表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（9/20）

Neutrophils

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	2	-	-	2	-	2	-	2
Normal	1	115	5	121	1	108	1	110
High	-	2	1	3	-	4	-	4
Total	3	117	6	126	1	114	1	116
Week 6								
Low	1	1	-	2	-	1	-	1
Normal	2	107	5	114	1	109	1	111
High	-	3	-	3	-	2	-	2
Total	3	111	5	119	1	112	1	114
Week 14								
Low	1	-	-	1	-	1	-	1
Normal	2	101	5	108	1	107	1	109
High	-	3	-	3	-	3	-	3
Total	3	104	5	112	1	111	1	113
Week 20								
Low	2	2	-	4	-	-	-	-
Normal	1	95	5	101	1	108	1	110
High	-	-	-	-	-	1	-	1
Total	3	97	5	105	1	109	1	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（10/20）

Neutrophils

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	1	-	-	1	-	1	-	1
Normal	2	89	5	96	1	105	1	107
High	-	3	-	3	-	2	-	2
Total	3	92	5	100	1	108	1	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（11/20）

Eosinophils

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	122	1	123	-	114	1	115
High	-	2	1	3	-	-	1	1
Total	-	124	2	126	-	114	2	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	117	1	118	-	110	1	111
High	-	1	-	1	-	2	1	3
Total	-	118	1	119	-	112	2	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	110	1	111	-	110	1	111
High	-	1	-	1	-	1	1	2
Total	-	111	1	112	-	111	2	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	104	1	105	-	109	1	110
High	-	-	-	-	-	-	1	1
Total	-	104	1	105	-	109	2	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（12/20）

Eosinophils

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	99	1	100	-	107	2	109
High	-	-	-	-	-	1	-	1
Total	-	99	1	100	-	108	2	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（13/20）

Monocytes

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	1	-	1
Normal	-	121	3	124	-	111	3	114
High	-	-	2	2	-	-	1	1
Total	-	121	5	126	-	112	4	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	114	4	118	-	108	1	109
High	-	-	1	1	-	2	3	5
Total	-	114	5	119	-	110	4	114
Week 14								
Low	-	1	-	1	-	-	-	-
Normal	-	106	4	110	-	106	2	108
High	-	-	1	1	-	3	2	5
Total	-	107	5	112	-	109	4	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	99	3	102	-	105	1	106
High	-	2	1	3	-	2	3	5
Total	-	101	4	105	-	107	4	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（14/20）

Monocytes

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	96	2	98	-	106	3	109
High	-	1	1	2	-	-	1	1
Total	-	97	3	100	-	106	4	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（15/20）

Lymphocytes

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	1	-	2	-	4	-	4
Normal	5	115	1	121	1	107	1	109
High	-	1	2	3	-	3	-	3
Total	6	117	3	126	1	114	1	116
Week 6								
Low	-	2	-	2	-	3	-	3
Normal	5	108	2	115	1	108	1	110
High	-	1	1	2	-	1	-	1
Total	5	111	3	119	1	112	1	114
Week 14								
Low	-	3	-	3	-	3	-	3
Normal	5	100	2	107	1	105	-	106
High	-	1	1	2	-	3	1	4
Total	5	104	3	112	1	111	1	113
Week 20								
Low	-	-	-	-	-	2	-	2
Normal	5	95	1	101	1	106	-	107
High	-	2	2	4	-	1	1	2
Total	5	97	3	105	1	109	1	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（16/20）

Lymphocytes

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	1	-	1	-	4	-	4
Normal	5	91	2	98	1	103	1	105
High	-	-	1	1	-	1	-	1
Total	5	92	3	100	1	108	1	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（17/20）

Basophils

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	126	-	126	-	116	-	116
High	-	-	-	-	-	-	-	-
Total	-	126	-	126	-	116	-	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	118	-	118	-	114	-	114
High	-	1	-	1	-	-	-	-
Total	-	119	-	119	-	114	-	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	112	-	112	-	111	-	111
High	-	-	-	-	-	2	-	2
Total	-	112	-	112	-	113	-	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	105	-	105	-	111	-	111
High	-	-	-	-	-	-	-	-
Total	-	105	-	105	-	111	-	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（18/20）

Basophils

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	100	-	100	-	110	-	110
High	-	-	-	-	-	-	-	-
Total	-	100	-	100	-	110	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（19/20）

Platelets

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	3	-	-	3	4	-	-	4
Normal	1	117	-	118	3	105	2	110
High	-	1	3	4	-	-	1	1
Total	4	118	3	125	7	105	3	115
Week 6								
Low	2	-	-	2	4	-	-	4
Normal	1	107	1	109	3	103	2	108
High	-	4	2	6	-	1	1	2
Total	3	111	3	117	7	104	3	114
Week 14								
Low	1	-	-	1	4	-	-	4
Normal	1	106	1	108	3	103	2	108
High	-	1	1	2	-	-	1	1
Total	2	107	2	111	7	103	3	113
Week 20								
Low	1	1	-	2	2	-	-	2
Normal	1	98	-	99	5	100	2	107
High	-	1	2	3	-	1	1	2
Total	2	100	2	104	7	101	3	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-51　血液学的検査の正異判定のクロス表（CCT-001 試験）（20/20）

Platelets

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	4	-	-	4
Normal	1	97	-	98	3	98	2	103
High	-	1	-	1	-	2	1	3
Total	1	98	-	99	7	100	3	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（1/57）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline				
N	126		116	
Mean	23.5		22.5	
SD	6.07		4.38	
Minimum	14		13	
Q1	20.0		19.0	
Median	22.0		22.0	
Q3	26.0		26.0	
Maximum	48		35	
Week 3				
N	126	126	115	115
Mean	24.3	0.8	22.6	0.1
SD	7.58	5.90	5.46	3.97
Minimum	14	-20	13	-8
Q1	20.0	-1.0	19.0	-1.0
Median	23.0	0.5	22.0	0.0
Q3	26.0	2.0	26.0	2.0
Maximum	63	42	53	26

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（2/57）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	113
Mean	23.9	0.2	22.4	-0.1
SD	7.18	4.83	5.21	3.55
Minimum	13	-21	13	-8
Q1	20.0	-2.0	19.0	-2.0
Median	23.0	0.0	22.0	0.0
Q3	25.0	2.0	25.0	1.0
Maximum	57	14	43	17
Week 14				
N	112	112	108	107
Mean	24.1	0.5	22.9	0.4
SD	6.74	4.86	4.90	4.13
Minimum	14	-20	13	-11
Q1	20.0	-2.0	20.0	-2.0
Median	23.0	0.0	22.0	0.0
Q3	26.0	2.5	25.5	3.0
Maximum	50	19	37	13

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（3/57）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	103	103	109	108
Mean	23.9	0.4	22.9	0.5
SD	7.92	6.56	4.36	3.59
Minimum	13	-20	15	-8
Q1	20.0	-2.0	20.0	-2.0
Median	22.0	1.0	23.0	0.0
Q3	26.0	3.0	25.0	3.0
Maximum	69	40	36	14
Week 26				
N	100	100	107	106
Mean	23.5	0.1	23.8	1.4
SD	6.92	5.55	8.43	7.27
Minimum	13	-20	13	-9
Q1	19.0	-2.0	19.0	-1.0
Median	22.0	0.0	23.0	1.0
Q3	26.0	2.0	26.0	3.0
Maximum	60	31	73	47

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（4/57）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	18.9		17.7	
SD	8.41		6.08	
Minimum	6		8	
Q1	13.0		14.0	
Median	17.0		16.0	
Q3	22.0		21.0	
Maximum	63		40	
Week 3				
N	126	126	116	116
Mean	19.3	0.4	17.4	-0.2
SD	8.23	4.99	6.63	4.53
Minimum	6	-20	8	-12
Q1	14.0	-2.0	13.0	-2.0
Median	17.0	0.0	16.0	0.0
Q3	22.0	3.0	21.0	1.5
Maximum	55	17	49	21

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（5/57）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	114
Mean	19.4	0.3	17.1	-0.5
SD	10.16	6.06	6.69	4.71
Minimum	6	-19	8	-14
Q1	14.0	-2.0	13.0	-3.0
Median	17.0	0.0	15.0	0.0
Q3	20.0	3.0	19.0	1.0
Maximum	76	25	39	19
Week 14				
N	112	112	113	113
Mean	20.1	0.9	17.6	0.0
SD	10.22	6.83	7.08	5.40
Minimum	5	-19	8	-15
Q1	14.0	-2.0	13.0	-3.0
Median	17.0	1.0	16.0	0.0
Q3	22.5	4.0	21.0	2.0
Maximum	64	31	56	17

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（6/57）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	20.0	1.0	17.7	0.1
SD	11.90	9.55	6.87	4.76
Minimum	4	-25	8	-14
Q1	13.0	-3.0	12.0	-3.0
Median	17.0	0.0	17.0	0.0
Q3	22.0	4.0	21.0	3.0
Maximum	102	69	52	13
Week 26				
N	100	100	110	110
Mean	19.8	0.8	18.7	1.1
SD	11.93	8.69	11.29	9.86
Minimum	6	-18	8	-15
Q1	13.0	-2.0	13.0	-3.0
Median	17.0	0.5	16.0	0.0
Q3	22.0	3.0	21.0	2.0
Maximum	100	67	96	75

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（7/57）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	26.2		24.7	
SD	24.59		18.16	
Minimum	6		9	
Q1	14.0		13.0	
Median	19.0		19.0	
Q3	29.0		29.0	
Maximum	196		115	
Week 3				
N	126	126	116	116
Mean	27.0	0.8	24.4	0.0
SD	31.87	11.29	20.27	6.18
Minimum	7	-25	8	-21
Q1	14.0	-2.0	13.0	-2.0
Median	18.0	0.0	19.5	0.0
Q3	28.0	2.0	30.0	1.0
Maximum	312	116	155	44

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（8/57）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	119	119	114	114
Mean	27.7	0.9	23.2	-1.0
SD	30.58	11.95	18.09	5.90
Minimum	7	-36	8	-28
Q1	14.0	-2.0	13.0	-3.0
Median	19.0	0.0	18.0	-0.5
Q3	31.0	2.0	28.0	1.0
Maximum	292	96	134	23
Week 14				
N	112	112	113	113
Mean	28.0	0.8	24.1	-0.3
SD	26.94	8.00	20.74	7.82
Minimum	8	-24	7	-33
Q1	13.0	-2.0	13.0	-3.0
Median	20.0	0.0	18.0	0.0
Q3	30.5	3.0	29.0	2.0
Maximum	218	31	149	38

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（9/57）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	25.6	0.2	24.6	0.2
SD	20.65	9.52	23.67	11.26
Minimum	8	-48	5	-32
Q1	13.0	-3.0	13.0	-3.0
Median	18.0	0.0	17.0	-1.0
Q3	29.0	3.0	29.0	2.0
Maximum	127	43	201	90
Week 26				
N	100	100	110	110
Mean	25.5	0.5	26.0	1.3
SD	21.57	9.92	23.48	13.20
Minimum	7	-24	7	-23
Q1	13.5	-3.5	13.0	-3.0
Median	19.0	-0.5	18.0	-1.0
Q3	30.5	3.0	27.0	2.0
Maximum	136	74	156	76

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（10/57）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	221.4		211.9	
SD	55.38		62.78	
Minimum	108		72	
Q1	181.0		171.0	
Median	212.5		196.0	
Q3	256.0		255.0	
Maximum	413		346	
Week 3				
N	126	126	116	116
Mean	224.1	2.7	210.8	-1.2
SD	56.60	23.96	62.61	18.63
Minimum	116	-53	71	-47
Q1	186.0	-7.0	165.5	-13.0
Median	217.0	0.5	199.5	-1.5
Q3	260.0	11.0	263.0	10.0
Maximum	440	138	415	78

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（11/57）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	114
Mean	227.5	7.2	211.2	-1.0
SD	65.02	32.80	62.53	18.10
Minimum	106	-75	69	-47
Q1	188.0	-6.0	166.0	-13.0
Median	217.0	5.0	196.5	-1.5
Q3	262.0	18.0	253.0	8.0
Maximum	555	146	373	62
Week 14				
N	112	112	113	113
Mean	226.0	4.9	212.8	0.5
SD	60.14	25.12	59.94	28.67
Minimum	95	-67	77	-89
Q1	190.5	-10.5	168.0	-13.0
Median	214.0	3.0	204.0	2.0
Q3	257.0	18.5	252.0	16.0
Maximum	483	87	396	64

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（12/57）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	224.8	4.4	218.6	5.8
SD	63.24	27.01	65.99	37.80
Minimum	108	-79	72	-85
Q1	183.0	-13.0	170.0	-13.0
Median	217.0	3.0	213.0	3.0
Q3	260.0	17.0	266.0	24.0
Maximum	416	71	429	192
Week 26				
N	100	100	110	110
Mean	223.6	4.4	215.2	2.8
SD	62.17	28.67	64.99	36.83
Minimum	118	-82	86	-111
Q1	183.0	-10.0	173.0	-17.0
Median	219.0	3.5	205.0	1.0
Q3	252.0	17.0	255.0	22.0
Maximum	514	113	467	149

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（13/57）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		116	
Mean	177.0		177.5	
SD	33.16		29.02	
Minimum	102		116	
Q1	157.0		156.0	
Median	174.5		173.0	
Q3	193.0		195.5	
Maximum	349		273	
Week 3				
N	126	126	115	115
Mean	178.5	1.5	177.5	0.2
SD	36.06	15.00	35.90	18.65
Minimum	109	-43	117	-37
Q1	155.0	-6.0	156.0	-9.0
Median	173.5	1.0	173.0	0.0
Q3	199.0	9.0	195.0	6.0
Maximum	369	71	376	158

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（14/57）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	113
Mean	177.8	1.2	176.8	-0.2
SD	34.97	14.60	32.71	15.19
Minimum	112	-39	113	-30
Q1	158.0	-7.0	157.0	-8.0
Median	172.0	1.0	173.0	-2.0
Q3	195.0	9.0	191.0	6.0
Maximum	372	51	316	98
Week 14				
N	112	112	108	107
Mean	179.8	2.7	178.5	1.0
SD	38.49	18.28	30.13	15.66
Minimum	119	-50	115	-39
Q1	153.5	-7.5	162.0	-8.0
Median	173.5	2.0	174.0	0.0
Q3	196.5	11.0	195.5	8.0
Maximum	361	97	261	57

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（15/57）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	103	103	109	108
Mean	175.5	-0.3	180.2	3.6
SD	29.11	16.31	34.21	18.35
Minimum	123	-36	119	-38
Q1	157.0	-11.0	158.0	-6.0
Median	175.0	-1.0	175.0	2.0
Q3	189.0	11.0	194.0	11.0
Maximum	269	38	319	74
Week 26				
N	100	100	107	106
Mean	175.1	0.0	177.0	0.2
SD	31.34	16.23	33.52	16.40
Minimum	122	-38	114	-42
Q1	154.5	-10.0	155.0	-10.0
Median	171.5	0.0	173.0	-1.0
Q3	192.0	10.5	194.0	10.0
Maximum	287	48	318	45

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（16/57）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	4.42		4.39	
SD	0.223		0.238	
Minimum	3.9		3.7	
Q1	4.30		4.20	
Median	4.40		4.40	
Q3	4.60		4.50	
Maximum	5.0		5.0	
Week 3				
N	126	126	116	116
Mean	4.43	0.01	4.38	-0.01
SD	0.229	0.149	0.233	0.165
Minimum	3.8	-0.3	3.8	-0.4
Q1	4.30	-0.10	4.20	-0.10
Median	4.50	0.00	4.40	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	4.9	0.4	5.1	0.6

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（17/57）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	119	119	114	114
Mean	4.41	-0.01	4.38	-0.01
SD	0.255	0.181	0.224	0.169
Minimum	3.8	-0.5	3.9	-0.4
Q1	4.30	-0.10	4.20	-0.10
Median	4.40	0.00	4.40	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	5.4	0.4	5.0	0.4
Week 14				
N	112	112	113	113
Mean	4.43	0.00	4.36	-0.03
SD	0.217	0.171	0.225	0.177
Minimum	3.8	-0.5	3.8	-0.6
Q1	4.30	-0.10	4.20	-0.10
Median	4.40	0.00	4.40	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	4.9	0.6	5.0	0.4

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（18/57）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	4.41	-0.02	4.36	-0.03
SD	0.237	0.196	0.201	0.189
Minimum	3.7	-0.4	3.8	-0.4
Q1	4.30	-0.20	4.20	-0.20
Median	4.40	0.00	4.40	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	4.8	0.4	5.0	0.4
Week 26				
N	100	100	110	110
Mean	4.42	-0.01	4.36	-0.02
SD	0.235	0.195	0.233	0.218
Minimum	3.7	-0.5	3.7	-0.6
Q1	4.30	-0.10	4.20	-0.10
Median	4.40	0.00	4.35	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	4.9	0.5	4.9	0.7

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（19/57）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	7.14		7.08	
SD	0.439		0.372	
Minimum	5.7		6.2	
Q1	6.90		6.80	
Median	7.10		7.10	
Q3	7.30		7.30	
Maximum	8.9		8.1	
Week 3				
N	126	126	116	116
Mean	7.16	0.02	7.07	-0.01
SD	0.424	0.241	0.385	0.245
Minimum	5.9	-0.5	6.1	-0.7
Q1	6.80	-0.20	6.80	-0.20
Median	7.10	0.00	7.00	0.00
Q3	7.40	0.20	7.20	0.10
Maximum	8.6	0.8	8.4	0.7

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（20/57）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6				
N	118	118	114	114
Mean	7.14	-0.01	7.05	-0.03
SD	0.465	0.291	0.386	0.278
Minimum	5.7	-1.0	6.1	-0.8
Q1	6.80	-0.20	6.80	-0.20
Median	7.10	0.00	7.00	-0.10
Q3	7.40	0.20	7.30	0.20
Maximum	8.8	0.6	8.2	0.7
Week 14				
N	112	112	113	113
Mean	7.17	0.02	7.05	-0.03
SD	0.420	0.258	0.384	0.274
Minimum	5.5	-0.5	5.9	-0.8
Q1	6.90	-0.20	6.80	-0.20
Median	7.15	0.00	7.10	-0.10
Q3	7.40	0.20	7.30	0.20
Maximum	8.6	0.8	7.9	0.7

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（21/57）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	7.16	0.00	7.04	-0.04
SD	0.444	0.302	0.354	0.309
Minimum	5.7	-0.7	6.2	-0.9
Q1	6.90	-0.20	6.80	-0.30
Median	7.10	0.00	7.10	0.00
Q3	7.40	0.20	7.30	0.20
Maximum	8.5	0.8	8.1	0.8
Week 26				
N	100	100	110	110
Mean	7.16	0.00	7.05	-0.03
SD	0.449	0.264	0.425	0.334
Minimum	5.6	-0.6	6.1	-1.0
Q1	6.90	-0.20	6.80	-0.30
Median	7.10	0.00	7.10	-0.10
Q3	7.40	0.20	7.30	0.20
Maximum	8.6	0.7	8.6	1.0

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（22/57）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	0.86		0.83	
SD	0.339		0.314	
Minimum	0.2		0.4	
Q1	0.60		0.60	
Median	0.80		0.80	
Q3	1.00		1.00	
Maximum	2.5		2.1	
Week 3				
N	126	126	116	116
Mean	0.87	0.01	0.85	0.02
SD	0.328	0.222	0.294	0.222
Minimum	0.3	-0.8	0.4	-0.6
Q1	0.60	-0.10	0.60	-0.10
Median	0.80	0.00	0.80	0.00
Q3	1.00	0.10	1.00	0.20
Maximum	2.0	0.9	1.7	0.7

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（23/57）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	114
Mean	0.86	-0.01	0.86	0.03
SD	0.374	0.254	0.283	0.223
Minimum	0.3	-0.6	0.3	-0.6
Q1	0.60	-0.10	0.60	-0.10
Median	0.80	0.00	0.80	0.00
Q3	1.00	0.10	1.00	0.10
Maximum	2.1	0.9	1.7	0.7
Week 14				
N	112	112	113	113
Mean	0.87	0.00	0.82	-0.01
SD	0.347	0.231	0.293	0.217
Minimum	0.3	-1.1	0.4	-0.6
Q1	0.65	-0.10	0.60	-0.10
Median	0.80	0.00	0.80	0.00
Q3	1.00	0.10	0.90	0.10
Maximum	2.3	0.6	1.9	0.6

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（24/57）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	0.88	0.01	0.82	-0.01
SD	0.354	0.287	0.299	0.229
Minimum	0.3	-0.9	0.3	-0.9
Q1	0.70	-0.20	0.60	-0.10
Median	0.80	0.00	0.80	0.00
Q3	1.00	0.20	1.00	0.10
Maximum	2.3	1.0	1.7	0.6
Week 26				
N	100	100	110	110
Mean	0.86	0.00	0.83	0.00
SD	0.280	0.247	0.290	0.233
Minimum	0.4	-1.0	0.4	-0.6
Q1	0.65	-0.10	0.60	-0.10
Median	0.80	0.00	0.80	0.00
Q3	1.00	0.10	0.90	0.10
Maximum	1.7	0.5	1.7	0.8

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（25/57）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	203.8		208.7	
SD	28.89		35.26	
Minimum	146		96	
Q1	185.0		185.0	
Median	202.5		206.0	
Q3	220.0		229.0	
Maximum	289		297	
Week 3				
N	126	126	116	116
Mean	206.1	2.3	204.9	-4.0
SD	29.34	15.84	33.38	17.44
Minimum	150	-26	99	-100
Q1	185.0	-9.0	183.0	-12.0
Median	204.5	1.5	204.0	-1.0
Q3	224.0	12.0	225.5	6.0
Maximum	300	75	302	33

