

16.2.8 ECG and Vital Signs

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Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-007	Screening	05JAN2016	158	52	20.83	115	86	72	12	36.2
	Day 1	26JAN2016		51.5	20.63	115	80	72	14	36
	Week 1	01FEB2016		51.5	20.63	115	80	73	14	36.5
	Week 2	11FEB2016		50.5	20.23	120	80	72	13	36.4
	Week 4	24FEB2016		50	20.03	110	60	72	12	36.2
	Week 6	08MAR2016		50.2	20.11	90	50	64	12	36.3
	Week 8	24MAR2016		50	20.03	120	70	64	12	36.4
	Week 24	21APR2016		50	20.03	90	50	64	13	36.4
	Week 28	19MAY2016		53	21.23	100	60	60	12	36.2
	Week 32	16JUN2016		52.7	21.11	100	60	64	13	36.2
	Week 40	11AUG2016		53.5	21.43	95	60	64	12	36.6
	Week 44	08SEP2016		54	21.63	100	60	60	13	36.1
	Week 48	06OCT2016		54.2	21.71	110	60	64	12	36.2

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-011	Screening	07JAN2016	172	97	32.79	130	80	72	12	36.4
	Day 1	27JAN2016		97.5	32.96	110	70	64	14	36.3
	Week 1	03FEB2016		97.8	33.06	120	80	64	13	36.3
	Week 2	11FEB2016		97.5	32.96	140	80	64	12	36.2
	Week 4	26FEB2016		94.5	31.94	110	70	64	13	36.3
	Week 6	10MAR2016		93	31.44	120	80	64	13	36.1
	Week 8	24MAR2016		93	31.44	130	90	66	12	36.5
	Week 12	19APR2016		90.5	30.59	130	70	60	13	36.5
	Week 16	18MAY2016		85.1	28.77	120	80	60	12	36.4
	Week 20	21JUN2016		85.2	28.8	120	70	64	13	36.5
	Week 24	12JUL2016		84.2	28.46	110	60	64	13	36.1
	Week 28	09AUG2016		85	28.73	110	70	60	12	36.4
	Week 32	06SEP2016		85.5	28.9	120	80	60	13	36.2
	Week 36	06OCT2016		85.5	28.9	130	80	68	13	36.2
	Week 40	03NOV2016		85.5	28.9	130	80	64	12	36.5
	Week 44	06DEC2016		85.2	28.8	120	70	60	13	36.1
	Week 48	03JAN2017		85.6	28.93	130	80	60	13	36.5

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-001	Screening	06JAN2016	175	105	34.29	130	70	64	12	36.1
	Day 1	02FEB2016		105	34.29	130	80	60	13	36
	Week 1	09FEB2016		105	34.29	130	80	60	12	36.4
	Week 2	16FEB2016		104	33.96	130	70	60	13	36.2
	Week 4	01MAR2016		104	33.96	140	70	72	13	36.4
	Week 6	16MAR2016		96	31.35	120	70	60	12	36.3
	Week 8	31MAR2016		96	31.35	150	90	60	12	36.9
	Week 12	28APR2016		96	31.35	120	70	60	12	36.2
	Week 16	26MAY2016		96	31.35	120	70	64	13	36.4
	Week 20	22JUN2016		96	31.35	120	70	56	12	36.1
	Week 24	20JUL2016		95	31.02	135	80	65	14	36.4
	Week 28	18AUG2016		95	31.02	120	80	64	13	36.1
	Week 32	15SEP2016		95	31.02	130	80	64	12	36.3
	Week 36	13OCT2016		95	31.02	120	70	56	12	36.2
	Week 40	10NOV2016		98	32	130	80	64	13	36.5
	Week 44	06DEC2016		96	31.35	120	60	60	13	36.4
	Week 48	03JAN2017		96	31.35	130	80	60	13	36.1

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-002	Screening	15DEC2015	181	83	25.34	140	80	72	12	36.1
	Day 1	05JAN2016		84	25.64	130	80	64	12	36.5
	Week 1	14JAN2016		86	26.25	110	70	60	12	36.2
	Week 2	20JAN2016		84	25.64	110	60	64	13	36.5
	Week 4	03FEB2016		84	25.64	110	70	60	13	36
	Week 6	17FEB2016		80	24.42	110	60	64	13	36.1
	Week 8	01MAR2016		78	23.81	120	60	64	12	36.5
	Week 12	30MAR2016		78	23.81	110	70	60	11	36.9
	Week 16	26APR2016		78	23.81	120	70	60	12	36.1
	Week 20	24MAY2016		79	24.11	100	60	60	12	36.1
	Week 24	21JUN2016		79	24.11	100	60	60	13	36.4
	Week 28	20JUL2016		81	24.72	120	80	66	15	36.4
	Week 32	18AUG2016		81	24.72	120	80	60	14	36.1
	Week 36	13SEP2016		81.2	24.79	110	60	60	13	36.4
	Week 40	11OCT2016		83.5	25.49	110	70	64	13	36.2
	Week 44	09NOV2016		82	25.03	120	70	60	12	36.1
	Week 48	06DEC2016		82.2	25.09	100	60	60	13	36.5

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-003	Screening	15DEC2015	163	64	24.09	100	60	64	12	36.2
	Day 1	06JAN2016		64	24.09	100	60	64	12	36.4
	Week 1	13JAN2016		64	24.09	105	70	76	12	36.2
	Week 2	20JAN2016		65	24.46	95	60	72	11	36.4
	Week 4	03FEB2016		65	24.46	100	60	64	12	36.4
	Week 6	18FEB2016		66	24.84	110	70	64	13	36.3
	Week 8	08MAR2016		65	24.46	100	60	60	12	36.2
	Week 12	29MAR2016		65	24.46	100	60	60	11	36.1
	Week 16	25APR2016		68	25.59	120	80	64	12	36.5
	Week 20	26MAY2016		68	25.59	100	50	64	13	36
	Week 24	22JUN2016		70	26.35	100	60	60	12	36.2
	Week 28	19JUL2016		68	25.59	110	80	80	13	36.2
	Week 32	16AUG2016		68	25.59	100	70	64	12	36.4
	Week 36	15SEP2016		68	25.59	100	60	60	13	36.1
	Week 40	12OCT2016		68	25.59	100	60	64	13	36.5
	Week 44	09NOV2016		68	25.59	100	70	60	13	36.2
	Week 48	14DEC2016		68	25.59	110	60	64	12	36.4

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-005	Screening	16DEC2015	178	80	25.25	120	80	68	12	36.2
	Day 1	07JAN2016		82	25.88	140	80	68	12	36.5
	Week 1	13JAN2016		80.4	25.38	120	70	68	12	36.2
	Week 2	21JAN2016		80.6	25.44	100	60	80	11	36.5
	Week 4	02FEB2016		81	25.56	130	80	68	12	36.2
	Week 6	17FEB2016		82	25.88	110	70	72	13	36.3
	Week 8	02MAR2016		82	25.88	110	70	66	12	36.4
	Week 12	31MAR2016		77	24.3	120	80	64	12	36.6
	Week 16	26APR2016		77	24.3	100	60	64	13	36.5
	Week 20	26MAY2016		80	25.25	110	60	64	12	36.2
	Week 24	23JUN2016		80	25.25	120	70	60	13	36.3
	Week 28	26JUL2016		82	25.88	120	80	60	14	36.5
	Week 32	16AUG2016		84	26.51	120	70	64	13	36.2
	Week 36	14SEP2016		83	26.2	110	70	60	13	36.2
	Week 40	12OCT2016		84	26.51	110	60	68	13	36.2
	Week 44	10NOV2016		84	26.51	120	80	66	15	36.3
	Week 48	07DEC2016		84	26.51	120	80	68	13	36.2

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-008	Screening	19JAN2016	173	80	26.73	130	70	68	11	36.4
	Day 1	11FEB2016		80	26.73	140	80	76	14	36.5
	Week 1	17FEB2016		78	26.06	120	70	72	13	36.3
	Week 2	24FEB2016		78	26.06	120	70	68	13	36.1
	Week 4	10MAR2016		78	26.06	120	80	68	12	36.4
	Week 6	24MAR2016		74.5	24.89	115	80	68	12	36.8
	Week 8	07APR2016		70.3	23.49	110	60	60	13	36.4
	Week 28	17MAY2016		76	25.39	110	70	64	13	36.5
	Week 32	09JUN2016		78.1	26.1	110	70	64	13	36.4
	Week 36	06JUL2016		78	26.06	120	80	64	13	36.4
	Week 40	03AUG2016		77.5	25.89	120	80	64	13	36.1
	Week 44	07SEP2016		78	26.06	120	80	68	12	36
	Week 48	19OCT2016		72	24.06	120	80	66	12	36.2
	Early Term	13APR2016		70.1	23.42	120	60	76	12	36.1

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-009	Screening	06JAN2016	171	81	27.7	105	70	78	12	36.3
	Day 1	27JAN2016		80	27.36	100	60	60	12	36.1
	Week 1	02FEB2016		80	27.36	100	60	64	14	36.3
	Week 2	10FEB2016		81	27.7	120	70	68	14	36.2
	Week 4	25FEB2016		81	27.7	110	70	72	13	36.5
	Week 6	09MAR2016		80	27.36	120	70	68	14	36.4
	Week 8	22MAR2016		79	27.02	105	80	78	14	36.9
	Week 12	19APR2016		80	27.36	100	60	60	13	36.5
	Week 16	18MAY2016		80	27.36	110	60	64	12	36.2
	Week 20	15JUN2016		80	27.36	110	60	60	13	36.4
	Week 24	20JUL2016		80	27.36	100	70	75	13	36.3
	Week 28	09AUG2016		80	27.36	110	70	72	12	36.2
	Week 32	06SEP2016		80.2	27.43	120	70	64	13	36.4
	Week 36	04OCT2016		79	27.02	100	60	64	13	36.5
	Week 40	01NOV2016		80	27.36	130	70	64	12	36.1
	Week 44	29NOV2016		80	27.36	110	60	64	13	36.2
	Week 48	02JAN2017		80	27.36	100	70	72	12	36.1

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-010	Screening	07JAN2016	172	88	29.75	130	80	68	12	36.4
	Day 1	27JAN2016		88	29.75	140	80	72	12	36.1
	Week 1	04FEB2016		86	29.07	130	80	64	13	36
	Week 2	09FEB2016		85	28.73	150	70	72	12	36.2
	Week 4	24FEB2016		85	28.73	120	70	68	13	36.3
	Week 6	09MAR2016		83	28.06	150	60	72	13	36.5
	Week 8	22MAR2016		83	28.06	110	85	78	10	36.3
	Week 12	19APR2016		78	26.37	130	70	64	12	36.1
	Week 16	17MAY2016		78.3	26.47	120	80	64	12	36.4
	Week 20	20JUN2016		78.3	26.47	120	80	64	14	36.5
	Week 24	12JUL2016		78	26.37	130	80	72	12	36.4
	Week 28	08AUG2016		79.5	26.87	130	80	66	13	36.5
	Week 32	06SEP2016		76.3	25.79	120	80	60	13	36.1
	Week 36	04OCT2016		77.4	26.16	130	70	64	13	36.4
	Week 40	01NOV2016		77	26.03	130	70	60	12	36.2
	Week 44	28NOV2016		77	26.03	120	80	66	15	36.6
	Week 48	03JAN2017		77.5	26.2	150	70	68	13	36.4

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-014	Screening	27JAN2016	183	84	25.08	120	80	72	12	36.4
	Day 1	23FEB2016		87	25.98	130	80	64	12	36.2
	Week 1	01MAR2016		88	26.28	140	80	72	12	36.2
	Week 2	09MAR2016		88	26.28	140	80	68	13	36.3
	Week 4	22MAR2016		88	26.28	120	80	72	11	36.8
	Week 6	05APR2016		86	25.68	120	80	76	12	36.5
	Week 8	20APR2016		87	25.98	110	70	64	13	36.4
	Week 12	19MAY2016		89.5	26.73	130	80	80	12	36.2
	Week 16	14JUN2016		89	26.58	120	80	64	12	36.4
	Week 20	13JUL2016		89	26.58	130	70	64	13	36.3
	Week 24	10AUG2016		89	26.58	130	80	80	12	36.2
	Week 28	07SEP2016		90.5	27.02	130	80	64	13	36.2
	Week 32	05OCT2016		91	27.17	140	80	72	13	36.3
	Week 36	02NOV2016		91	27.17	120	70	78	13	36.1
	Week 40	30NOV2016		90.2	26.93	140	70	64	13	36.1
	Week 44	22DEC2016		90.4	26.99	130	70	68	13	36.2
	Week 48	25JAN2017		90.4	26.99	120	80	66	13	36.5

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-016	Screening	03FEB2016	173	78	26.06	130	80	88	14	36.2
	Day 1	25FEB2016		78	26.06	110	60	84	13	36.4
	Week 1	02MAR2016		78	26.06	120	80	64	13	36.4
	Week 2	08MAR2016		78	26.06	130	70	80	12	36.4
	Week 4	24MAR2016		75	25.06	120	80	84	10	36.5
	Week 6	07APR2016		73.5	24.56	110	60	80	12	36.4
	Week 8	19APR2016		73.5	24.56	130	70	80	13	36.2
	Week 12	24MAY2016		71	23.72	130	70	100	12	36.1
	Week 16	14JUN2016		71	23.72	130	60	84	13	36.3
	Week 20	13JUL2016		66	22.05	110	60	80	12	36.4
	Week 24	28JUL2016		62	20.72	130	80	79	12	36.4
	Week 28	06SEP2016		69.6	23.26	130	60	90	13	36.2
	Week 32	05OCT2016		71.1	23.76	110	70	84	13	36.2
	Week 36	02NOV2016		71.2	23.79	120	80	76	13	36.2
	Week 40	29NOV2016		71.8	23.99	120	70	88	12	36.4
	Week 44	21DEC2016		73.8	24.66	130	70	76	13	36.2
	Week 48	24JAN2017		73.8	24.66	130	80	66	14	36.5

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-015	Screening	02FEB2016	178	95	29.98	140	80	60	12	36.5
	Day 1	23FEB2016		95	29.98	160	90	72	13	36.4
	Week 1	03MAR2016		95	29.98	130	90	64	12	36.5
	Week 2	08MAR2016		94	29.67	140	80	68	14	36.3
	Week 4	23MAR2016		94	29.67	130	85	58	11	36.4
	Week 6	06APR2016		95	29.98	130	70	64	13	36.3
	Week 8	20APR2016		90	28.41	110	60	60	12	36.2
	Week 12	17MAY2016		83.1	26.23	110	70	60	12	36
	Week 16	16JUN2016		81.5	25.72	110	60	64	13	36.2
	Week 20	14JUL2016		76	23.99	110	70	50	14	36.4
	Week 24	10AUG2016		77	24.3	110	60	60	13	36.5
	Week 28	07SEP2016		81	25.56	120	70	60	13	36.4
	Week 40	30NOV2016		85	26.83	140	70	64	12	36.3
	Week 44	28DEC2016		85	26.83	150	70	64	13	36.4
	Week 48	26JAN2017		86	27.14	160	80	60	13	36.2

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-018	Screening	17FEB2016	180	73	22.53	130	80	72	13	36
	Day 1	09MAR2016		73	22.53	140	80	68	12	36
	Week 1	16MAR2016		73	22.53	120	60	64	13	36.2
	Week 2	23MAR2016		73	22.53	110	70	60	12	36.9
	Week 4	06APR2016		74	22.84	110	60	64	13	36.1
	Week 6	21APR2016		74	22.84	130	70	64	12	36.2
	Week 8	28APR2016		74	22.84	120	70	64	13	36.1
	Week 12	01JUN2016		74	22.84	110	60	64	13	36.1
	Week 16	29JUN2016		74	22.84	130	70	64	12	36.2
	Week 20	27JUL2016		74	22.84	110	60	62	12	36.4
	Week 24	23AUG2016		74	22.84	110	70	60	13	36.4
	Week 28	20SEP2016		74	22.84	110	70	64	12	36.1
	Week 32	18OCT2016		74	22.84	110	70	68	13	36.4
	Week 36	15NOV2016		75	23.15	120	70	64	12	36.1
	Week 40	13DEC2016		75	23.15	110	80	66	13	36.5
	Week 44	10JAN2017		75	23.15	120	60	64	13	36.2
	Week 48	07FEB2017		77	23.77	120	70	64	12	36.5

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-006	Screening	14JAN2016	170	80	27.68	120	90	70	12	36.2
	Day 1	04FEB2016		80	27.68	110	70	68	14	36.2
	Week 1	10FEB2016		81	28.03	100	60	72	13	37.7
	Week 2	16FEB2016		81	28.03	100	50	68	14	36.6
	Week 4	03MAR2016		81	28.03	120	80	64	12	36.4
	Week 6	17MAR2016		80	27.68	110	70	68	13	36.2
	Week 8	31MAR2016		81	28.03	120	80	64	11	36.5
	Week 12	26APR2016		80	27.68	100	50	60	12	36.3
	Week 16	25MAY2016		76.4	26.44	110	60	64	13	36.5
	Week 20	23JUN2016		76.4	26.44	120	70	66	14	36.4
	Week 24	19JUL2016		76.4	26.44	120	80	64	15	36.6
	Week 28	18AUG2016		78.4	27.13	100	60	60	13	36.2
	Week 32	13SEP2016		79.2	27.4	100	60	60	13	36.1
	Week 36	13OCT2016		81.9	28.34	100	60	64	13	36.4
	Week 40	08NOV2016		82	28.37	100	60	68	13	36.2
	Week 44	08DEC2016		84.1	29.1	100	70	68	13	36.9
	Week 48	04JAN2017		84.5	29.24	110	70	64	13	36.5

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-017	Screening	17FEB2016	163	61	22.96	90	50	64	13	36.2
	Day 1	08MAR2016		61	22.96	100	60	68	13	36
	Week 1	15MAR2016		60	22.58	90	60	60	13	36.2
	Week 2	23MAR2016		59	22.21	90	65	54	12	36.1
	Week 4	05APR2016		58	21.83	100	55	64	13	36.1
	Week 6	19APR2016		57	21.45	100	50	56	12	36.4
	Week 8	28APR2016		58	21.83	95	60	56	12	36.2
	Week 12	01JUN2016		57	21.45	110	60	60	12	36.4
	Week 16	29JUN2016		57	21.45	95	60	60	13	36.2
	Week 20	26JUL2016		57	21.45	90	60	55	12	36.3
	Week 24	24AUG2016		57	21.45	100	60	60	12	36.4
	Week 28	20SEP2016		58.5	22.02	95	60	60	13	36.2
	Week 32	19OCT2016		59.5	22.39	90	50	60	12	36.4
	Week 36	15NOV2016		60	22.58	90	60	60	13	36.2
	Week 40	14DEC2016		60	22.58	100	60	60	12	36.1
	Week 44	11JAN2017		62	23.34	100	60	60	13	36.4
	Week 48	08FEB2017		62	23.34	110	60	64	13	36

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-004	Screening	16DEC2015	165	73	26.81	110	70	72	12	36.2

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-012	Screening	26JAN2016	178	103	32.51	130	70	68	13	36.5

Listing 16.2.8.1
Vital Sign Results
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date/Time of Assessment	Height (cm)	Weight (kg)	BMI (kg/m ²)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beat/min)	Respiration (breath/min)	Temperature (c)
301-013	Screening	26JAN2016	165	69	25.34	100	60	64	12	36.3

