

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Dry Eye Severity Level > 2**

Parameter	Visit	Statistics	Full Analysis Set N=9			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Median	85.0	1.0	88.0	0.0
		Max	89	9	90	9

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.12](#) - Visual acuity

Program: Tables\c1116-qs-01-tbl.sas

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Screening - Day -15/-1	N	20		20	
		Mean	85.5		86.1	

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Visit 2 - Day 1	SD	5.5		4.2	
		CV%	6.4		4.9	
		Min	75		78	
		Median	85.0		85.0	
		Max	98		95	
		N	20	20	20	20
		Mean	86.1	0.7	87.3	1.3
	Visit 3 - Day 8±1	SD	5.1	2.9	3.9	3.1
		CV%	5.9	444.4	4.5	248.8
		Min	78	-3	81	-4
		Median	85.0	0.0	88.0	0.5
		Max	95	10	94	9
		N	20	20	20	20
		Mean	85.9	0.5	87.1	1.1
		SD	5.1	2.9	4.1	3.0
		CV%	6.0	634.6	4.7	287.3
		Min	77	-6	80	-5

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Visit 6 - Day 29±1	Median	85.0	0.0	88.0	0.5
		Max	95	5	94	7
		N	20	20	20	20
		Mean	86.7	1.3	87.0	1.0
		SD	4.4	3.8	4.8	3.7
		CV%	5.0	301.4	5.5	391.6
		Min	78	-7	74	-5
		Median	85.5	1.5	88.5	0.5
		Max	95	9	95	10
Visual Acuity Score	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	86.6	1.2	87.0	1.0
		SD	3.7	3.8	4.0	3.9
		CV%	4.3	329.3	4.6	410.5
		Min	82	-7	76	-9
		Median	85.0	1.0	88.0	0.0
		Max	95	9	94	9

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Dry Eye Severity Level > 2**

Parameter	Visit	Statistics	Full Analysis Set N=7			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.12](#) - Visual acuity

Program: Tables\c116-qs-01-tbl.sas

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Screening - Day -15/-1	N	20		20	
		Mean	74.6		80.4	
		SD	21.9		14.1	
		CV%	29.4		17.5	

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Visit 2 - Day 1	Min	0		38	
		Median	84.0		85.0	
		Max	90		91	
		N	20	20	20	20
		Mean	76.2	1.6	80.9	0.5
		SD	20.9	5.8	10.7	5.2
		CV%	27.4	361.8	13.2	1049.3
		Min	5	-6	51	-6
		Median	84.0	1.0	85.0	0.0
		Max	90	21	91	18
		N	20	20	20	20
		Mean	78.0	3.4	81.2	0.8
		SD	19.4	6.3	11.6	4.8
		CV%	24.9	187.9	14.3	634.1
		Min	17	-4	51	-8
		Median	84.5	1.5	84.5	0.0
		Max	94	22	93	15

**Table 14.2.1.12 Visual acuity (Full analysis set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	78.9	5.1	81.0	0.8
		SD	15.4	11.7	11.5	5.3
		CV%	19.5	229.4	14.2	631.2
		Min	32	-5	53	-8
		Median	83.0	3.0	85.0	0.0
		Max	94	48	95	15
Visual Acuity Score	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	81.3	6.7	82.3	1.9
		SD	13.3	10.6	10.4	8.0
		CV%	16.3	158.0	12.7	434.3
		Min	45	-4	57	-12
		Median	85.0	4.0	85.0	1.5
		Max	95	45	94	27

**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Dry Eye Severity Level > 2**

Parameter	Visit	Statistics	Per Protocol Set N=6			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Median	85.5	2.0	88.5	1.5
		Max	89	9	89	9

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.12](#) - Visual acuity

Program: Tables\c1116-qs-01-tbl.sas

**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Screening - Day -15/-1	N	14		14	
		Mean	85.9		86.3	

**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score		SD	6.5		4.8	
		CV%	7.6		5.6	
		Min	75		78	
		Median	85.0		85.5	
		Max	98		95	
	Visit 2 - Day 1	N	14	14	14	14
		Mean	86.6	0.6	87.9	1.6
		SD	5.9	3.3	4.3	3.4
		CV%	6.8	516.3	4.8	204.8
		Min	78	-3	81	-2
		Median	86.5	0.0	88.0	1.0
		Max	95	10	94	9
Visual Acuity Score	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	85.8	-0.1	86.8	0.5
		SD	6.1	3.0	4.6	2.8
		CV%	7.1	-2124.2	5.3	569.8
		Min	77	-6	80	-5



**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Visit 6 - Day 29±1	Median	85.5	-1.0	87.5	0.0
		Max	95	5	94	5
		N	14	14	14	14
		Mean	87.3	1.4	87.4	1.1
		SD	5.1	4.4	5.5	4.3
		CV%	5.8	326.5	6.3	400.1
		Min	78	-7	74	-5
		Median	88.0	2.5	89.0	0.5
		Max	95	9	95	10
Visual Acuity Score	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	87.0	1.1	87.1	0.8
		SD	4.2	4.4	4.4	4.4
		CV%	4.8	410.1	5.1	563.0
		Min	82	-7	76	-9
		Median	86.0	0.5	88.5	0.0
		Max	95	9	94	9

**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Dry Eye Severity Level > 2**

Parameter	Visit	Statistics	Per Protocol Set N=5			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.12](#) - Visual acuity

Program: Tables\c116-qs-01-tbl.sas

**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Visual Acuity Score	Screening - Day -15/-1	N	16		16	
		Mean	78.3		82.1	
		SD	13.9		10.9	
		CV%	17.7		13.3	

**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Visit 2 - Day 1	Min	36		47	
		Median	84.0		85.0	
		Max	90		90	
		N	16	16	16	16
		Mean	78.5	0.3	81.9	-0.2
		SD	13.5	3.8	9.8	3.1
		CV%	17.2	1528.4	11.9	-1643.5
		Min	36	-6	51	-5
		Median	83.0	0.0	85.0	0.0
		Max	90	9	91	4
		N	16	16	16	16
		Mean	80.0	1.8	81.7	-0.4
		SD	14.4	3.1	10.3	3.4
		CV%	18.0	178.9	12.6	-787.2
		Min	36	-4	51	-8
		Median	83.5	1.0	84.5	0.0
		Max	94	10	93	4

**Table 14.2.1.27 Visual acuity (Per protocol set)**

**Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level**

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Visual Acuity Score	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	79.9	1.7	82.2	0.1
		SD	14.5	4.0	10.0	4.4
		CV%	18.1	238.7	12.1	7118.8
		Min	32	-5	57	-8
		Median	83.0	1.5	85.0	-1.0
		Max	94	11	95	10
Visual Acuity Score	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	82.8	4.6	81.9	-0.2
		SD	11.2	5.4	10.3	5.4
		CV%	13.5	118.7	12.6	-2876.8
		Min	51	-4	57	-12
		Median	85.0	4.0	84.0	0.5
		Max	95	15	94	10