

Table 14-7.01  
Summary of Vital Signs at Baseline and 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	Baseline	85	138.6	16.75	140.0	90.0	180.0
				Week 24	59	135.8	17.30	131.0	100.0	180.0
				End of Trt.	84	136.7	18.30	134.0	100.0	180.0
		Xan.Low	84	Baseline	84	138.8	16.55	138.0	100.0	178.0
				Week 24	27	134.1	16.74	136.0	100.0	173.0
				End of Trt.	84	135.7	17.17	134.0	100.0	190.0
		Xan.High	84	Baseline	84	140.1	17.82	141.0	100.0	188.0
				Week 24	30	132.2	18.18	130.0	101.0	178.0
				End of Trt.	82	134.0	17.86	130.0	101.0	178.0
	AFTER STANDING FOR 1 MINUTE	Placebo	86	Baseline	85	135.3	17.89	134.0	90.0	180.0
				Week 24	59	133.5	19.23	130.0	90.0	199.0
				End of Trt.	84	133.9	18.68	130.5	90.0	199.0
		Xan.Low	84	Baseline	84	135.6	18.04	136.0	100.0	186.0
				Week 24	27	131.0	17.82	130.0	92.0	168.0
				End of Trt.	84	132.8	17.53	130.0	92.0	180.0
		Xan.High	84	Baseline	84	137.3	19.71	138.0	100.0	194.0
				Week 24	30	130.4	20.83	128.0	96.0	198.0
				End of Trt.	82	130.4	20.37	128.0	90.0	198.0
	AFTER STANDING FOR 3 MINUTES	Placebo	86	Baseline	85	136.5	18.77	136.0	80.0	184.0

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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Summary of Vital Signs at Baseline and End of Treatment

Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Diastolic Blood Pressure (mmHg)	AFTER LYING DOWN FOR 5 MINUTES	Placebo	86	Week 24	59	134.8	17.35	131.0	100.0	190.0
				End of Trt.	84	134.1	18.01	130.0	90.0	190.0
				Xan.Low	84	Baseline	84	136.4	18.11	134.5
				Week 24	27	131.0	17.92	130.0	100.0	168.0
				End of Trt.	83	133.1	17.80	130.0	98.0	200.0
				Xan.High	84	Baseline	84	138.8	18.75	138.0
				Week 24	30	129.2	16.95	126.0	90.0	172.0
				End of Trt.	81	130.4	17.77	130.0	88.0	184.0
		Placebo	86	Baseline	85	75.7	11.09	76.0	40.0	99.0
				Week 24	59	72.9	11.32	74.0	44.0	109.0
				End of Trt.	84	74.5	11.11	76.0	44.0	109.0
				Xan.Low	84	Baseline	84	76.3	9.77	76.0
				Week 24	27	76.1	9.14	76.0	60.0	90.0
				End of Trt.	84	74.3	8.88	74.0	45.0	90.0
				Xan.High	84	Baseline	84	77.2	9.80	78.0
				Week 24	30	73.9	9.23	74.0	60.0	92.0
				End of Trt.	82	74.1	9.27	74.0	56.0	94.0
	AFTER STANDING FOR 1 MINUTE	Placebo	86	Baseline	85	77.9	10.63	78.0	51.0	104.0
				Week 24	59	74.2	12.89	74.0	45.0	117.0
				End of Trt.	84	74.9	12.16	76.0	45.0	117.0

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Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Pulse (bpm)		Xan.Low	84	Baseline	84	76.2	10.14	78.0	54.0	98.0
				Week 24	27	76.3	10.28	78.0	60.0	98.0
				End of Trt.	84	75.0	9.34	75.0	51.0	98.0
		Xan.High	84	Baseline	84	78.1	10.77	78.0	56.0	108.0
				Week 24	30	74.9	11.00	76.0	50.0	97.0
				End of Trt.	82	75.9	11.77	76.5	48.0	112.0
		Placebo	86	Baseline	85	77.7	11.00	78.0	46.0	110.0
				Week 24	59	74.3	11.38	74.0	51.0	110.0
				End of Trt.	84	75.0	11.19	74.5	51.0	110.0
	AFTER STANDING FOR 3 MINUTES	Xan.Low	84	Baseline	84	76.6	10.93	76.0	48.0	108.0
				Week 24	27	76.2	10.18	76.0	57.0	98.0
				End of Trt.	83	74.9	9.66	74.0	57.0	102.0
		Xan.High	84	Baseline	84	79.6	10.19	80.0	51.0	104.0
				Week 24	30	76.0	10.63	78.5	50.0	98.0
				End of Trt.	81	76.8	11.71	78.0	50.0	118.0
	AFTER LYING DOWN FOR 5 MINUTES	Placebo	86	Baseline	85	70.4	10.46	70.0	51.0	100.0
				Week 24	59	69.1	9.46	68.0	50.0	92.0
				End of Trt.	84	69.3	9.42	68.5	50.0	92.0
		Xan.Low	84	Baseline	84	68.8	9.52	68.0	50.0	88.0

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Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
AFTER STANDING FOR 1 MINUTE				Week 24	27	68.1	9.28	68.0	52.0	90.0
				End of Trt.	84	67.8	10.55	68.0	48.0	100.0
		Xan.High	84	Baseline	84	70.1	9.27	68.0	52.0	98.0
				Week 24	30	69.3	11.88	68.0	47.0	96.0
				End of Trt.	82	68.1	11.27	68.0	47.0	100.0
		Placebo	86	Baseline	85	75.5	12.68	76.0	56.0	133.0
				Week 24	59	72.8	8.98	74.0	52.0	88.0
				End of Trt.	84	73.5	9.09	74.0	52.0	96.0
		Xan.Low	84	Baseline	84	73.5	10.59	72.0	53.0	100.0
				Week 24	27	72.1	9.53	74.0	52.0	88.0
				End of Trt.	84	73.0	10.84	73.0	51.0	104.0
		Xan.High	84	Baseline	84	75.0	10.89	72.0	56.0	104.0
				Week 24	30	73.4	11.93	72.0	54.0	98.0
				End of Trt.	82	72.6	11.11	71.0	52.0	100.0
AFTER STANDING FOR 3 MINUTES		Placebo	86	Baseline	85	74.6	11.94	74.0	54.0	134.0
				Week 24	59	72.8	8.73	74.0	56.0	88.0
				End of Trt.	84	73.4	9.08	74.0	56.0	98.0
		Xan.Low	84	Baseline	84	72.3	10.99	70.0	51.0	104.0
				Week 24	27	70.7	10.78	72.0	52.0	96.0
				End of Trt.	83	71.6	10.42	72.0	52.0	97.0

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		Xan.High	84	Baseline	84	74.0	10.76	72.0	52.0	100.0
				Week 24	30	72.4	11.92	71.5	54.0	96.0
				End of Trt.	81	71.8	10.76	70.0	54.0	106.0

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