**Supplementary Figures and Tables**

**Safety of repeated administration of xenogeneic human apoptotic state (Allocetra-OTS) in Sprague Dawley rats**

**Figure S1: Average Allocetra-OTS concentration vs. time data following IV administration, linear scale**



# **FIGURE LEGENDS**

**Figure S1. Average Allocetra-OTS concentration vs. time data following IV administration, linear scale.** Biodistribution GLP-study results following single IV administration of Allocetra-OTS to ICR mice. The concentration of Allocetra-OTS in different mouse organs, tissues and body fluids was quantified using a highly sensitive quantitative polymerase chain reaction (qPCR) method based on the quantification of human unique Alu sequences. The analysis results are reported as the relative human to mouse DNA concentration

**Table S1: Hematology analysis, Male, Main Study**

| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS 140x106 cells/kg (2M)** | **Allocetra-OTS 700x106 cells/kg (3M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| --- | --- | --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **WBC (10\*3/µL)** | **6.4-18.8** | 6.48 | 0.32 | 10 | 8.06\*\* | 0.42 | 10 | 10.14\*\*\* | 0.66 | 10 | 11.63\*\*\* | 0.54 | 10 |
| **RBC (10\*6/µL)** | **7.8-9.38** | **7.40** | 0.11 | 10 | **7.28** | 0.13 | 10 | **7.17** | 0.08 | 10 | **7.31** | 0.06 | 10 |
| **HGB (g/dL)** | **14.6-16.8** | **14.26** | 0.15 | 10 | **14.37** | 0.21 | 10 | **14.15** | 0.13 | 10 | **14.47** | 0.11 | 10 |
| **Hematocrit (%)** | **45.4-54.1** | 46.78 | 0.58 | 10 | 46.97 | 0.81 | 10 | 45.75 | 0.42 | 10 | 47.04 | 0.53 | 10 |
| **MCV (fL)** | **53.3-62.4** | **63.24** | 0.61 | 10 | **64.56** | 0.61 | 10 | **63.83** | 0.71 | 10 | **64.33** | 0.55 | 10 |
| **MCH (pg)** | **17-19.6** | 19.29 | 0.23 | 10 | **19.78** | 0.18 | 10 | **19.74** | 0.19 | 10 | **19.80** | 0.16 | 10 |
| **MCHC (g/dL)** | **29.6-33.6** | 30.53 | 0.18 | 10 | 30.63 | 0.18 | 10 | 30.93 | 0.18 | 10 | 30.80 | 0.22 | 10 |
| **Neutrophils (%)** | **5.0-31.0** | 18.85 | 1.90 | 10 | 13.93\* | 1.25 | 10 | 13.31\* | 0.71 | 10 | 20.85 | 2.67 | 10 |
| **Bands (%)** | **NA** | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 |
| **Lymphocytes (%)** | **59-93** | 76.63 | 1.89 | 10 | 80.26 | 1.48 | 10 | 80.11 | 1.16 | 10 | 73.61 | 2.73 | 10 |
| **Monocytes (%)** | **0-6** | 2.00 | 0.13 | 10 | 1.87 | 0.15 | 10 | 2.31 | 0.22 | 10 | 2.49\* | 0.12 | 10 |
| **Eosinophils (%)** | **0-4** | 1.40 | 0.19 | 10 | 2.01 | 0.38 | 10 | 2.30 | 0.69 | 10 | 1.08 | 0.11 | 10 |
| **Basophils (%)** | **0-2** | 0.12 | 0.01 | 10 | **0.29\*\*\*** | 0.03 | 10 | **0.31\*\*\*** | 0.02 | 10 | **0.30\*\*\*** | 0.03 | 10 |
| **Platelets (10\*3/µL)** | **453-1081** | 722.20 | 67.15 | 10 | 835.70 | 24.34 | 10 | 795.30 | 51.60 | 10 | 762.00 | 63.97 | 10 |
| **Retic (%)** | **NA** | 3.556 | 0.18 | 10 | 2.98\* | 0.17 | 10 | 3.15 | 0.17 | 10 | 2.28\*\* | 0.30 | 10 |
| **MPV (FI)** |  **NA** | 9.64 | 0.38 | 10 | 8.93 | 0.20 | 10 | 9.46 | 0.22 | 10 | 9.96 | 0.65 | 10 |
| **RDW (%)** |  **NA** | 12.01 | 0.14 | 10 | 11.57\* | 0.11 | 10 | 11.59\* | 0.11 | 10 | 12.52 | 1.19 | 10 |
| **Neutrophils Absolute (10\*3/µL)** |  **NA** | 1.23 | 0.15 | 10 | 1.13 | 0.13 | 10 | 1.33 | 0.08 | 10 | 2.44\*\* | 0.34 | 10 |
| **Bands Absolute (10\*3/µL)** |  **NA** | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 |
| **Lymphocyte Absolute (10\*3/µL)** |  **NA** | 4.96 | 0.26 | 10 | 6.46\*\* | 0.34 | 10 | 8.16\*\*\* | 0.59 | 10 | 8.55\*\*\* | 0.51 | 10 |
| **Monocyte Absolute (10\*3/µL)** |  **NA** | 0.13 | 0.01 | 10 | 0.15 | 0.02 | 10 | 0.24\*\* | 0.03 | 10 | 0.29\*\*\* | 0.01 | 10 |
| **Eosinophils Absolute (10\*3/µL)** |  **NA** | 0.09 | 0.01 | 10 | 0.16 | 0.03 | 10 | 0.21\* | 0.04 | 10 | 0.13 | 0.01 | 10 |
| **Basophils Absolute (10\*3/µL)** |  **NA** | 0.01 | 0.00 | 10 | 0.02\*\*\* | 0.00 | 10 | 0.03\*\*\* | 0.00 | 10 | 0.04\*\*\* | 0.00 | 10 |