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（26/57）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	119	119	114	114
Mean	202.8	0.0	201.7	-7.3
SD	31.02	18.06	32.85	20.95
Minimum	142	-48	103	-120
Q1	180.0	-11.0	179.0	-18.0
Median	202.0	-1.0	201.5	-4.5
Q3	221.0	10.0	220.0	5.0
Maximum	282	60	292	40
Week 14				
N	112	112	113	113
Mean	202.3	-1.9	200.8	-7.9
SD	30.41	19.43	34.19	22.64
Minimum	147	-95	104	-95
Q1	179.0	-10.0	177.0	-21.0
Median	199.5	-2.0	198.0	-6.0
Q3	221.0	8.0	224.0	6.0
Maximum	294	68	310	75

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（27/57）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	202.7	-1.8	199.6	-9.1
SD	30.92	22.63	31.49	23.13
Minimum	126	-114	112	-160
Q1	182.0	-14.0	181.0	-21.0
Median	201.0	-1.0	197.0	-6.0
Q3	219.0	12.0	217.0	3.0
Maximum	286	60	303	42
Week 26				
N	100	100	110	110
Mean	206.6	1.4	202.1	-6.3
SD	31.74	22.68	35.51	24.58
Minimum	143	-104	104	-102
Q1	184.0	-12.0	178.0	-21.0
Median	204.0	2.5	199.5	-4.0
Q3	223.5	11.0	224.0	7.0
Maximum	296	84	332	91

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（28/57）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	91.9		112.0	
SD	41.08		160.90	
Minimum	27		37	
Q1	59.0		65.0	
Median	79.5		84.0	
Q3	120.0		114.0	
Maximum	252		1740	
Week 3				
N	126	126	116	116
Mean	96.0	4.1	101.3	-10.6
SD	44.58	33.53	75.26	99.68
Minimum	38	-150	36	-1014
Q1	63.0	-13.0	64.0	-17.0
Median	87.0	5.0	83.0	-1.5
Q3	112.0	19.0	113.0	13.0
Maximum	237	103	726	97

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（29/57）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6				
N	119	119	114	114
Mean	88.7	-2.8	100.2	-11.6
SD	40.61	36.22	70.36	129.26
Minimum	34	-183	40	-1290
Q1	61.0	-15.0	63.0	-16.0
Median	77.0	1.0	84.5	-1.0
Q3	109.0	13.0	114.0	17.0
Maximum	261	118	542	228
Week 14				
N	112	112	113	113
Mean	93.3	0.4	105.3	-7.0
SD	45.70	40.61	132.35	54.30
Minimum	34	-176	37	-365
Q1	63.0	-15.5	56.0	-20.0
Median	81.5	-1.0	82.0	-5.0
Q3	117.0	18.0	113.0	16.0
Maximum	304	156	1375	127

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（30/57）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	94.0	2.5	96.8	-15.4
SD	52.28	42.64	55.52	130.29
Minimum	34	-182	31	-1303
Q1	60.0	-18.0	64.0	-19.0
Median	77.0	-2.0	81.0	-1.0
Q3	118.0	17.0	112.0	13.0
Maximum	294	149	437	88
Week 26				
N	100	100	110	110
Mean	91.3	-0.8	108.6	-4.1
SD	43.96	41.04	111.90	117.77
Minimum	37	-184	30	-945
Q1	62.0	-16.0	61.0	-20.0
Median	75.5	3.0	81.0	-1.5
Q3	114.0	14.5	119.0	13.0
Maximum	249	156	875	674

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（31/57）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	0.721		0.749	
SD	0.1674		0.1805	
Minimum	0.41		0.44	
Q1	0.600		0.620	
Median	0.700		0.720	
Q3	0.820		0.880	
Maximum	1.47		1.50	
Week 3				
N	126	126	116	116
Mean	0.723	0.002	0.749	0.000
SD	0.1673	0.0508	0.1796	0.0507
Minimum	0.37	-0.16	0.45	-0.12
Q1	0.610	-0.030	0.620	-0.030
Median	0.695	0.010	0.720	0.000
Q3	0.830	0.030	0.880	0.030
Maximum	1.54	0.13	1.53	0.16

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（32/57）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	114
Mean	0.716	-0.002	0.747	-0.006
SD	0.1492	0.0527	0.1727	0.0606
Minimum	0.38	-0.18	0.43	-0.17
Q1	0.610	-0.030	0.610	-0.040
Median	0.685	0.000	0.710	-0.010
Q3	0.830	0.030	0.870	0.030
Maximum	1.13	0.14	1.36	0.19
Week 14				
N	112	112	113	113
Mean	0.723	0.004	0.744	-0.010
SD	0.1581	0.0575	0.1743	0.0517
Minimum	0.34	-0.16	0.42	-0.16
Q1	0.600	-0.025	0.610	-0.040
Median	0.715	0.000	0.710	-0.010
Q3	0.840	0.040	0.840	0.030
Maximum	1.18	0.18	1.48	0.12

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(33/57)

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	0.719	0.000	0.749	-0.007
SD	0.1604	0.0609	0.1746	0.0627
Minimum	0.43	-0.13	0.44	-0.17
Q1	0.590	-0.030	0.610	-0.050
Median	0.690	0.000	0.710	-0.010
Q3	0.830	0.040	0.880	0.030
Maximum	1.20	0.17	1.41	0.21
Week 26				
N	100	100	110	110
Mean	0.719	-0.003	0.748	-0.009
SD	0.1606	0.0631	0.1861	0.0689
Minimum	0.45	-0.18	0.44	-0.18
Q1	0.600	-0.045	0.600	-0.050
Median	0.685	0.000	0.710	-0.010
Q3	0.835	0.040	0.860	0.020
Maximum	1.22	0.20	1.53	0.27

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（34/57）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	14.9		15.0	
SD	4.06		3.48	
Minimum	6		7	
Q1	12.0		13.0	
Median	14.0		15.0	
Q3	18.0		17.0	
Maximum	29		26	
Week 3				
N	126	126	116	116
Mean	14.6	-0.3	15.1	0.1
SD	4.09	3.46	3.78	3.26
Minimum	6	-11	8	-9
Q1	12.0	-2.0	13.0	-2.0
Median	14.0	0.0	15.0	0.0
Q3	17.0	2.0	17.0	2.0
Maximum	29	8	28	14

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（35/57）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	119	119	114	114
Mean	14.8	-0.2	15.3	0.3
SD	4.16	3.72	3.96	3.02
Minimum	6	-13	9	-9
Q1	12.0	-2.0	12.0	-2.0
Median	15.0	-1.0	15.0	0.0
Q3	17.0	2.0	18.0	2.0
Maximum	34	12	29	15
Week 14				
N	112	112	113	113
Mean	14.2	-0.8	15.3	0.2
SD	3.43	3.19	4.11	3.26
Minimum	8	-14	7	-8
Q1	12.0	-2.0	13.0	-2.0
Median	14.0	-0.5	15.0	0.0
Q3	16.5	1.0	17.0	2.0
Maximum	23	7	40	15

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（36/57）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	15.0	0.2	15.5	0.5
SD	3.69	3.35	3.98	3.41
Minimum	6	-11	9	-11
Q1	12.0	-2.0	12.0	-2.0
Median	14.0	0.0	15.0	1.0
Q3	17.0	2.0	18.0	3.0
Maximum	25	7	29	14
Week 26				
N	100	100	110	110
Mean	14.8	-0.1	15.4	0.3
SD	3.48	2.96	4.14	3.19
Minimum	8	-9	7	-11
Q1	12.0	-2.0	13.0	-1.0
Median	14.0	0.0	15.0	0.0
Q3	17.0	2.0	17.0	2.0
Maximum	24	6	26	10

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（37/57）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline				
N	126		117	
Mean	4.84		4.80	
SD	1.178		1.262	
Minimum	2.1		1.8	
Q1	4.00		3.80	
Median	4.65		4.70	
Q3	5.50		5.60	
Maximum	8.2		8.2	
Week 3				
N	126	126	116	116
Mean	4.84	0.00	4.78	0.00
SD	1.182	0.484	1.148	0.483
Minimum	2.0	-1.2	2.0	-1.6
Q1	4.10	-0.30	3.80	-0.30
Median	4.80	0.10	4.70	0.00
Q3	5.40	0.30	5.80	0.30
Maximum	7.8	1.9	7.3	1.2

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（38/57）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6				
N	118	118	114	114
Mean	4.87	-0.01	4.77	-0.02
SD	1.123	0.575	1.191	0.547
Minimum	2.1	-1.7	2.1	-2.1
Q1	4.10	-0.30	3.80	-0.40
Median	4.70	0.00	4.75	0.00
Q3	5.50	0.30	5.70	0.40
Maximum	8.4	1.6	7.8	1.3
Week 14				
N	112	112	113	113
Mean	4.87	-0.02	4.76	-0.03
SD	1.217	0.547	1.207	0.610
Minimum	2.2	-1.7	2.1	-1.9
Q1	4.00	-0.45	3.90	-0.40
Median	4.60	0.10	4.60	0.00
Q3	5.80	0.40	5.50	0.30
Maximum	7.9	1.5	8.5	1.8

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（39/57）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	4.80	-0.08	4.68	-0.13
SD	1.098	0.616	1.193	0.687
Minimum	2.2	-1.7	2.0	-2.3
Q1	4.00	-0.40	3.70	-0.50
Median	4.70	0.00	4.50	-0.10
Q3	5.50	0.20	5.50	0.40
Maximum	7.5	1.9	8.9	2.7
Week 26				
N	100	100	110	110
Mean	4.80	-0.09	4.68	-0.15
SD	1.114	0.616	1.083	0.605
Minimum	2.2	-1.6	1.9	-1.9
Q1	4.10	-0.40	3.80	-0.50
Median	4.70	-0.05	4.70	-0.10
Q3	5.50	0.35	5.50	0.20
Maximum	8.1	1.7	7.5	1.3

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(40/57)

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	106.4		113.9	
SD	77.87		75.75	
Minimum	35		34	
Q1	70.0		72.0	
Median	90.0		94.0	
Q3	128.0		136.0	
Maximum	818		619	
Week 3				
N	126	126	116	116
Mean	122.7	16.3	121.2	8.5
SD	191.76	194.83	114.45	78.92
Minimum	37	-690	35	-215
Q1	70.0	-10.0	69.0	-10.5
Median	90.5	2.0	97.0	0.0
Q3	115.0	12.0	141.5	14.0
Maximum	2133	1993	1022	749

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(41/57)

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	114
Mean	107.0	0.8	126.6	13.0
SD	59.93	81.59	86.67	57.79
Minimum	34	-706	34	-265
Q1	67.0	-14.0	76.0	-11.0
Median	96.5	0.5	102.0	2.0
Q3	128.0	15.0	155.0	22.0
Maximum	398	325	598	249
Week 14				
N	112	112	113	113
Mean	103.5	-3.5	116.4	3.0
SD	50.44	77.15	77.05	44.31
Minimum	32	-725	37	-263
Q1	68.5	-15.0	68.0	-12.0
Median	88.0	0.0	97.0	4.0
Q3	124.5	13.0	138.0	18.0
Maximum	319	133	654	241

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(42/57)

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	99.1	-5.4	118.7	5.8
SD	41.71	73.29	96.74	55.87
Minimum	32	-699	33	-200
Q1	66.0	-12.0	69.0	-13.0
Median	89.0	2.0	93.0	1.0
Q3	125.0	15.0	138.0	19.0
Maximum	258	87	865	352
Week 26				
N	100	100	110	110
Mean	99.9	-4.7	111.6	-1.4
SD	42.85	81.43	82.40	50.62
Minimum	34	-708	31	-298
Q1	71.0	-15.5	66.0	-16.0
Median	88.5	1.0	93.5	-0.5
Q3	115.0	13.0	131.0	19.0
Maximum	264	162	778	162

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(43/57)

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	141.0		141.2	
SD	1.83		1.73	
Minimum	136		136	
Q1	140.0		140.0	
Median	141.0		141.0	
Q3	142.0		142.0	
Maximum	145		146	
Week 3				
N	126	126	116	116
Mean	141.1	0.1	140.8	-0.4
SD	1.99	1.61	1.54	1.64
Minimum	133	-8	135	-5
Q1	140.0	-1.0	140.0	-1.0
Median	141.0	0.0	141.0	0.0
Q3	142.0	1.0	142.0	1.0
Maximum	146	4	144	3

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（44/57）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	119	119	114	114
Mean	141.1	0.1	140.7	-0.4
SD	1.94	1.57	1.75	1.76
Minimum	134	-4	136	-4
Q1	140.0	-1.0	140.0	-2.0
Median	141.0	0.0	141.0	-0.5
Q3	142.0	1.0	142.0	0.0
Maximum	145	4	145	5
Week 14				
N	112	112	113	113
Mean	141.3	0.3	140.4	-0.8
SD	1.94	1.82	1.92	1.86
Minimum	133	-8	134	-6
Q1	140.0	-1.0	139.0	-2.0
Median	141.0	0.0	141.0	-1.0
Q3	142.0	2.0	141.0	1.0
Maximum	146	5	148	5

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(45/57)

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	141.2	0.2	140.3	-0.8
SD	1.85	1.71	1.84	2.08
Minimum	137	-4	132	-6
Q1	140.0	-1.0	139.0	-2.0
Median	141.0	0.0	140.0	-1.0
Q3	142.0	1.0	142.0	0.0
Maximum	146	6	145	6
Week 26				
N	100	100	110	110
Mean	141.1	0.1	140.5	-0.7
SD	2.08	1.83	1.68	1.94
Minimum	134	-6	136	-6
Q1	140.0	-1.0	140.0	-2.0
Median	141.0	0.0	140.0	-1.0
Q3	142.0	1.0	142.0	1.0
Maximum	146	5	144	3

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（46/57）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		116	
Mean	4.12		4.17	
SD	0.301		0.317	
Minimum	3.4		3.2	
Q1	3.90		4.00	
Median	4.10		4.20	
Q3	4.30		4.35	
Maximum	5.0		4.9	
Week 3				
N	126	126	115	115
Mean	4.14	0.02	4.16	-0.01
SD	0.307	0.272	0.275	0.305
Minimum	3.5	-0.6	3.3	-0.8
Q1	3.90	-0.20	4.00	-0.20
Median	4.10	0.00	4.10	0.00
Q3	4.30	0.20	4.30	0.20
Maximum	5.0	0.9	4.8	1.0

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(47/57)

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	113
Mean	4.14	0.00	4.17	0.01
SD	0.309	0.286	0.295	0.298
Minimum	3.5	-0.7	3.4	-1.0
Q1	3.90	-0.20	4.00	-0.20
Median	4.10	0.00	4.15	0.00
Q3	4.30	0.10	4.30	0.20
Maximum	5.5	0.9	5.3	0.9
Week 14				
N	112	112	108	107
Mean	4.15	0.02	4.20	0.02
SD	0.275	0.304	0.305	0.317
Minimum	3.5	-0.8	3.5	-0.9
Q1	3.90	-0.20	4.00	-0.20
Median	4.10	0.00	4.20	0.10
Q3	4.30	0.20	4.35	0.20
Maximum	4.8	0.6	5.2	0.7

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(48/57)

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	103	103	109	108
Mean	4.17	0.05	4.21	0.03
SD	0.313	0.282	0.335	0.347
Minimum	3.6	-0.9	3.5	-0.8
Q1	3.90	-0.20	4.00	-0.20
Median	4.10	0.10	4.20	0.10
Q3	4.30	0.20	4.40	0.25
Maximum	5.1	0.8	5.6	0.8
Week 26				
N	100	100	107	106
Mean	4.14	0.03	4.18	0.00
SD	0.320	0.303	0.309	0.325
Minimum	3.4	-0.7	3.3	-0.9
Q1	3.90	-0.20	4.00	-0.20
Median	4.10	0.00	4.20	0.00
Q3	4.30	0.20	4.30	0.20
Maximum	5.2	0.7	5.3	0.8

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(49/57)

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	103.1		103.4	
SD	1.92		2.04	
Minimum	97		97	
Q1	102.0		102.0	
Median	103.0		103.0	
Q3	104.0		105.0	
Maximum	107		109	
Week 3				
N	126	126	116	116
Mean	103.1	0.0	103.2	-0.2
SD	2.11	1.53	1.91	1.66
Minimum	95	-8	96	-5
Q1	102.0	-1.0	102.0	-1.0
Median	103.0	0.0	103.0	0.0
Q3	104.0	1.0	104.0	1.0
Maximum	107	3	107	4

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（50/57）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6				
N	119	119	114	114
Mean	103.1	0.1	103.1	-0.2
SD	2.16	1.52	1.95	1.77
Minimum	96	-4	98	-5
Q1	102.0	-1.0	102.0	-2.0
Median	103.0	0.0	103.0	0.0
Q3	105.0	1.0	104.0	1.0
Maximum	109	4	108	4
Week 14				
N	112	112	113	113
Mean	103.1	0.2	102.9	-0.5
SD	2.05	1.78	2.01	2.07
Minimum	96	-7	95	-7
Q1	102.0	-1.0	102.0	-2.0
Median	103.0	0.0	103.0	0.0
Q3	104.0	1.0	104.0	1.0
Maximum	108	5	108	4

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（51/57）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	103.2	0.2	102.9	-0.5
SD	2.11	1.92	2.13	2.30
Minimum	99	-5	95	-7
Q1	102.0	-1.0	102.0	-2.0
Median	103.0	0.0	103.0	0.0
Q3	104.0	1.0	104.0	1.0
Maximum	109	6	108	7
Week 26				
N	100	100	110	110
Mean	103.1	0.1	103.0	-0.4
SD	2.15	1.89	2.03	2.10
Minimum	96	-4	98	-7
Q1	102.0	-1.0	101.0	-2.0
Median	103.0	0.0	103.0	-0.5
Q3	104.0	2.0	104.0	1.0
Maximum	109	4	107	5

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（52/57）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	9.23		9.20	
SD	0.284		0.314	
Minimum	8.6		8.4	
Q1	9.00		9.00	
Median	9.20		9.20	
Q3	9.40		9.40	
Maximum	10.1		10.2	
Week 3				
N	126	126	116	116
Mean	9.28	0.04	9.18	-0.03
SD	0.281	0.249	0.322	0.253
Minimum	8.6	-0.7	7.7	-0.7
Q1	9.10	-0.10	9.00	-0.20
Median	9.30	0.10	9.20	0.00
Q3	9.40	0.20	9.40	0.10
Maximum	10.1	0.6	10.0	0.8

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（53/57）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6				
N	118	118	114	114
Mean	9.24	0.01	9.17	-0.03
SD	0.280	0.275	0.293	0.245
Minimum	8.5	-0.7	8.2	-0.6
Q1	9.10	-0.10	9.00	-0.20
Median	9.20	0.00	9.20	0.00
Q3	9.40	0.20	9.30	0.10
Maximum	10.3	0.9	10.0	0.6
Week 14				
N	112	112	113	113
Mean	9.20	-0.04	9.11	-0.08
SD	0.293	0.255	0.321	0.268
Minimum	8.3	-0.7	8.1	-0.7
Q1	9.00	-0.20	8.90	-0.20
Median	9.20	-0.05	9.10	-0.10
Q3	9.40	0.10	9.30	0.10
Maximum	10.4	0.7	10.1	0.9

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（54/57）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 20				
N	105	105	111	111
Mean	9.19	-0.06	9.08	-0.12
SD	0.282	0.270	0.321	0.270
Minimum	8.4	-0.8	8.4	-0.9
Q1	9.00	-0.20	8.90	-0.30
Median	9.20	0.00	9.10	-0.10
Q3	9.40	0.10	9.30	0.10
Maximum	9.9	0.5	10.0	0.5
Week 26				
N	100	100	110	110
Mean	9.15	-0.10	9.07	-0.13
SD	0.317	0.304	0.307	0.300
Minimum	8.4	-0.8	8.3	-0.7
Q1	8.90	-0.30	8.90	-0.30
Median	9.10	-0.10	9.10	-0.20
Q3	9.40	0.10	9.30	0.00
Maximum	10.0	0.6	9.8	0.9

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(55/57)

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Baseline				
N	126		117	
Mean	3.39		3.41	
SD	0.394		0.409	
Minimum	2.3		2.4	
Q1	3.10		3.10	
Median	3.45		3.40	
Q3	3.70		3.70	
Maximum	4.2		4.5	
Week 3				
N	126	126	116	116
Mean	3.41	0.02	3.36	-0.04
SD	0.426	0.340	0.419	0.311
Minimum	2.2	-1.4	2.4	-1.1
Q1	3.10	-0.20	3.10	-0.20
Median	3.45	0.10	3.40	-0.10
Q3	3.70	0.20	3.60	0.20
Maximum	4.5	1.0	4.5	0.9

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）（56/57）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=126) Observed Value at Visit	Placebo (N=126) Change from Baseline	1 mg (N=117) Observed Value at Visit	1 mg (N=117) Change from Baseline
Week 6				
N	118	118	114	114
Mean	3.36	-0.03	3.40	-0.01
SD	0.416	0.325	0.406	0.332
Minimum	2.2	-1.1	2.6	-1.1
Q1	3.00	-0.20	3.10	-0.20
Median	3.30	0.00	3.40	0.00
Q3	3.70	0.20	3.70	0.20
Maximum	4.6	0.8	4.4	0.7
Week 14				
N	112	112	113	113
Mean	3.40	0.01	3.39	-0.02
SD	0.392	0.358	0.425	0.336
Minimum	2.5	-0.9	2.1	-1.1
Q1	3.10	-0.20	3.10	-0.20
Median	3.40	0.00	3.40	0.00
Q3	3.70	0.20	3.60	0.30
Maximum	4.3	1.1	4.3	0.6

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-52　血液生化学検査の評価時点別変化量（CCT-001 試験）　(57/57)

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=126)		1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	105	105	111	111
Mean	3.34	-0.07	3.41	0.01
SD	0.426	0.372	0.431	0.377
Minimum	2.2	-1.1	2.3	-1.0
Q1	3.10	-0.30	3.10	-0.30
Median	3.40	0.00	3.40	0.00
Q3	3.70	0.20	3.70	0.30
Maximum	4.2	1.3	4.7	0.8
Week 26				
N	100	100	110	110
Mean	3.37	-0.04	3.37	-0.03
SD	0.413	0.381	0.424	0.334
Minimum	2.2	-1.0	2.3	-1.0
Q1	3.10	-0.20	3.10	-0.30
Median	3.40	0.00	3.40	0.00
Q3	3.60	0.20	3.60	0.20
Maximum	4.4	1.0	4.6	0.6

