14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| VS/BP/PE indicative of AE? | Anytime post baseline | n | 6 |
| Yes | 1 ( 16.7) |
| No | 5 ( 83.3) |
|  | | | |
| Weight (kg) | Baseline | n | 6 |
| Mean (SD) | 87.83 (17.68) |
| Median | 88.00 |
| Q1 ; Q3 | 83.00 ; 93.00 |
| Min ; Max | 60.0 ; 115.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 86.50 (18.14) |
| Median | 88.00 |
| Q1 ; Q3 | 81.00 ; 92.00 |
| Min ; Max | 57.0 ; 113.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 86.50 (18.35) |
| Median | 88.00 |
| Q1 ; Q3 | 81.00 ; 91.00 |
| Min ; Max | 57.0 ; 114.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 1 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Weight (kg) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 94.67 (15.57) |
| Median | 93.00 |
| Q1 ; Q3 | 80.00 ; 111.00 |
| Min ; Max | 80.0 ; 111.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 95.00 (15.10) |
| Median | 93.00 |
| Q1 ; Q3 | 81.00 ; 111.00 |
| Min ; Max | 81.0 ; 111.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 71.00 (21.21) |
| Median | 71.00 |
| Q1 ; Q3 | 56.00 ; 86.00 |
| Min ; Max | 56.0 ; 86.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 86.00 |
| Median | 86.00 |
| Q1 ; Q3 | 86.00 ; 86.00 |
| Min ; Max | 86.0 ; 86.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 2 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Sitting Diastolic Blood Pressure (mmHg) | Baseline | n | 6 |
| Mean (SD) | 76.00 (10.18) |
| Median | 77.00 |
| Q1 ; Q3 | 71.00 ; 84.00 |
| Min ; Max | 60.0 ; 87.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 79.33 (13.94) |
| Median | 78.00 |
| Q1 ; Q3 | 73.00 ; 85.00 |
| Min ; Max | 60.0 ; 102.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 81.33 (15.12) |
| Median | 82.00 |
| Q1 ; Q3 | 72.00 ; 89.00 |
| Min ; Max | 60.0 ; 103.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 78.33 (21.50) |
| Median | 73.00 |
| Q1 ; Q3 | 60.00 ; 102.00 |
| Min ; Max | 60.0 ; 102.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 3 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Sitting Diastolic Blood Pressure (mmHg) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 81.67 (14.57) |
| Median | 77.00 |
| Q1 ; Q3 | 70.00 ; 98.00 |
| Min ; Max | 70.0 ; 98.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 84.00 (8.49) |
| Median | 84.00 |
| Q1 ; Q3 | 78.00 ; 90.00 |
| Min ; Max | 78.0 ; 90.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 82.00 |
| Median | 82.00 |
| Q1 ; Q3 | 82.00 ; 82.00 |
| Min ; Max | 82.0 ; 82.0 |
|  | | | |
| Sitting Systolic Blood Pressure (mmHg) | Baseline | n | 6 |
| Mean (SD) | 126.17 (16.88) |
| Median | 127.50 |
| Q1 ; Q3 | 118.00 ; 134.00 |
| Min ; Max | 100.0 ; 150.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 4 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Sitting Systolic Blood Pressure (mmHg) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 125.83 (15.56) |
| Median | 124.00 |
| Q1 ; Q3 | 110.00 ; 138.00 |
| Min ; Max | 110.0 ; 149.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 124.00 (14.03) |
| Median | 128.00 |
| Q1 ; Q3 | 118.00 ; 135.00 |
| Min ; Max | 100.0 ; 135.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 125.67 (23.80) |
| Median | 130.00 |
| Q1 ; Q3 | 100.00 ; 147.00 |
| Min ; Max | 100.0 ; 147.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 147.00 (23.64) |
| Median | 137.00 |
| Q1 ; Q3 | 130.00 ; 174.00 |
| Min ; Max | 130.0 ; 174.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 5 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Sitting Systolic Blood Pressure (mmHg) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 136.00 (22.63) |
| Median | 136.00 |
| Q1 ; Q3 | 120.00 ; 152.00 |
| Min ; Max | 120.0 ; 152.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 146.00 |
| Median | 146.00 |
| Q1 ; Q3 | 146.00 ; 146.00 |
| Min ; Max | 146.0 ; 146.0 |
|  | | | |
| Supine Diastolic Blood Pressure (mmHg) | Baseline | n | 6 |
| Mean (SD) | 71.00 (9.63) |
| Median | 71.00 |
| Q1 ; Q3 | 70.00 ; 74.00 |
| Min ; Max | 55.0 ; 85.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 78.33 (11.08) |
| Median | 78.50 |
| Q1 ; Q3 | 76.00 ; 83.00 |
| Min ; Max | 60.0 ; 94.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 6 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Supine Diastolic Blood Pressure (mmHg) | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 73.67 (13.19) |
