

**Table 14.5.3: Laboratory Tests - 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 (%)
Albumin (g/L)					
Day 1					
Male					
n	24	21	33	54	78
Mean	41.54	41.90	41.27	41.52	41.53
Median	41.50	42.00	42.00	42.00	42.00
SD	5.44	4.69	4.03	4.27	4.62
Range	28.0 - 52.0	35.0 - 50.0	32.0 - 50.0	32.0 - 50.0	28.0 - 52.0
Albumin (g/L)					
Day 1					
Female					
n	42	36	45	81	123
Mean	41.48	42.28	41.89	42.06	41.86
Median	41.00	42.00	42.00	42.00	42.00
SD	5.57	3.53	4.90	4.32	4.77
Range	28.0 - 54.0	35.0 - 51.0	32.0 - 57.0	32.0 - 57.0	28.0 - 57.0

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

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	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Albumin (g/L)					
Screening					
Male					
n	8	7	11	18	26
Mean	44.00	42.57	40.82	41.50	42.27
Median	43.50	43.00	42.00	42.00	42.00
SD	3.74	2.44	5.21	4.34	4.26
Range	38.0 - 50.0	39.0 - 46.0	33.0 - 49.0	33.0 - 49.0	33.0 - 50.0
Female					
n	14	12	15	27	41
Mean	39.71	41.25	41.07	41.15	40.66
Median	38.50	41.00	42.00	41.00	41.00
SD	4.45	3.98	3.94	3.88	4.08
Range	34.0 - 49.0	35.0 - 49.0	34.0 - 50.0	34.0 - 50.0	34.0 - 50.0

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Albumin (g/L)					
Week 1					
Male					
n	5	5	7	12	17
Mean	43.40	42.40	42.29	42.33	42.65
Median	43.00	42.00	40.00	41.00	43.00
SD	2.30	6.58	7.65	6.91	5.86
Range	40.0 - 46.0	36.0 - 53.0	33.0 - 54.0	33.0 - 54.0	33.0 - 54.0
Albumin (g/L)					
Week 1					
Female					
n	13	10	11	21	34
Mean	42.54	41.60	40.82	41.19	41.71
Median	42.00	41.50	41.00	41.00	41.50
SD	4.14	5.62	4.85	5.11	4.75
Range	38.0 - 49.0	34.0 - 53.0	32.0 - 50.0	32.0 - 53.0	32.0 - 53.0

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Albumin (g/L)					
Week 2					
Male					
n	5	3	6	9	14
Mean	42.40	48.00	43.17	44.78	43.93
Median	41.00	45.00	42.00	42.00	42.00
SD	3.65	8.89	3.25	5.67	5.03
Range	39.0 - 48.0	41.0 - 58.0	39.0 - 48.0	39.0 - 58.0	39.0 - 58.0
Albumin (g/L)					
Week 2					
Female					
n	10	10	9	19	29
Mean	39.20	42.70	39.67	41.26	40.55
Median	38.50	43.00	39.00	42.00	41.00
SD	4.76	6.38	3.28	5.25	5.10
Range	33.0 - 48.0	30.0 - 50.0	34.0 - 46.0	30.0 - 50.0	30.0 - 50.0

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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 (%)
Chloride (mmol/L)					
Day 1					
Male					
n	24	21	33	54	78
Mean	101.58	101.76	101.33	101.50	101.53
Median	102.00	102.00	102.00	102.00	102.00
SD	1.41	1.45	1.47	1.46	1.44
Range	99.0 - 105.0	97.0 - 104.0	98.0 - 104.0	97.0 - 104.0	97.0 - 105.0
Chloride (mmol/L)					
Day 1					
Female					
n	42	36	45	81	123
Mean	102.05	102.36	101.80	102.05	102.05
Median	102.00	102.00	102.00	102.00	102.00
SD	1.78	1.82	1.29	1.56	1.63
Range	98.0 - 107.0	98.0 - 106.0	99.0 - 106.0	98.0 - 106.0	98.0 - 107.0

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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 (%)
Chloride (mmol/L)					
Screening					
Male					
n	8	7	11	18	26
Mean	102.50	101.57	101.64	101.61	101.88
Median	102.00	102.00	102.00	102.00	102.00
SD	1.93	1.90	1.43	1.58	1.70
Range	101.0 - 107.0	98.0 - 103.0	100.0 - 105.0	98.0 - 105.0	98.0 - 107.0
Chloride (mmol/L)					
Screening					
Female					
n	14	12	15	27	41
Mean	102.21	102.25	101.93	102.07	102.12
Median	102.00	102.00	102.00	102.00	102.00
SD	1.31	1.60	1.16	1.36	1.33
Range	101.0 - 106.0	100.0 - 106.0	99.0 - 104.0	99.0 - 106.0	99.0 - 106.0

