

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

| Measure                           | Position                             | Treatment | N  | Planned<br>Relative<br>Time | n  | Mean  | SD    | Median | Min.  | Max. |
|-----------------------------------|--------------------------------------|-----------|----|-----------------------------|----|-------|-------|--------|-------|------|
| Systolic Blood<br>Pressure (mmHg) | AFTER LYING<br>DOWN FOR 5<br>MINUTES | Placebo   | 86 | Week 24                     | 58 | -2.1  | 14.73 | -4.0   | -28.0 | 50.0 |
|                                   |                                      |           |    | End of<br>Trt.              | 81 | -3.7  | 18.98 | -5.0   | -46.0 | 48.0 |
|                                   |                                      | Xan.Low   | 84 | Week 24                     | 27 | -0.3  | 17.19 | 2.0    | -48.0 | 30.0 |
|                                   |                                      |           |    | End of<br>Trt.              | 72 | -3.5  | 16.69 | -4.0   | -42.0 | 34.0 |
|                                   |                                      | Xan.High  | 84 | Week 24                     | 30 | -5.6  | 17.18 | -7.0   | -36.0 | 26.0 |
|                                   |                                      |           |    | End of<br>Trt.              | 73 | -8.9  | 16.54 | -10.0  | -54.0 | 30.0 |
|                                   | AFTER STANDING<br>FOR 1 MINUTE       | Placebo   | 86 | Week 24                     | 58 | -1.7  | 16.87 | 0.0    | -32.0 | 40.0 |
|                                   |                                      |           |    | End of<br>Trt.              | 81 | -4.9  | 18.42 | -2.0   | -48.0 | 48.0 |
|                                   |                                      | Xan.Low   | 84 | Week 24                     | 27 | -0.1  | 17.73 | -1.0   | -30.0 | 48.0 |
|                                   |                                      |           |    | End of<br>Trt.              | 72 | -4.3  | 16.61 | -3.0   | -52.0 | 40.0 |
|                                   |                                      | Xan.High  | 84 | Week 24                     | 30 | -6.3  | 19.49 | -9.0   | -36.0 | 42.0 |
|                                   |                                      |           |    | End of<br>Trt.              | 73 | -10.0 | 18.41 | -14.0  | -62.0 | 35.0 |
|                                   | AFTER STANDING<br>FOR 3 MINUTES      | Placebo   | 86 | Week 24                     | 58 | -1.0  | 15.80 | -3.5   | -36.0 | 38.0 |
|                                   |                                      |           |    | End of                      | 81 | -5.5  | 17.57 | -6.0   | -50.0 | 48.0 |

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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| Measure                            | Position                             | Treatment | N  | Planned<br>Relative<br>Time<br>Trt. | n  | Mean  | SD    | Median | Min.  | Max. |
|------------------------------------|--------------------------------------|-----------|----|-------------------------------------|----|-------|-------|--------|-------|------|
| Diastolic Blood<br>Pressure (mmHg) | AFTER LYING<br>DOWN FOR 5<br>MINUTES | Xan.Low   | 84 | Week 24                             | 27 | -0.1  | 16.20 | 0.0    | -30.0 | 30.0 |
|                                    |                                      |           |    | End of<br>Trt.                      | 72 | -3.9  | 16.83 | -4.0   | -52.0 | 60.0 |
|                                    |                                      | Xan.High  | 84 | Week 24                             | 30 | -9.0  | 16.88 | -8.0   | -40.0 | 30.0 |
|                                    |                                      |           |    | End of<br>Trt.                      | 73 | -10.3 | 16.79 | -10.0  | -48.0 | 30.0 |
|                                    |                                      | Placebo   | 86 | Week 24                             | 58 | -0.8  | 10.82 | -0.5   | -18.0 | 41.0 |
|                                    |                                      |           |    | End of<br>Trt.                      | 81 | -1.5  | 9.41  | -1.0   | -24.0 | 20.0 |
|                                    | AFTER STANDING<br>FOR 1 MINUTE       | Xan.Low   | 84 | Week 24                             | 27 | -0.9  | 7.71  | -2.0   | -20.0 | 16.0 |
|                                    |                                      |           |    | End of<br>Trt.                      | 72 | -3.5  | 8.56  | -2.0   | -30.0 | 16.0 |
|                                    |                                      | Xan.High  | 84 | Week 24                             | 30 | -2.2  | 9.20  | -1.0   | -20.0 | 21.0 |
|                                    |                                      |           |    | End of<br>Trt.                      | 73 | -3.5  | 9.20  | -4.0   | -24.0 | 20.0 |
|                                    |                                      | Placebo   | 86 | Week 24                             | 58 | -2.3  | 10.08 | -4.0   | -23.0 | 24.0 |
|                                    |                                      |           |    | End of<br>Trt.                      | 81 | -3.3  | 9.96  | -2.0   | -27.0 | 24.0 |