| Median | 71.00 |
| Q1 ; Q3 | 69.00 ; 72.00 |
| Min ; Max | 60.0 ; 99.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 75.67 (16.56) |
| Median | 74.00 |
| Q1 ; Q3 | 60.00 ; 93.00 |
| Min ; Max | 60.0 ; 93.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 78.67 (15.01) |
| Median | 70.00 |
| Q1 ; Q3 | 70.00 ; 96.00 |
| Min ; Max | 70.0 ; 96.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 76.00 (2.83) |
| Median | 76.00 |
| Q1 ; Q3 | 74.00 ; 78.00 |
| Min ; Max | 74.0 ; 78.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 7 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Supine Diastolic Blood Pressure (mmHg) | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 73.00 |
| Median | 73.00 |
| Q1 ; Q3 | 73.00 ; 73.00 |
| Min ; Max | 73.0 ; 73.0 |
|  | | | |
| Supine Systolic Blood Pressure (mmHg) | Baseline | n | 6 |
| Mean (SD) | 125.33 (16.72) |
| Median | 125.00 |
| Q1 ; Q3 | 118.00 ; 134.00 |
| Min ; Max | 100.0 ; 150.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 132.33 (15.06) |
| Median | 130.00 |
| Q1 ; Q3 | 120.00 ; 137.00 |
| Min ; Max | 118.0 ; 159.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 126.67 (13.32) |
| Median | 124.50 |
| Q1 ; Q3 | 118.00 ; 135.00 |
| Min ; Max | 110.0 ; 148.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 8 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Supine Systolic Blood Pressure (mmHg) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 131.00 (21.52) |
| Median | 130.00 |
| Q1 ; Q3 | 110.00 ; 153.00 |
| Min ; Max | 110.0 ; 153.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 136.33 (15.50) |
| Median | 130.00 |
| Q1 ; Q3 | 125.00 ; 154.00 |
| Min ; Max | 125.0 ; 154.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 130.50 (21.92) |
| Median | 130.50 |
| Q1 ; Q3 | 115.00 ; 146.00 |
| Min ; Max | 115.0 ; 146.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 153.00 |
| Median | 153.00 |
| Q1 ; Q3 | 153.00 ; 153.00 |
| Min ; Max | 153.0 ; 153.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                                Page 9 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Standing Diastolic Blood Pressure (mmHg) | Baseline | n | 6 |
| Mean (SD) | 74.50 (14.11) |
| Median | 75.00 |
| Q1 ; Q3 | 60.00 ; 84.00 |
| Min ; Max | 58.0 ; 95.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 81.83 (15.45) |
| Median | 81.00 |
| Q1 ; Q3 | 72.00 ; 96.00 |
| Min ; Max | 60.0 ; 101.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 79.00 (12.87) |
| Median | 79.00 |
| Q1 ; Q3 | 72.00 ; 86.00 |
| Min ; Max | 60.0 ; 98.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 79.00 (17.69) |
| Median | 82.00 |
| Q1 ; Q3 | 60.00 ; 95.00 |
| Min ; Max | 60.0 ; 95.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 10 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Standing Diastolic Blood Pressure (mmHg) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 77.33 (18.04) |
| Median | 76.00 |
| Q1 ; Q3 | 60.00 ; 96.00 |
| Min ; Max | 60.0 ; 96.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 83.00 (9.90) |
| Median | 83.00 |
| Q1 ; Q3 | 76.00 ; 90.00 |
| Min ; Max | 76.0 ; 90.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 78.00 |
| Median | 78.00 |
| Q1 ; Q3 | 78.00 ; 78.00 |
| Min ; Max | 78.0 ; 78.0 |
|  | | | |
| Standing Systolic Blood Pressure (mmHg) | Baseline | n | 6 |
| Mean (SD) | 125.17 (16.30) |
| Median | 120.50 |
| Q1 ; Q3 | 116.00 ; 128.00 |
| Min ; Max | 110.0 ; 156.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 11 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Standing Systolic Blood Pressure (mmHg) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 129.00 (15.28) |
| Median | 126.00 |
| Q1 ; Q3 | 120.00 ; 139.00 |
| Min ; Max | 110.0 ; 153.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 128.83 (11.32) |
| Median | 130.00 |
| Q1 ; Q3 | 124.00 ; 136.00 |
| Min ; Max | 110.0 ; 143.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 124.67 (22.81) |
| Median | 129.00 |
| Q1 ; Q3 | 100.00 ; 145.00 |
| Min ; Max | 100.0 ; 145.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 129.67 (11.24) |
| Median | 127.00 |
| Q1 ; Q3 | 120.00 ; 142.00 |
