

# Table of Contents

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**Table 14.5.1.2: Adverse Events by preferred term and System organ class  
Safety Population**

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
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)
Vomiting	6 (27.3)	3 (15.8)	4 (15.4)	7 (15.6)	13 (19.4)
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)
Tremor	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
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)
Flushing	1 (4.5)	1 (5.3)	2 (7.7)	3 (6.7)	4 (6.0)
Poor venous access	0	3 (15.8)	2 (7.7)	5 (11.1)	5 (7.5)
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)
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)

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

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
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**

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
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 14.5.3: 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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**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)					
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

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

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)					
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

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

**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)					
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

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

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**Table 14.5.3: Laboratory Tests - Summary Statistics  
Safety Population**

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
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

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

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**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 (%)
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

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

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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 (%)
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

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

**Table 14.5.3: Laboratory Tests - Summary Statistics  
Safety Population**

	<b>Placebo (N=22) n (%)</b>	<b>Treatment A (N=19) n (%)</b>	<b>Treatment B (N=26) n (%)</b>	<b>Treatment A &amp; B (N=45) n (%)</b>	<b>Total (N=67) n (%)</b>
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

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

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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 (%)
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

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

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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 (%)
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

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

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**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 (%)
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

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

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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 (%)
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

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

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