表 2.7.4.7-付録-71　血液学的検査の正異判定のクロス表（133 試験）

TVP-1012/133 (PRESTO)	0.5 mg							1 mg							Placebo						
	All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*	
	N	N	%	N	%	N	%	N	N	%	N	%	N	%	N	N	%	N	%	N	%
WBC (x10^3/cumm)	163	18	11.04	1	0.61	144	88.34	145	11	7.59	2	1.38	132	91.03	158	9	5.70	3	1.90	146	92.41
Neutrophils (%)	163	.	.	12	7.36	151	92.64	145	.	.	14	9.66	131	90.34	158	.	.	14	8.86	144	91.14
Lymphocytes (%)	163	21	12.88	.	.	142	87.12	145	19	13.10	.	.	126	86.90	158	23	14.56	.	.	135	85.44
Monocytes (%)	163	8	4.91	.	.	155	95.09	145	13	8.97	.	.	132	91.03	158	17	10.76	.	.	141	89.24
Eosinophils (%)	163	.	.	4	2.45	159	97.55	145	.	.	2	1.38	143	98.62	158	.	.	3	1.90	155	98.10
Basophils (%)	163	.	.	.	.	163	100.0	145	.	.	1	0.69	144	99.31	158	.	.	.	.	158	100.0
Neutrophils absolute (x10^3/uL)	163	.	.	3	1.84	160	98.16	145	.	.	2	1.38	143	98.62	158	.	.	3	1.90	155	98.10
Lymphocytes absolute (x10^3/uL)	163	10	6.13	.	.	153	93.87	145	4	2.76	.	.	141	97.24	158	14	8.86	.	.	144	91.14
Monocytes absolute (x10^3/uL)	163	.	.	.	.	163	100.0	145	.	.	.	.	145	100.0	158	.	.	3	1.90	155	98.10
Eosinophils absolute (x10^3/uL)	163	.	.	.	.	163	100.0	145	.	.	1	0.69	144	99.31	158	.	.	3	1.90	155	98.10
Basophils absolute (x10^3/uL)	163	.	.	.	.	163	100.0	145	.	.	.	.	145	100.0	158	.	.	.	.	158	100.0
RBC (x10^6/cumm)	163	14	8.59	.	.	149	91.41	145	18	12.41	.	.	127	87.59	158	11	6.96	.	.	147	93.04
Hgb (gm/dL)	163	24	14.72	.	.	139	85.28	145	13	8.97	.	.	132	91.03	158	10	6.33	.	.	148	93.67
Hct (%)	163	19	11.66	.	.	144	88.34	145	18	12.41	.	.	127	87.59	158	13	8.23	.	.	145	91.77
MCV (fL)	163	.	.	6	3.68	157	96.32	145	1	0.69	8	5.52	136	93.79	158	1	0.63	9	5.70	148	93.67
MCH (pg)	163	1	0.61	5	3.07	157	96.32	145	.	.	7	4.83	138	95.17	158	.	.	7	4.43	151	95.57
MCHC (%)	163	9	5.52	.	.	154	94.48	145	6	4.14	.	.	139	95.86	158	9	5.70	.	.	149	94.30
Platelet count (x10^3/cumm)	163	2	1.23	.	.	161	98.77	144	1	0.69	2	1.39	141	97.92	157	1	0.64	.	.	156	99.36

*Other=Stayed at the Same Condition or Moved to Within Normal

総括報告書（5.3.5.1-4）Post-Text Table 60

表 2.7.4.7-付録-72　血液生化学検査の変化量（133 試験）（1/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
Creatinine (mg/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	0.88	0.86	-0.02	0.86	0.86	-0.00	0.86	0.87	0.01
	Std	0.25	0.23	0.16	0.18	0.16	0.13	0.19	0.20	0.14
	Median	0.80	0.80	0.00	0.90	0.80	0.00	0.80	0.90	0.00
	Min	0.40	0.30	-1.00	0.50	0.40	-0.60	0.40	0.50	-0.50
	Max	2.20	1.90	0.50	1.60	1.50	0.40	1.40	1.60	0.50
Bilirubin, total (mg/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	0.53	0.52	-0.01	0.55	0.53	-0.03	0.48	0.51	0.03
	Std	0.30	0.28	0.17	0.37	0.34	0.21	0.19	0.24	0.17
	Median	0.40	0.40	0.00	0.50	0.50	0.00	0.40	0.50	0.00
	Min	0.20	0.20	-0.60	0.20	0.10	-1.20	0.20	0.20	-0.40
	Max	1.60	1.90	0.60	3.20	3.00	0.60	1.20	1.60	0.90
Alkaline phosphatase (U/L)	N	163	163	163	145	145	145	158	158	158
	Mean	80.07	82.72	2.64	82.48	86.23	3.74	81.79	82.91	1.12
	Std	21.78	25.24	15.24	24.48	27.04	16.85	25.12	23.59	12.59
	Median	77.00	80.00	1.00	80.00	80.00	2.00	77.00	79.00	1.00
	Min	30.00	27.00	-37.00	34.00	38.00	-42.00	20.00	18.00	-65.00
	Max	155.00	179.00	72.00	164.00	190.00	105.00	220.00	161.00	32.00
GGTP (U/L)	N	163	163	163	145	145	145	158	158	158
	Mean	20.39	21.10	0.71	22.76	23.45	0.69	23.79	23.61	-0.18
	Std	11.91	13.27	7.57	15.17	19.75	10.53	17.87	17.00	9.92
	Median	17.00	17.00	0.00	19.00	18.00	0.00	18.00	18.00	0.00
	Min	7.00	6.00	-29.00	6.00	5.00	-18.00	7.00	7.00	-70.00
	Max	77.00	107.00	51.00	110.00	181.00	71.00	123.00	114.00	32.00
AST (SGOT) (U/L)	N	163	163	163	145	145	145	158	158	158
	Mean	19.03	19.48	0.45	20.09	20.58	0.49	20.02	19.06	-0.96
	Std	6.70	6.08	6.12	7.41	7.07	6.85	6.63	6.57	6.31
	Median	18.00	19.00	0.00	19.00	20.00	1.00	19.00	18.00	-1.00
	Min	9.00	9.00	-48.00	9.00	7.00	-30.00	9.00	9.00	-38.00
	Max	67.00	53.00	26.00	64.00	54.00	22.00	48.00	48.00	22.00

総括報告書（5.3.5.1-4）Post-Text Table 61～Post-Text Table 64

表 2.7.4.7-付録-72　血液生化学検査の変化量（133 試験）（2/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
ALT (SGPT) (U/L)	N	163	163	163	145	145	145	158	158	158
	Mean	15.12	14.46	-0.66	15.80	15.26	-0.54	14.01	13.97	-0.03
	Std	10.01	8.19	8.41	9.53	8.36	8.02	8.14	7.66	8.20
	Median	12.00	13.00	-1.00	14.00	13.00	-1.00	12.00	12.00	0.00
	Min	2.00	3.00	-55.00	3.00	2.00	-37.00	2.00	2.00	-45.00
	Max	68.00	56.00	23.00	60.00	43.00	29.00	48.00	48.00	20.00
Sodium (mmol/L)	N	163	163	163	145	145	145	158	158	158
	Mean	140.34	140.81	0.47	140.16	140.51	0.35	140.73	140.85	0.12
	Std	2.59	2.72	2.60	2.34	2.54	2.63	2.48	2.12	2.50
	Median	141.00	141.00	0.00	140.00	141.00	0.00	141.00	141.00	0.00
	Min	128.00	128.00	-8.00	131.00	131.00	-6.00	133.00	134.00	-7.00
	Max	147.00	147.00	10.00	146.00	147.00	6.00	147.00	145.00	7.00
Potassium (mmol/L)	N	163	163	163	145	145	145	158	158	158
	Mean	4.41	4.41	0.00	4.41	4.45	0.04	4.49	4.43	-0.06
	Std	0.42	0.42	0.41	0.38	0.39	0.39	0.35	0.36	0.39
	Median	4.40	4.40	0.00	4.40	4.40	0.00	4.50	4.40	0.00
	Min	2.70	3.20	-1.10	3.30	3.50	-0.90	3.50	3.40	-1.00
	Max	5.70	5.60	2.10	5.80	5.70	1.30	5.60	5.80	1.40
Chloride (mmol/L)	N	163	163	163	145	145	145	158	158	158
	Mean	103.23	103.78	0.55	102.49	102.84	0.35	103.38	103.60	0.22
	Std	2.79	3.10	2.83	2.54	2.79	2.58	2.75	2.46	2.57
	Median	103.00	104.00	0.00	103.00	103.00	0.00	103.00	103.50	0.00
	Min	91.00	94.00	-8.00	95.00	95.00	-10.00	94.00	95.00	-9.00
	Max	112.00	111.00	10.00	108.00	111.00	8.00	112.00	110.00	9.00
Glucose (mg/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	99.63	95.79	-3.83	97.13	94.66	-2.47	95.13	94.24	-0.89
	Std	33.58	23.94	31.36	22.24	19.65	25.67	17.00	17.83	20.69
	Median	92.00	92.00	1.00	94.00	92.00	-1.00	91.50	93.00	0.00
	Min	60.00	35.00	-249.0	59.00	52.00	-142.0	63.00	48.00	-63.00
	Max	284.00	301.00	58.00	261.00	199.00	128.00	165.00	185.00	87.00

総括報告書（5.3.5.1-4）Post-Text Table 61～Post-Text Table 64

表 2.7.4.7-付録-72　血液生化学検査の変化量（133 試験）（3/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
Calcium (mg/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	9.49	9.51	0.01	9.55	9.56	0.02	9.51	9.53	0.02
	Std	0.39	0.39	0.41	0.40	0.43	0.45	0.42	0.43	0.42
	Median	9.50	9.50	0.00	9.50	9.50	0.00	9.40	9.50	0.00
	Min	8.40	8.60	-1.30	8.40	8.60	-1.20	8.20	8.70	-1.20
	Max	11.00	10.70	1.20	10.60	11.00	1.30	10.80	10.90	1.00
Phosphorus (mg/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	3.58	3.57	-0.01	3.61	3.63	0.02	3.58	3.53	-0.04
	Std	0.53	0.55	0.53	0.51	0.51	0.51	0.51	0.54	0.51
	Median	3.60	3.50	0.00	3.60	3.50	0.00	3.60	3.50	0.00
	Min	2.30	2.30	-1.70	2.30	2.20	-1.10	2.20	2.40	-1.20
	Max	5.10	5.80	1.90	4.80	4.90	1.30	5.10	5.70	2.00
Protein, total (g/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	7.04	6.96	-0.08	7.05	6.97	-0.08	6.97	6.95	-0.02
	Std	0.42	0.41	0.38	0.43	0.44	0.40	0.44	0.46	0.37
	Median	7.00	6.90	-0.10	7.00	6.90	-0.10	7.00	7.00	0.00
	Min	5.90	5.60	-1.20	6.00	5.70	-1.10	4.80	5.80	-1.30
	Max	8.40	7.90	0.90	9.30	8.60	1.10	8.30	8.10	1.00
Albumin (g/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	4.06	4.05	-0.01	4.09	4.10	0.01	4.01	4.04	0.03
	Std	0.23	0.25	0.24	0.21	0.27	0.24	0.26	0.28	0.24
	Median	4.10	4.10	0.00	4.10	4.10	0.00	4.00	4.00	0.00
	Min	3.40	3.40	-0.80	3.50	3.20	-0.80	2.70	3.30	-0.80
	Max	4.80	4.70	0.60	4.80	4.90	0.70	4.70	4.70	0.70
Cholesterol (mg/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	190.34	184.80	-5.55	196.26	194.16	-2.10	191.90	189.92	-1.97
	Std	31.98	33.01	26.15	36.11	35.28	25.60	33.08	35.15	23.21
	Median	189.00	185.00	-4.00	196.00	194.00	0.00	193.00	185.50	-3.00
	Min	112.00	90.00	-110.0	115.00	85.00	-121.0	108.00	115.00	-71.00
	Max	301.00	272.00	60.00	312.00	284.00	63.00	305.00	374.00	69.00

総括報告書（5.3.5.1-4）Post-Text Table 61～Post-Text Table 64

表 2.7.4.7-付録-72　血液生化学検査の変化量（133 試験）（4/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
LDH (U/L)	N	163	163	163	145	145	145	158	158	158
	Mean	176.98	179.99	3.01	179.63	182.79	3.17	175.04	174.64	-0.40
	Std	30.99	37.93	29.81	36.11	53.78	41.03	34.43	42.30	38.45
	Median	175.00	175.00	-3.00	173.00	173.00	-1.00	171.50	168.00	-1.00
	Min	122.00	115.00	-58.00	106.00	74.00	-81.00	85.00	86.00	-104.0
	Max	276.00	305.00	158.00	372.00	618.00	263.00	273.00	491.00	300.00
BUN (mg/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	18.15	18.38	0.23	18.60	19.38	0.78	18.40	17.78	-0.61
	Std	6.40	5.85	4.40	5.99	5.36	5.13	4.31	4.38	4.39
	Median	17.00	18.00	0.00	18.00	19.00	1.00	18.00	17.00	-1.00
	Min	8.00	6.00	-27.00	9.00	8.00	-36.00	2.00	10.00	-11.00
	Max	53.00	42.00	15.00	57.00	39.00	16.00	33.00	32.00	22.00

総括報告書（5.3.5.1-4）Post-Text Table 61～Post-Text Table 64

表 2.7.4.7-付録-73　血液生化学検査の正異判定のクロス表（133 試験）

TVP-1012/133 (PRESTO)		0.5 mg							1 mg							Placebo						
		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*	
		N	N	%	N	%	N	%	N	N	%	N	%	N	%	N	N	%	N	%	N	%
Renal Function	Creatinine (mg/dL)	163	1	0.61	.	.	162	99.39	145	.	.	.	.	145	100.0	158	.	.	1	0.63	157	99.37
Liver Function	Bilirubin, total (mg/dL)	163	6	3.68	1	0.61	156	95.71	145	2	1.38	.	.	143	98.62	158	5	3.16	1	0.63	152	96.20
	Alkaline phosphatase (U/L)	163	.	.	5	3.07	158	96.93	145	.	.	1	0.69	144	99.31	158	.	.	1	0.63	157	99.37
	GGTP (U/L)	163	.	.	1	0.61	162	99.39	145	.	.	3	2.07	142	97.93	158	.	.	4	2.53	154	97.47
	AST (SGOT) (U/L)	163	.	.	1	0.61	162	99.39	145	.	.	1	0.69	144	99.31	158	.	.	3	1.90	155	98.10
	ALT (SGPT) (U/L)	163	.	.	1	0.61	162	99.39	145	.	.	.	.	145	100.0	158	.	.	.	.	158	100.0
Electrolytes	Sodium (mmol/L)	163	1	0.61	.	.	162	99.39	145	1	0.69	.	.	144	99.31	158	.	.	.	.	158	100.0
	Potassium (mmol/L)	163	1	0.61	3	1.84	159	97.55	145	.	.	2	1.38	143	98.62	158	1	0.63	1	0.63	156	98.73
	Chloride (mmol/L)	163	6	3.68	3	1.84	154	94.48	145	4	2.76	4	2.76	137	94.48	158	.	.	1	0.63	157	99.37
Other	Glucose (mg/dL)	163	2	1.23	11	6.75	150	92.02	145	1	0.69	12	8.28	132	91.03	158	3	1.90	14	8.86	141	89.24
	Calcium (mg/dL)	163	.	.	2	1.23	161	98.77	145	.	.	7	4.83	138	95.17	158	.	.	1	0.63	157	99.37
	Phosphorus (mg/dL)	163	3	1.84	2	1.23	158	96.93	145	1	0.69	1	0.69	143	98.62	158	2	1.27	1	0.63	155	98.10
	Protein, TOTAL (g/dL)	163	3	1.84	.	.	160	98.16	145	1	0.69	3	2.07	141	97.24	158	2	1.27	.	.	156	98.73
	Albumin (g/dL)	163	2	1.23	.	.	161	98.77	145	2	1.38	.	.	143	98.62	158	1	0.63	.	.	157	99.37
	Cholesterol (mg/dL)	163	2	1.23	11	6.75	150	92.02	145	2	1.38	6	4.14	137	94.48	158	1	0.63	12	7.59	145	91.77
	LDH (U/L)	163	.	.	15	9.20	148	90.80	145	1	0.69	7	4.83	137	94.48	158	1	0.63	11	6.96	146	92.41
	BUN (mg/dL)	163	.	.	12	7.36	151	92.64	145	.	.	19	13.10	126	86.90	158	.	.	17	10.76	141	89.24

*Other=Stayed at the Same Condition or Moved to Within Normal

総括報告書（5.3.5.1-4）Post-Text Table 66

表 2.7.4.7-付録-74　尿検査の正異判定のクロス表（133 試験）

0.5 mg

TVP-1012/133	All	Change From Abnormal to Normal		Change From High /Normal to Low		Change From Low /Normal to High		Change From Normal to Abnormal		Other*	
(PRESTO)	N	N	%	N	%	N	%	N	%	N	%
pH	162	.	.	20	12.35	7	4.32	.	.	135	83.33
PROTEIN	162	2	1.23	.	.	.	.	7	4.32	153	94.44
URINE GLUCOSE	162	2	1.23	.	.	.	.	1	0.62	159	98.15
KETONES	162	19	11.73	.	.	.	.	13	8.02	130	80.25
URINE WBCS (/HPF)	162	10	6.17	.	.	.	.	13	8.02	139	85.80
URINE RBCS (/HPF)	162	1	0.62	.	.	.	.	6	3.70	155	95.68
OCCULT BLOOD	162	1	0.62	.	.	.	.	3	1.85	158	97.53

1 mg

TVP-1012/133	All	Change From Abnormal to Normal		Change From High /Normal to Low		Change From Low /Normal to High		Change From Normal to Abnormal		Other*	
(PRESTO)	N	N	%	N	%	N	%	N	%	N	%
pH	143	.	.	16	11.19	6	4.20	.	.	121	84.62
PROTEIN	143	7	4.90	.	.	.	.	7	4.90	129	90.21
URINE GLUCOSE	143	2	1.40	.	.	.	.	.	.	141	98.60
KETONES	143	16	11.19	.	.	.	.	23	16.08	104	72.73
URINE WBCS (/HPF)	143	8	5.59	.	.	.	.	8	5.59	127	88.81
URINE RBCS (/HPF)	143	1	0.70	.	.	.	.	1	0.70	141	98.60
OCCULT BLOOD	143	3	2.10	.	.	.	.	1	0.70	139	97.20

Placebo

TVP-1012/133	All	Change From Abnormal to Normal		Change From High /Normal to Low		Change From Low /Normal to High		Change From Normal to Abnormal		Other*	
(PRESTO)	N	N	%	N	%	N	%	N	%	N	%
pH	158	.	.	11	6.96	7	4.43	.	.	140	88.61
PROTEIN	158	3	1.90	.	.	.	.	9	5.70	146	92.41
URINE GLUCOSE	158	1	0.63	.	.	.	.	1	0.63	156	98.73
KETONES	158	20	12.66	.	.	.	.	14	8.86	124	78.48
URINE WBCS (/HPF)	158	11	6.96	.	.	.	.	14	8.86	133	84.18
URINE RBCS (/HPF)	158	3	1.90	.	.	.	.	3	1.90	152	96.20
OCCULT BLOOD	158	1	0.63	.	.	.	.	3	1.90	154	97.47

*Other=Stayed at the same condition

総括報告書（5.3.5.1-4）Table 47

表 2.7.4.7-付録-75　血液学的検査の変化量（122 試験）（1/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
WBC (GI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	6.51	6.62	0.10	6.75	6.55	-0.20	6.65	6.58	-0.07
	Std	1.53	1.69	1.44	1.78	1.66	1.47	1.66	1.63	1.35
	Median	6.20	6.40	0.20	6.60	6.40	-0.20	6.40	6.50	-0.05
	Min	3.10	3.10	-5.50	3.20	2.60	-5.80	3.00	3.50	-4.70
	Max	13.00	16.30	5.40	16.90	13.00	4.50	13.60	13.10	5.50
NEUTROPHILS (%)	N	228	228	228	223	223	223	226	226	226
	Mean	65.31	64.83	-0.48	65.27	66.62	1.35	65.01	65.72	0.70
	Std	8.15	7.93	8.05	9.37	9.32	9.34	9.27	8.50	7.97
	Median	65.90	65.45	-0.50	66.60	67.80	1.50	65.50	66.00	0.05
	Min	40.20	43.60	-26.20	38.80	32.00	-35.00	32.70	41.10	-28.00
	Max	82.10	82.80	36.10	86.90	85.10	38.70	86.40	89.50	32.90
LYMPHOCYTES (%)	N	228	228	228	223	223	223	226	226	226
	Mean	26.31	26.74	0.43	26.67	25.77	-0.90	27.20	26.64	-0.56
	Std	7.36	7.12	7.13	8.50	8.53	7.96	8.60	7.81	7.02
	Median	25.75	26.40	0.45	25.80	25.00	-1.20	26.45	26.05	-0.30
	Min	7.50	7.00	-31.80	10.50	8.00	-22.10	11.70	6.30	-24.20
	Max	53.30	47.00	22.30	53.20	62.00	34.40	62.10	49.70	28.30
MONOCYTES (%)	N	228	228	228	223	223	223	226	226	226
	Mean	5.79	5.59	-0.20	5.71	5.39	-0.32	5.29	5.23	-0.06
	Std	2.27	1.98	2.38	2.96	2.13	3.09	2.04	2.01	2.30
	Median	5.60	5.60	-0.05	5.30	5.10	-0.20	5.30	5.10	-0.05
	Min	0.20	0.10	-16.40	0.00	0.10	-20.80	0.00	0.20	-7.80
	Max	19.00	13.20	7.70	24.30	12.70	8.20	11.20	10.30	9.70
EOSINOPHILS (%)	N	228	228	228	223	223	223	226	226	226
	Mean	2.29	2.54	0.25	2.09	1.93	-0.16	2.21	2.15	-0.06
	Std	1.90	2.22	1.96	1.74	1.53	1.53	2.02	1.81	1.60
	Median	1.80	2.00	0.10	1.70	1.70	-0.10	1.60	1.75	0.00
	Min	0.00	0.00	-9.30	0.00	0.00	-7.60	0.00	0.00	-8.30
	Max	12.60	17.00	9.70	13.10	10.00	7.00	13.80	12.00	6.00

