

**Table 14.2.1.2 Ocular surface staining with lissamine green (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
Total Score Conjunctiva	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	4.3	-3.9	3.6	-3.9
		SD	2.0	3.3	2.8	3.8
		CV%	47.0	-85.2	78.3	-98.0
		Min	1	-11	0	-9
		Median	4.0	-3.0	3.0	-5.0
		Max	9	1	11	6
Total Score	Screening - Day -15/-1	N	20		20	
		Mean	13.3		11.7	
		SD	4.9		6.7	
		CV%	36.6		57.6	
		Min	8		2	
		Median	13.0		10.5	
		Max	24		26	
Total Score	Visit 2 - Day 1	N	20	20	20	20
		Mean	11.8	-1.6	10.3	-1.4
		SD	3.5	4.1	4.1	5.5

**Table 14.2.1.2 Ocular surface staining with lissamine green (Full analysis set)**

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Total Score	Visit 3 - Day 8±1	CV%	30.1	-266.8	40.0	-393.6
		Min	6	-14	3	-18
		Median	11.0	0.0	9.0	0.0
		Max	20	3	16	5
		N	20	20	20	20
		Mean	7.4	-6.0	7.3	-4.4
		SD	2.8	3.7	3.9	5.7
		CV%	38.6	-62.5	53.4	-130.7
Total Score	Visit 6 - Day 29±1	Min	3	-16	1	-17
		Median	7.0	-4.5	7.0	-2.5
		Max	14	-2	17	3
		N	20	20	20	20
		Mean	3.8	-9.6	4.1	-7.6
		SD	3.1	4.0	3.6	4.5
		CV%	81.6	-42.0	87.4	-59.2
		Min	1	-18	0	-15
		Median	2.0	-9.0	3.0	-7.0

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**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
		Max	11	-2	13	1
Total Score	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	5.5	-7.9	5.0	-6.7
		SD	3.2	4.4	4.4	5.3
		CV%	58.5	-55.5	89.0	-80.2
		Min	1	-16	0	-18
		Median	5.5	-6.5	3.5	-6.0
		Max	13	-1	18	5

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.2](#) - Ocular surface staining with lissamine green

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

**Table 14.2.1.2 Ocular surface staining with lissamine green (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
Total Score Conjunctiva	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	4.6	-2.2	4.4	-0.8
		SD	2.9	2.0	2.8	3.3
		CV%	62.5	-94.6	64.3	-445.1
		Min	0	-5	0	-11
		Median	5.0	-2.5	3.5	-1.0
		Max	9	2	10	4
Total Score	Screening - Day -15/-1	N	20		20	
		Mean	12.6		8.9	
		SD	5.1		5.3	
		CV%	40.3		60.4	
		Min	8		3	
		Median	11.0		8.0	
		Max	28		28	
Total Score	Visit 2 - Day 1	N	20	20	20	20
		Mean	12.9	0.3	9.1	0.3
		SD	5.4	1.6	6.1	2.0

**Table 14.2.1.2 Ocular surface staining with lissamine green (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
Total Score	Visit 3 - Day 8±1	CV%	42.2	519.8	66.9	798.7
		Min	6	-4	3	-4
		Median	12.0	0.0	7.5	0.0
		Max	30	3	30	4
		N	20	20	20	20
		Mean	10.4	-2.3	9.3	0.4
		SD	5.5	2.2	6.1	3.1
		CV%	52.7	-98.7	66.3	775.4
Total Score	Visit 6 - Day 29±1	Min	3	-7	3	-4
		Median	9.0	-2.0	8.0	0.0
		Max	26	3	26	8
		N	19	19	19	19
		Mean	7.5	-5.1	7.6	-1.2
		SD	4.8	2.5	5.7	4.4
		CV%	64.5	-49.6	75.8	-378.9
		Min	1	-11	1	-10
		Median	6.0	-6.0	5.0	-1.0

**Table 14.2.1.2 Ocular surface staining with lissamine green (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
		Max	18	0	22	8
Total Score	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	7.7	-4.9	7.3	-1.6
		SD	5.3	3.3	5.5	5.5
		CV%	69.1	-66.5	75.8	-345.6
		Min	0	-10	0	-16
		Median	7.0	-5.0	5.0	-1.0
		Max	18	-1	20	9

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.2](#) - Ocular surface staining with lissamine green

