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**Table 14.5.1.1: Summary of Adverse Events
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Number of Subjects with Adverse Event	22 (100.0)	19 (100.0)	26 (100.0)	45 (100.0)	67 (100.0)
Number of Subjects with Treatment Emergent Adverse Event	20 (90.9)	18 (94.7)	24 (92.3)	42 (93.3)	62 (92.5)
Number of Subjects with Serious Adverse Events	4 (18.2)	3 (15.8)	6 (23.1)	9 (20.0)	13 (19.4)
Number of Subjects with Severe Adverse Event	4 (18.2)	3 (15.8)	1 (3.8)	4 (8.9)	8 (11.9)

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.1.3: Adverse Events by preferred term, System organ class & Severity
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Any Adverse Event	22 (100.0)	19 (100.0)	26 (100.0)	45 (100.0)	67 (100.0)
Gastrointestinal disorders	18 (81.8)	10 (52.6)	9 (34.6)	19 (42.2)	37 (55.2)
Diarrhea	15 (68.2)	7 (36.8)	5 (19.2)	12 (26.7)	27 (40.3)
Mild	12 (54.5)	6 (31.6)	3 (11.5)	9 (20.0)	21 (31.3)
Moderate	3 (13.6)	1 (5.3)	2 (7.7)	3 (6.7)	6 (9.0)
Severe	0	0	0	0	0
Vomitting	6 (27.3)	3 (15.8)	4 (15.4)	7 (15.6)	13 (19.4)
Mild	4 (18.2)	1 (5.3)	1 (3.8)	2 (4.4)	6 (9.0)
Moderate	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
Severe	1 (4.5)	1 (5.3)	0	1 (2.2)	2 (3.0)
Nervous system disorder	15 (68.2)	8 (42.1)	17 (65.4)	25 (55.6)	40 (59.7)
Headache	14 (63.6)	7 (36.8)	14 (53.8)	21 (46.7)	35 (52.2)
Mild	10 (45.5)	5 (26.3)	8 (30.8)	13 (28.9)	23 (34.3)
Moderate	4 (18.2)	1 (5.3)	6 (23.1)	7 (15.6)	11 (16.4)
Severe	2 (9.1)	2 (10.5)	1 (3.8)	3 (6.7)	5 (7.5)
Tremor	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
Mild	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Moderate	1 (4.5)	0	1 (3.8)	1 (2.2)	2 (3.0)
Severe	0	0	0	0	0
Vascular disorders	5 (22.7)	6 (31.6)	8 (30.8)	14 (31.1)	19 (28.4)
Hypotension	4 (18.2)	2 (10.5)	5 (19.2)	7 (15.6)	11 (16.4)
Mild	1 (4.5)	2 (10.5)	3 (11.5)	5 (11.1)	6 (9.0)
Moderate	2 (9.1)	0	2 (7.7)	2 (4.4)	4 (6.0)

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.1.3: Adverse Events by preferred term, System organ class & Severity
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Severe	1 (4.5)	0	0	0	1 (1.5)
Flushing	1 (4.5)	1 (5.3)	2 (7.7)	3 (6.7)	4 (6.0)
Mild	1 (4.5)	1 (5.3)	1 (3.8)	2 (4.4)	3 (4.5)
Moderate	0	0	1 (3.8)	1 (2.2)	1 (1.5)
Severe	0	0	0	0	0
Poor venous access	0	3 (15.8)	2 (7.7)	5 (11.1)	5 (7.5)
Mild	0	3 (15.8)	0	3 (6.7)	3 (4.5)
Moderate	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Severe	0	0	0	0	0
Cardiac disorders	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Tachycardia	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Mild	1 (4.5)	1 (5.3)	0	1 (2.2)	2 (3.0)
Moderate	1 (4.5)	0	0	0	1 (1.5)
Severe	0	0	0	0	0
Eye disorders	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)
Conjunctivitis allergic	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)
Mild	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Moderate	0	3 (15.8)	0	3 (6.7)	3 (4.5)
Severe	0	0	0	0	0

