13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Alanine aminotransferase (U/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 1 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Albumin (g/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 2 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Alkaline phosphatase (U/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 3 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Aspartate aminotransferase (U/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 4 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Calcium (mmol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 5 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Creatinine (Jaffe) (umol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 6 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Gamma-glutamyl transferase (U/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 5 ( 83.3) |
| No tox to Tox increased | 1 ( 16.7) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 5 ( 83.3) |
| No tox to Tox increased | 1 ( 16.7) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 2 ( 66.7) |
| No tox to Tox increased | 1 ( 33.3) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 2 ( 66.7) |
| No tox to Tox increased | 1 ( 33.3) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 1 ( 50.0) |
| No tox to Tox increased | 1 ( 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 7 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Gamma-glutamyl transferase (U/L) | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| Glucose (blood) (mmol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 8 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Glucose (blood) (mmol/L) | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| HDL-cholesterol (mmol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 5 ( 83.3) |
| Tox increased to No tox | 1 ( 16.7) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 5 ( 83.3) |
| Tox increased to No tox | 1 ( 16.7) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                    Page 9 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| HDL-cholesterol (mmol/L) | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 1 ( 50.0) |
| Tox increased to Tox increased | 1 ( 50.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| Potassium (mmol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                   Page 10 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Potassium (mmol/L) | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| Prothrombin time (plasma) (sec) | V5 (OLE Week 2) | n | 5 |
| No tox to No tox | 5 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 5 |
| No tox to No tox | 5 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                   Page 11 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Prothrombin time (plasma) (sec) | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| Sodium (mmol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                   Page 12 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Sodium (mmol/L) | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| Total bilirubin (TBL) (blood) (umol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                   Page 13 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Total bilirubin (TBL) (blood) (umol/L) | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| Total protein (blood) (g/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                   Page 14 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Total protein (blood) (g/L) | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
|  | | | |
| Urea Nitrogen (mmol/L) | V5 (OLE Week 2) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| No tox to No tox | 6 (100.0) |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| No tox to No tox | 3 (100.0) |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| No tox to No tox | 3 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                   Page 15 of 16 | | | |

13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6)   n (%) |
|  | | | |
| Urea Nitrogen (mmol/L) | V11 (OLE Month 12) | n | 2 |
| No tox to No tox | 2 (100.0) |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| No tox to No tox | 1 (100.0) |
| 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-CHEMTOX 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-CHEMTOX.sas                                                                                                   Page 16 of 16 | | | |