M= Male; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1M) using T-test

**Table S2: Hematology analysis, Female, Main Study**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 140x106 cells/kg (2F)** | **Allocetra-OTS** **700 x106 cells/kg (3F)** | **Allocetra-OTS** **1260 x106 cells/kg (4F)** |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **WBC (10\*3/µL)** | **5.3-16.7** | 6.35 | 0.36 | 10 | 6.81 | 0.21 | 10 | 7.43 | 0.50 | 10 | 7.02 | 0.49 | 10 |
| **RBC (10\*6/µL)** | **7.4-9.28** | **7.38** | 0.05 | 10 | **7.37** | 0.10 | 10 | **7.32** | 0.07 | 10 | **7.32** | 0.08 | 10 |
| **HGB (g/dL)** | **14-16.9** | 14.56 | 0.14 | 10 | 14.55 | 0.21 | 10 | 14.39 | 0.14 | 10 | 14.52 | 0.12 | 10 |
| **Hematocrit (%)** | **42.7-52.4** | 45.58 | 0.45 | 10 | 45.68 | 0.62 | 10 | 45.36 | 0.49 | 10 | 45.82 | 0.45 | 10 |
| **MCV (fL)** | **53.1-61.0** | **61.82** | 0.55 | 10 | **62.01** | 0.51 | 10 | **62.05** | 0.90 | 10 | **62.68** | 0.75 | 10 |
| **MCH (pg)** | **17.2-19.8** | 19.77 | 0.17 | 10 | 19.74 | 0.16 | 10 | 19.67 | 0.20 | 10 | **19.87** | 0.13 | 10 |
| **MCHC (g/dL)** | **31.0-34.0** | 32.00 | 0.28 | 10 | 31.88 | 0.22 | 10 | 31.74 | 0.20 | 10 | 31.74 | 0.27 | 10 |
| **Neutrophils (%)** | **5.0-19.0** | **23.10** | 2.34 | 10 | 17.72 | 2.70 | 10 | 15.00\* | 1.57 | 10 | **19.34** | 2.12 | 10 |
| **Bands (%)** | **NA** | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 |
| **Lymphocytes (%)** | **75-90** | **71.54** | 2.32 | 10 | 76.95 | 2.81 | 10 | 78.30\* | 1.53 | 10 | **72.50** | 2.27 | 10 |
| **Monocytes (%)** | **0-5** | 1.32 | 0.17 | 10 | 1.53 | 0.10 | 10 | 1.88\* | 0.17 | 10 | 1.92\*\* | 0.12 | 10 |
| **Eosinophils (%)** | **0-5** | 3.01 | 0.47 | 10 | 2.03 | 0.28 | 10 | 2.65 | 0.31 | 10 | 3.87 | 0.77 | 10 |
| **Basophils (%)** | **0-2** | 0.14 | 0.02 | 10 | **0.27\*\*** | 0.03 | 10 | **0.28\*\*** | 0.03 | 10 | **0.32\*\*\*** | 0.02 | 10 |
| **Platelets (10\*3/µL)** | **550-1140** | 624.70 | 42.34 | 10 | 646.10 | 53.73 | 10 | 701.90 | 18.90 | 10 | 583.90 | 40.10 | 10 |
| **Retic (%)** | **NA** | 2.17 | 0.17 | 10 | 2.19 | 0.08 | 10 | 2.44 | 0.25 | 10 | 2.39 | 0.17 | 10 |
| **MPV (FI)** |  **NA** | 8.84 | 0.41 | 10 | 8.81 | 0.33 | 10 | 8.95 | 0.28 | 10 | 9.61 | 0.31 | 10 |
| **RDW (%)** |  **NA** | 10.75 | 0.22 | 10 | 10.7 | 0.12 | 10 | 10.85 | 0.09 | 10 | 10.71 | 0.08 | 10 |
| **Neutrophils Absolute (10\*3/µL)** |  **NA** | 1.486 | 0.18 | 10 | 1.215 | 0.19 | 10 | 1.117 | 0.14 | 10 | 1.382 | 0.19 | 10 |
| **Bands Absolute (10\*3/µL)** |  **NA** | 0 | 0.00 | 10 | 0 | 0.00 | 10 | 0 | 0.00 | 10 | 0 | 0.00 | 10 |
| **Lymphocyte Absolute (10\*3/µL)** |  **NA** | 4.525 | 0.26 | 10 | 5.234 | 0.22 | 10 | 5.818\* | 0.42 | 10 | 5.082 | 0.36 | 10 |
| **Monocyte Absolute (10\*3/µL)** |  **NA** | 0.084 | 0.01 | 10 | 0.105 | 0.01 | 10 | 0.141\* | 0.02 | 10 | 0.131\*\* | 0.01 | 10 |
| **Eosinophils Absolute (10\*3/µL)** |  **NA** | 0.193 | 0.03 | 10 | 0.141 | 0.02 | 10 | 0.191 | 0.02 | 10 | 0.253 | 0.03 | 10 |
| **Basophils Absolute (10\*3/µL)** |  **NA** | 0.009 | 0.00 | 10 | 0.017\* | 0.00 | 10 | 0.021\*\* | 0.00 | 10 | 0.022\*\* | 0.00 | 10 |

F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1F) using T-test

**Table S3: Hematology analysis, Male, Recovery Phase 14 Days**

| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS** **1260x106 cells/kg (4M)** |
| --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **WBC (10\*3/µL)** | **6.4-18.8** | 7.35 | 1.26 | 5 | 6.47 | 0.88 | 5 |
| **RBC (10\*6/µL)** | **7.8-9.38** | 8.38 | 0.13 | 5 | 7.98 | 0.22 | 5 |
| **HGB (g/dL)** | **14.6-16.8** | 15.14 | 0.28 | 5 | 15.22 | 0.25 | 5 |
| **Hematocrit (%)** | **45.4-54.1** | 49.84 | 1.30 | 5 | 49.08 | 0.87 | 5 |
| **MCV (fL)** | **53.3-62.4** | 59.44 | 1.04 | 5 | 61.58 | 1.16 | 5 |
| **MCH (pg)** | **17-19.6** | 18.10 | 0.37 | 5 | 19.12 | 0.41 | 5 |
| **MCHC (g/dL)** | **29.6-33.6** | 30.42 | 0.40 | 5 | 31.02 | 0.13 | 5 |
| **Neutrophils (%)** | **5.0-31.0** | 18.40 | 1.95 | 5 | 18.60 | 1.94 | 5 |
| **Bands (%)** | **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocytes (%)** | **59-93** | 76.72 | 2.16 | 5 | 76.36 | 2.12 | 5 |
| **Monocytes (%)** | **0-6** | 2.32 | 0.09 | 5 | 1.92 | 0.16 | 5 |
| **Eosinophils (%)** | **0-4** | 1.16 | 0.20 | 5 | 1.90 | 0.34 | 5 |
| **Basophils (%)** | **0-2** | 0.14 | 0.05 | 5 | 0.18 | 0.04 | 5 |
| **Platelets (10\*3/µL)** | **453-1081** | 541.60 | 66.86 | 5 | 465.80 | 59.34 | 5 |
| **Retic (%)** | **NA** | 2.17 | 0.39 | 5 | 2.06 | 0.12 | 5 |
| **MPV (FI)** |  **NA** | 9.76 | 0.93 | 5 | 9.86 | 0.42 | 5 |
| **RDW (%)** |  **NA** | 11.60 | 0.31 | 5 | 11.16 | 0.21 | 5 |
| **Neutrophils Absolute (10\*3/µL)** |  **NA** | 1.35 | 0.26 | 5 | 1.14 | 0.06 | 5 |
| **Bands Absolute (10\*3/µL)** |  **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocyte Absolute (10\*3/µL)** |  **NA** | 5.65 | 1.00 | 5 | 5.01 | 0.83 | 5 |
| **Monocyte Absolute (10\*3/µL)** |  **NA** | 0.17 | 0.03 | 5 | 0.13 | 0.02 | 5 |
| **Eosinophils Absolute (10\*3/µL)** |  **NA** | 0.08 | 0.01 | 5 | 0.12 | 0.02 | 5 |
| **Basophils Absolute (10\*3/µL)** |  **NA** | 0.01 | 0.00 | 5 | 0.01 | 0.00 | 5 |

M= Male; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1M) using T-test

**Table S4: Hematology analysis, Female, Recovery Phase 14 Days**

| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **WBC (10\*3/µL)** | **5.3-16.7** | 6.41 | 0.33 | 5 | 6.16 | 1.01 | 5 |
| **RBC (10\*6/µL)** | **7.4-9.28** | 7.76 | 0.13 | 5 | 8.36\*\* | 0.03 | 5 |
| **HGB (g/dL)** | **14-16.9** | 15.06 | 0.28 | 5 | 15.70 | 0.16 | 5 |
| **Hematocrit (%)** | **42.7-52.4** | 47.22 | 0.77 | 5 | 49.86\* | 0.53 | 5 |
| **MCV (fL)** | **53.1-61.0** | 60.90 | 0.34 | 5 | 59.64 | 0.54 | 5 |
| **MCH (pg)** | **17.2-19.8** | 19.42 | 0.17 | 5 | 18.76\* | 0.14 | 5 |
| **MCHC (g/dL)** | **31.0-34.0** | 31.90 | 0.20 | 5 | 31.48 | 0.07 | 5 |
| **Neutrophils (%)** | **5.0-19.0** | **22.72** | 4.27 | 5 | **25.20** | 5.44 | 5 |
| **Bands (%)** | **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocytes (%)** | **75-90** | **72.18** | 4.15 | 5 | **68.84** | 5.62 | 5 |
| **Monocytes (%)** | **0-5** | 1.72 | 0.29 | 5 | 2.26 | 0.28 | 5 |
| **Eosinophils (%)** | **0-5** | 2.36 | 0.12 | 5 | 2.60 | 0.54 | 5 |
| **Basophils (%)** | **0-2** | 0.16 | 0.02 | 5 | **0.22** | 0.04 | 5 |
| **Platelets (10\*3/µL)** | **550-1140** | 610.80 | 69.28 | 5 | **537.60** | 93.67 | 5 |
| **Retic (%)** | **NA** | 1.67 | 0.19 | 5 | 1.56 | 0.14 | 5 |
| **MPV (FI)** | **NA** | 9.24 | 0.25 | 5 | 10.14 | 1.04 | 5 |
| **RDW %** | **NA** | 10.42 | 0.07 | 5 | 10.56 | 0.26 | 5 |
| **Neutrophils Absolute (10\*3/µL)** | **NA** | 1.45 | 0.29 | 5 | 1.76 | 0.68 | 5 |
| **Bands Absolute (10\*3/µL)** | **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocyte Absolute (10\*3/µL)** | **NA** | 4.63 | 0.35 | 5 | 4.02 | 0.27 | 5 |
| **Monocyte Absolute (10\*3/µL)** | **NA** | 0.11 | 0.02 | 5 | 0.15 | 0.05 | 5 |
| **Eosinophils Absolute (10\*3/µL)** | **NA** | 0.15 | 0.01 | 5 | 0.16 | 0.04 | 5 |
| **Basophils Absolute (10\*3/µL)** | **NA** | 0.01 | 0.00 | 5 | 0.01 | 0.01 | 5 |