総括報告書（5.3.5.1-5）Post-Text Table 43

表 2.7.4.7-付録-75　血液学的検査の変化量（122 試験）（2/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
BASOPHILS (%)	N	228	228	228	223	223	223	226	226	226
	Mean	0.29	0.30	0.01	0.27	0.27	0.01	0.27	0.25	-0.02
	Std	0.20	0.19	0.25	0.18	0.17	0.25	0.18	0.16	0.22
	Median	0.30	0.30	0.00	0.30	0.30	0.00	0.30	0.25	0.00
	Min	0.00	0.00	-1.40	0.00	0.00	-1.20	0.00	0.00	-1.10
	Max	2.00	1.30	0.80	1.20	0.70	0.60	1.10	0.80	0.50
NEUTROPHILS ABSOLUTE (GI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	4.29	4.33	0.04	4.45	4.42	-0.03	4.37	4.37	-0.00
	Std	1.31	1.40	1.34	1.51	1.47	1.48	1.40	1.39	1.20
	Median	4.09	4.09	0.03	4.26	4.08	-0.08	4.15	4.22	-0.10
	Min	1.65	1.47	-5.32	1.76	1.32	-7.35	1.54	1.93	-5.65
	Max	10.53	12.45	4.94	11.86	9.59	4.59	10.85	10.49	5.48
LYMPHOCYTES ABSOLUTE (GI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	1.68	1.73	0.05	1.76	1.64	-0.12	1.78	1.72	-0.06
	Std	0.53	0.54	0.46	0.64	0.57	0.50	0.61	0.61	0.54
	Median	1.63	1.65	0.07	1.65	1.55	-0.08	1.68	1.63	-0.05
	Min	0.58	0.57	-1.93	0.47	0.55	-2.08	0.61	0.63	-1.68
	Max	4.21	3.94	1.49	4.59	3.91	1.66	4.05	6.21	4.76
MONOCYTES ABSOLUTE (GI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	0.38	0.37	-0.01	0.38	0.35	-0.04	0.35	0.34	-0.01
	Std	0.18	0.16	0.19	0.24	0.16	0.23	0.16	0.14	0.16
	Median	0.35	0.35	0.00	0.34	0.32	-0.01	0.34	0.32	-0.02
	Min	0.01	0.01	-1.23	0.00	0.01	-1.73	0.00	0.02	-0.58
	Max	1.44	1.17	0.99	2.02	1.05	0.50	0.97	0.83	0.66
EOSINOPHILS ABSOLUTE (GI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	0.14	0.17	0.02	0.14	0.13	-0.01	0.14	0.14	-0.01
	Std	0.12	0.15	0.13	0.12	0.11	0.11	0.14	0.13	0.10
	Median	0.12	0.13	0.01	0.11	0.10	-0.01	0.11	0.11	0.00
	Min	0.00	0.00	-0.69	0.00	0.00	-0.61	0.00	0.00	-0.53
	Max	0.91	1.28	0.86	0.93	0.69	0.60	1.24	1.18	0.31

総括報告書（5.3.5.1-5）Post-Text Table 43

表 2.7.4.7-付録-75　血液学的検査の変化量（122 試験）（3/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
BASOPHILS ABSOLUTE (GI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	0.02	0.02	0.00	0.02	0.02	-0.00	0.02	0.02	-0.00
	Std	0.01	0.01	0.02	0.01	0.01	0.02	0.01	0.01	0.02
	Median	0.02	0.02	0.00	0.02	0.02	0.00	0.02	0.02	0.00
	Min	0.00	0.00	-0.09	0.00	0.00	-0.09	0.00	0.00	-0.12
	Max	0.14	0.11	0.07	0.09	0.06	0.04	0.12	0.05	0.04
RED CELL COUNT (TI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	4.61	4.55	-0.06	4.59	4.52	-0.08	4.49	4.47	-0.02
	Std	0.44	0.45	0.23	0.45	0.44	0.23	0.42	0.41	0.21
	Median	4.60	4.50	0.00	4.50	4.50	-0.10	4.50	4.50	0.00
	Min	3.50	3.60	-0.80	3.70	3.50	-0.80	3.00	3.20	-0.50
	Max	5.70	5.80	1.10	6.10	6.20	0.70	6.00	5.80	0.60
HEMOGLOBIN (G/L)	N	228	228	228	223	223	223	226	226	226
	Mean	140.19	138.39	-1.80	139.52	137.94	-1.58	136.80	136.00	-0.80
	Std	12.67	12.78	6.62	12.65	13.12	6.45	12.46	12.62	6.49
	Median	140.00	138.50	-2.00	139.00	138.00	-2.00	137.50	137.00	-1.00
	Min	95.00	100.00	-28.00	107.00	102.00	-22.00	96.00	77.00	-19.00
	Max	173.00	171.00	26.00	177.00	171.00	15.00	179.00	173.00	34.00
HEMATOCRIT (Ratio)	N	228	228	228	223	223	223	226	226	226
	Mean	0.42	0.42	-0.00	0.42	0.42	-0.01	0.42	0.41	-0.00
	Std	0.04	0.04	0.02	0.04	0.04	0.02	0.04	0.04	0.02
	Median	0.42	0.42	-0.01	0.42	0.42	-0.00	0.42	0.42	-0.00
	Min	0.31	0.30	-0.06	0.33	0.32	-0.07	0.29	0.28	-0.05
	Max	0.52	0.53	0.06	0.54	0.53	0.05	0.55	0.55	0.10
MCV (FL)	N	228	228	228	223	223	223	226	226	226
	Mean	92.48	92.40	-0.07	92.37	92.74	0.37	92.71	92.86	0.15
	Std	5.61	5.72	3.02	5.18	5.01	2.79	5.13	5.11	3.35
	Median	92.50	92.00	0.00	93.00	93.00	0.00	93.00	93.00	0.00
	Min	64.00	63.00	-13.00	66.00	66.00	-9.00	76.00	78.00	-11.00
	Max	109.00	108.00	14.00	104.00	105.00	8.00	107.00	109.00	14.00

総括報告書（5.3.5.1-5）Post-Text Table 43

表 2.7.4.7-付録-75　血液学的検査の変化量（122 試験）（4/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
MCH (PG)	N	228	228	228	223	223	223	226	226	226
	Mean	30.54	30.46	-0.07	30.47	30.66	0.18	30.54	30.48	-0.05
	Std	1.92	1.94	0.77	1.80	1.86	0.75	1.81	1.73	0.84
	Median	30.70	30.60	-0.10	30.60	30.70	0.20	30.60	30.60	0.00
	Min	19.70	20.10	-3.50	19.60	19.40	-2.50	22.80	23.80	-3.30
	Max	35.80	35.70	4.60	35.80	35.80	2.70	36.20	35.70	5.30
MCHC (G/L)	N	228	228	228	223	223	223	226	226	226
	Mean	330.23	329.69	-0.54	329.77	330.38	0.61	329.35	328.32	-1.03
	Std	9.50	9.40	9.58	9.67	10.07	9.96	9.01	10.26	9.90
	Median	330.00	330.00	0.00	330.00	332.00	2.00	329.00	330.00	-1.00
	Min	300.00	297.00	-33.00	295.00	293.00	-43.00	300.00	278.00	-39.00
	Max	355.00	356.00	34.00	355.00	359.00	28.00	360.00	355.00	32.00
PLATELETS COUNT (GI/L)	N	228	228	228	223	223	223	226	226	226
	Mean	239.66	234.27	-5.39	245.39	242.67	-2.72	248.80	242.26	-6.54
	Std	53.38	55.30	31.22	58.10	57.78	36.14	66.02	60.55	39.87
	Median	235.00	230.00	-6.00	239.00	242.00	-2.00	245.00	236.00	-4.00
	Min	115.00	109.00	-114.0	79.00	84.00	-134.0	8.00	44.00	-233.0
	Max	401.00	445.00	91.00	420.00	509.00	145.00	525.00	505.00	151.00

総括報告書（5.3.5.1-5）Post-Text Table 43

表 2.7.4.7-付録-76　血液学的検査の正異判定のクロス表（122 試験）

TVP-1012/122 (LARGO)	Rasagiline 1 mg							Entacapone							Placebo						
	All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*	
	N	N	%	N	%	N	%	N	N	%	N	%	N	%	N	N	%	N	%	N	%
WBC (GI/L)	228	2	0.88	2	0.88	224	98.25	223	2	0.90	2	0.90	219	98.21	226	3	1.33	4	1.77	219	96.90
NEUTROPHILS (%)	228	.	.	13	5.70	215	94.30	223	2	0.90	20	8.97	201	90.13	226	.	.	15	6.64	211	93.36
LYMPHOCYTES (%)	228	8	3.51	2	0.88	218	95.61	223	14	6.28	2	0.90	207	92.83	226	10	4.42	3	1.33	213	94.25
MONOCYTES (%)	228	.	.	1	0.44	227	99.56	223	.	.	3	1.35	220	98.65	226	.	.	.	.	226	100.0
EOSINOPHILS (%)	228	.	.	7	3.07	221	96.93	223	.	.	2	0.90	221	99.10	226	.	.	4	1.77	222	98.23
BASOPHILS (%)	228	.	.	.	.	228	100.0	223	.	.	.	.	223	100.0	226	.	.	.	.	226	100.0
NEUTROPHILS ABSOLUTE (GI/L)	228	2	0.88	5	2.19	221	96.93	223	4	1.79	4	1.79	215	96.41	226	.	.	3	1.33	223	98.67
LYMPHOCYTES ABSOLUTE (GI/L)	228	3	1.32	.	.	225	98.68	223	3	1.35	.	.	220	98.65	226	5	2.21	1	0.44	220	97.35
MONOCYTES ABSOLUTE (GI/L)	228	17	7.46	1	0.44	210	92.11	223	23	10.31	.	.	200	89.69	226	26	11.50	.	.	200	88.50
EOSINOPHILS ABSOLUTE (GI/L)	228	10	4.39	4	1.75	214	93.86	223	25	11.21	2	0.90	196	87.89	226	15	6.64	2	0.88	209	92.48
BASOPHILS ABSOLUTE (GI/L)	228	.	.	.	.	228	100.0	223	.	.	.	.	223	100.0	226	.	.	.	.	226	100.0
RED CELL COUNT (TI/L)	228	7	3.07	2	0.88	219	96.05	223	8	3.59	.	.	215	96.41	226	9	3.98	.	.	217	96.02
HEMOGLOBIN (G/L)	228	12	5.26	1	0.44	215	94.30	223	11	4.93	.	.	212	95.07	226	6	2.65	.	.	220	97.35
HEMATOCRIT (Ratio)	228	10	4.39	3	1.32	215	94.30	223	8	3.59	2	0.90	213	95.52	226	3	1.33	4	1.77	219	96.90
MCV (FL)	228	2	0.88	3	1.32	223	97.81	223	1	0.45	3	1.35	219	98.21	226	.	.	7	3.10	219	96.90
MCH (PG)	228	3	1.32	3	1.32	222	97.37	223	2	0.90	3	1.35	218	97.76	226	1	0.44	4	1.77	221	97.79
MCHC (G/L)	228	16	7.02	.	.	212	92.98	223	17	7.62	.	.	206	92.38	226	26	11.50	.	.	200	88.50
PLATELETS COUNT (GI/L)	228	4	1.75	1	0.44	223	97.81	223	.	.	2	0.90	221	99.10	226	3	1.33	2	0.88	221	97.79

*Other=Stayed at the Same Condition or Moved to Within Normal

総括報告書（5.3.5.1-5）Post-Text Table 46

表 2.7.4.7-付録-77　血液生化学検査の変化量（122 試験）（1/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
CREATININE (UMOL/L)	N	230	230	230	222	222	222	226	226	226
	Mean	71.48	73.27	1.79	71.38	73.64	2.25	70.28	70.96	0.68
	Std	19.12	17.53	13.35	17.98	16.69	11.43	15.03	15.76	11.33
	Median	69.50	71.50	1.00	70.00	71.00	2.00	69.00	71.00	0.50
	Min	32.00	33.00	-80.00	35.00	40.00	-45.00	43.00	36.00	-43.00
	Max	195.00	188.00	70.00	174.00	161.00	44.00	140.00	141.00	36.00
UREA NITROGEN (MMOL/L)	N	230	230	230	222	222	222	226	226	226
	Mean	6.54	6.64	0.10	6.22	6.22	0.00	6.44	6.55	0.11
	Std	1.90	1.78	1.40	1.72	1.60	1.36	1.71	1.79	1.43
	Median	6.50	6.50	0.10	6.00	6.10	0.00	6.30	6.35	0.05
	Min	1.90	2.80	-4.90	2.80	2.30	-5.00	2.00	2.50	-4.50
	Max	16.10	16.80	3.30	13.00	12.40	4.00	12.70	16.30	5.50
SODIUM (MMOL/L)	N	230	230	230	222	222	222	226	226	226
	Mean	141.46	141.16	-0.30	141.49	141.48	-0.00	141.42	141.46	0.04
	Std	2.38	2.36	2.82	2.66	2.45	3.12	2.61	2.43	2.68
	Median	141.00	141.00	0.00	141.50	141.00	0.00	141.00	141.00	0.00
	Min	133.00	132.00	-9.00	132.00	135.00	-12.00	132.00	129.00	-12.00
	Max	149.00	147.00	8.00	151.00	149.00	12.00	151.00	149.00	6.00
POTASSIUM (MMOL/L)	N	229	230	229	222	222	222	226	226	226
	Mean	4.40	4.38	-0.02	4.39	4.33	-0.07	4.42	4.37	-0.04
	Std	0.41	0.40	0.44	0.35	0.34	0.34	0.43	0.35	0.46
	Median	4.40	4.35	0.00	4.40	4.30	0.00	4.40	4.30	0.00
	Min	3.10	3.20	-2.20	3.10	3.10	-1.40	3.60	3.40	-3.20
	Max	6.60	6.10	2.00	5.60	5.60	0.70	7.40	5.80	1.10
CHLORIDE (MMOL/L)	N	230	230	230	222	222	222	226	226	226
	Mean	104.85	104.61	-0.24	105.00	106.64	1.64	105.23	105.08	-0.15
	Std	2.57	2.60	2.57	2.37	2.77	3.02	2.60	2.78	2.88
	Median	105.00	105.00	0.00	105.00	106.00	2.00	105.00	105.00	0.00
	Min	92.00	96.00	-8.00	96.00	100.00	-9.00	95.00	94.00	-8.00
	Max	114.00	111.00	6.00	113.00	117.00	10.00	114.00	112.00	8.00

総括報告書（5.3.5.1-5）Post-Text Table 47～Post-Text Table 50

表 2.7.4.7-付録-77　血液生化学検査の変化量（122 試験）（2/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
BILIRUBIN, TOTAL (UMOL/L)	N	230	230	230	222	222	222	226	226	226
	Mean	12.04	11.78	-0.26	12.11	11.57	-0.54	11.77	11.75	-0.01
	Std	5.00	5.33	4.21	6.24	5.31	5.22	5.48	6.00	4.22
	Median	10.50	11.00	0.00	11.00	10.00	0.00	11.00	10.00	0.00
	Min	5.00	1.00	-16.00	4.00	4.00	-46.00	4.00	3.00	-10.00
	Max	36.00	44.00	13.00	57.00	40.00	19.00	38.00	47.00	14.00
BILIRUBIN, DIRECT (UMOL/L)	N	10	16	10	12	16	12	11	19	11
	Mean	6.20	6.25	0.20	6.33	6.25	-0.42	6.64	7.00	1.00
	Std	1.14	1.48	1.23	1.72	2.08	3.32	1.36	1.63	1.61
	Median	6.00	6.00	0.00	6.00	6.00	0.00	6.00	7.00	1.00
	Min	5.00	5.00	-2.00	4.00	2.00	-8.00	5.00	5.00	-2.00
	Max	9.00	11.00	2.00	10.00	10.00	5.00	9.00	10.00	4.00
BILIRUBIN, INDIRECT (UMOL/L)	N	10	16	10	12	16	12	11	19	11
	Mean	20.30	20.94	1.20	20.75	20.81	1.25	21.64	22.21	2.55
	Std	3.56	4.25	5.55	4.05	3.95	5.82	4.27	4.95	5.56
	Median	20.00	20.00	1.00	19.50	20.50	2.50	20.00	21.00	2.00
	Min	17.00	17.00	-9.00	16.00	17.00	-7.00	17.00	17.00	-10.00
	Max	29.00	33.00	11.00	28.00	30.00	12.00	30.00	37.00	9.00
ALKALINE PHOSPHATASE (U/L)	N	230	230	230	222	222	222	226	226	226
	Mean	81.54	83.48	1.94	80.00	76.95	-3.05	84.18	84.46	0.28
	Std	26.32	27.48	17.57	24.64	29.05	20.24	23.46	28.74	16.98
	Median	77.50	79.00	1.00	74.00	71.50	-4.00	81.00	81.00	-1.00
	Min	21.00	22.00	-70.00	36.00	37.00	-92.00	38.00	16.00	-44.00
	Max	268.00	202.00	93.00	201.00	295.00	207.00	193.00	265.00	107.00
GGT (U/L)	N	230	230	230	222	222	222	226	226	226
	Mean	27.66	27.33	-0.32	30.94	27.82	-3.13	26.08	27.31	1.24
	Std	22.05	20.80	13.91	51.06	25.43	44.48	18.31	34.17	29.19
	Median	22.00	21.00	0.00	20.50	21.00	0.00	20.00	20.00	0.00
	Min	8.00	7.00	-115.0	1.00	5.00	-637.0	8.00	8.00	-51.00
	Max	207.00	185.00	87.00	678.00	177.00	78.00	110.00	381.00	364.00

総括報告書（5.3.5.1-5）Post-Text Table 47～Post-Text Table 50

表 2.7.4.7-付録-77　血液生化学検査の変化量（122 試験）（3/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
ASAT (SGOT) (U/L)	N	230	230	230	222	222	222	226	226	226
	Mean	17.62	18.31	0.69	17.95	17.82	-0.13	17.91	18.17	0.26
	Std	6.51	6.14	5.15	9.07	5.33	8.42	5.73	6.62	6.34
	Median	16.50	17.00	1.00	16.00	17.00	1.00	17.00	17.00	0.00
	Min	4.00	3.00	-30.00	7.00	8.00	-100.0	6.00	9.00	-31.00
	Max	83.00	53.00	19.00	126.00	46.00	17.00	59.00	53.00	35.00
ALAT (SGPT) (U/L)	N	230	230	230	222	222	222	226	226	226
	Mean	15.99	16.53	0.54	15.85	15.71	-0.14	15.10	15.56	0.46
	Std	9.20	10.54	8.64	9.98	8.52	9.89	9.07	10.69	10.09
	Median	14.00	14.00	0.00	14.00	14.00	0.00	14.00	13.00	0.00
	Min	1.00	2.00	-37.00	3.00	3.00	-64.00	1.00	3.00	-46.00
	Max	61.00	80.00	50.00	85.00	68.00	38.00	61.00	94.00	86.00
GLUCOSE (MMOL/L)	N	230	229	229	221	222	221	226	226	226
	Mean	5.61	5.63	0.01	5.80	5.86	0.06	5.74	5.72	-0.02
	Std	1.13	1.43	1.02	1.34	1.47	1.13	1.53	1.31	1.04
	Median	5.40	5.30	0.00	5.40	5.40	0.00	5.45	5.40	0.00
	Min	2.10	3.60	-2.80	3.30	3.10	-7.00	3.50	3.90	-6.70
	Max	13.10	15.60	7.40	15.00	13.70	4.80	18.20	16.70	3.00
CALCIUM (MMOL/L)	N	230	230	230	222	222	222	225	226	225
	Mean	2.36	2.35	-0.02	2.37	2.34	-0.03	2.37	2.36	-0.01
	Std	0.09	0.09	0.09	0.10	0.09	0.09	0.11	0.10	0.09
	Median	2.36	2.34	-0.01	2.36	2.33	-0.02	2.36	2.35	-0.02
	Min	2.04	2.12	-0.27	2.13	2.12	-0.28	2.12	2.07	-0.31
	Max	2.59	2.70	0.27	2.71	2.79	0.26	2.96	2.82	0.31
PHOSPHORUS INORGANIC (MMOL/L)	N	230	230	230	222	222	222	226	226	226
	Mean	1.14	1.14	-0.01	1.09	1.09	-0.01	1.11	1.10	-0.01
	Std	0.45	0.18	0.46	0.18	0.17	0.17	0.23	0.16	0.22
	Median	1.11	1.15	0.03	1.10	1.10	0.01	1.09	1.11	0.00
	Min	0.64	0.76	-6.07	0.33	0.60	-0.85	0.72	0.73	-2.72
	Max	7.09	2.51	1.30	1.80	1.60	0.90	3.82	1.55	0.35

総括報告書（5.3.5.1-5）Post-Text Table 47～Post-Text Table 50

表 2.7.4.7-付録-77　血液生化学検査の変化量（122 試験）（4/4）

TVP-1012/122 (LARGO)		Rasagiline 1 mg			Entacapone			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
PROTEIN, TOTAL SERUM (G/L)	N	230	230	230	222	222	222	226	226	226
	Mean	71.10	70.78	-0.31	71.00	70.11	-0.89	71.46	71.01	-0.44
	Std	4.41	4.60	3.61	4.80	4.43	3.66	4.46	4.53	3.66
	Median	71.00	71.00	0.00	71.00	70.00	-1.00	72.00	71.00	0.00
	Min	57.00	56.00	-12.00	58.00	59.00	-9.00	57.00	61.00	-10.00
	Max	86.00	83.00	10.00	85.00	88.00	17.00	85.00	87.00	11.00
ALBUMIN (G/L)	N	230	230	230	222	222	222	226	226	226
	Mean	42.79	42.73	-0.05	42.91	42.67	-0.24	43.09	42.81	-0.28
	Std	2.25	2.44	2.06	2.26	2.32	1.85	2.13	2.53	2.22
	Median	43.00	43.00	0.00	43.00	43.00	0.00	43.00	43.00	0.00
	Min	34.00	34.00	-11.00	37.00	37.00	-7.00	38.00	25.00	-17.00
	Max	49.00	48.00	4.00	49.00	49.00	5.00	50.00	49.00	5.00
CHOLESTEROL (MMOL/L)	N	230	230	230	222	222	222	226	226	226
	Mean	5.15	5.03	-0.11	5.12	5.04	-0.08	5.11	5.08	-0.03
	Std	1.01	0.98	0.56	0.98	1.00	0.60	1.03	1.05	0.63
	Median	5.10	5.05	-0.10	5.04	4.97	-0.05	5.09	5.03	-0.03
	Min	2.98	2.64	-1.80	2.91	2.83	-1.96	2.85	2.62	-2.12
	Max	9.71	10.72	2.31	11.52	9.56	1.76	8.40	9.44	1.82
LDH (U/L)	N	230	230	230	222	222	222	226	226	226
	Mean	151.83	155.36	3.53	149.29	151.37	2.08	153.68	154.49	0.81
	Std	33.47	34.67	24.98	30.39	28.54	24.59	31.41	35.97	32.03
	Median	146.50	149.00	5.00	144.50	149.00	4.50	150.00	149.50	-1.00
	Min	65.00	76.00	-95.00	93.00	83.00	-123.0	93.00	91.00	-131.0
	Max	271.00	282.00	98.00	296.00	248.00	69.00	267.00	442.00	240.00

総括報告書（5.3.5.1-5）Post-Text Table 47～Post-Text Table 50

表 2.7.4.7-付録-78　血液生化学検査の正異判定のクロス表（122 試験）

TVP-1012/122 (LARGO)		Rasagiline 1 mg							Entacapone							Placebo						
		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*	
		N	N	%	N	%	N	%	N	N	%	N	%	N	%	N	N	%	N	%	N	%
Renal Function	CREATININE (UMOL/L)	230	3	1.30	.	.	227	98.70	222	1	0.45	1	0.45	220	99.10	226	5	2.21	2	0.88	219	96.90
	UREA NITROGEN (MMOL/L)	230	.	.	6	2.61	224	97.39	222	1	0.45	3	1.35	218	98.20	226	.	.	4	1.77	222	98.23
Liver Function	BILIRUBIN, TOTAL (UMOL/L)	230	.	.	6	2.61	224	97.39	222	.	.	2	0.90	220	99.10	226	.	.	4	1.77	222	98.23
	BILIRUBIN, DIRECT (UMOL/L)	16	.	.	2	12.50	14	87.50	16	.	.	4	25.00	12	75.00	19	.	.	4	21.05	15	78.95
	BILIRUBIN, INDIRECT (UMOL/L)	16	.	.	2	12.50	14	87.50	16	.	.	3	18.75	13	81.25	19	.	.	3	15.79	16	84.21
	ALKALINE PHOSPHATASE (U/L)	230	.	.	8	3.48	222	96.52	222	.	.	5	2.25	217	97.75	226	1	0.44	6	2.65	219	96.90
	GGT (U/L)	230	.	.	1	0.43	229	99.57	222	.	.	2	0.90	220	99.10	226	.	.	1	0.44	225	99.56
	ASAT (SGOT) (U/L)	230	.	.	.	.	230	100.0	222	.	.	.	.	222	100.0	226	.	.	.	.	226	100.0
	ALAT (SGPT) (U/L)	230	.	.	2	0.87	228	99.13	222	.	.	2	0.90	220	99.10	226	.	.	3	1.33	223	98.67
Electrolytes	SODIUM (MMOL/L)	230	1	0.43	1	0.43	228	99.13	222	.	.	3	1.35	219	98.65	226	1	0.44	.	.	225	99.56
	POTASSIUM (MMOL/L)	230	.	.	3	1.30	227	98.70	222	2	0.90	1	0.45	219	98.65	226	1	0.44	1	0.44	224	99.12
	CHLORIDE (MMOL/L)	230	.	.	10	4.35	220	95.65	222	.	.	51	22.97	171	77.03	226	1	0.44	21	9.29	204	90.27
Other	GLUCOSE (MMOL/L)	230	2	0.87	10	4.35	218	94.78	222	1	0.45	7	3.15	214	96.40	226	.	.	13	5.75	213	94.25
	CALCIUM (MMOL/L)	230	.	.	4	1.74	226	98.26	222	.	.	.	.	222	100.0	226	3	1.33	2	0.88	221	97.79
	PHOSPHORUS INORGANIC (MMOL/L)	230	2	0.87	5	2.17	223	96.96	222	3	1.35	3	1.35	216	97.30	226	5	2.21	1	0.44	220	97.35
	PROTEIN, TOTAL SERUM (G/L)	230	2	0.87	2	0.87	226	98.26	222	.	.	2	0.90	220	99.10	226	.	.	.	.	226	100.0
	ALBUMIN (G/L)	230	.	.	.	.	230	100.0	222	.	.	.	.	222	100.0	226	1	0.44	.	.	225	99.56
	CHOLESTEROL (MMOL/L)	230	.	.	22	9.57	208	90.43	222	.	.	25	11.26	197	88.74	226	.	.	19	8.41	207	91.59
	LDH (U/L)	230	.	.	2	0.87	228	99.13	222	.	.	.	.	222	100.0	226	.	.	3	1.33	223	98.67