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Weight					
Screening					
n	22	19	26	45	67
Mean	84.61	80.16	82.67	81.61	82.59
Median	83.52	80.33	81.35	80.33	80.59
SD	13.58	9.61	13.82	12.16	12.62
Range	64.9 - 111.5	64.5 - 103.8	56.4 - 112.3	56.4 - 112.3	56.4 - 112.3
Day 1					
n	22	19	26	45	67
Mean	85.40	78.80	82.46	80.91	82.39
Median	85.58	79.12	84.35	79.35	80.92
SD	15.17	10.31	16.10	13.93	14.39
Range	55.7 - 111.6	63.1 - 102.6	54.5 - 115.4	54.5 - 115.4	54.5 - 115.4

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Week 1					
n	18	15	18	33	51
Mean	84.99	74.80	81.62	78.52	80.80
Median	81.96	77.00	82.82	79.04	81.12
SD	16.98	12.85	17.22	15.55	16.20
Range	53.2 - 115.7	52.2 - 99.7	55.2 - 114.1	52.2 - 114.1	52.2 - 115.7
Week 2					
n	15	13	15	28	43
Mean	84.50	72.72	82.29	77.85	80.17
Median	86.71	71.79	83.76	76.14	79.90
SD	18.42	14.94	15.66	15.81	16.85
Range	53.0 - 119.1	53.9 - 112.0	51.1 - 107.1	51.1 - 112.0	51.1 - 119.1

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Systolic Blood Pressure					
Screening					
n	22	19	26	45	67
Mean	98.00	102.79	101.38	101.98	100.67
Median	100.00	103.00	101.00	103.00	101.00
SD	10.92	11.15	10.63	10.75	10.89
Range	78.0 - 113.0	77.0 - 125.0	82.0 - 117.0	77.0 - 125.0	77.0 - 125.0
Day 1					
n	22	19	26	45	67
Mean	104.36	97.16	99.73	98.64	100.52
Median	106.00	96.00	100.00	98.00	100.00
SD	11.10	9.86	11.39	10.73	11.10
Range	84.0 - 123.0	79.0 - 115.0	81.0 - 125.0	79.0 - 125.0	79.0 - 125.0

n = Number of subjects in specified category, N = Number of Subjects

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**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Week 1					
n	18	15	18	33	51
Mean	102.83	99.67	99.44	99.55	100.71
Median	104.50	101.00	99.50	100.00	100.00
SD	10.10	9.48	6.58	7.90	8.78
Range	79.0 - 126.0	77.0 - 112.0	88.0 - 116.0	77.0 - 116.0	77.0 - 126.0
Week 2					
n	15	13	15	28	43
Mean	101.60	95.46	103.53	99.79	100.42
Median	102.00	96.00	101.00	100.00	100.00
SD	6.86	8.86	9.68	10.01	9.00
Range	93.0 - 115.0	81.0 - 109.0	90.0 - 122.0	81.0 - 122.0	81.0 - 122.0

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Diastolic Blood Pressure					
Screening					
n	22	19	26	45	67
Mean	81.73	82.84	78.08	80.09	80.63
Median	80.00	84.00	81.50	82.00	81.00
SD	14.10	15.94	13.73	14.72	14.43
Range	57.0 - 107.0	51.0 - 121.0	50.0 - 99.0	50.0 - 121.0	50.0 - 121.0
Day 1					
n	22	19	26	45	67
Mean	82.64	76.79	79.81	78.53	79.88
Median	78.50	75.00	75.00	75.00	76.00
SD	16.44	12.67	13.80	13.27	14.40
Range	54.0 - 115.0	57.0 - 98.0	60.0 - 112.0	57.0 - 112.0	54.0 - 115.0

