13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Alanine aminotransferase (U/L) | Baseline | n | 6 |
| Mean (SD) | 21.50 (8.24) |
| Median | 20.00 |
| Q1 ; Q3 | 15.00 ; 26.00 |
| Min ; Max | 13.0 ; 35.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 25.00 (10.10) |
| Median | 23.00 |
| Q1 ; Q3 | 18.00 ; 34.00 |
| Min ; Max | 13.0 ; 39.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 42.33 (27.16) |
| Median | 34.50 |
| Q1 ; Q3 | 24.00 ; 69.00 |
| Min ; Max | 12.0 ; 80.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 36.00 (12.29) |
| Median | 31.00 |
| Q1 ; Q3 | 27.00 ; 50.00 |
| Min ; Max | 27.0 ; 50.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 1 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Alanine aminotransferase (U/L) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 25.00 (8.19) |
| Median | 27.00 |
| Q1 ; Q3 | 16.00 ; 32.00 |
| Min ; Max | 16.0 ; 32.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 22.00 (8.49) |
| Median | 22.00 |
| Q1 ; Q3 | 16.00 ; 28.00 |
| Min ; Max | 16.0 ; 28.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 15.00 |
| Median | 15.00 |
| Q1 ; Q3 | 15.00 ; 15.00 |
| Min ; Max | 15.0 ; 15.0 |
|  | | | |
| Albumin (g/L) | Baseline | n | 6 |
| Mean (SD) | 43.67 (2.34) |
| Median | 44.00 |
| Q1 ; Q3 | 41.00 ; 45.00 |
| Min ; Max | 41.0 ; 47.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 2 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Albumin (g/L) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 45.83 (3.97) |
| Median | 48.00 |
| Q1 ; Q3 | 43.00 ; 48.00 |
| Min ; Max | 39.0 ; 49.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 45.33 (3.20) |
| Median | 46.00 |
| Q1 ; Q3 | 42.00 ; 48.00 |
| Min ; Max | 41.0 ; 49.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 45.33 (1.53) |
| Median | 45.00 |
| Q1 ; Q3 | 44.00 ; 47.00 |
| Min ; Max | 44.0 ; 47.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 45.33 (0.58) |
| Median | 45.00 |
| Q1 ; Q3 | 45.00 ; 46.00 |
| Min ; Max | 45.0 ; 46.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 3 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Albumin (g/L) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 45.50 (2.12) |
| Median | 45.50 |
| Q1 ; Q3 | 44.00 ; 47.00 |
| Min ; Max | 44.0 ; 47.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 45.00 |
| Median | 45.00 |
| Q1 ; Q3 | 45.00 ; 45.00 |
| Min ; Max | 45.0 ; 45.0 |
|  | | | |
| Alkaline phosphatase (U/L) | Baseline | n | 6 |
| Mean (SD) | 51.00 (20.30) |
| Median | 48.50 |
| Q1 ; Q3 | 36.00 ; 56.00 |
| Min ; Max | 30.0 ; 87.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 69.00 (30.98) |
| Median | 58.00 |
| Q1 ; Q3 | 44.00 ; 102.00 |
| Min ; Max | 39.0 ; 113.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 4 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Alkaline phosphatase (U/L) | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 71.33 (30.57) |
| Median | 56.50 |
| Q1 ; Q3 | 53.00 ; 100.00 |
| Min ; Max | 43.0 ; 119.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 71.33 (20.50) |
| Median | 60.00 |
| Q1 ; Q3 | 59.00 ; 95.00 |
| Min ; Max | 59.0 ; 95.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 79.67 (23.25) |
| Median | 71.00 |
| Q1 ; Q3 | 62.00 ; 106.00 |
| Min ; Max | 62.0 ; 106.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 66.50 (14.85) |
| Median | 66.50 |
| Q1 ; Q3 | 56.00 ; 77.00 |
| Min ; Max | 56.0 ; 77.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 5 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Alkaline phosphatase (U/L) | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 57.00 |
| Median | 57.00 |
| Q1 ; Q3 | 57.00 ; 57.00 |
| Min ; Max | 57.0 ; 57.0 |