*Other=Stayed at the Same Condition or Moved to Within Normal

総括報告書（5.3.5.1-5）Post-Text Table 53

表 2.7.4.7-付録-79　尿検査の正異判定のクロス表（122 試験）

TVP-1012/122 (LARGO)	Rasagiline 1 mg							Entacapone									Placebo								
	All	Change From Abnormal to Normal		Change From Normal to Abnormal		Other*		All	Change From Abnormal to Normal		Change From Low /Normal to High		Change From Normal to Abnormal		Other*		All	Change From Abnormal to Normal		Change From Low /Normal to High		Change From Normal to Abnormal		Other*	
	N	N	%	N	%	N	%	N	N	%	N	%	N	%	N	%	N	N	%	N	%	N	%	N	%
pH	228	.	.	.	.	228	100.0	222	.	.	1	0.45	.	.	221	99.55	225	.	.	1	0.44	.	.	224	99.56
PROTEIN	228	23	10.09	12	5.26	193	84.65	222	13	5.86	.	.	16	7.21	193	86.94	225	16	7.11	.	.	15	6.67	194	86.22
GLUCOSE	228	3	1.32	1	0.44	224	98.25	222	2	0.90	.	.	5	2.25	215	96.85	225	2	0.89	.	.	2	0.89	221	98.22
KETONES	228	30	13.16	21	9.21	177	77.63	222	13	5.86	.	.	69	31.08	140	63.06	225	29	12.89	.	.	29	12.89	167	74.22
WBC (/HPF)	228	20	8.77	23	10.09	185	81.14	222	18	8.11	.	.	33	14.86	171	77.03	225	16	7.11	.	.	28	12.44	181	80.44
RBC (/HPF)	228	11	4.82	10	4.39	207	90.79	222	10	4.50	.	.	12	5.41	200	90.09	225	12	5.33	.	.	10	4.44	203	90.22

*Other=Stayed at the Same Condition or Moved to Within Normal

総括報告書（5.3.5.1-5）Table 51

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（1/50）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	418.6	
SD	45.55	
Minimum	308	
Q1	386.0	
Median	419.0	
Q3	446.0	
Maximum	554	
Week 3		
N	221	221
Mean	415.0	-3.8
SD	44.52	14.84
Minimum	295	-46
Q1	386.0	-14.0
Median	414.0	-3.0
Q3	443.0	7.0
Maximum	536	35

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（2/50）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	415.0	-2.8
SD	44.43	18.18
Minimum	285	-61
Q1	380.0	-15.0
Median	415.0	-2.5
Q3	447.0	9.0
Maximum	539	56
Week 10		
N	206	206
Mean	416.5	-1.3
SD	43.57	21.40
Minimum	311	-78
Q1	385.0	-14.0
Median	420.0	0.0
Q3	447.0	11.0
Maximum	535	92

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（3/50）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	417.4	-1.6
SD	46.37	21.74
Minimum	294	-60
Q1	384.0	-14.5
Median	418.0	-3.0
Q3	452.0	12.5
Maximum	542	88
Week 26		
N	180	180
Mean	422.7	3.4
SD	46.16	23.56
Minimum	306	-86
Q1	391.5	-11.0
Median	422.5	5.0
Q3	450.0	19.0
Maximum	542	69

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（4/50）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	421.9	2.2
SD	45.77	21.77
Minimum	316	-55
Q1	394.0	-10.0
Median	422.0	1.0
Q3	450.0	15.0
Maximum	565	78
Week 42		
N	167	167
Mean	422.2	2.2
SD	46.59	21.21
Minimum	320	-52
Q1	387.0	-11.0
Median	420.0	2.0
Q3	454.0	16.0
Maximum	573	80

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（5/50）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	415.9	-4.7
SD	43.88	19.98
Minimum	309	-50
Q1	386.5	-17.0
Median	417.0	-5.0
Q3	443.5	7.5
Maximum	548	60

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（6/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	13.02	
SD	1.425	
Minimum	8.0	
Q1	12.10	
Median	13.10	
Q3	13.90	
Maximum	17.5	
Week 3		
N	221	221
Mean	12.91	-0.11
SD	1.389	0.467
Minimum	8.0	-1.3
Q1	12.00	-0.40
Median	13.00	-0.10
Q3	13.70	0.20
Maximum	17.6	1.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（7/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	12.94	-0.06
SD	1.358	0.574
Minimum	8.2	-1.8
Q1	12.00	-0.40
Median	13.00	-0.10
Q3	13.90	0.30
Maximum	17.5	3.1
Week 10		
N	206	206
Mean	13.00	0.00
SD	1.340	0.670
Minimum	9.8	-2.6
Q1	12.00	-0.40
Median	13.10	0.10
Q3	14.00	0.40
Maximum	17.8	2.7

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（8/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	13.03	0.02
SD	1.380	0.787
Minimum	9.6	-2.3
Q1	12.10	-0.40
Median	13.10	0.00
Q3	14.10	0.40
Maximum	17.8	4.7
Week 26		
N	180	180
Mean	13.12	0.10
SD	1.399	0.870
Minimum	9.9	-3.2
Q1	12.15	-0.40
Median	13.10	0.10
Q3	13.90	0.50
Maximum	18.3	5.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（9/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	12.99	-0.03
SD	1.398	0.778
Minimum	10.1	-2.1
Q1	12.10	-0.50
Median	12.90	-0.10
Q3	13.90	0.30
Maximum	18.8	5.3
Week 42		
N	167	167
Mean	12.93	-0.09
SD	1.449	0.742
Minimum	9.8	-1.9
Q1	11.90	-0.60
Median	13.00	-0.10
Q3	13.90	0.30
Maximum	19.1	4.4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（10/50）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	12.86	-0.17
SD	1.426	0.737
Minimum	9.6	-1.9
Q1	11.85	-0.60
Median	12.90	-0.20
Q3	13.75	0.20
Maximum	19.3	4.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（11/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	39.21	
SD	4.171	
Minimum	25.7	
Q1	36.30	
Median	39.50	
Q3	41.80	
Maximum	52.2	
Week 3		
N	221	221
Mean	39.01	-0.21
SD	4.089	1.429
Minimum	26.1	-4.2
Q1	36.20	-1.20
Median	39.20	-0.20
Q3	41.70	0.80
Maximum	53.3	3.2

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（12/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	39.17	0.00
SD	4.101	1.804
Minimum	26.5	-5.4
Q1	36.40	-1.20
Median	39.45	0.05
Q3	41.80	1.10
Maximum	53.1	8.5
Week 10		
N	206	206
Mean	39.37	0.20
SD	3.972	2.069
Minimum	29.9	-8.2
Q1	36.60	-1.10
Median	39.65	0.30
Q3	42.00	1.50
Maximum	53.4	8.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（13/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	39.50	0.29
SD	4.121	2.314
Minimum	28.8	-7.0
Q1	36.50	-1.00
Median	39.90	0.20
Q3	42.30	1.60
Maximum	53.4	14.2
Week 26		
N	180	180
Mean	39.59	0.36
SD	4.091	2.556
Minimum	30.4	-10.3
Q1	36.90	-1.20
Median	39.60	0.30
Q3	42.10	1.65
Maximum	54.5	15.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（14/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	39.06	-0.19
SD	4.128	2.298
Minimum	29.9	-6.7
Q1	36.20	-1.40
Median	39.00	-0.30
Q3	41.90	0.90
Maximum	57.3	15.0
Week 42		
N	167	167
Mean	38.82	-0.45
SD	4.219	2.199
Minimum	30.3	-5.9
Q1	35.80	-1.80
Median	38.70	-0.40
Q3	41.70	0.90
Maximum	57.1	12.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（15/50）

Laboratory Test: Hematocrit (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	38.20	-1.11
SD	4.030	2.197
Minimum	28.7	-6.2
Q1	35.65	-2.50
Median	38.10	-1.10
Q3	40.70	0.10
Maximum	56.5	11.4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（16/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	5870.3	
SD	1670.00	
Minimum	2700	
Q1	4600.0	
Median	5800.0	
Q3	6800.0	
Maximum	17200	
Week 3		
N	221	221
Mean	5744.3	-74.7
SD	1457.22	1049.63
Minimum	2600	-4500
Q1	4600.0	-600.0
Median	5700.0	0.0
Q3	6700.0	500.0
Maximum	11800	5500

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（17/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	5809.5	11.9
SD	1532.08	1166.81
Minimum	3100	-5000
Q1	4600.0	-600.0
Median	5700.0	100.0
Q3	6800.0	600.0
Maximum	12900	4100
Week 10		
N	206	206
Mean	5942.7	149.5
SD	1691.04	1432.64
Minimum	2300	-4300
Q1	4700.0	-800.0
Median	5750.0	100.0
Q3	6700.0	700.0
Maximum	13800	9500

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（18/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	5852.1	89.1
SD	1569.10	1264.76
Minimum	3000	-3300
Q1	4700.0	-650.0
Median	5600.0	0.0
Q3	6650.0	800.0
Maximum	11900	3500
Week 26		
N	180	180
Mean	5880.0	115.0
SD	1497.69	1192.83
Minimum	2700	-4000
Q1	4800.0	-600.0
Median	5750.0	200.0
Q3	6800.0	900.0
Maximum	9900	3600

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（19/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	5609.4	-130.4
SD	1394.37	1211.32
Minimum	2600	-5200
Q1	4600.0	-800.0
Median	5500.0	-200.0
Q3	6400.0	600.0
Maximum	11000	3400
Week 42		
N	167	167
Mean	5527.5	-170.7
SD	1402.74	1162.22
Minimum	2400	-3300
Q1	4400.0	-800.0
Median	5400.0	-100.0
Q3	6400.0	400.0
Maximum	10800	5400

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（20/50）

Laboratory Test: WBC (/μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	5647.0	-64.6
SD	1330.09	1165.86
Minimum	2600	-4300
Q1	4600.0	-750.0
Median	5500.0	0.0
Q3	6600.0	700.0
Maximum	9900	2900

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（21/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	62.76	
SD	9.219	
Minimum	38.3	
Q1	56.50	
Median	63.00	
Q3	69.70	
Maximum	86.6	
Week 3		
N	221	221
Mean	63.28	0.63
SD	8.551	6.898
Minimum	40.8	-25.9
Q1	57.30	-4.30
Median	63.20	-0.10
Q3	69.00	4.30
Maximum	88.0	21.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（22/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	63.03	0.63
SD	8.452	6.891
Minimum	40.4	-18.9
Q1	57.20	-3.90
Median	63.50	0.40
Q3	69.40	4.00
Maximum	83.5	28.9
Week 10		
N	205	205
Mean	64.09	1.64
SD	8.684	7.627
Minimum	41.3	-19.0
Q1	58.20	-3.50
Median	64.60	0.50
Q3	70.10	6.50
Maximum	87.0	26.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（23/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	191	191
Mean	64.34	1.87
SD	7.985	7.170
Minimum	36.8	-18.6
Q1	59.40	-2.40
Median	65.00	1.50
Q3	70.00	6.40
Maximum	80.0	22.0
Week 26		
N	179	179
Mean	64.31	2.02
SD	8.891	8.096
Minimum	37.9	-19.6
Q1	58.50	-2.60
Median	65.10	1.60
Q3	70.90	6.80
Maximum	90.0	36.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（24/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	170	170
Mean	63.33	1.18
SD	8.681	8.007
Minimum	35.9	-16.1
Q1	57.00	-4.20
Median	64.35	0.30
Q3	69.70	5.40
Maximum	82.0	28.1
Week 42		
N	166	166
Mean	62.45	0.47
SD	8.064	7.432
Minimum	35.3	-21.4
Q1	56.30	-4.60
Median	63.70	-0.40
Q3	68.30	4.50
Maximum	79.6	31.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（25/50）

Laboratory Test: Neutrophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	62.28	0.39
SD	7.982	7.998
Minimum	38.3	-21.3
Q1	56.90	-4.90
Median	63.00	-0.50
Q3	68.65	5.15
Maximum	81.5	21.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（26/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	2.06	
SD	1.857	
Minimum	0.0	
Q1	1.00	
Median	1.40	
Q3	2.70	
Maximum	12.3	
Week 3		
N	221	221
Mean	2.23	0.17
SD	1.927	1.031
Minimum	0.0	-4.0
Q1	1.00	-0.30
Median	1.70	0.00
Q3	3.00	0.70
Maximum	13.6	4.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（27/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	2.33	0.24
SD	2.010	1.445
Minimum	0.0	-3.8
Q1	1.00	-0.40
Median	1.90	0.00
Q3	3.00	0.80
Maximum	11.5	8.4
Week 10		
N	205	205
Mean	2.34	0.24
SD	2.169	1.309
Minimum	0.0	-3.6
Q1	1.00	-0.50
Median	1.70	0.00
Q3	3.00	0.70
Maximum	12.6	6.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（28/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	191	191
Mean	2.22	0.11
SD	2.074	1.576
Minimum	0.0	-5.3
Q1	1.00	-0.50
Median	1.60	0.00
Q3	2.70	0.70
Maximum	13.9	11.9
Week 26		
N	179	179
Mean	2.25	0.17
SD	1.947	1.286
Minimum	0.0	-5.3
Q1	1.00	-0.40
Median	1.70	0.10
Q3	3.00	0.80
Maximum	11.9	5.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（29/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	170	170
Mean	2.31	0.20
SD	1.933	1.259
Minimum	0.0	-4.1
Q1	1.00	-0.40
Median	1.90	0.20
Q3	2.90	0.80
Maximum	14.3	5.6
Week 42		
N	166	166
Mean	2.28	0.17
SD	1.884	1.253
Minimum	0.0	-4.6
Q1	1.00	-0.40
Median	1.60	0.10
Q3	3.10	0.80
Maximum	9.6	6.2

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（30/50）

Laboratory Test: Eosinophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	2.38	0.26
SD	2.016	1.360
Minimum	0.0	-4.6
Q1	1.00	-0.40
Median	1.80	0.30
Q3	3.00	0.90
Maximum	10.9	4.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（31/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	6.03	
SD	1.659	
Minimum	2.0	
Q1	5.00	
Median	6.00	
Q3	7.20	
Maximum	9.9	
Week 3		
N	221	221
Mean	6.12	0.09
SD	1.759	1.472
Minimum	1.0	-5.5
Q1	5.00	-0.70
Median	6.00	0.10
Q3	7.20	1.00
Maximum	11.1	4.4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（32/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	6.10	0.07
SD	1.868	1.612
Minimum	2.2	-5.1
Q1	5.00	-0.90
Median	6.00	0.10
Q3	7.30	1.00
Maximum	12.2	6.0
Week 10		
N	205	205
Mean	6.09	0.09
SD	1.844	1.722
Minimum	0.6	-8.0
Q1	5.00	-0.90
Median	6.00	0.10
Q3	7.30	1.00
Maximum	12.0	5.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（33/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	191	191
Mean	6.29	0.30
SD	1.744	1.618
Minimum	2.5	-3.9
Q1	5.00	-1.00
Median	6.10	0.40
Q3	7.50	1.40
Maximum	12.0	4.9
Week 26		
N	179	179
Mean	6.29	0.33
SD	1.728	1.719
Minimum	1.5	-5.0
Q1	5.00	-0.80
Median	6.20	0.30
Q3	7.30	1.40
Maximum	12.6	5.9

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（34/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	170	170
Mean	6.36	0.38
SD	1.741	1.758
Minimum	2.3	-5.4
Q1	5.10	-0.70
Median	6.10	0.40
Q3	7.50	1.40
Maximum	12.4	5.3
Week 42		
N	166	166
Mean	6.33	0.37
SD	1.782	1.756
Minimum	2.0	-6.4
Q1	5.20	-0.60
Median	6.10	0.35
Q3	7.40	1.30
Maximum	11.4	5.2

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（35/50）

Laboratory Test: Monocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	6.24	0.27
SD	1.850	1.635
Minimum	2.8	-3.7
Q1	5.00	-0.70
Median	6.00	0.10
Q3	7.35	1.40
Maximum	12.8	6.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（36/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	28.75	
SD	8.394	
Minimum	6.5	
Q1	22.00	
Median	28.65	
Q3	34.20	
Maximum	53.4	
Week 3		
N	221	221
Mean	27.97	-0.88
SD	7.738	5.764
Minimum	7.0	-19.9
Q1	22.60	-4.00
Median	28.00	-0.40
Q3	33.40	3.30
Maximum	52.2	20.7

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（37/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	28.14	-0.94
SD	7.619	5.856
Minimum	9.5	-23.4
Q1	23.00	-3.90
Median	27.65	-0.65
Q3	33.00	2.50
Maximum	53.5	14.9
Week 10		
N	205	205
Mean	27.04	-2.01
SD	7.698	6.466
Minimum	9.5	-21.6
Q1	22.00	-6.20
Median	26.00	-1.20
Q3	32.10	2.00
Maximum	47.0	18.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（38/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	191	191
Mean	26.70	-2.32
SD	7.226	6.073
Minimum	12.0	-19.5
Q1	21.30	-6.40
Median	26.00	-1.80
Q3	30.90	1.80
Maximum	54.2	16.5
Week 26		
N	179	179
Mean	26.73	-2.52
SD	7.954	6.993
Minimum	8.5	-30.9
Q1	21.00	-6.40
Median	26.00	-2.00
Q3	31.00	1.60
Maximum	49.2	16.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（39/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	170	170
Mean	27.57	-1.78
SD	7.724	6.806
Minimum	11.1	-25.0
Q1	22.30	-5.90
Median	26.20	-1.15
Q3	32.40	2.80
Maximum	55.1	12.0
Week 42		
N	166	166
Mean	28.56	-0.99
SD	7.271	6.260
Minimum	14.1	-23.5
Q1	23.50	-4.00
Median	28.00	-0.65
Q3	33.40	2.80
Maximum	53.7	16.4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（40/50）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	28.71	-0.90
SD	6.924	6.870
Minimum	13.1	-24.3
Q1	23.95	-4.65
Median	28.15	0.00
Q3	32.30	3.40
Maximum	48.6	17.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（41/50）

Laboratory Test: Basophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	0.41	
SD	0.310	
Minimum	0.0	
Q1	0.20	
Median	0.40	
Q3	0.50	
Maximum	1.6	
Week 3		
N	221	221
Mean	0.40	-0.01
SD	0.292	0.402
Minimum	0.0	-1.0
Q1	0.20	-0.20
Median	0.40	0.00
Q3	0.50	0.20
Maximum	1.4	1.3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（42/50）

Laboratory Test: Basophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	0.40	0.00
SD	0.321	0.445
Minimum	0.0	-1.5
Q1	0.20	-0.20
Median	0.40	0.00
Q3	0.50	0.20
Maximum	2.6	2.1
Week 10		
N	205	205
Mean	0.44	0.04
SD	0.333	0.437
Minimum	0.0	-1.0
Q1	0.30	-0.20
Median	0.40	0.00
Q3	0.60	0.20
Maximum	2.0	1.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（43/50）

Laboratory Test: Basophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	191	191
Mean	0.45	0.04
SD	0.317	0.427
Minimum	0.0	-1.1
Q1	0.30	-0.20
Median	0.40	0.00
Q3	0.60	0.30
Maximum	1.5	1.3
Week 26		
N	179	179
Mean	0.41	0.00
SD	0.326	0.433
Minimum	0.0	-1.4
Q1	0.20	-0.20
Median	0.40	0.00
Q3	0.50	0.30
Maximum	1.8	1.3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（44/50）

Laboratory Test: Basophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	170	170
Mean	0.43	0.02
SD	0.293	0.381
Minimum	0.0	-1.0
Q1	0.20	-0.20
Median	0.40	0.00
Q3	0.60	0.30
Maximum	1.4	1.1
Week 42		
N	166	166
Mean	0.38	-0.02
SD	0.323	0.423
Minimum	0.0	-1.6
Q1	0.20	-0.30
Median	0.30	0.00
Q3	0.50	0.20
Maximum	2.3	1.9

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（45/50）

Laboratory Test: Basophils (%)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	0.40	-0.01
SD	0.331	0.414
Minimum	0.0	-1.2
Q1	0.20	-0.30
Median	0.40	0.00
Q3	0.50	0.20
Maximum	2.0	2.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（46/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	21.40	
SD	5.388	
Minimum	10.2	
Q1	17.50	
Median	20.65	
Q3	24.90	
Maximum	48.5	
Week 3		
N	220	220
Mean	21.35	0.07
SD	4.960	1.926
Minimum	8.9	-7.4
Q1	17.50	-1.10
Median	21.20	0.10
Q3	25.00	1.20
Maximum	37.3	5.7

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（47/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	21.49	0.21
SD	4.878	2.233
Minimum	10.2	-11.0
Q1	17.80	-1.00
Median	21.25	0.10
Q3	25.00	1.40
Maximum	34.9	7.9
Week 10		
N	204	204
Mean	21.91	0.63
SD	5.138	2.759
Minimum	10.3	-13.3
Q1	18.40	-0.80
Median	21.00	0.60
Q3	25.45	1.95
Maximum	47.2	14.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（48/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	191	191
Mean	22.22	1.07
SD	5.377	2.863
Minimum	9.6	-7.1
Q1	18.30	-0.50
Median	22.10	0.70
Q3	25.60	2.50
Maximum	42.2	12.5
Week 26		
N	178	178
Mean	21.98	0.96
SD	5.086	2.895
Minimum	11.8	-12.3
Q1	18.10	-0.60
Median	21.70	0.65
Q3	25.50	2.50
Maximum	35.8	10.3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（49/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	170	170
Mean	21.68	0.73
SD	4.986	2.521
Minimum	9.7	-12.5
Q1	17.80	-0.60
Median	21.35	0.85
Q3	24.70	2.10
Maximum	36.4	7.1
Week 42		
N	166	166
Mean	21.57	0.69
SD	4.908	2.417
Minimum	10.2	-11.0
Q1	18.00	-0.60
Median	21.10	0.45
Q3	25.00	1.90
Maximum	35.0	11.4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-80　血液学的検査の評価時点別変化量（OCT-002 試験）（50/50）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	162	162
Mean	21.14	0.20
SD	5.003	2.849
Minimum	10.4	-6.8
Q1	17.60	-1.30
Median	20.00	0.00
Q3	24.90	1.20
Maximum	38.4	16.2

