

Table 14.3.5.2 Vital signs (Safety set)

Parameter	Visit - Time Point	Statistics	rhNGF 20 µg/mL N=20			rhNGF 4 µg/mL N=20			Overall N=40		
			Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose
Diastolic Blood Pressure (mmHg)	Final Visit - Day 56±4/ETV	CV%	11.8	-247.3		13.7	-533.8		12.6	-326.5	
		Min	62	-18		53	-11		53	-18	
		Median	73.0	-3.5		72.0	1.0		73.0	-2.0	
		Max	88	10		96	16		96	16	
		N	20	20		20	20		40	40	
		Mean	76.7	-1.8		75.8	0.1		76.2	-0.9	
		SD	7.4	7.5		10.9	7.4		9.2	7.4	
Pulse Rate (beats/min)	Screening - Day -15/-1	CV%	9.7	-416.4		14.3	7397.7		12.1	-872.1	
		Min	66	-14		55	-15		55	-15	
		Median	77.0	-1.0		76.5	1.0		77.0	1.0	
		Max	89	9		94	11		94	11	
		N	20			20			40		
		Mean	71.5			76.1			73.8		
		SD	7.4			11.0			9.6		
		CV%	10.4			14.5			13.0		
		Min	58			61			58		
		Median	71.5			74.5			73.5		
		Max	87			102			102		
		N	20			20			40		
		Mean	71.5			76.1			73.8		
		SD	7.4			11.0			9.6		

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Pulse Rate (beats/min)	Visit 2 - Day 1 - Pre-dose	N	20	20		20	20		40	40	
		Mean	75.3	3.9		74.5	-1.6		74.9	1.1	
		SD	11.0	9.6		10.4	10.6		10.6	10.4	
		CV%	14.6	250.5		13.9	-662.5		14.1	922.3	
		Min	53	-12		58	-17		53	-17	
		Median	76.0	4.0		76.5	-4.0		76.0	1.0	
		Max	99	25		92	19		99	25	
Pulse Rate (beats/min)	Visit 2 - Day 1 - Post-dose	N	20	20	20	20	20	20	40	40	40
		Mean	66.7	-4.8	-8.6	66.6	-9.5	-7.9	66.7	-7.1	-8.3
		SD	7.7	10.3	11.8	9.5	9.6	8.6	8.5	10.1	10.2
		CV%	11.5	-217.4	-137.5	14.3	-101.4	-108.6	12.8	-142.4	-123.7
		Min	52	-24	-42	49	-30	-26	49	-30	-42
		Median	67.5	-6.5	-6.0	68.5	-9.5	-8.5	68.0	-7.5	-7.0
		Max	80	14	11	85	8	7	85	14	11
Pulse Rate (beats/min)	Visit 3 - Day 8±1 - Pre-dose	N	19	19		20	20		39	39	
		Mean	77.9	6.4		76.1	0.0		77.0	3.1	
		SD	10.7	10.8		10.4	11.2		10.5	11.3	

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			Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose
Pulse Rate (beats/min)	Visit 3 - Day 8±1 - Post-dose	CV%	13.8	168.9		13.7	NC		13.6	364.1	
		Min	59	-9		57	-21		57	-21	
		Median	80.0	5.0		77.0	-1.0		79.0	1.0	
		Max	96	30		90	17		96	30	
		N	20	20	19	20	20	20	40	40	39
		Mean	68.5	-3.0	-10.3	65.4	-10.8	-10.8	66.9	-6.9	-10.5
		SD	8.6	10.9	9.6	9.0	11.9	6.2	8.8	11.9	7.9
Pulse Rate (beats/min)	Visit 6 - Day 29±1	CV%	12.6	-370.6	-93.2	13.8	-110.6	-57.6	13.2	-174.4	-75.2
		Min	53	-20	-31	54	-35	-21	53	-35	-31
		Median	67.5	-3.5	-8.0	62.0	-8.5	-12.0	67.0	-7.0	-10.0
		Max	84	19	4	86	6	2	86	19	4
		N	20	20		19	19		39	39	
		Mean	73.3	1.9		70.7	-5.7		72.1	-1.8	
		SD	10.4	10.0		12.2	12.4		11.2	11.7	
Pulse Rate (beats/min)	Visit 6 - Day 29±1	CV%	14.2	539.5		17.3	-215.8		15.6	-634.4	
		Min	50	-25		51	-35		50	-35	
		Median	72.5	1.5		69.0	-3.0		71.0	-1.0	
		Max	95	17		93	17		95	17	
		N	20	20		19	19		39	39	
		Mean	73.3	1.9		70.7	-5.7		72.1	-1.8	
		SD	10.4	10.0		12.2	12.4		11.2	11.7	

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			rhNGF 20 µg/mL N=20			rhNGF 4 µg/mL N=20			Overall N=40		
			Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose
Pulse Rate (beats/min)	Final Visit - Day 56±4/ETV	N	20	20		20	20		40	40	
		Mean	75.0	3.5		79.7	3.6		77.3	3.5	
		SD	8.6	10.7		12.4	11.8		10.8	11.1	
		CV%	11.5	305.6		15.5	331.5		14.0	314.9	
		Min	53	-15		60	-17		53	-17	
		Median	75.0	4.5		81.0	2.5		76.5	4.0	
		Max	88	27		107	31		107	31	

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

Baseline: Screening visit assessment,

Source: [Listing 16.2.9.1](#) - Vital signs

Program: Tables\c116-vs-tbl.sas