|  | | | |
| Aspartate aminotransferase (U/L) | Baseline | n | 6 |
| Mean (SD) | 21.33 (5.35) |
| Median | 19.00 |
| Q1 ; Q3 | 18.00 ; 27.00 |
| Min ; Max | 16.0 ; 29.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 23.17 (6.43) |
| Median | 22.00 |
| Q1 ; Q3 | 20.00 ; 24.00 |
| Min ; Max | 16.0 ; 35.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 36.83 (13.14) |
| Median | 39.00 |
| Q1 ; Q3 | 24.00 ; 43.00 |
| Min ; Max | 20.0 ; 56.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 6 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Aspartate aminotransferase (U/L) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 30.00 (11.36) |
| Median | 25.00 |
| Q1 ; Q3 | 22.00 ; 43.00 |
| Min ; Max | 22.0 ; 43.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 21.67 (2.89) |
| Median | 20.00 |
| Q1 ; Q3 | 20.00 ; 25.00 |
| Min ; Max | 20.0 ; 25.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 24.50 (0.71) |
| Median | 24.50 |
| Q1 ; Q3 | 24.00 ; 25.00 |
| Min ; Max | 24.0 ; 25.0 |
|  | | | |
|  | 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 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 7 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Calcium (mmol/L) | Baseline | n | 6 |
| Mean (SD) | 2.28 (0.07) |
| Median | 2.27 |
| Q1 ; Q3 | 2.24 ; 2.28 |
| Min ; Max | 2.2 ; 2.4 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 2.34 (0.04) |
| Median | 2.36 |
| Q1 ; Q3 | 2.32 ; 2.37 |
| Min ; Max | 2.3 ; 2.4 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 2.35 (0.05) |
| Median | 2.35 |
| Q1 ; Q3 | 2.30 ; 2.40 |
| Min ; Max | 2.3 ; 2.4 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 2.29 (0.10) |
| Median | 2.26 |
| Q1 ; Q3 | 2.21 ; 2.40 |
| Min ; Max | 2.2 ; 2.4 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 8 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Calcium (mmol/L) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 2.34 (0.05) |
| Median | 2.35 |
| Q1 ; Q3 | 2.29 ; 2.38 |
| Min ; Max | 2.3 ; 2.4 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 2.37 (0.06) |
| Median | 2.37 |
| Q1 ; Q3 | 2.33 ; 2.41 |
| Min ; Max | 2.3 ; 2.4 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 2.28 |
| Median | 2.28 |
| Q1 ; Q3 | 2.28 ; 2.28 |
| Min ; Max | 2.3 ; 2.3 |
|  | | | |
| Creatinine (Jaffe) (umol/L) | Baseline | n | 6 |
| Mean (SD) | 70.83 (13.76) |
| Median | 70.00 |
| Q1 ; Q3 | 61.00 ; 76.00 |
| Min ; Max | 54.0 ; 94.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                    Page 9 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Creatinine (Jaffe) (umol/L) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 72.50 (12.01) |
| Median | 71.00 |
| Q1 ; Q3 | 66.00 ; 76.00 |
| Min ; Max | 58.0 ; 93.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 72.83 (17.14) |
| Median | 72.00 |
| Q1 ; Q3 | 61.00 ; 86.00 |
| Min ; Max | 49.0 ; 97.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 72.33 (4.51) |
| Median | 72.00 |
| Q1 ; Q3 | 68.00 ; 77.00 |
| Min ; Max | 68.0 ; 77.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 67.33 (7.09) |
| Median | 66.00 |
| Q1 ; Q3 | 61.00 ; 75.00 |
| Min ; Max | 61.0 ; 75.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 10 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Creatinine (Jaffe) (umol/L) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 81.50 (12.02) |
| Median | 81.50 |
| Q1 ; Q3 | 73.00 ; 90.00 |
| Min ; Max | 73.0 ; 90.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 93.00 |
| Median | 93.00 |
| Q1 ; Q3 | 93.00 ; 93.00 |
| Min ; Max | 93.0 ; 93.0 |
|  | | | |
| Gamma-glutamyl transferase (U/L) | Baseline | n | 6 |
| Mean (SD) | 31.00 (20.72) |
| Median | 28.50 |
| Q1 ; Q3 | 13.00 ; 42.00 |
