

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
		Median	308.0	-6.0	316.0	13.0
		Max	326	28	336	17

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.14](#) - Tear film osmolarity

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

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Screening - Day -15/-1	N	20		20	
		Mean	313.6		311.2	

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 2 - Day 1	SD	13.7		18.6	
		CV%	4.4		6.0	
		Min	289		284	
		Median	311.0		309.0	
		Max	339		371	
		N	20	20	20	20
		Mean	304.6	-9.1	307.1	-4.1
		SD	9.1	13.1	20.5	25.4
		CV%	3.0	-144.7	6.7	-618.4
		Min	287	-32	278	-69
		Median	305.5	-4.5	302.0	-5.0
		Max	321	10	378	49
Tear Film Osmolarity (mOsm/L)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	309.6	-4.1	304.4	-6.9
		SD	11.9	16.2	11.3	22.0
		CV%	3.8	-399.1	3.7	-321.6
		Min	289	-39	286	-77

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 6 - Day 29±1	Median	309.0	0.5	304.0	-3.0
		Max	339	21	322	24
		N	20	20	20	20
		Mean	308.2	-5.5	307.0	-4.2
		SD	12.3	10.8	12.9	21.5
		CV%	4.0	-198.9	4.2	-513.1
		Min	293	-38	293	-74
		Median	306.0	-4.0	306.5	-2.0
		Max	331	6	351	42
		N	20	20	20	20
		Mean	308.8	-4.8	311.7	0.5
		SD	9.8	14.2	10.1	16.3
		CV%	3.2	-296.6	3.2	3623.2
		Min	291	-36	292	-51
		Median	308.5	-5.5	310.5	3.0
		Max	326	28	336	18

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.14](#) - Tear film osmolarity

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

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline

Tear Film Osmolarity (mOsm/L)	Screening - Day -15/-1	N	20		19	
		Mean	313.9		314.3	
		SD	16.1		17.5	
		CV%	5.1		5.6	

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 2 - Day 1	Min	290		298	
		Median	313.0		310.0	
		Max	365		372	
		N	20	20	20	19
		Mean	313.2	-0.8	319.9	3.8
		SD	16.8	18.3	20.9	24.2
		CV%	5.4	-2445.5	6.5	637.4
		Min	275	-25	295	-46
		Median	311.0	-2.5	316.5	6.0
		Max	362	53	385	64
		N	20	20	19	19
		Mean	314.4	0.5	314.1	-0.2
		SD	19.2	15.0	19.0	21.4
		CV%	6.1	3323.2	6.1	-10151.4
Tear Film Osmolarity (mOsm/L)	Visit 3 - Day 8±1	Min	297	-33	291	-42
		Median	310.0	0.5	312.0	-1.0
		Max	379	25	378	57

**Table 14.2.1.14 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 6 - Day 29±1	N	19	19	18	18
		Mean	312.5	-1.4	307.6	-7.2
		SD	12.3	19.0	12.7	19.5
		CV%	3.9	-1335.0	4.1	-270.2
		Min	292	-38	277	-56
		Median	309.0	-7.0	308.5	-0.5
		Max	336	46	337	19
Tear Film Osmolarity (mOsm/L)	Final Visit - Day 56±4/ETV	N	20	20	19	19
		Mean	318.0	4.1	313.7	-0.6
		SD	18.3	19.8	20.3	22.3
		CV%	5.8	489.7	6.5	-3844.8
		Min	295	-27	282	-49
		Median	314.5	2.5	312.0	2.0
		Max	353	40	380	67

**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
		Median	307.0	-0.5	314.5	14.0
		Max	326	28	336	17

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.14](#) - Tear film osmolarity

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

**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Screening - Day -15/-1	N	14		14	
		Mean	311.5		311.4	

**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 2 - Day 1	SD	13.3		21.7	
		CV%	4.3		7.0	
		Min	289		284	
		Median	310.0		307.5	
		Max	334		371	
		N	14	14	14	14
		Mean	303.4	-8.1	302.9	-8.5
		SD	9.5	13.6	14.0	26.3
		CV%	3.1	-167.9	4.6	-308.9
		Min	287	-32	278	-69
Tear Film Osmolarity (mOsm/L)	Visit 3 - Day 8±1	Median	305.5	-3.5	300.0	-7.0
		Max	320	10	339	32
		N	14	14	14	14
		Mean	308.3	-3.2	303.0	-8.4
		SD	13.4	18.0	12.1	25.5
		CV%	4.3	-558.7	4.0	-305.5
		Min	289	-39	286	-77



**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 6 - Day 29±1	Median	307.0	-2.0	302.0	-1.5
		Max	339	21	322	24
		N	14	14	14	14
		Mean	305.9	-5.6	303.7	-7.6
		SD	12.0	11.6	8.0	21.8
		CV%	3.9	-207.7	2.6	-285.5
		Min	293	-38	293	-74
		Median	302.5	-4.0	306.0	-2.0
		Max	331	6	317	13
		N	14	14	14	14
		Mean	308.1	-3.4	311.3	-0.1
		SD	11.1	13.8	11.4	18.7
		CV%	3.6	-411.9	3.6	-26182.8
		Min	291	-26	292	-51
		Median	307.0	-5.5	309.5	6.5
		Max	326	28	336	17

**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.14](#) - Tear film osmolarity

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

**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline

Tear Film Osmolarity (mOsm/L)	Screening - Day -15/-1	N	16		15	
		Mean	315.1		315.2	
		SD	17.1		19.5	
		CV%	5.4		6.2	

**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 2 - Day 1	Min	290		298	
		Median	312.5		310.0	
		Max	365		372	
		N	16	16	16	15
		Mean	314.6	-0.5	321.3	4.0
		SD	18.2	19.0	22.3	26.6
		CV%	5.8	-3797.5	6.9	665.5
		Min	275	-25	295	-46
		Median	312.0	2.0	316.5	6.0
		Max	362	53	385	64
		N	16	16	15	15
		Mean	313.2	-1.9	314.6	-0.6
		SD	21.0	14.9	21.5	24.0
		CV%	6.7	-769.6	6.8	-3992.0
		Min	297	-33	291	-42
		Median	307.0	-1.5	308.0	-1.0
		Max	379	23	378	57

**Table 14.2.1.29 Tear film osmolarity (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	
			Value	Change from Baseline	Value	Change from Baseline
Tear Film Osmolarity (mOsm/L)	Visit 6 - Day 29±1	N	16	16	15	15
		Mean	313.6	-1.6	307.8	-7.4
		SD	13.1	20.1	8.2	19.5
		CV%	4.2	-1285.5	2.7	-263.1
		Min	292	-38	291	-56
		Median	310.5	-7.0	309.0	0.0
		Max	336	46	319	12
Tear Film Osmolarity (mOsm/L)	Final Visit - Day 56±4/ETV	N	16	16	15	15
		Mean	315.3	0.2	314.0	-1.2
		SD	17.9	18.0	22.6	24.9
		CV%	5.7	9578.7	7.2	-2075.5
		Min	295	-27	282	-49
		Median	310.0	-0.5	312.0	2.0
		Max	353	29	380	67