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.1

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（1/38）

AST (GOT)

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	119	2	121	-	114	-	114
High	-	2	3	5	-	1	-	1
Total	-	121	5	126	-	115	-	115
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	110	2	112	-	112	-	112
High	-	3	3	6	-	1	-	1
Total	-	113	5	118	-	113	-	113
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	104	2	106	-	107	-	107
High	-	3	3	6	-	-	-	-
Total	-	107	5	112	-	107	-	107
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	97	3	100	-	108	-	108
High	-	2	1	3	-	-	-	-
Total	-	99	4	103	-	108	-	108

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（2/38）

AST (GOT)

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	95	2	97	-	103	-	103
High	-	1	2	3	-	3	-	3
Total	-	96	4	100	-	106	-	106

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（3/38）

ALT (GPT)

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	123	1	124	-	115	-	115
High	-	1	1	2	-	1	-	1
Total	-	124	2	126	-	116	-	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	114	-	114	-	114	-	114
High	-	2	2	4	-	-	-	-
Total	-	116	2	118	-	114	-	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	106	-	106	-	112	-	112
High	-	4	2	6	-	1	-	1
Total	-	110	2	112	-	113	-	113
Week 20								
Low	-	1	-	1	-	-	-	-
Normal	-	99	2	101	-	110	-	110
High	-	3	-	3	-	1	-	1
Total	-	103	2	105	-	111	-	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（4/38）

ALT (GPT)

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	95	1	96	-	106	-	106
High	-	3	1	4	-	4	-	4
Total	-	98	2	100	-	110	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（5/38）

GGT

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	112	1	113	-	102	3	105
High	-	1	12	13	-	2	9	11
Total	-	113	13	126	-	104	12	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	103	1	104	-	102	4	106
High	-	3	12	15	-	1	7	8
Total	-	106	13	119	-	103	11	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	98	-	98	-	99	3	102
High	-	1	13	14	-	3	8	11
Total	-	99	13	112	-	102	11	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	93	-	93	-	99	4	103
High	-	1	11	12	-	1	7	8
Total	-	94	11	105	-	100	11	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（6/38）

GGT

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	89	-	89	-	96	5	101
High	-	1	10	11	-	3	6	9
Total	-	90	10	100	-	99	11	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（7/38）

Alkaline Phosphatase

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	3	-	-	3
Normal	-	119	2	121	-	106	3	109
High	-	1	4	5	-	1	3	4
Total	-	120	6	126	3	107	6	116
Week 6								
Low	-	-	-	-	2	-	-	2
Normal	-	109	2	111	-	104	2	106
High	-	3	4	7	-	2	4	6
Total	-	112	6	118	2	106	6	114
Week 14								
Low	-	1	-	1	2	-	-	2
Normal	-	103	3	106	-	102	2	104
High	-	2	3	5	-	3	4	7
Total	-	106	6	112	2	105	6	113
Week 20								
Low	-	-	-	-	2	-	-	2
Normal	-	96	1	97	-	100	3	103
High	-	3	5	8	-	3	3	6
Total	-	99	6	105	2	103	6	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（8/38）

Alkaline Phosphatase

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	2	1	-	3
Normal	-	94	3	97	-	98	3	101
High	-	-	3	3	-	3	3	6
Total	-	94	6	100	2	102	6	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（9/38）

LDH

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	2	-	3	1	-	-	1
Normal	1	115	1	117	1	108	1	110
High	-	4	2	6	-	1	3	4
Total	2	121	3	126	2	109	4	115
Week 6								
Low	-	1	-	1	1	1	-	2
Normal	1	110	1	112	1	104	1	106
High	-	3	2	5	-	2	3	5
Total	1	114	3	118	2	107	4	113
Week 14								
Low	1	-	-	1	1	1	-	2
Normal	-	104	-	104	1	99	1	101
High	-	4	3	7	-	1	3	4
Total	1	108	3	112	2	101	4	107
Week 20								
Low	-	-	-	-	-	1	-	1
Normal	1	98	-	99	2	97	1	100
High	-	2	2	4	-	4	3	7
Total	1	100	2	103	2	102	4	108

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（10/38）

LDH

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	1	1	-	2
Normal	1	95	-	96	1	98	1	100
High	-	2	2	4	-	1	3	4
Total	1	97	2	100	2	100	4	106

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（11/38）

Albumin

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	126	-	126	1	115	-	116
High	-	-	-	-	-	-	-	-
Total	-	126	-	126	1	115	-	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	118	-	118	1	113	-	114
High	-	1	-	1	-	-	-	-
Total	-	119	-	119	1	113	-	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	112	-	112	1	112	-	113
High	-	-	-	-	-	-	-	-
Total	-	112	-	112	1	112	-	113
Week 20								
Low	-	1	-	1	-	-	-	-
Normal	-	104	-	104	1	110	-	111
High	-	-	-	-	-	-	-	-
Total	-	105	-	105	1	110	-	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（12/38）

Albumin

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	1	-	1	-	1	-	1
Normal	-	99	-	99	1	108	-	109
High	-	-	-	-	-	-	-	-
Total	-	100	-	100	1	109	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（13/38）

Total Protein

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	8	1	-	9	6	5	-	11
Normal	4	111	-	115	4	100	-	104
High	-	1	1	2	-	1	-	1
Total	12	113	1	126	10	106	-	116
Week 6								
Low	7	7	-	14	7	11	-	18
Normal	4	98	1	103	3	93	-	96
High	-	1	-	1	-	-	-	-
Total	11	106	1	118	10	104	-	114
Week 14								
Low	6	2	-	8	7	10	-	17
Normal	4	99	-	103	3	93	-	96
High	-	-	1	1	-	-	-	-
Total	10	101	1	112	10	103	-	113
Week 20								
Low	6	4	-	10	4	8	-	12
Normal	1	91	-	92	6	93	-	99
High	-	2	1	3	-	-	-	-
Total	7	97	1	105	10	101	-	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（14/38）

Total Protein

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	4	5	-	9	6	8	-	14
Normal	3	86	-	89	4	91	-	95
High	-	1	1	2	-	1	-	1
Total	7	92	1	100	10	100	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（15/38）

Total Bilirubin

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	109	3	112	-	100	4	104
High	-	5	9	14	-	6	6	12
Total	-	114	12	126	-	106	10	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	98	4	102	-	100	2	102
High	-	8	8	16	-	4	8	12
Total	-	106	12	118	-	104	10	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	96	5	101	-	101	3	104
High	-	5	6	11	-	2	7	9
Total	-	101	11	112	-	103	10	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	90	5	95	-	96	3	99
High	-	5	5	10	-	5	7	12
Total	-	95	10	105	-	101	10	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（16/38）

Total Bilirubin

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	85	5	90	-	95	3	98
High	-	5	5	10	-	5	7	12
Total	-	90	10	100	-	100	10	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（17/38）

Total Cholesterol

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	1	-	-	1
Normal	-	81	6	87	-	71	10	81
High	-	13	26	39	-	5	29	34
Total	-	94	32	126	1	76	39	116
Week 6								
Low	-	-	-	-	1	-	-	1
Normal	-	81	7	88	-	69	15	84
High	-	8	23	31	-	5	24	29
Total	-	89	30	119	1	74	39	114
Week 14								
Low	-	-	-	-	1	-	-	1
Normal	-	72	8	80	-	65	15	80
High	-	10	22	32	-	9	23	32
Total	-	82	30	112	1	74	38	113
Week 20								
Low	-	-	-	-	1	-	-	1
Normal	-	67	12	79	-	69	17	86
High	-	9	17	26	-	3	21	24
Total	-	76	29	105	1	72	38	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（18/38）

Total Cholesterol

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	1	-	-	1
Normal	-	57	12	69	-	65	12	77
High	-	15	16	31	-	7	25	32
Total	-	72	28	100	1	72	37	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（19/38）

Triglycerides

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	1	104	7	112	-	95	5	100
High	-	8	6	14	-	5	11	16
Total	1	112	13	126	-	100	16	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	1	100	8	109	-	94	8	102
High	-	5	5	10	-	5	7	12
Total	1	105	13	119	-	99	15	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	1	90	9	100	-	95	6	101
High	-	8	4	12	-	3	9	12
Total	1	98	13	112	-	98	15	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	1	87	6	94	-	92	7	99
High	-	6	5	11	-	4	8	12
Total	1	93	11	105	-	96	15	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（20/38）

Triglycerides

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	1	85	6	92	-	91	5	96
High	-	4	4	8	-	4	10	14
Total	1	89	10	100	-	95	15	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（21/38）

Creatinine

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	5	1	-	6	1	1	-	2
Normal	-	108	3	111	1	101	4	106
High	-	4	5	9	-	1	7	8
Total	5	113	8	126	2	103	11	116
Week 6								
Low	2	-	-	2	1	-	-	1
Normal	2	105	2	109	1	100	1	102
High	-	2	5	7	-	1	10	11
Total	4	107	7	118	2	101	11	114
Week 14								
Low	3	1	-	4	2	1	-	3
Normal	1	96	2	99	-	98	1	99
High	-	4	5	9	-	1	10	11
Total	4	101	7	112	2	100	11	113
Week 20								
Low	1	-	-	1	1	1	-	2
Normal	3	91	1	95	1	92	1	94
High	-	3	6	9	-	5	10	15
Total	4	94	7	105	2	98	11	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（22/38）

Creatinine

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	3	1	-	4	1	2	-	3
Normal	1	83	2	86	1	90	4	95
High	-	5	5	10	-	5	7	12
Total	4	89	7	100	2	97	11	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（23/38）

Blood Urea Nitrogen

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	1	-	1	-	-	-	-
Normal	2	120	1	123	1	109	2	112
High	-	2	-	2	-	3	1	4
Total	2	123	1	126	1	112	3	116
Week 6								
Low	1	2	-	3	-	-	-	-
Normal	1	113	1	115	1	109	-	110
High	-	1	-	1	-	1	3	4
Total	2	116	1	119	1	110	3	114
Week 14								
Low	-	-	-	-	-	1	-	1
Normal	2	109	1	112	1	108	1	110
High	-	-	-	-	-	-	2	2
Total	2	109	1	112	1	109	3	113
Week 20								
Low	1	-	-	1	-	-	-	-
Normal	1	99	1	101	1	105	2	108
High	-	3	-	3	-	2	1	3
Total	2	102	1	105	1	107	3	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（24/38）

Blood Urea Nitrogen

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	1	-	-	1
Normal	2	96	1	99	-	103	1	104
High	-	1	-	1	-	3	2	5
Total	2	97	1	100	1	106	3	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（25/38）

Uric Acid

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	2	3	-	5	4	1	-	5
Normal	-	110	3	113	2	103	4	109
High	-	3	5	8	-	1	1	2
Total	2	116	8	126	6	105	5	116
Week 6								
Low	2	4	-	6	2	-	-	2
Normal	-	103	5	108	4	102	3	109
High	-	1	3	4	-	1	2	3
Total	2	108	8	118	6	103	5	114
Week 14								
Low	2	1	-	3	4	-	-	4
Normal	-	98	3	101	2	100	4	106
High	-	3	5	8	-	2	1	3
Total	2	102	8	112	6	102	5	113
Week 20								
Low	2	1	-	3	4	-	-	4
Normal	-	93	5	98	2	97	5	104
High	-	1	3	4	-	3	-	3
Total	2	95	8	105	6	100	5	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（26/38）

Uric Acid

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	2	2	-	4	4	1	-	5
Normal	-	88	4	92	2	98	2	102
High	-	-	4	4	-	-	3	3
Total	2	90	8	100	6	99	5	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（27/38）

CK (CPK)

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	6	1	-	7	7	2	-	9
Normal	3	101	4	108	2	91	4	97
High	-	7	4	11	-	3	7	10
Total	9	109	8	126	9	96	11	116
Week 6								
Low	5	4	-	9	7	2	-	9
Normal	2	94	5	101	2	85	4	91
High	-	7	1	8	-	7	7	14
Total	7	105	6	118	9	94	11	114
Week 14								
Low	6	1	-	7	7	4	-	11
Normal	1	91	3	95	2	84	5	91
High	-	7	3	10	-	5	6	11
Total	7	99	6	112	9	93	11	113
Week 20								
Low	4	-	-	4	4	1	-	5
Normal	3	88	4	95	5	86	4	95
High	-	5	1	6	-	5	6	11
Total	7	93	5	105	9	92	10	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（28/38）

CK (CPK)

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	3	1	-	4	7	3	-	10
Normal	4	81	4	89	2	82	7	91
High	-	7	-	7	-	6	3	9
Total	7	89	4	100	9	91	10	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（29/38）

Sodium

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	2	-	3	1	1	-	2
Normal	1	122	-	123	1	113	-	114
High	-	-	-	-	-	-	-	-
Total	2	124	-	126	2	114	-	116
Week 6								
Low	1	1	-	2	1	-	-	1
Normal	1	116	-	117	1	112	-	113
High	-	-	-	-	-	-	-	-
Total	2	117	-	119	2	112	-	114
Week 14								
Low	-	1	-	1	2	1	-	3
Normal	2	109	-	111	-	109	-	109
High	-	-	-	-	-	1	-	1
Total	2	110	-	112	2	111	-	113
Week 20								
Low	-	-	-	-	1	1	-	2
Normal	1	104	-	105	1	108	-	109
High	-	-	-	-	-	-	-	-
Total	1	104	-	105	2	109	-	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（30/38）

Sodium

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	1	-	-	1	2	1	-	3
Normal	-	99	-	99	-	107	-	107
High	-	-	-	-	-	-	-	-
Total	1	99	-	100	2	108	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（31/38）

Potassium

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	1	-	-	1
Normal	1	125	-	126	-	114	-	114
High	-	-	-	-	-	-	-	-
Total	1	125	-	126	1	114	-	115
Week 6								
Low	-	-	-	-	1	-	-	1
Normal	-	117	-	117	-	111	-	111
High	-	1	-	1	-	1	-	1
Total	-	118	-	118	1	112	-	113
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	112	-	112	1	105	-	106
High	-	-	-	-	-	1	-	1
Total	-	112	-	112	1	106	-	107
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	102	-	102	1	106	-	107
High	-	1	-	1	-	1	-	1
Total	-	103	-	103	1	107	-	108

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（32/38）

Potassium

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	1	-	1	-	2	-	2
Normal	-	97	-	97	1	102	-	103
High	-	2	-	2	-	1	-	1
Total	-	100	-	100	1	105	-	106

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（33/38）

Chloride

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	2	-	2	-	1	-	1
Normal	1	123	-	124	1	113	1	115
High	-	-	-	-	-	-	-	-
Total	1	125	-	126	1	114	1	116
Week 6								
Low	1	1	-	2	-	-	-	-
Normal	-	116	-	116	1	112	1	114
High	-	1	-	1	-	-	-	-
Total	1	118	-	119	1	112	1	114
Week 14								
Low	-	1	-	1	1	-	-	1
Normal	1	110	-	111	-	111	1	112
High	-	-	-	-	-	-	-	-
Total	1	111	-	112	1	111	1	113
Week 20								
Low	-	-	-	-	1	1	-	2
Normal	1	102	-	103	-	108	1	109
High	-	2	-	2	-	-	-	-
Total	1	104	-	105	1	109	1	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（34/38）

Chloride

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	1	-	-	1	-	-	-	-
Normal	-	96	-	96	1	108	1	110
High	-	3	-	3	-	-	-	-
Total	1	99	-	100	1	108	1	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（35/38）

Calcium

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	1	-	1
Normal	-	126	-	126	-	115	-	115
High	-	-	-	-	-	-	-	-
Total	-	126	-	126	-	116	-	116
Week 6								
Low	-	-	-	-	-	1	-	1
Normal	-	118	-	118	-	113	-	113
High	-	-	-	-	-	-	-	-
Total	-	118	-	118	-	114	-	114
Week 14								
Low	-	1	-	1	-	1	-	1
Normal	-	111	-	111	-	112	-	112
High	-	-	-	-	-	-	-	-
Total	-	112	-	112	-	113	-	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	105	-	105	-	111	-	111
High	-	-	-	-	-	-	-	-
Total	-	105	-	105	-	111	-	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（36/38）

Calcium

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	1	-	1
Normal	-	100	-	100	-	109	-	109
High	-	-	-	-	-	-	-	-
Total	-	100	-	100	-	110	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（37/38）

Phosphorus

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	2	-	3	-	1	-	1
Normal	-	123	-	123	1	114	-	115
High	-	-	-	-	-	-	-	-
Total	1	125	-	126	1	115	-	116
Week 6								
Low	1	1	-	2	-	-	-	-
Normal	-	115	-	115	1	113	-	114
High	-	1	-	1	-	-	-	-
Total	1	117	-	118	1	113	-	114
Week 14								
Low	-	-	-	-	-	1	-	1
Normal	1	111	-	112	1	111	-	112
High	-	-	-	-	-	-	-	-
Total	1	111	-	112	1	112	-	113
Week 20								
Low	-	4	-	4	-	1	-	1
Normal	-	101	-	101	1	108	-	109
High	-	-	-	-	-	1	-	1
Total	-	105	-	105	1	110	-	111

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-53　血液生化学検査の正異判定のクロス表（CCT-001 試験）（38/38）

Phosphorus

	Baseline							
	Placebo (N=126)				1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	2	-	2	-	1	-	1
Normal	-	98	-	98	1	107	-	108
High	-	-	-	-	-	1	-	1
Total	-	100	-	100	1	109	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.1.3

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（1/8）

Protein

	Baseline													
	Placebo (N=126)							1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 3														
-	119	2	1	-	-	-	122	100	5	-	1	-	-	106
+-	1	2	-	-	-	-	3	4	-	1	-	-	-	5
1+	1	-	-	-	-	-	1	-	1	1	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	2	-	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	121	4	1	-	-	-	126	104	6	2	3	1	-	116
Week 6														
-	109	2	1	-	-	-	112	100	2	-	1	-	-	103
+-	5	2	-	-	-	-	7	4	2	-	-	-	-	6
1+	-	-	-	-	-	-	-	-	2	1	-	-	-	3
2+	-	-	-	-	-	-	-	-	-	-	1	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	114	4	1	-	-	-	119	104	6	1	2	1	-	114
Week 14														
-	102	4	1	-	-	-	107	101	5	-	1	-	-	107
+-	3	-	-	-	-	-	3	1	1	-	1	-	-	3
1+	2	-	-	-	-	-	2	1	-	1	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	107	4	1	-	-	-	112	103	6	1	2	1	-	113

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（2/8）

Protein

	Baseline													
	Placebo (N=126)							1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 20														
-	99	4	1	-	-	-	104	95	4	-	1	-	-	100
+-	1	-	-	-	-	-	1	5	1	-	-	-	-	6
1+	-	-	-	-	-	-	-	-	1	1	-	-	-	2
2+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	1	1	-	2
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100	4	1	-	-	-	105	101	6	1	2	1	-	111
Week 26														
-	94	4	1	-	-	-	99	97	5	-	-	-	-	102
+-	1	-	-	-	-	-	1	3	-	1	1	-	-	5
1+	-	-	-	-	-	-	-	1	1	-	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	95	4	1	-	-	-	100	101	6	1	1	1	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（3/8）

Glucose

	Baseline													
	Placebo (N=126)							1 mg (N=117)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 3														
-	124	-	-	-	-	-	124	115	-	-	-	-	-	115
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	1	-	-	-	-	1	2	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	125	-	-	-	-	1	126	116	-	-	-	-	-	116
Week 6														
-	115	-	-	-	-	-	115	113	-	-	-	-	-	113
1+	1	-	-	-	-	-	1	-	-	-	-	-	-	-
2+	2	-	-	-	-	-	2	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	1	1	-	-	-	-	-	-	-
Total	118	-	-	-	-	1	119	114	-	-	-	-	-	114
Week 14														
-	110	-	-	-	-	-	110	111	-	-	-	-	-	111
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	1	-	-	-	-	-	1	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	1	1	-	-	-	-	-	-	-
Total	111	-	-	-	-	1	112	113	-	-	-	-	-	113

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（4/8）

Glucose

	Baseline													
	Placebo (N=126)							1 mg (N=117)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 20														
-	104	-	-	-	-	-	104	109	-	-	-	-	-	109
1+	-	-	-	-	-	-	-	2	-	-	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	1	1	-	-	-	-	-	-	-
Total	104	-	-	-	-	1	105	111	-	-	-	-	-	111
Week 26														
-	97	-	-	-	-	-	97	108	-	-	-	-	-	108
1+	2	-	-	-	-	-	2	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	2	-	-	-	-	-	2
3+	-	-	-	-	-	1	1	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	99	-	-	-	-	1	100	110	-	-	-	-	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（5/8）

Occult Blood

	Baseline											
	Placebo (N=126)						1 mg (N=117)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 3												
-	95	6	1	-	1	103	75	9	2	-	-	86
+-	2	2	1	-	-	5	6	1	4	-	-	11
1+	1	4	3	2	-	10	1	1	4	1	1	8
2+	-	-	2	5	-	7	1	-	4	3	-	8
3+	-	-	-	-	1	1	1	-	1	1	-	3
Total	98	12	7	7	2	126	84	11	15	5	1	116
Week 6												
-	88	6	1	-	1	96	76	6	2	-	-	84
+-	3	4	3	1	-	11	7	4	2	-	-	13
1+	1	1	2	2	-	6	-	-	4	3	-	7
2+	-	1	-	4	-	5	-	-	7	1	-	8
3+	-	-	-	-	1	1	-	1	-	1	-	2
Total	92	12	6	7	2	119	83	11	15	5	-	114
Week 14												
-	82	5	2	1	1	91	79	5	5	-	-	89
+-	3	3	1	3	-	10	3	4	5	1	-	13
1+	2	2	2	-	-	6	1	1	3	-	-	5
2+	-	1	-	2	-	3	-	-	-	3	-	3
3+	-	1	-	-	1	2	-	1	1	1	-	3
Total	87	12	5	6	2	112	83	11	14	5	-	113