| Min ; Max | 11.0 ; 63.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 58.33 (68.47) |
| Median | 28.50 |
| Q1 ; Q3 | 20.00 ; 75.00 |
| Min ; Max | 8.0 ; 190.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 11 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Gamma-glutamyl transferase (U/L) | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 64.50 (54.45) |
| Median | 60.00 |
| Q1 ; Q3 | 21.00 ; 74.00 |
| Min ; Max | 9.0 ; 163.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 110.67 (154.95) |
| Median | 34.00 |
| Q1 ; Q3 | 9.00 ; 289.00 |
| Min ; Max | 9.0 ; 289.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 95.33 (135.15) |
| Median | 27.00 |
| Q1 ; Q3 | 8.00 ; 251.00 |
| Min ; Max | 8.0 ; 251.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 61.00 (63.64) |
| Median | 61.00 |
| Q1 ; Q3 | 16.00 ; 106.00 |
| Min ; Max | 16.0 ; 106.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 12 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Gamma-glutamyl transferase (U/L) | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 19.00 |
| Median | 19.00 |
| Q1 ; Q3 | 19.00 ; 19.00 |
| Min ; Max | 19.0 ; 19.0 |
|  | | | |
| Glucose (blood) (mmol/L) | Baseline | n | 6 |
| Mean (SD) | 4.93 (0.65) |
| Median | 4.95 |
| Q1 ; Q3 | 4.70 ; 5.30 |
| Min ; Max | 3.9 ; 5.8 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 4.73 (0.42) |
| Median | 4.95 |
| Q1 ; Q3 | 4.30 ; 5.00 |
| Min ; Max | 4.1 ; 5.1 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 4.97 (0.50) |
| Median | 5.00 |
| Q1 ; Q3 | 4.80 ; 5.40 |
| Min ; Max | 4.1 ; 5.5 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 13 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Glucose (blood) (mmol/L) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 5.50 (0.70) |
| Median | 5.20 |
| Q1 ; Q3 | 5.00 ; 6.30 |
| Min ; Max | 5.0 ; 6.3 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 5.23 (0.42) |
| Median | 5.10 |
| Q1 ; Q3 | 4.90 ; 5.70 |
| Min ; Max | 4.9 ; 5.7 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 4.70 (0.42) |
| Median | 4.70 |
| Q1 ; Q3 | 4.40 ; 5.00 |
| Min ; Max | 4.4 ; 5.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 5.30 |
| Median | 5.30 |
| Q1 ; Q3 | 5.30 ; 5.30 |
| Min ; Max | 5.3 ; 5.3 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 14 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| HDL-cholesterol (mmol/L) | Baseline | n | 6 |
| Mean (SD) | 1.50 (0.49) |
| Median | 1.30 |
| Q1 ; Q3 | 1.30 ; 1.40 |
| Min ; Max | 1.2 ; 2.5 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 1.55 (0.21) |
| Median | 1.55 |
| Q1 ; Q3 | 1.40 ; 1.60 |
| Min ; Max | 1.3 ; 1.9 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 1.52 (0.47) |
| Median | 1.45 |
| Q1 ; Q3 | 1.30 ; 1.50 |
| Min ; Max | 1.0 ; 2.4 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 1.23 (0.12) |
| Median | 1.30 |
| Q1 ; Q3 | 1.10 ; 1.30 |
| Min ; Max | 1.1 ; 1.3 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 15 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| HDL-cholesterol (mmol/L) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 1.30 (0.17) |
| Median | 1.20 |
| Q1 ; Q3 | 1.20 ; 1.50 |
| Min ; Max | 1.2 ; 1.5 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 2.25 (0.92) |
| Median | 2.25 |
| Q1 ; Q3 | 1.60 ; 2.90 |
| Min ; Max | 1.6 ; 2.9 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 1.20 |
| Median | 1.20 |
| Q1 ; Q3 | 1.20 ; 1.20 |
| Min ; Max | 1.2 ; 1.2 |
|  | | | |
| International normalized ratio | Baseline | n | 6 |
| Mean (SD) | 1.01 (0.04) |
| Median | 1.01 |
| Q1 ; Q3 | 0.97 ; 1.02 |