n = Number of subjects in specified category, N = Number of Subjects

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**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Week 1					
n	18	15	18	33	51
Mean	82.56	81.47	84.11	82.91	82.78
Median	85.00	82.00	82.50	82.00	83.00
SD	13.50	14.60	11.32	12.77	12.90
Range	49.0 - 103.0	55.0 - 101.0	64.0 - 101.0	55.0 - 101.0	49.0 - 103.0
Week 2					
n	15	13	15	28	43
Mean	80.33	72.08	87.67	80.43	80.40
Median	79.00	72.00	91.00	78.50	79.00
SD	9.00	10.24	14.72	14.89	13.02
Range	60.0 - 94.0	52.0 - 88.0	64.0 - 113.0	52.0 - 113.0	52.0 - 113.0

n = Number of subjects in specified category, N = Number of Subjects

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Albumin, Total				51
Week 1, Total				51
Placebo, Total	0	18 (100.0)	0	18
Low	0	1 (5.6)	0	1 (5.6)
Normal	0	16 (88.9)	0	16 (88.9)
High	0	1 (5.6)	0	1 (5.6)
Treatment A, Total	1 (6.7)	12 (80.0)	2 (13.3)	15
Low	0	0	0	0
Normal	1 (6.7)	12 (80.0)	2 (13.3)	15 (100.0)
High	0	0	0	0
Treatment B, Total	2 (11.1)	15 (83.3)	1 (5.6)	18
Low	0	0	0	0
Normal	2 (11.1)	15 (83.3)	1 (5.6)	18 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit	Post-Baseline Reference Range				
	Treatment Baseline Range	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Week 2, Total					43
Placebo, Total		2 (13.3)	13 (86.7)	0	15
Low		0	1 (6.7)	0	1 (6.7)
Normal		2 (13.3)	11 (73.3)	0	13 (86.7)
High		0	1 (6.7)	0	1 (6.7)
Treatment A, Total		2 (15.4)	10 (76.9)	1 (7.7)	13
Low		0	0	0	0
Normal		2 (15.4)	10 (76.9)	1 (7.7)	13 (100.0)
High		0	0	0	0
Treatment B, Total		1 (6.7)	14 (93.3)	0	15
Low		0	0	0	0
Normal		1 (6.7)	14 (93.3)	0	15 (100.0)
High		0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Chloride, Total				51
Week 1, Total				51
Placebo, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0
Treatment A, Total	0	15 (100.0)	0	15
Low	0	1 (6.7)	0	1 (6.7)
Normal	0	14 (93.3)	0	14 (93.3)
High	0	0	0	0
Treatment B, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Week 2, Total				43
Placebo, Total	0	15 (100.0)	0	15
Low	0	0	0	0
Normal	0	15 (100.0)	0	15 (100.0)
High	0	0	0	0
Treatment A, Total	0	13 (100.0)	0	13
Low	0	1 (7.7)	0	1 (7.7)
Normal	0	12 (92.3)	0	12 (92.3)
High	0	0	0	0
Treatment B, Total	0	15 (100.0)	0	15
Low	0	0	0	0
Normal	0	15 (100.0)	0	15 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Visit				
Treatment				
Baseline Range				
Potassium, Total				51
Week 1, Total				51
Placebo, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0
Treatment A, Total	0	15 (100.0)	0	15
Low	0	0	0	0
Normal	0	14 (93.3)	0	14 (93.3)
High	0	1 (6.7)	0	1 (6.7)
Treatment B, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Week 2, Total				43
Placebo, Total	0	12 (80.0)	3 (20.0)	15
Low	0	0	0	0
Normal	0	12 (80.0)	3 (20.0)	15 (100.0)
High	0	0	0	0
Treatment A, Total	0	13 (100.0)	0	13
Low	0	0	0	0
Normal	0	12 (92.3)	0	12 (92.3)
High	0	1 (7.7)	0	1 (7.7)
Treatment B, Total	0	14 (93.3)	1 (6.7)	15
Low	0	0	0	0
Normal	0	14 (93.3)	1 (6.7)	15 (100.0)
High	0	0	0	0