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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 (%)
Chloride (mmol/L)					
Week 1					
Male					
n	5	5	7	12	17
Mean	101.80	104.00	102.29	103.00	102.65
Median	101.00	105.00	102.00	102.50	102.00
SD	1.64	1.87	2.21	2.17	2.06
Range	100.0 - 104.0	102.0 - 106.0	99.0 - 105.0	99.0 - 106.0	99.0 - 106.0
Chloride (mmol/L)					
Week 1					
Female					
n	13	10	11	21	34
Mean	102.31	102.60	102.00	102.29	102.29
Median	102.00	102.50	102.00	102.00	102.00
SD	1.65	0.97	1.48	1.27	1.40
Range	100.0 - 106.0	101.0 - 104.0	100.0 - 105.0	100.0 - 105.0	100.0 - 106.0

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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 (%)
Chloride (mmol/L)					
Week 2					
Male					
n	5	3	6	9	14
Mean	101.40	106.33	102.50	103.78	102.93
Median	102.00	106.00	102.50	103.00	102.50
SD	1.34	0.58	1.64	2.33	2.30
Range	100.0 - 103.0	106.0 - 107.0	100.0 - 105.0	100.0 - 107.0	100.0 - 107.0
Chloride (mmol/L)					
Week 2					
Female					
n	10	10	9	19	29
Mean	101.40	102.40	101.44	101.95	101.76
Median	102.00	103.00	101.00	102.00	102.00
SD	1.71	2.63	0.88	2.01	1.90
Range	99.0 - 105.0	98.0 - 106.0	100.0 - 103.0	98.0 - 106.0	98.0 - 106.0

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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 (%)
Potassium (mmol/L)					
Day 1					
Male					
n	24	21	33	54	78
Mean	4.50	4.45	4.50	4.48	4.49
Median	4.50	4.50	4.50	4.50	4.50
SD	0.00	0.22	0.00	0.14	0.11
Range	4.5 - 4.5	3.5 - 4.5	4.5 - 4.5	3.5 - 4.5	3.5 - 4.5
Potassium (mmol/L)					
Day 1					
Female					
n	42	36	45	81	123
Mean	4.43	4.50	4.48	4.49	4.47
Median	4.50	4.50	4.50	4.50	4.50
SD	0.26	0.24	0.15	0.19	0.22
Range	3.5 - 4.5	3.5 - 5.5	3.5 - 4.5	3.5 - 5.5	3.5 - 5.5

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Potassium (mmol/L)					
Screening					
Male					
n	8	7	11	18	26
Mean	4.50	4.50	4.59	4.56	4.54
Median	4.50	4.50	4.50	4.50	4.50
SD	0.00	0.00	0.30	0.24	0.20
Range	4.5 - 4.5	4.5 - 4.5	4.5 - 5.5	4.5 - 5.5	4.5 - 5.5
Potassium (mmol/L)					
Screening					
Female					
n	14	12	15	27	41
Mean	4.50	4.50	4.50	4.50	4.50
Median	4.50	4.50	4.50	4.50	4.50
SD	0.39	0.00	0.00	0.00	0.22
Range	3.5 - 5.5	4.5 - 4.5	4.5 - 4.5	4.5 - 4.5	3.5 - 5.5

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Potassium (mmol/L)					
Week 1					
Male					
n	5	5	7	12	17
Mean	4.50	4.50	4.50	4.50	4.50
Median	4.50	4.50	4.50	4.50	4.50
SD	0.00	0.00	0.00	0.00	0.00
Range	4.5 - 4.5	4.5 - 4.5	4.5 - 4.5	4.5 - 4.5	4.5 - 4.5
Potassium (mmol/L)					
Week 1					
Female					
n	13	10	11	21	34
Mean	4.50	4.50	4.50	4.50	4.50
Median	4.50	4.50	4.50	4.50	4.50
SD	0.00	0.00	0.00	0.00	0.00
Range	4.5 - 4.5	4.5 - 4.5	4.5 - 4.5	4.5 - 4.5	4.5 - 4.5

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Potassium (mmol/L)					
Week 2					
Male					
n	5	3	6	9	14
Mean	4.50	4.17	4.67	4.50	4.50
Median	4.50	4.50	4.50	4.50	4.50
SD	0.00	0.58	0.41	0.50	0.39
Range	4.5 - 4.5	3.5 - 4.5	4.5 - 5.5	3.5 - 5.5	3.5 - 5.5
Potassium (mmol/L)					
Week 2					
Female					
n	10	10	9	19	29
Mean	4.80	4.40	4.50	4.45	4.57
Median	4.50	4.50	4.50	4.50	4.50
SD	0.48	0.32	0.00	0.23	0.37
Range	4.5 - 5.5	3.5 - 4.5	4.5 - 4.5	3.5 - 4.5	3.5 - 5.5

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