F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (F) using T-test

**Table S5: Hematology analysis, Male, Recovery Phase 28 Days**

| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **WBC (10\*3/µL)** | **6.4-18.8** | 7.76 | 0.76 | 5 | 7.87 | 0.25 | 5 |
| **RBC (10\*6/µL)** | **7.8-9.38** | 8.35 | 0.06 | 5 | 8.61 | 0.21 | 5 |
| **HGB (g/dL)** | **14.6-16.8** | 15.50 | 0.04 | 5 | 15.60 | 0.19 | 5 |
| **Hematocrit (%)** | **45.4-54.1** | 48.78 | 0.46 | 5 | 49.08 | 0.69 | 5 |
| **MCV (fL)** | **53.3-62.4** | 58.40 | 0.35 | 5 | 57.12 | 0.97 | 5 |
| **MCH (pg)** | **17-19.6** | 18.68 | 0.10 | 5 | 18.16 | 0.39 | 5 |
| **MCHC (g/dL)** | **29.6-33.6** | 32.00 | 0.14 | 5 | 31.78 | 0.21 | 5 |
| **Neutrophils (%)** | **5.0-31.0** | 21.16 | 5.75 | 5 | 24.16 | 4.70 | 5 |
| **Bands (%)** | **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocytes (%)** | **59-93** | 73.24 | 5.63 | 5 | 69.92 | 4.80 | 5 |
| **Monocytes (%)** | **0-6** | 2.40 | 0.22 | 5 | 2.74 | 0.32 | 5 |
| **Eosinophils (%)** | **0-4** | 1.96 | 0.24 | 5 | 1.96 | 0.61 | 5 |
| **Basophils (%)** | **0-2** | **0.24** | 0.02 | 5 | 0.20 | 0.03 | 5 |
| **Platelets (10\*3/µL)** | **453-1081** | 569.50 | 46.33 | 5 | 520.00 | 107.52 | 5 |
| **Retic (%)** | **NA** | 2.04 | 0.06 | 5 | 2.10 | 0.04 | 5 |
| **MPV (FI)** | **NA** | 7.88 | 0.40 | 5 | 9.40 | 1.57 | 5 |
| **RDW %** | **NA** | 10.82 | 0.08 | 5 | 11.10 | 0.26 | 5 |
| **Neutrophils Absolute (10\*3/µL)** | **NA** | 1.78 | 0.65 | 5 | 1.93 | 0.42 | 5 |
| **Bands Absolute (10\*3/µL)** | **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocyte Absolute (10\*3/µL)** | **NA** | 5.55 | 0.42 | 5 | 5.48 | 0.34 | 5 |
| **Monocyte Absolute (10\*3/µL)** | **NA** | 0.18 | 0.02 | 5 | 0.22 | 0.03 | 5 |
| **Eosinophils Absolute (10\*3/µL)** | **NA** | 0.16 | 0.03 | 5 | 0.15 | 0.04 | 5 |
| **Basophils Absolute (10\*3/µL)** | **NA** | 0.02 | 0.00 | 5 | 0.02 | 0.00 | 5 |

M= Male; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1M) using T-test

**Table S6: Hematology analysis, Female, Recovery Phase 28 Days**

| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **WBC (10\*3/µL)** | **5.3-16.7** | 5.58 | 0.44 | 5 | 5.56 | 0.48 | 5 |
| **RBC (10\*6/µL)** | **7.4-9.28** | 8.25 | 0.23 | 5 | 7.99 | 0.09 | 5 |
| **HGB (g/dL)** | **14-16.9** | 15.30 | 0.23 | 5 | 15.10 | 0.20 | 5 |
| **Hematocrit (%)** | **42.7-52.4** | 47.26 | 1.00 | 5 | 46.16 | 0.70 | 5 |
| **MCV (fL)** | **53.1-61.0** | 57.34 | 0.52 | 5 | 57.70 | 0.31 | 5 |
| **MCH (pg)** | **17.2-19.8** | 18.58 | 0.26 | 5 | 18.86 | 0.07 | 5 |
| **MCHC (g/dL)** | **31.0-34.0** | 32.42 | 0.22 | 5 | 32.68 | 0.14 | 5 |
| **Neutrophils (%)** | **5.0-19.0** | 17.40 | 3.28 | 5 | **25.78** | 4.82 | 5 |
| **Bands (%)** | **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocytes (%)** | **75-90** | 77.70 | 3.23 | 5 | **69.12** | 4.81 | 5 |
| **Monocytes (%)** | **0-5** | 2.06 | 0.28 | 5 | 1.60 | 0.18 | 5 |
| **Eosinophils (%)** | **0-5** | 1.88 | 0.22 | 5 | 2.66 | 0.85 | 5 |
| **Basophils (%)** | **0-2** | 0.16 | 0.02 | 5 | 0.16 | 0.02 | 5 |
| **Platelets (10\*3/µL)** | **550-1140** | 717.80 | 55.14 | 5 | 611.60 | 35.98 | 5 |
| **Retic (%)** | **NA** | 1.64 | 0.16 | 5 | 1.63 | 0.16 | 5 |
| **MPV (FI)** | **NA** | 7.66 | 0.06 | 5 | 8.38 | 0.43 | 5 |
| **RDW %** | **NA** | 10.38 | 0.13 | 5 | 10.72 | 0.14 | 5 |
| **Neutrophils Absolute (10\*3/µL)** | **NA** | 0.92 | 0.11 | 5 | 1.45 | 0.33 | 5 |
| **Bands Absolute (10\*3/µL)** | **NA** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |
| **Lymphocyte Absolute (10\*3/µL)** | **NA** | 4.39 | 0.51 | 5 | 3.82 | 0.35 | 5 |
| **Monocyte Absolute (10\*3/µL)** | **NA** | 0.11 | 0.02 | 5 | 0.09 | 0.02 | 5 |
| **Eosinophils Absolute (10\*3/µL)** | **NA** | 0.10 | 0.01 | 5 | 0.15 | 0.05 | 5 |
| **Basophils Absolute (10\*3/µL)** | **NA** | 0.01 | 0.00 | 5 | 0.01 | 0.00 | 5 |