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**Table 14.5.1.1: Summary of Adverse Events
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Number of Subjects with Adverse Event	22 (100.0)	19 (100.0)	26 (100.0)	45 (100.0)	67 (100.0)
Number of Subjects with Treatment Emergent Adverse Event	20 (90.9)	18 (94.7)	24 (92.3)	42 (93.3)	62 (92.5)
Number of Subjects with Serious Adverse Events	4 (18.2)	3 (15.8)	6 (23.1)	9 (20.0)	13 (19.4)
Number of Subjects with Severe Adverse Event	4 (18.2)	3 (15.8)	1 (3.8)	4 (8.9)	8 (11.9)

n = Number of subjects in specified category, N = Number of Subjects

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**Table 14.5.1.3: Adverse Events by preferred term, System organ class & Severity
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Any Adverse Event	22 (100.0)	19 (100.0)	26 (100.0)	45 (100.0)	67 (100.0)
Gastrointestinal disorders	18 (81.8)	10 (52.6)	9 (34.6)	19 (42.2)	37 (55.2)
Diarrhea	15 (68.2)	7 (36.8)	5 (19.2)	12 (26.7)	27 (40.3)
Mild	12 (54.5)	6 (31.6)	3 (11.5)	9 (20.0)	21 (31.3)
Moderate	3 (13.6)	1 (5.3)	2 (7.7)	3 (6.7)	6 (9.0)
Severe	0	0	0	0	0
Vomitting	6 (27.3)	3 (15.8)	4 (15.4)	7 (15.6)	13 (19.4)
Mild	4 (18.2)	1 (5.3)	1 (3.8)	2 (4.4)	6 (9.0)
Moderate	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
Severe	1 (4.5)	1 (5.3)	0	1 (2.2)	2 (3.0)
Nervous system disorder	15 (68.2)	8 (42.1)	17 (65.4)	25 (55.6)	40 (59.7)
Headache	14 (63.6)	7 (36.8)	14 (53.8)	21 (46.7)	35 (52.2)
Mild	10 (45.5)	5 (26.3)	8 (30.8)	13 (28.9)	23 (34.3)
Moderate	4 (18.2)	1 (5.3)	6 (23.1)	7 (15.6)	11 (16.4)
Severe	2 (9.1)	2 (10.5)	1 (3.8)	3 (6.7)	5 (7.5)
Tremor	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
Mild	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Moderate	1 (4.5)	0	1 (3.8)	1 (2.2)	2 (3.0)
Severe	0	0	0	0	0
Vascular disorders	5 (22.7)	6 (31.6)	8 (30.8)	14 (31.1)	19 (28.4)
Hypotension	4 (18.2)	2 (10.5)	5 (19.2)	7 (15.6)	11 (16.4)
Mild	1 (4.5)	2 (10.5)	3 (11.5)	5 (11.1)	6 (9.0)
Moderate	2 (9.1)	0	2 (7.7)	2 (4.4)	4 (6.0)

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.1.3: Adverse Events by preferred term, System organ class & Severity
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Severe	1 (4.5)	0	0	0	1 (1.5)
Flushing	1 (4.5)	1 (5.3)	2 (7.7)	3 (6.7)	4 (6.0)
Mild	1 (4.5)	1 (5.3)	1 (3.8)	2 (4.4)	3 (4.5)
Moderate	0	0	1 (3.8)	1 (2.2)	1 (1.5)
Severe	0	0	0	0	0
Poor venous access	0	3 (15.8)	2 (7.7)	5 (11.1)	5 (7.5)
Mild	0	3 (15.8)	0	3 (6.7)	3 (4.5)
Moderate	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Severe	0	0	0	0	0
Cardiac disorders	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Tachycardia	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Mild	1 (4.5)	1 (5.3)	0	1 (2.2)	2 (3.0)
Moderate	1 (4.5)	0	0	0	1 (1.5)
Severe	0	0	0	0	0
Eye disorders	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)
Conjunctivitis allergic	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)
Mild	0	1 (5.3)	2 (7.7)	3 (6.7)	3 (4.5)
Moderate	0	3 (15.8)	0	3 (6.7)	3 (4.5)
Severe	0	0	0	0	0