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-007	Screening/ Average	05JAN2016	64.5	64.5	0.93	159	92	412	421.96	
	Screening/ ECG #1	05JAN2016/ 14:13	65	65	0.92	158	94	414	425.08	Sign For Left Atrial Enlargement, NCS
	Screening/ ECG #2	05JAN2016/ 14:15	64	64	0.94	160	90	410	418.83	Sign For Left Atrial Enlargement, NCS
	Day 1/ Average	26JAN2016	68.67	68.67	0.87	142	86	386.67	404.26	
	Day 1/ ECG #1	26JAN2016/ 13:36	68	68	0.88	134	88	384	400.19	
	Day 1/ ECG #2	26JAN2016/ 13:38	68	68	0.88	154	86	390	406.45	
	Day 1/ ECG #3	26JAN2016/ 13:40	70	70	0.86	138	84	386	406.14	
	Week 1/ Average	01FEB2016	73	73	0.82	139.33	90.67	386.67	412.52	
	Week 1/ ECG #1	01FEB2016/ 10:38	73	73	0.82	126	90	384	409.67	
	Week 1/ ECG #2	01FEB2016/ 10:41	73	73	0.82	146	90	388	413.94	
	Week 1/ ECG #3	01FEB2016/ 10:44	73	73	0.82	146	92	388	413.94	
	Week 2/ Average	11FEB2016	62	62	0.97	135.33	88.67	409.33	413.78	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-007	Week 2/ ECG #1	11FEB2016/ 11:57	61	61	0.98	152	90	410	412.24	
	Week 2/ ECG #2	11FEB2016/ 11:59	63	63	0.95	126	88	410	416.65	
	Week 2/ ECG #3	11FEB2016/ 12:01	62	62	0.97	128	88	408	412.44	
	Week 4/ Average	24FEB2016	64	64	0.94	160	94.67	422	431.09	
	Week 4/ ECG #1	24FEB2016/ 12:18	64	64	0.94	158	96	418	427	Qrs Low Voltage, NCS
	Week 4/ ECG #2	24FEB2016/ 12:20	64	64	0.94	156	94	424	433.13	Qrs Low Voltage, NCS
	Week 4/ ECG #3	24FEB2016/ 12:22	64	64	0.94	166	94	424	433.13	Qrs Low Voltage, NCS
	Week 6/ Average	08MAR2016	64.33	64.33	0.94	140.67	86	388.67	397.69	
	Week 6/ ECG #1	08MAR2016/ 11:14	62	62	0.97	140	88	384	388.18	Qrs Low Voltage, NCS
	Week 6/ ECG #2	08MAR2016/ 11:17	64	64	0.94	142	84	392	400.44	Qrs Low Voltage, NCS
	Week 6/ ECG #3	08MAR2016/ 11:18	67	67	0.9	140	86	390	404.46	Qrs Low Voltage, NCS
	Week 8/ Average	24MAR2016	65.33	65.33	0.92	122	90.67	386.67	397.68	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-007	Week 8/ ECG #1	24MAR2016/ 10:46	65	65	0.92	120	92	382	392.22	
	Week 8/ ECG #2	24MAR2016/ 10:48	67	67	0.9	122	90	390	404.46	Qrs Low Voltage, NCS
	Week 8/ ECG #3	24MAR2016/ 10:50	64	64	0.94	124	90	388	396.35	Qrs Low Voltage, NCS
	Week 24/ Average	21APR2016	69	69	0.87	153.33	89.33	388.67	406.93	
	Week 24/ ECG #1	21APR2016/ 7:54	71	71	0.85	154	88	376	397.48	P-Mitral, NCS
	Week 24/ ECG #2	21APR2016/ 7:56	68	68	0.88	158	92	394	410.61	P-Mitral, NCS
	Week 24/ ECG #3	21APR2016/ 7:58	68	68	0.88	148	88	396	412.7	P-Mitral, NCS
	Week 28/ Average	19MAY2016	64.33	64.33	0.93	134.67	90.67	410.67	420.24	
	Week 28/ ECG #1	19MAY2016/ 12:10	64	64	0.94	110	94	404	412.7	Short Pq Time, NCS
	Week 28/ ECG #2	19MAY2016/ 12:12	64	64	0.94	154	88	410	418.83	
	Week 28/ ECG #3	19MAY2016/ 12:14	65	65	0.92	140	90	418	429.19	
	Week 32/ Average	16JUN2016	65.67	65.67	0.92	145.33	87.33	397.33	409.32	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-007	Week 32/ ECG #1	16JUN2016/ 9:55	64	64	0.94	160	82	398	406.57	Premature Supraventricular Complex, NCS
	Week 32/ ECG #2	16JUN2016/ 9:58	66	66	0.91	134	90	400	412.78	
	Week 32/ ECG #3	16JUN2016/ 10:01	67	67	0.9	142	90	394	408.61	Premature Supraventricular Complex, NCS
	Week 40/ Average	11AUG2016	62.67	62.67	0.96	158	90.67	414	419.92	
	Week 40/ ECG #1	11AUG2016/ 11:36	62	62	0.97	156	90	414	418.5	
	Week 40/ ECG #2	11AUG2016/ 11:36	65	65	0.92	160	92	410	420.97	
	Week 40/ ECG #3	11AUG2016/ 11:41	61	61	0.98	158	90	418	420.29	
	Week 44/ Average	08SEP2016	69.67	69.67	0.86	132.67	87.33	406.67	427.21	
	Week 44/ ECG #1	08SEP2016/ 11:27	69	69	0.87	132	88	408	427.26	
	Week 44/ ECG #2	08SEP2016/ 11:29	70	70	0.86	134	86	404	425.08	
	Week 44/ ECG #3	08SEP2016/ 11:31	70	70	0.86	132	88	408	429.29	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-007	Week 48/ Average	06OCT2016	74	74	0.81	128.67	85.33	400	428.66	
	Week 48/ ECG #1	06OCT2016/ 11:42	74	74	0.81	132	86	400	428.66	
	Week 48/ ECG #2	06OCT2016/ 11:44	74	74	0.81	124	86	400	428.66	
	Week 48/ ECG #3	06OCT2016/ 11:46	74	74	0.81	130	84	400	428.66	
	Screening/ Average	07JAN2016	71.67	71.67	0.84	144.67	86.67	412	436.78	
301-011	Screening/ ECG #1	07JAN2016/ 14:09	71	71	0.85	140	84	404	427.08	Extended Qt Time, NCS
	Screening/ ECG #2	07JAN2016/ 14:11	75	75	0.8	146	88	410	441.33	Extended Qt Time, NCS
	Screening/ ECG #3	07JAN2016/ 14:13	69	69	0.87	148	88	422	441.92	Extended Qt Time, NCS
	Day 1/ Average	27JAN2016	65.67	65.67	0.91	148.67	87.33	420	432.69	
	Day 1/ ECG #1	27JAN2016/ 11:43	65	65	0.92	144	88	412	423.03	
	Day 1/ ECG #2	27JAN2016/ 11:45	67	67	0.9	148	88	420	435.58	
	Day 1/ ECG #3	27JAN2016/ 11:48	65	65	0.92	154	86	428	439.46	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-011	Week 1/ Average	03FEB2016	64.67	64.67	0.93	157.33	92	422	432.57	
	Week 1/ ECG #1	03FEB2016/ 11:10	63	63	0.95	156	90	416	422.75	
	Week 1/ ECG #2	03FEB2016/ 11:13	65	65	0.92	160	94	426	437.4	
	Week 1/ ECG #3	03FEB2016/ 11:16	66	66	0.91	156	92	424	437.55	
	Week 2/ Average	11FEB2016	69.33	69.33	0.87	150.67	94.67	420	440.43	
	Week 2/ ECG #1	11FEB2016/ 11:16	71	71	0.85	148	96	404	427.08	Ventricular Extra Systoles, NCS
	Week 2/ ECG #2	11FEB2016/ 11:19	69	69	0.87	152	94	422	441.92	
	Week 2/ ECG #3	11FEB2016/ 11:22	68	68	0.88	152	94	434	452.3	
	Week 4/ Average	26FEB2016	56	56	1.07	143.33	91.33	447.33	437.24	
	Week 4/ ECG #1	26FEB2016/ 10:08	57	57	1.05	146	92	442	434.58	Sinus Bradycardia, NCS
	Week 4/ ECG #2	26FEB2016/ 10:10	56	56	1.07	138	92	448	437.92	Sinus Bradycardia, NCS
	Week 4/ ECG #3	26FEB2016/ 10:12	55	55	1.09	146	90	452	439.21	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-011	Week 6/ Average	10MAR2016	57.67	57.67	1.04	145.33	93.33	436.67	430.98	
	Week 6/ ECG #1	10MAR2016/ 10:17	58	58	1.03	146	94	422	417.31	Sinus Bradycardia, NCS
	Week 6/ ECG #2	10MAR2016/ 10:19	57	57	1.05	146	94	442	434.58	Sinus Bradycardia, NCS
	Week 6/ ECG #3	10MAR2016/ 10:21	58	58	1.03	144	92	446	441.04	Sinus Bradycardia, NCS
	Week 8/ Average	24MAR2016	52.67	52.67	1.14	146	89.33	455.33	436.16	
	Week 8/ ECG #1	24MAR2016/ 9:25	52	52	1.15	142	90	452	431.15	Sinus Bradycardia, NCS
	Week 8/ ECG #2	24MAR2016/ 9:27	53	53	1.13	146	90	460	441.55	Sinus Bradycardia, NCS
	Week 8/ ECG #3	24MAR2016/ 9:29	53	53	1.13	150	88	454	435.79	Sinus Bradycardia, NCS
	Week 12/ Average	19APR2016	60.33	60.33	0.99	145.33	90.67	452.67	453.48	
	Week 12/ ECG #1	19APR2016/ 9:12	61	61	0.98	142	92	448	450.45	
	Week 12/ ECG #2	19APR2016/ 9:14	61	61	0.98	146	90	456	458.49	Occasionally Extrasystole, NCS
	Week 12/ ECG #3	19APR2016/ 9:16	59	59	1.02	148	90	454	451.49	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-011	Week 16/ Average	18MAY2016	61.67	61.67	0.97	148	90	436	439.88	
	Week 16/ ECG #1	18MAY2016/ 9:29	60	60	1	148	90	448	448	
	Week 16/ ECG #2	18MAY2016/ 9:31	62	62	0.97	150	90	432	436.7	
	Week 16/ ECG #3	18MAY2016/ 9:33	63	63	0.95	146	90	428	434.95	
	Week 20/ Average	21JUN2016	64	64	0.94	142.67	83.33	414.67	423.55	
	Week 20/ ECG #1	21JUN2016/ 10:29	65	65	0.92	140	86	406	416.87	Premature Supraventricular Complexes, NCS
	Week 20/ ECG #2	21JUN2016/ 10:31	65	65	0.92	144	82	420	431.24	
	Week 20/ ECG #3	21JUN2016/ 10:33	62	62	0.97	144	82	418	422.55	
	Week 24/ Average	12JUL2016	55	55	1.09	134	88	454	441.09	
	Week 24/ ECG #1	12JUL2016/ 9:32	55	55	1.09	130	88	442	429.49	Sinusbradycardia, NCS
	Week 24/ ECG #2	12JUL2016/ 9:34	57	57	1.05	142	88	458	450.31	Sinusbradycardia, NCS
	Week 24/ ECG #3	12JUL2016/ 9:36	53	53	1.13	130	88	462	443.47	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-011	Week 28/ Average	09AUG2016	54.33	54.33	1.1	126.67	86	462	447.12	
	Week 28/ ECG #1	09AUG2016/ 9:18	54	54	1.11	124	86	456	440.42	Sinusbradycardia, NCS
	Week 28/ ECG #2	09AUG2016/ 9:20	55	55	1.09	128	86	464	450.87	Sinusbradycardia, NCS
	Week 28/ ECG #3	09AUG2016/ 9:23	54	54	1.11	128	86	466	450.08	Sinusbradycardia, NCS
	Week 32/ Average	06SEP2016	61.33	61.33	0.98	146	86.67	437.33	440.53	
	Week 32/ ECG #1	06SEP2016/ 9:07	61	61	0.98	142	86	420	422.3	
	Week 32/ ECG #2	06SEP2016/ 9:08	62	62	0.97	146	86	446	450.85	
	Week 32/ ECG #3	06SEP2016/ 9:12	61	61	0.98	150	88	446	448.44	
	Week 36/ Average	06OCT2016	60.33	60.33	1	149.33	86.67	447.33	448.16	
	Week 36/ ECG #1	06OCT2016/ 9:32	60	60	1	144	86	440	440	
	Week 36/ ECG #2	06OCT2016/ 9:34	62	62	0.97	152	88	456	460.96	
	Week 36/ ECG #3	06OCT2016/ 9:36	59	59	1.02	152	86	446	443.53	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-011	Week 40/ Average	03NOV2016	66.67	66.67	0.9	150.67	90.67	436.67	452.11	
	Week 40/ ECG #1	03NOV2016/ 9:39	66	66	0.91	152	90	430	443.74	
	Week 40/ ECG #2	03NOV2016/ 9:41	68	68	0.88	146	92	436	454.39	
	Week 40/ ECG #3	03NOV2016/ 9:43	66	66	0.91	154	90	444	458.19	
	Week 44/ Average	06DEC2016	66.67	66.67	0.9	142.67	90.67	414	428.58	
	Week 44/ ECG #1	06DEC2016/ 8:55	68	68	0.88	140	94	410	427.29	
	Week 44/ ECG #2	06DEC2016/ 8:58	63	63	0.95	142	88	414	420.72	
	Week 44/ ECG #3	06DEC2016/ 9:00	69	69	0.87	146	90	418	437.73	
	Week 48/ Average	03JAN2017	65.67	65.67	0.92	151.33	88.67	418	430.09	
	Week 48/ ECG #1	03JAN2017/ 9:23	61	61	0.98	146	88	422	424.31	
	Week 48/ ECG #2	03JAN2017/ 9:25	73	73	0.82	152	90	404	431.01	
	Week 48/ ECG #3	03JAN2017/ 9:27	63	63	0.95	156	88	428	434.95	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-001	Screening/ Average	06JAN2016	61	61	0.98	194.67	88.67	416	418.26	
	Screening/ ECG #1	06JAN2016/ 14:24	60	60	1	196	90	408	408	
	Screening/ ECG #2	06JAN2016/ 14:25	60	60	1	194	88	422	422	Sinus Arrhythmia, NCS
	Screening/ ECG #3	06JAN2016/ 14:28	63	63	0.95	194	88	418	424.78	
	Day 1/ Average	02FEB2016	53.33	53.33	1.12	210.67	88	416	400.13	
	Day 1/ ECG #1	02FEB2016/ 12:38	53	53	1.13	208	88	410	393.55	Sinus Bradycardia, Premature Atrial Complex, Disturbance Of Repolarization Iii+ Avf, Atrioventricular Block Grad I, NCS
	Day 1/ ECG #2	02FEB2016/ 12:41	53	53	1.13	210	90	422	405.07	Sinus Bradycardia, Atrioventricular Block Grad I,disturbance Of Repolarization Iii+ Avf, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-001	Day 1/ ECG #3	02FEB2016/ 12:44	54	54	1.11	214	86	416	401.78	Sinus Bradycardia, Atrioventricular Block Grad I, disturbance Of Repolarization Iii+ Avf, NCS
	Week 1/ Average	09FEB2016	59.67	59.67	1.01	214	90	402	401.27	
	Week 1/ ECG #1	09FEB2016/ 9:35	59	59	1.02	218	92	398	395.8	Sinus Bradycardia, Atrioventricular Block Grad I,, NCS
	Week 1/ ECG #2	09FEB2016/ 9:37	60	60	1	210	88	404	404	Atrioventricular Block Grad I,, NCS
	Week 1/ ECG #3	09FEB2016/ 9:39	60	60	1	214	90	404	404	Atrioventricular Block Grad I,, NCS
	Week 2/ Average	16FEB2016	54.33	54.33	1.1	212	94.67	414.67	401.22	
	Week 2/ ECG #1	16FEB2016/ 10:23	56	56	1.07	208	96	402	392.95	Atrioventricular Block Grad I, Sinus Bradycardia With Sinus Arrhythmia, NCS
	Week 2/ ECG #2	16FEB2016/ 10:25	53	53	1.13	206	96	422	405.07	Sinus Bradycardia, NCS
	Week 2/ ECG #3	16FEB2016/ 10:27	54	54	1.11	222	92	420	405.65	Sinus Bradycardia With Atrioventricular Block Grad I, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-001	Week 4/ Average	01MAR2016	56.33	56.33	1.06	210	92.67	407.33	398.91	
	Week 4/ ECG #1	01MAR2016/ 10:19	57	57	1.05	208	92	400	393.29	Sinus Bradycardia, NCS
	Week 4/ ECG #2	01MAR2016/ 10:22	55	55	1.09	210	94	414	402.28	Sinus Bradycardia With Atrioventricular Block Grad I,, NCS
	Week 4/ ECG #3	01MAR2016/ 10:25	57	57	1.05	212	92	408	401.15	Sinus Bradycardia With Atrioventricular Block Grad I,, NCS
	Week 6/ Average	16MAR2016	65	65	0.92	205.33	91.33	398.67	409.33	
	Week 6/ ECG #1	16MAR2016/ 11:25	63	63	0.95	206	90	396	402.43	Atrioventricular Block Grad I, NCS
	Week 6/ ECG #2	16MAR2016/ 11:27	66	66	0.91	206	92	400	412.78	Atrioventricular Block Grad I, Premature Atrial Complex, NCS
	Week 6/ ECG #3	16MAR2016/ 11:29	66	66	0.91	204	92	400	412.78	Av Block I, NCS
	Week 8/ Average	31MAR2016	63.67	63.67	0.94	212	88	387.33	394.99	
	Week 8/ ECG #1	31MAR2016/ 9:43	63	63	0.95	206	88	386	392.27	Atrioventricular Block Grad I, NCS
	Week 8/ ECG #2	31MAR2016/ 9:45	64	64	0.94	214	88	386	394.31	Atrioventricular Block Grad I, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-001	Week 8/ ECG #3	31MAR2016/ 9:47	64	64	0.94	216	88	390	398.4	Atrioventricular Block Grad I, NCS
	Week 12/ Average	28APR2016	62.67	62.67	0.96	209.33	87.33	398	403.63	
	Week 12/ ECG #1	28APR2016/ 8:10	66	66	0.91	208	86	392	404.53	
	Week 12/ ECG #2	28APR2016/ 8:12	62	62	0.97	220	88	400	404.35	Atrioventricular Block Grad I, NCS P-Mitral, NCS
	Week 12/ ECG #3	28APR2016/ 8:14	60	60	1	200	88	402	402	
	Week 16/ Average	26MAY2016	61.33	61.33	0.98	206.67	87.33	394.67	397.53	
	Week 16/ ECG #1	26MAY2016/ 12:02	61	61	0.98	208	86	396	398.17	Sinus Bradycardia With Av Block I.Grad, NCS
	Week 16/ ECG #2	26MAY2016/ 12:04	62	62	0.97	206	88	392	396.26	
	Week 16/ ECG #3	26MAY2016/ 12:06	61	61	0.98	206	88	396	398.17	
	Week 20/ Average	22JUN2016	52.67	52.67	1.14	215.33	87.33	435.33	416.82	
	Week 20/ ECG #1	22JUN2016/ 9:23	56	56	1.07	214	88	426	416.41	
	Week 20/ ECG #2	22JUN2016/ 9:25	51	51	1.18	214	88	438	415.13	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-001	Week 20/ ECG #3	22JUN2016/ 9:27	51	51	1.18	218	86	442	418.92	Sinus Bradycardia With Av Block I.Grad, NCS
	Week 24/ Average	20JUL2016	64	64	0.94	207.33	90.67	406.67	415.37	
	Week 24/ ECG #1	20JUL2016/ 8:46	64	64	0.94	206	92	406	414.74	
	Week 24/ ECG #2	20JUL2016/ 8:48	66	66	0.91	204	90	404	416.91	Av-Block Grad I, NCS
	Week 24/ ECG #3	20JUL2016/ 8:51	62	62	0.97	212	90	410	414.46	
	Week 28/ Average	18AUG2016	57	57	1.05	188.67	87.33	420	412.97	
	Week 28/ ECG #1	18AUG2016/ 10:02	56	56	1.07	194	88	412	402.73	Sinusbradycardia, NCS
	Week 28/ ECG #2	18AUG2016/ 10:04	57	57	1.05	186	86	422	414.92	Sinusbradycardia, NCS
	Week 28/ ECG #3	18AUG2016/ 10:06	58	58	1.03	186	88	426	421.26	Sinusbradycardia, NCS
	Week 32/ Average	15SEP2016	56	56	1.07	200.67	92	412	402.68	Sinusbradycardia, NCS
	Week 32/ ECG #1	15SEP2016/ 9:52	57	57	1.05	200	90	400	393.29	
	Week 32/ ECG #2	15SEP2016/ 9:54	56	56	1.07	200	94	416	406.64	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-001	Week 32/ ECG #3	15SEP2016/ 9:56	55	55	1.09	202	92	420	408.11	Sinusbradycardia, NCS
	Week 36/ Average	13OCT2016	58	58	1.04	190.67	87.33	408	403.42	
	Week 36/ ECG #1	13OCT2016/ 10:06	56	56	1.07	190	88	410	400.77	Sinusbradycardia, NCS
	Week 36/ ECG #2	13OCT2016/ 10:08	59	59	1.02	190	86	404	401.77	Sinusbradycardia, NCS
	Week 36/ ECG #3	13OCT2016/ 10:10	59	59	1.02	192	88	410	407.73	Sinusbradycardia, NCS
	Week 40/ Average	10NOV2016	57	57	1.05	213.33	90.67	412.67	405.74	
	Week 40/ ECG #1	10NOV2016/ 9:54	57	57	1.05	210	92	406	399.19	Sinusbradycardia With Av Block Grad I Hesitant R Progress Over Front Wall, NCS
	Week 40/ ECG #2	10NOV2016/ 9:56	57	57	1.05	216	90	418	410.98	Sinusbradycardia With Av Block Grade I, NCS
	Week 40/ ECG #3	10NOV2016/ 9:58	57	57	1.05	214	90	414	407.05	Sinusbradycardia With Av Block Grade I, NCS
	Week 44/ Average	06DEC2016	54	54	1.11	206.67	87.33	418	403.7	
	Week 44/ ECG #1	06DEC2016/ 10:38	53	53	1.13	204	88	418	401.23	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-001	Week 44/ ECG #2	06DEC2016/ 10:40	56	56	1.07	206	88	420	410.55	Sinusbradycardia, NCS
	Week 44/ ECG #3	06DEC2016/ 10:42	53	53	1.13	210	86	416	399.31	Sinusbradycardia, NCS
	Week 48/ Average	03JAN2017	55	55	1.09	208.67	92	420	408.07	
	Week 48/ ECG #1	03JAN2017/ 11:53	56	56	1.07	208	90	410	400.77	Sinusbradycardia, NCS
	Week 48/ ECG #2	03JAN2017/ 11:55	55	55	1.09	208	94	424	412	Sinusbradycardia, NCS
	Week 48/ ECG #3	03JAN2017/ 11:57	54	54	1.11	210	92	426	411.44	Sinusbradycardia+ Av Block I, NCS
	Screening/ Average	15DEC2015	69.67	69.67	0.86	155.33	99.33	372	390.75	
	Screening/ ECG #1	15DEC2015/ 13:31	66	66	0.91	150	100	368	379.76	
301-002	Screening/ ECG #2	15DEC2015/ 13:33	70	70	0.86	156	100	376	395.62	
	Screening/ ECG #3	15DEC2015/ 13:34	73	73	0.82	160	98	372	396.87	
	Day 1/ Average	05JAN2016	68	68	0.88	159.33	98	380	396.02	
	Day 1/ ECG #1	05JAN2016/ 10:16	69	69	0.87	152	98	384	402.13	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-002	Day 1/ ECG #2	05JAN2016/ 10:19	69	69	0.87	160	96	378	395.84	
	Day 1/ ECG #3	05JAN2016/ 10:22	66	66	0.91	166	100	378	390.08	
	Week 1/ Average	14JAN2016	64	64	0.94	144.67	97.33	380	388.18	
	Week 1/ ECG #1	14JAN2016/ 10:14	62	62	0.97	134	100	374	378.07	Negativ T Waves Iii, NCS
	Week 1/ ECG #2	14JAN2016/ 10:17	66	66	0.91	146	94	382	394.21	Negativ T Waves Iii, NCS
	Week 1/ ECG #3	14JAN2016/ 10:20	64	64	0.94	154	98	384	392.27	Negativ T Waves Iii, NCS
	Week 2/ Average	20JAN2016	57.67	57.67	1.04	148	96.67	392	386.92	
	Week 2/ ECG #1	20JAN2016/ 11:54	55	55	1.09	144	98	384	373.13	Abnormal P Wave, Potentially Ectopic Atrial Bradycardia, NCS
	Week 2/ ECG #2	20JAN2016/ 11:56	60	60	1	150	96	400	400	
	Week 2/ ECG #3	20JAN2016/ 11:58	58	58	1.03	150	96	392	387.64	Sinus Bradycardia, NCS
	Week 4/ Average	03FEB2016	57.33	57.33	1.05	153.33	99.33	406	399.98	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-002	Week 4/ ECG #1	03FEB2016/ 10:38	56	56	1.07	142	100	396	387.09	Abnormal P Wave, Potentially Ectopic Atrial Bradycardia, NCS Sinus Bradycardia, NCS
	Week 4/ ECG #2	03FEB2016/ 10:41	57	57	1.05	160	98	410	403.12	
	Week 4/ ECG #3	03FEB2016/ 10:44	59	59	1.02	158	100	412	409.72	
	Week 6/ Average	17FEB2016	54	54	1.11	146.67	99.33	405.33	391.47	Sinus Bradycardia, NCS
	Week 6/ ECG #1	17FEB2016/ 13:40	54	54	1.11	144	100	398	384.4	Abnormal P Wave, Potentially Ectopic Atrial Bradycardia, NCS Abnormal P Wave, Potentially Ectopic Atrial Bradycardia, NCS Sinus Bradycardia, NCS
	Week 6/ ECG #2	17FEB2016/ 13:42	53	53	1.13	152	100	410	393.55	
	Week 6/ ECG #3	17FEB2016/ 13:43	55	55	1.09	144	98	408	396.45	
	Week 8/ Average	01MAR2016	58	58	1.03	155.33	100.67	404.67	400.13	
	Week 8/ ECG #1	01MAR2016/ 8:51	57	57	1.05	150	100	406	399.19	Sinus Bradycardia, NCS
	Week 8/ ECG #2	01MAR2016/ 8:54	57	57	1.05	156	102	406	399.19	Sinus Bradycardia, NCS
	Week 8/ ECG #3	01MAR2016/ 8:57	60	60	1	160	100	402	402	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-002	Week 12/ Average	30MAR2016	65	65	0.92	162	100	381.33	391.54	
	Week 12/ ECG #1	30MAR2016/ 9:41	65	65	0.92	158	102	374	384.01	
	Week 12/ ECG #2	30MAR2016/ 9:43	65	65	0.92	164	98	388	398.39	
	Week 12/ ECG #3	30MAR2016/ 9:46	65	65	0.92	164	100	382	392.22	
	Week 16/ Average	26APR2016	63.67	63.67	0.94	142	93.33	371.33	378.62	
	Week 16/ ECG #1	26APR2016/ 10:20	61	61	0.98	134	94	370	372.02	
	Week 16/ ECG #2	26APR2016/ 10:22	64	64	0.94	140	92	376	384.09	
	Week 16/ ECG #3	26APR2016/ 10:23	66	66	0.91	152	94	368	379.76	
	Week 20/ Average	24MAY2016	64.67	64.67	0.93	145.33	95.33	366.67	375.8	
	Week 20/ ECG #1	24MAY2016/ 11:33	66	66	0.91	142	96	356	367.37	
	Week 20/ ECG #2	24MAY2016/ 11:35	63	63	0.95	146	94	368	373.97	
	Week 20/ ECG #3	24MAY2016/ 11:37	65	65	0.92	148	96	376	386.06	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-002	Week 24/ Average	21JUN2016	58.67	58.67	1.02	157.33	91.33	384.67	381.85	
	Week 24/ ECG #1	21JUN2016/ 11:17	56	56	1.07	148	92	374	365.58	Sinus Bradycardia, NCS
	Week 24/ ECG #2	21JUN2016/ 11:19	59	59	1.02	156	92	390	387.84	Sinus Bradycardia, NCS
	Week 24/ ECG #3	21JUN2016/ 11:21	61	61	0.98	168	90	390	392.13	
	Week 28/ Average	20JUL2016	56.33	56.33	1.07	154.67	94.67	396	387.54	
	Week 28/ ECG #1	20JUL2016/ 11:25	61	61	0.98	148	98	384	386.1	
	Week 28/ ECG #2	20JUL2016/ 11:27	54	54	1.11	156	94	402	388.26	Sinusbradycardia, NCS
	Week 28/ ECG #3	20JUL2016/ 11:29	54	54	1.11	160	92	402	388.26	Sinusbradycardia With Ventricular Extrasystole, NCS
	Week 32/ Average	18AUG2016	55.67	55.67	1.08	146	98	402	392.24	
	Week 32/ ECG #1	18AUG2016/ 9:44	54	54	1.11	138	100	384	370.88	Sinusbradycardia, NCS
	Week 32/ ECG #2	18AUG2016/ 9:46	57	57	1.05	138	98	412	405.08	Sinusbradycardia, NCS
	Week 32/ ECG #3	18AUG2016/ 9:49	56	56	1.07	162	96	410	400.77	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-002	Week 36/ Average	13SEP2016	65.67	65.67	0.91	152.67	96	378	389.43	
	Week 36/ ECG #1	13SEP2016/ 10:36	63	63	0.95	148	96	370	376.01	
	Week 36/ ECG #2	13SEP2016/ 10:38	66	66	0.91	154	96	384	396.27	
	Week 36/ ECG #3	13SEP2016/ 10:40	68	68	0.88	156	96	380	396.02	
	Week 40/ Average	11OCT2016	63	63	0.95	160.67	92	371.33	377.34	
	Week 40/ ECG #1	11OCT2016/ 11:33	60	60	1	162	92	368	368	
	Week 40/ ECG #2	11OCT2016/ 11:35	64	64	0.94	160	90	372	380.01	
	Week 40/ ECG #3	11OCT2016/ 11:37	65	65	0.92	160	94	374	384.01	
	Week 44/ Average	09NOV2016	60	60	1	153.33	99.33	390.67	390.57	
	Week 44/ ECG #1	09NOV2016/ 11:45	62	62	0.97	142	98	378	382.11	
	Week 44/ ECG #2	09NOV2016/ 11:47	59	59	1.02	152	102	398	395.8	Sinusbradycardia, NCS
	Week 44/ ECG #3	09NOV2016/ 11:49	59	59	1.02	166	98	396	393.81	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-002	Week 48/ Average	06DEC2016	63.67	63.67	0.94	164.67	94.67	392	399.73	
	Week 48/ ECG #1	06DEC2016/ 11:05	60	60	1	160	90	386	386	
	Week 48/ ECG #2	06DEC2016/ 11:07	66	66	0.91	166	96	396	408.65	
	Week 48/ ECG #3	06DEC2016/ 11:09	65	65	0.92	168	98	394	404.55	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-003	Screening/ Average	15DEC2015	63	63	0.95	158.67	80	415.33	422.05	
	Screening/ ECG #1	15DEC2015/ 13:11	64	64	0.94	158	80	408	416.78	Normal Sinus Rhythm With Sinus Arrhythmia, NCS
	Screening/ ECG #2	15DEC2015/ 13:11	63	63	0.95	158	80	420	426.82	
	Screening/ ECG #3	15DEC2015/ 13:14	62	62	0.97	160	80	418	422.55	Normal Sinus Rhythm With Sinus Arrhythmia, NCS
	Day 1/ Average	06JAN2016	67.33	67.33	0.89	164.67	78.67	394	409.13	
	Day 1/ ECG #1	06JAN2016/ 12:35	70	70	0.86	162	78	378	397.73	Normal Sinus Rhythm With Sinus Arrhythmia, NCS
	Day 1/ ECG #2	06JAN2016/ 12:38	67	67	0.9	168	78	402	416.91	
	Day 1/ ECG #3	06JAN2016/ 12:40	65	65	0.92	164	80	402	412.76	Normal Sinus Rhythm With Sinus Arrhythmia, NCS
	Week 1/ Average	13JAN2016	71	71	0.85	166.67	76	396.67	419.32	
	Week 1/ ECG #1	13JAN2016/ 12:03	70	70	0.86	166	76	390	410.35	
	Week 1/ ECG #2	13JAN2016/ 12:06	70	70	0.86	166	76	400	420.87	
	Week 1/ ECG #3	13JAN2016/ 12:09	73	73	0.82	168	76	400	426.74	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-003	Week 2/ Average	20JAN2016	66.33	66.33	0.91	151.33	78.67	384.67	397.61	
	Week 2/ ECG #1	20JAN2016/ 12:04	66	66	0.91	148	78	380	392.14	
	Week 2/ ECG #2	20JAN2016/ 12:06	66	66	0.91	154	80	390	402.46	
	Week 2/ ECG #3	20JAN2016/ 12:08	67	67	0.9	152	78	384	398.24	
	Week 4/ Average	03FEB2016	57.33	57.33	1.04	158	81.33	417.33	411.11	
	Week 4/ ECG #1	03FEB2016/ 12:51	58	58	1.03	160	82	414	409.39	Sinus Bradycardia, NCS
	Week 4/ ECG #2	03FEB2016/ 12:53	57	57	1.05	158	80	416	409.02	Sinus Bradycardia, NCS
	Week 4/ ECG #3	03FEB2016/ 12:55	57	57	1.05	156	82	422	414.92	Sinus Bradycardia, NCS
	Week 6/ Average	18FEB2016	71.33	71.33	0.84	165.33	80.67	380.67	403.01	
	Week 6/ ECG #1	18FEB2016/ 12:26	72	72	0.83	164	80	380	403.56	
	Week 6/ ECG #2	18FEB2016/ 12:28	70	70	0.86	164	82	384	404.04	
	Week 6/ ECG #3	18FEB2016/ 12:32	72	72	0.83	168	80	378	401.44	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-003	Week 8/ Average	08MAR2016	69.33	69.33	0.87	145.33	80.67	390.67	409.68	
	Week 8/ ECG #1	08MAR2016/ 8:28	69	69	0.87	156	82	392	410.5	Sinus Arrhythmia, NCS
	Week 8/ ECG #2	08MAR2016/ 8:30	72	72	0.83	130	80	386	409.94	
	Week 8/ ECG #3	08MAR2016/ 8:32	67	67	0.9	150	80	394	408.61	
	Week 12/ Average	29MAR2016	62	62	0.97	162.67	80.67	414	418.48	
	Week 12/ ECG #1	29MAR2016/ 8:58	63	63	0.95	162	80	408	414.62	
	Week 12/ ECG #2	29MAR2016/ 9:00	61	61	0.98	164	80	416	418.28	
	Week 12/ ECG #3	29MAR2016/ 9:02	62	62	0.97	162	82	418	422.55	
	Week 16/ Average	25APR2016	65.33	65.33	0.92	152.67	79.33	388.67	399.75	
	Week 16/ ECG #1	25APR2016/ 8:36	64	64	0.94	148	78	384	392.27	
	Week 16/ ECG #2	25APR2016/ 8:39	65	65	0.92	156	80	390	400.44	
	Week 16/ ECG #3	25APR2016/ 8:40	67	67	0.9	154	80	392	406.54	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-003	Week 20/ Average	26MAY2016	57.33	57.33	1.04	165.33	78.67	444.67	438.03	
	Week 20/ ECG #1	26MAY2016/ 13:50	56	56	1.07	162	78	446	435.96	Sinus Bardycardia With Sinus Arrhythmia, NCS
	Week 20/ ECG #2	26MAY2016/ 13:52	58	58	1.03	170	78	444	439.06	Sinus Bardycardia With Sinus Arrhythmia, NCS
	Week 20/ ECG #3	26MAY2016/ 13:55	58	58	1.03	164	80	444	439.06	Sinus Bradycardia, NCS
	Week 24/ Average	22JUN2016	51.33	51.33	1.17	146.67	80	452	429.31	
	Week 24/ ECG #1	22JUN2016/ 11:55	51	51	1.18	142	80	450	426.5	Sinus Bradycardia, NCS
	Week 24/ ECG #2	22JUN2016/ 11:57	51	51	1.18	144	82	454	430.29	Sinus Bradycardia, NCS
	Week 24/ ECG #3	22JUN2016/ 12:00	52	52	1.15	154	78	452	431.15	Sinus Bradycardia, NCS
	Week 28/ Average	19JUL2016	82	82	0.73	158	79.33	363.33	402.78	
	Week 28/ ECG #1	19JUL2016/ 9:18	82	82	0.73	150	82	362	401.31	
	Week 28/ ECG #2	19JUL2016/ 9:20	81	81	0.74	160	78	366	404.1	
	Week 28/ ECG #3	19JUL2016/ 9:23	83	83	0.72	164	78	362	402.92	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-003	Week 32/ Average	16AUG2016	68.67	68.67	0.87	156.67	81.33	396.67	414.7	
	Week 32/ ECG #1	16AUG2016/ 12:08	70	70	0.86	154	82	390	410.35	
	Week 32/ ECG #2	16AUG2016/ 12:10	68	68	0.88	156	82	400	416.87	
	Week 32/ ECG #3	16AUG2016/ 12:10	68	68	0.88	160	80	400	416.87	
	Week 36/ Average	15SEP2016	76.33	76.33	0.79	158.67	77.33	377.33	408.32	
	Week 36/ ECG #1	15SEP2016/ 12:27	83	83	0.72	162	76	374	416.27	
	Week 36/ ECG #2	15SEP2016/ 12:29	73	73	0.82	150	78	380	405.41	
	Week 36/ ECG #3	15SEP2016/ 12:31	73	73	0.82	164	78	378	403.27	
	Week 40/ Average	12OCT2016	81	81	0.74	156.67	76	362.67	400.36	
	Week 40/ ECG #1	12OCT2016/ 10:03	82	82	0.73	154	76	356	394.66	
	Week 40/ ECG #2	12OCT2016/ 10:05	78	78	0.77	150	76	368	401.28	
	Week 40/ ECG #3	12OCT2016/ 10:07	83	83	0.72	166	76	364	405.14	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-003	Week 44/ Average	09NOV2016	74	74	0.81	157.33	80.67	388.67	416.53	
	Week 44/ ECG #1	09NOV2016/ 11:31	73	73	0.82	154	82	380	405.41	
	Week 44/ ECG #2	09NOV2016/ 11:33	76	76	0.79	156	82	394	425.97	Sinusarrythmia, NCS
	Week 44/ ECG #3	09NOV2016/ 11:35	73	73	0.82	162	78	392	418.21	
	Week 48/ Average	14DEC2016	79.33	79.33	0.76	157.33	77.33	374	410.11	
	Week 48/ ECG #1	14DEC2016/ 11:26	80	80	0.75	154	78	374	411.25	
	Week 48/ ECG #2	14DEC2016/ 11:28	80	80	0.75	158	78	374	411.25	
	Week 48/ ECG #3	14DEC2016/ 11:30	78	78	0.77	160	76	374	407.82	
	Screening/ Average	16DEC2015	71	71	0.85	182	100	377.33	398.87	
	Screening/ ECG #1	16DEC2015/ 12:08	71	71	0.85	178	98	378	399.59	Missing R-Progression In V3-6, NCS
301-005	Screening/ ECG #2	16DEC2015/ 12:14	72	72	0.83	182	100	374	397.19	
	Screening/ ECG #3	16DEC2015/ 12:17	70	70	0.86	186	102	380	399.83	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-005	Day 1/ Average	07JAN2016	73.33	73.33	0.82	172	94.67	372.67	398.15	
	Day 1/ ECG #1	07JAN2016/ 11:19	75	75	0.8	172	92	370	398.27	
	Day 1/ ECG #2	07JAN2016/ 11:23	73	73	0.82	170	96	374	399	
	Day 1/ ECG #3	07JAN2016/ 11:26	72	72	0.83	174	96	374	397.19	
	Week 1/ Average	13JAN2016	73.67	73.67	0.81	163.33	95.33	374	400.19	
	Week 1/ ECG #1	13JAN2016/ 11:29	74	74	0.81	164	90	368	394.37	T-Negativity, Iii, Avf, NCS
	Week 1/ ECG #2	13JAN2016/ 11:32	73	73	0.82	162	98	378	403.27	T-Negativity, Iii, Avf, NCS
	Week 1/ ECG #3	13JAN2016/ 11:35	74	74	0.81	164	98	376	402.94	T-Negativity,iii, Avf, NCS
	Week 2/ Average	21JAN2016	73.33	73.33	0.82	162.67	92.67	364.67	389.64	
	Week 2/ ECG #1	21JAN2016/ 13:04	73	73	0.82	164	90	356	379.8	
	Week 2/ ECG #2	21JAN2016/ 13:06	73	73	0.82	162	94	368	392.6	
	Week 2/ ECG #3	21JAN2016/ 13:08	74	74	0.81	162	94	370	396.51	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-005	Week 4/ Average	02FEB2016	76	76	0.79	164.67	94.67	360	389.17	
	Week 4/ ECG #1	02FEB2016/ 11:37	73	73	0.82	160	94	360	384.07	T-Negativity, Iii, Avf, NCS
	Week 4/ ECG #2	02FEB2016/ 11:40	78	78	0.77	166	94	360	392.56	T-Negativity, Iii, Avf, NCS
	Week 4/ ECG #3	02FEB2016/ 11:42	77	77	0.78	168	96	360	390.89	T-Negativity, Iii, Avf, NCS
	Week 6/ Average	17FEB2016	82.33	82.33	0.73	154	88.67	368	408.45	
	Week 6/ ECG #1	17FEB2016/ 14:10	80	80	0.75	152	90	368	404.65	Qrs Low Voltage, NCS
	Week 6/ ECG #2	17FEB2016/ 14:12	85	85	0.71	156	86	362	406.09	Qrs Low Voltage, NCS
	Week 6/ ECG #3	17FEB2016/ 14:13	82	82	0.73	154	90	374	414.61	Qrs Low Voltage, NCS
	Week 8/ Average	02MAR2016	84.33	84.33	0.71	155.33	90	350.67	392.36	
	Week 8/ ECG #1	02MAR2016/ 9:07	82	82	0.73	156	90	348	385.79	Qrs Low Voltage, NCS
	Week 8/ ECG #2	02MAR2016/ 9:09	86	86	0.7	154	90	354	398.66	Qrs Low Voltage, NCS
	Week 8/ ECG #3	02MAR2016/ 9:11	85	85	0.71	156	90	350	392.63	Qrs Low Voltage, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-005	Week 12/ Average	31MAR2016	90	90	0.66	153.33	84	350	400.1	
	Week 12/ ECG #1	31MAR2016/ 10:06	89	89	0.67	152	86	346	394.08	Qrs Low Voltage, NCS
	Week 12/ ECG #2	31MAR2016/ 10:09	92	92	0.65	152	84	350	403.02	Qrs Low Voltage, NCS
	Week 12/ ECG #3	31MAR2016/ 10:11	89	89	0.67	156	82	354	403.19	Qrs Low Voltage, NCS
	Week 16/ Average	26APR2016	69.67	69.67	0.86	163.33	96.67	378	397.04	
	Week 16/ ECG #1	26APR2016/ 9:48	67	67	0.9	164	94	378	392.02	Qrs Low Voltage, NCS
	Week 16/ ECG #2	26APR2016/ 9:51	73	73	0.82	162	100	378	403.27	Qrs Low Voltage, NCS
	Week 16/ ECG #3	26APR2016/ 9:53	69	69	0.87	164	96	378	395.84	Qrs Low Voltage, NCS
	Week 20/ Average	26MAY2016	66.33	66.33	0.91	166	94	388.67	401.72	
	Week 20/ ECG #1	26MAY2016/ 12:11	68	68	0.88	164	92	388	404.36	
	Week 20/ ECG #2	26MAY2016/ 12:13	67	67	0.9	168	90	390	404.46	
	Week 20/ ECG #3	26MAY2016/ 12:15	64	64	0.94	166	100	388	396.35	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-005	Week 24/ Average	23JUN2016	64	64	0.94	173.33	96.67	400	408.61	
	Week 24/ ECG #1	23JUN2016/ 11:03	63	63	0.95	172	96	398	404.46	
	Week 24/ ECG #2	23JUN2016/ 11:05	64	64	0.94	172	96	402	410.65	
	Week 24/ ECG #3	23JUN2016/ 11:07	65	65	0.92	176	98	400	410.71	
	Week 28/ Average	26JUL2016	77.33	77.33	0.78	171.33	90.67	363.33	395.03	
	Week 28/ ECG #1	26JUL2016/ 9:24	79	79	0.76	170	88	356	389.83	Peripheral Low Voltage, NCS
	Week 28/ ECG #2	26JUL2016/ 9:27	77	77	0.78	172	94	368	399.58	
	Week 28/ ECG #3	26JUL2016/ 9:29	76	76	0.79	172	90	366	395.69	
	Week 32/ Average	16AUG2016	70	70	0.86	167.33	91.33	382	401.92	
	Week 32/ ECG #1	16AUG2016/ 10:03	70	70	0.86	166	90	378	397.73	
	Week 32/ ECG #2	16AUG2016/ 10:05	71	71	0.85	168	92	382	403.82	
	Week 32/ ECG #3	16AUG2016/ 10:07	69	69	0.87	168	92	386	404.22	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-005	Week 36/ Average	14SEP2016	69.33	69.33	0.87	166.67	92	384	402.75	
	Week 36/ ECG #1	14SEP2016/ 11:34	69	69	0.87	162	92	378	395.84	Peripheral Low Voltage Delayed R-S Umschlag In V5/V6, NCS
	Week 36/ ECG #2	14SEP2016/ 11:36	68	68	0.88	168	90	388	404.36	
	Week 36/ ECG #3	14SEP2016/ 11:38	71	71	0.85	170	94	386	408.05	
	Week 40/ Average	12OCT2016	82.67	82.67	0.72	166	92	360	400.17	
	Week 40/ ECG #1	12OCT2016/ 10:48	81	81	0.74	164	94	356	393.06	Qrs Low Voltage, NCS
	Week 40/ ECG #2	12OCT2016/ 10:49	84	84	0.71	168	92	364	406.75	
	Week 40/ ECG #3	12OCT2016/ 10:51	83	83	0.72	166	90	360	400.69	
	Week 44/ Average	10NOV2016	71.67	71.67	0.84	166	98.67	384.67	407.89	
	Week 44/ ECG #1	10NOV2016/ 10:06	71	71	0.85	164	100	382	403.82	
	Week 44/ ECG #2	10NOV2016/ 10:08	73	73	0.82	166	96	386	411.81	
	Week 44/ ECG #3	10NOV2016/ 10:10	71	71	0.85	168	100	386	408.05	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-005	Week 48/ Average	07DEC2016	71	71	0.85	163.33	89.33	386	408.05	
	Week 48/ ECG #1	07DEC2016/ 11:03	70	70	0.86	162	82	380	399.83	
	Week 48/ ECG #2	07DEC2016/ 11:06	71	71	0.85	166	94	392	414.39	
	Week 48/ ECG #3	07DEC2016/ 11:11	72	72	0.83	162	92	386	409.94	
301-008	Screening/ Average	19JAN2016	74	74	0.81	108	82.67	390.67	418.66	
	Screening/ ECG #1	19JAN2016/ 11:34	74	74	0.81	98	86	386	413.66	Short Pq Interval Ascending St Segment Elevation Ii, NCS
	Screening/ ECG #2	19JAN2016/ 11:37	74	74	0.81	110	80	400	428.66	Short Pq Interval Ascending St Segment Elevation Ii, NCS
	Screening/ ECG #3	19JAN2016/ 11:41	74	74	0.81	116	82	386	413.66	Short Pq Interval Ascending St Segment Elevation Ii, NCS
	Day 1/ Average	11FEB2016	76.67	76.67	0.78	114.67	82	380.67	412.74	
	Day 1/ ECG #3	11FEB2016/ 8:43	76	76	0.79	104	82	372	402.18	Short Pq Interval, NCS
	Day 1/ ECG #1	11FEB2016/ 8:47	78	78	0.77	126	82	384	418.73	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-008	Day 1/ ECG #2	11FEB2016/ 8:49	76	76	0.79	114	82	386	417.32	
	Week 1/ Average	17FEB2016	83	83	0.73	100	86	368	409.64	
	Week 1/ ECG #1	17FEB2016/ 8:27	80	80	0.75	102	84	360	395.85	Short Pq Time, NCS
	Week 1/ ECG #2	17FEB2016/ 8:32	86	86	0.7	98	88	376	423.43	Short Pq Time, NCS
	Week 2/ Average	24FEB2016	74.67	74.67	0.8	116.67	86	379.33	407.65	
	Week 2/ ECG #1	24FEB2016/ 8:27	76	76	0.79	120	84	368	397.86	
	Week 2/ ECG #2	24FEB2016/ 8:29	72	72	0.83	108	86	386	409.94	Short Pq Time, NCS
	Week 2/ ECG #3	24FEB2016/ 8:31	76	76	0.79	122	88	384	415.15	
	Week 4/ Average	10MAR2016	72.33	72.33	0.83	108	85.33	386	410.53	
	Week 4/ ECG #1	10MAR2016/ 7:50	72	72	0.83	104	86	378	401.44	Short Pq Time, NCS
	Week 4/ ECG #2	10MAR2016/ 7:52	75	75	0.8	104	86	390	419.8	Short Pq Time, NCS
	Week 4/ ECG #3	10MAR2016/ 7:55	70	70	0.86	116	84	390	410.35	Slightly Elevated St Disposal I,ii, Avf, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-008	Week 6/ Average	24MAR2016	71	71	0.84	104	84.67	393.33	415.77	
	Week 6/ ECG #1	24MAR2016/ 7:47	68	68	0.88	98	86	392	408.53	Short Pq Time, NCS
	Week 6/ ECG #2	24MAR2016/ 7:49	73	73	0.82	106	84	396	422.48	Short Pq Time, NCS
	Week 6/ ECG #3	24MAR2016/ 7:52	72	72	0.83	108	84	392	416.31	Short Pq Time, NCS
	Week 8/ Average	07APR2016	66.33	66.33	0.91	121.33	95.33	414.67	428.63	
	Week 8/ ECG #1	07APR2016/ 8:25	65	65	0.92	120	92	410	420.97	
	Week 8/ ECG #2	07APR2016/ 8:27	67	67	0.9	120	100	420	435.58	
	Week 8/ ECG #3	07APR2016/ 8:29	67	67	0.9	124	94	414	429.35	
	Week 28/ Average	17MAY2016	71.67	71.67	0.84	114.67	83.33	396	419.9	
	Week 28/ ECG #1	17MAY2016/ 8:05	72	72	0.83	108	80	392	416.31	Short Pq Time T-Wave Inversion Iii, NCS
	Week 28/ ECG #2	17MAY2016/ 8:08	70	70	0.86	118	86	398	418.77	T-Wave Inversion, Iii, NCS
	Week 28/ ECG #3	17MAY2016/ 8:11	73	73	0.82	118	84	398	424.61	T-Wave Inversion, Iii, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-008	Week 32/ Average	09JUN2016	70.67	70.67	0.85	108.67	87.33	404.67	427.12	
	Week 32/ ECG #1	09JUN2016/ 8:17	69	69	0.87	104	88	400	418.88	Short Pq, NCS
	Week 32/ ECG #2	09JUN2016/ 8:19	72	72	0.83	110	90	406	431.18	Short Pq, NCS
	Week 32/ ECG #3	09JUN2016/ 8:21	71	71	0.85	112	84	408	431.31	Asc St Segment Elevation In All Derivation, NCS
	Week 36/ Average	06JUL2016	65.67	65.67	0.91	111.33	84	406.67	418.86	
	Week 36/ ECG #1	06JUL2016/ 8:29	68	68	0.88	104	86	396	412.7	Short Pq Elevated St Line Ii,iii,avf+v6, NCS
	Week 36/ ECG #2	06JUL2016/ 8:31	65	65	0.92	112	82	408	418.92	Elevated St Line Ii,iii,avf+v6, NCS
	Week 36/ ECG #3	06JUL2016/ 8:33	64	64	0.94	118	84	416	424.95	Elevated St Line Ii,iii,avf, NCS
	Week 40/ Average	03AUG2016	68.67	68.67	0.87	114.67	82.67	394	411.73	
	Week 40/ ECG #1	03AUG2016/ 8:06	72	72	0.83	112	84	380	403.56	St Elevations Ii+iii+avf, NCS
	Week 40/ ECG #2	03AUG2016/ 8:08	69	69	0.87	114	82	400	418.88	St Elevations Ii+iii+avf, NCS
	Week 40/ ECG #3	03AUG2016/ 8:11	65	65	0.92	118	82	402	412.76	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-008	Week 44/ Average	07SEP2016	72	72	0.83	108.67	83.33	398	422.66	
	Week 44/ ECG #1	07SEP2016/ 8:11	73	73	0.82	106	82	392	418.21	Short Pq, NCS
	Week 44/ ECG #2	07SEP2016/ 8:13	71	71	0.85	108	84	402	424.96	Short Pq, NCS
	Week 44/ ECG #3	07SEP2016/ 8:15	72	72	0.83	112	84	400	424.81	
	Week 48/ Average	19OCT2016	71.67	71.67	0.84	107.33	86	411.33	436.17	
	Week 48/ ECG #1	19OCT2016/ 7:47	71	71	0.85	102	84	408	431.31	Short Pq, NCS
	Week 48/ ECG #2	19OCT2016/ 7:49	71	71	0.85	110	86	414	437.65	Short Pq, NCS
	Week 48/ ECG #3	19OCT2016/ 7:51	73	73	0.82	110	88	412	439.55	Short Pq, NCS
	Early Term/ Average	13APR2016	82.67	82.67	0.73	94	93.33	397.33	441.61	
	Early Term/ ECG #1	13APR2016/ 12:07	82	82	0.73	80	94	382	423.48	Short Pq Time, NCS
	Early Term/ ECG #2	13APR2016/ 12:09	80	80	0.75	96	92	408	448.63	Short Pq Time, NCS
	Early Term/ ECG #3	13APR2016/ 12:11	86	86	0.7	106	94	402	452.71	Short Pq Time, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-009	Screening/ Average	06JAN2016	66	66	0.91	118.67	98	414	427.19	
	Screening/ ECG #1	06JAN2016/ 15:04	67	67	0.9	118	98	404	418.98	
	Screening/ ECG #2	06JAN2016/ 15:06	66	66	0.91	120	98	418	431.36	
	Screening/ ECG #3	06JAN2016/ 15:07	65	65	0.92	118	98	420	431.24	
	Day 1/ Average	27JAN2016	69.67	69.67	0.86	122.67	94	398.67	418.61	
	Day 1/ ECG #1	27JAN2016/ 12:50	74	74	0.81	124	94	388	415.8	
	Day 1/ ECG #2	27JAN2016/ 12:53	68	68	0.88	122	94	404	421.04	Increased R/S Ratio V1, NCS
	Day 1/ ECG #3	27JAN2016/ 12:55	67	67	0.9	122	94	404	418.98	Increased R/S Ratio V1, NCS
	Week 1/ Average	02FEB2016	62.33	62.33	0.96	120	102	380	384.81	
	Week 1/ ECG #1	02FEB2016/ 13:01	62	62	0.97	122	104	376	380.09	Ascendant St Segment Elevation In I And Avl T Negativation In V4-V6, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-009	Week 1/ ECG #2	02FEB2016/ 13:03	61	61	0.98	124	102	380	382.08	Ascendant St Segment Elevation In I And Avl T-Negativation In V4-V6, NCS
	Week 1/ ECG #3	02FEB2016/ 13:05	64	64	0.94	114	100	384	392.27	Ascendant St Segment Elevation In I And Avl T Negativation V4-V6, NCS
	Week 2/ Average	10FEB2016	59.33	59.33	1.01	124	101.33	406	404.48	
	Week 2/ ECG #1	10FEB2016/ 12:31	58	58	1.03	124	104	406	401.48	Sinus Bradycardia, NCS
	Week 2/ ECG #2	10FEB2016/ 12:33	59	59	1.02	122	100	406	403.75	Sinus Bradycardia, NCS
	Week 2/ ECG #3	10FEB2016/ 12:35	61	61	0.98	126	100	406	408.22	
	Week 4/ Average	25FEB2016	78	78	0.77	121.33	98.67	363.33	396.18	
	Week 4/ ECG #1	25FEB2016/ 11:16	78	78	0.77	120	98	364	396.92	
	Week 4/ ECG #2	25FEB2016/ 11:18	76	76	0.79	122	98	362	391.37	
	Week 4/ ECG #3	25FEB2016/ 11:20	80	80	0.75	122	100	364	400.25	
	Week 6/ Average	09MAR2016	73	73	0.82	120	94	375.33	400.4	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-009	Week 6/ ECG #1	09MAR2016/ 11:12	72	72	0.83	118	92	376	399.32	
	Week 6/ ECG #2	09MAR2016/ 11:14	72	72	0.83	118	96	378	401.44	
	Week 6/ ECG #3	09MAR2016/ 11:16	75	75	0.8	124	94	372	400.43	
	Week 8/ Average	22MAR2016	78.33	78.33	0.77	126.67	104	392.67	428.78	
	Week 8/ ECG #1	22MAR2016/ 8:13	78	78	0.77	128	104	394	429.63	Negativ T-Waves Avf Disturbance Of Repolarisation, NCS
	Week 8/ ECG #2	22MAR2016/ 8:15	79	79	0.76	126	106	394	431.44	Disturbance Of Repolarisation, NCS
	Week 8/ ECG #3	22MAR2016/ 8:17	78	78	0.77	126	102	390	425.27	Disturbance Of Repolarisation, NCS
	Week 12/ Average	19APR2016	69.33	69.33	0.87	120.67	98	385.33	404.15	
	Week 12/ ECG #1	19APR2016/ 11:12	68	68	0.88	118	98	386	402.28	
	Week 12/ ECG #2	19APR2016/ 11:14	69	69	0.87	120	98	384	402.13	