F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1F) using T-test

**Table S7: Clinical chemistry, Male, Main Study**

| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS 140x106 cells/kg (2M)** | **Allocetra-OTS 700x106 cells/kg (3M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| --- | --- | --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **Average** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Creatinine (mg/dL)** | **0.27-0.65** | **0.26** | 0.01 | 10 | **0.26** | 0.01 | 10 | 0.28 | 0.02 | 10 | 0.27 | 0.01 | 10 |
| **Calcium (mg/dL)** | **9.92-12.28** | 11.97 | 0.06 | 10 | 11.80 | 0.11 | 10 | 11.76\* | 0.06 | 10 | 11.83 | 0.08 | 10 |
| **Phosphorus(mg/dL)** | **8.1-12.1** | 9.36 | 0.17 | 10 | 9.39 | 0.17 | 10 | 9.55 | 0.19 | 10 | 9.94\* | 0.14 | 10 |
| **Glucose (mg/dL)** | **50-140** | 135.60 | 2.20 | 10 | **141.00** | 2.78 | 10 | 133.80 | 1.08 | 10 | 135.10 | 2.67 | 10 |
| **Urea (mg/dL)** | **29.3-59.2** | 35.04 | 1.00 | 10 | 32.55 | 0.73 | 10 | 30.56\*\* | 0.98 | 10 | 32.42 | 0.99 | 10 |
| **Cholesterol (mg/dL)** | **79-137** | **152.60** | 3.71 | 10 | **138.00\*** | 4.74 | 10 | **141.30\*** | 3.43 | 10 | 135.70\*\* | 4.13 | 10 |
| **Total Protein (g/dL)** | **5.92-7.46** | 6.53 | 0.05 | 10 | 6.36\* | 0.04 | 10 | 6.40\* | 0.03 | 10 | 6.33\* | 0.05 | 10 |
| **Albumin (g/dL)** | **3.96-4.73** | 4.72 | 0.04 | 10 | 4.62 | 0.05 | 10 | 4.58\* | 0.04 | 10 | 4.35\*\*\* | 0.06 | 10 |
| **Globulin (g/dL)** | **1.69-3.01** | 1.81 | 0.05 | 10 | 1.74 | 0.04 | 10 | 1.82 | 0.05 | 10 | 1.98\* | 0.04 | 10 |
| **Alb/Glob (Ratio)** | **-** | 2.63 | 0.09 | 10 | 2.67 | 0.09 | 10 | 2.55 | 0.09 | 10 | 2.21\*\* | 0.07 | 10 |
| **Total Bilirubin (mg/dL)** | **0.03-0.18** | 0.05 | 0.00 | 10 | 0.04 | 0.00 | 10 | 0.05 | 0.00 | 10 | 0.05 | 0.01 | 10 |
| **Alkaline Phosphatase (IU/L)** | **81-197** | **247.60** | 10.20 | 10 | **222.70** | 8.02 | 10 | **230.20** | 6.83 | 10 | **236.40** | 5.07 | 10 |
| **LDH (IU/L)** | **0-2990** | 443.30 | 41.82 | 10 | 451.90 | 46.54 | 10 | 517.10 | 44.33 | 10 | 416.10 | 33.99 | 10 |
| **SGOT (IU/L)** | **57-210** | 97.30 | 3.62 | 10 | 94.30 | 1.87 | 10 | 103.00 | 7.26 | 10 | 88.50 | 2.35 | 10 |
| **SGPT (IU/L)** | **30-106** | 59.50 | 2.80 | 10 | 57.40 | 1.09 | 10 | 60.30 | 3.11 | 10 | 55.30 | 1.19 | 10 |
| **Triglycerides (mg/dL)** | **21-86** | **93.30** | 8.19 | 10 | 84.60 | 8.50 | 10 | **87.10** | 8.35 | 10 | 80.50 | 3.80 | 10 |
| **CPK (IU/L)** | **0-2296** | 589.10 | 75.47 | 10 | 656.10 | 80.06 | 10 | 656.40 | 55.39 | 10 | 690.00 | 100.13 | 10 |
| **Na (mmol/L)** | **142-147** | 142.00 | 0.26 | 10 | 142.10 | 0.38 | 10 | 142.00 | 0.26 | 10 | 142.10 | 0.31 | 10 |
| **K (mmol/L)** | **5.3-7.3** | 6.05 | 0.09 | 10 | 5.89 | 0.06 | 10 | 5.77\* | 0.08 | 10 | 5.89 | 0.07 | 10 |
| **Chloride (mmol/L)** | **94-101** | 99.10 | 0.38 | 10 | 99.20 | 0.42 | 10 | 99.40 | 0.45 | 10 | 99.20 | 0.33 | 10 |
| **GGTP (IU/L)** | **0-1** | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 |

M= Male; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1M) using T-test

**Table S8: Clinical chemistry, Female, Main Study**

| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 140x106 cells/kg (2F)** | **Allocetra-OTS 700x106 cells/kg (3F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| --- | --- | --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Creatinine (mg/dL)** | **0.28-0.65** | **0.27** | 0.01 | 10 | 0.28 | 0.01 | 10 | 0.29\* | 0.01 | 10 | 0.30 | 0.01 | 10 |
| **Calcium (mg/dL)** | **10.16-12.03** | 11.72 | 0.09 | 10 | 11.97 | 0.10 | 10 | 11.72 | 0.09 | 10 | 11.80 | 0.11 | 10 |
| **Phosphorus(mg/dL)** | **7.1-11.6** | 9.25 | 0.26 | 10 | 9.20 | 0.30 | 10 | 8.79 | 0.11 | 10 | 9.52 | 0.28 | 10 |
| **Glucose (mg/dL)** | **52-132** | 127.90 | 2.24 | 10 | **136.20** | 3.60 | 10 | **139.56\*\*** | 1.78 | 10 | **136.10\*** | 2.44 | 10 |
| **Urea (mg/dL)** | **28.8-61.3** | 33.19 | 1.16 | 10 | 34.03 | 1.26 | 10 | 31.07 | 1.71 | 10 | 30.89 | 1.20 | 10 |
| **Cholesterol (mg/dL)** | **71-148** | 130.10 | 4.66 | 10 | 133.50 | 6.14 | 10 | 130.90 | 4.36 | 10 | 133.30 | 5.65 | 10 |
| **Total Protein (g/dL)** | **6-7.31** | 6.44 | 0.05 | 10 | 6.36 | 0.08 | 10 | 6.41 | 0.08 | 10 | 6.52 | 0.06 | 10 |
| **Albumin (g/dL)** | **4.20-4.99** | 4.84 | 0.06 | 10 | 4.74 | 0.05 | 10 | 4.65\* | 0.06 | 10 | 4.61\*\* | 0.05 | 10 |
| **Globulin (g/dL)** | **1.59-2.54** | 1.60 | 0.05 | 10 | 1.62 | 0.06 | 10 | 1.76\* | 0.05 | 10 | 1.91\*\*\* | 0.04 | 10 |
| **Alb/Glob (Ratio)** | **-** | 3.06 | 0.12 | 10 | 2.97 | 0.13 | 10 | 2.66\* | 0.09 | 10 | 2.43\*\*\* | 0.06 | 10 |
| **Total Bilirubin (mg/dL)** | **0.04-0.21** | **0.03** | 0.00 | 10 | **0.03** | 0.01 | 10 | 0.04 | 0.00 | 10 | **0.03** | 0.01 | 10 |
| **Alkaline Phosphatase (IU/L)** | **50-153** | **185.30** | 8.30 | 10 | **192.00** | 11.33 | 10 | **176.60** | 7.69 | 10 | **174.00** | 8.50 | 10 |
| **LDH (IU/L)** | **0-3062** | 727.60 | 60.05 | 10 | 524.80\* | 56.97 | 10 | 574.20 | 52.68 | 10 | 481.80\*\* | 30.67 | 10 |
| **SGOT (IU/L)** | **70-178** | 109.60 | 3.34 | 10 | 98.20\* | 2.79 | 10 | 98.70\* | 3.83 | 10 | 102.40 | 5.12 | 10 |
| **SGPT (IU/L)** | **30-82** | 56.30 | 2.81 | 10 | 55.80 | 2.57 | 10 | 48.60\* | 1.75 | 10 | 51.00 | 1.62 | 10 |
| **Triglycerides (mg/dL)** | **16-77** | 73.00 | 4.53 | 10 | 64.30 | 2.88 | 10 | 65.70 | 5.33 | 10 | 64.40 | 4.82 | 10 |
| **CPK (IU/L)** | **0-1595** | 1094.00 | 246.38 | 10 | 619.50 | 73.75 | 10 | 696.30 | 82.55 | 10 | 891.50 | 294.61 | 10 |
| **Na (mmol/L)** | **141-148** | **139.30** | 0.37 | 10 | **139.60** | 0.40 | 10 | **140.80\*\*** | 0.13 | 10 | **139.90** | 0.46 | 10 |
| **K (mmol/L)** | **5.1-6.8** | 5.68 | 0.08 | 10 | 5.63 | 0.06 | 10 | 5.78 | 0.06 | 10 | 5.72 | 0.07 | 10 |
| **Chloride (mmol/L)** | **94-104** | 99.30 | 0.40 | 10 | 99.20 | 0.47 | 10 | 99.70 | 0.40 | 10 | 99.60 | 0.37 | 10 |
| **GGTP (IU/L)** | **0-1** | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 | 0.00 | 0.00 | 10 |