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（1/20）

RBC

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	71	13	-	84
Normal	5	129	1	135
High	-	1	1	2
Total	76	143	2	221
Week 6				
Low	65	13	-	78
Normal	7	123	1	131
High	-	-	1	1
Total	72	136	2	210
Week 10				
Low	60	13	-	73
Normal	12	118	1	131
High	-	1	1	2
Total	72	132	2	206
Week 18				
Low	57	13	-	70
Normal	10	110	1	121
High	-	-	1	1
Total	67	123	2	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（2/20）

RBC

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	46	10	-	56
Normal	16	105	1	122
High	-	1	1	2
Total	62	116	2	180
Week 34				
Low	45	7	-	52
Normal	12	104	1	117
High	-	1	1	2
Total	57	112	2	171
Week 42				
Low	44	9	-	53
Normal	11	99	1	111
High	-	2	1	3
Total	55	110	2	167
Week 52				
Low	45	14	-	59
Normal	9	94	1	104
High	-	-	1	1
Total	54	108	2	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（3/20）

Hemoglobin

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	52	16	-	68
Normal	5	144	-	149
High	-	2	2	4
Total	57	162	2	221
Week 6				
Low	45	13	-	58
Normal	8	142	1	151
High	-	-	1	1
Total	53	155	2	210
Week 10				
Low	41	12	-	53
Normal	11	139	1	151
High	-	1	1	2
Total	52	152	2	206
Week 18				
Low	39	15	-	54
Normal	10	125	-	135
High	-	2	1	3
Total	49	142	1	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（4/20）

Hemoglobin

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	28	13	-	41
Normal	16	120	-	136
High	-	2	1	3
Total	44	135	1	180
Week 34				
Low	29	10	-	39
Normal	11	119	-	130
High	-	1	1	2
Total	40	130	1	171
Week 42				
Low	30	17	-	47
Normal	9	108	-	117
High	-	2	1	3
Total	39	127	1	167
Week 52				
Low	31	20	-	51
Normal	7	104	1	112
High	-	1	-	1
Total	38	125	1	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（5/20）

Hematocrit

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	43	15	-	58
Normal	11	147	1	159
High	-	3	1	4
Total	54	165	2	221
Week 6				
Low	37	11	-	48
Normal	15	144	1	160
High	-	1	1	2
Total	52	156	2	210
Week 10				
Low	37	11	-	48
Normal	14	141	1	156
High	-	1	1	2
Total	51	153	2	206
Week 18				
Low	36	8	-	44
Normal	11	133	-	144
High	-	3	1	4
Total	47	144	1	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（6/20）

Hematocrit

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	27	11	-	38
Normal	16	123	-	139
High	-	2	1	3
Total	43	136	1	180
Week 34				
Low	29	10	-	39
Normal	10	119	-	129
High	-	2	1	3
Total	39	131	1	171
Week 42				
Low	31	13	-	44
Normal	7	114	-	121
High	-	1	1	2
Total	38	128	1	167
Week 52				
Low	33	25	-	58
Normal	4	100	1	105
High	-	1	-	1
Total	37	126	1	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（7/20）

WBC

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	3	4	-	7
Normal	1	206	5	212
High	-	2	-	2
Total	4	212	5	221
Week 6				
Low	-	3	-	3
Normal	3	193	4	200
High	-	7	-	7
Total	3	203	4	210
Week 10				
Low	2	-	-	2
Normal	1	189	3	193
High	-	10	1	11
Total	3	199	4	206
Week 18				
Low	1	1	-	2
Normal	2	177	3	182
High	-	7	1	8
Total	3	185	4	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（8/20）

WBC

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	3	2	-	5
Normal	-	166	2	168
High	-	6	1	7
Total	3	174	3	180
Week 34				
Low	2	3	-	5
Normal	1	159	3	163
High	-	3	-	3
Total	3	165	3	171
Week 42				
Low	1	2	-	3
Normal	2	157	2	161
High	-	3	-	3
Total	3	162	2	167
Week 52				
Low	2	2	-	4
Normal	1	155	1	157
High	-	2	1	3
Total	3	159	2	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（9/20）

Neutrophils

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	-	-	-
Normal	4	196	8	208
High	-	7	6	13
Total	4	203	14	221
Week 6				
Low	-	-	-	-
Normal	3	183	9	195
High	-	12	3	15
Total	3	195	12	210
Week 10				
Low	-	-	-	-
Normal	3	176	8	187
High	-	15	3	18
Total	3	191	11	205
Week 18				
Low	1	-	-	1
Normal	2	169	7	178
High	-	9	3	12
Total	3	178	10	191

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（10/20）

Neutrophils

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	1	-	1
Normal	3	158	5	166
High	-	8	4	12
Total	3	167	9	179
Week 34				
Low	2	-	-	2
Normal	1	152	5	158
High	-	6	4	10
Total	3	158	9	170
Week 42				
Low	1	-	-	1
Normal	2	149	7	158
High	-	6	1	7
Total	3	155	8	166
Week 52				
Low	-	1	-	1
Normal	3	150	7	160
High	-	2	1	3
Total	3	153	8	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（11/20）

Eosinophils

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	-	-	-
Normal	-	215	3	218
High	-	1	2	3
Total	-	216	5	221
Week 6				
Low	-	-	-	-
Normal	-	200	3	203
High	-	5	2	7
Total	-	205	5	210
Week 10				
Low	-	-	-	-
Normal	-	197	1	198
High	-	3	4	7
Total	-	200	5	205
Week 18				
Low	-	-	-	-
Normal	-	182	4	186
High	-	4	1	5
Total	-	186	5	191

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（12/20）

Eosinophils

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	-	172	2	174
High	-	3	2	5
Total	-	175	4	179
Week 34				
Low	-	-	-	-
Normal	-	164	2	166
High	-	2	2	4
Total	-	166	4	170
Week 42				
Low	-	-	-	-
Normal	-	160	3	163
High	-	2	1	3
Total	-	162	4	166
Week 52				
Low	-	-	-	-
Normal	-	157	4	161
High	-	3	-	3
Total	-	160	4	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（13/20）

Monocytes

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	1	-	1
Normal	-	217	-	217
High	-	3	-	3
Total	-	221	-	221
Week 6				
Low	-	-	-	-
Normal	-	205	-	205
High	-	5	-	5
Total	-	210	-	210
Week 10				
Low	-	1	-	1
Normal	-	201	-	201
High	-	3	-	3
Total	-	205	-	205
Week 18				
Low	-	-	-	-
Normal	-	186	-	186
High	-	5	-	5
Total	-	191	-	191

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（14/20）

Monocytes

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	1	-	1
Normal	-	173	-	173
High	-	5	-	5
Total	-	179	-	179
Week 34				
Low	-	-	-	-
Normal	-	166	-	166
High	-	4	-	4
Total	-	170	-	170
Week 42				
Low	-	-	-	-
Normal	-	160	-	160
High	-	6	-	6
Total	-	166	-	166
Week 52				
Low	-	-	-	-
Normal	-	158	-	158
High	-	6	-	6
Total	-	164	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（15/20）

Lymphocytes

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	6	10	-	16
Normal	6	193	4	203
High	-	2	-	2
Total	12	205	4	221
Week 6				
Low	4	13	-	17
Normal	5	183	2	190
High	-	2	1	3
Total	9	198	3	210
Week 10				
Low	5	22	-	27
Normal	3	172	3	178
High	-	-	-	-
Total	8	194	3	205
Week 18				
Low	4	12	-	16
Normal	3	170	1	174
High	-	-	1	1
Total	7	182	2	191

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（16/20）

Lymphocytes

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	5	10	-	15
Normal	2	159	1	162
High	-	1	1	2
Total	7	170	2	179
Week 34				
Low	4	7	-	11
Normal	3	154	1	158
High	-	-	1	1
Total	7	161	2	170
Week 42				
Low	2	6	-	8
Normal	4	152	1	157
High	-	-	1	1
Total	6	158	2	166
Week 52				
Low	2	3	-	5
Normal	4	153	2	159
High	-	-	-	-
Total	6	156	2	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（17/20）

Basophils

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	-	-	-
Normal	-	221	-	221
High	-	-	-	-
Total	-	221	-	221
Week 6				
Low	-	-	-	-
Normal	-	209	-	209
High	-	1	-	1
Total	-	210	-	210
Week 10				
Low	-	-	-	-
Normal	-	205	-	205
High	-	-	-	-
Total	-	205	-	205
Week 18				
Low	-	-	-	-
Normal	-	191	-	191
High	-	-	-	-
Total	-	191	-	191

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（18/20）

Basophils

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	-	179	-	179
High	-	-	-	-
Total	-	179	-	179
Week 34				
Low	-	-	-	-
Normal	-	170	-	170
High	-	-	-	-
Total	-	170	-	170
Week 42				
Low	-	-	-	-
Normal	-	165	-	165
High	-	1	-	1
Total	-	166	-	166
Week 52				
Low	-	-	-	-
Normal	-	164	-	164
High	-	-	-	-
Total	-	164	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（19/20）

Platelets

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	9	1	-	10
Normal	1	206	1	208
High	-	1	1	2
Total	10	208	2	220
Week 6				
Low	8	3	-	11
Normal	2	193	2	197
High	-	2	-	2
Total	10	198	2	210
Week 10				
Low	4	2	-	6
Normal	4	189	2	195
High	-	3	-	3
Total	8	194	2	204
Week 18				
Low	6	1	-	7
Normal	2	176	1	179
High	-	4	1	5
Total	8	181	2	191

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-81　血液学的検査の正異判定のクロス表（OCT-002 試験）（20/20）

Platelets

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	4	1	-	5
Normal	4	165	1	170
High	-	2	1	3
Total	8	168	2	178
Week 34				
Low	4	3	-	7
Normal	3	157	1	161
High	-	1	1	2
Total	7	161	2	170
Week 42				
Low	5	2	-	7
Normal	2	154	2	158
High	-	1	-	1
Total	7	157	2	166
Week 52				
Low	5	1	-	6
Normal	2	151	1	154
High	-	1	1	2
Total	7	153	2	162

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（1/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	22.7	
SD	6.08	
Minimum	11	
Q1	19.0	
Median	22.0	
Q3	25.0	
Maximum	55	
Week 3		
N	221	221
Mean	22.5	-0.2
SD	5.35	4.13
Minimum	12	-26
Q1	19.0	-2.0
Median	22.0	0.0
Q3	25.0	2.0
Maximum	53	20

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（2/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	208	208
Mean	22.6	-0.2
SD	5.37	4.97
Minimum	12	-24
Q1	19.0	-2.0
Median	22.0	0.0
Q3	25.0	2.0
Maximum	47	16
Week 10		
N	206	206
Mean	23.7	0.9
SD	8.08	8.05
Minimum	13	-33
Q1	20.0	-1.0
Median	23.0	1.0
Q3	26.0	3.0
Maximum	110	87

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（3/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	187	187
Mean	24.0	1.5
SD	5.87	5.24
Minimum	13	-21
Q1	20.0	-1.0
Median	24.0	1.0
Q3	27.0	4.0
Maximum	50	21
Week 26		
N	179	179
Mean	23.8	1.3
SD	7.02	6.51
Minimum	15	-21
Q1	19.0	-1.0
Median	23.0	1.0
Q3	26.0	4.0
Maximum	78	55

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（4/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	22.8	0.4
SD	6.03	5.79
Minimum	13	-23
Q1	19.0	-2.0
Median	22.0	1.0
Q3	25.0	2.0
Maximum	57	29
Week 42		
N	167	167
Mean	23.8	1.2
SD	16.30	16.19
Minimum	13	-20
Q1	19.0	-3.0
Median	21.0	0.0
Q3	25.0	2.0
Maximum	221	200

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（5/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	162	162
Mean	23.0	0.5
SD	5.79	5.54
Minimum	13	-22
Q1	19.0	-3.0
Median	22.0	0.0
Q3	26.0	2.0
Maximum	55	37

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（6/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	13.5	
SD	8.76	
Minimum	3	
Q1	7.0	
Median	11.0	
Q3	17.0	
Maximum	59	
Week 3		
N	221	221
Mean	12.7	-0.7
SD	8.22	7.09
Minimum	3	-51
Q1	7.0	-2.0
Median	11.0	0.0
Q3	16.0	2.0
Maximum	58	21

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（7/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	12.3	-1.1
SD	6.58	6.53
Minimum	3	-30
Q1	7.0	-2.0
Median	11.0	0.0
Q3	16.0	2.0
Maximum	39	17
Week 10		
N	206	206
Mean	12.5	-1.1
SD	6.27	7.04
Minimum	4	-31
Q1	7.0	-4.0
Median	11.0	0.0
Q3	16.0	2.0
Maximum	36	16

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（8/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	13.1	-0.3
SD	7.44	8.69
Minimum	3	-49
Q1	7.0	-3.0
Median	12.0	1.0
Q3	17.0	3.0
Maximum	47	37
Week 26		
N	180	180
Mean	13.3	-0.4
SD	8.28	8.66
Minimum	3	-47
Q1	7.5	-3.0
Median	12.0	0.0
Q3	16.0	3.0
Maximum	49	41

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（9/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	11.9	-1.6
SD	7.04	7.51
Minimum	2	-50
Q1	7.0	-4.0
Median	10.0	-1.0
Q3	16.0	2.0
Maximum	56	13
Week 42		
N	167	167
Mean	12.4	-1.2
SD	7.36	8.63
Minimum	2	-51
Q1	7.0	-4.0
Median	10.0	0.0
Q3	15.0	2.0
Maximum	47	40

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（10/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	12.5	-1.2
SD	7.62	8.47
Minimum	3	-49
Q1	7.0	-4.0
Median	11.0	-1.0
Q3	16.0	2.5
Maximum	54	30

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（11/95）

Laboratory Test: GGT (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	22.9	
SD	18.03	
Minimum	4	
Q1	14.0	
Median	17.0	
Q3	26.0	
Maximum	173	
Week 3		
N	221	221
Mean	23.3	0.8
SD	20.00	15.44
Minimum	5	-108
Q1	13.0	-2.0
Median	18.0	0.0
Q3	24.0	2.0
Maximum	178	162

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（12/95）

Laboratory Test: GGT (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	22.6	0.6
SD	13.74	7.58
Minimum	4	-46
Q1	13.0	-1.0
Median	18.0	0.0
Q3	27.0	2.0
Maximum	85	58
Week 10		
N	206	206
Mean	23.7	1.8
SD	16.29	9.54
Minimum	5	-22
Q1	13.0	-1.0
Median	18.0	1.0
Q3	27.0	3.0
Maximum	106	71

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（13/95）

Laboratory Test: GGT (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	24.3	2.5
SD	19.94	13.23
Minimum	5	-45
Q1	13.0	-1.0
Median	19.0	1.0
Q3	26.5	3.0
Maximum	211	127
Week 26		
N	180	180
Mean	24.3	2.2
SD	18.83	12.09
Minimum	5	-24
Q1	14.0	-1.0
Median	18.0	1.0
Q3	26.5	3.5
Maximum	160	83

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（14/95）

Laboratory Test: GGT (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	22.6	0.6
SD	14.37	10.15
Minimum	5	-64
Q1	13.0	-2.0
Median	18.0	1.0
Q3	28.0	3.0
Maximum	91	61
Week 42		
N	167	167
Mean	23.5	1.7
SD	20.32	15.93
Minimum	5	-59
Q1	12.0	-2.0
Median	18.0	0.0
Q3	27.0	3.0
Maximum	185	169

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（15/95）

Laboratory Test: GGT (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	23.8	2.1
SD	18.40	14.44
Minimum	5	-53
Q1	13.0	-2.5
Median	17.0	1.0
Q3	27.0	3.0
Maximum	147	132

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（16/95）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	241.8	
SD	78.74	
Minimum	89	
Q1	187.0	
Median	230.5	
Q3	284.0	
Maximum	605	
Week 3		
N	221	221
Mean	239.3	-2.0
SD	77.74	36.54
Minimum	87	-134
Q1	186.0	-13.0
Median	230.0	-3.0
Q3	268.0	9.0
Maximum	572	317

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（17/95）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	238.6	-2.9
SD	74.39	34.55
Minimum	87	-179
Q1	189.0	-15.0
Median	227.0	0.0
Q3	273.0	13.0
Maximum	555	112
Week 10		
N	206	206
Mean	243.5	1.9
SD	76.08	46.81
Minimum	93	-217
Q1	192.0	-17.0
Median	233.5	1.0
Q3	279.0	23.0
Maximum	534	147

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（18/95）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	251.3	11.9
SD	91.77	58.91
Minimum	94	-197
Q1	198.5	-14.0
Median	239.5	9.0
Q3	283.0	28.0
Maximum	817	411
Week 26		
N	180	180
Mean	253.5	17.4
SD	87.03	65.17
Minimum	114	-174
Q1	197.0	-12.0
Median	236.0	13.0
Q3	290.0	36.5
Maximum	654	431

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（19/95）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	251.3	15.0
SD	82.94	62.39
Minimum	91	-161
Q1	195.0	-14.0
Median	231.0	12.0
Q3	292.0	37.0
Maximum	603	371
Week 42		
N	167	167
Mean	246.6	10.6
SD	87.41	63.76
Minimum	83	-160
Q1	191.0	-17.0
Median	233.0	5.0
Q3	278.0	30.0
Maximum	771	552

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（20/95）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	239.1	4.6
SD	75.09	51.43
Minimum	115	-166
Q1	184.0	-22.0
Median	226.0	0.0
Q3	276.5	23.0
Maximum	504	260

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（21/95）

Laboratory Test: LDH (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	Change from Baseline
Baseline		
N	222	
Mean	190.6	
SD	39.03	
Minimum	116	
Q1	166.0	
Median	183.5	
Q3	211.0	
Maximum	408	
Week 3		
N	221	221
Mean	189.1	-1.5
SD	35.78	16.52
Minimum	122	-136
Q1	161.0	-10.0
Median	181.0	-1.0
Q3	211.0	8.0
Maximum	304	37

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（22/95）

Laboratory Test: LDH (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	208	208
Mean	191.1	0.3
SD	39.02	23.57
Minimum	116	-145
Q1	164.5	-9.0
Median	186.0	-1.0
Q3	213.0	10.0
Maximum	384	161
Week 10		
N	206	206
Mean	189.4	-0.7
SD	35.14	23.44
Minimum	123	-171
Q1	163.0	-10.0
Median	183.0	-1.0
Q3	210.0	12.0
Maximum	323	83

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（23/95）

Laboratory Test: LDH (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	187	187
Mean	192.6	2.4
SD	36.08	25.55
Minimum	125	-104
Q1	167.0	-13.0
Median	188.0	3.0
Q3	212.0	13.0
Maximum	305	109
Week 26		
N	179	179
Mean	193.1	4.1
SD	36.11	28.52
Minimum	122	-156
Q1	166.0	-9.0
Median	189.0	5.0
Q3	215.0	16.0
Maximum	329	133

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（24/95）

Laboratory Test: LDH (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	189.2	0.9
SD	34.23	26.32
Minimum	120	-135
Q1	166.0	-11.0
Median	187.0	1.0
Q3	207.0	13.0
Maximum	298	104
Week 42		
N	167	167
Mean	193.0	4.0
SD	36.92	26.20
Minimum	113	-115
Q1	165.0	-10.0
Median	190.0	4.0
Q3	212.0	18.0
Maximum	340	150

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（25/95）

Laboratory Test: LDH (U/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	162	162
Mean	193.4	3.8
SD	35.48	27.06
Minimum	117	-111
Q1	168.0	-11.0
Median	187.5	3.5
Q3	221.0	16.0
Maximum	297	104

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（26/95）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	4.30	
SD	0.250	
Minimum	3.4	
Q1	4.10	
Median	4.30	
Q3	4.50	
Maximum	5.0	
Week 3		
N	221	221
Mean	4.28	-0.02
SD	0.231	0.181
Minimum	3.5	-0.4
Q1	4.10	-0.20
Median	4.30	0.00
Q3	4.40	0.10
Maximum	4.9	0.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（27/95）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	4.27	-0.03
SD	0.250	0.208
Minimum	3.5	-0.7
Q1	4.10	-0.10
Median	4.30	0.00
Q3	4.40	0.10
Maximum	5.0	0.4
Week 10		
N	206	206
Mean	4.27	-0.03
SD	0.231	0.215
Minimum	3.5	-0.7
Q1	4.10	-0.20
Median	4.30	0.00
Q3	4.40	0.10
Maximum	4.8	0.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（28/95）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	4.27	-0.04
SD	0.270	0.216
Minimum	3.4	-0.7
Q1	4.10	-0.20
Median	4.30	0.00
Q3	4.40	0.10
Maximum	4.9	0.5
Week 26		
N	180	180
Mean	4.28	-0.03
SD	0.259	0.228
Minimum	3.3	-1.0
Q1	4.10	-0.20
Median	4.30	0.00
Q3	4.50	0.10
Maximum	4.9	0.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（29/95）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	4.26	-0.05
SD	0.251	0.204
Minimum	3.2	-0.6
Q1	4.10	-0.20
Median	4.30	-0.10
Q3	4.40	0.10
Maximum	4.9	0.5
Week 42		
N	167	167
Mean	4.28	-0.03
SD	0.251	0.202
Minimum	3.4	-0.6
Q1	4.10	-0.20
Median	4.30	0.00
Q3	4.40	0.10
Maximum	4.9	0.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（30/95）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	4.27	-0.04
SD	0.227	0.189
Minimum	3.7	-0.7
Q1	4.10	-0.20
Median	4.30	0.00
Q3	4.40	0.10
Maximum	5.0	0.7

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（31/95）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	7.02	
SD	0.427	
Minimum	5.5	
Q1	6.70	
Median	7.00	
Q3	7.30	
Maximum	8.5	
Week 3		
N	221	221
Mean	6.95	-0.07
SD	0.417	0.298
Minimum	5.5	-0.8
Q1	6.70	-0.30
Median	6.90	-0.10
Q3	7.20	0.10
Maximum	8.6	0.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（32/95）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	6.98	-0.04
SD	0.414	0.322
Minimum	5.6	-1.2
Q1	6.70	-0.20
Median	7.00	0.00
Q3	7.20	0.20
Maximum	8.4	0.6
Week 10		
N	206	206
Mean	6.95	-0.06
SD	0.389	0.331
Minimum	5.6	-1.0
Q1	6.70	-0.30
Median	7.00	-0.10
Q3	7.20	0.10
Maximum	8.3	0.9