| Min ; Max | 1.0 ; 1.1 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 16 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| International normalized ratio | V5 (OLE Week 2) | n | 5 |
| Mean (SD) | 0.98 (0.05) |
| Median | 1.00 |
| Q1 ; Q3 | 0.97 ; 1.01 |
| Min ; Max | 0.9 ; 1.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 5 |
| Mean (SD) | 0.97 (0.03) |
| Median | 0.97 |
| Q1 ; Q3 | 0.97 ; 0.98 |
| Min ; Max | 0.9 ; 1.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 1.01 (0.04) |
| Median | 1.01 |
| Q1 ; Q3 | 0.97 ; 1.04 |
| Min ; Max | 1.0 ; 1.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 0.98 (0.02) |
| Median | 0.97 |
| Q1 ; Q3 | 0.96 ; 1.00 |
| Min ; Max | 1.0 ; 1.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 17 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| International normalized ratio | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 1.04 (0.05) |
| Median | 1.04 |
| Q1 ; Q3 | 1.00 ; 1.07 |
| Min ; Max | 1.0 ; 1.1 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 1.03 |
| Median | 1.03 |
| Q1 ; Q3 | 1.03 ; 1.03 |
| Min ; Max | 1.0 ; 1.0 |
|  | | | |
| Potassium (mmol/L) | Baseline | n | 6 |
| Mean (SD) | 4.30 (0.28) |
| Median | 4.35 |
| Q1 ; Q3 | 4.10 ; 4.40 |
| Min ; Max | 3.9 ; 4.7 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 4.48 (0.16) |
| Median | 4.55 |
| Q1 ; Q3 | 4.40 ; 4.60 |
| Min ; Max | 4.2 ; 4.6 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 18 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Potassium (mmol/L) | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 4.43 (0.16) |
| Median | 4.40 |
| Q1 ; Q3 | 4.40 ; 4.50 |
| Min ; Max | 4.2 ; 4.7 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 4.47 (0.31) |
| Median | 4.40 |
| Q1 ; Q3 | 4.20 ; 4.80 |
| Min ; Max | 4.2 ; 4.8 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 4.27 (0.12) |
| Median | 4.20 |
| Q1 ; Q3 | 4.20 ; 4.40 |
| Min ; Max | 4.2 ; 4.4 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 4.30 (0.14) |
| Median | 4.30 |
| Q1 ; Q3 | 4.20 ; 4.40 |
| Min ; Max | 4.2 ; 4.4 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 19 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Potassium (mmol/L) | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 4.00 |
| Median | 4.00 |
| Q1 ; Q3 | 4.00 ; 4.00 |
| Min ; Max | 4.0 ; 4.0 |
|  | | | |
| Prolactin (mIU/L) | Baseline | n | 6 |
| Mean (SD) | 228.80 (117.12) |
| Median | 194.95 |
| Q1 ; Q3 | 160.00 ; 215.40 |
| Min ; Max | 145.8 ; 461.7 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 127.58 (30.76) |
| Median | 126.05 |
| Q1 ; Q3 | 110.20 ; 154.90 |
| Min ; Max | 81.4 ; 166.9 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 160.98 (28.23) |
| Median | 163.35 |
| Q1 ; Q3 | 154.40 ; 172.10 |
| Min ; Max | 113.8 ; 198.9 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 20 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Prolactin (mIU/L) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 138.03 (3.57) |
| Median | 139.30 |
| Q1 ; Q3 | 134.00 ; 140.80 |
| Min ; Max | 134.0 ; 140.8 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 136.23 (22.75) |
| Median | 123.30 |
| Q1 ; Q3 | 122.90 ; 162.50 |
| Min ; Max | 122.9 ; 162.5 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 96.65 (18.31) |
| Median | 96.65 |
| Q1 ; Q3 | 83.70 ; 109.60 |
| Min ; Max | 83.7 ; 109.6 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 169.80 |
| Median | 169.80 |
| Q1 ; Q3 | 169.80 ; 169.80 |
| Min ; Max | 169.8 ; 169.8 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 21 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Prothrombin time (plasma) (sec) | Baseline | n | 6 |
| Mean (SD) | 10.88 (0.43) |
| Median | 10.90 |
| Q1 ; Q3 | 10.50 ; 11.00 |
| Min ; Max | 10.4 ; 11.6 |
|  | | | |
