

Table 14.2.1.3 Schirmer's test type I (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	3.0	2.0	2.0	0.0
		Max	16	11	21	8

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.3](#) - Schirmer's test type I

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

Table 14.2.1.3 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Screening - Day -15/-1	N	20		20	
		Mean	4.1		8.9	

Table 14.2.1.3 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 2 - Day 1	SD	3.3		8.4	
		CV%	81.0		94.6	
		Min	0		0	
		Median	3.5		7.5	
		Max	10		28	
		N	20	20	20	20
		Mean	5.4	1.3	10.1	1.2
		SD	5.7	4.9	8.1	8.6
		CV%	106.0	394.4	80.4	720.7
		Min	0	-4	0	-19
		Median	2.0	0.0	8.0	0.5
		Max	21	20	30	22
Schirmer's Test I Result (mm/5 min)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	8.6	4.5	7.4	-1.5
		SD	9.0	7.2	9.4	9.3
		CV%	105.4	162.8	127.3	-622.6
		Min	0	-4	0	-24

Table 14.2.1.3 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 6 - Day 29±1	Median	4.5	1.0	3.5	-1.0
		Max	32	23	35	27
		N	20	20	20	20
		Mean	9.4	5.3	11.4	2.6
		SD	7.8	6.5	10.7	9.1
		CV%	82.9	124.5	94.0	357.0
		Min	0	-3	1	-16
		Median	7.0	4.5	6.5	1.5
		Max	31	24	35	26
Schirmer's Test I Result (mm/5 min)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	8.7	4.6	8.8	-0.1
		SD	10.2	8.3	8.8	9.7
		CV%	118.4	181.7	99.8	-19493.3
		Min	0	-5	1	-26
		Median	4.0	2.0	6.0	0.5
		Max	34	27	29	21

Table 14.2.1.3 Schirmer's test type I (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 16.2.6.3](#) - Schirmer's test type I

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

Table 14.2.1.3 Schirmer's test type I (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

Schirmer's Test I Result (mm/5 min)	Screening - Day -15/-1	N	20		20	
		Mean	5.2		7.5	
		SD	3.7		7.7	
		CV%	72.7		102.2	

Table 14.2.1.3 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 2 - Day 1	Min	0		0	
		Median	6.5		7.5	
		Max	10		35	
		N	20	20	20	20
		Mean	6.5	1.4	8.6	1.1
		SD	6.7	5.2	8.7	7.7
		CV%	103.6	388.5	101.6	699.2
		Min	0	-4	0	-10
		Median	5.5	0.0	5.5	0.0
		Max	30	21	35	26
		N	20	20	20	20
		Mean	5.9	0.8	7.5	0.0
		SD	6.8	5.6	8.1	8.4
		CV%	115.2	742.8	107.4	NC
		Min	0	-6	0	-20
		Median	4.0	0.0	4.5	0.0
		Max	30	21	35	26

Table 14.2.1.3 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	8.2	3.2	9.4	2.0
		SD	6.8	6.0	8.4	9.2
		CV%	83.4	186.5	88.7	460.7
		Min	0	-4	0	-23
		Median	8.0	1.0	9.0	1.0
		Max	25	16	31	22
Schirmer's Test I Result (mm/5 min)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	9.8	4.6	9.6	2.1
		SD	8.8	6.7	9.5	11.3
		CV%	90.6	146.3	99.2	536.1
		Min	0	-3	0	-32
		Median	8.0	2.0	6.5	1.0
		Max	30	21	30	21

Table 14.2.1.18 Schirmer's test type I (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	4.5	3.0	2.0	-0.5
		Max	16	11	21	5

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.3](#) - Schirmer's test type I

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

Table 14.2.1.18 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Screening - Day -15/-1	N	14		14	
		Mean	3.7		8.2	

Table 14.2.1.18 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 2 - Day 1	SD	2.9		7.5	
		CV%	78.6		91.4	
		Min	1		1	
		Median	2.5		7.0	
		Max	10		28	
		N	14	14	14	14
		Mean	5.4	1.6	9.4	1.1
		SD	5.7	5.6	6.2	7.9
		CV%	106.8	338.2	66.6	689.7
		Min	1	-3	1	-19
Schirmer's Test I Result (mm/5 min)	Visit 3 - Day 8±1	Median	2.0	0.0	8.0	0.5
		Max	21	20	20	19
		N	14	14	14	14
		Mean	5.9	2.2	4.6	-3.6
		SD	6.8	5.6	5.5	6.8
		CV%	114.7	251.9	118.8	-190.1
		Min	0	-4	0	-24

Table 14.2.1.18 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 6 - Day 29±1	Median	2.0	1.0	3.0	-2.0
		Max	20	13	20	4
		N	14	14	14	14
		Mean	8.4	4.6	10.8	2.6
		SD	8.1	6.7	11.2	8.9
		CV%	96.6	144.8	104.1	345.7
		Min	0	-3	1	-6
		Median	5.5	4.0	4.0	0.5
		Max	31	24	35	26
Schirmer's Test I Result (mm/5 min)	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	7.7	4.0	7.6	-0.6
		SD	9.6	8.1	8.4	8.9
		CV%	124.7	203.1	109.4	-1555.8
		Min	0	-5	1	-26
		Median	4.0	2.0	2.0	0.5
		Max	34	27	25	11

Table 14.2.1.18 Schirmer's test type I (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 16.2.6.3](#) - Schirmer's test type I

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

Table 14.2.1.18 Schirmer's test type I (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

Schirmer's Test I Result (mm/5 min)	Screening - Day -15/-1	N	16		16	
		Mean	5.8		8.7	
		SD	3.5		8.0	
		CV%	60.7		91.6	

Table 14.2.1.18 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 2 - Day 1	Min	0		1	
		Median	7.5		8.5	
		Max	10		35	
		N	16	16	16	16
		Mean	7.3	1.5	10.2	1.5
		SD	7.2	5.7	9.1	8.3
		CV%	99.9	382.6	89.1	554.6
		Min	0	-4	1	-10
		Median	6.0	0.0	9.0	0.0
		Max	30	21	35	26
		N	16	16	16	16
		Mean	6.6	0.9	8.9	0.2
		SD	7.3	6.2	8.5	9.4
		CV%	110.2	713.0	95.2	5019.1
		Min	0	-6	1	-20
		Median	4.5	0.0	6.0	-0.5
		Max	30	21	35	26

Table 14.2.1.18 Schirmer's test type I (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
Schirmer's Test I Result (mm/5 min)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	8.8	3.1	10.8	2.1
		SD	6.9	6.0	8.3	9.9
		CV%	77.9	195.7	77.6	482.1
		Min	0	-4	0	-23
		Median	8.0	1.0	10.0	1.0
		Max	25	16	31	22
Schirmer's Test I Result (mm/5 min)	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	10.8	5.0	11.3	2.6
		SD	8.9	7.3	9.9	12.6
		CV%	83.2	145.3	88.3	490.5
		Min	0	-3	0	-32
		Median	9.5	2.0	7.5	1.0
		Max	30	21	30	21