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

**Table 14.2.1.17 Ocular surface staining with lissamine green (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
Total Score Conjunctiva	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	4.6	-3.5	3.7	-3.5
		SD	2.0	3.5	3.0	3.8
		CV%	43.5	-101.3	80.0	-109.7
		Min	1	-11	0	-8
		Median	4.5	-2.5	3.5	-5.0
		Max	9	1	11	6
Total Score	Screening - Day -15/-1	N	14		14	
		Mean	13.5		11.6	
		SD	5.0		6.8	
		CV%	37.1		58.8	
		Min	8		2	
		Median	13.0		10.5	
		Max	24		26	
Total Score	Visit 2 - Day 1	N	14	14	14	14
		Mean	11.9	-1.6	9.9	-1.7
		SD	3.6	3.9	4.4	6.0

**Table 14.2.1.17 Ocular surface staining with lissamine green (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
Total Score	Visit 3 - Day 8±1	CV%	30.0	-248.0	44.3	-351.8
		Min	8	-14	3	-18
		Median	10.5	0.0	8.5	0.0
		Max	20	2	16	5
		N	14	14	14	14
		Mean	7.6	-5.9	7.4	-4.2
		SD	3.1	3.6	3.3	5.6
		CV%	40.7	-60.1	44.8	-132.3
Total Score	Visit 6 - Day 29±1	Min	3	-16	1	-17
		Median	7.5	-5.0	8.0	-3.0
		Max	14	-2	13	3
		N	14	14	14	14
		Mean	3.9	-9.6	4.2	-7.4
		SD	3.3	4.6	3.3	4.7
		CV%	85.0	-47.2	78.0	-63.7
		Min	1	-18	0	-15
		Median	2.0	-9.0	3.0	-7.0



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**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
		Max	11	-2	11	1
Total Score	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	6.1	-7.4	5.2	-6.4
		SD	3.5	4.6	4.7	5.8
		CV%	58.0	-62.4	90.9	-91.6
		Min	1	-16	1	-18
		Median	6.0	-6.0	4.0	-6.5
		Max	13	-1	18	5

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.2](#) - Ocular surface staining with lissamine green

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

**Table 14.2.1.17 Ocular surface staining with lissamine green (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
Total Score Conjunctiva	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	4.3	-2.1	4.4	-0.2
		SD	2.9	1.8	2.9	2.1
		CV%	66.5	-85.7	65.3	-1139.2
		Min	0	-5	0	-3
		Median	4.0	-2.5	4.0	-1.0
		Max	9	1	10	4
Total Score	Screening - Day -15/-1	N	16		16	
		Mean	11.9		7.8	
		SD	3.8		3.1	
		CV%	32.0		39.4	
		Min	8		3	
		Median	11.0		8.0	
		Max	23		14	
Total Score	Visit 2 - Day 1	N	16	16	16	16
		Mean	12.0	0.1	8.1	0.3
		SD	4.0	1.6	4.0	2.1

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**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
Total Score	Visit 3 - Day 8±1	CV%	33.3	2577.9	49.7	845.4
		Min	6	-4	3	-4
		Median	11.5	0.0	7.5	0.0
		Max	22	3	17	4
		N	16	16	16	16
		Mean	9.2	-2.8	8.1	0.3
		SD	4.4	1.7	5.2	3.3
Total Score	Visit 6 - Day 29±1	CV%	47.9	-60.1	64.6	1318.6
		Min	3	-7	3	-4
		Median	9.0	-2.0	7.5	-0.5
		Max	21	0	21	8
		N	16	16	16	16
		Mean	7.2	-4.8	7.1	-0.8
		SD	4.6	2.2	5.6	4.0
Total Score	Visit 6 - Day 29±1	CV%	63.7	-45.8	79.0	-538.9
		Min	1	-7	1	-7
		Median	6.5	-5.5	5.0	-1.0

**Table 14.2.1.17 Ocular surface staining with lissamine green (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
		Max	18	0	22	8
Total Score	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	7.1	-4.8	6.9	-0.9
		SD	5.3	2.9	5.7	3.9
		CV%	73.7	-60.8	82.6	-420.3
		Min	0	-10	0	-6
		Median	6.5	-5.0	5.0	-1.0
		Max	17	-1	20	9

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.2](#) - Ocular surface staining with lissamine green

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