|  | V5 (OLE Week 2) | n | 5 |
| Mean (SD) | 10.58 (0.53) |
| Median | 10.80 |
| Q1 ; Q3 | 10.50 ; 10.90 |
| Min ; Max | 9.7 ; 11.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 5 |
| Mean (SD) | 10.46 (0.36) |
| Median | 10.50 |
| Q1 ; Q3 | 10.40 ; 10.60 |
| Min ; Max | 9.9 ; 10.9 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 10.87 (0.35) |
| Median | 10.90 |
| Q1 ; Q3 | 10.50 ; 11.20 |
| Min ; Max | 10.5 ; 11.2 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 22 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Prothrombin time (plasma) (sec) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 10.57 (0.21) |
| Median | 10.50 |
| Q1 ; Q3 | 10.40 ; 10.80 |
| Min ; Max | 10.4 ; 10.8 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 11.15 (0.49) |
| Median | 11.15 |
| Q1 ; Q3 | 10.80 ; 11.50 |
| Min ; Max | 10.8 ; 11.5 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 11.10 |
| Median | 11.10 |
| Q1 ; Q3 | 11.10 ; 11.10 |
| Min ; Max | 11.1 ; 11.1 |
|  | | | |
| Sodium (mmol/L) | Baseline | n | 6 |
| Mean (SD) | 142.17 (2.14) |
| Median | 142.00 |
| Q1 ; Q3 | 140.00 ; 144.00 |
| Min ; Max | 140.0 ; 145.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 23 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Sodium (mmol/L) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 143.67 (1.97) |
| Median | 143.00 |
| Q1 ; Q3 | 142.00 ; 145.00 |
| Min ; Max | 142.0 ; 147.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 143.50 (1.52) |
| Median | 143.50 |
| Q1 ; Q3 | 142.00 ; 144.00 |
| Min ; Max | 142.0 ; 146.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 143.00 (1.73) |
| Median | 144.00 |
| Q1 ; Q3 | 141.00 ; 144.00 |
| Min ; Max | 141.0 ; 144.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 142.00 (2.00) |
| Median | 142.00 |
| Q1 ; Q3 | 140.00 ; 144.00 |
| Min ; Max | 140.0 ; 144.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 24 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Sodium (mmol/L) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 142.50 (0.71) |
| Median | 142.50 |
| Q1 ; Q3 | 142.00 ; 143.00 |
| Min ; Max | 142.0 ; 143.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 143.00 |
| Median | 143.00 |
| Q1 ; Q3 | 143.00 ; 143.00 |
| Min ; Max | 143.0 ; 143.0 |
|  | | | |
| Total bilirubin (TBL) (blood) (umol/L) | Baseline | n | 6 |
| Mean (SD) | 6.42 (1.41) |
| Median | 6.35 |
| Q1 ; Q3 | 5.10 ; 7.30 |
| Min ; Max | 4.8 ; 8.6 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 6.43 (1.09) |
| Median | 6.30 |
| Q1 ; Q3 | 5.50 ; 7.60 |
| Min ; Max | 5.2 ; 7.7 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 25 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Total bilirubin (TBL) (blood) (umol/L) | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 5.90 (1.77) |
| Median | 5.85 |
| Q1 ; Q3 | 4.10 ; 7.80 |
| Min ; Max | 3.8 ; 8.0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 6.73 (2.56) |
| Median | 6.50 |
| Q1 ; Q3 | 4.30 ; 9.40 |
| Min ; Max | 4.3 ; 9.4 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 5.43 (1.15) |
| Median | 5.40 |
| Q1 ; Q3 | 4.30 ; 6.60 |
| Min ; Max | 4.3 ; 6.6 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 7.30 (2.55) |
| Median | 7.30 |
| Q1 ; Q3 | 5.50 ; 9.10 |
| Min ; Max | 5.5 ; 9.1 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 26 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Total bilirubin (TBL) (blood) (umol/L) | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 3.80 |
| Median | 3.80 |
| Q1 ; Q3 | 3.80 ; 3.80 |
| Min ; Max | 3.8 ; 3.8 |
|  | | | |
| Total protein (blood) (g/L) | Baseline | n | 6 |
| Mean (SD) | 68.17 (4.26) |
| Median | 68.50 |
| Q1 ; Q3 | 64.00 ; 71.00 |