F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1F) using T-test

**Table S9: Clinical chemistry, Male, Recovery 14 Days Phase**

| **Group** | **Normal range** | **Vehicle (1M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Creatinine (mg/dL)** | **0.27-0.65** | 0.31 | 0.02 | 5 | 0.31 | 0.01 | 5 |
| **Calcium (mg/dL)** | **9.92-12.28** | 11.89 | 0.06 | 5 | 11.92 | 0.10 | 5 |
| **Phosphorus(mg/dL)** | **8.1-12.1** | 8.90 | 0.20 | 5 | 9.10 | 0.16 | 5 |
| **Glucose (mg/dL)** | **50-140** | **140.40** | 3.53 | 5 | **142.80** | 2.35 | 5 |
| **Urea (mg/dL)** | **29.3-59.2** | 35.10 | 1.11 | 5 | 35.92 | 1.66 | 5 |
| **Cholesterol (mg/dL)** | **79-137** | **141.00** | 4.86 | 5 | 135.40 | 8.12 | 5 |
| **Total Protein (g/dL)** | **5.92-7.46** | 6.90 | 0.04 | 5 | 6.85 | 0.19 | 5 |
| **Albumin (g/dL)** | **3.96-4.73** | 4.70 | 0.11 | 5 | 4.56 | 0.10 | 5 |
| **Globulin (g/dL)** | **1.69-3.01** | 2.20 | 0.09 | 5 | 2.29 | 0.13 | 5 |
| **Alb/Glob (Ratio)** | **-** | 2.16 | 0.13 | 5 | 2.01 | 0.12 | 5 |
| **Total Bilirubin (mg/dL)** | **0.03-0.18** | 0.04 | 0.00 | 5 | 0.03 | 0.00 | 5 |
| **Alkaline Phosphatase (IU/L)** | **81-197** | **262.60** | 13.95 | 5 | **231.20** | 8.47 | 5 |
| **LDH (IU/L)** | **0-2990** | 564.60 | 102.31 | 5 | 442.20 | 58.71 | 5 |
| **SGOT (IU/L)** | **57-210** | 106.80 | 7.52 | 5 | 98.60 | 2.40 | 5 |
| **SGPT (IU/L)** | **30-106** | 66.80 | 3.79 | 5 | 69.20 | 2.65 | 5 |
| **Triglycerides (mg/dL)** | **21-86** | **94.00** | 6.19 | 5 | **110.40** | 8.87 | 5 |
| **CPK (IU/L)** | **0-2296** | 635.60 | 67.43 | 5 | 682.40 | 157.40 | 5 |
| **Na (mmol/L)** | **142-147** | 142.00 | 0.55 | 5 | 142.80 | 0.58 | 5 |
| **K (mmol/L)** | **5.3-7.3** | 5.88 | 0.12 | 5 | 5.54\* | 0.07 | 5 |
| **Chloride (mmol/L)** | **94-101** | 100.60 | 0.60 | 5 | **101.20** | 0.58 | 5 |
| **GGTP (IU/L)** | **0-1** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |

M= Male; AVG= Average; SEM= Standard Error of the Mean; N= Number; \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1M) using T-test

**Table S10: Clinical chemistry, Female, Recovery 14 Days Phase**

| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Creatinine (mg/dL)** | **0.28-0.65** | 0.33 | 0.01 | 5 | 0.33 | 0.03 | 5 |
| **Calcium (mg/dL)** | **10.16-12.03** | 11.40 | 0.19 | 5 | 11.68 | 0.16 | 5 |
| **Phosphorus(mg/dL)** | **7.1-11.6** | 8.68 | 0.16 | 5 | 8.22 | 0.49 | 5 |
| **Glucose (mg/dL)** | **52-132** | **138.80** | 3.84 | 5 | **152.20** | 9.14 | 5 |
| **Urea (mg/dL)** | **28.8-61.3** | 37.94 | 2.35 | 5 | 37.40 | 1.40 | 5 |
| **Cholesterol (mg/dL)** | **71-148** | 129.80 | 7.00 | 5 | 142.40 | 12.15 | 5 |
| **Total Protein (g/dL)** | **6-7.31** | 6.72 | 0.10 | 5 | 6.91 | 0.09 | 5 |
| **Albumin (g/dL)** | **4.20-4.99** | 4.78 | 0.10 | 5 | 4.98 | 0.07 | 5 |
| **Globulin (g/dL)** | **1.59-2.54** | 1.94 | 0.07 | 5 | 1.93 | 0.10 | 5 |
| **Alb/Glob (Ratio)** | **-** | 2.47 | 0.11 | 5 | 2.61 | 0.16 | 5 |
| **Total Bilirubin (mg/dL)** | **0.04-0.21** | 0.04 | 0.01 | 5 | 0.04 | 0.01 | 5 |
| **Alkaline Phosphatase (IU/L)** | **50-153** | **192.80** | 7.96 | 5 | **200.40** | 8.29 | 5 |
| **LDH (IU/L)** | **0-3062** | 792.20 | 66.21 | 5 | 547.20\* | 49.79 | 5 |
| **SGOT (IU/L)** | **70-178** | 110.40 | 4.93 | 5 | 168.80 | 72.32 | 5 |
| **SGPT (IU/L)** | **30-82** | 68.60 | 4.20 | 5 | **96.80** | 37.21 | 5 |
| **Triglycerides (mg/dL)** | **16-77** | 58.40 | 4.83 | 5 | 69.40 | 7.70 | 5 |
| **CPK (IU/L)** | **0-1595** | 1298.60 | 414.49 | 5 | 907.80 | 188.42 | 5 |
| **Na (mmol/L)** | **141-148** | 141.80 | 0.49 | 5 | 142.20 | 0.58 | 5 |
| **K (mmol/L)** | **5.1-6.8** | 5.50 | 0.11 | 5 | 5.50 | 0.13 | 5 |
| **Chloride (mmol/L)** | **94-104** | 101.80 | 0.80 | 5 | 102.20 | 0.66 | 5 |
| **GGTP (IU/L)** | **0-1** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |

F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number

 \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1F) using T-test

**Table S11: Clinical chemistry, Male, Recovery 28 Days Phase**

| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Creatinine (mg/dL)** | **0.27-0.65** | 0.29 | 0.07 | 5 | 0.27 | 0.05 | 5 |
| **Calcium (mg/dL)** | **9.92-12.28** | 11.53 | 0.15 | 5 | 11.55 | 0.05 | 5 |
| **Phosphorus(mg/dL)** | **8.1-12.1** | 8.40 | 0.19 | 5 | 8.60 | 0.12 | 5 |
| **Glucose (mg/dL)** | **50-140** | 132.60 | 2.84 | 5 | 134.60 | 4.12 | 5 |
| **Urea (mg/dL)** | **29.3-59.2** | 37.60 | 0.93 | 5 | 36.70 | 1.35 | 5 |
| **Cholesterol (mg/dL)** | **79-137** | **145.00** | 7.86 | 5 | 132.80 | 13.92 | 5 |
| **Total Protein (g/dL)** | **5.92-7.46** | 7.01 | 0.11 | 5 | 6.95 | 0.09 | 5 |
| **Albumin (g/dL)** | **3.96-4.73** | 4.32 | 0.06 | 5 | 4.24 | 0.05 | 5 |
| **Globulin (g/dL)** | **1.69-3.01** | 2.69 | 0.11 | 5 | 2.71 | 0.12 | 5 |
| **Alb/Glob (Ratio)** |  | 1.62 | 0.07 | 5 | 1.58 | 0.09 | 5 |
| **Total Bilirubin (mg/dL)** | **0.03-0.18** | 0.05 | 0.01 | 5 | 0.06 | 0.00 | 5 |
| **Alkaline Phosphatase (IU/L)** | **81-197** | **230.20** | 16.21 | 5 | **223.80** | 15.59 | 5 |
| **LDH (IU/L)** | **0-2990** | 442.20 | 73.70 | 5 | 331.20 | 44.46 | 5 |
| **SGOT (IU/L)** | **57-210** | 103.00 | 6.58 | 5 | 99.40 | 3.63 | 5 |
| **SGPT (IU/L)** | **30-106** | 71.60 | 2.62 | 5 | 75.40 | 2.94 | 5 |
| **Triglycerides (mg/dL)** | **21-86** | 76.40 | 5.30 | 5 | 81.40 | 5.14 | 5 |
| **CPK (IU/L)** | **0-2296** | 523.60 | 144.03 | 5 | 458.60 | 82.52 | 5 |
| **Na (mmol/L)** | **142-147** | **140.00** | 0.55 | 5 | **141.40** | 0.93 | 5 |
| **K (mmol/L)** | **5.3-7.3** | 5.70 | 0.07 | 5 | 5.64 | 0.07 | 5 |
| **Chloride (mmol/L)** | **94-101** | 96.20 | 1.32 | 5 | 96.60 | 1.69 | 5 |
| **GGTP (IU/L)** | **0-1** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |

