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
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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
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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
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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
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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
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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
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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
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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.
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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
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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.
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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.
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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.
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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.
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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.
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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.
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13. Laboratory Evaluations
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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
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