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（6/8）

Occult Blood

	Baseline											
	Placebo (N=126)						1 mg (N=117)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 20												
-	71	6	-	-	1	78	78	5	4	-	-	87
+-	4	1	1	2	-	8	5	3	2	1	-	11
1+	5	3	2	2	-	12	-	3	5	1	-	9
2+	1	2	1	2	-	6	-	-	1	2	-	3
3+	-	-	-	-	1	1	-	-	-	1	-	1
Total	81	12	4	6	2	105	83	11	12	5	-	111
Week 26												
-	72	6	1	1	1	81	77	6	4	-	-	87
+-	4	2	1	1	-	8	2	2	4	-	-	8
1+	1	1	1	3	-	6	4	2	2	1	-	9
2+	-	2	1	1	1	5	-	-	2	4	-	6
3+	-	-	-	-	-	-	-	-	-	-	-	-
Total	77	11	4	6	2	100	83	10	12	5	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（7/8）

Ketones

	Baseline													
	Placebo (N=126)							1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 3														
-	117	2	-	-	-	-	119	107	2	1	-	-	-	110
+-	1	1	1	-	-	-	3	4	-	-	-	-	-	4
1+	2	1	-	-	-	-	3	2	-	-	-	-	-	2
2+	-	1	-	-	-	-	1	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	120	5	1	-	-	-	126	113	2	1	-	-	-	116
Week 6														
-	109	3	-	-	-	-	112	109	2	-	-	-	-	111
+-	2	1	1	-	-	-	4	1	-	1	-	-	-	2
1+	1	1	-	-	-	-	2	-	-	-	-	-	-	-
2+	1	-	-	-	-	-	1	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	113	5	1	-	-	-	119	111	2	1	-	-	-	114
Week 14														
-	102	5	1	-	-	-	108	109	2	-	-	-	-	111
+-	4	-	-	-	-	-	4	1	-	1	-	-	-	2
1+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	106	5	1	-	-	-	112	110	2	1	-	-	-	113

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-54　尿検査の正異判定のクロス表（CCT-001 試験）（8/8）

Ketones

	Baseline													
	Placebo (N=126)							1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 20														
-	97	5	1	-	-	-	103	106	2	-	-	-	-	108
+-	2	-	-	-	-	-	2	1	-	1	-	-	-	2
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	99	5	1	-	-	-	105	108	2	1	-	-	-	111
Week 26														
-	91	5	1	-	-	-	97	105	2	1	-	-	-	108
+-	2	-	-	-	-	-	2	1	-	-	-	-	-	1
1+	1	-	-	-	-	-	1	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	94	5	1	-	-	-	100	107	2	1	-	-	-	110

Statistical Analysis Report (5.3.5.1-6) Table 3.3.1.2

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（1/60）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	443.2		439.5	
SD	41.43		46.05	
Minimum	344		339	
Q1	418.0		408.0	
Median	445.0		436.0	
Q3	473.0		467.0	
Maximum	527		588	
Week 3				
N	91	91	116	116
Mean	441.7	-1.2	437.7	-1.1
SD	42.29	14.07	45.36	14.95
Minimum	338	-35	336	-40
Q1	415.0	-11.0	409.0	-9.5
Median	442.0	-2.0	435.0	-1.0
Q3	473.0	8.0	464.0	8.0
Maximum	532	34	581	34

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（2/60）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	441.7	-1.7	436.9	-1.9
SD	41.51	16.77	46.01	16.75
Minimum	343	-34	331	-50
Q1	416.0	-13.5	410.0	-11.0
Median	444.5	0.0	431.0	-2.0
Q3	473.5	9.5	465.0	10.0
Maximum	535	40	585	43
Week 14				
N	88	88	113	113
Mean	438.8	-3.4	437.3	-1.9
SD	41.66	18.27	46.94	17.54
Minimum	331	-41	325	-45
Q1	416.0	-17.0	413.0	-15.0
Median	441.5	-3.0	435.0	-3.0
Q3	466.5	8.5	462.0	10.0
Maximum	551	53	589	48

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（3/60）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	439.4	-2.3	437.5	-2.1
SD	43.39	18.95	47.99	20.20
Minimum	338	-34	304	-60
Q1	413.0	-18.0	409.0	-11.0
Median	442.0	-5.0	432.0	-1.0
Q3	469.0	10.0	461.0	11.0
Maximum	549	57	599	37
Week 26				
N	80	80	109	109
Mean	437.7	-4.6	437.4	-3.7
SD	50.16	25.02	46.34	18.90
Minimum	285	-133	308	-49
Q1	411.0	-19.0	405.0	-15.0
Median	439.5	-6.0	433.0	-4.0
Q3	472.5	10.5	463.0	10.0
Maximum	549	55	597	52

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（4/60）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	418.0	-18.5	436.5	-4.8
SD	50.72	21.46	48.35	20.92
Minimum	371	-46	328	-53
Q1	387.0	-35.5	408.0	-17.0
Median	405.5	-14.0	428.0	-3.0
Q3	449.0	-1.5	462.0	8.0
Maximum	490	0	593	47
Week 32				
N	0	0	101	101
Mean			437.5	-4.7
SD			46.10	20.44
Minimum			348	-53
Q1			410.0	-19.0
Median			432.0	-4.0
Q3			466.0	12.0
Maximum			584	34

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（5/60）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			435.9	-3.6
SD			46.33	17.44
Minimum			324	-44
Q1			410.0	-14.0
Median			434.0	-3.0
Q3			461.0	8.0
Maximum			593	34
Week 46				
N	0	0	87	87
Mean			433.1	-4.4
SD			45.20	18.54
Minimum			310	-54
Q1			410.0	-18.0
Median			430.0	-3.0
Q3			459.0	8.0
Maximum			565	41

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（6/60）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			432.6	-4.9
SD			46.60	19.32
Minimum			298	-53
Q1			411.0	-17.0
Median			430.0	-3.0
Q3			463.0	6.0
Maximum			595	47

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（7/60）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	13.58		13.58	
SD	1.209		1.368	
Minimum	10.9		9.1	
Q1	12.60		12.70	
Median	13.60		13.60	
Q3	14.60		14.30	
Maximum	15.9		17.0	
Week 3				
N	91	91	116	116
Mean	13.51	-0.04	13.50	-0.07
SD	1.248	0.430	1.376	0.482
Minimum	10.5	-1.0	9.2	-1.2
Q1	12.60	-0.40	12.60	-0.40
Median	13.50	0.00	13.45	0.00
Q3	14.50	0.30	14.35	0.20
Maximum	16.1	1.0	17.1	1.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（8/60）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	13.50	-0.06	13.51	-0.06
SD	1.249	0.517	1.400	0.514
Minimum	10.7	-1.2	8.8	-1.6
Q1	12.55	-0.40	12.60	-0.40
Median	13.50	-0.05	13.50	-0.10
Q3	14.40	0.30	14.40	0.30
Maximum	16.8	1.1	16.9	1.4
Week 14				
N	88	88	113	113
Mean	13.42	-0.10	13.49	-0.10
SD	1.253	0.579	1.403	0.600
Minimum	10.8	-1.3	10.2	-1.8
Q1	12.55	-0.50	12.60	-0.50
Median	13.45	-0.10	13.40	-0.20
Q3	14.15	0.20	14.20	0.30
Maximum	17.4	1.7	17.1	1.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（9/60）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	13.43	-0.07	13.49	-0.12
SD	1.345	0.631	1.379	0.706
Minimum	10.6	-1.2	9.7	-2.4
Q1	12.60	-0.40	12.60	-0.50
Median	13.40	-0.20	13.40	-0.10
Q3	14.20	0.20	14.20	0.30
Maximum	17.2	2.0	17.4	2.2
Week 26				
N	80	80	109	109
Mean	13.37	-0.12	13.50	-0.13
SD	1.553	0.833	1.391	0.672
Minimum	7.6	-4.4	9.8	-1.5
Q1	12.50	-0.55	12.70	-0.60
Median	13.25	-0.20	13.50	-0.20
Q3	14.50	0.25	14.20	0.20
Maximum	17.2	2.0	17.0	2.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（10/60）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	13.30	-0.75	13.48	-0.16
SD	1.463	0.532	1.439	0.734
Minimum	11.8	-1.4	9.6	-1.7
Q1	12.35	-1.10	12.60	-0.70
Median	13.05	-0.75	13.30	-0.20
Q3	14.25	-0.40	14.30	0.30
Maximum	15.3	-0.1	17.6	3.0
Week 32				
N	0	0	101	101
Mean			13.50	-0.18
SD			1.359	0.750
Minimum			10.4	-1.9
Q1			12.70	-0.70
Median			13.40	-0.30
Q3			14.10	0.30
Maximum			17.3	3.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（11/60）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			13.46	-0.15
SD			1.297	0.647
Minimum			10.3	-1.3
Q1			12.70	-0.60
Median			13.40	-0.15
Q3			14.20	0.20
Maximum			17.1	3.6
Week 46				
N	0	0	87	87
Mean			13.39	-0.17
SD			1.343	0.684
Minimum			9.2	-1.7
Q1			12.60	-0.60
Median			13.30	-0.20
Q3			14.20	0.30
Maximum			16.5	3.1

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（12/60）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			13.39	-0.17
SD			1.345	0.688
Minimum			9.2	-1.7
Q1			12.60	-0.50
Median			13.40	-0.20
Q3			14.20	0.10
Maximum			17.2	3.1

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（13/60）

Laboratory Test: Hematocrit (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	40.78		40.83	
SD	3.575		4.036	
Minimum	33.8		28.6	
Q1	38.00		38.50	
Median	40.90		40.50	
Q3	43.80		42.80	
Maximum	48.5		51.5	
Week 3				
N	91	91	116	116
Mean	40.49	-0.20	40.69	-0.09
SD	3.653	1.301	4.038	1.535
Minimum	33.1	-2.7	29.4	-4.0
Q1	38.00	-1.10	38.60	-1.00
Median	40.20	-0.20	40.45	-0.20
Q3	43.70	0.70	43.35	0.90
Maximum	49.1	2.9	51.3	4.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（14/60）

Laboratory Test: Hematocrit (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	40.34	-0.36	40.69	-0.12
SD	3.651	1.592	4.095	1.602
Minimum	32.3	-4.4	27.8	-4.6
Q1	37.75	-1.40	38.20	-1.00
Median	40.10	-0.50	40.50	-0.05
Q3	42.85	0.60	43.20	1.00
Maximum	51.0	3.3	51.0	4.4
Week 14				
N	88	88	113	113
Mean	39.91	-0.65	40.62	-0.22
SD	3.681	1.732	4.170	1.930
Minimum	32.2	-3.7	31.2	-5.7
Q1	37.20	-1.90	38.20	-1.50
Median	39.80	-0.70	40.10	-0.40
Q3	42.60	0.30	42.60	0.90
Maximum	53.3	5.2	51.6	6.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（15/60）

Laboratory Test: Hematocrit (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	39.69	-0.83	40.67	-0.22
SD	3.758	1.826	4.099	2.231
Minimum	31.4	-4.3	29.3	-5.6
Q1	37.10	-2.10	38.10	-1.60
Median	39.60	-1.20	40.30	-0.10
Q3	42.10	0.30	43.10	1.40
Maximum	51.5	3.8	51.7	5.4
Week 26				
N	80	80	109	109
Mean	39.51	-0.97	40.57	-0.39
SD	4.465	2.451	4.086	2.192
Minimum	23.1	-13.8	29.5	-5.5
Q1	36.55	-2.25	38.20	-1.90
Median	39.20	-1.00	40.20	-0.50
Q3	42.85	0.40	42.80	1.10
Maximum	51.2	3.9	51.4	6.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（16/60）

Laboratory Test: Hematocrit (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	38.98	-3.13	40.42	-0.58
SD	3.821	1.926	4.245	2.374
Minimum	35.2	-5.7	29.3	-5.5
Q1	36.70	-4.45	37.40	-2.30
Median	38.20	-2.85	40.00	-0.60
Q3	41.25	-1.80	42.90	0.80
Maximum	44.3	-1.1	51.1	8.1
Week 32				
N	0	0	101	101
Mean			40.34	-0.75
SD			3.994	2.433
Minimum			31.7	-5.9
Q1			37.90	-2.40
Median			40.00	-1.20
Q3			42.10	0.70
Maximum			51.1	9.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（17/60）

Laboratory Test: Hematocrit (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			40.09	-0.76
SD			3.790	2.186
Minimum			31.4	-5.4
Q1			37.80	-2.20
Median			39.90	-0.80
Q3			42.10	0.20
Maximum			49.6	10.2
Week 46				
N	0	0	87	87
Mean			39.79	-0.90
SD			3.776	2.054
Minimum			28.0	-5.8
Q1			37.60	-2.30
Median			39.70	-1.00
Q3			41.50	0.40
Maximum			49.4	8.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（18/60）

Laboratory Test: Hematocrit (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			39.60	-1.09
SD			3.832	2.077
Minimum			27.7	-6.1
Q1			37.50	-2.40
Median			39.80	-1.10
Q3			42.30	0.10
Maximum			50.8	7.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（19/60）

Laboratory Test: WBC (/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	5638.9		5474.4	
SD	1336.34		1371.58	
Minimum	2600		2800	
Q1	4700.0		4400.0	
Median	5500.0		5300.0	
Q3	6400.0		6400.0	
Maximum	9400		10200	
Week 3				
N	91	91	116	116
Mean	5693.4	30.8	5457.8	-30.2
SD	1486.59	996.85	1225.89	878.95
Minimum	3200	-3200	2700	-2800
Q1	4700.0	-500.0	4600.0	-500.0
Median	5500.0	0.0	5350.0	0.0
Q3	6400.0	600.0	6250.0	400.0
Maximum	10400	2800	10000	2100

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（20/60）

Laboratory Test: WBC (/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	5718.5	92.4	5420.2	-47.4
SD	1551.53	988.75	1229.23	1136.54
Minimum	2500	-2100	3200	-2500
Q1	4600.0	-450.0	4600.0	-500.0
Median	5600.0	100.0	5300.0	-100.0
Q3	6600.0	600.0	6200.0	400.0
Maximum	11600	4000	10400	7400
Week 14				
N	88	88	113	113
Mean	5651.1	36.4	5468.1	2.7
SD	1675.24	1343.80	1198.16	1024.30
Minimum	3300	-3800	3100	-2500
Q1	4300.0	-700.0	4500.0	-500.0
Median	5400.0	50.0	5400.0	0.0
Q3	6300.0	650.0	6400.0	600.0
Maximum	12200	7300	8800	3500

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（21/60）

Laboratory Test: WBC (/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	5503.5	-124.7	5531.5	88.3
SD	1536.34	1034.74	1340.49	1173.32
Minimum	3000	-3100	3200	-3300
Q1	4200.0	-700.0	4700.0	-500.0
Median	5200.0	-200.0	5200.0	0.0
Q3	6500.0	500.0	6500.0	600.0
Maximum	11000	2900	11300	5600
Week 26				
N	80	80	109	109
Mean	5656.3	-2.5	5274.3	-129.4
SD	1663.60	1285.06	1213.38	1002.99
Minimum	2800	-3100	3000	-2700
Q1	4400.0	-700.0	4400.0	-800.0
Median	5250.0	0.0	5200.0	-200.0
Q3	6500.0	400.0	6100.0	600.0
Maximum	12500	6500	9000	2500

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（22/60）

Laboratory Test: WBC (/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	4675.0	-300.0	5356.3	-87.4
SD	684.96	739.37	1273.46	987.64
Minimum	3900	-1200	3200	-3500
Q1	4150.0	-900.0	4300.0	-700.0
Median	4650.0	-200.0	5300.0	-100.0
Q3	5200.0	300.0	6300.0	400.0
Maximum	5500	400	10800	2600
Week 32				
N	0	0	101	101
Mean			5382.2	-87.1
SD			1330.37	1011.60
Minimum			3200	-3100
Q1			4400.0	-800.0
Median			5200.0	-100.0
Q3			6100.0	500.0
Maximum			11800	3400

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（23/60）

Laboratory Test: WBC (/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			5226.7	-224.4
SD			1160.57	884.49
Minimum			2900	-3600
Q1			4400.0	-800.0
Median			5150.0	-100.0
Q3			5900.0	300.0
Maximum			8500	1900
Week 46				
N	0	0	87	87
Mean			5377.0	-60.9
SD			1334.66	1048.40
Minimum			3100	-2500
Q1			4200.0	-700.0
Median			5200.0	-200.0
Q3			6100.0	500.0
Maximum			9200	3000

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（24/60）

Laboratory Test: WBC (/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			5304.6	-133.3
SD			1247.41	1033.58
Minimum			3000	-2700
Q1			4300.0	-800.0
Median			5200.0	-100.0
Q3			6100.0	400.0
Maximum			9300	2800

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（25/60）

Laboratory Test: Neutrophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	60.79		59.52	
SD	8.125		8.652	
Minimum	33.2		35.5	
Q1	55.40		53.50	
Median	60.70		60.30	
Q3	66.00		65.90	
Maximum	77.0		77.0	
Week 3				
N	91	91	116	116
Mean	59.23	-1.31	60.23	0.62
SD	7.959	6.841	8.765	5.824
Minimum	38.4	-27.1	37.4	-13.2
Q1	52.80	-4.70	54.55	-3.70
Median	60.70	-1.60	59.50	0.35
Q3	64.60	2.50	66.90	4.00
Maximum	76.7	24.6	76.9	13.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（26/60）

Laboratory Test: Neutrophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	60.39	-0.43	59.21	-0.32
SD	8.554	7.326	8.697	7.064
Minimum	36.3	-27.8	38.9	-13.5
Q1	55.15	-3.00	53.80	-5.10
Median	61.25	-0.55	59.30	-1.05
Q3	66.55	3.15	66.10	3.20
Maximum	78.5	25.8	85.5	31.1
Week 14				
N	88	88	113	113
Mean	60.16	-0.97	59.12	-0.29
SD	8.704	7.915	9.002	6.959
Minimum	35.8	-30.3	35.9	-15.4
Q1	55.10	-5.10	52.40	-5.10
Median	60.75	-0.90	59.60	-0.60
Q3	65.80	3.80	66.10	4.00
Maximum	84.0	24.2	80.0	19.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（27/60）

Laboratory Test: Neutrophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	59.12	-1.99	59.36	0.12
SD	9.019	8.352	8.174	7.008
Minimum	35.0	-29.9	40.0	-15.4
Q1	54.60	-6.20	52.70	-3.90
Median	59.00	-1.40	59.90	-0.30
Q3	64.70	2.40	65.80	3.80
Maximum	80.5	20.5	84.0	22.0
Week 26				
N	80	80	109	109
Mean	60.04	-1.46	58.54	-0.72
SD	9.166	8.985	8.323	6.545
Minimum	37.6	-39.4	39.0	-16.5
Q1	53.30	-6.90	51.80	-5.00
Median	60.85	-0.55	59.00	-0.40
Q3	65.75	3.25	64.50	3.10
Maximum	88.0	31.3	77.4	16.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（28/60）

Laboratory Test: Neutrophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	54.00	-1.63	57.81	-1.11
SD	7.706	7.081	8.896	6.846
Minimum	42.6	-7.9	36.0	-17.5
Q1	49.70	-7.75	50.80	-5.20
Median	56.90	-1.75	57.40	-1.20
Q3	58.30	4.50	64.40	2.80
Maximum	59.6	4.9	78.0	17.4
Week 32				
N	0	0	101	101
Mean			57.86	-1.04
SD			9.708	7.269
Minimum			34.0	-21.8
Q1			50.20	-6.00
Median			57.20	-1.70
Q3			65.00	3.80
Maximum			80.0	22.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（29/60）

Laboratory Test: Neutrophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			58.32	-0.80
SD			8.292	6.668
Minimum			37.3	-16.7
Q1			52.20	-5.50
Median			58.95	-0.70
Q3			65.00	2.50
Maximum			74.0	20.1
Week 46				
N	0	0	87	87
Mean			58.45	-0.52
SD			9.272	7.259
Minimum			32.4	-16.1
Q1			53.30	-6.00
Median			58.60	-1.00
Q3			64.00	3.90
Maximum			80.5	17.5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（30/60）

Laboratory Test: Neutrophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			57.67	-1.30
SD			9.191	7.573
Minimum			34.3	-23.8
Q1			50.80	-6.10
Median			58.00	-0.50
Q3			63.70	2.90
Maximum			76.5	17.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（31/60）

Laboratory Test: Eosinophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	1.97		2.21	
SD	1.570		1.728	
Minimum	0.0		0.0	
Q1	1.00		1.00	
Median	1.40		1.90	
Q3	2.70		2.90	
Maximum	6.6		10.3	
Week 3				
N	91	91	116	116
Mean	2.30	0.33	2.29	0.09
SD	1.745	0.935	1.671	1.051
Minimum	0.3	-2.5	0.0	-5.7
Q1	1.10	-0.20	1.00	-0.40
Median	1.90	0.20	2.00	0.10
Q3	2.90	0.90	3.00	0.80
Maximum	8.1	2.7	10.5	3.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（32/60）

Laboratory Test: Eosinophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	2.17	0.18	2.34	0.13
SD	1.957	1.504	1.780	1.370
Minimum	0.0	-4.0	0.0	-7.7
Q1	1.00	-0.30	1.10	-0.30
Median	1.75	0.10	1.90	0.10
Q3	2.75	0.55	3.00	0.70
Maximum	12.7	10.4	10.0	3.6
Week 14				
N	88	88	113	113
Mean	2.45	0.44	2.44	0.22
SD	1.762	1.247	1.820	1.424
Minimum	0.0	-3.2	0.0	-8.4
Q1	1.15	-0.30	1.20	-0.50
Median	2.00	0.40	1.90	0.20
Q3	3.00	1.15	3.10	0.90
Maximum	8.6	4.0	10.6	5.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（33/60）