M= Male; AVG= Average; SEM= Standard Error of the Mean; N= Number

 \*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1M) using T-test

**Table S12: Clinical chemistry, Female, Recovery 28 Days Phase**

|  |  |  |  |
| --- | --- | --- | --- |
| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Creatinine (mg/dL)** | **0.28-0.65** | 0.35 | 0.01 | 5 | 0.36 | 0.01 | 5 |
| **Calcium (mg/dL)** | **10.16-12.03** | 11.28 | 0.14 | 5 | 11.32 | 0.10 | 5 |
| **Phosphorus(mg/dL)** | **7.1-11.6** | 8.20 | 0.43 | 5 | 7.70 | 0.35 | 5 |
| **Glucose (mg/dL)** | **52-132** | **135.40** | 2.42 | 5 | **136.60** | 4.57 | 5 |
| **Urea (mg/dL)** | **28.8-61.3** | 38.62 | 1.13 | 5 | 40.28 | 1.87 | 5 |
| **Cholesterol (mg/dL)** | **71-148** | 114.60 | 4.40 | 5 | 131.40 | 10.33 | 5 |
| **Total Protein (g/dL)** | **6-7.31** | 6.80 | 0.17 | 5 | 7.00 | 0.07 | 5 |
| **Albumin (g/dL)** | **4.20-4.99** | 4.56 | 0.10 | 5 | 4.54 | 0.02 | 5 |
| **Globulin (g/dL)** | **1.59-2.54** | 2.24 | 0.08 | 5 | 2.46 | 0.09 | 5 |
| **Alb/Glob (Ratio)** | **-** | 2.05 | 0.06 | 5 | 1.86 | 0.08 | 5 |
| **Total Bilirubin (mg/dL)** | **0.04-0.21** | 0.05 | 0.01 | 5 | 0.06 | 0.01 | 5 |
| **Alkaline Phosphatase (IU/L)** | **50-153** | **203.60** | 20.69 | 5 | **194.40** | 16.27 | 5 |
| **LDH (IU/L)** | **0-3062** | 539.20 | 68.21 | 5 | 545.80 | 60.20 | 5 |
| **SGOT (IU/L)** | **70-178** | 104.20 | 5.58 | 5 | 104.00 | 4.79 | 5 |
| **SGPT (IU/L)** | **30-82** | 64.60 | 0.87 | 5 | 73.00 | 4.16 | 5 |
| **Triglycerides (mg/dL)** | **16-77** | 64.60 | 2.20 | 5 | 55.00 | 4.36 | 5 |
| **CPK (IU/L)** | **0-1595** | 527.40 | 84.15 | 5 | **1651.20** | 586.67 | 5 |
| **Na (mmol/L)** | **141-148** | **140.80** | 0.20 | 5 | **140.60** | 0.24 | 5 |
| **K (mmol/L)** | **5.1-6.8** | 5.50 | 0.05 | 5 | 5.48 | 0.10 | 5 |
| **Chloride (mmol/L)** | **94-104** | 99.60 | 0.68 | 5 | 99.60 | 0.68 | 5 |
| **GGTP (IU/L)** | **0-1** | 0.00 | 0.00 | 5 | 0.00 | 0.00 | 5 |

F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number

\*p<0.05, \*\*p<0.01, \*\*\*p<0.001 compared to Vehicle (1F) using T-test

**Table S13: Coagulation, Males and Females, Main study**

| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS 140x106 cells/kg (2M)** | **Allocetra-OTS 700x106 cells/kg (3M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| --- | --- | --- | --- | --- | --- |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Fibrinogen (mg/dL)** | **NA** | 191.00 | 14.20 | 10 | 201.90 | 16.14 | 10 | 232.90\* | 12.17 | 10 | 277.56\*\* | 16.51 | 10 |
| **PT (sec)** | **10-17.1** | 10.45 | 0.18 | 10 | 10.45 | 0.17 | 10 | 10.27 | 0.08 | 10 | 10.14 | 0.05 | 10 |
| **aPTT (sec)** | **12.2-42.6** | 14.03 | 0.68 | 10 | 14.18 | 0.58 | 10 | 16.16 | 0.91 | 10 | 15.89\* | 0.54 | 10 |
| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 140x106 cells/kg (2F)** | **Allocetra-OTS 700x106 cells/kg (3F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Fibrinogen (mg/dL)** | **NA** | 209.4 | 14.68 | 10 | 244.5 | 8.31 | 10 | 232.9 | 11.12 | 10 | 209.6 | 16.98 | 10 |
| **PT (sec)** | **10-17.1** | 10.43 | 0.19 | 10 | 10.22 | 0.06 | 10 | 10.4 | 0.09 | 10 | 10.57 | 0.18 | 10 |
| **aPTT (sec)** | **12.2-42.6** | 15.27 | 0.63 | 10 | 15.89 | 1.08 | 10 | 15.54 | 0.86 | 10 | 14.41 | 1.35 | 10 |

M= Male; F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number, NA=Not Applicable

\*p<0.05, \*\*p<0.01 compared to Vehicle (1M) using T-test

**Table S14: Coagulation, Males and Females, Recovery 14 Days Phase**

|  |  |  |  |
| --- | --- | --- | --- |
| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Fibrinogen (mg/dL)** | **NA**  | 257.40 | 6.70 | 5 | 243.00 | 14.46 | 5 |
| **PT (sec)** | **10-17.1** | 10.30 | 0.03 | 5 | 10.38 | 0.07 | 5 |
| **aPTT (sec)** | **12.2-42.6** | 14.80 | 0.44 | 5 | 15.20 | 0.29 | 5 |
| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Fibrinogen (mg/dL)** | **NA**  | 202.80 | 8.56 | 5 | 203.60 | 13.64 | 5 |
| **PT (sec)** | **10-17.1** | 10.34 | 0.09 | 5 | 10.34 | 0.13 | 5 |
| **aPTT (sec)** | **12.2-42.6** | 18.14 | 0.74 | 5 | 16.96 | 0.65 | 5 |

M= Male; F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number, NA=Not Applicable

**Table S15: Coagulation, Males and Females, Recovery 28 Days Phase**

|  |  |  |  |
| --- | --- | --- | --- |
| **Group** | **Normal Range** | **Vehicle (1M)** | **Allocetra-OTS 1260x106 cells/kg (4M)** |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Fibrinogen (mg/dL)** | **NA** | 252.80 | 13.47 | 5 | 239.6 | 19.48 | 5 |
| **PT (sec)** | **10-17.1** | 10.28 | 0.12 | 5 | 10.42 | 0.17 | 5 |
| **aPTT (sec)** | **12.2-42.6** | 15.64 | 0.46 | 5 | 17.62\*\* | 0.30 | 5 |
| **Group** | **Normal Range** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells/kg (4F)** |
| **AVG** | **SEM** | **N** | **AVG** | **SEM** | **N** |
| **Fibrinogen (mg/dL)** | **NA** | 225.6 | 7.33 | 5 | 223.2 | 17.30 | 5 |
| **PT (sec)** | **10-17.1** | **9.88** | 0.04 | 5 | 10.06 | 0.10 | 5 |
| **aPTT (sec)** | **12.2-42.6** | 15.08 | 0.12 | 5 | 15.98 | 0.56 | 5 |

M= Male; F= Female; AVG= Average; SEM= Standard Error of the Mean; N= Number; NA=Not Applicable \*\*p<0.01 compared to Vehicle (1M) using T-test