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**Summary of Vital Signs Change from Baseline at End of Treatment**

| Measure     | Position                             | Treatment | N  | Planned<br>Relative<br>Time | n  | Mean | SD    | Median | Min.  | Max. |
|-------------|--------------------------------------|-----------|----|-----------------------------|----|------|-------|--------|-------|------|
| Pulse (bpm) |                                      | Xan.Low   | 84 | Week 24                     | 27 | 1.0  | 7.30  | 2.0    | -20.0 | 18.0 |
|             |                                      |           |    | End of<br>Trt.              | 72 | -2.2 | 9.20  | -2.0   | -30.0 | 20.0 |
|             |                                      | Xan.High  | 84 | Week 24                     | 30 | -2.3 | 10.85 | -7.0   | -18.0 | 22.0 |
|             |                                      |           |    | End of<br>Trt.              | 73 | -2.2 | 11.77 | -1.0   | -34.0 | 22.0 |
|             | AFTER STANDING<br>FOR 3 MINUTES      | Placebo   | 86 | Week 24                     | 58 | -2.3 | 9.56  | -3.5   | -22.0 | 20.0 |
|             |                                      |           |    | End of<br>Trt.              | 81 | -3.9 | 8.77  | -4.0   | -26.0 | 16.0 |
|             |                                      | Xan.Low   | 84 | Week 24                     | 27 | -1.6 | 8.29  | 0.0    | -20.0 | 10.0 |
|             |                                      |           |    | End of<br>Trt.              | 72 | -3.0 | 10.19 | -2.0   | -24.0 | 38.0 |
|             |                                      | Xan.High  | 84 | Week 24                     | 30 | -2.1 | 9.77  | -3.5   | -20.0 | 16.0 |
|             |                                      |           |    | End of<br>Trt.              | 73 | -3.7 | 10.47 | -2.0   | -40.0 | 20.0 |
|             | AFTER LYING<br>DOWN FOR 5<br>MINUTES | Placebo   | 86 | Week 24                     | 58 | -0.3 | 8.77  | -1.0   | -24.0 | 24.0 |
|             |                                      |           |    | End of<br>Trt.              | 81 | 0.1  | 10.48 | 0.0    | -24.0 | 40.0 |
|             |                                      | Xan.Low   | 84 | Week 24                     | 27 | -1.6 | 10.53 | 0.0    | -24.0 | 25.0 |
|             |                                      |           |    | End of<br>Trt.              | 72 | -1.4 | 11.40 | -2.0   | -24.0 | 32.0 |

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|---------|---------------------------------|-----------|----|-----------------------------|----|------|-------|--------|-------|------|
|         | AFTER STANDING<br>FOR 1 MINUTE  | Xan.High  | 84 | Week 24                     | 30 | -2.0 | 11.16 | -2.0   | -34.0 | 20.0 |
|         |                                 |           |    | End of<br>Trt.              | 73 | -2.1 | 9.13  | -2.0   | -26.0 | 24.0 |
|         |                                 | Placebo   | 86 | Week 24                     | 58 | -1.7 | 11.72 | 0.5    | -53.0 | 18.0 |
|         |                                 |           |    | End of<br>Trt.              | 81 | -0.9 | 11.72 | -2.0   | -45.0 | 44.0 |
|         |                                 | Xan.Low   | 84 | Week 24                     | 27 | -1.3 | 9.05  | 0.0    | -20.0 | 12.0 |
|         |                                 |           |    | End of<br>Trt.              | 72 | 0.0  | 13.09 | -1.5   | -24.0 | 34.0 |
|         | AFTER STANDING<br>FOR 3 MINUTES | Xan.High  | 84 | Week 24                     | 30 | -1.8 | 13.41 | -3.0   | -36.0 | 20.0 |
|         |                                 |           |    | End of<br>Trt.              | 73 | -1.6 | 9.57  | -2.0   | -28.0 | 22.0 |
|         |                                 | Placebo   | 86 | Week 24                     | 58 | -1.5 | 10.47 | 0.0    | -46.0 | 14.0 |
|         |                                 |           |    | End of<br>Trt.              | 81 | 0.1  | 11.09 | 0.0    | -46.0 | 32.0 |
|         |                                 | Xan.Low   | 84 | Week 24                     | 27 | -2.1 | 8.77  | -2.0   | -20.0 | 16.0 |
|         |                                 |           |    | End of<br>Trt.              | 72 | -0.2 | 11.71 | -1.0   | -26.0 | 29.0 |
|         |                                 | Xan.High  | 84 | Week 24                     | 30 | -2.7 | 11.12 | -2.0   | -40.0 | 14.0 |
|         |                                 |           |    | End of                      | 73 | -1.2 | 9.36  | 0.0    | -32.0 | 22.0 |

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|---------|----------|-----------|---|-----------------------------|---|------|----|--------|------|------|
|         |          |           |   | Trt.                        |   |      |    |        |      |      |

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