	Week 12/ ECG #3	19APR2016/ 11:16	71	71	0.85	124	98	386	408.05	
	Week 16/ Average	18MAY2016	59.33	59.33	1.01	120.67	103.33	422.67	421.1	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-009	Week 16/ ECG #1	18MAY2016/ 11:54	60	60	1	120	106	424	424	Negativ T Waves Iii And Avf Q In Iii, Avf, V5 And V6, NCS
	Week 16/ ECG #2	18MAY2016/ 11:56	60	60	1	122	102	422	422	Negativ T Waves Iii And Avf Q In Iii, Avf, V5 And V6, NCS
	Week 16/ ECG #3	18MAY2016/ 11:58	58	58	1.03	120	102	422	417.31	Negativ T Waves Iii And Avf Q In Iii, Avf, V5 And V6 Sinus Bradycardia, NCS
	Week 20/ Average	15JUN2016	68	68	0.88	123.33	106	404.67	421.7	
	Week 20/ ECG #1	15JUN2016/ 11:54	69	69	0.87	122	106	396	414.69	Pre-Terminal T-Negativity V5,v6,ii,iii,avf, NCS
	Week 20/ ECG #2	15JUN2016/ 11:56	68	68	0.88	122	108	410	427.29	Pre-Terminal T-Negativity Ii,iii,avf,v5 And V6, NCS
	Week 20/ ECG #3	15JUN2016/ 11:58	67	67	0.9	126	104	408	423.13	Pre-Terminal T-Negativity Ii,iii,avf, NCS
	Week 24/ Average	20JUL2016	76	76	0.79	126	96	398.67	431	
	Week 24/ ECG #1	20JUL2016/ 12:53	75	75	0.8	126	96	402	432.72	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-009	Week 24/ ECG #2	20JUL2016/ 12:55	76	76	0.79	126	96	396	428.13	
	Week 24/ ECG #3	20JUL2016/ 12:57	77	77	0.78	126	96	398	432.15	
	Week 28/ Average	09AUG2016	69.33	69.33	0.87	120	96	407.33	427.14	
	Week 28/ ECG #1	09AUG2016/ 11:46	67	67	0.9	116	98	408	423.13	T-Negativ In Iii, NCS
	Week 28/ ECG #2	09AUG2016/ 11:48	73	73	0.82	120	96	404	431.01	
	Week 28/ ECG #3	09AUG2016/ 11:50	68	68	0.88	124	94	410	427.29	
	Week 32/ Average	06SEP2016	60.33	60.33	0.99	120.67	102	414.67	415.39	
	Week 32/ ECG #1	06SEP2016/ 12:35	62	62	0.97	120	102	412	416.48	
	Week 32/ ECG #2	06SEP2016/ 12:37	61	61	0.98	120	102	418	420.29	
	Week 32/ ECG #3	06SEP2016/ 12:39	58	58	1.03	122	102	414	409.39	Sinusbradycardia, NCS
	Week 36/ Average	04OCT2016	69	69	0.87	122.67	95.33	408.67	427.89	
	Week 36/ ECG #1	04OCT2016/ 11:51	68	68	0.88	120	96	410	427.29	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-009	Week 36/ ECG #2	04OCT2016/ 11:54	67	67	0.9	124	94	410	425.21	
	Week 36/ ECG #3	04OCT2016/ 12:04	72	72	0.83	124	96	406	431.18	
	Week 40/ Average	01NOV2016	59.67	59.67	1.01	125.33	96	435.33	434.54	
	Week 40/ ECG #1	01NOV2016/ 11:59	59	59	1.02	124	96	432	429.61	Sinusbradycardia, NCS
	Week 40/ ECG #2	01NOV2016/ 12:01	60	60	1	126	96	438	438	
	Week 40/ ECG #3	01NOV2016/ 12:03	60	60	1	126	96	436	436	
	Week 44/ Average	29NOV2016	79.67	79.67	0.75	124.67	93.33	377.33	414.31	
	Week 44/ ECG #1	29NOV2016/ 13:43	77	77	0.78	126	94	376	408.26	
	Week 44/ ECG #2	29NOV2016/ 13:45	80	80	0.75	124	94	380	417.84	
	Week 44/ ECG #3	29NOV2016/ 13:47	82	82	0.73	124	92	376	416.83	
	Week 48/ Average	02JAN2017	71.67	71.67	0.84	117.33	98.67	386.67	410.01	
	Week 48/ ECG #1	02JAN2017/ 11:53	72	72	0.83	114	98	384	407.81	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-009	Week 48/ ECG #2	02JAN2017/ 11:55	72	72	0.83	116	98	386	409.94	
	Week 48/ ECG #3	02JAN2017/ 11:57	71	71	0.85	122	100	390	412.28	
301-010	Screening/ Average	07JAN2016	72.67	72.67	0.82	154	86.67	371.33	395.58	
	Screening/ ECG #1	07JAN2016/ 14:27	72	72	0.83	154	88	358	380.2	Sinusalrhythmie R Loss V2, NCS
	Screening/ ECG #2	07JAN2016/ 14:29	74	74	0.81	148	88	378	405.09	R Loss V2, NCS
	Screening/ ECG #3	07JAN2016/ 14:31	72	72	0.83	160	84	378	401.44	R Loss V2, NCS
	Day 1/ Average	27JAN2016	81.33	81.33	0.74	156.67	86.67	354	391.32	
	Day 1/ ECG #1	27JAN2016/ 12:23	83	83	0.72	156	86	340	378.43	Sinus Arrhythmia, NCS
	Day 1/ ECG #2	27JAN2016/ 12:25	81	81	0.74	156	88	358	395.27	
	Day 1/ ECG #3	27JAN2016/ 12:27	80	80	0.75	158	86	364	400.25	R Loss In V2, NCS
	Week 1/ Average	04FEB2016	58.33	58.33	1.03	163.33	93.33	390.67	387.05	
	Week 1/ ECG #1	04FEB2016/ 12:48	57	57	1.05	156	92	390	383.45	Sinus Bradycardia R Loss In V2, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-010	Week 1/ ECG #2	04FEB2016/ 12:50	60	60	1	166	94	396	396	R Loss In V2, NCS
	Week 1/ ECG #3	04FEB2016/ 12:52	58	58	1.03	168	94	386	381.71	R Loss In V2 Sinus Bradycardia, NCS
	Week 2/ Average	09FEB2016	61	61	0.98	161.33	90	386.67	388.82	
	Week 2/ ECG #1	09FEB2016/ 11:39	60	60	1	164	90	374	374	
	Week 2/ ECG #2	09FEB2016/ 11:41	63	63	0.95	160	90	398	404.46	
	Week 2/ ECG #3	09FEB2016/ 11:43	60	60	1	160	90	388	388	
	Week 4/ Average	24FEB2016	72.67	72.67	0.83	159.33	88.67	370	393.97	
	Week 4/ ECG #1	24FEB2016/ 12:26	74	74	0.81	162	90	346	370.79	R Loss In V2, NCS
	Week 4/ ECG #2	24FEB2016/ 12:28	75	75	0.8	158	88	378	406.89	R Loss In V2, NCS
	Week 4/ ECG #3	24FEB2016/ 12:30	69	69	0.87	158	88	386	404.22	R Loss In V2 Sinusarhythmie, NCS
	Week 6/ Average	09MAR2016	60.67	60.67	0.99	153.33	90.67	398	399.45	
	Week 6/ ECG #1	09MAR2016/ 10:44	61	61	0.98	152	88	396	398.17	Sinusarhythmie, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-010	Week 6/ ECG #2	09MAR2016/ 10:47	60	60	1	152	92	398	398	
	Week 6/ ECG #3	09MAR2016/ 10:49	61	61	0.98	156	92	400	402.19	
	Week 8/ Average	22MAR2016	74.67	74.67	0.8	164	93.33	384	412.66	
	Week 8/ ECG #1	22MAR2016/ 8:25	73	73	0.82	164	94	380	405.41	
	Week 8/ ECG #2	22MAR2016/ 8:27	78	78	0.77	164	92	380	414.37	
	Week 8/ ECG #3	22MAR2016/ 8:29	73	73	0.82	164	94	392	418.21	
	Week 12/ Average	19APR2016	63	63	0.95	142	85.33	380.67	386.77	
	Week 12/ ECG #1	19APR2016/ 12:19	61	61	0.98	136	86	370	372.02	
	Week 12/ ECG #2	19APR2016/ 12:21	61	61	0.98	144	86	390	392.13	R Loss In V2, NCS
	Week 12/ ECG #3	19APR2016/ 12:24	67	67	0.9	146	84	382	396.17	Sinusrhythmic R Loss In V2, NCS
	Week 16/ Average	17MAY2016	64.67	64.67	0.93	156	90	388.67	398.32	
	Week 16/ ECG #1	17MAY2016/ 12:30	62	62	0.97	156	92	394	398.29	R Loss In V2, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-010	Week 16/ ECG #2	17MAY2016/ 12:32	67	67	0.9	150	90	388	402.39	Sinusarrhythmie, NCS
	Week 16/ ECG #3	17MAY2016/ 12:35	65	65	0.92	162	88	384	394.28	
	Week 20/ Average	20JUN2016	57.67	57.67	1.04	138.67	89.33	411.33	405.88	
	Week 20/ ECG #1	20JUN2016/ 12:00	60	60	1	136	88	400	400	Sinusbradycardia Sinusarrhythmia, NCS
	Week 20/ ECG #2	20JUN2016/ 12:02	57	57	1.05	140	90	422	414.92	
	Week 20/ ECG #3	20JUN2016/ 12:04	56	56	1.07	140	90	412	402.73	
	Week 24/ Average	12JUL2016	71	71	0.85	152.67	89.33	377.33	398.84	
	Week 24/ ECG #1	12JUL2016/ 11:36	67	67	0.9	152	90	372	385.8	
	Week 24/ ECG #2	12JUL2016/ 11:38	71	71	0.85	152	90	382	403.82	
	Week 24/ ECG #3	12JUL2016/ 11:40	75	75	0.8	154	88	378	406.89	
	Week 28/ Average	08AUG2016	68.33	68.33	0.88	156	89.33	382	398.56	
	Week 28/ ECG #1	08AUG2016/ 11:40	63	63	0.95	150	90	382	388.2	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-010	Week 28/ ECG #2	08AUG2016/ 11:42	69	69	0.87	158	90	386	404.22	
	Week 28/ ECG #3	08AUG2016/ 11:45	73	73	0.82	160	88	378	403.27	Sinusarrythmia, NCS
	Week 32/ Average	06SEP2016	62.33	62.33	0.96	152.67	92	398	402.99	
	Week 32/ ECG #1	06SEP2016/ 11:35	64	64	0.94	150	92	390	398.4	Sinusarryhtmia, NCS
	Week 32/ ECG #2	06SEP2016/ 11:38	62	62	0.97	152	92	402	406.37	
	Week 32/ ECG #3	06SEP2016/ 11:41	61	61	0.98	156	92	402	404.2	
	Week 36/ Average	04OCT2016	65.33	65.33	0.92	151.33	90.67	390.67	401.79	
	Week 36/ ECG #1	04OCT2016/ 11:03	63	63	0.95	146	90	388	394.3	
	Week 36/ ECG #2	04OCT2016/ 11:06	67	67	0.9	154	92	392	406.54	
	Week 36/ ECG #3	04OCT2016/ 11:08	66	66	0.91	154	90	392	404.53	Sinusarrythmia, NCS
	Week 40/ Average	01NOV2016	60	60	1	148	90.67	407.33	407.3	
	Week 40/ ECG #1	01NOV2016/ 11:27	61	61	0.98	144	90	400	402.19	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-010	Week 40/ ECG #2	01NOV2016/ 11:29	59	59	1.02	146	94	416	413.7	Sinusbradycardia, sinusarrhythmia, NCS
	Week 40/ ECG #3	01NOV2016/ 11:31	60	60	1	154	88	406	406	
	Week 44/ Average	28NOV2016	64.33	64.33	0.94	152	94	393.33	402.42	
	Week 44/ ECG #1	28NOV2016/ 11:17	64	64	0.94	150	94	380	388.18	
	Week 44/ ECG #2	28NOV2016/ 11:19	62	62	0.97	152	94	404	408.4	
	Week 44/ ECG #3	28NOV2016/ 11:21	67	67	0.9	154	94	396	410.69	
	Week 48/ Average	03JAN2017	73	73	0.83	152.67	88	374	398.95	
	Week 48/ ECG #1	03JAN2017/ 12:21	70	70	0.86	150	88	364	383	
	Week 48/ ECG #2	03JAN2017/ 12:23	79	79	0.76	156	88	380	416.11	
	Week 48/ ECG #3	03JAN2017/ 12:25	70	70	0.86	152	88	378	397.73	
301-014	Screening/ Average	27JAN2016	79	79	0.76	145.33	86.67	384.67	421.19	
	Screening/ ECG #1	27JAN2016/ 13:16	78	78	0.77	142	88	388	423.09	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-014	Screening/ ECG #2	27JAN2016/ 13:18	78	78	0.77	144	86	386	420.91	
	Screening/ ECG #3	27JAN2016/ 13:20	81	81	0.74	150	86	380	419.56	
	Day 1/ Average	23FEB2016	71	71	0.85	156	91.33	405.33	428.24	
	Day 1/ ECG #1	23FEB2016/ 11:07	66	66	0.91	154	90	414	427.23	
	Day 1/ ECG #2	23FEB2016/ 11:09	72	72	0.83	156	92	402	426.93	
	Day 1/ ECG #3	23FEB2016/ 11:11	75	75	0.8	158	92	400	430.57	
	Week 1/ Average	01MAR2016	74	74	0.81	152	85.33	395.33	423.6	
	Week 1/ ECG #1	01MAR2016/ 10:50	71	71	0.85	152	84	394	416.51	
	Week 1/ ECG #2	01MAR2016/ 10:54	74	74	0.81	150	88	400	428.66	
	Week 1/ ECG #3	01MAR2016/ 10:56	77	77	0.78	154	84	392	425.64	
	Week 2/ Average	09MAR2016	72	72	0.83	154.67	95.33	394	418.36	
	Week 2/ ECG #1	09MAR2016/ 10:27	69	69	0.87	150	94	396	414.69	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-014	Week 2/ ECG #2	09MAR2016/ 10:29	72	72	0.83	158	96	394	418.43	
	Week 2/ ECG #3	09MAR2016/ 10:31	75	75	0.8	156	96	392	421.96	
	Week 4/ Average	22MAR2016	72.33	72.33	0.83	150.67	89.33	396.67	421.88	
	Week 4/ ECG #1	22MAR2016/ 9:37	72	72	0.83	150	88	400	424.81	
	Week 4/ ECG #2	22MAR2016/ 9:39	71	71	0.85	150	90	398	420.73	
	Week 4/ ECG #3	22MAR2016/ 9:41	74	74	0.81	152	90	392	420.09	
	Week 6/ Average	05APR2016	81	81	0.74	141.33	88.67	376.67	415.89	
	Week 6/ ECG #1	05APR2016/ 11:41	79	79	0.76	138	90	368	402.97	
	Week 6/ ECG #2	05APR2016/ 11:43	83	83	0.72	144	86	378	420.72	
	Week 6/ ECG #3	05APR2016/ 11:45	81	81	0.74	142	90	384	423.98	
	Week 8/ Average	20APR2016	75.33	75.33	0.8	154	98	400.67	431.83	
	Week 8/ ECG #1	20APR2016/ 9:03	72	72	0.83	156	94	406	431.18	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-014	Week 8/ ECG #2	20APR2016/ 9:05	77	77	0.78	150	100	396	429.98	
	Week 8/ ECG #3	20APR2016/ 9:08	77	77	0.78	156	100	400	434.32	
	Week 12/ Average	19MAY2016	84.33	84.33	0.71	139.33	90.67	379.33	424.39	
	Week 12/ ECG #1	19MAY2016/ 11:29	80	80	0.75	138	90	378	415.64	
	Week 12/ ECG #2	19MAY2016/ 11:31	87	87	0.69	136	90	384	434.09	
	Week 12/ ECG #3	19MAY2016/ 11:33	86	86	0.7	144	92	376	423.43	
	Week 16/ Average	14JUN2016	82.33	82.33	0.73	142	93.33	377.33	418.83	
	Week 16/ ECG #1	14JUN2016/ 11:01	80	80	0.75	140	94	378	415.64	
	Week 16/ ECG #2	14JUN2016/ 11:03	85	85	0.71	142	92	376	421.8	
	Week 16/ ECG #3	14JUN2016/ 11:06	82	82	0.73	144	94	378	419.04	
	Week 20/ Average	13JUL2016	83.33	83.33	0.72	145.33	90.67	380	423.51	
	Week 20/ ECG #1	13JUL2016/ 10:29	82	82	0.73	144	92	378	419.04	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-014	Week 20/ ECG #2	13JUL2016/ 10:31	84	84	0.71	146	90	382	426.86	
	Week 20/ ECG #3	13JUL2016/ 10:33	84	84	0.71	146	90	380	424.63	
	Week 24/ Average	10AUG2016	75.67	75.67	0.79	148	90.67	396.67	428.22	
	Week 24/ ECG #1	10AUG2016/ 10:20	74	74	0.81	146	90	394	422.23	
	Week 24/ ECG #2	10AUG2016/ 10:22	76	76	0.79	150	90	400	432.45	
	Week 24/ ECG #3	10AUG2016/ 10:24	77	77	0.78	148	92	396	429.98	
	Week 28/ Average	07SEP2016	85.33	85.33	0.7	144	88	381.33	428.22	
	Week 28/ ECG #1	07SEP2016/ 11:03	80	80	0.75	144	88	382	420.04	
	Week 28/ ECG #2	07SEP2016/ 11:05	89	89	0.67	142	88	378	430.53	
	Week 28/ ECG #3	07SEP2016/ 11:07	87	87	0.69	146	88	384	434.09	
	Week 32/ Average	05OCT2016	84.33	84.33	0.71	146.67	85.33	385.33	431.02	
	Week 32/ ECG #1	05OCT2016/ 10:57	89	89	0.67	146	84	382	435.08	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-014	Week 32/ ECG #2	05OCT2016/ 11:01	84	84	0.71	146	84	386	431.33	
	Week 32/ ECG #3	05OCT2016/ 11:04	80	80	0.75	148	88	388	426.64	
	Week 36/ Average	02NOV2016	69.67	69.67	0.86	150.67	87.33	412.67	433.52	
	Week 36/ ECG #1	02NOV2016/ 10:05	69	69	0.87	148	86	404	423.07	
	Week 36/ ECG #2	02NOV2016/ 10:07	69	69	0.87	150	88	418	437.73	
	Week 36/ ECG #3	02NOV2016/ 10:09	71	71	0.85	154	88	416	439.76	
	Week 40/ Average	30NOV2016	70.67	70.67	0.85	147.33	86	400.67	422.94	
	Week 40/ ECG #1	30NOV2016/ 11:30	68	68	0.88	140	86	388	404.36	
	Week 40/ ECG #2	30NOV2016/ 11:32	70	70	0.86	148	86	404	425.08	
	Week 40/ ECG #3	30NOV2016/ 11:34	74	74	0.81	154	86	410	439.38	
	Week 44/ Average	22DEC2016	96.67	96.67	0.62	138.67	80.67	348	407.31	
	Week 44/ ECG #1	22DEC2016/ 11:27	94	94	0.64	136	80	344	398.93	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-014	Week 44/ ECG #2	22DEC2016/ 11:29	99	99	0.61	138	82	350	412.89	
	Week 44/ ECG #3	22DEC2016/ 11:31	97	97	0.62	142	80	350	410.12	
	Week 48/ Average	25JAN2017	82.67	82.67	0.73	144.67	86	386	429.04	
	Week 48/ ECG #1	25JAN2017/ 10:09	79	79	0.76	144	88	380	416.11	
	Week 48/ ECG #2	25JAN2017/ 10:11	86	86	0.7	146	84	388	436.94	
	Week 48/ ECG #3	25JAN2017/ 10:13	83	83	0.72	144	86	390	434.08	
	Screening/ Average	03FEB2016	79.67	79.67	0.75	138	95.33	374.67	411.29	
301-016	Screening/ ECG #1	03FEB2016/ 13:32	83	83	0.72	136	94	366	407.37	
	Screening/ ECG #2	03FEB2016/ 13:33	80	80	0.75	136	94	380	417.84	
	Screening/ ECG #3	03FEB2016/ 13:36	76	76	0.79	142	98	378	408.67	
	Day 1/ Average	25FEB2016	81	81	0.74	156.67	100.67	368	406.27	
	Day 1/ ECG #1	25FEB2016/ 11:36	80	80	0.75	152	104	370	406.85	S Persistence Until V6, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-016	Day 1/ ECG #2	25FEB2016/ 11:38	84	84	0.71	162	96	366	408.98	S Persistence Until V6, NCS
	Day 1/ ECG #3	25FEB2016/ 11:40	79	79	0.76	156	102	368	402.97	S Persistence Until V6, NCS
	Week 1/ Average	02MAR2016	91.33	91.33	0.66	151.33	93.33	354.67	407.4	
	Week 1/ ECG #1	02MAR2016/ 11:17	91	91	0.66	150	92	348	399.28	Hesitant R-Progression V1-V6, NCS
	Week 1/ ECG #2	02MAR2016/ 11:19	89	89	0.67	152	94	358	407.75	Hesitant R-Progression V1-V6, NCS
	Week 1/ ECG #3	02MAR2016/ 11:21	94	94	0.64	152	94	358	415.17	Hesitant R-Progression V1-V6, NCS
	Week 2/ Average	08MAR2016	94.67	94.67	0.64	152	96	363.33	422.31	
	Week 2/ ECG #1	08MAR2016/ 10:49	93	93	0.65	150	92	368	425.26	Hesitant R-Progression V1-V6, NCS
	Week 2/ ECG #2	08MAR2016/ 10:50	95	95	0.63	152	104	366	425.93	Hesitant R-Progression V1-V6, NCS
	Week 2/ ECG #3	08MAR2016/ 10:51	96	96	0.63	154	92	356	415.73	Hesitant R-Progression V1-V6, NCS
	Week 4/ Average	24MAR2016	88.33	88.33	0.68	156	98.67	372	422.62	
	Week 4/ ECG #1	24MAR2016/ 11:28	89	89	0.67	156	96	370	421.42	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-016	Week 4/ ECG #2	24MAR2016/ 11:30	90	90	0.67	156	100	372	425.26	
	Week 4/ ECG #3	24MAR2016/ 11:32	86	86	0.7	156	100	374	421.18	
	Week 6/ Average	07APR2016	90.33	90.33	0.67	151.33	93.33	372	425.78	
	Week 6/ ECG #1	07APR2016/ 11:02	90	90	0.67	150	92	372	425.26	
	Week 6/ ECG #2	07APR2016/ 11:04	91	91	0.66	152	92	372	426.81	
	Week 6/ ECG #3	07APR2016/ 11:06	90	90	0.67	152	96	372	425.26	
	Week 8/ Average	19APR2016	83.33	83.33	0.72	131.33	92.67	366	407.92	
	Week 8/ ECG #1	19APR2016/ 8:47	82	82	0.73	130	88	360	399.09	Right Axis Deviation Ascending St-Track Ii,iii And Avf, NCS
	Week 8/ ECG #2	19APR2016/ 8:50	85	85	0.71	130	94	372	417.31	Ascending St-Track V3, NCS
	Week 8/ ECG #3	19APR2016/ 8:52	83	83	0.72	134	96	366	407.37	
	Week 12/ Average	24MAY2016	91	91	0.66	150.67	100	376	431.37	
	Week 12/ ECG #1	24MAY2016/ 11:49	93	93	0.65	150	102	374	432.2	Right Axis Deviation Negative T Waves Iii, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-016	Week 12/ ECG #2	24MAY2016/ 11:52	88	88	0.68	152	100	376	426.66	
	Week 12/ ECG #3	24MAY2016/ 11:54	92	92	0.65	150	98	378	435.26	
	Week 16/ Average	14JUN2016	86.67	86.67	0.69	141.33	104	385.33	435.05	
	Week 16/ ECG #1	14JUN2016/ 10:18	85	85	0.71	138	102	382	428.53	Late R / S Alteration In V4-V5, NCS
	Week 16/ ECG #2	14JUN2016/ 10:20	88	88	0.68	142	104	386	438	
	Week 16/ ECG #3	14JUN2016/ 10:23	87	87	0.69	144	106	388	438.61	
	Week 20/ Average	13JUL2016	84.67	84.67	0.71	134.67	91.33	366	410.01	
	Week 20/ ECG #1	13JUL2016/ 11:10	86	86	0.7	134	90	358	403.16	
	Week 20/ ECG #2	13JUL2016/ 11:12	85	85	0.71	136	92	368	412.83	
	Week 20/ ECG #3	13JUL2016/ 11:14	83	83	0.72	134	92	372	414.05	
	Week 24/ Average	28JUL2016	68.67	68.67	0.88	138.67	96.67	394.67	411.88	
	Week 24/ ECG #1	28JUL2016/ 10:37	79	79	0.76	134	102	386	422.68	Hesitant R - Progression Ekg V1-V6, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-016	Week 24/ ECG #2	28JUL2016/ 10:39	65	65	0.92	140	94	394	404.55	
	Week 24/ ECG #3	28JUL2016/ 10:42	62	62	0.97	142	94	404	408.4	Sinusarrythmia Hesitant R - Progression Ekg V1-V6, NCS
	Week 28/ Average	06SEP2016	88	88	0.68	142.67	96	380.67	431.86	
	Week 28/ ECG #1	06SEP2016/ 9:41	90	90	0.67	138	96	380	434.4	Right Axis Deviation, NCS
	Week 28/ ECG #2	06SEP2016/ 9:43	83	83	0.72	140	96	382	425.18	Right Axis Deviation, NCS
	Week 28/ ECG #3	06SEP2016/ 9:45	91	91	0.66	150	96	380	435.99	Right Axis Deviation, NCS
	Week 32/ Average	05OCT2016	89.67	89.67	0.67	152.67	94.67	373.33	426.26	
	Week 32/ ECG #1	05OCT2016/ 9:40	89	89	0.67	150	96	372	423.69	Right Axis Deviation, NCS
	Week 32/ ECG #2	05OCT2016/ 9:43	90	90	0.67	154	94	376	429.83	Right Axis Deviation, NCS
	Week 32/ ECG #3	05OCT2016/ 9:45	90	90	0.67	154	94	372	425.26	Right Axis Deviation, NCS
	Week 36/ Average	02NOV2016	83.67	83.67	0.72	154.67	100.67	370	412.78	
	Week 36/ ECG #1	02NOV2016/ 11:18	88	88	0.68	152	96	364	413.04	Right Axis Deviation, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-016	Week 36/ ECG #2	02NOV2016/ 11:20	83	83	0.72	156	100	372	414.05	Right Axis Deviation, NCS
	Week 36/ ECG #3	02NOV2016/ 11:22	80	80	0.75	156	106	374	411.25	Right Axis Deviation, NCS
	Week 40/ Average	29NOV2016	90	90	0.67	153.33	97.33	366.67	418.96	
	Week 40/ ECG #1	29NOV2016/ 10:14	96	96	0.63	152	94	360	420.4	Delayed Rs Progression, NCS
	Week 40/ ECG #2	29NOV2016/ 10:16	88	88	0.68	154	98	366	415.31	Right Axis Deviation, NCS
	Week 40/ ECG #3	29NOV2016/ 10:18	86	86	0.7	154	100	374	421.18	Right Axis Deviation, NCS
	Week 44/ Average	21DEC2016	78.67	78.67	0.76	156	96	383.33	419.14	
	Week 44/ ECG #1	21DEC2016/ 10:30	80	80	0.75	156	94	374	411.25	
	Week 44/ ECG #2	21DEC2016/ 10:33	79	79	0.76	158	96	388	424.87	
	Week 44/ ECG #3	21DEC2016/ 10:35	77	77	0.78	154	98	388	421.29	Right Axis Deviation, NCS
	Week 48/ Average	24JAN2017	87.33	87.33	0.69	151.33	91.33	355.33	402.17	
	Week 48/ ECG #1	24JAN2017/ 10:27	89	89	0.67	150	90	354	403.19	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular	Heart	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
			Rate (cycles/ minute)	Rate (beats/ minute)						
301-016	Week 48/ ECG #2	24JAN2017/ 10:29	86	86	0.7	152	92	360	405.41	
	Week 48/ ECG #3	24JAN2017/ 10:31	87	87	0.69	152	92	352	397.92	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-015	Screening/ Average	02FEB2016	60	60	1	180	88	416	415.9	
	Screening/ ECG #1	02FEB2016/ 14:01	57	57	1.05	178	88	418	410.98	Sinus Bradycardia, NCS
	Screening/ ECG #2	02FEB2016/ 14:03	60	60	1	182	88	416	416	
	Screening/ ECG #3	02FEB2016/ 14:05	63	63	0.95	180	88	414	420.72	
	Day 1/ Average	23FEB2016	69	69	0.87	185.33	92.67	408	427.27	
	Day 1/ ECG #1	23FEB2016/ 12:01	70	70	0.86	178	96	416	437.71	
	Day 1/ ECG #2	23FEB2016/ 12:04	68	68	0.88	192	90	404	421.04	
	Day 1/ ECG #3	23FEB2016/ 12:06	69	69	0.87	186	92	404	423.07	
	Week 1/ Average	03MAR2016	57.33	57.33	1.04	178.67	93.33	420.67	414.37	
	Week 1/ ECG #1	03MAR2016/ 11:27	58	58	1.03	180	94	414	409.39	Sinus Bradycardia, NCS
	Week 1/ ECG #2	03MAR2016/ 11:29	56	56	1.07	178	94	426	416.41	Sinus Bradycardia, NCS
	Week 1/ ECG #3	03MAR2016/ 11:30	58	58	1.03	178	92	422	417.31	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-015	Week 2/ Average	08MAR2016	62	62	0.97	180.67	96	404.67	409.04	
	Week 2/ ECG #1	08MAR2016/ 10:01	62	62	0.97	184	96	402	406.37	
	Week 2/ ECG #2	08MAR2016/ 10:03	64	64	0.94	186	96	406	414.74	
	Week 2/ ECG #3	08MAR2016/ 10:04	60	60	1	172	96	406	406	
	Week 4/ Average	23MAR2016	58	58	1.03	183.33	93.33	407.33	402.8	
	Week 4/ ECG #1	23MAR2016/ 11:24	58	58	1.03	182	94	410	405.44	Sinus Bradycardia, NCS
	Week 4/ ECG #2	23MAR2016/ 11:27	58	58	1.03	184	94	402	397.53	Sinus Bradycardia, NCS
	Week 4/ ECG #3	23MAR2016/ 11:30	58	58	1.03	184	92	410	405.44	Sinus Bradycardia, NCS
	Week 6/ Average	06APR2016	57	57	1.05	185.33	96.67	424.67	417.54	
	Week 6/ ECG #1	06APR2016/ 11:20	57	57	1.05	178	98	426	418.85	Sinus Bradycardia, NCS
	Week 6/ ECG #2	06APR2016/ 11:22	57	57	1.05	190	96	424	416.88	Sinus Bradycardia, NCS
	Week 6/ ECG #3	06APR2016/ 11:24	57	57	1.05	188	96	424	416.88	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-015	Week 8/ Average	20APR2016	53.67	53.67	1.12	181.33	97.33	432.67	417.02	
	Week 8/ ECG #1	20APR2016/ 8:53	54	54	1.11	174	98	430	415.31	Sinus Bradycardia, NCS
	Week 8/ ECG #2	20APR2016/ 8:55	54	54	1.11	190	98	432	417.24	Sinus Bradycardia, NCS
	Week 8/ ECG #3	20APR2016/ 8:57	53	53	1.13	180	96	436	418.51	Sinus Bradycardia, NCS
	Week 12/ Average	17MAY2016	53	53	1.13	179.33	97.33	425.33	408.27	
	Week 12/ ECG #1	17MAY2016/ 11:32	53	53	1.13	180	98	426	408.91	Sinus Bradycardia, NCS
	Week 12/ ECG #2	17MAY2016/ 11:35	53	53	1.13	180	96	426	408.91	Sinus Bradycardia, NCS
	Week 12/ ECG #3	17MAY2016/ 11:38	53	53	1.13	178	98	424	406.99	Sinus Bradycardia, NCS
	Week 16/ Average	16JUN2016	54	54	1.11	179.33	95.33	427.33	412.57	
	Week 16/ ECG #1	16JUN2016/ 11:41	57	57	1.05	178	96	418	410.98	Sinus Bradycardia, NCS
	Week 16/ ECG #2	16JUN2016/ 11:43	53	53	1.13	180	96	430	412.75	Sinus Bradycardia, NCS
	Week 16/ ECG #3	16JUN2016/ 11:45	52	52	1.15	180	94	434	413.98	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-015	Week 20/ Average	14JUL2016	50.33	50.33	1.19	196	99.33	438.67	413.83	
	Week 20/ ECG #1	14JUL2016/ 11:27	53	53	1.13	198	98	434	416.59	Sinusbradycardia, NCS
	Week 20/ ECG #2	14JUL2016/ 11:29	50	50	1.2	186	100	438	412.42	Sinusbradycardia, NCS
	Week 20/ ECG #3	14JUL2016/ 11:31	48	48	1.25	204	100	444	412.48	Sinusbradycardia, NCS
	Week 24/ Average	10AUG2016	51.33	51.33	1.17	181.33	90.67	426	404.6	
	Week 24/ ECG #1	10AUG2016/ 10:04	52	52	1.15	178	92	418	398.72	Sinusbradycardia, NCS
	Week 24/ ECG #2	10AUG2016/ 10:06	51	51	1.18	186	90	426	403.75	Sinusbradycardia, NCS
	Week 24/ ECG #3	10AUG2016/ 10:15	51	51	1.18	180	90	434	411.34	Sinusbradycarida, NCS
	Week 28/ Average	07SEP2016	52.33	52.33	1.15	176.67	88	447.33	427.56	
	Week 28/ ECG #1	07SEP2016/ 10:09	52	52	1.15	172	88	438	417.8	Sinusbradycardia, NCS
	Week 28/ ECG #2	07SEP2016/ 10:11	54	54	1.11	178	88	448	432.69	Sinusbradycardia, NCS
	Week 28/ ECG #3	07SEP2016/ 10:13	51	51	1.18	180	88	456	432.19	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-015	Week 40/ Average	30NOV2016	58	58	1.04	172	91.33	430.67	425.78	
	Week 40/ ECG #1	30NOV2016/ 10:34	59	59	1.02	178	90	416	413.7	Sinusbradycardia, NCS
	Week 40/ ECG #2	30NOV2016/ 10:36	59	59	1.02	168	92	434	431.6	Sinusbradycardia, NCS
	Week 40/ ECG #3	30NOV2016/ 10:38	56	56	1.07	170	92	442	432.05	Sinusbradycardia, NCS
	Week 44/ Average	28DEC2016	55	55	1.09	178	92	432.67	420.33	
	Week 44/ ECG #1	28DEC2016/ 11:41	54	54	1.11	172	92	434	419.17	Sinusbradycardia, NCS
	Week 44/ ECG #2	28DEC2016/ 11:45	58	58	1.03	182	92	430	425.22	Snusbradycardia, NCS
	Week 44/ ECG #3	28DEC2016/ 11:47	53	53	1.13	180	92	434	416.59	Sinusbradycardia, NCS
	Week 48/ Average	26JAN2017	58	58	1.04	174.67	90	418.67	413.94	
	Week 48/ ECG #1	26JAN2017/ 12:06	59	59	1.02	172	90	410	407.73	Sinusbradycardia T-Neg.In Avl, NCS
	Week 48/ ECG #2	26JAN2017/ 12:08	59	59	1.02	174	90	420	417.68	Sinusbradycardia T-Neg. In Avl, NCS
	Week 48/ ECG #3	26JAN2017/ 12:10	56	56	1.07	178	90	426	416.41	Sinusbradycardia T-Neg In Avl, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-018	Screening/ Average	17FEB2016	60	60	1	142	98.67	424	423.96	
	Screening/ ECG #1	17FEB2016/ 12:48	61	61	0.98	138	102	420	422.3	
	Screening/ ECG #2	17FEB2016/ 12:49	61	61	0.98	150	96	426	428.33	
	Screening/ ECG #3	17FEB2016/ 12:50	58	58	1.03	138	98	426	421.26	Sinus Bradycardia, NCS
	Day 1/ Average	09MAR2016	65.33	65.33	0.92	138.67	99.33	407.33	418.94	
	Day 1/ ECG #1	09MAR2016/ 9:45	65	65	0.92	136	100	404	414.81	Q In Iii And Avf, NCS
	Day 1/ ECG #2	09MAR2016/ 9:47	66	66	0.91	138	100	408	421.04	Q Iii And Avf, NCS
	Day 1/ ECG #3	09MAR2016/ 9:49	65	65	0.92	142	98	410	420.97	Q In Iii And Avf, NCS
	Week 1/ Average	16MAR2016	65.67	65.67	0.91	140	100	404	416.22	
	Week 1/ ECG #1	16MAR2016/ 10:49	65	65	0.92	140	102	400	410.71	
	Week 1/ ECG #2	16MAR2016/ 10:51	66	66	0.91	138	100	406	418.97	
	Week 1/ ECG #3	16MAR2016/ 10:53	66	66	0.91	142	98	406	418.97	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-018	Week 2/ Average	23MAR2016	63	63	0.95	138.67	100.67	416	422.75	
	Week 2/ ECG #1	23MAR2016/ 9:24	61	61	0.98	142	98	410	412.24	
	Week 2/ ECG #2	23MAR2016/ 9:26	65	65	0.92	136	102	418	429.19	Prematurely Supraventricular Complex, NCS
	Week 2/ ECG #3	23MAR2016/ 9:28	63	63	0.95	138	102	420	426.82	Prematurely Supraventricular Complex, NCS
	Week 4/ Average	06APR2016	61	61	0.98	143.33	98	418	420.27	
	Week 4/ ECG #1	06APR2016/ 10:04	61	61	0.98	142	94	416	418.28	
	Week 4/ ECG #2	06APR2016/ 10:06	60	60	1	142	100	422	422	
	Week 4/ ECG #3	06APR2016/ 10:08	62	62	0.97	146	100	416	420.53	Prematurely Supraventricular Complex, NCS
	Week 6/ Average	21APR2016	61.33	61.33	0.98	141.33	102	417.33	420.36	
	Week 6/ ECG #1	21APR2016/ 9:54	62	62	0.97	140	100	412	416.48	
	Week 6/ ECG #2	21APR2016/ 9:56	61	61	0.98	142	102	420	422.3	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-018	Week 6/ ECG #3	21APR2016/ 9:58	61	61	0.98	142	104	420	422.3	
	Week 8/ Average	28APR2016	58	58	1.03	142	102	422	417.27	
	Week 8/ ECG #1	28APR2016/ 9:34	60	60	1	140	104	420	420	
	Week 8/ ECG #2	28APR2016/ 9:36	57	57	1.05	142	102	422	414.92	Sinus Bradycardia, NCS
	Week 8/ ECG #3	28APR2016/ 9:38	57	57	1.05	144	100	424	416.88	Prematurely Supraventricular Complex Sinusbradycardia, NCS
	Week 12/ Average	01JUN2016	60.33	60.33	1	140	98.67	410.67	411.22	
	Week 12/ ECG #1	01JUN2016/ 8:26	64	64	0.94	140	96	400	408.61	
	Week 12/ ECG #2	01JUN2016/ 8:29	60	60	1	138	100	418	418	Prematurely Atrial Complex, NCS
	Week 12/ ECG #3	01JUN2016/ 8:34	57	57	1.05	142	100	414	407.05	Sinus Bradycardia, NCS
	Week 16/ Average	29JUN2016	61	61	0.99	141.33	105.33	427.33	429.65	
	Week 16/ ECG #1	29JUN2016/ 9:35	62	62	0.97	140	104	426	430.63	Q In Iii+avf, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-018	Week 16/ ECG #2	29JUN2016/ 9:37	59	59	1.02	142	106	426	423.64	Sinus Bradicardia Disturbance Of Repolarization And Q Iii+ Avf, NCS
	Week 16/ ECG #3	29JUN2016/ 9:40	62	62	0.97	142	106	430	434.68	Disturbance Of Repolarization Iii And Avf, NCS
	Week 20/ Average	27JUL2016	65.33	65.33	0.92	130.67	100.67	420	431.94	
	Week 20/ ECG #1	27JUL2016/ 9:25	66	66	0.91	134	102	418	431.36	Q In Ii+iii+avf, NCS
	Week 20/ ECG #2	27JUL2016/ 9:27	67	67	0.9	118	100	422	437.65	Q In Ii,iii, Avf,v5+v6 Short Pq Time, NCS
	Week 20/ ECG #3	27JUL2016/ 9:29	63	63	0.95	140	100	420	426.82	Q In Ii,iii, Avf, NCS
	Week 24/ Average	23AUG2016	57	57	1.05	144.67	102.67	422.67	415.4	
	Week 24/ ECG #1	23AUG2016/ 9:24	61	61	0.98	144	102	418	420.29	St Depression Inferiorer Infact, NCS
	Week 24/ ECG #2	23AUG2016/ 9:26	54	54	1.11	146	102	424	409.51	Sinusbradycardia With Premature Atrial Complexes, NCS
	Week 24/ ECG #3	23AUG2016/ 9:28	56	56	1.07	144	104	426	416.41	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-018	Week 28/ Average	20SEP2016	70.67	70.67	0.85	136.67	96.67	406.67	429.08	
	Week 28/ ECG #1	20SEP2016/ 9:26	65	65	0.92	136	96	406	416.87	
	Week 28/ ECG #2	20SEP2016/ 9:33	75	75	0.8	136	98	408	439.18	
	Week 28/ ECG #3	20SEP2016/ 9:35	72	72	0.83	138	96	406	431.18	
	Week 32/ Average	18OCT2016	61.67	61.67	0.97	144	98.67	414	417.69	
	Week 32/ ECG #1	18OCT2016/ 9:52	59	59	1.02	146	98	412	409.72	Sinusbradycardia, NCS
	Week 32/ ECG #2	18OCT2016/ 9:54	65	65	0.92	142	98	414	425.08	
	Week 32/ ECG #3	18OCT2016/ 9:56	61	61	0.98	144	100	416	418.28	
	Week 36/ Average	15NOV2016	59.33	59.33	1.01	143.33	95.33	415.33	413.69	
	Week 36/ ECG #1	15NOV2016/ 10:06	55	55	1.09	140	96	412	400.34	Sinusarryhtmia Sinusbradycardia Q In V5+v6,i,ii And Avf, NCS
	Week 36/ ECG #2	15NOV2016/ 10:08	63	63	0.95	148	92	414	420.72	Q In Ii, Iii, Avf, V5+v6, NCS
	Week 36/ ECG #3	15NOV2016/ 10:10	60	60	1	142	98	420	420	Q In Ii,iii, Avr, V5+v6, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-018	Week 40/ Average	13DEC2016	65.33	65.33	0.92	138.67	96	411.33	423.05	
	Week 40/ ECG #1	13DEC2016/ 10:47	64	64	0.94	136	96	412	420.87	
	Week 40/ ECG #2	13DEC2016/ 10:50	66	66	0.91	140	96	408	421.04	
	Week 40/ ECG #3	13DEC2016/ 10:52	66	66	0.91	140	96	414	427.23	
	Week 44/ Average	10JAN2017	60.67	60.67	0.99	138	94	416	417.53	
	Week 44/ ECG #1	10JAN2017/ 10:26	60	60	1	138	94	410	410	
	Week 44/ ECG #2	10JAN2017/ 10:28	61	61	0.98	136	96	420	422.3	
	Week 44/ ECG #3	10JAN2017/ 10:31	61	61	0.98	140	92	418	420.29	
	Week 48/ Average	07FEB2017	61.67	61.67	0.97	136.67	97.33	422	425.78	
	Week 48/ ECG #1	07FEB2017/ 9:23	63	63	0.95	134	100	414	420.72	
	Week 48/ ECG #2	07FEB2017/ 9:25	60	60	1	138	96	426	426	
	Week 48/ ECG #3	07FEB2017/ 9:27	62	62	0.97	138	96	426	430.63	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-006	Screening/ Average	14JAN2016	68.33	68.33	0.88	150.67	104.67	416.67	434.9	
	Screening/ ECG #1	14JAN2016/ 14:51	68	68	0.88	148	106	410	427.29	
	Screening/ ECG #2	14JAN2016/ 14:53	71	71	0.85	150	104	420	443.99	
	Screening/ ECG #3	14JAN2016/ 14:55	66	66	0.91	154	104	420	433.42	
	Day 1/ Average	04FEB2016	73	73	0.82	144.67	105.33	404.67	431.71	
	Day 1/ ECG #1	04FEB2016/ 13:02	71	71	0.85	140	106	402	424.96	Incomplete Right Bundle Branch Block, NCS
	Day 1/ ECG #2	04FEB2016/ 13:04	73	73	0.82	148	104	406	433.14	Incomplete Right Bundle Branch Block, NCS
	Day 1/ ECG #3	04FEB2016/ 13:06	75	75	0.8	146	106	406	437.03	Incomplete Right Bundle Branch Block, NCS
	Week 1/ Average	10FEB2016	80	80	0.75	137.33	101.33	384	422.21	
	Week 1/ ECG #1	10FEB2016/ 11:47	77	77	0.78	134	102	384	416.95	Disturbance Of Repolarization Iii And Avf, NCS
	Week 1/ ECG #2	10FEB2016/ 11:49	81	81	0.74	138	102	384	423.98	
	Week 1/ ECG #3	10FEB2016/ 11:51	82	82	0.73	140	100	384	425.7	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-006	Week 2/ Average	16FEB2016	57.33	57.33	1.04	155.33	104.67	428.67	422.25	
	Week 2/ ECG #1	16FEB2016/ 13:06	58	58	1.03	150	104	412	407.42	Sinus Bradycardia, NCS
	Week 2/ ECG #2	16FEB2016/ 13:08	57	57	1.05	156	106	440	432.61	Sinus Bradycardia, NCS
	Week 2/ ECG #3	16FEB2016/ 13:10	57	57	1.05	160	104	434	426.72	Sinus Bradycardia, NCS
	Week 4/ Average	03MAR2016	65	65	0.92	151.33	107.33	415.33	426.42	
	Week 4/ ECG #1	03MAR2016/ 11:50	66	66	0.91	148	106	402	414.84	
	Week 4/ ECG #2	03MAR2016/ 11:52	65	65	0.92	152	108	428	439.46	
	Week 4/ ECG #3	03MAR2016/ 11:54	64	64	0.94	154	108	416	424.95	
	Week 6/ Average	17MAR2016	59	59	1.02	154.67	106.67	428.67	426.22	
	Week 6/ ECG #1	17MAR2016/ 11:24	60	60	1	154	106	408	408	
	Week 6/ ECG #2	17MAR2016/ 11:26	60	60	1	150	108	440	440	
	Week 6/ ECG #3	17MAR2016/ 11:29	57	57	1.05	160	106	438	430.65	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-006	Week 8/ Average	31MAR2016	58.67	58.67	1.02	152.67	107.33	437.33	433.88	
	Week 8/ ECG #1	31MAR2016/ 11:15	62	62	0.97	150	106	424	428.61	Sinus Arrhythmia, NCS
	Week 8/ ECG #2	31MAR2016/ 11:17	58	58	1.03	154	108	440	435.1	Sinus Bradycardia, NCS
	Week 8/ ECG #3	31MAR2016/ 11:19	56	56	1.07	154	108	448	437.92	Sinus Bradycardia, NCS
	Week 12/ Average	26APR2016	60.33	60.33	1	143.33	112	438	438.8	
	Week 12/ ECG #1	26APR2016/ 8:01	59	59	1.02	140	110	432	429.61	Negative T Waves Iii, NCS
	Week 12/ ECG #2	26APR2016/ 8:03	60	60	1	146	114	442	442	Negative T Waves, Iii, NCS
	Week 12/ ECG #3	26APR2016/ 8:05	62	62	0.97	144	112	440	444.79	Negative T Waves, Iii, NCS
	Week 16/ Average	25MAY2016	57.67	57.67	1.04	158	114	452.67	446.7	
	Week 16/ ECG #1	25MAY2016/ 11:49	59	59	1.02	156	114	456	453.48	Sinus Bradycardia, NCS
	Week 16/ ECG #2	25MAY2016/ 11:51	55	55	1.09	158	116	456	443.09	Sinus Bradycardia, NCS
	Week 16/ ECG #3	25MAY2016/ 11:55	59	59	1.02	160	112	446	443.53	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-006	Week 20/ Average	23JUN2016	65.33	65.33	0.92	147.33	106	412	423.66	
	Week 20/ ECG #1	23JUN2016/ 12:24	63	63	0.95	146	106	408	414.62	
	Week 20/ ECG #2	23JUN2016/ 12:26	64	64	0.94	144	106	418	427	
	Week 20/ ECG #3	23JUN2016/ 12:28	69	69	0.87	152	106	410	429.35	
	Week 24/ Average	19JUL2016	67.33	67.33	0.89	146	104.67	405.33	421.01	
	Week 24/ ECG #1	19JUL2016/ 11:10	68	68	0.88	142	106	396	412.7	
	Week 24/ ECG #2	19JUL2016/ 11:12	69	69	0.87	148	104	410	429.35	
	Week 24/ ECG #3	19JUL2016/ 11:15	65	65	0.92	148	104	410	420.97	
	Week 28/ Average	18AUG2016	63.33	63.33	0.95	145.33	102	420	427.56	
	Week 28/ ECG #1	18AUG2016/ 11:57	62	62	0.97	140	102	418	422.55	
	Week 28/ ECG #2	18AUG2016/ 11:59	63	63	0.95	148	102	420	426.82	
	Week 28/ ECG #3	18AUG2016/ 12:01	65	65	0.92	148	102	422	433.3	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-006	Week 32/ Average	13SEP2016	59.33	59.33	1.01	150	100	444.67	442.98	
	Week 32/ ECG #1	13SEP2016/ 11:07	58	58	1.03	148	100	438	433.13	Sinusbradycardia, NCS
	Week 32/ ECG #2	13SEP2016/ 11:09	58	58	1.03	148	100	452	446.97	Sinusbradycardia, NCS
	Week 32/ ECG #3	13SEP2016/ 11:11	62	62	0.97	154	100	444	448.83	
	Week 36/ Average	13OCT2016	62.33	62.33	0.96	148.67	98.67	413.33	418.55	
	Week 36/ ECG #1	13OCT2016/ 11:28	61	61	0.98	142	98	414	416.26	
	Week 36/ ECG #2	13OCT2016/ 11:30	63	63	0.95	150	96	410	416.65	
	Week 36/ ECG #3	13OCT2016/ 11:32	63	63	0.95	154	102	416	422.75	
	Week 40/ Average	08NOV2016	67.33	67.33	0.89	142.67	101.33	404	419.71	
	Week 40/ ECG #1	08NOV2016/ 11:16	65	65	0.92	142	100	392	402.49	
	Week 40/ ECG #2	08NOV2016/ 11:18	69	69	0.87	142	102	408	427.26	
	Week 40/ ECG #3	08NOV2016/ 11:20	68	68	0.88	144	102	412	429.37	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-006	Week 44/ Average	08DEC2016	73.33	73.33	0.82	136.67	100.67	397.33	424.53	
	Week 44/ ECG #1	08DEC2016/ 11:11	71	71	0.85	128	100	394	416.51	
	Week 44/ ECG #2	08DEC2016/ 11:13	76	76	0.79	138	102	402	434.61	
	Week 44/ ECG #3	08DEC2016/ 11:15	73	73	0.82	144	100	396	422.48	
	Week 48/ Average	04JAN2017	65.67	65.67	0.91	149.33	100	418	430.7	
	Week 48/ ECG #1	04JAN2017/ 11:17	63	63	0.95	148	98	402	408.52	
	Week 48/ ECG #2	04JAN2017/ 11:19	66	66	0.91	148	102	426	439.61	
	Week 48/ ECG #3	04JAN2017/ 11:21	68	68	0.88	152	100	426	443.96	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Heart Rate (cycles/ minute)	Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-017	Screening/ Average	17FEB2016	60.67	60.67	0.99	128	82.67	448	449.62	
	Screening/ ECG #1	17FEB2016/ 11:04	61	61	0.98	128	84	442	444.42	Ventricular Extrasystole Unspecified Disturbance Of Repolarization, NCS Disturbance Of Repolarization V2-3, NCS Disturbance Of Repolarization V2-3, NCS
	Screening/ ECG #2	17FEB2016/ 11:06	62	62	0.97	132	82	452	456.92	
	Screening/ ECG #3	17FEB2016/ 11:08	59	59	1.02	124	82	450	447.51	
	Day 1/ Average	08MAR2016	68.33	68.33	0.89	124.67	80.67	425.33	442.96	
	Day 1/ ECG #1	08MAR2016/ 9:42	59	59	1.02	122	82	442	439.56	Sinus Bradycardia, NCS
	Day 1/ ECG #2	08MAR2016/ 9:44	76	76	0.79	134	80	408	441.1	
	Day 1/ ECG #3	08MAR2016/ 9:47	70	70	0.86	118	80	426	448.23	
	Week 1/ Average	15MAR2016	58.67	58.67	1.03	122.67	80	432.67	429.25	
	Week 1/ ECG #1	15MAR2016/ 9:17	62	62	0.97	122	80	420	424.57	
	Week 1/ ECG #2	15MAR2016/ 9:19	55	55	1.09	122	80	438	425.6	Sinus Bradycardia, NCS
	Week 1/ ECG #3	15MAR2016/ 9:21	59	59	1.02	124	80	440	437.57	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-017	Week 2/ Average	23MAR2016	51.67	51.67	1.17	133.33	86.67	465.33	442.59	
	Week 2/ ECG #1	23MAR2016/ 9:01	55	55	1.09	126	88	462	448.92	Sinus Bradycardia, NCS
	Week 2/ ECG #2	23MAR2016/ 9:03	53	53	1.13	132	86	460	441.55	Sinus Bradycardia, NCS
	Week 2/ ECG #3	23MAR2016/ 9:05	47	47	1.28	142	86	474	437.3	Sinus Bradycardia Ventricular Extrasystole, NCS
	Week 4/ Average	05APR2016	50	50	1.2	148.67	88	468	440.6	
	Week 4/ ECG #1	05APR2016/ 10:10	51	51	1.18	150	86	466	441.67	Sinus Bradycardia, NCS
	Week 4/ ECG #2	05APR2016/ 10:12	51	51	1.18	150	88	464	439.77	Sinus Bradycardia, NCS
	Week 4/ ECG #3	05APR2016/ 10:14	48	48	1.25	146	90	474	440.35	Sinus Bradycardia, NCS
	Week 6/ Average	19APR2016	49.67	49.67	1.21	129.33	90.67	458.67	430.92	
	Week 6/ ECG #1	19APR2016/ 9:37	50	50	1.2	126	92	454	427.49	Sinus Bradycardia, NCS
	Week 6/ ECG #2	19APR2016/ 9:39	50	50	1.2	130	90	462	435.02	Sinus Bradycardia, NCS
	Week 6/ ECG #3	19APR2016/ 9:40	49	49	1.22	132	90	460	430.26	Sinus Bradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-017	Week 8/ Average	28APR2016	53.33	53.33	1.12	130.67	84.67	462.67	445.04	
	Week 8/ ECG #1	28APR2016/ 10:02	53	53	1.13	128	84	450	431.95	Sinus Bradycardia, NCS
	Week 8/ ECG #2	28APR2016/ 10:04	54	54	1.11	134	86	468	452.01	Sinus Bradycardia, NCS
	Week 8/ ECG #3	28APR2016/ 10:06	53	53	1.13	130	84	470	451.15	Sinus Bradycardia, NCS
	Week 12/ Average	01JUN2016	53	53	1.13	127.33	84	461.33	442.82	
	Week 12/ ECG #1	01JUN2016/ 8:19	52	52	1.15	128	84	452	431.15	Sinus Bradycardia, NCS
	Week 12/ ECG #2	01JUN2016/ 8:21	52	52	1.15	126	82	466	444.51	Sinus Bradycardia, NCS
	Week 12/ ECG #3	01JUN2016/ 8:23	55	55	1.09	128	86	466	452.81	Sinus Bradycardia, NCS
	Week 16/ Average	29JUN2016	56.67	56.67	1.06	124.67	83.33	452	443.54	
	Week 16/ ECG #1	29JUN2016/ 9:17	57	57	1.05	124	84	446	438.51	Sinusbradycardia, NCS
	Week 16/ ECG #2	29JUN2016/ 9:19	56	56	1.07	124	82	456	445.74	Sinusbradycardia, NCS
	Week 16/ ECG #3	29JUN2016/ 9:21	57	57	1.05	126	84	454	446.38	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-017	Week 20/ Average	26JUL2016	54	54	1.11	123.33	77.33	448	432.66	
	Week 20/ ECG #1	26JUL2016/ 9:39	55	55	1.09	122	78	440	427.55	Sinusbradycardia, NCS
	Week 20/ ECG #2	26JUL2016/ 9:42	53	53	1.13	126	76	450	431.95	Sinusbradycardia Sinusarrhythmia, NCS
	Week 20/ ECG #3	26JUL2016/ 9:44	54	54	1.11	122	78	454	438.49	Sinusbradycardia, NCS
	Week 24/ Average	24AUG2016	54.67	54.67	1.1	121.33	80.67	453.33	439.61	
	Week 24/ ECG #1	24AUG2016/ 9:03	53	53	1.13	122	82	446	428.11	Sinusbradycardia, NCS
	Week 24/ ECG #2	24AUG2016/ 9:05	54	54	1.11	120	80	456	440.42	Sinusbradycardia, NCS
	Week 24/ ECG #3	24AUG2016/ 9:06	57	57	1.05	122	80	458	450.31	Sinusbradycardia, NCS
	Week 28/ Average	20SEP2016	62.67	62.67	0.96	118.67	76	428.67	434.79	
	Week 28/ ECG #1	20SEP2016/ 10:20	63	63	0.95	116	76	420	426.82	
	Week 28/ ECG #2	20SEP2016/ 10:22	60	60	1	120	76	434	434	
	Week 28/ ECG #3	20SEP2016/ 10:24	65	65	0.92	120	76	432	443.56	