Laboratory Test: Eosinophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	2.40	0.46	2.26	0.02
SD	1.769	1.220	1.478	1.380
Minimum	0.0	-2.0	0.0	-8.7
Q1	1.00	-0.10	1.20	-0.50
Median	1.90	0.30	2.00	0.10
Q3	3.00	1.10	2.80	0.80
Maximum	9.1	5.5	9.7	3.2
Week 26				
N	80	80	109	109
Mean	2.56	0.69	2.39	0.17
SD	2.068	1.611	1.677	1.668
Minimum	0.0	-2.5	0.0	-8.6
Q1	1.25	0.00	1.20	-0.40
Median	2.00	0.35	2.00	0.20
Q3	3.15	1.20	3.00	0.90
Maximum	11.5	8.8	10.0	8.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（34/60）

Laboratory Test: Eosinophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	4.15	0.70	2.42	0.16
SD	1.827	1.206	1.702	1.432
Minimum	2.2	-0.4	0.0	-8.6
Q1	2.60	-0.10	1.20	-0.30
Median	4.25	0.40	2.00	0.20
Q3	5.70	1.50	3.10	0.80
Maximum	5.9	2.4	7.6	6.3
Week 32				
N	0	0	101	101
Mean			2.57	0.32
SD			1.858	1.542
Minimum			0.0	-8.0
Q1			1.30	-0.20
Median			2.10	0.30
Q3			3.40	0.90
Maximum			10.0	4.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（35/60）

Laboratory Test: Eosinophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			2.55	0.30
SD			1.699	1.512
Minimum			0.2	-8.3
Q1			1.40	-0.40
Median			2.15	0.30
Q3			3.30	1.00
Maximum			9.8	4.0
Week 46				
N	0	0	87	87
Mean			2.29	0.05
SD			1.625	1.666
Minimum			0.0	-9.4
Q1			1.30	-0.60
Median			2.00	0.10
Q3			2.80	0.90
Maximum			9.3	4.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（36/60）

Laboratory Test: Eosinophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			2.28	0.04
SD			1.609	1.464
Minimum			0.0	-8.1
Q1			1.10	-0.60
Median			2.00	0.10
Q3			3.10	0.70
Maximum			10.5	4.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（37/60）

Laboratory Test: Monocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	6.11		6.32	
SD	1.708		1.629	
Minimum	2.9		3.3	
Q1	4.90		5.20	
Median	6.00		6.00	
Q3	7.10		7.20	
Maximum	11.4		11.1	
Week 3				
N	91	91	116	116
Mean	6.28	0.17	6.05	-0.27
SD	1.621	1.549	1.617	1.420
Minimum	3.0	-4.6	1.8	-4.5
Q1	5.20	-0.50	5.00	-1.15
Median	6.10	0.20	6.00	-0.20
Q3	7.10	1.10	7.00	0.55
Maximum	10.1	5.1	11.8	3.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（38/60）

Laboratory Test: Monocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	6.46	0.33	6.34	0.00
SD	1.772	1.740	1.846	1.690
Minimum	2.8	-5.1	2.0	-5.9
Q1	5.25	-0.70	5.00	-0.90
Median	6.50	0.10	6.05	-0.05
Q3	7.60	1.55	7.40	1.00
Maximum	11.1	4.4	12.6	5.0
Week 14				
N	88	88	113	113
Mean	6.38	0.33	6.45	0.11
SD	1.576	1.938	1.876	1.613
Minimum	2.1	-6.1	2.6	-5.1
Q1	5.35	-0.60	5.20	-0.70
Median	6.40	0.20	6.30	0.10
Q3	7.55	1.30	7.30	1.00
Maximum	9.7	4.6	12.2	4.3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（39/60）

Laboratory Test: Monocytes (%)

Visit / Statistics	P -> 1 mg (N=95)		1 mg -> 1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	85	85	111	111
Mean	6.43	0.42	6.54	0.19
SD	1.538	1.769	1.770	1.396
Minimum	3.0	-3.0	3.7	-4.7
Q1	5.40	-0.70	5.40	-0.50
Median	6.30	0.10	6.30	0.30
Q3	7.50	1.60	7.40	1.00
Maximum	10.5	5.5	12.4	3.9
Week 26				
N	80	80	109	109
Mean	6.17	0.22	6.46	0.12
SD	1.570	1.789	1.566	1.513
Minimum	2.0	-4.1	3.0	-5.1
Q1	5.05	-0.95	5.30	-0.60
Median	6.05	0.45	6.30	0.30
Q3	7.25	1.35	7.30	1.00
Maximum	10.2	5.2	12.0	4.1

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（40/60）

Laboratory Test: Monocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	7.18	-0.45	6.75	0.39
SD	0.645	1.204	1.936	1.712
Minimum	6.6	-1.6	3.0	-4.8
Q1	6.80	-1.30	5.40	-0.70
Median	7.00	-0.70	6.60	0.40
Q3	7.55	0.40	7.80	1.50
Maximum	8.1	1.2	13.5	5.5
Week 32				
N	0	0	101	101
Mean			6.52	0.17
SD			1.985	1.827
Minimum			3.0	-5.0
Q1			5.00	-0.80
Median			6.40	0.20
Q3			7.50	0.90
Maximum			12.9	6.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（41/60）

Laboratory Test: Monocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			6.43	0.08
SD			1.716	1.821
Minimum			2.9	-4.8
Q1			5.10	-0.90
Median			6.25	0.20
Q3			7.50	1.10
Maximum			11.5	4.1
Week 46				
N	0	0	87	87
Mean			6.38	0.07
SD			1.629	1.585
Minimum			2.4	-3.1
Q1			5.00	-1.00
Median			6.20	0.10
Q3			7.10	1.00
Maximum			11.3	3.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（42/60）

Laboratory Test: Monocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			6.42	0.11
SD			1.585	1.639
Minimum			2.2	-3.8
Q1			5.30	-0.80
Median			6.20	0.30
Q3			7.60	1.00
Maximum			10.3	5.1

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（43/60）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	30.76		31.51	
SD	7.450		7.754	
Minimum	17.2		17.2	
Q1	24.40		25.30	
Median	30.00		31.50	
Q3	36.00		37.20	
Maximum	58.0		55.9	
Week 3				
N	91	91	116	116
Mean	31.81	0.81	31.10	-0.34
SD	7.504	5.882	8.203	4.923
Minimum	14.1	-21.8	13.6	-13.5
Q1	25.70	-2.40	24.85	-3.25
Median	30.90	1.00	31.35	-0.50
Q3	37.00	3.60	36.35	3.10
Maximum	52.3	24.0	54.7	13.3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（44/60）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	30.63	-0.04	31.76	0.28
SD	7.895	6.278	7.841	5.655
Minimum	16.0	-19.8	9.0	-23.7
Q1	25.00	-3.00	27.00	-2.40
Median	29.55	-0.05	31.50	0.60
Q3	36.15	3.45	36.70	4.40
Maximum	55.0	23.9	53.6	14.3
Week 14				
N	88	88	113	113
Mean	30.58	0.15	31.49	-0.08
SD	8.304	6.665	8.286	6.110
Minimum	12.0	-20.7	12.5	-18.3
Q1	25.10	-4.20	25.80	-4.00
Median	29.45	-0.05	31.20	0.20
Q3	35.40	4.15	36.30	3.80
Maximum	57.3	24.3	51.7	13.3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（45/60）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	31.65	1.08	31.42	-0.32
SD	8.718	7.168	7.672	6.274
Minimum	11.5	-20.0	11.0	-21.2
Q1	26.20	-2.20	25.80	-3.50
Median	30.40	0.40	30.50	-0.40
Q3	36.20	3.70	37.20	2.70
Maximum	56.0	25.8	49.9	14.9
Week 26				
N	80	80	109	109
Mean	30.83	0.52	32.19	0.45
SD	8.501	7.857	7.718	5.626
Minimum	8.0	-28.3	14.7	-15.6
Q1	25.65	-3.30	26.10	-2.60
Median	30.10	-0.60	32.00	0.50
Q3	36.85	3.75	37.90	4.10
Maximum	54.2	33.9	51.0	15.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（46/60）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	34.38	1.53	32.60	0.59
SD	7.192	5.555	8.022	5.872
Minimum	27.5	-3.2	14.8	-17.7
Q1	30.00	-3.05	26.90	-2.90
Median	32.75	0.55	32.80	0.80
Q3	38.75	6.10	39.30	4.40
Maximum	44.5	8.2	50.0	14.3
Week 32				
N	0	0	101	101
Mean			32.63	0.58
SD			8.777	6.213
Minimum			11.5	-15.7
Q1			25.00	-3.20
Median			33.00	0.40
Q3			39.80	4.80
Maximum			53.4	19.3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（47/60）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			32.25	0.42
SD			7.432	5.314
Minimum			19.0	-17.1
Q1			26.50	-3.00
Median			31.40	0.65
Q3			37.20	3.70
Maximum			51.4	12.3
Week 46				
N	0	0	87	87
Mean			32.48	0.46
SD			8.632	5.983
Minimum			12.9	-17.1
Q1			26.50	-3.10
Median			32.80	0.20
Q3			37.40	3.80
Maximum			52.9	15.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（48/60）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			33.19	1.17
SD			8.222	6.364
Minimum			19.4	-11.7
Q1			27.30	-3.20
Median			33.00	0.30
Q3			39.20	5.20
Maximum			51.6	19.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（49/60）

Laboratory Test: Basophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	0.37		0.45	
SD	0.271		0.284	
Minimum	0.0		0.0	
Q1	0.20		0.30	
Median	0.40		0.40	
Q3	0.50		0.50	
Maximum	1.2		1.9	
Week 3				
N	91	91	116	116
Mean	0.38	0.00	0.34	-0.10
SD	0.263	0.360	0.305	0.368
Minimum	0.0	-1.2	0.0	-1.3
Q1	0.20	-0.20	0.20	-0.30
Median	0.30	0.00	0.30	-0.10
Q3	0.50	0.20	0.45	0.10
Maximum	1.3	1.0	1.8	1.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（50/60）

Laboratory Test: Basophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	0.34	-0.04	0.36	-0.08
SD	0.251	0.344	0.245	0.323
Minimum	0.0	-1.0	0.0	-1.5
Q1	0.20	-0.20	0.20	-0.20
Median	0.30	0.00	0.30	-0.10
Q3	0.50	0.20	0.50	0.10
Maximum	1.0	1.0	1.2	1.1
Week 14				
N	88	88	113	113
Mean	0.43	0.06	0.49	0.05
SD	0.327	0.359	0.406	0.441
Minimum	0.0	-1.2	0.0	-1.1
Q1	0.20	-0.10	0.20	-0.20
Median	0.35	0.00	0.40	0.00
Q3	0.60	0.30	0.60	0.30
Maximum	1.4	0.9	2.6	1.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（51/60）

Laboratory Test: Basophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	0.40	0.03	0.44	-0.01
SD	0.311	0.432	0.338	0.406
Minimum	0.0	-1.0	0.0	-1.3
Q1	0.20	-0.20	0.20	-0.20
Median	0.30	0.10	0.40	0.00
Q3	0.50	0.30	0.50	0.20
Maximum	1.3	1.2	1.7	1.2
Week 26				
N	80	80	109	109
Mean	0.41	0.03	0.42	-0.02
SD	0.305	0.400	0.331	0.397
Minimum	0.0	-1.0	0.0	-1.2
Q1	0.20	-0.20	0.30	-0.20
Median	0.35	0.00	0.40	0.00
Q3	0.60	0.20	0.50	0.20
Maximum	1.3	1.0	1.7	1.1

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（52/60）

Laboratory Test: Basophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	0.30	-0.15	0.43	-0.03
SD	0.200	0.311	0.299	0.376
Minimum	0.0	-0.6	0.0	-1.3
Q1	0.20	-0.35	0.30	-0.20
Median	0.40	-0.05	0.40	0.00
Q3	0.40	0.05	0.50	0.10
Maximum	0.4	0.1	1.7	1.7
Week 32				
N	0	0	101	101
Mean			0.42	-0.03
SD			0.278	0.362
Minimum			0.0	-1.0
Q1			0.30	-0.20
Median			0.40	0.00
Q3			0.50	0.20
Maximum			1.5	1.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（53/60）

Laboratory Test: Basophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			0.46	0.00
SD			0.341	0.418
Minimum			0.0	-1.4
Q1			0.30	-0.20
Median			0.40	0.00
Q3			0.60	0.10
Maximum			1.6	1.2
Week 46				
N	0	0	87	87
Mean			0.41	-0.06
SD			0.374	0.439
Minimum			0.0	-1.4
Q1			0.20	-0.30
Median			0.30	0.00
Q3			0.60	0.10
Maximum			2.3	1.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（54/60）

Laboratory Test: Basophils (%)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			0.44	-0.03
SD			0.337	0.419
Minimum			0.0	-1.3
Q1			0.20	-0.20
Median			0.40	0.00
Q3			0.60	0.10
Maximum			2.0	1.5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（55/60）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	P -> 1 mg (N=95)		1 mg -> 1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline				
N	94		117	
Mean	21.97		21.26	
SD	4.048		5.407	
Minimum	15.0		12.5	
Q1	19.30		17.50	
Median	21.55		20.60	
Q3	24.20		24.30	
Maximum	34.7		41.5	
Week 3				
N	90	90	115	115
Mean	22.63	0.54	21.30	-0.01
SD	4.679	2.324	4.649	2.728
Minimum	14.7	-4.3	12.0	-17.0
Q1	19.50	-0.80	17.90	-1.20
Median	21.80	0.30	20.50	0.00
Q3	25.40	1.70	23.70	1.20
Maximum	36.7	12.4	34.1	11.3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（56/60）

Laboratory Test: Platelets (10^4/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	91	91	114	114
Mean	22.14	0.15	21.48	0.24
SD	4.441	2.073	5.318	2.482
Minimum	13.9	-6.6	10.6	-12.7
Q1	19.50	-1.00	17.50	-0.80
Median	21.80	0.10	21.40	0.25
Q3	24.40	1.20	24.30	1.30
Maximum	36.2	6.0	44.4	8.1
Week 14				
N	87	87	113	113
Mean	22.07	0.08	21.16	-0.07
SD	4.675	2.101	4.475	2.515
Minimum	13.5	-5.6	11.3	-13.1
Q1	19.60	-1.30	18.10	-1.20
Median	21.60	-0.20	20.40	0.20
Q3	24.60	1.40	23.30	1.30
Maximum	37.4	5.1	34.1	7.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（57/60）

Laboratory Test: Platelets (10^4/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	84	84	111	111
Mean	21.77	-0.11	21.31	0.07
SD	4.636	2.105	4.788	3.268
Minimum	13.9	-4.8	11.3	-16.7
Q1	18.80	-1.40	18.00	-1.40
Median	20.80	-0.05	21.00	0.30
Q3	24.40	1.25	23.80	1.70
Maximum	37.5	8.7	37.0	12.2
Week 26				
N	79	79	109	109
Mean	21.88	0.13	21.20	0.04
SD	5.295	2.858	4.601	2.767
Minimum	13.9	-5.4	10.8	-14.8
Q1	18.10	-1.40	18.10	-1.20
Median	20.40	-0.40	21.20	0.30
Q3	24.70	1.20	23.30	1.40
Maximum	41.8	11.6	37.5	7.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（58/60）

Laboratory Test: Platelets (10^4/μL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	22.68	-1.10	21.38	0.08
SD	6.184	2.074	5.270	3.478
Minimum	16.4	-2.3	10.0	-14.7
Q1	18.20	-2.25	17.60	-1.80
Median	21.70	-2.05	20.50	0.30
Q3	27.15	0.05	24.30	1.30
Maximum	30.9	2.0	36.2	17.0
Week 32				
N	0	0	101	101
Mean			21.10	-0.23
SD			4.998	2.843
Minimum			10.2	-13.5
Q1			18.20	-1.70
Median			20.20	0.10
Q3			23.30	1.50
Maximum			40.4	4.5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（59/60）

Laboratory Test: Platelets (10^4/μL)

Visit / Statistics	P -> 1 mg (N=95)		1 mg -> 1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 40				
N	0	0	89	89
Mean			21.30	-0.09
SD			4.618	2.929
Minimum			12.9	-14.6
Q1			18.40	-1.20
Median			20.40	0.10
Q3			23.90	1.40
Maximum			38.9	6.9
Week 46				
N	0	0	85	85
Mean			21.29	-0.17
SD			4.958	3.486
Minimum			12.5	-15.3
Q1			18.20	-1.30
Median			20.70	-0.10
Q3			23.40	1.20
Maximum			36.8	16.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-55　血液学的検査の評価時点別変化量（OCT-001 試験）（60/60）

Laboratory Test: Platelets (10^4/μL)

Visit / Statistics	P -> 1 mg (N=95)		1 mg -> 1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 52				
N	0	0	86	86
Mean			20.92	-0.52
SD			4.338	2.628
Minimum			13.5	-13.1
Q1			18.50	-1.50
Median			20.55	0.00
Q3			22.40	0.80
Maximum			35.6	4.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（1/30）

RBC

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	10	3	-	13	13	4	-	17
Normal	3	71	1	75	3	93	1	97
High	-	1	2	3	-	-	2	2
Total	13	75	3	91	16	97	3	116
Week 6								
Low	10	2	-	12	14	4	-	18
Normal	2	74	3	79	2	91	2	95
High	-	1	-	1	-	-	1	1
Total	12	77	3	92	16	95	3	114
Week 14								
Low	11	5	-	16	13	5	-	18
Normal	2	67	2	71	3	89	2	94
High	-	1	-	1	-	-	1	1
Total	13	73	2	88	16	94	3	113
Week 20								
Low	10	5	-	15	12	5	-	17
Normal	3	64	2	69	4	86	2	92
High	-	1	-	1	-	1	1	2
Total	13	70	2	85	16	92	3	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（2/30）

RBC

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	11	6	-	17	11	3	-	14
Normal	1	59	1	61	4	88	2	94
High	-	1	1	2	-	-	1	1
Total	12	66	2	80	15	91	3	109
Week 29								
Low	1	1	-	2	12	5	-	17
Normal	-	2	-	2	3	80	-	83
High	-	-	-	-	-	-	3	3
Total	1	3	-	4	15	85	3	103
Week 32								
Low	-	-	-	-	12	3	-	15
Normal	-	-	-	-	2	81	2	85
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	14	84	3	101
Week 40								
Low	-	-	-	-	13	3	-	16
Normal	-	-	-	-	1	70	2	73
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	14	73	3	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（3/30）

RBC

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	9	8	-	17
Normal	-	-	-	-	5	63	2	70
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	14	71	2	87
Week 52								
Low	-	-	-	-	12	7	-	19
Normal	-	-	-	-	2	64	1	67
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	14	71	2	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（4/30）

Hemoglobin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	10	1	-	11	9	3	-	12
Normal	3	74	2	79	5	99	-	104
High	-	-	1	1	-	-	-	-
Total	13	75	3	91	14	102	-	116
Week 6								
Low	11	1	-	12	10	4	-	14
Normal	2	76	2	80	4	95	-	99
High	-	-	-	-	-	1	-	1
Total	13	77	2	92	14	100	-	114
Week 14								
Low	10	4	-	14	9	10	-	19
Normal	3	70	1	74	5	89	-	94
High	-	-	-	-	-	-	-	-
Total	13	74	1	88	14	99	-	113
Week 20								
Low	10	4	-	14	8	8	-	16
Normal	2	66	1	69	6	88	-	94
High	-	2	-	2	-	1	-	1
Total	12	72	1	85	14	97	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（5/30）

Hemoglobin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	9	6	-	15	7	7	-	14
Normal	2	61	-	63	6	89	-	95
High	-	1	1	2	-	-	-	-
Total	11	68	1	80	13	96	-	109
Week 29								
Low	1	1	-	2	7	9	-	16
Normal	-	2	-	2	6	79	-	85
High	-	-	-	-	-	2	-	2
Total	1	3	-	4	13	90	-	103
Week 32								
Low	-	-	-	-	9	8	-	17
Normal	-	-	-	-	3	80	-	83
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	12	89	-	101
Week 40								
Low	-	-	-	-	9	3	-	12
Normal	-	-	-	-	3	75	-	78
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	12	78	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（6/30）

Hemoglobin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	8	5	-	13
Normal	-	-	-	-	4	69	-	73
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	12	75	-	87
Week 52								
Low	-	-	-	-	7	5	-	12
Normal	-	-	-	-	5	70	-	75
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	12	75	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（7/30）

Hematocrit

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	7	4	-	11	8	2	-	10
Normal	4	73	2	79	4	102	-	106
High	-	-	1	1	-	-	-	-
Total	11	77	3	91	12	104	-	116
Week 6								
Low	8	3	-	11	8	4	-	12
Normal	3	76	2	81	4	98	-	102
High	-	-	-	-	-	-	-	-
Total	11	79	2	92	12	102	-	114
Week 14								
Low	8	5	-	13	10	7	-	17
Normal	3	70	1	74	2	93	-	95
High	-	1	-	1	-	1	-	1
Total	11	76	1	88	12	101	-	113
Week 20								
Low	8	6	-	14	9	6	-	15
Normal	2	68	1	71	3	92	-	95
High	-	-	-	-	-	1	-	1
Total	10	74	1	85	12	99	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（8/30）

Hematocrit

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	7	11	-	18	8	7	-	15
Normal	2	59	-	61	3	91	-	94
High	-	-	1	1	-	-	-	-
Total	9	70	1	80	11	98	-	109
Week 29								
Low	1	1	-	2	8	5	-	13
Normal	-	2	-	2	3	86	-	89
High	-	-	-	-	-	1	-	1
Total	1	3	-	4	11	92	-	103
Week 32								
Low	-	-	-	-	8	8	-	16
Normal	-	-	-	-	1	83	-	84
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	9	92	-	101
Week 40								
Low	-	-	-	-	8	5	-	13
Normal	-	-	-	-	1	76	-	77
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	9	81	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（9/30）

