

Table 14-7.02
Summary of Vital Signs Change from Baseline at End of Treatment

Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic Blood Pressure (mmHg)	AFTER LYING DOWN FOR 5 MINUTES	Placebo	86	Week 24	58	-2.1	14.73	-4.0	-28.0	50.0
				End of Trt.	83	-2.0	16.76	-4.0	-32.0	50.0
		Xan.Low	84	Week 24	27	-0.3	17.19	2.0	-48.0	30.0
				End of Trt.	84	-3.1	16.57	-2.0	-48.0	34.0
		Xan.High	84	Week 24	30	-5.6	17.18	-7.0	-36.0	26.0
				End of Trt.	82	-5.8	14.48	-8.0	-36.0	29.0
	AFTER STANDING FOR 1 MINUTE	Placebo	86	Week 24	58	-1.7	16.87	0.0	-32.0	40.0
				End of Trt.	83	-1.6	17.76	0.0	-46.0	48.0
		Xan.Low	84	Week 24	27	-0.1	17.73	-1.0	-30.0	48.0
				End of Trt.	84	-2.8	17.40	-1.5	-52.0	48.0
		Xan.High	84	Week 24	30	-6.3	19.49	-9.0	-36.0	42.0
				End of Trt.	82	-6.7	16.98	-8.0	-44.0	42.0
	AFTER STANDING FOR 3 MINUTES	Placebo	86	Week 24	58	-1.0	15.80	-3.5	-36.0	38.0
				End of Trt.	83	-2.5	16.61	-4.0	-40.0	48.0
		Xan.Low	84	Week 24	27	-0.1	16.20	0.0	-30.0	30.0
				End of Trt.	83	-3.5	16.51	-4.0	-52.0	60.0
		Xan.High	84	Week 24	30	-9.0	16.88	-8.0	-40.0	30.0

End of treatment is the last on-treatment assessment of the specified vital sign (on or before the Week 24 visit).

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rtvs.sas

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Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
				End of Trt.	81	-8.3	15.21	-8.0	-40.0	30.0
Diastolic Blood Pressure (mmHg)	AFTER LYING DOWN FOR 5 MINUTES	Placebo	86	Week 24	58	-0.8	10.82	-0.5	-18.0	41.0
				End of Trt.	83	-1.0	10.99	0.0	-34.0	41.0
		Xan.Low	84	Week 24	27	-0.9	7.71	-2.0	-20.0	16.0
				End of Trt.	84	-2.0	8.80	-2.0	-30.0	18.0
		Xan.High	84	Week 24	30	-2.2	9.20	-1.0	-20.0	21.0
				End of Trt.	82	-3.1	8.79	-4.0	-24.0	21.0
	AFTER STANDING FOR 1 MINUTE	Placebo	86	Week 24	58	-2.3	10.08	-4.0	-23.0	24.0
				End of Trt.	83	-2.8	10.17	-2.0	-34.0	24.0
		Xan.Low	84	Week 24	27	1.0	7.30	2.0	-20.0	18.0
				End of Trt.	84	-1.2	8.93	0.0	-30.0	20.0
		Xan.High	84	Week 24	30	-2.3	10.85	-7.0	-18.0	22.0
				End of Trt.	82	-2.1	12.10	-2.0	-34.0	28.0
	AFTER STANDING FOR 3 MINUTES	Placebo	86	Week 24	58	-2.3	9.56	-3.5	-22.0	20.0
				End of Trt.	83	-2.7	9.36	-2.0	-30.0	20.0
		Xan.Low	84	Week 24	27	-1.6	8.29	0.0	-20.0	10.0
				End of Trt.	83	-1.8	9.69	-1.0	-24.0	38.0

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Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Pulse (bpm)	AFTER LYING DOWN FOR 5 MINUTES	Xan.High	84	Week 24	30	-2.1	9.77	-3.5	-20.0	16.0
				End of Trt.	81	-2.6	10.81	-2.0	-40.0	27.0
		Placebo	86	Week 24	58	-0.3	8.77	-1.0	-24.0	24.0
				End of Trt.	83	-0.9	8.69	-1.0	-24.0	24.0
		Xan.Low	84	Week 24	27	-1.6	10.53	0.0	-24.0	25.0
				End of Trt.	84	-1.0	11.12	-0.5	-24.0	32.0
	AFTER STANDING FOR 1 MINUTE	Xan.High	84	Week 24	30	-2.0	11.16	-2.0	-34.0	20.0
				End of Trt.	82	-1.7	8.95	-2.0	-34.0	20.0
		Placebo	86	Week 24	58	-1.7	11.72	0.5	-53.0	18.0
				End of Trt.	83	-1.8	11.05	-1.0	-53.0	20.0
		Xan.Low	84	Week 24	27	-1.3	9.05	0.0	-20.0	12.0
				End of Trt.	84	-0.5	11.69	0.0	-24.0	34.0
	AFTER STANDING FOR 3 MINUTES	Xan.High	84	Week 24	30	-1.8	13.41	-3.0	-36.0	20.0
				End of Trt.	82	-2.1	10.43	-1.5	-36.0	22.0
		Placebo	86	Week 24	58	-1.5	10.47	0.0	-46.0	14.0
				End of Trt.	83	-1.0	9.89	0.0	-46.0	18.0

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		Xan.Low	84	Week 24	27	-2.1	8.77	-2.0	-20.0	16.0
				End of Trt.	83	-0.7	10.73	-1.0	-22.0	29.0
		Xan.High	84	Week 24	30	-2.7	11.12	-2.0	-40.0	14.0
				End of Trt.	81	-1.9	9.49	-1.0	-40.0	20.0

End of treatment is the last on-treatment assessment of the specified vital sign (on or before the Week 24 visit).

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