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-017	Week 32/ Average	19OCT2016	69	69	0.88	126.67	80	422	440.77	
	Week 32/ ECG #1	19OCT2016/ 9:59	60	60	1	126	82	422	422	
	Week 32/ ECG #2	19OCT2016/ 10:01	65	65	0.92	118	80	432	443.56	
	Week 32/ ECG #3	19OCT2016/ 10:03	82	82	0.73	136	78	412	456.74	Qt Prolongation, NCS
	Week 36/ Average	15NOV2016	64.33	64.33	0.93	132	80.67	432.67	442.74	
	Week 36/ ECG #1	15NOV2016/ 10:37	64	64	0.94	142	82	428	437.21	Sinusarrythmia Delayed .R-Programming Over Front Wall, NCS
	Week 36/ ECG #2	15NOV2016/ 10:39	65	65	0.92	114	80	436	447.67	Delayed .R-Programming Over Front Wall, NCS
	Week 36/ ECG #3	15NOV2016/ 10:41	64	64	0.94	140	80	434	443.34	Sinusarrythmia Delayed .R-Programming Over Front Wall, NCS
	Week 40/ Average	14DEC2016	60	60	1	122	84	446.67	446.52	
	Week 40/ ECG #1	14DEC2016/ 8:43	63	63	0.95	120	90	436	443.08	
	Week 40/ ECG #2	14DEC2016/ 8:45	59	59	1.02	124	82	454	451.49	Sinusbradycardia, NCS