Hematocrit

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	7	7	-	14
Normal	-	-	-	-	2	70	-	72
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	9	78	-	87
Week 52								
Low	-	-	-	-	7	8	-	15
Normal	-	-	-	-	2	70	-	72
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	9	78	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（10/30）

WBC

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	1	-	2	1	1	-	2
Normal	1	84	-	85	2	109	2	113
High	-	3	1	4	-	-	1	1
Total	2	88	1	91	3	110	3	116
Week 6								
Low	1	1	-	2	1	-	-	1
Normal	1	85	1	87	1	108	3	112
High	-	3	-	3	1	-	-	1
Total	2	89	1	92	3	108	3	114
Week 14								
Low	-	-	-	-	1	-	-	1
Normal	2	82	-	84	2	107	3	112
High	-	3	1	4	-	-	-	-
Total	2	85	1	88	3	107	3	113
Week 20								
Low	2	-	-	2	1	1	-	2
Normal	-	80	1	81	2	102	3	107
High	-	2	-	2	-	2	-	2
Total	2	82	1	85	3	105	3	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（11/30）

WBC

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	2	-	-	2	-	2	-	2
Normal	-	76	1	77	3	102	2	107
High	-	1	-	1	-	-	-	-
Total	2	77	1	80	3	104	2	109
Week 29								
Low	-	-	-	-	-	1	-	1
Normal	-	4	-	4	3	96	2	101
High	-	-	-	-	-	-	1	1
Total	-	4	-	4	3	97	3	103
Week 32								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	3	94	2	99
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	3	95	3	101
Week 40								
Low	-	-	-	-	2	1	-	3
Normal	-	-	-	-	1	84	2	87
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	3	85	2	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（12/30）

WBC

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	2	82	1	85
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	3	82	2	87
Week 52								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	3	80	2	85
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	3	82	2	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（13/30）

Neutrophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	1	-	2	-	2	-	2
Normal	-	86	2	88	1	108	1	110
High	-	1	-	1	-	4	-	4
Total	1	88	2	91	1	114	1	116
Week 6								
Low	1	-	-	1	-	1	-	1
Normal	-	87	2	89	1	109	1	111
High	-	1	1	2	-	2	-	2
Total	1	88	3	92	1	112	1	114
Week 14								
Low	1	3	-	4	-	1	-	1
Normal	-	80	3	83	1	107	1	109
High	-	1	-	1	-	3	-	3
Total	1	84	3	88	1	111	1	113
Week 20								
Low	1	3	-	4	-	-	-	-
Normal	-	76	3	79	1	108	1	110
High	-	2	-	2	-	1	-	1
Total	1	81	3	85	1	109	1	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（14/30）

Neutrophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	1	1	1	3	-	1	-	1
Normal	-	72	2	74	1	104	1	106
High	-	3	-	3	-	2	-	2
Total	1	76	3	80	1	107	1	109
Week 29								
Low	-	-	-	-	-	1	-	1
Normal	-	4	-	4	1	96	1	98
High	-	-	-	-	-	4	-	4
Total	-	4	-	4	1	101	1	103
Week 32								
Low	-	-	-	-	1	2	-	3
Normal	-	-	-	-	-	95	1	96
High	-	-	-	-	-	2	-	2
Total	-	-	-	-	1	99	1	101
Week 40								
Low	-	-	-	-	-	2	-	2
Normal	-	-	-	-	-	87	1	88
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	89	1	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（15/30）

Neutrophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	3	-	3
Normal	-	-	-	-	-	78	1	79
High	-	-	-	-	-	5	-	5
Total	-	-	-	-	-	86	1	87
Week 52								
Low	-	-	-	-	-	3	-	3
Normal	-	-	-	-	-	82	1	83
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	86	1	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（16/30）

Eosinophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	90	-	90	-	114	1	115
High	-	1	-	1	-	-	1	1
Total	-	91	-	91	-	114	2	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	91	-	91	-	110	1	111
High	-	1	-	1	-	2	1	3
Total	-	92	-	92	-	112	2	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	87	-	87	-	110	1	111
High	-	1	-	1	-	1	1	2
Total	-	88	-	88	-	111	2	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	84	-	84	-	109	1	110
High	-	1	-	1	-	-	1	1
Total	-	85	-	85	-	109	2	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（17/30）

Eosinophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	77	-	77	-	106	2	108
High	-	3	-	3	-	1	-	1
Total	-	80	-	80	-	107	2	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	101	2	103
High	-	-	-	-	-	-	-	-
Total	-	4	-	4	-	101	2	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	97	1	98
High	-	-	-	-	-	2	1	3
Total	-	-	-	-	-	99	2	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	88	1	89
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	89	1	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（18/30）

Eosinophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	84	1	85
High	-	-	-	-	-	2	-	2
Total	-	-	-	-	-	86	1	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	85	1	86
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	86	1	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（19/30）

Monocytes

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	1	-	1
Normal	-	88	2	90	-	111	3	114
High	-	1	-	1	-	-	1	1
Total	-	89	2	91	-	112	4	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	88	1	89	-	108	1	109
High	-	2	1	3	-	2	3	5
Total	-	90	2	92	-	110	4	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	87	1	88	-	106	2	108
High	-	-	-	-	-	3	2	5
Total	-	87	1	88	-	109	4	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	82	1	83	-	105	1	106
High	-	2	-	2	-	2	3	5
Total	-	84	1	85	-	107	4	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（20/30）

Monocytes

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	78	1	79	-	105	3	108
High	-	1	-	1	-	-	1	1
Total	-	79	1	80	-	105	4	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	93	2	95
High	-	-	-	-	-	6	2	8
Total	-	4	-	4	-	99	4	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	92	2	94
High	-	-	-	-	-	5	2	7
Total	-	-	-	-	-	97	4	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	85	2	87
High	-	-	-	-	-	2	1	3
Total	-	-	-	-	-	87	3	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（21/30）

Monocytes

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	83	1	84
High	-	-	-	-	-	2	1	3
Total	-	-	-	-	-	85	2	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	84	2	86
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	85	2	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（22/30）

Lymphocytes

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	1	-	1	-	4	-	4
Normal	1	86	-	87	1	107	1	109
High	-	2	1	3	-	3	-	3
Total	1	89	1	91	1	114	1	116
Week 6								
Low	-	4	-	4	-	3	-	3
Normal	1	85	-	86	1	108	1	110
High	-	1	1	2	-	1	-	1
Total	1	90	1	92	1	112	1	114
Week 14								
Low	-	1	-	1	-	3	-	3
Normal	1	83	-	84	1	105	-	106
High	-	2	1	3	-	3	1	4
Total	1	86	1	88	1	111	1	113
Week 20								
Low	-	3	-	3	-	2	-	2
Normal	1	77	-	78	1	106	-	107
High	-	3	1	4	-	1	1	2
Total	1	83	1	85	1	109	1	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（23/30）

Lymphocytes

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	3	-	3	-	3	-	3
Normal	-	73	-	73	1	103	1	105
High	1	2	1	4	-	1	-	1
Total	1	78	1	80	1	107	1	109
Week 29								
Low	-	-	-	-	-	3	-	3
Normal	-	4	-	4	1	97	1	99
High	-	-	-	-	-	1	-	1
Total	-	4	-	4	1	101	1	103
Week 32								
Low	-	-	-	-	-	4	-	4
Normal	-	-	-	-	1	93	-	94
High	-	-	-	-	-	2	1	3
Total	-	-	-	-	1	99	1	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	89	-	89
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	90	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（24/30）

Lymphocytes

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	6	-	6
Normal	-	-	-	-	-	78	-	78
High	-	-	-	-	-	3	-	3
Total	-	-	-	-	-	87	-	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	84	-	84
High	-	-	-	-	-	3	-	3
Total	-	-	-	-	-	87	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（25/30）

Basophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	91	-	91	-	116	-	116
High	-	-	-	-	-	-	-	-
Total	-	91	-	91	-	116	-	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	92	-	92	-	114	-	114
High	-	-	-	-	-	-	-	-
Total	-	92	-	92	-	114	-	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	88	-	88	-	111	-	111
High	-	-	-	-	-	2	-	2
Total	-	88	-	88	-	113	-	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	85	-	85	-	111	-	111
High	-	-	-	-	-	-	-	-
Total	-	85	-	85	-	111	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（26/30）

Basophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	80	-	80	-	109	-	109
High	-	-	-	-	-	-	-	-
Total	-	80	-	80	-	109	-	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	103	-	103
High	-	-	-	-	-	-	-	-
Total	-	4	-	4	-	103	-	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	101	-	101
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	101	-	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	90	-	90
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	90	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（27/30）

Basophils

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	86	-	86
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	87	-	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	87	-	87
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	87	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（28/30）

Platelets

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	4	-	-	4
Normal	-	88	-	88	3	105	2	110
High	-	1	1	2	-	-	1	1
Total	-	89	1	90	7	105	3	115
Week 6								
Low	-	1	-	1	4	-	-	4
Normal	-	88	-	88	3	103	2	108
High	-	1	1	2	-	1	1	2
Total	-	90	1	91	7	104	3	114
Week 14								
Low	-	1	-	1	4	-	-	4
Normal	-	85	-	85	3	103	2	108
High	-	-	1	1	-	-	1	1
Total	-	86	1	87	7	103	3	113
Week 20								
Low	-	1	-	1	2	-	-	2
Normal	-	82	-	82	5	100	2	107
High	-	-	1	1	-	1	1	2
Total	-	83	1	84	7	101	3	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（29/30）

Platelets

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	1	-	1	4	-	-	4
Normal	-	76	-	76	3	97	2	102
High	-	1	1	2	-	2	1	3
Total	-	78	1	79	7	99	3	109
Week 29								
Low	-	-	-	-	4	-	-	4
Normal	-	4	-	4	3	92	1	96
High	-	-	-	-	-	1	2	3
Total	-	4	-	4	7	93	3	103
Week 32								
Low	-	-	-	-	6	-	-	6
Normal	-	-	-	-	1	90	2	93
High	-	-	-	-	-	1	1	2
Total	-	-	-	-	7	91	3	101
Week 40								
Low	-	-	-	-	3	-	-	3
Normal	-	-	-	-	1	82	2	85
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	4	82	3	89

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-56　血液学的検査の正異判定のクロス表（OCT-001 試験）（30/30）

Platelets

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	3	-	-	3
Normal	-	-	-	-	1	75	2	78
High	-	-	-	-	-	3	1	4
Total	-	-	-	-	4	78	3	85
Week 52								
Low	-	-	-	-	3	1	-	4
Normal	-	-	-	-	1	78	2	81
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	4	79	3	86

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（1/114）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		116	
Mean	23.7		22.5	
SD	7.00		4.38	
Minimum	13		13	
Q1	19.0		19.0	
Median	22.0		22.0	
Q3	26.0		26.0	
Maximum	60		35	
Week 3				
N	91	91	115	115
Mean	23.9	0.3	22.6	0.1
SD	8.78	4.20	5.46	3.97
Minimum	14	-13	13	-8
Q1	19.0	-2.0	19.0	-1.0
Median	22.0	0.0	22.0	0.0
Q3	25.0	2.0	26.0	2.0
Maximum	81	21	53	26

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（2/114）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	113
Mean	24.1	0.7	22.4	-0.1
SD	8.09	5.67	5.21	3.55
Minimum	11	-11	13	-8
Q1	20.0	-2.0	19.0	-2.0
Median	22.0	0.0	22.0	0.0
Q3	25.5	2.5	25.0	1.0
Maximum	63	37	43	17
Week 14				
N	88	88	108	107
Mean	23.5	0.3	22.9	0.4
SD	6.84	4.22	4.90	4.13
Minimum	15	-12	13	-11
Q1	19.0	-2.0	20.0	-2.0
Median	22.0	0.0	22.0	0.0
Q3	25.0	2.0	25.5	3.0
Maximum	50	16	37	13

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（3/114）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	P -> 1 mg (N=95)		1 mg -> 1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20				
N	85	85	109	108
Mean	24.1	0.9	22.9	0.5
SD	8.67	5.95	4.36	3.59
Minimum	13	-11	15	-8
Q1	20.0	-1.0	20.0	-2.0
Median	21.0	0.0	23.0	0.0
Q3	25.0	2.0	25.0	3.0
Maximum	66	40	36	14
Week 26				
N	80	80	106	105
Mean	23.4	0.5	23.8	1.4
SD	6.94	4.78	8.46	7.30
Minimum	14	-16	13	-9
Q1	20.0	-2.0	19.0	-1.0
Median	22.0	0.0	22.5	1.0
Q3	25.0	3.0	26.0	3.0
Maximum	52	20	73	47

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）　(4/114)

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	102
Mean	30.3	2.0	23.4	1.0
SD	6.55	8.25	6.39	5.45
Minimum	22	-7	12	-7
Q1	26.0	-3.0	20.0	-2.0
Median	30.5	1.0	23.0	0.0
Q3	34.5	7.0	25.0	3.0
Maximum	38	13	68	42
Week 32				
N	0	0	100	99
Mean			24.4	1.9
SD			13.80	12.74
Minimum			14	-8
Q1			19.0	-2.0
Median			23.0	1.0
Q3			25.0	2.0
Maximum			144	114

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（5/114）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	85	84
Mean			23.8	1.8
SD			7.02	6.30
Minimum			14	-6
Q1			20.0	-1.0
Median			23.0	1.0
Q3			26.0	3.0
Maximum			70	44
Week 46				
N	0	0	85	85
Mean			23.8	1.6
SD			8.07	7.38
Minimum			14	-8
Q1			19.0	-2.0
Median			23.0	1.0
Q3			26.0	2.0
Maximum			79	53

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（6/114）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	86	86
Mean			23.5	1.3
SD			6.43	5.69
Minimum			16	-7
Q1			20.0	-2.0
Median			22.0	1.0
Q3			25.0	3.0
Maximum			65	39

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（7/114）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	20.2		17.7	
SD	12.06		6.08	
Minimum	6		8	
Q1	13.0		14.0	
Median	17.0		16.0	
Q3	23.0		21.0	
Maximum	100		40	
Week 3				
N	91	91	116	116
Mean	21.0	0.6	17.4	-0.2
SD	14.83	5.07	6.63	4.53
Minimum	4	-10	8	-12
Q1	14.0	-1.0	13.0	-2.0
Median	17.0	0.0	16.0	0.0
Q3	21.0	2.0	21.0	1.5
Maximum	122	22	49	21

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）　(8/114)

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	19.9	0.5	17.1	-0.5
SD	10.74	6.17	6.69	4.71
Minimum	4	-14	8	-14
Q1	13.0	-2.0	13.0	-3.0
Median	17.0	0.0	15.0	0.0
Q3	22.5	2.5	19.0	1.0
Maximum	64	38	39	19
Week 14				
N	88	88	113	113
Mean	19.0	-0.4	17.6	0.0
SD	10.20	6.16	7.08	5.40
Minimum	5	-23	8	-15
Q1	13.0	-2.0	13.0	-3.0
Median	16.5	0.0	16.0	0.0
Q3	22.0	1.0	21.0	2.0
Maximum	80	34	56	17

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（9/114）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	19.5	0.5	17.7	0.1
SD	10.94	6.23	6.87	4.76
Minimum	6	-15	8	-14
Q1	13.0	-2.0	12.0	-3.0
Median	16.0	0.0	17.0	0.0
Q3	21.0	2.0	21.0	3.0
Maximum	59	33	52	13
Week 26				
N	80	80	109	109
Mean	19.1	0.2	18.7	1.1
SD	9.92	6.36	11.34	9.90
Minimum	6	-24	8	-15
Q1	13.0	-3.0	13.0	-3.0
Median	16.5	0.0	16.0	0.0
Q3	20.0	3.5	21.0	2.0
Maximum	63	18	96	75

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（10/114）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	28.3	3.3	17.7	0.0
SD	9.91	9.84	7.38	6.42
Minimum	17	-2	9	-14
Q1	21.5	-2.0	13.0	-3.0
Median	27.5	-1.5	16.0	0.0
Q3	35.0	8.5	20.0	2.0
Maximum	41	18	63	46
Week 32				
N	0	0	101	101
Mean			19.7	1.9
SD			21.19	19.64
Minimum			9	-14
Q1			13.0	-3.0
Median			16.0	0.0
Q3			20.0	3.0
Maximum			218	187

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（11/114）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			18.8	1.5
SD			11.33	10.61
Minimum			8	-13
Q1			13.0	-2.0
Median			17.0	0.0
Q3			20.0	3.0
Maximum			86	74
Week 46				
N	0	0	87	87
Mean			18.6	1.3
SD			11.04	9.51
Minimum			10	-13
Q1			13.0	-2.0
Median			16.0	0.0
Q3			20.0	2.0
Maximum			79	48

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（12/114）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			17.8	0.5
SD			7.82	6.62
Minimum			9	-14
Q1			13.0	-3.0
Median			16.0	0.0
Q3			20.0	3.0
Maximum			54	37

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（13/114）

Laboratory Test: GGT (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	26.0		24.7	
SD	21.97		18.16	
Minimum	7		9	
Q1	14.0		13.0	
Median	19.0		19.0	
Q3	31.0		29.0	
Maximum	136		115	
Week 3				
N	91	91	116	116
Mean	25.8	-0.5	24.4	0.0
SD	18.47	6.67	20.27	6.18
Minimum	7	-42	8	-21
Q1	14.0	-2.0	13.0	-2.0
Median	20.0	0.0	19.5	0.0
Q3	34.0	2.0	30.0	1.0
Maximum	104	18	155	44

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（14/114）

Laboratory Test: GGT (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	26.1	1.3	23.2	-1.0
SD	19.60	6.72	18.09	5.90
Minimum	8	-39	8	-28
Q1	14.0	-1.0	13.0	-3.0
Median	20.5	0.0	18.0	-0.5
Q3	31.5	3.0	28.0	1.0
Maximum	131	28	134	23
Week 14				
N	88	88	113	113
Mean	24.7	-0.3	24.1	-0.3
SD	19.01	5.39	20.74	7.82
Minimum	5	-17	7	-33
Q1	14.0	-3.0	13.0	-3.0
Median	18.0	0.0	18.0	0.0
Q3	30.5	1.0	29.0	2.0
Maximum	117	16	149	38

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（15/114）

Laboratory Test: GGT (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	24.9	-0.2	24.6	0.2
SD	17.99	8.18	23.67	11.26
Minimum	7	-35	5	-32
Q1	13.0	-2.0	13.0	-3.0
Median	19.0	0.0	17.0	-1.0
Q3	31.0	2.0	29.0	2.0
Maximum	92	25	201	90
Week 26				
N	80	80	109	109
Mean	24.8	0.1	26.0	1.3
SD	18.77	9.31	23.59	13.26
Minimum	5	-38	7	-23
Q1	13.0	-2.5	13.0	-3.0
Median	18.5	0.0	18.0	-1.0
Q3	27.5	3.0	27.0	2.0
Maximum	107	40	156	76

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（16/114）

Laboratory Test: GGT (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	38.3	0.0	24.9	0.0
SD	13.99	15.53	18.74	10.15
Minimum	29	-19	6	-42
Q1	30.0	-12.0	13.0	-2.0
Median	32.5	1.0	19.0	0.0
Q3	46.5	12.0	28.0	2.0
Maximum	59	17	111	57
Week 32				
N	0	0	101	101
Mean			24.7	-0.4
SD			18.37	10.45
Minimum			7	-52
Q1			13.0	-3.0
Median			20.0	0.0
Q3			28.0	3.0
Maximum			106	56

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（17/114）

Laboratory Test: GGT (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			26.0	2.5
SD			33.18	30.55
Minimum			8	-39
Q1			13.0	-3.0
Median			19.0	0.0
Q3			27.0	2.0
Maximum			290	276
Week 46				
N	0	0	87	87
Mean			23.4	0.0
SD			19.55	10.68
Minimum			7	-40
Q1			13.0	-3.0
Median			19.0	0.0
Q3			28.0	2.0
Maximum			145	42

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（18/114）

Laboratory Test: GGT (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			22.9	-0.6
SD			16.53	8.95
Minimum			7	-47
Q1			13.0	-3.0
Median			18.0	0.0
Q3			27.0	2.0
Maximum			102	29

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（19/114）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	222.6		211.9	
SD	62.98		62.78	
Minimum	118		72	
Q1	182.0		171.0	
Median	218.0		196.0	
Q3	252.0		255.0	
Maximum	514		346	
Week 3				
N	91	91	116	116
Mean	223.9	-1.0	210.8	-1.2
SD	62.33	20.60	62.61	18.63
Minimum	109	-47	71	-47
Q1	179.0	-12.0	165.5	-13.0
Median	222.0	-3.0	199.5	-1.5
Q3	255.0	10.0	263.0	10.0
Maximum	476	65	415	78

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（20/114）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	216.5	-2.1	211.2	-1.0
SD	57.85	21.54	62.53	18.10
Minimum	120	-62	69	-47
Q1	177.0	-13.5	166.0	-13.0
Median	218.0	-4.0	196.5	-1.5
Q3	254.5	9.0	253.0	8.0
Maximum	417	58	373	62
Week 14				
N	88	88	113	113
Mean	221.5	-0.3	212.8	0.5
SD	57.87	26.20	59.94	28.67
Minimum	127	-74	77	-89
Q1	175.5	-17.0	168.0	-13.0
Median	218.0	-3.5	204.0	2.0
Q3	256.0	15.5	252.0	16.0
Maximum	395	69	396	64