| Min ; Max | 63.0 ; 74.0 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 71.67 (3.72) |
| Median | 70.50 |
| Q1 ; Q3 | 69.00 ; 74.00 |
| Min ; Max | 68.0 ; 78.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 70.67 (7.31) |
| Median | 69.00 |
| Q1 ; Q3 | 64.00 ; 75.00 |
| Min ; Max | 64.0 ; 83.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 27 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Total protein (blood) (g/L) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 71.33 (3.79) |
| Median | 73.00 |
| Q1 ; Q3 | 67.00 ; 74.00 |
| Min ; Max | 67.0 ; 74.0 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 70.67 (2.89) |
| Median | 69.00 |
| Q1 ; Q3 | 69.00 ; 74.00 |
| Min ; Max | 69.0 ; 74.0 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 71.00 (4.24) |
| Median | 71.00 |
| Q1 ; Q3 | 68.00 ; 74.00 |
| Min ; Max | 68.0 ; 74.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 66.00 |
| Median | 66.00 |
| Q1 ; Q3 | 66.00 ; 66.00 |
| Min ; Max | 66.0 ; 66.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 28 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Triglycerides (mmol/L) | Baseline | n | 6 |
| Mean (SD) | 1.10 (0.48) |
| Median | 1.11 |
| Q1 ; Q3 | 0.71 ; 1.24 |
| Min ; Max | 0.5 ; 1.9 |
|  | | | |
|  | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 1.47 (0.82) |
| Median | 1.25 |
| Q1 ; Q3 | 0.84 ; 1.70 |
| Min ; Max | 0.8 ; 3.0 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 1.34 (0.25) |
| Median | 1.34 |
| Q1 ; Q3 | 1.11 ; 1.45 |
| Min ; Max | 1.1 ; 1.7 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 1.68 (1.14) |
| Median | 1.17 |
| Q1 ; Q3 | 0.89 ; 2.99 |
| Min ; Max | 0.9 ; 3.0 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 29 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Triglycerides (mmol/L) | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 1.39 (0.30) |
| Median | 1.22 |
| Q1 ; Q3 | 1.22 ; 1.74 |
| Min ; Max | 1.2 ; 1.7 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 0.91 (0.16) |
| Median | 0.91 |
| Q1 ; Q3 | 0.80 ; 1.02 |
| Min ; Max | 0.8 ; 1.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 1.64 |
| Median | 1.64 |
| Q1 ; Q3 | 1.64 ; 1.64 |
| Min ; Max | 1.6 ; 1.6 |
|  | | | |
| Urea Nitrogen (mmol/L) | Baseline | n | 6 |
| Mean (SD) | 5.47 (1.14) |
| Median | 5.20 |
| Q1 ; Q3 | 5.00 ; 5.80 |
| Min ; Max | 4.1 ; 7.5 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 30 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Urea Nitrogen (mmol/L) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 4.82 (1.54) |
| Median | 4.45 |
| Q1 ; Q3 | 3.60 ; 5.50 |
| Min ; Max | 3.4 ; 7.5 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | 4.95 (1.10) |
| Median | 4.85 |
| Q1 ; Q3 | 4.30 ; 6.00 |
| Min ; Max | 3.4 ; 6.3 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 4.07 (1.12) |
| Median | 3.80 |
| Q1 ; Q3 | 3.10 ; 5.30 |
| Min ; Max | 3.1 ; 5.3 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 4.47 (1.44) |
| Median | 3.90 |
| Q1 ; Q3 | 3.40 ; 6.10 |
| Min ; Max | 3.4 ; 6.1 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 31 of 32 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Urea Nitrogen (mmol/L) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 5.75 (0.35) |
| Median | 5.75 |
| Q1 ; Q3 | 5.50 ; 6.00 |
| Min ; Max | 5.5 ; 6.0 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 5.40 |
| Median | 5.40 |
| Q1 ; Q3 | 5.40 ; 5.40 |
| Min ; Max | 5.4 ; 5.4 |
| Source: Listing 13.1 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-CHEMVAL 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMVAL.sas                                                                                                   Page 32 of 32 | | | |