Listing 16.2.8.2
Electrocardiogram Results
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit/ Timepoint	Date/Time of Assessment	Ventricular Rate (cycles/ minute)	Heart Rate (beats/ minute)	RR Interval (msecs)	PR Interval (msecs)	QRS Interval (msecs)	QT Interval (msecs)	QTcF Interval (msecs)	Overall Assessment
301-017	Week 40/ ECG #3	14DEC2016/ 8:47	58	58	1.03	122	80	450	444.99	Sinusbradycardia, NCS
	Week 44/ Average	11JAN2017	66.67	66.67	0.9	114.67	78	435.33	450.72	
	Week 44/ ECG #1	11JAN2017/ 9:02	67	67	0.9	116	78	416	431.43	
	Week 44/ ECG #2	11JAN2017/ 9:04	66	66	0.91	112	78	444	458.19	
	Week 44/ ECG #3	11JAN2017/ 9:06	67	67	0.9	116	78	446	462.54	
	Week 48/ Average	08FEB2017	69	69	0.87	120	79.33	431.33	451.67	
	Week 48/ ECG #1	08FEB2017/ 8:56	70	70	0.86	124	80	424	446.13	
	Week 48/ ECG #2	08FEB2017/ 8:58	68	68	0.88	116	78	434	452.3	
	Week 48/ ECG #3	08FEB2017/ 9:00	69	69	0.87	120	80	436	456.58	

