

Table 14.2.1.7 Tear film break-up time (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

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.7](#) - Tear film break-up time

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

Table 14.2.1.7 Tear film break-up time (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

Average Tear Film Break-Up Time (sec)	Screening - Day -15/-1	N	20		20	
		Mean	3.4		4.3	
		SD	2.0		2.0	
		CV%	57.6		47.2	

Table 14.2.1.7 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 2 - Day 1	Min	0		1	
		Median	3.0		4.0	
		Max	8		9	
		N	20	20	20	20
		Mean	4.0	0.6	4.5	0.2
		SD	1.8	2.1	2.2	2.3
		CV%	44.4	343.7	49.2	1502.8
		Min	2	-3	0	-3
		Median	4.0	1.0	4.0	0.0
		Max	8	4	9	5
		N	20	20	20	20
		Mean	4.9	1.5	5.2	0.9
		SD	2.2	2.6	2.4	2.4
		CV%	44.4	171.0	45.3	271.9
		Min	1	-4	0	-4
		Median	4.5	1.0	4.5	0.5
		Max	9	5	9	5

Table 14.2.1.7 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	6.0	2.6	6.0	1.7
		SD	2.5	2.9	2.6	3.0
		CV%	42.8	114.1	43.4	183.7
		Min	1	-4	1	-5
		Median	6.0	3.0	5.5	1.5
		Max	11	8	11	7
Average Tear Film Break-Up Time (sec)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	5.6	2.2	5.7	1.4
		SD	2.4	2.8	2.5	3.3
		CV%	43.1	129.2	45.0	241.9
		Min	2	-4	3	-5
		Median	5.0	2.0	5.0	1.5
		Max	12	7	15	10

Table 14.2.1.7 Tear film break-up time (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 16.2.6.7](#) - Tear film break-up time

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

Table 14.2.1.7 Tear film break-up time (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

Average Tear Film Break-Up Time (sec)	Screening - Day -15/-1	N	20		20	
		Mean	3.0		3.3	
		SD	2.4		2.1	
		CV%	80.4		66.1	

Table 14.2.1.7 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 2 - Day 1	Min	0		0	
		Median	2.0		3.0	
		Max	8		8	
		N	20	20	20	20
		Mean	2.3	-0.7	2.9	-0.4
		SD	2.1	1.7	1.9	1.6
		CV%	94.4	-241.3	64.2	-456.7
		Min	0	-5	0	-4
		Median	2.0	0.0	3.0	0.0
		Max	7	2	6	2
		N	20	20	20	20
		Mean	2.7	-0.3	3.0	-0.3
		SD	1.7	2.1	1.6	1.9
		CV%	63.7	-859.6	55.5	-631.5
Average Tear Film Break-Up Time (sec)	Visit 3 - Day 8±1	Min	0	-6	0	-5
		Median	2.5	0.0	3.0	0.0
		Max	7	3	7	2
		N	20	20	20	20
		Mean	2.7	-0.3	3.0	-0.3
		SD	1.7	2.1	1.6	1.9

Table 14.2.1.7 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	2.5	-0.6	2.6	-0.6
		SD	1.3	2.2	1.2	2.1
		CV%	52.8	-378.9	46.0	-330.5
		Min	0	-6	0	-6
		Median	2.0	0.0	3.0	0.0
		Max	5	3	4	2
Average Tear Film Break-Up Time (sec)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	2.7	-0.3	2.6	-0.7
		SD	2.1	2.8	1.6	2.0
		CV%	77.0	-1107.9	60.4	-304.7
		Min	0	-6	0	-5
		Median	2.0	0.0	2.0	-0.5
		Max	9	6	6	3

Table 14.2.1.22 Tear film break-up time (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

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.7](#) - Tear film break-up time

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

Table 14.2.1.22 Tear film break-up time (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

Average Tear Film Break-Up Time (sec)	Screening - Day -15/-1	N	14		14	
		Mean	3.6		4.6	
		SD	2.1		2.1	
		CV%	58.6		46.8	

Table 14.2.1.22 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 2 - Day 1	Min	0		1	
		Median	3.0		4.5	
		Max	8		9	
		N	14	14	14	14
		Mean	4.1	0.4	4.4	-0.2
		SD	2.0	2.1	2.4	2.1
		CV%	49.6	498.9	54.5	-971.6
		Min	2	-3	0	-3
		Median	3.5	0.5	4.0	-0.5
		Max	8	4	9	5
		N	14	14	14	14
		Mean	5.1	1.5	5.6	1.1
		SD	2.2	2.9	2.2	2.5
		CV%	43.0	191.7	38.5	235.7
		Min	2	-4	3	-4
		Median	5.0	1.0	5.5	0.5
		Max	9	5	9	5

Table 14.2.1.22 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	5.9	2.3	6.0	1.4
		SD	2.4	3.1	2.9	3.4
		CV%	41.0	135.6	48.0	237.3
		Min	1	-4	1	-5
		Median	6.0	3.0	5.5	1.5
		Max	11	8	11	7
Average Tear Film Break-Up Time (sec)	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	5.3	1.6	5.9	1.3
		SD	1.9	2.7	3.0	3.6
		CV%	36.7	163.0	50.5	283.6
		Min	2	-4	3	-5
		Median	5.0	1.5	5.0	1.5
		Max	8	6	15	10

Table 14.2.1.22 Tear film break-up time (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 16.2.6.7](#) - Tear film break-up time

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

Table 14.2.1.22 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Screening - Day -15/-1	N	16		16	
		Mean	3.3		3.5	
		SD	2.5		2.2	
		CV%	75.8		63.5	

Table 14.2.1.22 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 2 - Day 1	Min	0		0	
		Median	2.5		3.0	
		Max	8		8	
		N	16	16	16	16
		Mean	2.6	-0.7	2.9	-0.6
		SD	2.2	1.6	1.8	1.7
		CV%	86.6	-235.9	62.7	-297.3
		Min	0	-5	0	-4
		Median	2.5	-0.5	3.0	-0.5
		Max	7	2	6	2
		N	16	16	16	16
		Mean	2.7	-0.6	3.1	-0.4
		SD	1.7	2.2	1.7	2.1
		CV%	61.8	-394.7	53.9	-479.2
		Min	0	-6	0	-5
		Median	2.5	0.0	3.0	0.0
		Max	7	3	7	2

Table 14.2.1.22 Tear film break-up time (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
Average Tear Film Break-Up Time (sec)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	2.6	-0.6	2.8	-0.7
		SD	1.3	2.4	1.1	2.2
		CV%	47.9	-382.6	39.4	-321.8
		Min	1	-6	0	-6
		Median	2.0	0.0	3.0	0.0
		Max	5	3	4	2
Average Tear Film Break-Up Time (sec)	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	2.9	-0.4	2.8	-0.8
		SD	2.1	2.8	1.6	2.1
		CV%	72.8	-753.5	57.1	-286.0
		Min	0	-6	0	-5
		Median	2.0	0.0	2.5	-1.0
		Max	9	6	6	3