

Table 14.3.5-1.1: Summary of Intraocular Pressure (Safety Set)

Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Intraocular Pressure (mmHg)	Baseline	n (missing)	31 (0)	30 (0)	30 (0)	91 (0)
		Mean (SD)	13.5 (2.20)	14.5 (1.81)	14.2 (1.97)	14.1 (2.03)
		Median	13.0	14.0	14.0	14.0
		Q1, Q3	12.0, 15.0	13.0, 16.0	13.0, 16.0	12.0, 16.0
		Min, Max	10, 18	11, 18	10, 18	10, 18
	Week 2	n (missing)	28 (3)	28 (2)	30 (0)	86 (5)
		Mean (SD)	13.8 (1.40)	14.4 (1.64)	14.4 (2.30)	14.2 (1.84)
		Median	14.0	14.5	14.0	14.0
		Q1, Q3	13.0, 14.0	13.0, 16.0	13.0, 16.0	13.0, 15.0
		Min, Max	12, 18	10, 17	8, 19	8, 19
	Week 2 change from Baseline	n (missing)	28 (3)	28 (2)	30 (0)	86 (5)
		Mean (SD)	0.2 (2.42)	-0.2 (1.98)	0.2 (3.03)	0.1 (2.51)
		Median	0.0	0.0	0.0	0.0
		Q1, Q3	-0.5, 2.0	-2.0, 1.0	-2.0, 2.0	-2.0, 2.0
		Min, Max	-5, 6	-4, 5	-7, 8	-7, 8

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Intraocular Pressure (mmHg)	Week 4	n (missing)	28 (3)	29 (1)	30 (0)	87 (4)
		Mean (SD)	13.1 (1.74)	13.8 (1.94)	14.4 (1.35)	13.8 (1.75)
		Median	13.0	14.0	14.0	14.0
		Q1, Q3	12.0, 14.0	12.0, 15.0	13.0, 15.0	12.0, 15.0
		Min, Max	10, 16	10, 18	12, 18	10, 18
	Week 4 change from Baseline	n (missing)	28 (3)	29 (1)	30 (0)	87 (4)
		Mean (SD)	-0.3 (2.29)	-0.9 (2.29)	0.2 (2.23)	-0.3 (2.29)
		Median	0.0	0.0	0.0	0.0
		Q1, Q3	-1.5, 1.5	-2.0, 0.0	-1.0, 1.0	-2.0, 1.0
		Min, Max	-5, 4	-6, 4	-4, 5	-6, 5
	Week 8	n (missing)	24 (7)	28 (2)	28 (2)	80 (11)
		Mean (SD)	13.5 (1.53)	14.5 (1.93)	14.8 (3.01)	14.3 (2.31)
		Median	13.0	14.0	14.0	14.0
		Q1, Q3	12.0, 14.0	13.5, 16.0	13.0, 16.0	13.0, 15.5
		Min, Max	11, 17	10, 20	10, 26	10, 26

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Parameter	Visit	Statistic	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Intraocular Pressure (mmHg)	Week 8 change from Baseline	n (missing)	24 (7)	28 (2)	28 (2)	80 (11)
		Mean (SD)	0.3 (2.49)	-0.1 (1.88)	0.6 (3.16)	0.3 (2.56)
		Median	0.0	0.0	0.0	0.0
		Q1, Q3	-1.0, 1.5	-1.0, 1.0	-2.0, 2.0	-1.0, 1.0
		Min, Max	-5, 5	-6, 4	-3, 12	-6, 12
	Week 12	n (missing)	25 (6)	28 (2)	27 (3)	80 (11)
		Mean (SD)	13.8 (1.41)	13.7 (2.03)	13.8 (1.93)	13.8 (1.80)
		Median	13.0	14.0	14.0	14.0
		Q1, Q3	13.0, 15.0	12.0, 15.0	12.0, 15.0	13.0, 15.0
		Min, Max	11, 16	10, 18	10, 18	10, 18
	Week 12 change from Baseline	n (missing)	25 (6)	28 (2)	27 (3)	80 (11)
		Mean (SD)	0.4 (2.38)	-0.9 (2.73)	-0.3 (2.18)	-0.3 (2.47)
		Median	1.0	-1.0	0.0	0.0
		Q1, Q3	-2.0, 2.0	-2.0, 1.0	-2.0, 1.0	-2.0, 1.0
		Min, Max	-4, 4	-8, 5	-6, 3	-8, 5

Table 14.3.5-1.2: Analysis of Intraocular Pressure (Safety Set)

Visit		Adjusted Mean		P-value
		n	LS Mean (95% CI)	
Week 2	1% Pro-ocular	28	0.23 (-0.57, 1.02)	-
	0.5% Pro-ocular	28	-0.37 (-1.18, 0.45)	-
	Placebo	30	0.18 (-0.62, 0.98)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		0.05 (-0.93, 1.03)	0.924
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-0.55 (-1.53, 0.44)	0.272
Week 4	1% Pro-ocular	29	-0.70 (-1.39, 0.00)	-
	0.5% Pro-ocular	28	-1.07 (-1.79, -0.35)	-
	Placebo	30	0.01 (-0.70, 0.73)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-0.71 (-1.57, 0.16)	0.107
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-1.08 (-1.96, -0.21)	0.016
Week 8	1% Pro-ocular	28	0.24 (-0.74, 1.22)	-
	0.5% Pro-ocular	24	-0.31 (-1.37, 0.74)	-
	Placebo	28	0.72 (-0.30, 1.74)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-0.48 (-1.69, 0.74)	0.438
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		-1.03 (-2.31, 0.25)	0.112

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Visit		Adjusted Mean		P-value
		n	LS Mean (95% CI)	
Week 12	1% Pro-ocular	28	-0.69 (-1.49, 0.10)	-
	0.5% Pro-ocular	25	-0.45 (-1.30, 0.40)	-
	Placebo	27	-0.55 (-1.39, 0.28)	-
	LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		-0.14 (-1.12, 0.84)	0.771
	LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.10 (-0.91, 1.12)	0.837