**Table S16: Individual histopathological findings- Male Main Study (Group 1M)**

| **Block No.** | **Group/Animal****Tissue Name** | **Vehicle (1M)** |
| --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** | **81** | **82** | **83** | **84** | **85** |
| **1** | **Heart (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Lungs (TS x 2)** |  | 0 | 0 |  |  | 0 | 0 | 0 | 0 | 0 |
| *Alveolar histiocytosis* | 1 |  |  | 1 | 1 |  |  |  |  |  |
| *Crystals* |  |  |  |  |  |  |  |  |  |  |
| **2** | **Liver (Left and median lobes x2)** |  | 0 |  |  | 0 |  |  |  |  |  |
| *Extramedullary hematopoiesis* | 1 |  | 1 | 1 |  | 1 | 1 | 1 | 1 | 1 |
| *Hepato-diaphragmatic nodule* |  |  |  |  |  |  |  |  |  | 2 |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **3** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **4** | **Brain (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **5** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **6** | **Kidneys (Left LS x 1,****Right TS x1)** | 0 | 0 | 0 |  |  | 0 | 0 |  |  |  |
| *Nephropathy* |  |  |  | 1 | 1 |  |  | 1 | 1 | 1 |
| **Urinary bladder** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **7** | **Testes (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **8** | **Thymus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **9** | **Injection Site (Tail TS x 3)** |  |  |  |  | 0 |  |  |  |  |  |
| *Perivascular - hemorrhage* | 1 | 2 | 2 | 1 |  | 2 |  | 2 | 2 | 2 |
| *Perivascular - inflammation* | 1 | 2 | 2 | 1 |  | 1 | 1 | 2 | 2 | 1 |
| **10** | **Aorta (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Trachea (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Esophagus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **11** | **Pancreas** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mesenteric Lymph Nodes** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mesentery** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **12** | **Stomach** **(Cardia/ Fundic/ Pylorus LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Duodenum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Jejunum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Ileum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **13** | **Caecum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Colon (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Rectum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **14** | **Males – Skin (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Muscle (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **15** | **Salivary Glands****(Mandibular LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mandibular Lymph Nodes** |  |  |  |  |  |  |  |  |  |  |
| *Lymphoid follicles – increased cellularity* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **16** | **Pituitary** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **17** | **Adrenals** | 0 | 0 | 0 | 0 |  | 0 | 0 | 0 | 0 | 0 |
| *Accessory nodules*  |  |  |  |  | 1 |  |  |  |  |  |
| **18** | **Thyroids**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Parathyroids** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **19** | **Eyes** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Optic Nerves (x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **20** | **Sciatic Nerve (LS x 1, TS x 1)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **21** | **Spinal Cord (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **22** | **Epididymis (LS whole x 2)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **23** | **Seminal Vesicles (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Prostate (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **24** | **Sternum/ Bone Marrow** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **25** | **Femur (femoro-tibial joint)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S17: Individual histopathological findings- Male Main study (Group 2M)**

| **Block No.** | **Group/Animal****Tissue Name** | **Allocetra-OTS 140x106 cells /kg (2M)** |
| --- | --- | --- |
| **6** | **7** | **8** | **9** | **10** | **86** | **87** | **88** | **89** | **90** |
| 2 | **Liver (Left and median lobes x2)** |  |  | 0 |  | 0 |  |  |  |  | 0 |
| *Extramedullary hematopoiesis* | 1 | 1 |  | 1 |  | 1 | 1 | 1 | 1 |  |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| *Red pulp – single cell necrosis (apoptosis)* | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S18: Individual histopathological findings- Male Main study (Group 3M)**

| **Block No.** | **Group/Animal****Tissue Name** | **Allocetra-OTS 700x106 cells /kg (3M)** |
| --- | --- | --- |
| **21** | **22** | **23** | **24** | **25** | **91** | **92** | **93** | **94** | **95** |
| 2 | **Liver (Left and median lobes x2)** |  |  |  |  |  |  |  |  |  |  |
| *Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| *Red pulp – single cell necrosis (apoptosis)* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S19: Individual histopathological findings- Male Main Study (Group 4M)**

| **Block No.** | **Group/Animal****Tissue Name** | **Allocetra-OTS 1260x106 cells /kg (4M)** |
| --- | --- | --- |
| **26** | **27** | **28** | **29** | **30** | **96** | **97** | **98** | **99** | **100** |
| **1** | **Heart (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Lungs (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *Alveolar histiocytosis* |  |  |  |  |  |  |  |  |  |  |
| *Crystals* |  |  |  |  |  |  |  |  |  |  |
| **2** | **Liver (Left and median lobes x2)** |  |  |  |  | 0 |  |  |  |  |  |
| *Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 |  | 1 | 1 | 1 | 1 | 1 |
| *Hepato-diaphragmatic nodule* |  | 2 | 2 |  |  |  |  | 2 |  |  |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| *Red pulp – single cell necrosis (apoptosis)* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **3** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **4** | **Brain (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **5** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **6** | **Kidneys (Left LS x 1,** **Right TS x1)** | 0 | 0 |  | 0 |  | 0 | 0 | 0 | 0 |  |
| *Nephropathy* |  |  | 1 |  | 1 |  |  |  |  | 1 |
| **Urinary bladder** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **7** | **Testes (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **8** | **Thymus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **9** | **Injection Site (Tail TS x 3)** |  |  |  |  |  |  |  |  |  |  |
| *Perivascular - hemorrhage* | 2 | 1 | 1 | 1 | 2 | 1 | 1 | 2 | 2 | 2 |
| *Perivascular - inflammation* | 1 | 2 | 2 | 1 | 1 | 2 | 1 | 2 | 2 | 2 |
| **10** | **Aorta (TS)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Trachea (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Esophagus (TS)** | 0 | 0 | 0 | 0 | 0 | M | 0 | 0 | 0 | 0 |
| **11** | **Pancreas** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mesenteric Lymph Nodes** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mesentery** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **12** | **Stomach (Cardia/ Fundic/ Pylorus LS x 2)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Duodenum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Jejunum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Ileum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **13** | **Caecum (TS)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Colon (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Rectum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **14** | **Males – Skin (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Muscle (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **15** | **Salivary Glands** **(Mandibular LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mandibular Lymph Nodes** |  |  |  |  |  |  |  |  |  |  |
| *Lymphoid follicles – increased cellularity*  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **16** | **Pituitary** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **17** | **Adrenals** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **18** | **Thyroids** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Parathyroids** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | M | 0 |
| **19** | **Eyes** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Optic Nerves (x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **20** | **Sciatic Nerve (LS x 1, TS x 1)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **21** | **Spinal Cord (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **22** | **Epididymis (LS whole x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **23** | **Seminal Vesicles (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Prostate (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **24** | **Sternum/ Bone Marrow** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **25** | **Femur (femoro-tibial joint)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Table S20: Individual histopathological findings- Female Main Study (Group 1F)**

| **Block No.** | **Group/Animal****Tissue Name** | **Vehicle (1F)** |
| --- | --- | --- |
| **51** | **52** | **53** | **54** | **55** | **101** | **102** | **103** | **104** | **105** |
| **1** | **Heart (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Lungs (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  | *Alveolar histiocytosis* |  |  |  |  |  |  |  |  |  |  |
|  | *Crystals* |  |  |  |  |  |  |  |  |  |  |
| **2** | **Liver (Left and median lobes x2)** |  | 0 | 0 |  |  |  | 0 | 0 |  | 0 |
| *Extramedullary hematopoiesis* | 1 |  |  | 1 | 1 | 1 |  |  | 1 | 1 |
| *Hepato-diaphragmatic nodule* |  |  |  |  |  |  |  |  |  |  |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| *Red pulp – single cell necrosis (apoptosis)* |  |  |  |  |  |  |  |  |  |  |
| **3** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **4** | **Brain (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **5** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **6** | **Kidneys (Left LS x 1,** **Right TS x1)** | 0 | 0 | 0 | 0 |  | 0 | 0 | 0 | 0 | 0 |
| *Nephropathy* |  |  |  |  | 1 |  |  |  |  |  |
| **Urinary bladder** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **7** | **Ovaries (x2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Oviducts (LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **8** | **Thymus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **9** | **Injection Site (Tail TS x 3)** |  |  |  |  |  |  |  |  |  |  |
| *Perivascular - hemorrhage* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 |
| *Perivascular - inflammation* | 1 | 1 | 1 |  | 2 | 2 | 2 | 2 | 2 | 1 |
| **10** | **Aorta (TS)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Trachea (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Esophagus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | M | 0 | 0 |
| **11** | **Pancreas** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mesenteric Lymph Nodes/ Mesentery** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **12** | **Stomach (Cardia/ Fundic/ Pylorus LS x 2)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Duodenum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Jejunum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Ileum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **13** | **Caecum (TS)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Colon (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Rectum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **14** | **Skin/ Mammary Gland (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Muscle (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **15** | **Salivary Glands** **(Mandibular LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mandibular Lymph Nodes** |  |  |  |  |  |  |  |  |  |  |
| *Lymphoid follicles – increased cellularity* | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 |
| **16** | **Pituitary** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **17** | **Adrenals** | 0 |  |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *Accessory nodules* |  | 1 | 1 |  |  |  |  |  |  |  |
| **18** | **Thyroids** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Parathyroids** | 0 | 0 | 0 | 0 | 0 | 0 | M | 0 | 0 | 0 |
| **19** | **Eyes (x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Optic Nerves (x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **20** | **Sciatic Nerve (LS x 1, TS x 1)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **21** | **Spinal Cord (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **22** | **Uterus/ Cervix/ Vagina (LS x 1, TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **24** | **Sternum/ Bone Marrow** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **25** | **Femur (femoro-tibial joint)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change; M=Missing