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（33/95）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	6.97	-0.03
SD	0.421	0.336
Minimum	5.4	-1.0
Q1	6.70	-0.20
Median	6.90	-0.10
Q3	7.20	0.20
Maximum	8.8	0.8
Week 26		
N	180	180
Mean	6.97	-0.03
SD	0.430	0.331
Minimum	5.4	-1.4
Q1	6.70	-0.30
Median	7.00	0.00
Q3	7.30	0.20
Maximum	8.7	1.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（34/95）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	6.91	-0.09
SD	0.408	0.319
Minimum	5.4	-1.1
Q1	6.70	-0.30
Median	6.90	-0.10
Q3	7.10	0.10
Maximum	8.5	0.8
Week 42		
N	167	167
Mean	6.95	-0.06
SD	0.397	0.298
Minimum	5.5	-0.9
Q1	6.70	-0.30
Median	6.90	-0.10
Q3	7.20	0.10
Maximum	8.5	0.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（35/95）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	6.96	-0.04
SD	0.378	0.330
Minimum	6.0	-1.0
Q1	6.70	-0.25
Median	7.00	0.00
Q3	7.20	0.10
Maximum	8.4	1.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（36/95）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	0.78	
SD	0.302	
Minimum	0.3	
Q1	0.60	
Median	0.70	
Q3	0.90	
Maximum	2.4	
Week 3		
N	221	221
Mean	0.77	-0.02
SD	0.284	0.203
Minimum	0.3	-0.7
Q1	0.60	-0.10
Median	0.70	0.00
Q3	0.90	0.10
Maximum	1.9	1.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（37/95）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	0.76	-0.02
SD	0.279	0.219
Minimum	0.3	-0.9
Q1	0.60	-0.10
Median	0.70	0.00
Q3	0.90	0.10
Maximum	2.1	0.7
Week 10		
N	206	206
Mean	0.76	-0.03
SD	0.276	0.240
Minimum	0.3	-0.9
Q1	0.60	-0.20
Median	0.70	0.00
Q3	0.90	0.10
Maximum	2.1	0.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（38/95）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	0.72	-0.07
SD	0.231	0.221
Minimum	0.3	-1.2
Q1	0.50	-0.20
Median	0.70	0.00
Q3	0.80	0.10
Maximum	1.5	0.5
Week 26		
N	180	180
Mean	0.74	-0.05
SD	0.246	0.242
Minimum	0.3	-1.4
Q1	0.60	-0.10
Median	0.70	-0.05
Q3	0.90	0.10
Maximum	1.7	0.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（39/95）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	0.73	-0.05
SD	0.288	0.232
Minimum	0.2	-0.8
Q1	0.50	-0.20
Median	0.70	-0.10
Q3	0.90	0.10
Maximum	2.3	1.1
Week 42		
N	167	167
Mean	0.75	-0.04
SD	0.252	0.208
Minimum	0.3	-1.0
Q1	0.60	-0.10
Median	0.70	0.00
Q3	0.90	0.10
Maximum	1.8	0.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（40/95）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	0.77	-0.02
SD	0.305	0.197
Minimum	0.3	-0.7
Q1	0.60	-0.10
Median	0.70	0.00
Q3	0.90	0.10
Maximum	2.3	1.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（41/95）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	194.3	
SD	30.63	
Minimum	100	
Q1	174.0	
Median	193.5	
Q3	213.0	
Maximum	294	
Week 3		
N	221	221
Mean	192.7	-1.8
SD	29.24	14.96
Minimum	113	-48
Q1	175.0	-11.0
Median	191.0	-3.0
Q3	211.0	8.0
Maximum	283	45

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（42/95）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	191.6	-2.3
SD	28.67	16.61
Minimum	113	-53
Q1	172.0	-11.0
Median	192.0	-1.0
Q3	209.0	9.0
Maximum	270	56
Week 10		
N	206	206
Mean	190.6	-2.8
SD	28.89	16.71
Minimum	112	-60
Q1	171.0	-12.0
Median	188.5	-2.0
Q3	210.0	6.0
Maximum	271	50

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（43/95）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	190.3	-2.5
SD	28.00	17.91
Minimum	112	-53
Q1	171.0	-12.5
Median	189.5	-3.0
Q3	210.0	7.0
Maximum	263	55
Week 26		
N	180	180
Mean	194.0	0.8
SD	29.03	21.45
Minimum	120	-91
Q1	175.0	-10.0
Median	191.5	0.0
Q3	212.0	14.0
Maximum	288	95

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（44/95）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	193.7	0.5
SD	28.19	21.17
Minimum	137	-91
Q1	173.0	-11.0
Median	192.0	0.0
Q3	211.0	15.0
Maximum	268	53
Week 42		
N	167	167
Mean	192.3	-0.3
SD	29.12	21.42
Minimum	120	-92
Q1	171.0	-9.0
Median	193.0	1.0
Q3	213.0	10.0
Maximum	262	87

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（45/95）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	191.8	-1.0
SD	27.79	20.10
Minimum	128	-80
Q1	175.0	-11.0
Median	191.0	-1.0
Q3	211.0	10.0
Maximum	265	62

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（46/95）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	85.4	
SD	40.59	
Minimum	32	
Q1	57.0	
Median	76.5	
Q3	103.0	
Maximum	276	
Week 3		
N	221	221
Mean	83.3	-2.0
SD	41.45	32.04
Minimum	28	-145
Q1	56.0	-18.0
Median	73.0	-1.0
Q3	100.0	13.0
Maximum	335	148

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（47/95）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	84.0	-0.4
SD	38.14	32.70
Minimum	23	-168
Q1	58.0	-15.0
Median	74.5	-1.0
Q3	101.0	14.0
Maximum	254	141
Week 10		
N	206	206
Mean	84.3	-0.6
SD	38.05	34.29
Minimum	24	-177
Q1	58.0	-17.0
Median	78.5	1.0
Q3	98.0	14.0
Maximum	301	195

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（48/95）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	83.7	-1.5
SD	35.07	36.04
Minimum	31	-178
Q1	57.0	-17.0
Median	76.0	0.0
Q3	103.0	15.0
Maximum	203	125
Week 26		
N	180	180
Mean	84.2	-1.8
SD	41.40	33.21
Minimum	31	-176
Q1	56.5	-15.5
Median	75.0	-1.0
Q3	99.5	11.5
Maximum	312	148

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（49/95）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	85.4	-0.9
SD	42.75	36.62
Minimum	29	-167
Q1	58.0	-20.0
Median	77.0	-2.0
Q3	99.0	14.0
Maximum	355	158
Week 42		
N	167	167
Mean	81.7	-4.0
SD	38.50	36.10
Minimum	25	-153
Q1	59.0	-18.0
Median	74.0	-4.0
Q3	93.0	8.0
Maximum	258	186

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（50/95）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	83.1	-2.9
SD	38.23	35.11
Minimum	29	-151
Q1	56.5	-21.0
Median	80.0	-1.0
Q3	101.0	12.5
Maximum	268	139

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（51/95）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	0.747	
SD	0.2134	
Minimum	0.35	
Q1	0.620	
Median	0.705	
Q3	0.830	
Maximum	1.95	
Week 3		
N	221	221
Mean	0.743	-0.004
SD	0.2105	0.0543
Minimum	0.34	-0.16
Q1	0.610	-0.040
Median	0.710	0.000
Q3	0.820	0.040
Maximum	1.97	0.14

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（52/95）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	0.741	0.002
SD	0.2128	0.0764
Minimum	0.37	-0.26
Q1	0.600	-0.040
Median	0.700	0.000
Q3	0.820	0.040
Maximum	2.06	0.41
Week 10		
N	206	206
Mean	0.741	-0.001
SD	0.2102	0.0901
Minimum	0.39	-0.20
Q1	0.600	-0.050
Median	0.700	0.000
Q3	0.820	0.040
Maximum	1.87	0.69

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（53/95）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	0.721	-0.019
SD	0.1918	0.0763
Minimum	0.34	-0.22
Q1	0.590	-0.065
Median	0.690	-0.020
Q3	0.810	0.025
Maximum	2.05	0.37
Week 26		
N	180	180
Mean	0.710	-0.025
SD	0.1813	0.0826
Minimum	0.37	-0.27
Q1	0.590	-0.070
Median	0.670	-0.030
Q3	0.820	0.020
Maximum	1.56	0.37

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（54/95）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	0.713	-0.022
SD	0.1861	0.0710
Minimum	0.36	-0.23
Q1	0.580	-0.070
Median	0.680	-0.020
Q3	0.820	0.020
Maximum	1.91	0.23
Week 42		
N	167	167
Mean	0.727	-0.010
SD	0.1984	0.0803
Minimum	0.34	-0.27
Q1	0.610	-0.050
Median	0.690	-0.010
Q3	0.830	0.030
Maximum	2.19	0.51

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（55/95）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	0.750	0.011
SD	0.2280	0.1042
Minimum	0.39	-0.18
Q1	0.615	-0.050
Median	0.710	0.000
Q3	0.860	0.045
Maximum	2.64	0.96

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（56/95）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	16.4	
SD	4.40	
Minimum	7	
Q1	13.0	
Median	16.0	
Q3	19.0	
Maximum	33	
Week 3		
N	221	221
Mean	16.6	0.1
SD	4.63	2.79
Minimum	7	-7
Q1	13.0	-2.0
Median	16.0	0.0
Q3	19.0	2.0
Maximum	36	9

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（57/95）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	16.4	0.1
SD	4.86	3.45
Minimum	7	-9
Q1	13.0	-2.0
Median	15.0	0.0
Q3	18.0	2.0
Maximum	36	13
Week 10		
N	206	206
Mean	16.7	0.3
SD	5.18	3.78
Minimum	7	-7
Q1	14.0	-2.0
Median	16.0	0.0
Q3	20.0	3.0
Maximum	41	17

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（58/95）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	17.0	0.6
SD	5.15	3.79
Minimum	7	-9
Q1	14.0	-2.0
Median	17.0	0.5
Q3	20.0	2.0
Maximum	42	18
Week 26		
N	180	180
Mean	16.5	0.1
SD	4.56	3.73
Minimum	9	-10
Q1	13.0	-2.0
Median	16.0	0.0
Q3	19.0	2.0
Maximum	31	12

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（59/95）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	17.2	0.9
SD	5.20	4.02
Minimum	8	-11
Q1	14.0	-2.0
Median	17.0	1.0
Q3	20.0	3.0
Maximum	54	30
Week 42		
N	167	167
Mean	17.1	0.9
SD	4.80	3.80
Minimum	9	-8
Q1	14.0	-2.0
Median	16.0	1.0
Q3	20.0	3.0
Maximum	38	14

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（60/95）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	17.3	1.1
SD	4.64	3.84
Minimum	8	-10
Q1	14.0	-1.0
Median	16.5	1.0
Q3	20.0	3.5
Maximum	36	13

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（61/95）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	4.62	
SD	1.406	
Minimum	1.4	
Q1	3.60	
Median	4.50	
Q3	5.60	
Maximum	8.7	
Week 3		
N	221	221
Mean	4.57	-0.04
SD	1.345	0.545
Minimum	1.6	-1.9
Q1	3.60	-0.40
Median	4.50	0.00
Q3	5.50	0.30
Maximum	8.8	2.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（62/95）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	4.56	-0.06
SD	1.327	0.605
Minimum	1.6	-2.6
Q1	3.60	-0.50
Median	4.50	0.00
Q3	5.40	0.30
Maximum	8.0	2.4
Week 10		
N	206	206
Mean	4.53	-0.08
SD	1.347	0.636
Minimum	1.5	-3.1
Q1	3.60	-0.40
Median	4.50	0.00
Q3	5.40	0.30
Maximum	7.9	3.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（63/95）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	4.45	-0.14
SD	1.283	0.687
Minimum	1.7	-3.1
Q1	3.50	-0.50
Median	4.40	-0.10
Q3	5.20	0.30
Maximum	8.7	2.2
Week 26		
N	180	180
Mean	4.43	-0.15
SD	1.404	0.723
Minimum	1.2	-3.3
Q1	3.35	-0.60
Median	4.40	-0.10
Q3	5.25	0.30
Maximum	9.2	3.4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（64/95）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	4.48	-0.14
SD	1.369	0.698
Minimum	1.8	-2.3
Q1	3.50	-0.50
Median	4.30	-0.10
Q3	5.30	0.20
Maximum	10.5	3.7
Week 42		
N	167	167
Mean	4.53	-0.10
SD	1.279	0.685
Minimum	1.5	-3.2
Q1	3.60	-0.50
Median	4.40	0.00
Q3	5.30	0.30
Maximum	9.3	2.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（65/95）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	4.61	-0.03
SD	1.369	0.830
Minimum	1.7	-2.5
Q1	3.70	-0.40
Median	4.50	0.00
Q3	5.40	0.40
Maximum	10.6	3.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（66/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	126.8	
SD	82.83	
Minimum	30	
Q1	76.0	
Median	104.5	
Q3	153.0	
Maximum	757	
Week 3		
N	221	221
Mean	131.6	4.4
SD	95.37	56.85
Minimum	31	-226
Q1	75.0	-13.0
Median	108.0	3.0
Q3	149.0	15.0
Maximum	769	596

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（67/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	132.8	5.6
SD	93.12	56.85
Minimum	32	-163
Q1	79.0	-14.0
Median	111.5	0.5
Q3	151.0	21.0
Maximum	679	319
Week 10		
N	206	206
Mean	124.6	-1.8
SD	81.47	57.77
Minimum	38	-213
Q1	78.0	-21.0
Median	101.0	0.0
Q3	141.0	15.0
Maximum	755	337

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（68/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	134.7	7.6
SD	85.63	75.18
Minimum	36	-291
Q1	81.5	-22.0
Median	114.5	2.0
Q3	155.0	21.0
Maximum	639	479
Week 26		
N	180	180
Mean	136.6	11.2
SD	144.29	136.47
Minimum	33	-266
Q1	78.5	-23.5
Median	101.5	0.0
Q3	144.0	17.5
Maximum	1399	1254

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（69/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	130.2	8.2
SD	116.81	106.14
Minimum	36	-190
Q1	75.0	-22.0
Median	108.0	0.0
Q3	138.0	26.0
Maximum	1216	1095
Week 42		
N	167	167
Mean	133.1	9.9
SD	86.90	72.76
Minimum	27	-126
Q1	83.0	-17.0
Median	114.0	-1.0
Q3	155.0	25.0
Maximum	614	525

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（70/95）

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

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	129.0	5.4
SD	79.06	64.57
Minimum	28	-162
Q1	83.0	-18.5
Median	109.0	0.0
Q3	152.0	29.0
Maximum	634	318

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（71/95）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	141.1	
SD	1.96	
Minimum	132	
Q1	140.0	
Median	141.0	
Q3	142.0	
Maximum	147	
Week 3		
N	221	221
Mean	140.7	-0.4
SD	2.16	1.76
Minimum	132	-6
Q1	139.0	-2.0
Median	141.0	0.0
Q3	142.0	1.0
Maximum	146	5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（72/95）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	140.3	-0.8
SD	2.06	1.73
Minimum	130	-8
Q1	139.0	-2.0
Median	140.0	-1.0
Q3	142.0	0.0
Maximum	145	3
Week 10		
N	206	206
Mean	140.1	-1.0
SD	2.44	2.03
Minimum	129	-11
Q1	139.0	-2.0
Median	140.0	-1.0
Q3	142.0	0.0
Maximum	146	3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（73/95）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	140.0	-1.1
SD	2.40	1.92
Minimum	127	-9
Q1	139.0	-2.0
Median	140.0	-1.0
Q3	142.0	0.0
Maximum	144	4
Week 26		
N	180	180
Mean	140.1	-1.1
SD	2.33	1.95
Minimum	128	-10
Q1	139.0	-2.0
Median	140.0	-1.0
Q3	142.0	0.0
Maximum	146	3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（74/95）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	140.4	-0.9
SD	2.07	1.97
Minimum	130	-7
Q1	139.0	-2.0
Median	140.0	-1.0
Q3	142.0	0.0
Maximum	145	5
Week 42		
N	167	167
Mean	140.7	-0.6
SD	2.10	2.02
Minimum	133	-6
Q1	140.0	-2.0
Median	141.0	0.0
Q3	142.0	1.0
Maximum	146	3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（75/95）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	140.7	-0.5
SD	2.13	2.10
Minimum	133	-7
Q1	139.5	-2.0
Median	141.0	0.0
Q3	142.0	1.0
Maximum	146	5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（76/95）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	4.10	
SD	0.331	
Minimum	3.1	
Q1	3.90	
Median	4.10	
Q3	4.30	
Maximum	5.3	
Week 3		
N	221	221
Mean	4.10	0.00
SD	0.344	0.280
Minimum	3.2	-0.9
Q1	3.90	-0.20
Median	4.10	0.00
Q3	4.30	0.20
Maximum	5.7	0.9

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（77/95）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	208	208
Mean	4.10	0.00
SD	0.324	0.323
Minimum	3.2	-1.4
Q1	3.90	-0.20
Median	4.10	0.00
Q3	4.30	0.20
Maximum	5.4	0.9
Week 10		
N	206	206
Mean	4.10	0.00
SD	0.347	0.323
Minimum	2.6	-1.3
Q1	3.90	-0.20
Median	4.10	0.00
Q3	4.30	0.20
Maximum	5.3	1.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（78/95）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	187	187
Mean	4.16	0.06
SD	0.349	0.355
Minimum	3.2	-1.0
Q1	3.90	-0.20
Median	4.10	0.10
Q3	4.40	0.30
Maximum	5.5	1.1
Week 26		
N	179	179
Mean	4.14	0.05
SD	0.351	0.365
Minimum	3.0	-1.0
Q1	3.90	-0.20
Median	4.10	0.10
Q3	4.30	0.20
Maximum	6.2	1.7

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（79/95）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	4.15	0.06
SD	0.306	0.311
Minimum	3.4	-0.7
Q1	4.00	-0.10
Median	4.10	0.10
Q3	4.30	0.30
Maximum	5.8	1.3
Week 42		
N	167	167
Mean	4.15	0.07
SD	0.337	0.332
Minimum	3.2	-0.9
Q1	4.00	-0.10
Median	4.10	0.10
Q3	4.40	0.30
Maximum	6.0	1.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（80/95）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	162	162
Mean	4.14	0.05
SD	0.323	0.318
Minimum	3.3	-0.8
Q1	4.00	-0.10
Median	4.10	0.00
Q3	4.30	0.20
Maximum	5.7	1.2

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（81/95）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	Change from Baseline
Baseline		
N	222	
Mean	103.9	
SD	2.16	
Minimum	94	
Q1	102.0	
Median	104.0	
Q3	105.0	
Maximum	109	
Week 3		
N	221	221
Mean	103.5	-0.4
SD	2.40	1.88
Minimum	95	-7
Q1	102.0	-2.0
Median	103.0	0.0
Q3	105.0	1.0
Maximum	110	6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（82/95）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	103.0	-0.9
SD	2.36	1.92
Minimum	90	-10
Q1	102.0	-2.0
Median	103.0	-1.0
Q3	105.0	0.0
Maximum	108	5
Week 10		
N	206	206
Mean	102.6	-1.4
SD	2.78	2.43
Minimum	84	-20
Q1	101.0	-2.0
Median	103.0	-1.0
Q3	104.0	0.0
Maximum	109	3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（83/95）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	102.4	-1.6
SD	2.52	2.08
Minimum	91	-10
Q1	101.0	-3.0
Median	103.0	-2.0
Q3	104.0	0.0
Maximum	108	4
Week 26		
N	180	180
Mean	102.4	-1.6
SD	2.46	2.03
Minimum	91	-8
Q1	101.0	-3.0
Median	102.5	-2.0
Q3	104.0	0.0
Maximum	108	3

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（84/95）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	103.0	-1.0
SD	2.49	2.20
Minimum	93	-8
Q1	101.0	-3.0
Median	103.0	-1.0
Q3	105.0	0.0
Maximum	112	4
Week 42		
N	167	167
Mean	103.5	-0.5
SD	2.23	2.04
Minimum	98	-6
Q1	102.0	-2.0
Median	104.0	-1.0
Q3	105.0	1.0
Maximum	109	5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（85/95）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	103.6	-0.5
SD	2.41	2.18
Minimum	93	-11
Q1	102.0	-2.0
Median	104.0	0.0
Q3	105.0	1.0
Maximum	110	4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（86/95）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	9.13	
SD	0.324	
Minimum	8.3	
Q1	8.90	
Median	9.10	
Q3	9.30	
Maximum	9.9	
Week 3		
N	221	221
Mean	9.09	-0.05
SD	0.318	0.290
Minimum	8.3	-0.8
Q1	8.90	-0.20
Median	9.10	0.00
Q3	9.30	0.20
Maximum	10.1	0.8

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（87/95）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	9.11	-0.02
SD	0.312	0.306
Minimum	8.4	-1.1
Q1	8.90	-0.20
Median	9.10	0.00
Q3	9.30	0.20
Maximum	10.2	0.8
Week 10		
N	206	206
Mean	9.10	-0.02
SD	0.328	0.322
Minimum	8.4	-1.1
Q1	8.90	-0.20
Median	9.10	0.00
Q3	9.30	0.20
Maximum	10.3	1.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（88/95）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	9.05	-0.08
SD	0.309	0.279
Minimum	8.3	-0.8
Q1	8.80	-0.20
Median	9.10	-0.10
Q3	9.20	0.10
Maximum	9.9	0.8
Week 26		
N	180	180
Mean	9.00	-0.14
SD	0.320	0.289
Minimum	8.3	-0.9
Q1	8.80	-0.40
Median	9.00	-0.20
Q3	9.20	0.00
Maximum	10.3	0.7

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（89/95）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	8.93	-0.22
SD	0.313	0.270
Minimum	7.9	-1.0
Q1	8.70	-0.40
Median	9.00	-0.20
Q3	9.10	-0.10
Maximum	9.9	0.5
Week 42		
N	167	167
Mean	8.95	-0.19
SD	0.305	0.273
Minimum	8.1	-0.9
Q1	8.80	-0.30
Median	9.00	-0.20
Q3	9.10	0.00
Maximum	9.9	0.6

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（90/95）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	8.94	-0.20
SD	0.302	0.271
Minimum	8.0	-1.0
Q1	8.70	-0.40
Median	8.90	-0.20
Q3	9.10	0.00
Maximum	9.8	0.5

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（91/95）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	Change from Baseline
Baseline		
N	222	
Mean	3.32	
SD	0.453	
Minimum	2.2	
Q1	3.00	
Median	3.30	
Q3	3.70	
Maximum	4.5	
Week 3		
N	221	221
Mean	3.35	0.04
SD	0.433	0.377
Minimum	2.1	-1.4
Q1	3.00	-0.20
Median	3.40	0.00
Q3	3.70	0.30
Maximum	4.3	1.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（92/95）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	3.41	0.09
SD	0.421	0.403
Minimum	2.1	-1.3
Q1	3.10	-0.10
Median	3.40	0.10
Q3	3.70	0.40
Maximum	4.6	1.3
Week 10		
N	206	206
Mean	3.40	0.08
SD	0.417	0.339
Minimum	2.1	-0.9
Q1	3.10	-0.10
Median	3.40	0.10
Q3	3.70	0.30
Maximum	4.4	1.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（93/95）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	192	192
Mean	3.37	0.07
SD	0.458	0.400
Minimum	2.2	-1.0
Q1	3.10	-0.20
Median	3.40	0.10
Q3	3.70	0.30
Maximum	4.4	1.7
Week 26		
N	180	180
Mean	3.31	0.02
SD	0.451	0.391
Minimum	2.0	-1.0
Q1	3.00	-0.20
Median	3.30	0.00
Q3	3.70	0.20
Maximum	4.5	1.4

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（94/95）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	3.26	-0.03
SD	0.427	0.381
Minimum	2.1	-1.3
Q1	3.00	-0.20
Median	3.30	-0.10
Q3	3.50	0.20
Maximum	4.2	1.1
Week 42		
N	167	167
Mean	3.27	-0.01
SD	0.428	0.393
Minimum	2.1	-1.4
Q1	3.00	-0.30
Median	3.30	0.00
Q3	3.50	0.20
Maximum	4.8	1.1

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-82　血液生化学検査の評価時点別変化量（OCT-002 試験）（95/95）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	3.27	-0.01
SD	0.412	0.354
Minimum	2.0	-1.2
Q1	2.90	-0.25
Median	3.30	0.00
Q3	3.55	0.20
Maximum	4.3	1.0

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.1

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（1/38）

AST (GOT)

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	-	-	-
Normal	-	216	4	220
High	-	-	1	1
Total	-	216	5	221
Week 6				
Low	-	-	-	-
Normal	-	201	5	206
High	-	2	-	2
Total	-	203	5	208
Week 10				
Low	-	-	-	-
Normal	-	199	4	203
High	-	2	1	3
Total	-	201	5	206
Week 18				
Low	-	-	-	-
Normal	-	180	3	183
High	-	3	1	4
Total	-	183	4	187

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（2/38）

AST (GOT)