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（21/114）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	223.5	1.2	218.6	5.8
SD	57.67	24.96	65.99	37.80
Minimum	123	-68	72	-85
Q1	182.0	-16.0	170.0	-13.0
Median	216.0	-1.0	213.0	3.0
Q3	259.0	14.0	266.0	24.0
Maximum	406	80	429	192
Week 26				
N	80	80	109	109
Mean	228.9	5.3	214.7	2.6
SD	60.28	32.00	65.02	36.91
Minimum	114	-101	86	-111
Q1	182.0	-14.0	173.0	-17.0
Median	223.0	3.5	204.0	1.0
Q3	268.5	24.0	250.0	21.0
Maximum	371	114	467	149

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（22/114）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	194.3	-3.5	216.3	2.2
SD	35.14	13.77	67.87	35.61
Minimum	144	-17	76	-90
Q1	170.0	-13.5	169.0	-20.0
Median	207.0	-6.0	201.0	2.0
Q3	218.5	6.5	259.0	21.0
Maximum	219	15	492	170
Week 32				
N	0	0	101	101
Mean			215.7	1.0
SD			62.32	29.91
Minimum			88	-100
Q1			173.0	-14.0
Median			200.0	6.0
Q3			255.0	15.0
Maximum			453	131

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（23/114）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			216.8	4.1
SD			68.71	41.19
Minimum			81	-90
Q1			167.0	-13.0
Median			202.0	2.5
Q3			257.0	17.0
Maximum			431	188
Week 46				
N	0	0	87	87
Mean			215.6	1.4
SD			59.97	31.23
Minimum			80	-98
Q1			167.0	-17.0
Median			211.0	3.0
Q3			255.0	22.0
Maximum			375	91

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（24/114）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			212.6	-1.7
SD			57.81	32.15
Minimum			73	-100
Q1			163.0	-18.0
Median			209.0	-1.0
Q3			252.0	16.0
Maximum			344	102

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（25/114）

Laboratory Test: LDH (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		116	
Mean	174.9		177.5	
SD	31.96		29.02	
Minimum	122		116	
Q1	154.0		156.0	
Median	171.0		173.0	
Q3	193.0		195.5	
Maximum	287		273	
Week 3				
N	91	91	115	115
Mean	173.6	-2.0	177.5	0.2
SD	29.92	12.74	35.90	18.65
Minimum	120	-49	117	-37
Q1	154.0	-8.0	156.0	-9.0
Median	171.0	-1.0	173.0	0.0
Q3	189.0	5.0	195.0	6.0
Maximum	291	30	376	158

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（26/114）

Laboratory Test: LDH (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	113
Mean	172.5	-2.3	176.8	-0.2
SD	29.83	14.53	32.71	15.19
Minimum	120	-44	113	-30
Q1	148.5	-9.0	157.0	-8.0
Median	168.0	-2.5	173.0	-2.0
Q3	190.5	7.5	191.0	6.0
Maximum	268	35	316	98
Week 14				
N	88	88	108	107
Mean	175.4	0.4	178.5	1.0
SD	31.73	14.96	30.13	15.66
Minimum	126	-35	115	-39
Q1	156.0	-9.5	162.0	-8.0
Median	171.0	2.0	174.0	0.0
Q3	186.5	9.5	195.5	8.0
Maximum	300	47	261	57

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（27/114）

Laboratory Test: LDH (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	109	108
Mean	178.6	4.0	180.2	3.6
SD	33.53	21.31	34.21	18.35
Minimum	119	-39	119	-38
Q1	155.0	-6.0	158.0	-6.0
Median	173.0	1.0	175.0	2.0
Q3	196.0	11.0	194.0	11.0
Maximum	281	131	319	74
Week 26				
N	80	80	106	105
Mean	176.5	1.0	176.8	0.4
SD	33.17	19.95	33.65	16.35
Minimum	120	-40	114	-42
Q1	154.0	-9.5	155.0	-9.0
Median	169.0	-0.5	172.5	-1.0
Q3	197.0	9.0	194.0	10.0
Maximum	286	92	318	45

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（28/114）

Laboratory Test: LDH (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	102
Mean	164.8	6.5	179.3	3.1
SD	20.93	3.32	32.52	15.80
Minimum	142	4	119	-27
Q1	147.0	4.0	158.0	-7.0
Median	166.5	5.5	175.0	1.0
Q3	182.5	9.0	196.0	11.0
Maximum	184	11	296	52
Week 32				
N	0	0	100	99
Mean			177.8	2.0
SD			32.29	17.26
Minimum			116	-37
Q1			156.5	-8.0
Median			171.0	0.0
Q3			197.0	9.0
Maximum			298	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（29/114）

Laboratory Test: LDH (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	85	84
Mean			180.5	4.3
SD			33.75	14.67
Minimum			123	-41
Q1			156.0	-7.0
Median			174.0	3.0
Q3			199.0	14.0
Maximum			292	42
Week 46				
N	0	0	85	85
Mean			179.7	3.2
SD			34.28	16.59
Minimum			129	-36
Q1			151.0	-8.0
Median			177.0	0.0
Q3			197.0	14.0
Maximum			304	47

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（30/114）

Laboratory Test: LDH (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	86	86
Mean			181.0	4.7
SD			35.47	15.83
Minimum			112	-31
Q1			155.0	-6.0
Median			175.5	2.0
Q3			195.0	16.0
Maximum			299	48

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（31/114）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	4.43		4.39	
SD	0.234		0.238	
Minimum	3.7		3.7	
Q1	4.30		4.20	
Median	4.40		4.40	
Q3	4.60		4.50	
Maximum	4.9		5.0	
Week 3				
N	91	91	116	116
Mean	4.40	-0.03	4.38	-0.01
SD	0.228	0.160	0.233	0.165
Minimum	3.7	-0.4	3.8	-0.4
Q1	4.30	-0.20	4.20	-0.10
Median	4.40	0.00	4.40	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	4.9	0.4	5.1	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（32/114）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	4.42	-0.01	4.38	-0.01
SD	0.223	0.168	0.224	0.169
Minimum	3.9	-0.4	3.9	-0.4
Q1	4.25	-0.10	4.20	-0.10
Median	4.40	0.00	4.40	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	4.8	0.4	5.0	0.4
Week 14				
N	88	88	113	113
Mean	4.40	-0.03	4.36	-0.03
SD	0.222	0.172	0.225	0.177
Minimum	3.8	-0.4	3.8	-0.6
Q1	4.25	-0.10	4.20	-0.10
Median	4.40	0.00	4.40	0.00
Q3	4.55	0.10	4.50	0.10
Maximum	5.0	0.5	5.0	0.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（33/114）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	4.40	-0.02	4.36	-0.03
SD	0.245	0.172	0.201	0.189
Minimum	3.8	-0.4	3.8	-0.4
Q1	4.20	-0.10	4.20	-0.20
Median	4.40	0.00	4.40	0.00
Q3	4.60	0.10	4.50	0.10
Maximum	4.9	0.5	5.0	0.4
Week 26				
N	80	80	109	109
Mean	4.38	-0.04	4.37	-0.03
SD	0.266	0.191	0.231	0.217
Minimum	3.3	-0.7	3.7	-0.6
Q1	4.30	-0.10	4.20	-0.10
Median	4.40	0.00	4.40	0.00
Q3	4.50	0.10	4.50	0.10
Maximum	4.9	0.4	4.9	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（34/114）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	4.45	-0.03	4.37	-0.02
SD	0.173	0.206	0.245	0.231
Minimum	4.2	-0.3	3.8	-0.6
Q1	4.35	-0.15	4.20	-0.20
Median	4.50	0.00	4.40	0.00
Q3	4.55	0.10	4.50	0.10
Maximum	4.6	0.2	5.0	0.5
Week 32				
N	0	0	101	101
Mean			4.35	-0.04
SD			0.227	0.199
Minimum			3.8	-0.5
Q1			4.20	-0.20
Median			4.30	-0.10
Q3			4.50	0.10
Maximum			4.9	0.4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（35/114）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			4.36	-0.02
SD			0.237	0.172
Minimum			3.7	-0.4
Q1			4.20	-0.10
Median			4.30	0.00
Q3			4.50	0.10
Maximum			4.9	0.4
Week 46				
N	0	0	87	87
Mean			4.34	-0.04
SD			0.262	0.235
Minimum			3.8	-0.5
Q1			4.10	-0.20
Median			4.30	0.00
Q3			4.50	0.10
Maximum			5.1	0.5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（36/114）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			4.35	-0.03
SD			0.251	0.195
Minimum			3.6	-0.6
Q1			4.20	-0.20
Median			4.30	0.00
Q3			4.50	0.10
Maximum			4.9	0.5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（37/114）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	7.16		7.08	
SD	0.453		0.372	
Minimum	5.6		6.2	
Q1	6.90		6.80	
Median	7.10		7.10	
Q3	7.40		7.30	
Maximum	8.6		8.1	
Week 3				
N	91	91	116	116
Mean	7.13	-0.01	7.07	-0.01
SD	0.415	0.234	0.385	0.245
Minimum	5.7	-0.5	6.1	-0.7
Q1	6.90	-0.20	6.80	-0.20
Median	7.10	0.00	7.00	0.00
Q3	7.40	0.10	7.20	0.10
Maximum	8.2	0.6	8.4	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（38/114）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	7.11	-0.04	7.05	-0.03
SD	0.405	0.259	0.386	0.278
Minimum	5.9	-0.7	6.1	-0.8
Q1	6.80	-0.25	6.80	-0.20
Median	7.10	0.00	7.00	-0.10
Q3	7.35	0.10	7.30	0.20
Maximum	8.3	0.6	8.2	0.7
Week 14				
N	88	88	113	113
Mean	7.06	-0.08	7.05	-0.03
SD	0.435	0.268	0.384	0.274
Minimum	6.1	-0.6	5.9	-0.8
Q1	6.80	-0.20	6.80	-0.20
Median	7.00	-0.10	7.10	-0.10
Q3	7.30	0.10	7.30	0.20
Maximum	8.4	0.7	7.9	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（39/114）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	7.10	-0.04	7.04	-0.04
SD	0.437	0.243	0.354	0.309
Minimum	5.5	-0.5	6.2	-0.9
Q1	6.80	-0.20	6.80	-0.30
Median	7.10	0.00	7.10	0.00
Q3	7.30	0.10	7.30	0.20
Maximum	8.5	0.6	8.1	0.8
Week 26				
N	80	80	109	109
Mean	7.08	-0.06	7.04	-0.04
SD	0.429	0.283	0.400	0.326
Minimum	5.6	-0.9	6.1	-1.0
Q1	6.90	-0.20	6.80	-0.30
Median	7.10	-0.10	7.10	-0.10
Q3	7.30	0.10	7.30	0.20
Maximum	8.4	0.8	8.2	1.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（40/114）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	7.00	-0.15	7.07	-0.01
SD	0.356	0.265	0.406	0.337
Minimum	6.5	-0.4	6.1	-1.0
Q1	6.75	-0.35	6.80	-0.20
Median	7.10	-0.20	7.10	0.00
Q3	7.25	0.05	7.30	0.20
Maximum	7.3	0.2	8.4	0.8
Week 32				
N	0	0	101	101
Mean			7.04	-0.05
SD			0.346	0.296
Minimum			6.2	-0.9
Q1			6.80	-0.30
Median			7.10	-0.10
Q3			7.20	0.20
Maximum			8.2	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（41/114）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			7.04	-0.03
SD			0.418	0.280
Minimum			5.9	-0.7
Q1			6.80	-0.20
Median			7.00	0.00
Q3			7.30	0.20
Maximum			8.3	0.6
Week 46				
N	0	0	87	87
Mean			7.00	-0.06
SD			0.424	0.343
Minimum			6.0	-0.8
Q1			6.70	-0.30
Median			7.00	-0.10
Q3			7.20	0.10
Maximum			8.4	0.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（42/114）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	P -> 1 mg (N=95)		1 mg -> 1 mg (N=117)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 52				
N	0	0	87	87
Mean			7.00	-0.06
SD			0.403	0.310
Minimum			5.9	-0.9
Q1			6.70	-0.30
Median			6.90	-0.10
Q3			7.20	0.20
Maximum			8.3	0.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（43/114）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	0.87		0.83	
SD	0.281		0.314	
Minimum	0.5		0.4	
Q1	0.70		0.60	
Median	0.80		0.80	
Q3	1.00		1.00	
Maximum	1.7		2.1	
Week 3				
N	91	91	116	116
Mean	0.84	-0.03	0.85	0.02
SD	0.300	0.176	0.294	0.222
Minimum	0.3	-0.5	0.4	-0.6
Q1	0.60	-0.10	0.60	-0.10
Median	0.80	0.00	0.80	0.00
Q3	1.00	0.10	1.00	0.20
Maximum	1.8	0.5	1.7	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（44/114）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	0.88	0.01	0.86	0.03
SD	0.341	0.225	0.283	0.223
Minimum	0.4	-0.5	0.3	-0.6
Q1	0.70	-0.10	0.60	-0.10
Median	0.80	0.00	0.80	0.00
Q3	1.00	0.10	1.00	0.10
Maximum	1.9	0.8	1.7	0.7
Week 14				
N	88	88	113	113
Mean	0.83	-0.03	0.82	-0.01
SD	0.308	0.178	0.293	0.217
Minimum	0.4	-0.4	0.4	-0.6
Q1	0.60	-0.10	0.60	-0.10
Median	0.80	-0.10	0.80	0.00
Q3	0.95	0.10	0.90	0.10
Maximum	2.0	0.7	1.9	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（45/114）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	0.83	-0.04	0.82	-0.01
SD	0.323	0.183	0.299	0.229
Minimum	0.3	-0.6	0.3	-0.9
Q1	0.60	-0.10	0.60	-0.10
Median	0.80	-0.10	0.80	0.00
Q3	0.90	0.10	1.00	0.10
Maximum	2.0	0.6	1.7	0.6
Week 26				
N	80	80	109	109
Mean	0.81	-0.06	0.83	0.00
SD	0.294	0.207	0.291	0.234
Minimum	0.3	-0.7	0.4	-0.6
Q1	0.60	-0.20	0.60	-0.10
Median	0.75	-0.10	0.80	0.00
Q3	0.90	0.10	0.90	0.10
Maximum	1.7	0.4	1.7	0.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（46/114）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	0.83	-0.10	0.81	-0.02
SD	0.250	0.216	0.279	0.211
Minimum	0.5	-0.4	0.4	-1.1
Q1	0.65	-0.25	0.60	-0.10
Median	0.85	-0.05	0.80	0.00
Q3	1.00	0.05	0.90	0.10
Maximum	1.1	0.1	1.9	0.5
Week 32				
N	0	0	101	101
Mean			0.78	-0.05
SD			0.266	0.231
Minimum			0.4	-0.7
Q1			0.60	-0.20
Median			0.70	-0.10
Q3			0.90	0.10
Maximum			1.7	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（47/114）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			0.82	0.01
SD			0.279	0.216
Minimum			0.4	-0.7
Q1			0.60	-0.10
Median			0.80	0.00
Q3			0.90	0.10
Maximum			1.8	0.7
Week 46				
N	0	0	87	87
Mean			0.81	-0.01
SD			0.295	0.233
Minimum			0.3	-0.7
Q1			0.60	-0.10
Median			0.70	0.00
Q3			0.90	0.10
Maximum			1.7	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（48/114）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			0.84	0.03
SD			0.304	0.266
Minimum			0.3	-0.8
Q1			0.60	-0.10
Median			0.80	0.00
Q3			1.10	0.20
Maximum			2.0	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（49/114）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	207.6		208.7	
SD	32.09		35.26	
Minimum	143		96	
Q1	185.0		185.0	
Median	205.0		206.0	
Q3	226.0		229.0	
Maximum	296		297	
Week 3				
N	91	91	116	116
Mean	203.2	-4.2	204.9	-4.0
SD	28.41	15.53	33.38	17.44
Minimum	141	-48	99	-100
Q1	183.0	-15.0	183.0	-12.0
Median	204.0	-5.0	204.0	-1.0
Q3	221.0	5.0	225.5	6.0
Maximum	282	32	302	33

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（50/114）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	202.1	-4.5	201.7	-7.3
SD	28.52	16.85	32.85	20.95
Minimum	135	-54	103	-120
Q1	182.0	-16.0	179.0	-18.0
Median	202.0	-5.5	201.5	-4.5
Q3	221.5	7.5	220.0	5.0
Maximum	263	31	292	40
Week 14				
N	88	88	113	113
Mean	200.5	-6.2	200.8	-7.9
SD	30.06	17.28	34.19	22.64
Minimum	127	-36	104	-95
Q1	178.5	-16.0	177.0	-21.0
Median	199.0	-8.0	198.0	-6.0
Q3	222.0	3.0	224.0	6.0
Maximum	266	37	310	75

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（51/114）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	203.2	-3.6	199.6	-9.1
SD	27.40	15.35	31.49	23.13
Minimum	150	-40	112	-160
Q1	184.0	-14.0	181.0	-21.0
Median	201.0	-3.0	197.0	-6.0
Q3	222.0	5.0	217.0	3.0
Maximum	276	35	303	42
Week 26				
N	80	80	109	109
Mean	205.1	-1.3	202.4	-6.6
SD	32.96	16.83	35.45	24.47
Minimum	124	-49	104	-102
Q1	181.0	-12.0	179.0	-21.0
Median	203.0	1.0	200.0	-4.0
Q3	221.0	11.5	224.0	7.0
Maximum	287	31	332	91

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（52/114）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	201.0	-14.5	201.3	-8.0
SD	32.32	20.17	35.55	28.71
Minimum	169	-33	104	-135
Q1	181.5	-30.0	177.0	-19.0
Median	194.5	-18.5	202.0	-7.0
Q3	220.5	1.0	223.0	8.0
Maximum	246	12	306	96
Week 32				
N	0	0	101	101
Mean			200.1	-8.5
SD			34.98	27.68
Minimum			108	-111
Q1			178.0	-18.0
Median			199.0	-4.0
Q3			223.0	4.0
Maximum			307	66

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（53/114）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			201.9	-3.9
SD			34.87	21.85
Minimum			104	-72
Q1			183.0	-16.0
Median			196.5	-5.0
Q3			221.0	6.0
Maximum			315	105
Week 46				
N	0	0	87	87
Mean			203.1	-3.3
SD			37.16	25.08
Minimum			104	-92
Q1			179.0	-15.0
Median			201.0	-3.0
Q3			221.0	11.0
Maximum			344	134

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（54/114）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			201.0	-5.4
SD			34.82	25.10
Minimum			97	-122
Q1			177.0	-16.0
Median			200.0	-2.0
Q3			217.0	7.0
Maximum			328	118

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（55/114）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	92.0		112.0	
SD	44.73		160.90	
Minimum	37		37	
Q1	62.0		65.0	
Median	75.0		84.0	
Q3	114.0		114.0	
Maximum	249		1740	
Week 3				
N	91	91	116	116
Mean	100.1	7.3	101.3	-10.6
SD	48.12	33.78	75.26	99.68
Minimum	31	-104	36	-1014
Q1	65.0	-10.0	64.0	-17.0
Median	90.0	5.0	83.0	-1.5
Q3	125.0	21.0	113.0	13.0
Maximum	274	131	726	97

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（56/114）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	91.3	0.5	100.2	-11.6
SD	55.42	45.84	70.36	129.26
Minimum	36	-157	40	-1290
Q1	58.0	-17.0	63.0	-16.0
Median	76.0	-3.5	84.5	-1.0
Q3	111.5	11.0	114.0	17.0
Maximum	458	309	542	228
Week 14				
N	88	88	113	113
Mean	87.6	-4.1	105.3	-7.0
SD	38.57	31.30	132.35	54.30
Minimum	34	-152	37	-365
Q1	57.0	-18.0	56.0	-20.0
Median	74.0	-1.0	82.0	-5.0
Q3	114.5	8.5	113.0	16.0
Maximum	186	109	1375	127

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（57/114）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	89.8	-3.0	96.8	-15.4
SD	42.71	37.23	55.52	130.29
Minimum	36	-151	31	-1303
Q1	57.0	-18.0	64.0	-19.0
Median	81.0	-4.0	81.0	-1.0
Q3	117.0	11.0	112.0	13.0
Maximum	234	120	437	88
Week 26				
N	80	80	109	109
Mean	95.9	2.8	109.1	-4.0
SD	48.27	34.66	112.29	118.32
Minimum	35	-74	30	-945
Q1	56.5	-16.0	62.0	-20.0
Median	84.5	-1.5	81.0	-1.0
Q3	121.0	22.0	119.0	13.0
Maximum	285	171	875	674

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（58/114）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	97.8	7.3	99.5	-15.0
SD	30.80	50.18	66.42	131.48
Minimum	67	-47	35	-1273
Q1	75.5	-28.0	57.0	-24.0
Median	92.5	1.5	85.0	-7.0
Q3	120.0	42.5	123.0	16.0
Maximum	139	73	467	141
Week 32				
N	0	0	101	101
Mean			106.3	-9.2
SD			84.23	118.94
Minimum			39	-1070
Q1			63.0	-27.0
Median			84.0	-6.0
Q3			109.0	16.0
Maximum			670	205

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（59/114）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			103.1	2.8
SD			97.70	88.74
Minimum			36	-230
Q1			57.0	-20.0
Median			80.0	-5.5
Q3			111.0	20.0
Maximum			890	689
Week 46				
N	0	0	87	87
Mean			111.7	11.5
SD			133.33	119.09
Minimum			31	-195
Q1			61.0	-17.0
Median			88.0	-4.0
Q3			112.0	20.0
Maximum			1235	1034

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（60/114）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			98.1	-2.1
SD			83.79	77.05
Minimum			29	-214
Q1			60.0	-27.0
Median			77.0	-4.0
Q3			110.0	11.0
Maximum			752	551

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（61/114）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	0.718		0.749	
SD	0.1629		0.1805	
Minimum	0.45		0.44	
Q1	0.600		0.620	
Median	0.690		0.720	
Q3	0.830		0.880	
Maximum	1.22		1.50	
Week 3				
N	91	91	116	116
Mean	0.725	0.001	0.749	0.000
SD	0.1553	0.0437	0.1796	0.0507
Minimum	0.44	-0.10	0.45	-0.12
Q1	0.620	-0.030	0.620	-0.030
Median	0.710	0.000	0.720	0.000
Q3	0.820	0.020	0.880	0.030
Maximum	1.24	0.13	1.53	0.16