| Min ; Max | 120.0 ; 142.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 12 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Standing Systolic Blood Pressure (mmHg) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 127.50 (16.26) |
| Median | 127.50 |
| Q1 ; Q3 | 116.00 ; 139.00 |
| Min ; Max | 116.0 ; 139.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 133.00 |
| Median | 133.00 |
| Q1 ; Q3 | 133.00 ; 133.00 |
| Min ; Max | 133.0 ; 133.0 |
|  | | | |
| Pulse Rate (Beats/min) | Baseline | n | 6 |
| Mean (SD) | 72.00 (9.82) |
| Median | 69.00 |
| Q1 ; Q3 | 65.00 ; 75.00 |
| Min ; Max | 64.0 ; 90.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 83.83 (6.94) |
| Median | 85.00 |
| Q1 ; Q3 | 76.00 ; 87.00 |
| Min ; Max | 76.0 ; 94.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 13 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Pulse Rate (Beats/min) | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 75.50 (6.75) |
| Median | 76.00 |
| Q1 ; Q3 | 70.00 ; 78.00 |
| Min ; Max | 67.0 ; 86.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 75.67 (3.21) |
| Median | 77.00 |
| Q1 ; Q3 | 72.00 ; 78.00 |
| Min ; Max | 72.0 ; 78.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 74.67 (4.16) |
| Median | 76.00 |
| Q1 ; Q3 | 70.00 ; 78.00 |
| Min ; Max | 70.0 ; 78.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 76.50 (17.68) |
| Median | 76.50 |
| Q1 ; Q3 | 64.00 ; 89.00 |
| Min ; Max | 64.0 ; 89.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 14 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Pulse Rate (Beats/min) | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 75.00 |
| Median | 75.00 |
| Q1 ; Q3 | 75.00 ; 75.00 |
| Min ; Max | 75.0 ; 75.0 |
|  | | | |
| Temperature (C) | Baseline | n | 6 |
| Mean (SD) | 36.83 (0.41) |
| Median | 37.00 |
| Q1 ; Q3 | 37.00 ; 37.00 |
| Min ; Max | 36.0 ; 37.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 36.83 (0.41) |
| Median | 37.00 |
| Q1 ; Q3 | 37.00 ; 37.00 |
| Min ; Max | 36.0 ; 37.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 36.83 (0.41) |
| Median | 37.00 |
| Q1 ; Q3 | 37.00 ; 37.00 |
| Min ; Max | 36.0 ; 37.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 15 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Temperature (C) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 36.67 (0.58) |
| Median | 37.00 |
| Q1 ; Q3 | 36.00 ; 37.00 |
| Min ; Max | 36.0 ; 37.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 36.67 (0.58) |
| Median | 37.00 |
| Q1 ; Q3 | 36.00 ; 37.00 |
| Min ; Max | 36.0 ; 37.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 36.50 (0.71) |
| Median | 36.50 |
| Q1 ; Q3 | 36.00 ; 37.00 |
| Min ; Max | 36.0 ; 37.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 37.00 |
| Median | 37.00 |
| Q1 ; Q3 | 37.00 ; 37.00 |
| Min ; Max | 37.0 ; 37.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 16 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Respiratory Rate (Breaths/min) | Baseline | n | 6 |
| Mean (SD) | 16.83 (1.17) |
| Median | 16.50 |
| Q1 ; Q3 | 16.00 ; 17.00 |
| Min ; Max | 16.0 ; 19.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 17.17 (0.75) |
| Median | 17.00 |
| Q1 ; Q3 | 17.00 ; 18.00 |
| Min ; Max | 16.0 ; 18.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 16.50 (1.05) |
| Median | 16.50 |
| Q1 ; Q3 | 16.00 ; 17.00 |
| Min ; Max | 15.0 ; 18.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 17.33 (1.53) |
| Median | 17.00 |
| Q1 ; Q3 | 16.00 ; 19.00 |
| Min ; Max | 16.0 ; 19.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 17 of 18 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Respiratory Rate (Breaths/min) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 17.67 (1.15) |
| Median | 17.00 |
| Q1 ; Q3 | 17.00 ; 19.00 |
| Min ; Max | 17.0 ; 19.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 16.50 (0.71) |
| Median | 16.50 |
| Q1 ; Q3 | 16.00 ; 17.00 |
| Min ; Max | 16.0 ; 17.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 17.00 |
| Median | 17.00 |
| Q1 ; Q3 | 17.00 ; 17.00 |
| Min ; Max | 17.0 ; 17.0 |
| Source: Listing 14.1 VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination. Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-VS 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-VS.sas                                                                                               Page 18 of 18 | | | |