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	-	173	2	175
High	-	3	1	4
Total	-	176	3	179
Week 34				
Low	-	-	-	-
Normal	-	166	2	168
High	-	2	1	3
Total	-	168	3	171
Week 42				
Low	-	-	-	-
Normal	-	162	2	164
High	-	2	1	3
Total	-	164	3	167
Week 52				
Low	-	-	-	-
Normal	-	158	2	160
High	-	1	1	2
Total	-	159	3	162

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（3/38）

ALT (GPT)

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	3	10	-	13
Normal	9	195	1	205
High	-	2	1	3
Total	12	207	2	221
Week 6				
Low	5	6	-	11
Normal	7	190	2	199
High	-	-	-	-
Total	12	196	2	210
Week 10				
Low	2	2	-	4
Normal	10	190	2	202
High	-	-	-	-
Total	12	192	2	206
Week 18				
Low	4	6	-	10
Normal	8	171	2	181
High	-	1	-	1
Total	12	178	2	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（4/38）

ALT (GPT)

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	2	3	-	5
Normal	8	163	1	172
High	-	2	1	3
Total	10	168	2	180
Week 34				
Low	1	10	-	11
Normal	9	149	1	159
High	-	-	1	1
Total	10	159	2	171
Week 42				
Low	1	7	-	8
Normal	8	148	2	158
High	-	1	-	1
Total	9	156	2	167
Week 52				
Low	2	4	-	6
Normal	7	148	1	156
High	-	1	1	2
Total	9	153	2	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（5/38）

GGT

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	-	-	-
Normal	-	204	1	205
High	-	4	12	16
Total	-	208	13	221
Week 6				
Low	-	-	-	-
Normal	-	194	1	195
High	-	4	11	15
Total	-	198	12	210
Week 10				
Low	-	-	-	-
Normal	-	183	2	185
High	-	11	10	21
Total	-	194	12	206
Week 18				
Low	-	-	-	-
Normal	-	174	3	177
High	-	7	8	15
Total	-	181	11	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（6/38）

GGT

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	-	163	2	165
High	-	6	9	15
Total	-	169	11	180
Week 34				
Low	-	-	-	-
Normal	-	153	3	156
High	-	7	8	15
Total	-	160	11	171
Week 42				
Low	-	-	-	-
Normal	-	151	3	154
High	-	5	8	13
Total	-	156	11	167
Week 52				
Low	-	-	-	-
Normal	-	147	3	150
High	-	6	8	14
Total	-	153	11	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（7/38）

Alkaline Phosphatase

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	1	-	-	1
Normal	-	187	7	194
High	-	8	18	26
Total	1	195	25	221
Week 6				
Low	1	-	-	1
Normal	-	179	8	187
High	-	5	17	22
Total	1	184	25	210
Week 10				
Low	1	-	-	1
Normal	-	170	7	177
High	-	10	18	28
Total	1	180	25	206
Week 18				
Low	1	-	-	1
Normal	-	158	9	167
High	-	12	12	24
Total	1	170	21	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（8/38）

Alkaline Phosphatase

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	1	144	8	153
High	-	16	11	27
Total	1	160	19	180
Week 34				
Low	1	-	-	1
Normal	-	135	8	143
High	-	16	11	27
Total	1	151	19	171
Week 42				
Low	1	-	-	1
Normal	-	135	7	142
High	-	13	11	24
Total	1	148	18	167
Week 52				
Low	-	-	-	-
Normal	1	136	5	142
High	-	11	11	22
Total	1	147	16	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（9/38）

LDH

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	-	-	-
Normal	1	193	5	199
High	-	6	16	22
Total	1	199	21	221
Week 6				
Low	1	-	-	1
Normal	-	177	4	181
High	-	9	17	26
Total	1	186	21	208
Week 10				
Low	-	-	-	-
Normal	1	179	11	191
High	-	6	9	15
Total	1	185	20	206
Week 18				
Low	-	-	-	-
Normal	1	158	8	167
High	-	11	9	20
Total	1	169	17	187

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（10/38）

LDH

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	1	153	7	161
High	-	10	8	18
Total	1	163	15	179
Week 34				
Low	-	-	-	-
Normal	1	146	9	156
High	-	10	5	15
Total	1	156	14	171
Week 42				
Low	-	1	-	1
Normal	1	140	5	146
High	-	11	9	20
Total	1	152	14	167
Week 52				
Low	-	1	-	1
Normal	-	137	9	146
High	-	10	5	15
Total	-	148	14	162

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（11/38）

Albumin

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	4	-	-	4
Normal	1	216	-	217
High	-	-	-	-
Total	5	216	-	221
Week 6				
Low	2	2	-	4
Normal	3	203	-	206
High	-	-	-	-
Total	5	205	-	210
Week 10				
Low	1	3	-	4
Normal	4	198	-	202
High	-	-	-	-
Total	5	201	-	206
Week 18				
Low	1	4	-	5
Normal	3	184	-	187
High	-	-	-	-
Total	4	188	-	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（12/38）

Albumin

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	1	4	-	5
Normal	2	173	-	175
High	-	-	-	-
Total	3	177	-	180
Week 34				
Low	2	1	-	3
Normal	1	167	-	168
High	-	-	-	-
Total	3	168	-	171
Week 42				
Low	3	1	-	4
Normal	-	163	-	163
High	-	-	-	-
Total	3	164	-	167
Week 52				
Low	-	1	-	1
Normal	3	160	-	163
High	-	-	-	-
Total	3	161	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（13/38）

Total Protein

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	30	22	-	52
Normal	11	157	-	168
High	-	-	1	1
Total	41	179	1	221
Week 6				
Low	18	22	-	40
Normal	20	149	-	169
High	-	-	1	1
Total	38	171	1	210
Week 10				
Low	22	23	-	45
Normal	16	144	1	161
High	-	-	-	-
Total	38	167	1	206
Week 18				
Low	18	18	-	36
Normal	16	139	-	155
High	-	-	1	1
Total	34	157	1	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（14/38）

Total Protein

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	16	19	-	35
Normal	16	128	-	144
High	-	-	1	1
Total	32	147	1	180
Week 34				
Low	20	19	-	39
Normal	11	119	1	131
High	-	1	-	1
Total	31	139	1	171
Week 42				
Low	17	17	-	34
Normal	12	120	-	132
High	-	-	1	1
Total	29	137	1	167
Week 52				
Low	17	17	-	34
Normal	12	116	1	129
High	-	1	-	1
Total	29	134	1	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（15/38）

Total Bilirubin

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	-	-	-
Normal	-	202	5	207
High	-	6	8	14
Total	-	208	13	221
Week 6				
Low	-	-	-	-
Normal	-	190	6	196
High	-	7	7	14
Total	-	197	13	210
Week 10				
Low	-	-	-	-
Normal	-	189	7	196
High	-	5	5	10
Total	-	194	12	206
Week 18				
Low	-	-	-	-
Normal	-	179	8	187
High	-	1	4	5
Total	-	180	12	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（16/38）

Total Bilirubin

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	-	167	7	174
High	-	2	4	6
Total	-	169	11	180
Week 34				
Low	-	-	-	-
Normal	-	158	4	162
High	-	2	7	9
Total	-	160	11	171
Week 42				
Low	-	-	-	-
Normal	-	153	5	158
High	-	3	6	9
Total	-	156	11	167
Week 52				
Low	-	-	-	-
Normal	-	148	4	152
High	-	5	7	12
Total	-	153	11	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（17/38）

Total Cholesterol

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	1	-	1
Normal	1	168	11	180
High	-	10	30	40
Total	1	179	41	221
Week 6				
Low	-	1	-	1
Normal	1	163	18	182
High	-	6	21	27
Total	1	170	39	210
Week 10				
Low	-	2	-	2
Normal	1	155	11	167
High	-	11	26	37
Total	1	168	37	206
Week 18				
Low	-	1	-	1
Normal	1	145	15	161
High	-	12	18	30
Total	1	158	33	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（18/38）

Total Cholesterol

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	1	130	16	147
High	-	17	16	33
Total	1	147	32	180
Week 34				
Low	-	-	-	-
Normal	1	126	12	139
High	-	14	18	32
Total	1	140	30	171
Week 42				
Low	-	-	-	-
Normal	1	124	13	138
High	-	14	15	29
Total	1	138	28	167
Week 52				
Low	-	-	-	-
Normal	1	124	12	137
High	-	11	16	27
Total	1	135	28	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（19/38）

Triglycerides

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	2	-	2
Normal	-	197	12	209
High	-	6	4	10
Total	-	205	16	221
Week 6				
Low	-	1	-	1
Normal	-	185	11	196
High	-	10	3	13
Total	-	196	14	210
Week 10				
Low	-	1	-	1
Normal	-	186	11	197
High	-	5	3	8
Total	-	192	14	206
Week 18				
Low	-	-	-	-
Normal	-	170	10	180
High	-	8	4	12
Total	-	178	14	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（20/38）

Triglycerides

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	-	163	7	170
High	-	3	7	10
Total	-	166	14	180
Week 34				
Low	-	2	-	2
Normal	-	150	9	159
High	-	5	5	10
Total	-	157	14	171
Week 42				
Low	-	2	-	2
Normal	-	148	8	156
High	-	4	5	9
Total	-	154	13	167
Week 52				
Low	-	1	-	1
Normal	-	147	9	156
High	-	3	4	7
Total	-	151	13	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（21/38）

Creatinine

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	3	4	-	7
Normal	1	184	4	189
High	-	7	18	25
Total	4	195	22	221
Week 6				
Low	4	7	-	11
Normal	-	172	3	175
High	-	8	16	24
Total	4	187	19	210
Week 10				
Low	2	5	-	7
Normal	1	168	6	175
High	-	11	13	24
Total	3	184	19	206
Week 18				
Low	3	6	-	9
Normal	-	160	6	166
High	-	6	11	17
Total	3	172	17	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（22/38）

Creatinine

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	3	7	-	10
Normal	-	147	9	156
High	-	9	5	14
Total	3	163	14	180
Week 34				
Low	2	5	-	7
Normal	1	145	6	152
High	-	4	8	12
Total	3	154	14	171
Week 42				
Low	1	4	-	5
Normal	2	143	3	148
High	-	3	11	14
Total	3	150	14	167
Week 52				
Low	3	5	-	8
Normal	-	133	3	136
High	-	9	11	20
Total	3	147	14	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（23/38）

Blood Urea Nitrogen

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	-	1	-	1
Normal	1	197	4	202
High	-	7	11	18
Total	1	205	15	221
Week 6				
Low	-	1	-	1
Normal	1	184	5	190
High	-	10	9	19
Total	1	195	14	210
Week 10				
Low	-	1	-	1
Normal	1	175	5	181
High	-	15	9	24
Total	1	191	14	206
Week 18				
Low	-	2	-	2
Normal	-	166	6	172
High	-	11	7	18
Total	-	179	13	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（24/38）

Blood Urea Nitrogen

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	-	-	-
Normal	-	158	8	166
High	-	11	3	14
Total	-	169	11	180
Week 34				
Low	-	-	-	-
Normal	-	149	5	154
High	-	12	5	17
Total	-	161	10	171
Week 42				
Low	-	-	-	-
Normal	-	145	4	149
High	-	13	5	18
Total	-	158	9	167
Week 52				
Low	-	-	-	-
Normal	-	141	6	147
High	-	14	3	17
Total	-	155	9	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（25/38）

Uric Acid

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	14	4	-	18
Normal	9	180	5	194
High	-	2	7	9
Total	23	186	12	221
Week 6				
Low	15	5	-	20
Normal	6	168	6	180
High	-	4	6	10
Total	21	177	12	210
Week 10				
Low	13	5	-	18
Normal	9	164	6	179
High	-	3	6	9
Total	22	172	12	206
Week 18				
Low	14	8	-	22
Normal	6	152	5	163
High	-	2	5	7
Total	20	162	10	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（26/38）

Uric Acid

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	13	8	-	21
Normal	7	139	6	152
High	-	3	4	7
Total	20	150	10	180
Week 34				
Low	10	6	-	16
Normal	7	136	5	148
High	-	3	4	7
Total	17	145	9	171
Week 42				
Low	8	7	-	15
Normal	8	133	4	145
High	-	2	5	7
Total	16	142	9	167
Week 52				
Low	7	3	-	10
Normal	9	133	4	146
High	-	3	5	8
Total	16	139	9	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（27/38）

CK (CPK)

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	6	8	-	14
Normal	-	160	14	174
High	1	6	26	33
Total	7	174	40	221
Week 6				
Low	5	3	-	8
Normal	2	152	17	171
High	-	10	21	31
Total	7	165	38	210
Week 10				
Low	3	2	-	5
Normal	4	147	23	174
High	-	13	14	27
Total	7	162	37	206
Week 18				
Low	3	4	-	7
Normal	1	134	17	152
High	1	14	18	33
Total	5	152	35	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（28/38）

CK (CPK)

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	4	4	-	8
Normal	-	128	18	146
High	-	14	12	26
Total	4	146	30	180
Week 34				
Low	3	4	-	7
Normal	1	128	17	146
High	-	7	11	18
Total	4	139	28	171
Week 42				
Low	4	2	-	6
Normal	-	117	16	133
High	-	16	12	28
Total	4	135	28	167
Week 52				
Low	3	4	-	7
Normal	1	122	11	134
High	-	7	16	23
Total	4	133	27	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（29/38）

Sodium

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	4	4	-	8
Normal	-	213	-	213
High	-	-	-	-
Total	4	217	-	221
Week 6				
Low	2	5	-	7
Normal	1	202	-	203
High	-	-	-	-
Total	3	207	-	210
Week 10				
Low	2	8	-	10
Normal	1	195	-	196
High	-	-	-	-
Total	3	203	-	206
Week 18				
Low	3	10	-	13
Normal	-	179	-	179
High	-	-	-	-
Total	3	189	-	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（30/38）

Sodium

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	2	7	-	9
Normal	-	171	-	171
High	-	-	-	-
Total	2	178	-	180
Week 34				
Low	1	1	-	2
Normal	-	169	-	169
High	-	-	-	-
Total	1	170	-	171
Week 42				
Low	1	5	-	6
Normal	-	161	-	161
High	-	-	-	-
Total	1	166	-	167
Week 52				
Low	-	5	-	5
Normal	1	158	-	159
High	-	-	-	-
Total	1	163	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（31/38）

Potassium

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	2	4	-	6
Normal	3	209	2	214
High	-	1	-	1
Total	5	214	2	221
Week 6				
Low	1	2	-	3
Normal	4	197	2	203
High	-	2	-	2
Total	5	201	2	208
Week 10				
Low	1	5	-	6
Normal	4	193	2	199
High	-	1	-	1
Total	5	199	2	206
Week 18				
Low	-	6	-	6
Normal	5	172	2	179
High	-	2	-	2
Total	5	180	2	187

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（32/38）

Potassium

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	2	-	2
Normal	5	169	2	176
High	-	1	-	1
Total	5	172	2	179
Week 34				
Low	1	-	-	1
Normal	4	163	2	169
High	-	1	-	1
Total	5	164	2	171
Week 42				
Low	1	2	-	3
Normal	4	157	1	162
High	-	2	-	2
Total	5	161	1	167
Week 52				
Low	-	3	-	3
Normal	5	152	1	158
High	-	1	-	1
Total	5	156	1	162

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（33/38）

Chloride

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	1	3	-	4
Normal	-	213	-	213
High	-	2	2	4
Total	1	218	2	221
Week 6				
Low	-	3	-	3
Normal	-	206	1	207
High	-	-	-	-
Total	-	209	1	210
Week 10				
Low	-	5	-	5
Normal	-	199	1	200
High	-	1	-	1
Total	-	205	1	206
Week 18				
Low	-	6	-	6
Normal	-	185	1	186
High	-	-	-	-
Total	-	191	1	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（34/38）

Chloride

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	3	-	3
Normal	-	176	1	177
High	-	-	-	-
Total	-	179	1	180
Week 34				
Low	-	3	-	3
Normal	-	165	1	166
High	-	2	-	2
Total	-	170	1	171
Week 42				
Low	-	-	-	-
Normal	-	165	1	166
High	-	1	-	1
Total	-	166	1	167
Week 52				
Low	-	2	-	2
Normal	-	159	1	160
High	-	2	-	2
Total	-	163	1	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（35/38）

Calcium

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	1	1	-	2
Normal	1	218	-	219
High	-	-	-	-
Total	2	219	-	221
Week 6				
Low	-	-	-	-
Normal	2	208	-	210
High	-	-	-	-
Total	2	208	-	210
Week 10				
Low	-	-	-	-
Normal	2	204	-	206
High	-	-	-	-
Total	2	204	-	206
Week 18				
Low	-	3	-	3
Normal	2	187	-	189
High	-	-	-	-
Total	2	190	-	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（36/38）

Calcium

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	-	2	-	2
Normal	1	177	-	178
High	-	-	-	-
Total	1	179	-	180
Week 34				
Low	1	3	-	4
Normal	-	167	-	167
High	-	-	-	-
Total	1	170	-	171
Week 42				
Low	1	5	-	6
Normal	-	161	-	161
High	-	-	-	-
Total	1	166	-	167
Week 52				
Low	1	1	-	2
Normal	-	162	-	162
High	-	-	-	-
Total	1	163	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（37/38）

Phosphorus

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 3				
Low	3	-	-	3
Normal	4	214	-	218
High	-	-	-	-
Total	7	214	-	221
Week 6				
Low	3	2	-	5
Normal	3	201	-	204
High	-	1	-	1
Total	6	204	-	210
Week 10				
Low	2	2	-	4
Normal	4	198	-	202
High	-	-	-	-
Total	6	200	-	206
Week 18				
Low	3	3	-	6
Normal	3	183	-	186
High	-	-	-	-
Total	6	186	-	192

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-83　血液生化学検査の正異判定のクロス表（OCT-002 試験）（38/38）

Phosphorus

	Baseline			
	1 mg (N=222)			
Visit	Low	Normal	High	Total
Week 26				
Low	3	1	-	4
Normal	3	173	-	176
High	-	-	-	-
Total	6	174	-	180
Week 34				
Low	5	3	-	8
Normal	1	162	-	163
High	-	-	-	-
Total	6	165	-	171
Week 42				
Low	3	2	-	5
Normal	3	158	-	161
High	-	1	-	1
Total	6	161	-	167
Week 52				
Low	2	-	-	2
Normal	4	158	-	162
High	-	-	-	-
Total	6	158	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.1.3

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（1/12）

Protein

	Baseline						
	1 mg (N=222)						
Visit	-	+-	1+	2+	3+	4+	Total
Week 3							
-	181	8	1	-	-	-	190
+-	14	7	3	-	-	-	24
1+	-	3	1	-	-	-	4
2+	1	-	2	-	-	-	3
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	196	18	7	-	-	-	221
Week 6							
-	175	5	1	-	-	-	181
+-	8	9	2	-	-	-	19
1+	4	1	1	-	-	-	6
2+	-	-	1	-	-	-	1
3+	-	1	-	-	-	-	1
4+	-	-	-	-	-	-	-
Total	187	16	5	-	-	-	208
Week 10							
-	169	7	2	-	-	-	178
+-	6	5	1	-	-	-	12
1+	6	2	2	-	-	-	10
2+	2	1	1	-	-	-	4
3+	-	1	-	-	-	-	1
4+	-	-	-	-	-	-	-
Total	183	16	6	-	-	-	205

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（2/12）

Protein

	Baseline						
	1 mg (N=222)						
Visit	-	+-	1+	2+	3+	4+	Total
Week 18							
-	164	10	1	-	-	-	175
+-	7	1	1	-	-	-	9
1+	1	2	2	-	-	-	5
2+	-	1	1	-	-	-	2
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	172	14	5	-	-	-	191
Week 26							
-	151	6	3	-	-	-	160
+-	7	4	-	-	-	-	11
1+	4	2	-	-	-	-	6
2+	2	-	1	-	-	-	3
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	164	12	4	-	-	-	180
Week 34							
-	148	5	-	-	-	-	153
+-	4	2	4	-	-	-	10
1+	3	3	-	-	-	-	6
2+	-	2	-	-	-	-	2
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	155	12	4	-	-	-	171

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（3/12）

Protein

	Baseline						
	1 mg (N=222)						
Visit	-	+-	1+	2+	3+	4+	Total
Week 42							
-	139	6	2	-	-	-	147
+-	11	4	2	-	-	-	17
1+	1	1	-	-	-	-	2
2+	-	1	-	-	-	-	1
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	151	12	4	-	-	-	167
Week 52							
-	138	9	2	-	-	-	149
+-	8	-	2	-	-	-	10
1+	2	3	-	-	-	-	5
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	148	12	4	-	-	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（4/12）

Glucose

	Baseline						
	1 mg (N=222)						
Visit	-	1+	2+	3+	4+	5+	Total
Week 3							
-	211	2	-	-	-	-	213
1+	3	1	-	-	-	-	4
2+	-	1	-	-	-	-	1
3+	1	-	-	-	-	-	1
4+	1	-	1	-	-	-	2
5+	-	-	-	-	-	-	-
Total	216	4	1	-	-	-	221
Week 6							
-	202	2	-	-	-	-	204
1+	1	1	-	-	-	-	2
2+	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-
4+	1	-	-	-	-	-	1
5+	-	-	-	-	-	-	-
Total	205	3	-	-	-	-	208
Week 10							
-	193	2	-	-	-	-	195
1+	6	1	-	-	-	-	7
2+	2	-	-	-	-	-	2
3+	1	-	-	-	-	-	1
4+	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-
Total	202	3	-	-	-	-	205

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（5/12）

Glucose

	Baseline						
	1 mg (N=222)						
Visit	-	1+	2+	3+	4+	5+	Total
Week 18							
-	182	2	-	-	-	-	184
1+	3	-	-	-	-	-	3
2+	2	-	-	-	-	-	2
3+	1	1	-	-	-	-	2
4+	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-
Total	188	3	-	-	-	-	191
Week 26							
-	167	2	-	-	-	-	169
1+	6	1	-	-	-	-	7
2+	1	-	-	-	-	-	1
3+	3	-	-	-	-	-	3
4+	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-
Total	177	3	-	-	-	-	180
Week 34							
-	162	2	-	-	-	-	164
1+	2	1	-	-	-	-	3
2+	4	-	-	-	-	-	4
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-
Total	168	3	-	-	-	-	171

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（6/12）

Glucose

	Baseline						
	1 mg (N=222)						
Visit	-	1+	2+	3+	4+	5+	Total
Week 42							
-	157	2	-	-	-	-	159
1+	4	1	-	-	-	-	5
2+	3	-	-	-	-	-	3
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-
Total	164	3	-	-	-	-	167
Week 52							
-	154	3	-	-	-	-	157
1+	1	-	-	-	-	-	1
2+	3	-	-	-	-	-	3
3+	1	-	-	-	-	-	1
4+	1	-	-	-	-	-	1
5+	1	-	-	-	-	-	1
Total	161	3	-	-	-	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（7/12）

Occult Blood

	Baseline					
	1 mg (N=222)					
Visit	-	+-	1+	2+	3+	Total
Week 3						
-	197	4	3	1	-	205
+-	2	1	-	-	-	3
1+	5	-	3	-	-	8
2+	1	-	-	2	2	5
3+	-	-	-	-	-	-
Total	205	5	6	3	2	221
Week 6						
-	183	4	1	1	1	190
+-	4	-	-	-	-	4
1+	4	-	5	2	-	11
2+	1	-	-	-	1	2
3+	1	-	-	-	-	1
Total	193	4	6	3	2	208
Week 10						
-	183	3	3	1	1	191
+-	3	1	-	-	-	4
1+	2	-	2	1	-	5
2+	2	-	-	1	-	3
3+	1	-	-	-	1	2
Total	191	4	5	3	2	205

