
Min, Max	-13.33, 24.40	-1.01, 7.94	-8.60, 23.43	-13.33, 24.40

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