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-007	Screening	05JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	26JAN2016	Abnormalities found in brief PE	No		
	Week 1	01FEB2016	Abnormalities found in brief PE	No		
	Week 2	11FEB2016	Abnormalities found in brief PE	No		
	Week 4	24FEB2016	Abnormalities found in brief PE	No		
	Week 6	08MAR2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-007	Week 8	24MAR2016	Abnormalities found in brief PE	No		
	Week 24	21APR2016	Abnormalities found in brief PE	No		
			Genital Examination	Normal		
	Week 28	19MAY2016	Abnormalities found in brief PE	No		
	Week 32	16JUN2016	Abnormalities found in brief PE	No		
	Week 40	11AUG2016	Abnormalities found in brief PE	No		
	Week 44	08SEP2016	Abnormalities found in brief PE	No		
	Week 48	06OCT2016	Abnormalities found in brief PE	No		
301-011	Screening	07JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Abnormal	Stabismus Divergens	NCS

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-011	Screening	07JAN2016	Immunologic	Normal		
			Musculoskeletal	Abnormal	Scoliosis	NCS
			Neurologic	Normal		
			Other Body System	Abnormal	Varicosis Leg	NCS
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	27JAN2016	Abnormalities found in brief PE	No		
	Week 1	03FEB2016	Abnormalities found in brief PE	No		
	Week 2	11FEB2016	Abnormalities found in brief PE	No		
	Week 4	26FEB2016	Abnormalities found in brief PE	No		
	Week 6	10MAR2016	Abnormalities found in brief PE	Yes		
	Week 8	24MAR2016	Abnormalities found in brief PE	No		
	Week 12	19APR2016	Abnormalities found in brief PE	No		
	Week 16	18MAY2016	Abnormalities found in brief PE	No		
	Week 20	21JUN2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-011	Week 24	12JUL2016	Abnormalities found in brief PE	No		
			Genital Examination	Normal		
	Week 28	09AUG2016	Abnormalities found in brief PE	No		
	Week 32	06SEP2016	Abnormalities found in brief PE	No		
	Week 36	06OCT2016	Abnormalities found in brief PE	No		
	Week 40	03NOV2016	Abnormalities found in brief PE	No		
	Week 44	06DEC2016	Abnormalities found in brief PE	No		
	Week 48	03JAN2017	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-001	Screening	06JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	02FEB2016	Abnormalities found in brief PE	No		
	Week 1	09FEB2016	Abnormalities found in brief PE	Yes		
	Week 2	16FEB2016	Abnormalities found in brief PE	No		
	Week 4	01MAR2016	Abnormalities found in brief PE	No		
	Week 6	16MAR2016	Abnormalities found in brief PE	Yes		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-001	Week 8	31MAR2016	Abnormalities found in brief PE	No		
	Week 12	28APR2016	Abnormalities found in brief PE	No		
	Week 16	26MAY2016	Abnormalities found in brief PE	No		
	Week 20	22JUN2016	Abnormalities found in brief PE	No		
	Week 24	20JUL2016	Abnormalities found in brief PE	No		
	Week 28	18AUG2016	Genital Examination	NOT DONE		
	Week 32	15SEP2016	Abnormalities found in brief PE	No		
	Week 36	13OCT2016	Abnormalities found in brief PE	No		
	Week 40	10NOV2016	Abnormalities found in brief PE	No		
	Week 44	06DEC2016	Abnormalities found in brief PE	Yes		
	Week 48	03JAN2017	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-002	Screening	15DEC2015	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	05JAN2016	Abnormalities found in brief PE	No		
	Week 1	14JAN2016	Abnormalities found in brief PE	No		
	Week 2	20JAN2016	Abnormalities found in brief PE	No		
	Week 4	03FEB2016	Abnormalities found in brief PE	No		
	Week 6	17FEB2016	Abnormalities found in brief PE	Yes		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-002	Week 8	01MAR2016	Abnormalities found in brief PE	No		
	Week 12	30MAR2016	Abnormalities found in brief PE	No		
	Week 16	26APR2016	Abnormalities found in brief PE	No		
	Week 20	24MAY2016	Abnormalities found in brief PE	No		
	Week 24	21JUN2016	Abnormalities found in brief PE	No		
	Week 28	20JUL2016	Genital Examination	Normal		
	Week 32	18AUG2016	Abnormalities found in brief PE	No		
	Week 36	13SEP2016	Abnormalities found in brief PE	No		
	Week 40	11OCT2016	Abnormalities found in brief PE	No		
	Week 44	09NOV2016	Abnormalities found in brief PE	No		
	Week 48	06DEC2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-003	Screening	15DEC2015	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Screening	04JAN2016	Genital Examination	Normal		
	Day 1	06JAN2016	Abnormalities found in brief PE	No		
	Week 1	13JAN2016	Abnormalities found in brief PE	No		
	Week 2	20JAN2016	Abnormalities found in brief PE	No		
	Week 4	03FEB2016	Abnormalities found in brief PE	No		
	Week 6	18FEB2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-003	Week 8	08MAR2016	Abnormalities found in brief PE	No		
	Week 12	29MAR2016	Abnormalities found in brief PE	No		
	Week 16	25APR2016	Abnormalities found in brief PE	No		
	Week 20	26MAY2016	Abnormalities found in brief PE	No		
	Week 24	22JUN2016	Abnormalities found in brief PE	No		
	Week 28	19JUL2016	Genital Examination	Normal		
	Week 32	16AUG2016	Abnormalities found in brief PE	No		
	Week 36	15SEP2016	Abnormalities found in brief PE	No		
	Week 40	12OCT2016	Abnormalities found in brief PE	No		
	Week 44	09NOV2016	Abnormalities found in brief PE	No		
	Week 48	14DEC2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-005	Screening	16DEC2015	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	07JAN2016	Abnormalities found in brief PE	No		
	Week 1	13JAN2016	Abnormalities found in brief PE	Yes		
	Week 2	21JAN2016	Abnormalities found in brief PE	No		
	Week 4	02FEB2016	Abnormalities found in brief PE	No		
	Week 6	17FEB2016	Abnormalities found in brief PE	Yes		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-005	Week 8	02MAR2016	Abnormalities found in brief PE	No		
	Week 12	31MAR2016	Abnormalities found in brief PE	No		
	Week 16	26APR2016	Abnormalities found in brief PE	No		
	Week 20	26MAY2016	Abnormalities found in brief PE	No		
	Week 24	23JUN2016	Abnormalities found in brief PE	No		
	Week 28	26JUL2016	Genital Examination	Normal		
	Week 32	16AUG2016	Abnormalities found in brief PE	No		
	Week 36	14SEP2016	Abnormalities found in brief PE	No		
	Week 40	12OCT2016	Abnormalities found in brief PE	Yes		
	Week 44	10NOV2016	Abnormalities found in brief PE	Yes		
	Week 48	07DEC2016	Abnormalities found in brief PE	Yes		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-008	Screening	19JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	11FEB2016	Abnormalities found in brief PE	No		
	Week 1	17FEB2016	Abnormalities found in brief PE	No		
	Week 2	24FEB2016	Abnormalities found in brief PE	No		
	Week 4	10MAR2016	Abnormalities found in brief PE	No		
	Week 6	24MAR2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-008	Week 8	07APR2016	Abnormalities found in brief PE	No		
	Early Term	13APR2016	Abnormalities found in brief PE	Yes		
			Genital Examination	NOT DONE		
	Week 28	17MAY2016	Abnormalities found in brief PE	No		
	Week 32	09JUN2016	Abnormalities found in brief PE	No		
	Week 36	06JUL2016	Abnormalities found in brief PE	No		
	Week 40	03AUG2016	Abnormalities found in brief PE	No		
	Week 44	07SEP2016	Abnormalities found in brief PE	No		
	Week 48	19OCT2016	Abnormalities found in brief PE	No		
301-009	Screening	06JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Abnormal	Liver Hardened	NCS
			Genital Examination	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-009	Screening	06JAN2016	Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	27JAN2016	Abnormalities found in brief PE	No		
	Week 1	02FEB2016	Abnormalities found in brief PE	Yes		
	Week 2	10FEB2016	Abnormalities found in brief PE	No		
	Week 4	25FEB2016	Abnormalities found in brief PE	No		
	Week 6	09MAR2016	Abnormalities found in brief PE	No		
	Week 8	22MAR2016	Abnormalities found in brief PE	No		
	Week 12	19APR2016	Abnormalities found in brief PE	No		
	Week 16	18MAY2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-009	Week 20	15JUN2016	Abnormalities found in brief PE	No		
	Week 24	20JUL2016	Abnormalities found in brief PE	No		
			Genital Examination	NOT DONE		
	Week 28	09AUG2016	Abnormalities found in brief PE	No		
	Week 32	06SEP2016	Abnormalities found in brief PE	No		
	Week 36	04OCT2016	Abnormalities found in brief PE	No		
	Week 40	01NOV2016	Abnormalities found in brief PE	No		
	Week 44	29NOV2016	Abnormalities found in brief PE	No		
	Week 48	02JAN2017	Abnormalities found in brief PE	No		
301-010	Screening	07JAN2016	Cardiovascular	Normal		
			Dermatologic	Abnormal	Skin Lesion Right Lower Arm	NCS
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-010	Screening	07JAN2016	Head, Ears, Eyes, Nose, Throat	Abnormal	Amaurosis	NCS
			Immunologic	Normal		
			Musculoskeletal	Abnormal	Spastic Paresis	NCS
			Neurologic	Abnormal	Spastic Paresis	NCS
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Screening	27JAN2016	Genital Examination	Normal		
	Day 1	27JAN2016	Abnormalities found in brief PE	No		
	Week 1	04FEB2016	Abnormalities found in brief PE	No		
	Week 2	09FEB2016	Abnormalities found in brief PE	No		
	Week 4	24FEB2016	Abnormalities found in brief PE	No		
	Week 6	09MAR2016	Abnormalities found in brief PE	Yes		
	Week 8	22MAR2016	Abnormalities found in brief PE	Yes		
	Week 12	19APR2016	Abnormalities found in brief PE	Yes		
	Week 16	17MAY2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-010	Week 20	20JUN2016	Abnormalities found in brief PE	No		
	Week 24	12JUL2016	Abnormalities found in brief PE	No		
			Genital Examination	Normal		
	Week 28	08AUG2016	Abnormalities found in brief PE	No		
	Week 32	06SEP2016	Abnormalities found in brief PE	No		
	Week 36	04OCT2016	Abnormalities found in brief PE	No		
	Week 40	01NOV2016	Abnormalities found in brief PE	No		
	Week 44	28NOV2016	Abnormalities found in brief PE	No		
	Week 48	03JAN2017	Abnormalities found in brief PE	No		
301-014	Screening	27JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-014	Screening	27JAN2016	Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	23FEB2016	Abnormalities found in brief PE	No		
	Week 1	01MAR2016	Abnormalities found in brief PE	No		
	Week 2	09MAR2016	Abnormalities found in brief PE	No		
	Week 4	22MAR2016	Abnormalities found in brief PE	Yes		
	Week 6	05APR2016	Abnormalities found in brief PE	No		
	Week 8	20APR2016	Abnormalities found in brief PE	No		
	Week 12	19MAY2016	Abnormalities found in brief PE	No		
	Week 16	14JUN2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-014	Week 20	13JUL2016	Abnormalities found in brief PE	Yes		
	Week 24	10AUG2016	Abnormalities found in brief PE	No		
			Genital Examination	Normal		
	Week 28	07SEP2016	Abnormalities found in brief PE	Yes		
	Week 32	05OCT2016	Abnormalities found in brief PE	Yes		
	Week 36	02NOV2016	Abnormalities found in brief PE	Yes		
	Week 40	30NOV2016	Abnormalities found in brief PE	Yes		
	Week 44	22DEC2016	Abnormalities found in brief PE	Yes		
	Week 48	25JAN2017	Abnormalities found in brief PE	No		
301-016	Screening	03FEB2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-016	Screening	03FEB2016	Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	25FEB2016	Abnormalities found in brief PE	No		
	Week 1	02MAR2016	Abnormalities found in brief PE	Yes		
	Week 2	08MAR2016	Abnormalities found in brief PE	No		
	Week 4	24MAR2016	Abnormalities found in brief PE	No		
	Week 6	07APR2016	Abnormalities found in brief PE	No		
	Week 8	19APR2016	Abnormalities found in brief PE	No		
	Week 12	24MAY2016	Abnormalities found in brief PE	No		
	Week 16	14JUN2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-016	Week 20	13JUL2016	Abnormalities found in brief PE	No		
	Week 24	28JUL2016	Abnormalities found in brief PE	No		
			Genital Examination	Normal		
	Week 28	06SEP2016	Abnormalities found in brief PE	No		
	Week 32	05OCT2016	Abnormalities found in brief PE	No		
	Week 36	02NOV2016	Abnormalities found in brief PE	No		
	Week 40	29NOV2016	Abnormalities found in brief PE	No		
	Week 44	21DEC2016	Abnormalities found in brief PE	No		
	Week 48	24JAN2017	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-015	Screening	02FEB2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Abnormal	Muscular Weakness Half On The Face	NCS
			Neurologic	Abnormal	Muscular Weakness Half On The Face	NCS
			Other Body System	Abnormal	Haematoma	NCS
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Screening Day 1	23FEB2016	Genital Examination	Normal		
		23FEB2016	Abnormalities found in brief PE	No		
	Week 1	03MAR2016	Abnormalities found in brief PE	Yes		
	Week 2	08MAR2016	Abnormalities found in brief PE	No		
	Week 4	23MAR2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-015	Week 6	06APR2016	Abnormalities found in brief PE	No		
	Week 8	20APR2016	Abnormalities found in brief PE	No		
	Week 12	17MAY2016	Abnormalities found in brief PE	No		
	Week 16	16JUN2016	Abnormalities found in brief PE	No		
	Week 20	14JUL2016	Abnormalities found in brief PE	No		
	Week 24	10AUG2016	Abnormalities found in brief PE	No		
	Week 28	07SEP2016	Genital Examination Abnormalities found in brief PE	Normal No		
	Week 40	30NOV2016	Abnormalities found in brief PE	No		
	Week 44	28DEC2016	Abnormalities found in brief PE	No		
	Week 48	26JAN2017	Abnormalities found in brief PE	No		
301-018	Screening	17FEB2016	Cardiovascular	Normal		
			Dermatologic	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-018	Screening	17FEB2016	Endocrine/Metabolic	Normal	Liver Hardened	NCS
			Gastrointestinal and Hepatic	Abnormal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	09MAR2016	Abnormalities found in brief PE	No		
	Week 1	16MAR2016	Abnormalities found in brief PE	No		
	Week 2	23MAR2016	Abnormalities found in brief PE	No		
	Week 4	06APR2016	Abnormalities found in brief PE	No		
	Week 6	21APR2016	Abnormalities found in brief PE	No		
	Week 8	28APR2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-018	Week 12	01JUN2016	Abnormalities found in brief PE	No		
	Week 16	29JUN2016	Abnormalities found in brief PE	No		
	Week 20	27JUL2016	Abnormalities found in brief PE	No		
	Week 24	23AUG2016	Abnormalities found in brief PE	No		
	Week 28	20SEP2016	Genital Examination	Normal		
	Week 32	18OCT2016	Abnormalities found in brief PE	No		
	Week 36	15NOV2016	Abnormalities found in brief PE	No		
	Week 40	13DEC2016	Abnormalities found in brief PE	No		
	Week 44	10JAN2017	Abnormalities found in brief PE	No		
	Week 48	07FEB2017	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-006	Screening	14JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	04FEB2016	Abnormalities found in brief PE	No		
	Week 1	10FEB2016	Abnormalities found in brief PE	No		
	Week 2	16FEB2016	Abnormalities found in brief PE	No		
	Week 4	03MAR2016	Abnormalities found in brief PE	No		
	Week 6	17MAR2016	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-006	Week 8	31MAR2016	Abnormalities found in brief PE	No		
	Week 12	26APR2016	Abnormalities found in brief PE	No		
	Week 16	25MAY2016	Abnormalities found in brief PE	No		
	Week 20	23JUN2016	Abnormalities found in brief PE	No		
	Week 24	19JUL2016	Abnormalities found in brief PE	No		
	Week 28	18AUG2016	Genital Examination	Normal		
	Week 32	13SEP2016	Abnormalities found in brief PE	No		
	Week 36	13OCT2016	Abnormalities found in brief PE	No		
	Week 40	08NOV2016	Abnormalities found in brief PE	No		
	Week 44	08DEC2016	Abnormalities found in brief PE	No		
	Week 48	04JAN2017	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-017	Screening	17FEB2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
	Day 1	08MAR2016	Abnormalities found in brief PE	No		
	Week 1	15MAR2016	Abnormalities found in brief PE	No		
	Week 2	23MAR2016	Abnormalities found in brief PE	Yes		
	Week 4	05APR2016	Abnormalities found in brief PE	No		
	Week 6	19APR2016	Abnormalities found in brief PE	Yes		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-017	Week 8	28APR2016	Abnormalities found in brief PE	No		
	Week 12	01JUN2016	Abnormalities found in brief PE	No		
	Week 16	29JUN2016	Abnormalities found in brief PE	No		
	Week 20	26JUL2016	Abnormalities found in brief PE	No		
	Week 24	24AUG2016	Abnormalities found in brief PE	No		
	Week 28	20SEP2016	Genital Examination	Normal		
	Week 32	19OCT2016	Abnormalities found in brief PE	No		
	Week 36	15NOV2016	Abnormalities found in brief PE	No		
	Week 40	14DEC2016	Abnormalities found in brief PE	Yes		
	Week 44	11JAN2017	Abnormalities found in brief PE	No		
	Week 48	08FEB2017	Abnormalities found in brief PE	No		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-004	Screening	16DEC2015	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Normal		
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		
			Neurologic	Normal		
			Psychologic/Psychiatric	Normal		
			Respiratory	Normal		
301-012	Screening	26JAN2016	Cardiovascular	Normal		
			Dermatologic	Normal		
			Endocrine/Metabolic	Normal		
			Gastrointestinal and Hepatic	Abnormal	Light Abdominal Pain NCS	
			Genital Examination	Normal		
			Head, Ears, Eyes, Nose, Throat	Normal		
			Immunologic	Normal		
			Musculoskeletal	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.3
Physical and Genital Exam
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date of Exam	Test Name	Result	Abnormal Finding	Clinical Significance [1]
301-012	Screening	26JAN2016	Neurologic Psychologic/Psychiatric Respiratory	Normal Normal Normal		
301-013	Screening	26JAN2016	Cardiovascular Dermatologic Endocrine/Metabolic Gastrointestinal and Hepatic Genital Examination Head, Ears, Eyes, Nose, Throat Immunologic Musculoskeletal Neurologic Psychologic/Psychiatric Respiratory	Normal Normal Normal Normal Normal Normal Normal Abnormal Normal Normal Normal	Muscle defect	NCS