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（62/114）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	0.709	-0.008	0.747	-0.006
SD	0.1564	0.0474	0.1727	0.0606
Minimum	0.45	-0.18	0.43	-0.17
Q1	0.575	-0.030	0.610	-0.040
Median	0.695	0.000	0.710	-0.010
Q3	0.825	0.020	0.870	0.030
Maximum	1.14	0.17	1.36	0.19
Week 14				
N	88	88	113	113
Mean	0.709	-0.008	0.744	-0.010
SD	0.1676	0.0670	0.1743	0.0517
Minimum	0.46	-0.23	0.42	-0.16
Q1	0.590	-0.040	0.610	-0.040
Median	0.660	-0.010	0.710	-0.010
Q3	0.815	0.020	0.840	0.030
Maximum	1.17	0.32	1.48	0.12

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（63/114）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	0.700	-0.018	0.749	-0.007
SD	0.1620	0.0642	0.1746	0.0627
Minimum	0.44	-0.17	0.44	-0.17
Q1	0.580	-0.050	0.610	-0.050
Median	0.660	-0.020	0.710	-0.010
Q3	0.820	0.020	0.880	0.030
Maximum	1.12	0.15	1.41	0.21
Week 26				
N	80	80	109	109
Mean	0.743	0.021	0.750	-0.009
SD	0.2646	0.2486	0.1864	0.0692
Minimum	0.48	-0.19	0.44	-0.18
Q1	0.600	-0.050	0.610	-0.050
Median	0.680	-0.010	0.710	-0.010
Q3	0.840	0.040	0.860	0.020
Maximum	2.62	2.13	1.53	0.27

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（64/114）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	0.708	-0.010	0.750	-0.012
SD	0.1723	0.0424	0.1852	0.0601
Minimum	0.47	-0.06	0.43	-0.17
Q1	0.595	-0.045	0.610	-0.060
Median	0.740	-0.005	0.710	-0.010
Q3	0.820	0.025	0.890	0.020
Maximum	0.88	0.03	1.44	0.16
Week 32				
N	0	0	101	101
Mean			0.744	-0.018
SD			0.1861	0.0603
Minimum			0.42	-0.18
Q1			0.600	-0.060
Median			0.720	-0.020
Q3			0.870	0.020
Maximum			1.44	0.18

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（65/114）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			0.736	-0.026
SD			0.1777	0.0671
Minimum			0.44	-0.21
Q1			0.610	-0.070
Median			0.705	-0.025
Q3			0.850	0.020
Maximum			1.50	0.12
Week 46				
N	0	0	87	87
Mean			0.746	-0.018
SD			0.1785	0.0630
Minimum			0.47	-0.19
Q1			0.610	-0.050
Median			0.700	-0.020
Q3			0.870	0.020
Maximum			1.46	0.16

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（66/114）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			0.755	-0.009
SD			0.1870	0.0596
Minimum			0.45	-0.18
Q1			0.620	-0.050
Median			0.720	-0.010
Q3			0.880	0.020
Maximum			1.52	0.20

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（67/114）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	14.8		15.0	
SD	3.51		3.48	
Minimum	8		7	
Q1	12.0		13.0	
Median	14.0		15.0	
Q3	17.0		17.0	
Maximum	24		26	
Week 3				
N	91	91	116	116
Mean	15.0	0.1	15.1	0.1
SD	3.82	3.27	3.78	3.26
Minimum	9	-8	8	-9
Q1	12.0	-2.0	13.0	-2.0
Median	15.0	0.0	15.0	0.0
Q3	17.0	2.0	17.0	2.0
Maximum	26	12	28	14

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（68/114）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	14.8	0.0	15.3	0.3
SD	3.60	2.96	3.96	3.02
Minimum	9	-7	9	-9
Q1	12.0	-2.0	12.0	-2.0
Median	14.5	0.0	15.0	0.0
Q3	17.0	2.0	18.0	2.0
Maximum	25	7	29	15
Week 14				
N	88	88	113	113
Mean	15.5	0.6	15.3	0.2
SD	4.04	3.06	4.11	3.26
Minimum	9	-6	7	-8
Q1	12.0	-2.0	13.0	-2.0
Median	15.0	1.0	15.0	0.0
Q3	18.0	2.5	17.0	2.0
Maximum	30	9	40	15

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（69/114）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	15.2	0.3	15.5	0.5
SD	3.74	2.91	3.98	3.41
Minimum	8	-8	9	-11
Q1	12.0	-1.0	12.0	-2.0
Median	15.0	1.0	15.0	1.0
Q3	18.0	2.0	18.0	3.0
Maximum	25	6	29	14
Week 26				
N	80	80	109	109
Mean	15.5	0.5	15.5	0.4
SD	4.30	3.34	4.11	3.18
Minimum	9	-7	7	-11
Q1	13.0	-1.5	13.0	-1.0
Median	15.0	0.0	15.0	0.0
Q3	17.0	2.0	17.0	2.0
Maximum	34	20	26	10

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（70/114）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	13.3	1.3	15.1	0.0
SD	4.27	2.99	3.90	3.27
Minimum	8	-2	8	-8
Q1	10.0	-1.0	12.0	-2.0
Median	13.5	1.0	15.0	0.0
Q3	16.5	3.5	17.0	1.0
Maximum	18	5	26	8
Week 32				
N	0	0	101	101
Mean			15.3	0.2
SD			4.08	3.03
Minimum			8	-8
Q1			12.0	-2.0
Median			15.0	0.0
Q3			18.0	2.0
Maximum			28	7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（71/114）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			15.4	0.1
SD			3.85	3.03
Minimum			6	-8
Q1			13.0	-1.0
Median			15.0	0.0
Q3			18.0	1.0
Maximum			28	12
Week 46				
N	0	0	87	87
Mean			15.7	0.3
SD			4.37	3.07
Minimum			9	-8
Q1			12.0	-2.0
Median			15.0	0.0
Q3			18.0	2.0
Maximum			31	14

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（72/114）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

	P -> 1 mg (N=95)		1 mg -> 1 mg (N=117)	
Visit / Statistics	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 52				
N	0	0	87	87
Mean			15.8	0.5
SD			3.97	2.98
Minimum			8	-12
Q1			13.0	-1.0
Median			15.0	1.0
Q3			18.0	2.0
Maximum			26	6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（73/114）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	4.81		4.80	
SD	1.118		1.262	
Minimum	2.2		1.8	
Q1	4.10		3.80	
Median	4.70		4.70	
Q3	5.50		5.60	
Maximum	8.1		8.2	
Week 3				
N	91	91	116	116
Mean	4.82	-0.02	4.78	0.00
SD	1.105	0.456	1.148	0.483
Minimum	2.4	-1.1	2.0	-1.6
Q1	4.00	-0.30	3.80	-0.30
Median	4.70	0.00	4.70	0.00
Q3	5.60	0.20	5.80	0.30
Maximum	7.6	1.2	7.3	1.2

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（74/114）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	4.73	-0.08	4.77	-0.02
SD	1.162	0.561	1.191	0.547
Minimum	2.3	-2.0	2.1	-2.1
Q1	4.00	-0.40	3.80	-0.40
Median	4.50	0.00	4.75	0.00
Q3	5.40	0.20	5.70	0.40
Maximum	7.9	1.2	7.8	1.3
Week 14				
N	88	88	113	113
Mean	4.73	-0.06	4.76	-0.03
SD	1.240	0.626	1.207	0.610
Minimum	1.6	-1.5	2.1	-1.9
Q1	4.00	-0.55	3.90	-0.40
Median	4.55	0.00	4.60	0.00
Q3	5.35	0.30	5.50	0.30
Maximum	7.8	1.8	8.5	1.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（75/114）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	4.73	-0.11	4.68	-0.13
SD	1.184	0.642	1.193	0.687
Minimum	2.1	-1.6	2.0	-2.3
Q1	3.80	-0.40	3.70	-0.50
Median	4.60	-0.10	4.50	-0.10
Q3	5.40	0.30	5.50	0.40
Maximum	8.3	1.2	8.9	2.7
Week 26				
N	80	80	109	109
Mean	4.77	-0.04	4.68	-0.15
SD	1.217	0.746	1.088	0.607
Minimum	2.3	-1.8	1.9	-1.9
Q1	3.95	-0.50	3.80	-0.50
Median	4.60	0.00	4.70	-0.10
Q3	5.60	0.35	5.50	0.20
Maximum	8.6	3.2	7.5	1.3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（76/114）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	5.73	0.08	4.74	-0.11
SD	1.552	0.457	1.180	0.633
Minimum	4.0	-0.4	1.7	-2.5
Q1	4.60	-0.30	3.80	-0.60
Median	5.60	0.05	4.70	-0.10
Q3	6.85	0.45	5.50	0.30
Maximum	7.7	0.6	8.5	1.7
Week 32				
N	0	0	101	101
Mean			4.72	-0.17
SD			1.091	0.691
Minimum			2.8	-2.4
Q1			4.00	-0.60
Median			4.70	-0.20
Q3			5.50	0.30
Maximum			8.2	1.5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（77/114）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			4.79	-0.13
SD			1.151	0.638
Minimum			2.8	-2.1
Q1			3.90	-0.60
Median			4.60	-0.10
Q3			5.60	0.30
Maximum			8.3	1.2
Week 46				
N	0	0	87	87
Mean			4.71	-0.17
SD			1.085	0.621
Minimum			2.9	-2.5
Q1			3.80	-0.60
Median			4.70	-0.10
Q3			5.40	0.30
Maximum			7.6	1.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（78/114）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			4.75	-0.14
SD			1.197	0.696
Minimum			2.5	-2.1
Q1			3.80	-0.60
Median			4.60	-0.10
Q3			5.40	0.20
Maximum			8.5	3.1

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（79/114）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	100.4		113.9	
SD	43.48		75.75	
Minimum	34		34	
Q1	71.0		72.0	
Median	89.0		94.0	
Q3	115.0		136.0	
Maximum	264		619	
Week 3				
N	91	91	116	116
Mean	98.8	-2.6	121.2	8.5
SD	44.55	37.92	114.45	78.92
Minimum	31	-156	35	-215
Q1	72.0	-10.0	69.0	-10.5
Median	90.0	-1.0	97.0	0.0
Q3	120.0	8.0	141.5	14.0
Maximum	324	173	1022	749

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（80/114）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	95.9	-5.0	126.6	13.0
SD	39.08	31.91	86.67	57.79
Minimum	40	-145	34	-265
Q1	69.5	-13.5	76.0	-11.0
Median	88.0	-1.0	102.0	2.0
Q3	116.0	9.0	155.0	22.0
Maximum	210	81	598	249
Week 14				
N	88	88	113	113
Mean	101.9	1.6	116.4	3.0
SD	51.04	32.72	77.05	44.31
Minimum	31	-122	37	-263
Q1	67.0	-12.5	68.0	-12.0
Median	87.0	0.0	97.0	4.0
Q3	118.5	12.0	138.0	18.0
Maximum	356	106	654	241

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（81/114）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	97.2	-3.0	118.7	5.8
SD	43.72	37.95	96.74	55.87
Minimum	36	-166	33	-200
Q1	67.0	-10.0	69.0	-13.0
Median	86.0	-1.0	93.0	1.0
Q3	117.0	9.0	138.0	19.0
Maximum	305	143	865	352
Week 26				
N	80	80	109	109
Mean	96.7	-3.4	112.2	-1.5
SD	41.18	42.36	82.58	50.83
Minimum	32	-188	31	-298
Q1	71.5	-17.0	66.0	-16.0
Median	87.0	-2.5	94.0	-1.0
Q3	117.0	15.0	131.0	19.0
Maximum	240	171	778	162

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（82/114）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	120.8	5.5	126.3	11.5
SD	65.57	3.32	82.34	52.04
Minimum	63	1	29	-235
Q1	64.0	3.0	79.0	-7.0
Median	120.0	6.5	106.0	4.0
Q3	177.5	8.0	155.0	25.0
Maximum	180	8	638	198
Week 32				
N	0	0	101	101
Mean			122.4	8.3
SD			75.90	53.12
Minimum			35	-277
Q1			78.0	-11.0
Median			106.0	4.0
Q3			148.0	27.0
Maximum			597	186

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（83/114）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			122.7	9.9
SD			78.25	46.94
Minimum			37	-239
Q1			77.0	-7.0
Median			102.5	7.5
Q3			153.0	28.0
Maximum			626	184
Week 46				
N	0	0	87	87
Mean			126.2	14.4
SD			111.71	91.80
Minimum			33	-198
Q1			69.0	-10.0
Median			94.0	0.0
Q3			142.0	19.0
Maximum			721	659

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（84/114）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			120.3	8.4
SD			87.01	54.55
Minimum			29	-278
Q1			67.0	-7.0
Median			96.0	5.0
Q3			158.0	25.0
Maximum			708	197

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（85/114）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	141.0		141.2	
SD	2.08		1.73	
Minimum	134		136	
Q1	140.0		140.0	
Median	141.0		141.0	
Q3	142.0		142.0	
Maximum	146		146	
Week 3				
N	91	91	116	116
Mean	141.0	0.0	140.8	-0.4
SD	1.97	1.58	1.54	1.64
Minimum	136	-4	135	-5
Q1	140.0	-1.0	140.0	-1.0
Median	141.0	0.0	141.0	0.0
Q3	142.0	1.0	142.0	1.0
Maximum	145	3	144	3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（86/114）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	140.8	-0.2	140.7	-0.4
SD	1.73	1.58	1.75	1.76
Minimum	136	-4	136	-4
Q1	140.0	-1.0	140.0	-2.0
Median	141.0	0.0	141.0	-0.5
Q3	142.0	1.0	142.0	0.0
Maximum	144	3	145	5
Week 14				
N	88	88	113	113
Mean	140.7	-0.3	140.4	-0.8
SD	1.78	1.70	1.92	1.86
Minimum	136	-5	134	-6
Q1	140.0	-1.0	139.0	-2.0
Median	141.0	0.0	141.0	-1.0
Q3	142.0	1.0	141.0	1.0
Maximum	144	7	148	5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（87/114）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	140.4	-0.5	140.3	-0.8
SD	1.84	1.69	1.84	2.08
Minimum	133	-4	132	-6
Q1	140.0	-1.0	139.0	-2.0
Median	140.0	0.0	140.0	-1.0
Q3	142.0	1.0	142.0	0.0
Maximum	144	3	145	6
Week 26				
N	80	80	109	109
Mean	140.6	-0.4	140.5	-0.7
SD	1.97	1.96	1.69	1.95
Minimum	134	-7	136	-6
Q1	140.0	-1.0	140.0	-2.0
Median	141.0	0.0	140.0	-1.0
Q3	142.0	1.0	142.0	1.0
Maximum	144	4	144	3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（88/114）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	139.8	-0.3	140.4	-0.7
SD	1.89	0.50	1.79	1.84
Minimum	137	-1	134	-6
Q1	138.5	-0.5	139.0	-2.0
Median	140.5	0.0	140.0	0.0
Q3	141.0	0.0	142.0	1.0
Maximum	141	0	145	4
Week 32				
N	0	0	101	101
Mean			140.3	-0.7
SD			1.90	1.88
Minimum			135	-6
Q1			139.0	-2.0
Median			140.0	-1.0
Q3			141.0	0.0
Maximum			146	3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（89/114）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			140.5	-0.6
SD			1.68	1.67
Minimum			134	-5
Q1			140.0	-2.0
Median			140.0	-1.0
Q3			141.0	1.0
Maximum			144	3
Week 46				
N	0	0	87	87
Mean			140.5	-0.7
SD			1.77	1.84
Minimum			135	-6
Q1			139.0	-2.0
Median			141.0	-1.0
Q3			142.0	1.0
Maximum			144	4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（90/114）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			140.6	-0.6
SD			1.73	1.50
Minimum			136	-4
Q1			139.0	-2.0
Median			141.0	-1.0
Q3			142.0	0.0
Maximum			144	4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（91/114）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		116	
Mean	4.15		4.17	
SD	0.322		0.317	
Minimum	3.4		3.2	
Q1	3.90		4.00	
Median	4.10		4.20	
Q3	4.40		4.35	
Maximum	5.2		4.9	
Week 3				
N	91	91	115	115
Mean	4.22	0.06	4.16	-0.01
SD	0.284	0.319	0.275	0.305
Minimum	3.6	-0.8	3.3	-0.8
Q1	4.00	-0.10	4.00	-0.20
Median	4.20	0.10	4.10	0.00
Q3	4.40	0.30	4.30	0.20
Maximum	5.0	0.8	4.8	1.0

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（92/114）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	113
Mean	4.20	0.05	4.17	0.01
SD	0.332	0.320	0.295	0.298
Minimum	3.3	-0.7	3.4	-1.0
Q1	4.00	-0.20	4.00	-0.20
Median	4.20	0.00	4.15	0.00
Q3	4.40	0.30	4.30	0.20
Maximum	5.3	1.2	5.3	0.9
Week 14				
N	88	88	108	107
Mean	4.21	0.06	4.20	0.02
SD	0.346	0.289	0.305	0.317
Minimum	3.6	-1.0	3.5	-0.9
Q1	4.00	-0.10	4.00	-0.20
Median	4.20	0.10	4.20	0.10
Q3	4.40	0.20	4.35	0.20
Maximum	5.6	0.7	5.2	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（93/114）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	109	108
Mean	4.20	0.05	4.21	0.03
SD	0.320	0.301	0.335	0.347
Minimum	3.2	-0.6	3.5	-0.8
Q1	4.00	-0.10	4.00	-0.20
Median	4.20	0.10	4.20	0.10
Q3	4.40	0.20	4.40	0.25
Maximum	4.8	0.8	5.6	0.8
Week 26				
N	80	80	106	105
Mean	4.21	0.06	4.18	0.01
SD	0.295	0.342	0.298	0.326
Minimum	3.5	-0.7	3.4	-0.9
Q1	4.00	-0.15	4.00	-0.20
Median	4.20	0.05	4.20	0.00
Q3	4.40	0.30	4.30	0.20
Maximum	4.9	0.8	5.3	0.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（94/114）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	102
Mean	4.05	-0.05	4.17	0.00
SD	0.238	0.100	0.339	0.335
Minimum	3.8	-0.2	3.3	-0.8
Q1	3.85	-0.10	4.00	-0.20
Median	4.05	0.00	4.10	0.00
Q3	4.25	0.00	4.30	0.20
Maximum	4.3	0.0	5.7	1.5
Week 32				
N	0	0	100	99
Mean			4.20	0.02
SD			0.294	0.330
Minimum			3.4	-0.8
Q1			4.00	-0.20
Median			4.20	0.00
Q3			4.40	0.30
Maximum			5.2	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（95/114）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	85	84
Mean			4.22	0.06
SD			0.263	0.303
Minimum			3.4	-0.7
Q1			4.10	-0.15
Median			4.20	0.10
Q3			4.40	0.20
Maximum			5.0	0.7
Week 46				
N	0	0	85	85
Mean			4.24	0.08
SD			0.289	0.300
Minimum			3.5	-0.6
Q1			4.00	-0.10
Median			4.30	0.10
Q3			4.40	0.30
Maximum			4.9	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（96/114）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	86	86
Mean			4.18	0.02
SD			0.258	0.281
Minimum			3.4	-0.6
Q1			4.00	-0.10
Median			4.20	0.00
Q3			4.40	0.20
Maximum			5.0	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（97/114）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	103.0		103.4	
SD	2.11		2.04	
Minimum	96		97	
Q1	102.0		102.0	
Median	103.0		103.0	
Q3	104.0		105.0	
Maximum	109		109	
Week 3				
N	91	91	116	116
Mean	103.0	-0.1	103.2	-0.2
SD	1.89	1.50	1.91	1.66
Minimum	97	-4	96	-5
Q1	102.0	-1.0	102.0	-1.0
Median	103.0	0.0	103.0	0.0
Q3	104.0	1.0	104.0	1.0
Maximum	107	4	107	4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（98/114）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	102.7	-0.3	103.1	-0.2
SD	2.09	1.71	1.95	1.77
Minimum	97	-5	98	-5
Q1	101.0	-1.0	102.0	-2.0
Median	103.0	0.0	103.0	0.0
Q3	104.0	1.0	104.0	1.0
Maximum	108	3	108	4
Week 14				
N	88	88	113	113
Mean	102.9	-0.2	102.9	-0.5
SD	1.84	1.81	2.01	2.07
Minimum	97	-4	95	-7
Q1	102.0	-1.0	102.0	-2.0
Median	103.0	0.0	103.0	0.0
Q3	104.0	1.0	104.0	1.0
Maximum	107	4	108	4

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（99/114）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	103.0	0.0	102.9	-0.5
SD	2.23	2.08	2.13	2.30
Minimum	95	-6	95	-7
Q1	102.0	-1.0	102.0	-2.0
Median	103.0	0.0	103.0	0.0
Q3	104.0	1.0	104.0	1.0
Maximum	108	5	108	7
Week 26				
N	80	80	109	109
Mean	102.9	-0.2	103.0	-0.4
SD	2.12	2.05	2.03	2.11
Minimum	97	-7	98	-7
Q1	102.0	-1.0	101.0	-2.0
Median	103.0	0.0	103.0	-1.0
Q3	104.0	1.0	104.0	1.0
Maximum	107	4	107	5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（100/114）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	102.3	0.3	102.8	-0.5
SD	1.89	1.26	2.17	2.20
Minimum	101	-1	96	-6
Q1	101.0	-0.5	101.0	-2.0
Median	101.5	0.0	103.0	-1.0
Q3	103.5	1.0	104.0	1.0
Maximum	105	2	108	6
Week 32				
N	0	0	101	101
Mean			102.9	-0.4
SD			2.20	2.01
Minimum			95	-7
Q1			102.0	-2.0
Median			103.0	0.0
Q3			104.0	1.0
Maximum			108	5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1