

**Table 14.2.1.13 Fundus ophthalmoscopy (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	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Vitreous	Screening - Day -15/-1	N	20		20	
		Mean	0.1		0.1	

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Vitreous	Visit 2 - Day 1	SD	0.2		0.2	
		CV%	447.2		447.2	
		Min	0		0	
		Median	0.0		0.0	
		Max	1		1	
		N	20	20	20	20
		Mean	0.1	0.0	0.1	0.0
		SD	0.2	0.0	0.2	0.0
		CV%	447.2	NC	447.2	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.1	0.0	0.1	0.0
		SD	0.2	0.0	0.2	0.0
		CV%	447.2	NC	447.2	NC
		Min	0	0	0	0

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Vitreous	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
		N	20	20	20	20
		Mean	0.1	0.0	0.1	0.0
		SD	0.2	0.0	0.2	0.0
		CV%	447.2	NC	447.2	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Vitreous	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.1	0.0	0.1	0.0
		SD	0.2	0.0	0.2	0.0
		CV%	447.2	NC	447.2	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Macula, Retina and Optic Nerve Head	Visit 2 - Day 1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Macula, Retina and Optic Nerve Head	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Visit 6 - Day 29±1	CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Macula, Retina and Optic Nerve Head	Final Visit - Day 56±4/ETV	Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
Macula, Retina and Optic Nerve Head	Final Visit - Day 56±4/ETV	Min	0	0	0	0

**Table 14.2.1.13 Fundus ophthalmoscopy (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
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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

**Table 14.2.1.13 Fundus ophthalmoscopy (Full analysis set)**

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

Parameter	Visit	Statistics	Full Analysis Set N=13			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Vitreous	Screening - Day -15/-1	N	13		13	
		Mean	0.0		0.0	

**Table 14.2.1.13 Fundus ophthalmoscopy (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
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Vitreous	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Vitreous	Visit 2 - Day 1	SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
		N	20	20	20	20
	Visit 3 - Day 8±1	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0



**Table 14.2.1.13 Fundus ophthalmoscopy (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
Vitreous	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	19	19	19	19
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Vitreous	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Macula, Retina and Optic Nerve Head	Visit 2 - Day 1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Macula, Retina and Optic Nerve Head	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0

**Table 14.2.1.13 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Visit 6 - Day 29±1	CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	19	19	19	19
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Macula, Retina and Optic Nerve Head	Final Visit - Day 56±4/ETV	Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0

**Table 14.2.1.13 Fundus ophthalmoscopy (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
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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

**Table 14.2.1.28 Fundus ophthalmoscopy (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	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Vitreous	Screening - Day -15/-1	N	14		14	
		Mean	0.0		0.0	

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Vitreous	Visit 2 - Day 1	SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
Vitreous	Visit 3 - Day 8±1	SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Vitreous	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Vitreous	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Screening - Day -15/-1	N	14		14	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Macula, Retina and Optic Nerve Head	Visit 2 - Day 1	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Macula, Retina and Optic Nerve Head	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0



**Table 14.2.1.28 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Visit 6 - Day 29±1	CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Macula, Retina and Optic Nerve Head	Final Visit - Day 56±4/ETV	Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
Macula, Retina and Optic Nerve Head	Final Visit - Day 56±4/ETV	Min	0	0	0	0

**Table 14.2.1.28 Fundus ophthalmoscopy (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
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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

**Table 14.2.1.28 Fundus ophthalmoscopy (Per protocol set)**

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

Parameter	Visit	Statistics	Per Protocol Set N=11			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Vitreous	Screening - Day -15/-1	N	11		11	
		Mean	0.0		0.0	

**Table 14.2.1.28 Fundus ophthalmoscopy (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
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Vitreous	Screening - Day -15/-1	N	16		16	
		Mean	0.0		0.0	

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Vitreous	Visit 2 - Day 1	SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
	Visit 3 - Day 8±1	SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Vitreous	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Screening - Day -15/-1	N	16		16	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Macula, Retina and Optic Nerve Head	Visit 2 - Day 1	N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Macula, Retina and Optic Nerve Head	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0

**Table 14.2.1.28 Fundus ophthalmoscopy (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
Macula, Retina and Optic Nerve Head	Visit 6 - Day 29±1	CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Macula, Retina and Optic Nerve Head	Final Visit - Day 56±4/ETV	Max	0	0	0	0
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0

**Table 14.2.1.28 Fundus ophthalmoscopy (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
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.13](#) - Fundus ophthalmoscopy

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