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-007	Day 1	26JAN2016	No
	Week 1	01FEB2016	No
	Week 2	11FEB2016	No
	Week 4	24FEB2016	No
	Week 6	08MAR2016	No
	Week 8	24MAR2016	No
	Week 24	21APR2016	No
	Week 28	19MAY2016	No
	Week 32	16JUN2016	No
	Week 40	11AUG2016	No
	Week 44	08SEP2016	No
	Week 48	06OCT2016	No
301-011	Day 1	27JAN2016	No
	Week 1	03FEB2016	No
	Week 2	11FEB2016	No
	Week 4	26FEB2016	No
	Week 6	10MAR2016	Yes
	Week 8	24MAR2016	No
	Week 12	19APR2016	No
	Week 16	18MAY2016	No
	Week 20	21JUN2016	No
	Week 24	12JUL2016	No
	Week 28	09AUG2016	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-011	Week 32	06SEP2016	No
	Week 36	06OCT2016	No
	Week 40	03NOV2016	No
	Week 44	06DEC2016	No
	Week 48	03JAN2017	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-001	Day 1	02FEB2016	No
	Week 1	09FEB2016	Yes
	Week 2	16FEB2016	No
	Week 4	01MAR2016	No
	Week 6	16MAR2016	Yes
	Week 8	31MAR2016	No
	Week 12	28APR2016	No
	Week 16	26MAY2016	No
	Week 20	22JUN2016	No
	Week 24	20JUL2016	No
	Week 28	18AUG2016	No
	Week 32	15SEP2016	No
	Week 36	13OCT2016	No
	Week 40	10NOV2016	No
	Week 44	06DEC2016	Yes
	Week 48	03JAN2017	No
301-002	Day 1	05JAN2016	No
	Week 1	14JAN2016	No
	Week 2	20JAN2016	No
	Week 4	03FEB2016	No
	Week 6	17FEB2016	Yes
	Week 8	01MAR2016	No
	Week 12	30MAR2016	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-002	Week 16	26APR2016	No
	Week 20	24MAY2016	No
	Week 24	21JUN2016	No
	Week 28	20JUL2016	No
	Week 32	18AUG2016	No
	Week 36	13SEP2016	No
	Week 40	11OCT2016	No
	Week 44	09NOV2016	No
	Week 48	06DEC2016	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-003	Day 1	06JAN2016	No
	Week 1	13JAN2016	No
	Week 2	20JAN2016	No
	Week 4	03FEB2016	No
	Week 6	18FEB2016	No
	Week 8	08MAR2016	No
	Week 12	29MAR2016	No
	Week 16	25APR2016	No
	Week 20	26MAY2016	No
	Week 24	22JUN2016	No
	Week 28	19JUL2016	No
	Week 32	16AUG2016	No
	Week 36	15SEP2016	No
	Week 40	12OCT2016	No
	Week 44	09NOV2016	No
	Week 48	14DEC2016	No
301-005	Day 1	07JAN2016	No
	Week 1	13JAN2016	Yes
	Week 2	21JAN2016	No
	Week 4	02FEB2016	No
	Week 6	17FEB2016	Yes
	Week 8	02MAR2016	No
	Week 12	31MAR2016	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-005	Week 16	26APR2016	No
	Week 20	26MAY2016	No
	Week 24	23JUN2016	No
	Week 28	26JUL2016	No
	Week 32	16AUG2016	No
	Week 36	14SEP2016	No
	Week 40	12OCT2016	Yes
	Week 44	10NOV2016	Yes
	Week 48	07DEC2016	Yes
301-008	Day 1	11FEB2016	No
	Week 1	17FEB2016	No
	Week 2	24FEB2016	No
	Week 4	10MAR2016	No
	Week 6	24MAR2016	No
	Week 8	07APR2016	No
	Week 28	17MAY2016	No
	Week 32	09JUN2016	No
	Week 36	06JUL2016	No
	Week 40	03AUG2016	No
	Week 44	07SEP2016	No
	Week 48	19OCT2016	No
	Early Term	13APR2016	Yes