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（8/12）

Occult Blood

	Baseline					
	1 mg (N=222)					
Visit	-	+-	1+	2+	3+	Total
Week 18						
-	170	2	2	1	-	175
+-	-	1	1	1	1	4
1+	4	-	1	-	-	5
2+	2	-	1	1	1	5
3+	2	-	-	-	-	2
Total	178	3	5	3	2	191
Week 26						
-	160	1	2	1	1	165
+-	1	2	1	-	-	4
1+	5	-	1	1	-	7
2+	-	-	1	1	1	3
3+	1	-	-	-	-	1
Total	167	3	5	3	2	180
Week 34						
-	150	1	2	1	1	155
+-	4	-	1	-	-	5
1+	3	2	2	2	-	9
2+	-	-	-	-	1	1
3+	1	-	-	-	-	1
Total	158	3	5	3	2	171

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（9/12）

Occult Blood

	Baseline					
	1 mg (N=222)					
Visit	-	+-	1+	2+	3+	Total
Week 42						
-	143	2	2	2	-	149
+-	4	1	-	-	-	5
1+	2	-	2	1	2	7
2+	1	-	1	-	-	2
3+	4	-	-	-	-	4
Total	154	3	5	3	2	167
Week 52						
-	146	-	3	1	1	151
+-	-	1	-	-	-	1
1+	4	1	2	1	-	8
2+	1	-	-	1	1	3
3+	1	-	-	-	-	1
Total	152	2	5	3	2	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（10/12）

Ketones

	Baseline						
	1 mg (N=222)						
Visit	-	+-	1+	2+	3+	4+	Total
Week 3							
-	162	16	3	-	-	-	181
+-	10	22	2	-	-	-	34
1+	2	3	1	-	-	-	6
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	174	41	6	-	-	-	221
Week 6							
-	145	14	1	-	-	-	160
+-	18	25	4	-	-	-	47
1+	-	-	1	-	-	-	1
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	163	39	6	-	-	-	208
Week 10							
-	140	20	3	-	-	-	163
+-	19	18	2	-	-	-	39
1+	1	1	1	-	-	-	3
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	160	39	6	-	-	-	205

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（11/12）

Ketones

	Baseline						
	1 mg (N=222)						
Visit	-	+-	1+	2+	3+	4+	Total
Week 18							
-	130	23	2	-	-	-	155
+-	14	13	2	-	-	-	29
1+	4	1	2	-	-	-	7
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	148	37	6	-	-	-	191
Week 26							
-	126	20	3	-	-	-	149
+-	13	10	3	-	-	-	26
1+	4	1	-	-	-	-	5
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	143	31	6	-	-	-	180
Week 34							
-	122	13	2	-	-	-	137
+-	14	16	2	-	-	-	32
1+	1	-	1	-	-	-	2
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	137	29	5	-	-	-	171

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-84　尿検査の正異判定のクロス表（OCT-002 試験）（12/12）

Ketones

	Baseline						
	1 mg (N=222)						
Visit	-	+-	1+	2+	3+	4+	Total
Week 42							
-	117	14	1	-	-	-	132
+-	16	14	2	-	-	-	32
1+	1	-	2	-	-	-	3
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	134	28	5	-	-	-	167
Week 52							
-	113	14	3	-	-	-	130
+-	16	13	2	-	-	-	31
1+	3	-	-	-	-	-	3
2+	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-
Total	132	27	5	-	-	-	164

Statistical Analysis Report (5.3.5.2-1) Table 3.3.1.2

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（1/8）

Systolic Blood Pressure (mmHg)

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	129.0		128.5	
SD	16.04		15.81	
Minimum	94		92	
Q1	116.0		116.0	
Median	127.5		128.0	
Q3	143.0		139.0	
Maximum	164		174	
Week 3				
N	126	126	116	116
Mean	127.1	-1.9	128.1	-0.1
SD	16.51	11.78	16.34	13.57
Minimum	86	-26	90	-42
Q1	115.0	-10.0	117.0	-7.5
Median	128.0	-2.0	129.0	0.0
Q3	139.0	7.0	139.0	7.0
Maximum	160	41	180	42

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（2/8）

Systolic Blood Pressure (mmHg)

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	128.4	-0.3	125.7	-2.6
SD	14.75	12.59	16.35	13.86
Minimum	87	-32	91	-54
Q1	120.0	-9.0	113.0	-11.0
Median	129.0	0.0	127.0	-1.0
Q3	140.0	8.0	137.0	7.0
Maximum	164	36	166	34
Week 10				
N	115	115	113	113
Mean	127.2	-1.7	125.2	-2.7
SD	15.66	13.11	15.19	12.80
Minimum	90	-30	89	-35
Q1	115.0	-11.0	115.0	-12.0
Median	128.0	-2.0	127.0	-4.0
Q3	139.0	8.0	135.0	6.0
Maximum	162	34	158	30

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（3/8）

Systolic Blood Pressure (mmHg)

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 14				
N	109	109	112	112
Mean	126.4	-2.7	125.4	-2.6
SD	15.26	13.47	15.93	13.97
Minimum	92	-42	88	-33
Q1	115.0	-10.0	111.5	-11.0
Median	124.0	-3.0	128.0	-1.5
Q3	136.0	8.0	136.5	6.0
Maximum	172	27	166	38
Week 20				
N	105	105	111	111
Mean	127.0	-2.2	126.5	-1.6
SD	17.45	12.00	16.00	15.20
Minimum	90	-33	87	-39
Q1	113.0	-10.0	116.0	-11.0
Median	129.0	-4.0	126.0	-2.0
Q3	140.0	5.0	138.0	8.0
Maximum	163	38	168	47

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（4/8）

Systolic Blood Pressure (mmHg)

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 26				
N	100	100	110	110
Mean	127.8	-1.7	127.0	-1.2
SD	16.62	12.10	15.45	14.35
Minimum	93	-29	90	-29
Q1	117.5	-10.0	118.0	-13.0
Median	126.0	-2.0	127.0	-2.0
Q3	140.0	5.5	140.0	9.0
Maximum	167	30	161	43

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（5/8）

Diastolic Blood Pressure (mmHg)

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	78.9		78.3	
SD	11.26		11.31	
Minimum	51		53	
Q1	71.0		71.0	
Median	79.0		79.0	
Q3	86.0		86.0	
Maximum	109		107	
Week 3				
N	126	126	116	116
Mean	77.3	-1.6	78.5	0.2
SD	11.04	8.35	11.21	9.76
Minimum	50	-26	53	-28
Q1	70.0	-7.0	70.0	-6.0
Median	78.0	-1.5	80.0	1.0
Q3	84.0	5.0	86.0	6.0
Maximum	106	25	105	29

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（6/8）

Diastolic Blood Pressure (mmHg)

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	77.6	-1.4	78.2	-0.5
SD	10.54	9.21	10.01	9.70
Minimum	46	-39	56	-27
Q1	70.0	-7.0	70.0	-7.0
Median	78.0	-2.0	79.0	0.0
Q3	85.0	5.0	86.0	5.0
Maximum	102	33	108	33
Week 10				
N	115	115	113	113
Mean	76.5	-2.4	76.8	-1.8
SD	11.36	9.04	10.33	9.02
Minimum	43	-27	50	-26
Q1	68.0	-8.0	69.0	-9.0
Median	76.0	-2.0	77.0	-2.0
Q3	85.0	3.0	84.0	3.0
Maximum	102	28	102	22

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（7/8）

Diastolic Blood Pressure (mmHg)

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 14				
N	109	109	112	112
Mean	76.6	-2.5	77.5	-1.1
SD	10.08	8.93	11.19	10.60
Minimum	57	-24	52	-21
Q1	69.0	-8.0	70.0	-10.0
Median	77.0	-2.0	77.0	-1.5
Q3	84.0	3.0	86.0	5.0
Maximum	99	21	106	32
Week 20				
N	105	105	111	111
Mean	76.1	-2.7	77.8	-0.9
SD	11.20	9.11	11.47	11.61
Minimum	47	-32	54	-28
Q1	70.0	-9.0	71.0	-9.0
Median	76.0	-3.0	76.0	-1.0
Q3	84.0	4.0	86.0	6.0
Maximum	102	20	104	37

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-85　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-001 試験）（8/8）

Diastolic Blood Pressure (mmHg)

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 26				
N	100	100	110	110
Mean	77.1	-2.1	78.6	-0.2
SD	10.12	8.12	10.10	11.21
Minimum	52	-28	58	-27
Q1	71.0	-7.5	72.0	-8.0
Median	78.0	-2.0	79.0	-1.5
Q3	84.5	3.0	86.0	6.0
Maximum	106	13	105	40

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（1/14）

Systolic Blood Pressure (mmHg)

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	128.1		128.5	
SD	16.68		15.81	
Minimum	93		92	
Q1	117.0		116.0	
Median	126.0		128.0	
Q3	141.0		139.0	
Maximum	167		174	
Week 3				
N	91	91	116	116
Mean	128.0	0.3	128.1	-0.1
SD	15.56	12.59	16.34	13.57
Minimum	85	-35	90	-42
Q1	118.0	-9.0	117.0	-7.5
Median	128.0	1.0	129.0	0.0
Q3	138.0	10.0	139.0	7.0
Maximum	176	30	180	42

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（2/14）

Systolic Blood Pressure (mmHg)

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	90	90	114	114
Mean	126.7	-1.5	125.7	-2.6
SD	15.41	12.03	16.35	13.86
Minimum	89	-40	91	-54
Q1	117.0	-8.0	113.0	-11.0
Median	125.5	-1.5	127.0	-1.0
Q3	138.0	7.0	137.0	7.0
Maximum	161	22	166	34
Week 10				
N	86	86	113	113
Mean	125.9	-1.3	125.2	-2.7
SD	17.37	12.69	15.19	12.80
Minimum	91	-40	89	-35
Q1	115.0	-8.0	115.0	-12.0
Median	126.0	-0.5	127.0	-4.0
Q3	138.0	7.0	135.0	6.0
Maximum	166	31	158	30

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（3/14）

Systolic Blood Pressure (mmHg)

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 14				
N	87	87	112	112
Mean	124.3	-4.1	125.4	-2.6
SD	15.80	13.15	15.93	13.97
Minimum	88	-35	88	-33
Q1	112.0	-13.0	111.5	-11.0
Median	124.0	-4.0	128.0	-1.5
Q3	137.0	5.0	136.5	6.0
Maximum	170	22	166	38
Week 20				
N	85	85	111	111
Mean	126.1	-2.5	126.5	-1.6
SD	16.12	14.09	16.00	15.20
Minimum	92	-34	87	-39
Q1	116.0	-13.0	116.0	-11.0
Median	128.0	-3.0	126.0	-2.0
Q3	136.0	9.0	138.0	8.0
Maximum	164	32	168	47

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（4/14）

Systolic Blood Pressure (mmHg)

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 26				
N	80	80	109	109
Mean	124.8	-3.5	127.0	-1.1
SD	15.81	12.22	15.50	14.38
Minimum	94	-38	90	-29
Q1	110.5	-12.0	118.0	-13.0
Median	125.0	-1.0	127.0	-2.0
Q3	137.0	4.5	140.0	9.0
Maximum	166	20	161	43
Week 29				
N	4	4	103	103
Mean	125.3	-8.0	125.5	-2.1
SD	19.02	6.38	15.94	16.38
Minimum	103	-14	92	-41
Q1	111.0	-13.5	114.0	-14.0
Median	125.0	-8.0	125.0	0.0
Q3	139.5	-2.5	138.0	11.0
Maximum	148	-2	162	36

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（5/14）

Systolic Blood Pressure (mmHg)

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 32				
N	0	0	101	101
Mean			126.7	-1.1
SD			14.54	15.10
Minimum			100	-37
Q1			115.0	-12.0
Median			127.0	0.0
Q3			136.0	9.0
Maximum			158	33
Week 36				
N	0	0	94	94
Mean			126.7	-0.5
SD			15.50	13.17
Minimum			91	-37
Q1			115.0	-8.0
Median			126.5	-1.0
Q3			139.0	8.0
Maximum			160	35

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（6/14）

Systolic Blood Pressure (mmHg)

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	88	88
Mean			124.4	-1.7
SD			14.88	12.86
Minimum			90	-37
Q1			115.0	-10.0
Median			124.0	-2.5
Q3			134.5	7.5
Maximum			154	29
Week 46				
N	0	0	87	87
Mean			125.9	0.0
SD			16.59	14.61
Minimum			83	-33
Q1			113.0	-10.0
Median			128.0	0.0
Q3			138.0	9.0
Maximum			171	40

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（7/14）

Systolic Blood Pressure (mmHg)

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			123.9	-1.9
SD			15.63	14.10
Minimum			95	-35
Q1			111.0	-13.0
Median			122.0	-1.0
Q3			137.0	7.0
Maximum			162	37

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（8/14）

Diastolic Blood Pressure (mmHg)

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	77.3		78.3	
SD	10.17		11.31	
Minimum	52		53	
Q1	71.0		71.0	
Median	78.0		79.0	
Q3	85.0		86.0	
Maximum	106		107	
Week 3				
N	91	91	116	116
Mean	78.2	1.0	78.5	0.2
SD	10.74	8.71	11.21	9.76
Minimum	39	-24	53	-28
Q1	72.0	-3.0	70.0	-6.0
Median	79.0	1.0	80.0	1.0
Q3	84.0	7.0	86.0	6.0
Maximum	109	23	105	29

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（9/14）

Diastolic Blood Pressure (mmHg)

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	90	90	114	114
Mean	76.7	-0.8	78.2	-0.5
SD	12.07	8.03	10.01	9.70
Minimum	45	-19	56	-27
Q1	70.0	-6.0	70.0	-7.0
Median	76.5	-1.0	79.0	0.0
Q3	84.0	6.0	86.0	5.0
Maximum	118	21	108	33
Week 10				
N	86	86	113	113
Mean	75.2	-2.3	76.8	-1.8
SD	11.31	8.38	10.33	9.02
Minimum	52	-21	50	-26
Q1	66.0	-8.0	69.0	-9.0
Median	75.5	-2.0	77.0	-2.0
Q3	82.0	4.0	84.0	3.0
Maximum	103	15	102	22

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（10/14）

Diastolic Blood Pressure (mmHg)

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 14				
N	87	87	112	112
Mean	75.2	-2.6	77.5	-1.1
SD	11.81	8.67	11.19	10.60
Minimum	45	-21	52	-21
Q1	68.0	-8.0	70.0	-10.0
Median	75.0	-3.0	77.0	-1.5
Q3	82.0	2.0	86.0	5.0
Maximum	114	21	106	32
Week 20				
N	85	85	111	111
Mean	76.3	-1.4	77.8	-0.9
SD	10.73	7.62	11.47	11.61
Minimum	54	-27	54	-28
Q1	70.0	-7.0	71.0	-9.0
Median	75.0	0.0	76.0	-1.0
Q3	83.0	4.0	86.0	6.0
Maximum	102	17	104	37

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（11/14）

Diastolic Blood Pressure (mmHg)

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 26				
N	80	80	109	109
Mean	76.1	-1.3	78.7	-0.4
SD	10.86	8.14	10.11	11.16
Minimum	47	-25	58	-27
Q1	68.5	-6.0	72.0	-8.0
Median	75.5	-3.0	79.0	-2.0
Q3	83.0	3.5	86.0	6.0
Maximum	105	21	105	40
Week 29				
N	4	4	103	103
Mean	73.3	-8.0	77.9	-0.6
SD	12.69	6.98	12.58	12.21
Minimum	64	-16	50	-33
Q1	66.0	-13.5	70.0	-10.0
Median	68.5	-8.0	77.0	0.0
Q3	80.5	-2.5	86.0	9.0
Maximum	92	0	114	27

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（12/14）

Diastolic Blood Pressure (mmHg)

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 32				
N	0	0	101	101
Mean			78.5	0.0
SD			10.69	10.02
Minimum			57	-21
Q1			71.0	-8.0
Median			77.0	-1.0
Q3			88.0	6.0
Maximum			100	28
Week 36				
N	0	0	94	94
Mean			77.5	-0.4
SD			11.46	9.48
Minimum			53	-22
Q1			69.0	-7.0
Median			77.0	0.0
Q3			86.0	5.0
Maximum			102	24

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（13/14）

Diastolic Blood Pressure (mmHg)

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	88	88
Mean			78.1	1.0
SD			11.51	8.20
Minimum			52	-21
Q1			70.0	-5.0
Median			76.0	2.0
Q3			86.0	6.0
Maximum			103	18
Week 46				
N	0	0	87	87
Mean			78.2	1.1
SD			11.64	10.01
Minimum			54	-24
Q1			70.0	-5.0
Median			79.0	0.0
Q3			86.0	5.0
Maximum			116	28

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-86　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-001 試験）（14/14）

Diastolic Blood Pressure (mmHg)

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			76.7	-0.3
SD			10.37	10.25
Minimum			60	-31
Q1			70.0	-8.0
Median			75.0	0.0
Q3			83.0	7.0
Maximum			112	26

Statistical Analysis Report (5.3.5.2-4) Table 3.2.2.1.1

表 2.7.4.7-付録-87　収縮期血圧の評価時点別変化量（232 試験）

TVP-1012/232 Placebo-Controlled Phase	Supine SBP (mmHg)								
	1 mg			2 mg			PLACEBO		
	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*
Baseline	134	128.3	0.0	132	132.4	0.0	138	129.8	0.0
Week 4	129	128.7	0.3	128	131.3	-1.3	135	130.1	0.2
Week 8	123	126.3	-1.9	122	131.2	-1.3	135	129.6	-0.1
Week 14	117	129.6	1.0	117	129.3	-3.3	120	127.4	-1.6
Week 20	114	128.9	0.3	106	129.9	-2.0	115	127.6	-1.3
Termination	133	128.5	0.2	132	132.4	0.0	137	127.6	-2.1

*BL=Baseline

総括報告書（5.3.5.1-7）Table 41

表 2.7.4.7-付録-88　拡張期血圧の評価時点別変化量（232 試験）

TVP-1012/232 Placebo-Controlled Phase	Supine DBP (mmHg)								
	1 mg			2 mg			PLACEBO		
	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*
Baseline	134	76.9	0.0	132	79.1	0.0	138	78.2	0.0
Week 4	129	77.5	0.4	128	78.6	-0.7	135	77.6	-0.6
Week 8	123	76.3	-0.4	122	78.5	-0.6	135	76.8	-1.3
Week 14	117	77.3	0.6	117	76.6	-2.5	120	76.0	-1.8
Week 20	114	76.5	-0.2	106	77.0	-2.0	115	76.8	-0.9
Termination	133	76.4	-0.5	132	77.7	-1.4	137	77.4	-0.8

*BL=Baseline

総括報告書（5.3.5.1-7）Table 45

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（1/8）

Systolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	120.5		122.0		123.1	
SD	17.29		15.56		16.73	
Minimum	71		82		83	
Q1	108.0		112.0		112.0	
Median	119.0		122.0		122.0	
Q3	131.0		134.0		134.0	
Maximum	165		158		164	
Week 3						
N	141	141	133	133	127	127
Mean	119.3	-1.3	120.0	-2.0	118.4	-4.5
SD	17.92	15.15	14.44	14.48	20.78	17.53
Minimum	81	-47	84	-37	72	-51
Q1	105.0	-12.0	109.0	-11.0	103.0	-15.0
Median	120.0	-3.0	120.0	-4.0	116.0	-6.0
Q3	133.0	10.0	130.0	8.0	133.0	3.0
Maximum	156	37	152	42	181	57

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（2/8）

Systolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	118.4	-2.0	119.2	-3.2	116.0	-7.2
SD	18.03	13.73	14.34	13.15	18.40	15.42
Minimum	79	-41	80	-41	62	-56
Q1	106.0	-10.0	110.0	-12.0	102.0	-18.0
Median	117.0	-3.0	121.0	-2.0	116.5	-6.0
Q3	130.0	7.0	130.0	6.0	126.0	3.0
Maximum	168	28	153	28	168	26
Week 10						
N	131	131	122	122	116	116
Mean	121.2	1.3	121.7	-0.2	120.6	-2.8
SD	17.75	15.64	16.52	16.07	18.96	17.61
Minimum	85	-35	73	-36	82	-46
Q1	108.0	-10.0	112.0	-9.0	107.0	-16.0
Median	120.0	-2.0	122.0	-1.5	120.5	-2.5
Q3	133.0	14.0	133.0	9.0	132.5	10.5
Maximum	171	46	164	49	173	49

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（3/8）

Systolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 14						
N	128	128	119	119	110	110
Mean	118.4	-1.9	118.9	-3.2	116.2	-7.5
SD	18.01	13.81	16.53	14.75	19.96	17.88
Minimum	80	-46	63	-43	73	-60
Q1	105.5	-10.0	108.0	-12.0	100.0	-18.0
Median	118.5	-2.0	119.0	-4.0	117.5	-10.0
Q3	130.0	6.5	130.0	6.0	130.0	0.0
Maximum	162	46	154	42	164	51
Week 20						
N	123	123	110	110	108	108
Mean	117.1	-3.4	118.4	-3.6	115.7	-8.0
SD	17.86	16.12	16.85	17.38	17.67	17.70
Minimum	71	-62	61	-51	70	-57
Q1	104.0	-12.0	107.0	-14.0	102.5	-19.0
Median	117.0	-4.0	118.0	-3.5	113.5	-8.0
Q3	130.0	5.0	133.0	9.0	129.5	4.0
Maximum	161	44	159	40	164	49

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（4/8）

Systolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 26						
N	120	120	107	107	105	105
Mean	119.4	-1.3	119.1	-2.9	115.5	-8.1
SD	17.95	17.00	18.23	15.34	17.11	18.90
Minimum	71	-42	74	-36	74	-87
Q1	106.5	-13.0	105.0	-13.0	104.0	-19.0
Median	118.5	-1.0	118.0	-3.0	115.0	-7.0
Q3	132.0	10.0	131.0	6.0	127.0	0.0
Maximum	173	62	177	54	151	38

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（5/8）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	73.0		72.1		73.3	
SD	11.93		10.98		10.94	
Minimum	36		48		50	
Q1	65.0		64.0		66.0	
Median	72.0		74.0		73.0	
Q3	81.0		80.0		82.0	
Maximum	104		91		104	
Week 3						
N	141	141	133	133	127	127
Mean	71.0	-2.0	71.6	-0.5	71.0	-2.3
SD	12.01	11.82	11.11	9.13	12.65	11.33
Minimum	38	-54	45	-25	42	-29
Q1	62.0	-8.0	64.0	-6.0	62.0	-10.0
Median	70.0	-2.0	73.0	0.0	71.0	-2.0
Q3	79.0	5.0	80.0	5.0	80.0	4.0
Maximum	100	28	95	30	99	42

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（6/8）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	72.1	-0.9	71.2	-1.3	71.0	-2.4
SD	12.02	10.49	11.07	8.98	11.66	10.52
Minimum	38	-42	42	-25	35	-32
Q1	65.0	-7.0	64.0	-6.0	64.0	-9.0
Median	71.0	0.0	72.0	-1.0	70.0	-2.0
Q3	80.0	6.0	78.0	5.0	79.0	4.0
Maximum	102	26	96	25	104	28
Week 10						
N	131	131	122	122	116	116
Mean	72.6	-0.4	72.3	0.0	71.4	-2.2
SD	11.18	11.00	12.60	10.67	11.89	11.00
Minimum	46	-40	40	-33	35	-31
Q1	63.0	-7.0	64.0	-8.0	63.0	-10.0
Median	72.0	-2.0	74.0	1.0	73.0	-2.5
Q3	80.0	6.0	79.0	7.0	80.0	6.0
Maximum	100	43	99	30	99	23