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Weight					
Screening					
n	22	19	26	45	67
Mean	84.61	80.16	82.67	81.61	82.59
Median	83.52	80.33	81.35	80.33	80.59
SD	13.58	9.61	13.82	12.16	12.62
Range	64.9 - 111.5	64.5 - 103.8	56.4 - 112.3	56.4 - 112.3	56.4 - 112.3
Day 1					
n	22	19	26	45	67
Mean	85.40	78.80	82.46	80.91	82.39
Median	85.58	79.12	84.35	79.35	80.92
SD	15.17	10.31	16.10	13.93	14.39
Range	55.7 - 111.6	63.1 - 102.6	54.5 - 115.4	54.5 - 115.4	54.5 - 115.4

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Week 1					
n	18	15	18	33	51
Mean	84.99	74.80	81.62	78.52	80.80
Median	81.96	77.00	82.82	79.04	81.12
SD	16.98	12.85	17.22	15.55	16.20
Range	53.2 - 115.7	52.2 - 99.7	55.2 - 114.1	52.2 - 114.1	52.2 - 115.7
Week 2					
n	15	13	15	28	43
Mean	84.50	72.72	82.29	77.85	80.17
Median	86.71	71.79	83.76	76.14	79.90
SD	18.42	14.94	15.66	15.81	16.85
Range	53.0 - 119.1	53.9 - 112.0	51.1 - 107.1	51.1 - 112.0	51.1 - 119.1

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Systolic Blood Pressure					
Screening					
n	22	19	26	45	67
Mean	98.00	102.79	101.38	101.98	100.67
Median	100.00	103.00	101.00	103.00	101.00
SD	10.92	11.15	10.63	10.75	10.89
Range	78.0 - 113.0	77.0 - 125.0	82.0 - 117.0	77.0 - 125.0	77.0 - 125.0
Day 1					
n	22	19	26	45	67
Mean	104.36	97.16	99.73	98.64	100.52
Median	106.00	96.00	100.00	98.00	100.00
SD	11.10	9.86	11.39	10.73	11.10
Range	84.0 - 123.0	79.0 - 115.0	81.0 - 125.0	79.0 - 125.0	79.0 - 125.0

n = Number of subjects in specified category, N = Number of Subjects

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**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Week 1					
n	18	15	18	33	51
Mean	102.83	99.67	99.44	99.55	100.71
Median	104.50	101.00	99.50	100.00	100.00
SD	10.10	9.48	6.58	7.90	8.78
Range	79.0 - 126.0	77.0 - 112.0	88.0 - 116.0	77.0 - 116.0	77.0 - 126.0
Week 2					
n	15	13	15	28	43
Mean	101.60	95.46	103.53	99.79	100.42
Median	102.00	96.00	101.00	100.00	100.00
SD	6.86	8.86	9.68	10.01	9.00
Range	93.0 - 115.0	81.0 - 109.0	90.0 - 122.0	81.0 - 122.0	81.0 - 122.0

n = Number of subjects in specified category, N = Number of Subjects

**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Diastolic Blood Pressure					
Screening					
n	22	19	26	45	67
Mean	81.73	82.84	78.08	80.09	80.63
Median	80.00	84.00	81.50	82.00	81.00
SD	14.10	15.94	13.73	14.72	14.43
Range	57.0 - 107.0	51.0 - 121.0	50.0 - 99.0	50.0 - 121.0	50.0 - 121.0
Day 1					
n	22	19	26	45	67
Mean	82.64	76.79	79.81	78.53	79.88
Median	78.50	75.00	75.00	75.00	76.00
SD	16.44	12.67	13.80	13.27	14.40
Range	54.0 - 115.0	57.0 - 98.0	60.0 - 112.0	57.0 - 112.0	54.0 - 115.0