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-009	Day 1	27JAN2016	No
	Week 1	02FEB2016	Yes
	Week 2	10FEB2016	No
	Week 4	25FEB2016	No
	Week 6	09MAR2016	No
	Week 8	22MAR2016	No
	Week 12	19APR2016	No
	Week 16	18MAY2016	No
	Week 20	15JUN2016	No
	Week 24	20JUL2016	No
	Week 28	09AUG2016	No
	Week 32	06SEP2016	No
	Week 36	04OCT2016	No
	Week 40	01NOV2016	No
	Week 44	29NOV2016	No
	Week 48	02JAN2017	No
301-010	Day 1	27JAN2016	No
	Week 1	04FEB2016	No
	Week 2	09FEB2016	No
	Week 4	24FEB2016	No
	Week 6	09MAR2016	Yes
	Week 8	22MAR2016	Yes
	Week 12	19APR2016	Yes

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-010	Week 16	17MAY2016	No
	Week 20	20JUN2016	No
	Week 24	12JUL2016	No
	Week 28	08AUG2016	No
	Week 32	06SEP2016	No
	Week 36	04OCT2016	No
	Week 40	01NOV2016	No
	Week 44	28NOV2016	No
	Week 48	03JAN2017	No
301-014	Day 1	23FEB2016	No
	Week 1	01MAR2016	No
	Week 2	09MAR2016	No
	Week 4	22MAR2016	Yes
	Week 6	05APR2016	No
	Week 8	20APR2016	No
	Week 12	19MAY2016	No
	Week 16	14JUN2016	No
	Week 20	13JUL2016	Yes
	Week 24	10AUG2016	No
	Week 28	07SEP2016	Yes
	Week 32	05OCT2016	Yes
	Week 36	02NOV2016	Yes
	Week 40	30NOV2016	Yes

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-014	Week 44	22DEC2016	Yes
	Week 48	25JAN2017	No
301-016	Day 1	25FEB2016	No
	Week 1	02MAR2016	Yes
	Week 2	08MAR2016	No
	Week 4	24MAR2016	No
	Week 6	07APR2016	No
	Week 8	19APR2016	No
	Week 12	24MAY2016	No
	Week 16	14JUN2016	No
	Week 20	13JUL2016	No
	Week 24	28JUL2016	No
	Week 28	06SEP2016	No
	Week 32	05OCT2016	No
	Week 36	02NOV2016	No
	Week 40	29NOV2016	No
	Week 44	21DEC2016	No
	Week 48	24JAN2017	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-015	Day 1	23FEB2016	No
	Week 1	03MAR2016	Yes
	Week 2	08MAR2016	No
	Week 4	23MAR2016	No
	Week 6	06APR2016	No
	Week 8	20APR2016	No
	Week 12	17MAY2016	No
	Week 16	16JUN2016	No
	Week 20	14JUL2016	No
	Week 24	10AUG2016	No
	Week 28	07SEP2016	No
	Week 40	30NOV2016	No
	Week 44	28DEC2016	No
	Week 48	26JAN2017	No
301-018	Day 1	09MAR2016	No
	Week 1	16MAR2016	No
	Week 2	23MAR2016	No
	Week 4	06APR2016	No
	Week 6	21APR2016	No
	Week 8	28APR2016	No
	Week 12	01JUN2016	No
	Week 16	29JUN2016	No
	Week 20	27JUL2016	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-018	Week 24	23AUG2016	No
	Week 28	20SEP2016	No
	Week 32	18OCT2016	No
	Week 36	15NOV2016	No
	Week 40	13DEC2016	No
	Week 44	10JAN2017	No
	Week 48	07FEB2017	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-006	Day 1	04FEB2016	No
	Week 1	10FEB2016	No
	Week 2	16FEB2016	No
	Week 4	03MAR2016	No
	Week 6	17MAR2016	No
	Week 8	31MAR2016	No
	Week 12	26APR2016	No
	Week 16	25MAY2016	No
	Week 20	23JUN2016	No
	Week 24	19JUL2016	No
	Week 28	18AUG2016	No
	Week 32	13SEP2016	No
	Week 36	13OCT2016	No
	Week 40	08NOV2016	No
	Week 44	08DEC2016	No
	Week 48	04JAN2017	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.4
Brief Physical Exam
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Were any abnormalities found?
301-017	Day 1	08MAR2016	No
	Week 1	15MAR2016	No
	Week 2	23MAR2016	Yes
	Week 4	05APR2016	No
	Week 6	19APR2016	Yes
	Week 8	28APR2016	No
	Week 12	01JUN2016	No
	Week 16	29JUN2016	No
	Week 20	26JUL2016	No
	Week 24	24AUG2016	No
	Week 28	20SEP2016	No
	Week 32	19OCT2016	No
	Week 36	15NOV2016	No
	Week 40	14DEC2016	Yes
	Week 44	11JAN2017	No
	Week 48	08FEB2017	No

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-007	Screening	05JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	21APR2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Abnormal (CS)		
				Cornea Findings		Keratitis	
				Eyelids	Abnormal (NCS)		
				Iris	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-007	Week 24	21APR2016	LEFT EYE	Lacrimal Glands	Normal	Keratitis	
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Abnormal (CS)		
				Cornea Findings			
				Eyelids	Abnormal (NCS)		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-011	Screening	07JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-011	Screening	07JAN2016	RIGHT EYE	Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	12JUL2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
			RIGHT EYE	Lashes	Normal		
				Orbit	Normal		
				Sclera	Abnormal (NCS)		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-011	Week 24	12JUL2016	RIGHT EYE	Orbit	Normal		
				Sclera	Normal		
301-001	Screening	06JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Abnormal (NCS)		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	20JUL2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Abnormal (NCS)		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-001	Week 24	20JUL2016	LEFT EYE	Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Abnormal (NCS)		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
301-002	Screening	15DEC2015	LEFT EYE	Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		
			RIGHT EYE	Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

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Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-002	Screening	15DEC2015	RIGHT EYE	Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
	Week 24	21JUN2016	LEFT EYE	Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
			RIGHT EYE	Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-002	Week 24	21JUN2016	RIGHT EYE	Orbit	Normal		
				Sclera	Normal		
301-003	Screening	15DEC2015	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	22JUN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-003	Week 24	22JUN2016	LEFT EYE	Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-005	Screening	16DEC2015	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-005	Screening	16DEC2015	RIGHT EYE	Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	23JUN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
			RIGHT EYE	Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-005	Week 24	23JUN2016	RIGHT EYE	Orbit	Normal		
				Sclera	Normal		
301-008	Screening	19JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-009	Screening	06JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-009	Screening	06JAN2016	LEFT EYE	Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	20JUL2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Abnormal (NCS)		
				Eyelids	Normal		
				Iris	Normal		
			RIGHT EYE	Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-009	Week 24	20JUL2016	RIGHT EYE	Conjunctiva	Abnormal (NCS)		
				Cornea	Abnormal (NCS)		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-010	Screening	07JAN2016	LEFT EYE	Anterior Chamber	Abnormal (CS)		
				Anterior Chamber Findings		Front Synnechien Ophthalmologist Approved	
				Conjunctiva	Normal		
				Cornea	Abnormal (CS)		
				Cornea Findings		Amaurosis	
				Eyelids	Normal		
				Iris	Abnormal (CS)		
				Iris Findings		Iris Defect , Front Synechien Ophthalmologist Approved	
				Lacrimal Glands	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-010	Screening	07JAN2016	LEFT EYE	Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	12JUL2016	LEFT EYE	Anterior Chamber	Abnormal (CS)	Flat Repealed	
				Anterior Chamber Findings			
				Conjunctiva	Normal		
				Cornea	Abnormal (CS)		
				Cornea Findings		Whitish Scar	
				Eyelids	Normal		
				Iris	Abnormal (CS)		
				Iris Findings		Front Synechia	
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-010	Week 24	12JUL2016	LEFT EYE	Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-014	Screening	27JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Abnormal (NCS)		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Abnormal (NCS)		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-014	Screening	27JAN2016	RIGHT EYE	Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	10AUG2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Abnormal (NCS)		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Abnormal (NCS)		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-016	Screening	03FEB2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-016	Screening	03FEB2016	LEFT EYE	Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	06SEP2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-016	Week 24	06SEP2016	LEFT EYE	Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		
				Sclera	Normal		
301-015	Screening	02FEB2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
			RIGHT EYE	Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-015	Screening	02FEB2016	RIGHT EYE	Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	10AUG2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Abnormal (NCS)		
				Eyelids	Abnormal (NCS)		
			RIGHT EYE	Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Abnormal (NCS)		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-018	Screening	17FEB2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-018	Screening	17FEB2016	LEFT EYE	Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		
				Sclera	Normal		
	Week 24	23AUG2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-018	Week 24	23AUG2016	LEFT EYE	Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		
				Sclera	Normal		
301-006	Screening	14JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
			RIGHT EYE	Orbit	Normal		
				Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-006	Screening	14JAN2016	RIGHT EYE	Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
	Week 24	18AUG2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-017	Screening	17FEB2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-017	Screening	17FEB2016	LEFT EYE	Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		
				Sclera	Normal		
	Week 24	24AUG2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-017	Week 24	24AUG2016	LEFT EYE	Sclera	Normal		
				Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Not Done		
				Sclera	Normal		
301-004	Screening	16DEC2015	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-004	Screening	16DEC2015	RIGHT EYE	Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-012	Screening	26JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Normal		
				Cornea	Normal		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
301-013	Screening	26JAN2016	LEFT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.5
Slit Lamp Examination
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-013	Screening	26JAN2016	LEFT EYE	Cornea	Abnormal (NCS)		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		
			RIGHT EYE	Anterior Chamber	Normal		
				Conjunctiva	Abnormal (NCS)		
				Cornea	Abnormal (NCS)		
				Eyelids	Normal		
				Iris	Normal		
				Lacrimal Glands	Normal		
				Lashes	Normal		
				Orbit	Normal		
				Sclera	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.6
Visual Acuity Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result	Reason Not Done
301-007	Screening	05JAN2016	LEFT EYE	Visual Acuity	20/25	
			RIGHT EYE	Visual Acuity	20/20	
	Week 24	21APR2016	LEFT EYE	Visual Acuity	20/25	
			RIGHT EYE	Visual Acuity	20/20	
301-011	Screening	07JAN2016	LEFT EYE	Visual Acuity	20/400	
			RIGHT EYE	Visual Acuity	20/20	
	Week 24	12JUL2016	LEFT EYE	Visual Acuity	20/400	
			RIGHT EYE	Visual Acuity	20/20	
301-001	Screening	06JAN2016	LEFT EYE	Visual Acuity	20/25	
			RIGHT EYE	Visual Acuity	20/20	
	Week 24	20JUL2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	
301-002	Screening	15DEC2015	LEFT EYE	Visual Acuity	20/16	
			RIGHT EYE	Visual Acuity	20/16	
	Week 24	21JUN2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/16	
301-003	Screening	15DEC2015	LEFT EYE	Visual Acuity	20/16	
			RIGHT EYE	Visual Acuity	20/16	
	Week 24	22JUN2016	LEFT EYE	Visual Acuity	20/16	
			RIGHT EYE	Visual Acuity	20/16	
301-005	Screening	16DEC2015	LEFT EYE	Visual Acuity	20/80	
			RIGHT EYE	Visual Acuity	20/80	
	Week 24	23JUN2016	LEFT EYE	Visual Acuity	20/50	
			RIGHT EYE	Visual Acuity	20/50	
301-008	Screening	19JAN2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	

Listing 16.2.8.6
Visual Acuity Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result	Reason Not Done
301-009	Screening	06JAN2016	LEFT EYE	Visual Acuity	20/15	
			RIGHT EYE	Visual Acuity	20/15	
	Week 24	20JUL2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/15	
301-010	Screening	07JAN2016	LEFT EYE	Visual Acuity Examination Tests		Defect Projektion Ophthalmologist Approved
			RIGHT EYE	Visual Acuity	20/40	
	Week 24	12JUL2016	LEFT EYE	Visual Acuity Examination Tests		Light Perception, Defective Projektiv
			RIGHT EYE	Visual Acuity	20/32	
301-014	Screening	27JAN2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	
	Week 24	10AUG2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	
301-016	Screening	03FEB2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	
	Week 24	06SEP2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/16	
301-015	Screening	02FEB2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	
	Week 24	10AUG2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	
301-018	Screening	17FEB2016	LEFT EYE	Visual Acuity	20/16	
			RIGHT EYE	Visual Acuity	20/20	
	Week 24	23AUG2016	LEFT EYE	Visual Acuity	20/16	

Listing 16.2.8.6
Visual Acuity Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result	Reason Not Done
301-018	Week 24	23AUG2016	RIGHT EYE	Visual Acuity	20/16	
301-006	Screening	14JAN2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/25	
	Week 24	18AUG2016	LEFT EYE	Visual Acuity	20/25	
			RIGHT EYE	Visual Acuity	20/25	
301-017	Screening	17FEB2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/25	
	Week 24	24AUG2016	LEFT EYE	Visual Acuity	20/25	
			RIGHT EYE	Visual Acuity	20/25	
301-004	Screening	16DEC2015	LEFT EYE	Visual Acuity	20/25	
			RIGHT EYE	Visual Acuity	20/25	
301-012	Screening	26JAN2016	LEFT EYE	Visual Acuity	20/25	
			RIGHT EYE	Visual Acuity	20/20	
301-013	Screening	26JAN2016	LEFT EYE	Visual Acuity	20/20	
			RIGHT EYE	Visual Acuity	20/20	

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-007	Screening	05JAN2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
	Week 24	21APR2016	LEFT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
301-011	Screening	07JAN2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-011	Week 24	12JUL2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Abnormal (NCS)		
301-001	Screening	06JAN2016	LEFT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
			RIGHT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
	Week 24	20JUL2016	LEFT EYE	Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
			RIGHT EYE	Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-002	Screening	15DEC2015	LEFT EYE	Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (NCS)		
			RIGHT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Abnormal (NCS)		
	Week 24	21JUN2016	LEFT EYE	Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		
			RIGHT EYE	Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
301-003	Screening	15DEC2015	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Abnormal (NCS)		
			RIGHT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
			RIGHT EYE	Retina	Abnormal (NCS)		
				Vitreous	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-003	Week 24	22JUN2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
301-005	Screening	16DEC2015	LEFT EYE	Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (CS)		
				Retina Findings		Myopic Disc Degenerations Central+periphe ral	
	Week 24	23JUN2016	LEFT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (CS)		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-005	Week 24	23JUN2016	LEFT EYE	Retina Findings		Myopic Degeneration	
			RIGHT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (CS)	Myopic Degeneration	
301-008	Screening	19JAN2016	LEFT EYE	Retina Findings			
				Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
			RIGHT EYE	Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
301-009	Screening	06JAN2016	LEFT EYE	Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
			RIGHT EYE	Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-009	Screening Week 24	06JAN2016 20JUL2016	RIGHT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
			LEFT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		
301-010	Screening	07JAN2016	LEFT EYE	Lens	Not Done		
				Optic Disc	Not Done		
				Retina	Not Done		
				Vitreous	Not Done		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		
		12JUL2016	LEFT EYE	Lens	Not Done		
				Optic Disc	Not Done		
				Retina	Not Done		
				Vitreous	Not Done		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-010	Week 24	12JUL2016	RIGHT EYE	Vitreous	Normal		
301-014	Screening	27JAN2016	LEFT EYE	Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		
	Week 24	10AUG2016	LEFT EYE	Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Abnormal (NCS)		
				Retina	Abnormal (NCS)		
				Vitreous	Normal		
301-016	Screening	03FEB2016	LEFT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-016	Screening Week 24	03FEB2016 06SEP2016	RIGHT EYE	Vitreous	Normal		
			LEFT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
301-015	Screening	02FEB2016	LEFT EYE	Vitreous	Normal		
				Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
	Week 24	10AUG2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-015	Week 24	10AUG2016	RIGHT EYE	Vitreous	Normal		
301-018	Screening	17FEB2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
	Week 24	23AUG2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
301-006	Screening	14JAN2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-006	Screening Week 24	14JAN2016 18AUG2016	RIGHT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
			LEFT EYE	Vitreous	Normal		
				Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
				Lens	Normal		
301-017	Screening	17FEB2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-017	Week 24	24AUG2016	RIGHT EYE	Vitreous	Normal		
301-004	Screening	16DEC2015	LEFT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
301-012	Screening	26JAN2016	LEFT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Abnormal (NCS)		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
301-013	Screening	26JAN2016	LEFT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		
				Vitreous	Normal		
			RIGHT EYE	Lens	Normal		
				Optic Disc	Normal		
				Retina	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Listing 16.2.8.7
Dilated Fundus Examination
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Visit	Date of Exam	Eye	Parameter	Result [1]	Findings	Reason Not Done
301-013	Screening	26JAN2016	RIGHT EYE	Vitreous	Normal		

[1] CS=Clinically Significant; NCS=Not Clinically Significant.

Source: D:\TriStat\Eiger\EIG_LNF_002_L0WR_4\tasks\final\version3\prog\l-dil-fundus.sas 11JUL2017 22:20

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Listing 16.2.8.8
Retinal Photography
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Date of Retinal Photography	Eye	Result	Reason Not Done	Finding
301-007	Screening	05JAN2016	Left Eye	Normal		
			Right Eye	Normal		
Week 24		21APR2016	Left Eye	Normal		
			Right Eye	Normal		
301-011	Screening	07JAN2016	Left Eye	Normal		
			Right Eye	Normal		
Week 24		12JUL2016	Left Eye	Normal		
			Right Eye	Normal		
301-001	Screening	06JAN2016	Left Eye	Normal		
			Right Eye	Normal		
Week 24		20JUL2016	Left Eye	Normal		
			Right Eye	Normal		
301-002	Screening	15DEC2015	Left Eye	Normal		
			Right Eye	Normal		
Week 24		21JUN2016	Left Eye	Normal		
			Right Eye	Normal		
301-003	Screening	15DEC2015	Left Eye	Normal		
			Right Eye	Normal		
Week 24		22JUN2016	Left Eye	Normal		
			Right Eye	Normal		
301-005	Screening	16DEC2015	Left Eye	Abnormal		Myopic Degeneration
			Right Eye	Abnormal		Myopic Degeneration
	Week 24	23JUN2016	Left Eye	Abnormal		Myopic Degeneration

Listing 16.2.8.8
Retinal Photography
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Date of Retinal Photography	Eye	Result	Reason Not Done	Finding
301-005	Week 24	23JUN2016	Right Eye	Abnormal		Myopic Degeneration
301-008	Screening	19JAN2016	Left Eye	Normal		
			Right Eye	Normal		
301-009	Screening	06JAN2016	Left Eye	Normal		
			Right Eye	Normal		
	Week 24	20JUL2016	Left Eye	Normal		
			Right Eye	Normal		
301-010	Screening	07JAN2016	Left Eye	Abnormal		Not Done
			Right Eye	Normal		
	Week 24	12JUL2016	Left Eye	Abnormal		Not Done Due To Opaque Cornea
			Right Eye	Normal		
301-014	Screening	27JAN2016	Left Eye	Normal		
			Right Eye	Normal		
	Week 24	10AUG2016	Left Eye	Normal		
			Right Eye	Normal		
301-016	Screening	03FEB2016	Left Eye	Normal		
			Right Eye	Normal		
	Week 24	06SEP2016	Left Eye	Normal		
			Right Eye	Normal		
301-015	Screening	02FEB2016	Left Eye	Normal		
			Right Eye	Normal		
	Week 24	10AUG2016	Left Eye	Normal		

Listing 16.2.8.8
Retinal Photography
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Date of Retinal Photography	Eye	Result	Reason Not Done	Finding
301-015	Week 24	10AUG2016	Right Eye	Normal		
301-018	Screening	17FEB2016	Left Eye	Normal		
			Right Eye	Normal		
	Week 24	23AUG2016	Left Eye	Normal		
			Right Eye	Normal		
301-006	Screening	14JAN2016	Left Eye	Normal		
			Right Eye	Normal		
	Week 24	18AUG2016	Left Eye	Normal		
			Right Eye	Normal		
301-017	Screening	17FEB2016	Left Eye	Normal		
			Right Eye	Normal		
	Week 24	24AUG2016	Left Eye	Normal		
			Right Eye	Normal		
301-004	Screening	16DEC2015	Left Eye	Normal		
			Right Eye	Normal		
301-012	Screening	26JAN2016	Left Eye	Normal		
			Right Eye	Normal		
301-013	Screening	26JAN2016	Left Eye	Normal		
			Right Eye	Normal		