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（7/8）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 14						
N	128	128	119	119	110	110
Mean	71.4	-2.0	71.3	-1.2	70.1	-4.0
SD	11.70	10.47	12.11	10.47	12.97	10.87
Minimum	40	-37	33	-23	43	-29
Q1	62.5	-8.0	63.0	-10.0	60.0	-12.0
Median	70.0	-1.0	71.0	-1.0	70.0	-4.0
Q3	78.5	4.5	79.0	6.0	80.0	2.0
Maximum	101	26	97	31	100	32
Week 20						
N	123	123	110	110	108	108
Mean	71.1	-2.7	71.6	-0.5	70.4	-3.7
SD	12.34	11.41	12.78	10.95	12.10	10.63
Minimum	43	-36	31	-24	41	-25
Q1	62.0	-9.0	62.0	-8.0	62.5	-11.0
Median	71.0	-2.0	72.0	-1.5	69.5	-4.0
Q3	79.0	5.0	82.0	7.0	79.5	3.0
Maximum	98	26	97	29	98	28

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-89　収縮期血圧及び拡張期血圧の評価時点別変化量（CCT-002 試験）（8/8）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 26						
N	120	120	107	107	105	105
Mean	71.6	-2.3	70.2	-1.8	70.0	-4.2
SD	11.51	12.11	12.34	11.31	12.07	12.23
Minimum	42	-36	38	-32	37	-36
Q1	63.5	-10.0	60.0	-9.0	62.0	-12.0
Median	70.0	-2.0	71.0	-4.0	70.0	-4.0
Q3	78.0	5.0	79.0	6.0	79.0	2.0
Maximum	101	36	99	32	96	28

Statistical Analysis Report (5.3.5.1-3) Table 3.3.2.1.1

表 2.7.4.7-付録-90　収縮期血圧の評価時点別変化量（133 試験）（1/2）

TVP-1012/133 (PRESTO)		0.5 mg		1 mg		Placebo		All	
		Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)
Baseline	N	164	164	149	149	159	159	472	472
	Mean	127.0	0.0	128.8	0.0	124.9	0.0	126.9	0.0
	Std	17.1	0.0	16.2	0.0	17.1	0.0	16.8	0.0
	Median	126.0	0.0	126.0	0.0	122.0	0.0	125.0	0.0
	Min	91	0	89	0	84	0	84	0
	Max	186	0	174	0	182	0	186	0
Week 3	N	158	158	142	142	153	153	453	453
	Mean	125.1	-2.0	127.4	-1.5	124.9	0.1	125.8	-1.1
	Std	18.1	14.6	16.4	14.7	18.0	16.4	17.5	15.3
	Median	123.5	0.0	126.0	0.0	125.0	0.0	124.0	0.0
	Min	87	-38	90	-36	84	-50	84	-50
	Max	194	45	180	38	178	52	194	52
Week 6	N	153	153	141	141	151	151	445	445
	Mean	124.1	-3.0	127.8	-1.1	127.0	2.0	126.2	-0.7
	Std	16.8	13.9	16.2	14.3	16.9	16.9	16.7	15.2
	Median	122.0	-4.0	130.0	0.0	127.0	0.0	125.0	-2.0
	Min	91	-33	83	-48	84	-41	83	-48
	Max	186	38	170	40	169	74	186	74
Week 10	N	150	150	139	139	145	145	434	434
	Mean	125.3	-1.6	127.4	-1.2	126.2	1.8	126.3	-0.3
	Std	15.8	15.0	17.5	14.4	16.7	18.4	16.7	16.1
	Median	124.0	-2.0	126.0	0.0	124.0	0.0	124.0	-0.5
	Min	92	-44	83	-38	94	-36	83	-44
	Max	174	45	190	42	170	64	190	64
Week 14	N	148	148	137	137	142	142	427	427
	Mean	127.5	0.4	127.1	-1.7	126.5	1.8	127.0	0.2
	Std	16.9	16.7	16.4	13.5	15.1	16.9	16.1	15.8
	Median	127.0	0.0	124.0	-3.0	125.0	0.0	125.0	0.0
	Min	94	-48	90	-36	99	-35	90	-48
	Max	180	44	170	40	172	64	180	64

総括報告書（5.3.5.1-4） Post-Text Table 67

表 2.7.4.7-付録-付録-90　収縮期血圧の評価時点別変化量（133 試験）（2/2）

TVP-1012/133 (PRESTO)		0.5 mg		1 mg		Placebo		All	
		Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)
Week 20	N	145	145	134	134	140	140	419	419
	Mean	125.3	-1.5	127.7	-1.1	127.7	2.9	126.9	0.1
	Std	16.7	17.8	17.4	15.5	16.5	18.0	16.9	17.2
	Median	124.0	-2.0	126.0	-0.5	125.5	2.0	125.0	0.0
	Min	84	-54	100	-40	98	-40	84	-54
	Max	185	61	186	50	184	70	186	70
Unscheduled	N	9	9	5	5	9	9	23	23
	Mean	115.7	-12.3	133.8	0.8	124.1	0.0	122.9	-4.7
	Std	8.9	18.4	15.9	7.8	16.1	11.9	14.8	15.0
	Median	112.0	-20.0	130.0	4.0	120.0	-3.0	120.0	-4.0
	Min	107	-38	117	-9	102	-20	102	-38
	Max	130	23	158	8	152	22	158	23
Termination	N	160	160	143	143	158	158	461	461
	Mean	125.8	-1.4	128.3	-0.5	127.5	2.5	127.1	0.2
	Std	16.0	15.9	15.8	15.5	17.3	20.0	16.4	17.3
	Median	124.5	0.0	126.0	0.0	125.0	0.0	126.0	0.0
	Min	80	-45	95	-50	90	-38	80	-50
	Max	172	41	180	42	180	67	180	67

総括報告書（5.3.5.1-4）Post-Text Table 67

表 2.7.4.7-付録-91　拡張期血圧の評価時点別変化量（133 試験）（1/2）

TVP-1012/133 (PRESTO)		0.5 mg		1 mg		Placebo		All	
		Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)
Baseline	N	164	164	149	149	159	159	472	472
	Mean	75.1	0.0	75.8	0.0	75.2	0.0	75.4	0.0
	Std	9.5	0.0	8.1	0.0	10.1	0.0	9.3	0.0
	Median	75.0	0.0	76.0	0.0	75.0	0.0	76.0	0.0
	Min	54	0	52	0	40	0	40	0
	Max	110	0	92	0	102	0	110	0
Week 3	N	158	158	142	142	153	153	453	453
	Mean	74.0	-1.2	73.7	-2.1	74.6	-0.5	74.1	-1.2
	Std	9.7	9.7	8.9	8.3	10.6	9.6	9.8	9.3
	Median	72.0	-1.0	73.0	-2.0	75.0	0.0	73.0	0.0
	Min	46	-40	45	-23	40	-30	40	-40
	Max	100	30	95	30	102	36	102	36
Week 6	N	153	153	141	141	151	151	445	445
	Mean	73.8	-1.5	75.5	-0.3	74.9	-0.2	74.7	-0.7
	Std	9.5	9.1	8.8	9.7	9.9	10.3	9.4	9.7
	Median	72.0	-1.0	74.0	-1.0	75.0	0.0	74.0	0.0
	Min	51	-26	56	-20	44	-32	44	-32
	Max	97	28	108	44	103	34	108	44
Week 10	N	150	150	139	139	145	145	434	434
	Mean	73.5	-1.6	74.5	-1.2	74.3	-0.6	74.1	-1.1
	Std	9.1	9.8	9.1	9.3	9.1	10.5	9.1	9.8
	Median	72.5	-2.0	75.0	-2.0	74.0	0.0	74.0	-2.0
	Min	48	-26	50	-28	52	-26	48	-28
	Max	93	28	100	30	98	35	100	35
Week 14	N	148	148	137	137	142	142	427	427
	Mean	74.9	-0.2	74.7	-1.0	75.1	0.1	74.9	-0.4
	Std	9.7	9.8	8.8	9.7	9.4	10.6	9.3	10.0
	Median	75.5	0.0	73.0	-1.0	76.0	0.0	74.0	0.0
	Min	51	-40	60	-22	54	-28	51	-40
	Max	100	21	104	30	100	32	104	32

総括報告書（5.3.5.1-4）Post-Text Table 70

表 2.7.4.7-付録-91　拡張期血圧の評価時点別変化量（133 試験）（2/2）

TVP-1012/133 (PRESTO)		0.5 mg		1 mg		Placebo		All	
		Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)
Week 20	N	145	145	134	134	140	140	419	419
	Mean	73.8	-1.2	75.0	-0.5	75.0	0.1	74.6	-0.6
	Std	10.3	11.1	9.4	10.0	9.6	10.8	9.8	10.6
	Median	72.0	-2.0	75.0	-1.0	76.0	0.0	74.0	-1.0
	Min	52	-30	48	-20	52	-30	48	-30
	Max	99	26	115	43	102	38	115	43
Unscheduled	N	9	9	5	5	9	9	23	23
	Mean	72.1	-2.8	78.8	-1.2	75.8	1.1	75.0	-0.9
	Std	8.0	12.1	8.7	9.2	5.7	4.9	7.5	9.0
	Median	70.0	0.0	82.0	2.0	78.0	0.0	74.0	0.0
	Min	60	-22	70	-12	66	-5	60	-22
	Max	88	14	90	8	82	10	90	14
Termination	N	160	160	143	143	158	158	461	461
	Mean	74.2	-1.1	74.7	-1.1	75.4	0.2	74.7	-0.7
	Std	9.1	10.5	8.5	9.2	10.6	12.4	9.5	10.8
	Median	72.0	-2.0	74.0	-1.0	76.0	0.0	74.0	0.0
	Min	49	-40	52	-22	55	-28	49	-40
	Max	102	26	96	30	135	71	135	71

総括報告書（5.3.5.1-4）Post-Text Table 70

表 2.7.4.7-付録-92　収縮期血圧の評価時点別変化量（122 試験）（1/2）

TVP-1012/122 (LARGO)		Rasagiline 1 mg		Entacapone		Placebo		All	
		Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)
Baseline	N	231	230	227	224	229	227	687	681
	Mean	129.1	0.0	130.4	0.0	130.8	0.0	130.1	0.0
	Std	17.2	0.0	17.1	0.0	16.8	0.0	17.0	0.0
	Median	130.0	0.0	130.0	0.0	130.0	0.0	130.0	0.0
	Min	90	0	90	0	80	0	80	0
	Max	190	0	220	0	178	0	220	0
Week 3	N	224	224	218	218	220	220	662	662
	Mean	129.4	0.6	127.9	-2.7	128.0	-2.9	128.4	-1.7
	Std	16.9	12.3	16.7	14.3	15.1	13.0	16.2	13.3
	Median	130.0	0.0	130.0	0.0	130.0	0.0	130.0	0.0
	Min	80	-30	90	-60	70	-42	70	-60
	Max	180	40	190	40	165	40	190	40
Week 6	N	220	220	213	213	211	211	644	644
	Mean	129.7	0.8	127.2	-3.3	129.5	-1.4	128.8	-1.3
	Std	17.9	15.0	16.2	13.9	16.7	15.0	17.0	14.7
	Median	130.0	0.0	124.0	-3.0	130.0	0.0	130.0	0.0
	Min	90	-42	90	-60	80	-46	80	-60
	Max	180	50	180	50	201	55	201	55
Week 10	N	214	214	206	206	200	200	620	620
	Mean	127.7	-1.3	128.2	-2.3	127.7	-3.2	127.9	-2.2
	Std	16.5	16.2	16.3	14.7	17.5	15.5	16.7	15.5
	Median	126.5	0.0	130.0	0.0	129.5	0.0	130.0	0.0
	Min	85	-46	90	-80	80	-50	80	-80
	Max	180	40	190	40	180	40	190	40
Week 14	N	212	212	198	198	197	197	607	607
	Mean	127.5	-1.4	125.9	-4.7	128.5	-2.4	127.3	-2.8
	Std	16.4	16.5	16.1	14.8	15.5	15.0	16.0	15.5
	Median	130.0	0.0	125.0	-5.0	130.0	0.0	130.0	0.0
	Min	90	-55	80	-60	95	-43	80	-60
	Max	175	45	180	50	186	40	186	50

総括報告書（5.3.5.1-5）Post-Text Table 54

表 2.7.4.7-付録-92　収縮期血圧の評価時点別変化量（122 試験）（2/2）

TVP-1012/122 (LARGO)		Rasagiline 1 mg		Entacapone		Placebo		All	
		Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)	Supine SBP (mmHg)	Supine SBP (mmHg) (Change)
Unscheduled	N	75	39	79	39	83	53	237	131
	Mean	130.3	4.0	127.0	-1.5	125.4	-0.8	127.5	0.4
	Std	16.8	16.2	18.0	25.9	16.7	14.1	17.2	18.9
	Median	130.0	0.0	120.0	0.0	125.0	0.0	130.0	0.0
	Min	100	-50	90	-70	80	-20	80	-70
	Max	170	50	170	60	170	40	170	60
Termination	N	221	221	222	222	218	218	661	661
	Mean	128.0	-1.1	126.1	-4.2	128.7	-2.1	127.6	-2.5
	Std	17.0	16.0	16.3	17.5	15.7	17.0	16.4	16.9
	Median	130.0	0.0	127.5	0.0	130.0	0.0	130.0	0.0
	Min	90	-50	90	-80	90	-58	90	-80
	Max	182	55	190	37	180	60	190	60

総括報告書（5.3.5.1-5）Post-Text Table 54

表 2.7.4.7-付録-93　拡張期血圧の評価時点別変化量（122 試験）（1/2）

TVP-1012/122 (LARGO)		Rasagiline 1 mg		Entacapone		Placebo		All	
		Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)
Baseline	N	231	230	227	224	229	227	687	681
	Mean	78.4	0.0	79.0	0.0	79.2	0.0	78.9	0.0
	Std	8.9	0.0	9.7	0.0	9.7	0.0	9.4	0.0
	Median	80.0	0.0	80.0	0.0	80.0	0.0	80.0	0.0
	Min	60	0	50	0	50	0	50	0
	Max	100	0	120	0	110	0	120	0
Week 3	N	224	224	218	218	220	220	662	662
	Mean	79.0	0.8	78.4	-0.8	77.9	-1.2	78.4	-0.4
	Std	9.0	7.8	10.0	8.9	8.8	9.5	9.3	8.8
	Median	80.0	0.0	80.0	0.0	80.0	0.0	80.0	0.0
	Min	60	-20	50	-30	50	-40	50	-40
	Max	110	30	110	20	100	30	110	30
Week 6	N	220	220	213	213	211	211	644	644
	Mean	78.9	0.6	78.2	-0.9	78.6	-0.6	78.6	-0.3
	Std	9.9	9.6	9.2	9.1	9.3	9.5	9.5	9.4
	Median	80.0	0.0	80.0	0.0	80.0	0.0	80.0	0.0
	Min	60	-30	55	-30	40	-42	40	-42
	Max	105	25	105	30	112	40	112	40
Week 10	N	214	214	206	206	200	200	620	620
	Mean	78.4	0.1	78.1	-1.0	77.8	-1.4	78.1	-0.7
	Std	8.9	10.5	9.2	8.6	9.4	10.0	9.1	9.8
	Median	80.0	0.0	80.0	0.0	80.0	0.0	80.0	0.0
	Min	60	-24	54	-20	53	-31	53	-31
	Max	110	35	110	25	100	30	110	35
Week 14	N	212	212	198	198	197	197	607	607
	Mean	78.1	-0.2	77.1	-2.0	78.2	-1.1	77.8	-1.1
	Std	8.9	10.7	8.5	9.8	8.9	10.4	8.8	10.3
	Median	80.0	0.0	80.0	0.0	80.0	0.0	80.0	0.0
	Min	55	-30	55	-30	50	-42	50	-42
	Max	110	35	100	30	100	35	110	35

総括報告書（5.3.5.1-5）Post-Text Table 57

表 2.7.4.7-付録-93　拡張期血圧の評価時点別変化量（122 試験）（2/2）

TVP-1012/122 (LARGO)		Rasagiline 1 mg		Entacapone		Placebo		All	
		Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)	Supine DBP (mmHg)	Supine DBP (mmHg) (Change)
Unscheduled	N	75	39	79	39	83	53	237	131
	Mean	79.7	2.9	77.5	-0.1	78.1	1.4	78.4	1.4
	Std	9.7	9.4	8.8	11.9	9.0	9.0	9.2	10.1
	Median	80.0	0.0	80.0	0.0	80.0	0.0	80.0	0.0
	Min	50	-20	60	-30	60	-20	50	-30
	Max	100	20	98	30	110	25	110	30
Termination	N	221	221	222	222	218	218	661	661
	Mean	77.9	-0.5	77.6	-1.4	78.6	-0.7	78.0	-0.8
	Std	9.3	9.9	9.0	9.8	9.6	10.8	9.3	10.2
	Median	80.0	0.0	80.0	0.0	80.0	0.0	80.0	0.0
	Min	50	-23	55	-40	50	-38	50	-40
	Max	100	25	105	21	100	50	105	50

総括報告書（5.3.5.1-5）Post-Text Table 57

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（1/10）

Systolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	126.5	
SD	16.88	
Minimum	77	
Q1	116.0	
Median	127.0	
Q3	137.0	
Maximum	170	
Week 3		
N	221	221
Mean	123.9	-2.6
SD	18.19	15.65
Minimum	79	-40
Q1	113.0	-12.0
Median	124.0	-4.0
Q3	134.0	5.0
Maximum	182	72

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（2/10）

Systolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	119.9	-6.3
SD	18.56	17.01
Minimum	76	-63
Q1	106.0	-17.0
Median	120.0	-6.0
Q3	131.0	3.0
Maximum	182	50
Week 10		
N	205	205
Mean	118.3	-7.4
SD	17.75	17.52
Minimum	66	-56
Q1	105.0	-18.0
Median	118.0	-9.0
Q3	131.0	3.0
Maximum	163	52

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（3/10）

Systolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	193	193
Mean	119.3	-5.8
SD	16.74	17.54
Minimum	72	-47
Q1	106.0	-17.0
Median	120.0	-8.0
Q3	130.0	5.0
Maximum	170	51
Week 26		
N	179	179
Mean	121.6	-4.0
SD	18.92	19.39
Minimum	63	-68
Q1	108.0	-15.0
Median	123.0	-3.0
Q3	134.0	8.0
Maximum	168	64

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（4/10）

Systolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	117.7	-7.9
SD	16.62	17.18
Minimum	76	-49
Q1	105.0	-19.0
Median	119.0	-8.0
Q3	129.0	3.0
Maximum	177	47
Week 42		
N	167	167
Mean	119.9	-5.9
SD	18.58	15.16
Minimum	74	-49
Q1	106.0	-16.0
Median	121.0	-6.0
Q3	132.0	3.0
Maximum	170	34

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（5/10）

Systolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	119.3	-6.4
SD	18.46	17.30
Minimum	76	-56
Q1	108.0	-16.5
Median	118.5	-6.5
Q3	131.5	3.0
Maximum	180	63

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（6/10）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Baseline		
N	222	
Mean	74.0	
SD	11.88	
Minimum	34	
Q1	67.0	
Median	74.0	
Q3	83.0	
Maximum	101	
Week 3		
N	221	221
Mean	72.0	-2.1
SD	11.72	10.20
Minimum	42	-34
Q1	65.0	-8.0
Median	72.0	-2.0
Q3	81.0	3.0
Maximum	100	38

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（7/10）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 6		
N	210	210
Mean	71.3	-2.7
SD	11.83	11.29
Minimum	41	-34
Q1	63.0	-10.0
Median	70.0	-3.0
Q3	81.0	4.0
Maximum	101	42
Week 10		
N	205	205
Mean	70.6	-3.2
SD	12.34	11.59
Minimum	38	-35
Q1	63.0	-10.0
Median	70.0	-3.0
Q3	79.0	3.0
Maximum	124	64

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（8/10）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 18		
N	193	193
Mean	71.9	-1.9
SD	11.99	12.12
Minimum	37	-34
Q1	63.0	-10.0
Median	73.0	-2.0
Q3	80.0	5.0
Maximum	101	53
Week 26		
N	179	179
Mean	71.6	-2.5
SD	12.33	12.67
Minimum	31	-57
Q1	64.0	-9.0
Median	71.0	-2.0
Q3	80.0	5.0
Maximum	105	29

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（9/10）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 34		
N	171	171
Mean	71.0	-3.0
SD	11.44	12.44
Minimum	44	-40
Q1	62.0	-11.0
Median	71.0	-3.0
Q3	80.0	4.0
Maximum	96	40
Week 42		
N	167	167
Mean	71.3	-2.6
SD	11.24	9.70
Minimum	45	-33
Q1	62.0	-9.0
Median	72.0	-2.0
Q3	80.0	4.0
Maximum	104	22

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-94　収縮期血圧及び拡張期血圧の評価時点別変化量（OCT-002 試験）（10/10）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	1 mg (N=222) Observed Value at Visit	1 mg (N=222) Change from Baseline
Week 52		
N	164	164
Mean	71.0	-2.8
SD	12.06	11.75
Minimum	42	-35
Q1	63.0	-11.0
Median	71.0	-4.0
Q3	80.0	4.0
Maximum	99	37

Statistical Analysis Report (5.3.5.2-1) Table 3.3.2.1.1

表 2.7.4.7-付録-95　脈拍数の評価時点別変化量（CCT-001 試験）（1/4）

Pulse (bpm)

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	75.7		72.8	
SD	12.23		9.96	
Minimum	53		49	
Q1	66.0		67.0	
Median	76.0		72.0	
Q3	84.0		79.0	
Maximum	116		98	
Week 3				
N	126	126	116	116
Mean	75.1	-0.6	72.2	-0.7
SD	10.98	7.18	10.20	7.00
Minimum	53	-28	52	-18
Q1	66.0	-5.0	65.0	-6.0
Median	75.5	0.0	71.0	0.0
Q3	81.0	3.0	78.5	4.0
Maximum	111	22	103	14

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-95　脈拍数の評価時点別変化量（CCT-001 試験）（2/4）

Pulse (bpm)

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	75.8	0.3	72.1	-0.8
SD	11.72	7.86	9.55	8.02
Minimum	50	-21	50	-31
Q1	68.0	-5.0	66.0	-6.0
Median	74.0	0.0	72.0	-1.0
Q3	83.0	6.0	78.0	3.0
Maximum	111	22	97	28
Week 10				
N	115	115	113	113
Mean	76.3	0.8	73.4	0.6
SD	12.35	8.07	10.34	7.74
Minimum	51	-15	42	-26
Q1	66.0	-5.0	66.0	-4.0
Median	75.0	1.0	74.0	0.0
Q3	85.0	5.0	80.0	6.0
Maximum	110	36	101	18

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-95　脈拍数の評価時点別変化量（CCT-001 試験）（3/4）

Pulse (bpm)

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 14				
N	109	109	112	112
Mean	76.3	0.5	71.9	-0.9
SD	13.18	8.16	9.81	7.85
Minimum	50	-23	47	-27
Q1	67.0	-3.0	65.5	-6.0
Median	76.0	0.0	72.0	0.0
Q3	84.0	5.0	78.5	3.0
Maximum	117	23	99	22
Week 20				
N	105	105	111	111
Mean	74.7	-1.2	72.0	-0.8
SD	12.02	7.61	10.51	8.17
Minimum	53	-18	46	-28
Q1	65.0	-6.0	64.0	-5.0
Median	73.0	-1.0	72.0	-1.0
Q3	83.0	4.0	79.0	4.0
Maximum	108	24	96	19

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1

表 2.7.4.7-付録-95　脈拍数の評価時点別変化量（CCT-001 試験）（4/4）

Pulse (bpm)

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 26				
N	100	100	110	110
Mean	75.7	-0.1	73.4	0.6
SD	11.30	8.40	11.14	8.95
Minimum	54	-18	48	-27
Q1	68.0	-6.0	65.0	-4.0
Median	75.0	0.0	74.0	1.0
Q3	84.0	6.0	81.0	5.0
Maximum	105	18	98	26

Statistical Analysis Report (5.3.5.1-6) Table 3.3.2.1.1