n = Number of subjects in specified category, N = Number of Subjects

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**Table 14.5.2: Vital Signs - Summary Statistics
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Week 1					
n	18	15	18	33	51
Mean	82.56	81.47	84.11	82.91	82.78
Median	85.00	82.00	82.50	82.00	83.00
SD	13.50	14.60	11.32	12.77	12.90
Range	49.0 - 103.0	55.0 - 101.0	64.0 - 101.0	55.0 - 101.0	49.0 - 103.0
Week 2					
n	15	13	15	28	43
Mean	80.33	72.08	87.67	80.43	80.40
Median	79.00	72.00	91.00	78.50	79.00
SD	9.00	10.24	14.72	14.89	13.02
Range	60.0 - 94.0	52.0 - 88.0	64.0 - 113.0	52.0 - 113.0	52.0 - 113.0

n = Number of subjects in specified category, N = Number of Subjects

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Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Albumin, Total				51
Week 1, Total				51
Placebo, Total	0	18 (100.0)	0	18
Low	0	1 (5.6)	0	1 (5.6)
Normal	0	16 (88.9)	0	16 (88.9)
High	0	1 (5.6)	0	1 (5.6)
Treatment A, Total	1 (6.7)	12 (80.0)	2 (13.3)	15
Low	0	0	0	0
Normal	1 (6.7)	12 (80.0)	2 (13.3)	15 (100.0)
High	0	0	0	0
Treatment B, Total	2 (11.1)	15 (83.3)	1 (5.6)	18
Low	0	0	0	0
Normal	2 (11.1)	15 (83.3)	1 (5.6)	18 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Week 2, Total				43
Placebo, Total	2 (13.3)	13 (86.7)	0	15
Low	0	1 (6.7)	0	1 (6.7)
Normal	2 (13.3)	11 (73.3)	0	13 (86.7)
High	0	1 (6.7)	0	1 (6.7)
Treatment A, Total	2 (15.4)	10 (76.9)	1 (7.7)	13
Low	0	0	0	0
Normal	2 (15.4)	10 (76.9)	1 (7.7)	13 (100.0)
High	0	0	0	0
Treatment B, Total	1 (6.7)	14 (93.3)	0	15
Low	0	0	0	0
Normal	1 (6.7)	14 (93.3)	0	15 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Chloride, Total				51
Week 1, Total				51
Placebo, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0
Treatment A, Total	0	15 (100.0)	0	15
Low	0	1 (6.7)	0	1 (6.7)
Normal	0	14 (93.3)	0	14 (93.3)
High	0	0	0	0
Treatment B, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Week 2, Total				43
Placebo, Total	0	15 (100.0)	0	15
Low	0	0	0	0
Normal	0	15 (100.0)	0	15 (100.0)
High	0	0	0	0
Treatment A, Total	0	13 (100.0)	0	13
Low	0	1 (7.7)	0	1 (7.7)
Normal	0	12 (92.3)	0	12 (92.3)
High	0	0	0	0
Treatment B, Total	0	15 (100.0)	0	15
Low	0	0	0	0
Normal	0	15 (100.0)	0	15 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Potassium, Total				51
Week 1, Total				51
Placebo, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0
Treatment A, Total	0	15 (100.0)	0	15
Low	0	0	0	0
Normal	0	14 (93.3)	0	14 (93.3)
High	0	1 (6.7)	0	1 (6.7)
Treatment B, Total	0	18 (100.0)	0	18
Low	0	0	0	0
Normal	0	18 (100.0)	0	18 (100.0)
High	0	0	0	0

Table 14.5.4: Lab Shift Table
Safety Population

Lab Test Visit Treatment Baseline Range	Post-Baseline Reference Range			
	Low n (%)	Normal n (%)	High n (%)	Total n (%)
Week 2, Total				43
Placebo, Total	0	12 (80.0)	3 (20.0)	15
Low	0	0	0	0
Normal	0	12 (80.0)	3 (20.0)	15 (100.0)
High	0	0	0	0
Treatment A, Total	0	13 (100.0)	0	13
Low	0	0	0	0
Normal	0	12 (92.3)	0	12 (92.3)
High	0	1 (7.7)	0	1 (7.7)
Treatment B, Total	0	14 (93.3)	1 (6.7)	15
Low	0	0	0	0
Normal	0	14 (93.3)	1 (6.7)	15 (100.0)
High	0	0	0	0