**Table S21: Individual histopathological findings- Female Main study (Group 2F)**

| **Block No.** | **Group/Animal****Tissue Name** | **Allocetra-OTS 140x106 cells /kg (2F)** |
| --- | --- | --- |
| **56** | **57** | **58** | **59** | **60** | **106** | **107** | **108** | **109** | **110** |
| 2 | **Liver (Left and median lobes x2)** |  |  |  |  |  | 0 |  |  |  |  |
| *Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 |  | 1 | 1 | 1 | 1 |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| *Red pulp – single cell necrosis (apoptosis)* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S22: Individual histopathological findings- Female Main study (Group 3F)**

| **Block No.** | **Group/Animal****Tissue Name** | **Allocetra-OTS 700x106 cells /kg (3F)** |
| --- | --- | --- |
| **71** | **72** | **73** | **74** | **75** | **111** | **112** | **113** | **114** | **115** |
| 2 | **Liver (Left and median lobes x2)** |  |  |  |  |  |  |  |  |  |  |
| *Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| *Red pulp – single cell necrosis (apoptosis)* | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S23: Individual histopathological findings- Female Main Study (Group 4F)**

| **Block No.** | **Group/Animal****Tissue Name** | **Allocetra-OTS 1260x106 cells /kg (4F)** |
| --- | --- | --- |
| **76** | **77** | **78** | **79** | **80** | **116** | **117** | **118** | **119** | **120** |
| **1** | **Heart (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Lungs (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  | 0 | 0 |
| *Alveolar histiocytosis* |  |  |  |  |  |  |  | 1 |  |  |
| *Crystals* |  |  |  |  |  |  |  | 1 |  |  |
| **2** | **Liver (Left and median lobes x2)** |  | 0 | 0 |  |  | 0 |  |  |  |  |
| *Extramedullary hematopoiesis* | 2 |  |  | 1 | 1 |  | 1 | 1 | 1 | 1 |
| *Hepato-diaphragmatic nodule* |  |  |  |  |  |  |  |  |  |  |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| *Red pulp – single cell necrosis (apoptosis)* | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **3** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **4** | **Brain (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **5** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **6** | **Kidneys (Left LS x 1,** **Right TS x1)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |  |  |
| *Nephropathy* |  |  |  |  |  |  |  | 1 | 1 | 1 |
| **Urinary bladder** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **7** | **Ovaries (x2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Oviducts (LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **8** | **Thymus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **9** | **Injection Site (Tail TS x 3)** |  |  |  |  |  |  | 0 |  |  |  |
| *Perivascular - hemorrhage* | 2 | 2 | 2 | 2 |  | 2 |  | 2 | 2 | 2 |
| *Perivascular - inflammation* | 2 | 1 | 2 | 2 | 1 | 1 |  | 2 | 1 | 2 |
| **10** | **Aorta (TS)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Trachea (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Esophagus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | M | 0 | 0 |
| **11** | **Pancreas** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mesenteric Lymph Nodes/ Mesentery** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **12** | **Stomach (Cardia/ Fundic/ Pylorus LS x 2)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Duodenum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Jejunum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Ileum/ Peyer’s Patch (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **13** | **Caecum (TS)**  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Colon (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Rectum (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **14** | **Skin/ Mammary Gland (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Muscle (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **15** | **Salivary Glands** **(Mandibular LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mandibular Lymph Nodes** |  |  |  |  |  |  |  |  |  |  |
| *Lymphoid follicles – increased cellularity* | 2 | 2 | 2 | 2 | 2 | 2 |  | 2 | 2 | 2 |
| *Congestion* |  |  |  |  |  |  | 2 |  |  |  |
| **16** | **Pituitary** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **17** | **Adrenals** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| *Accessory nodules* |  |  |  |  |  |  |  |  |  | 1 |
| **18** | **Thyroids** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Parathyroids** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **19** | **Eyes (x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Optic Nerves (x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **20** | **Sciatic Nerve (LS x 1, TS x 1)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **21** | **Spinal Cord (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **22** | **Uterus/ Cervix/ Vagina (LS x 1, TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **24** | **Sternum/ Bone Marrow** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **25** | **Femur (femoro-tibial joint)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change; M=Missing

**Table S24: Individual histopathological findings- 14 days Recovery Phase, Groups 1M and 4M**

| **Block No.** | **Group/Animal****Tissue Name** | **Vehicle (1M)** | **Allocetra-OTS 1260x106 cells /kg (4M)** |
| --- | --- | --- | --- |
| **41** | **42** | **43** | **44** | **45** | **46** | **47** | **48** | **49** | **50** |
| **1** | **Heart (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  | 0 |
| *Fibrosis*  |  |  |  |  |  |  |  |  | 1 |  |
| **Lungs (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **2** | **Liver (Left and median lobes x2)** |  |  |  |  |  |  | 0 |  | 0 | 0 |
| *Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 |  | 1 |  |  |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| *Red pulp – single cell necrosis (apoptosis)* |  |  |  |  |  |  |  |  |  |  |
| **3** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **4** | **Brain (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **5** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **6** | **Kidneys (Left LS x 1,** **Right TS x1)** |  | 0 | 0 |  | 0 | 0 | 0 |  | 0 | 0 |
| *Nephropathy* | 1 |  |  | 1 |  |  |  | 1 |  |  |
| **7** | **Testes (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **8** | **Thymus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **9** | **Injection Site (Tail TS x 3)** |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  | 0 |
| *Crust* | 1 |  |  |  |  |  |  |  | 1 |  |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S25: Individual histopathological findings- 14 days Recovery Phase, Groups 1F and 4F**

| **Block No.** | **Group/Animal****Tissue Name** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells /kg (4F)** |
| --- | --- | --- | --- |
| **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** |
| **1** | **Heart (LS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Lungs (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  | 0 |
| *Alveolar histiocytosis* |  |  |  |  |  |  |  |  | 1 |  |
| **2** | **Liver (Left and median lobes x2)** |  |  |  | 0 |  | 0 | 0 |  |  |  |
| *Extramedullary hematopoiesis* | 1 | 1 | 1 |  | 1 |  |  | 1 | 1 | 1 |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| *Red pulp – single cell necrosis (apoptosis)* |  |  |  |  |  |  |  |  |  |  |
| **3** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **4** | **Brain (TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **5** | **Brain (TS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **6** | **Kidneys (Left LS x 1,** **Right TS x1)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |  | 0 |
| *Nephropathy* |  |  |  |  |  |  |  | 1 | 1 |  |
| **7** | **Ovaries (x2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Oviducts (LS x 2)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **8** | **Thymus (TS)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **9** | **Injection Site (Tail TS x 3)** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *Crust* |  |  |  |  |  |  |  |  |  |  |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S26: Individual histopathological findings- 28 days Recovery phase, Group 1M and 4M**

| **Block No.** | **Group/Animal****Tissue Name** | **Vehicle (1M)** | **Allocetra-OTS 1260x106 cells /kg (4M)** |
| --- | --- | --- | --- |
| **61** | **62** | **63** | **64** | **65** | **66** | **67** | **68** | **69** | **70** |
| 2 | **Liver (Left and median lobes x2)** | 0 |  |  |  |  |  |  |  | 0 |  |
| *Extramedullary hematopoiesis* |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 |  | 1 |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| *Red pulp – single cell necrosis (apoptosis)* |  |  |  |  |  |  |  |  |  |  |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change

**Table S27: Individual histopathological findings- 28 days Recovery phase, Group 1F and 4F**

| **Block No.** | **Group/Animal****Tissue Name** | **Vehicle (1F)** | **Allocetra-OTS 1260x106 cells /kg (4F)** |
| --- | --- | --- | --- |
| **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** |
| 2 | **Liver (Left and median lobes x2)** |  |  |  |  |  |  |  |  |  |  |
| *Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Spleen (TS)** |  |  |  |  |  |  |  |  |  |  |
| *Red pulp - Extramedullary hematopoiesis* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| *Red pulp – single cell necrosis (apoptosis)* |  |  |  |  |  |  |  |  |  |  |

0 = No Lesion; 1 = Minimal Change; 2 = Mild Change; 3 = Moderate Change; 4 = Marked Change