

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	7 (100)	0	7 (100)	7	
	High	0	0	0	0	0	
	Total	0	7 (100)	0	7 (100)	7	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	4 (100)	0	4 (100)	10	
	High	0	0	0	0	0	
	Total	0	4 (100)	0	4 (100)	10	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Single Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	13	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	13	
Multiple Dose Hour 0	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 8	Low	0	0	0	0		0
	Normal	0	13 (92.9)	1 (7.1)	14 (100)		0
	High	0	0	0	0		0
	Total	0	13 (92.9)	1 (7.1)	14 (100)		0
Multiple Dose Hour 12	Low	0	0	0	0		0
	Normal	0	14 (100)	0	14 (100)		0
	High	0	0	0	0		0
	Total	0	14 (100)	0	14 (100)		0
Multiple Dose Hour 16	Low	0	0	0	0		0
	Normal	0	14 (100)	0	14 (100)		0
	High	0	0	0	0		0
	Total	0	14 (100)	0	14 (100)		0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	13 (92.9)	1 (7.1)	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	13 (92.9)	1 (7.1)	14 (100)	0	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 44	Low	0	0	0	0		0
	Normal	0	11 (91.7)	1 (8.3)	12 (100)		2
	High	0	0	0	0		0
	Total	0	11 (91.7)	1 (8.3)	12 (100)		2
Multiple Dose Hour 48	Low	0	0	0	0		0
	Normal	0	11 (84.6)	2 (15.4)	13 (100)		1
	High	0	0	0	0		0
	Total	0	11 (84.6)	2 (15.4)	13 (100)		1
Early Termination	Low	0	0	0	0		0
	Normal	0	1 (100)	0	1 (100)		0
	High	0	0	0	0		0
	Total	0	1 (100)	0	1 (100)		0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Diastolic BP (mmHg)						
Blinded Follow-up	Low	0	0	0	0	0
	Normal	0	8 (100)	0	8 (100)	0
	High	0	0	0	0	0
	Total	0	8 (100)	0	8 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Single Dose Hour 1	Low	0	0	0	0		0
	Normal	0	11 (91.7)	0	11 (91.7)		0
	High	0	0	1 (8.3)	1 (8.3)		0
	Total	0	11 (91.7)	1 (8.3)	12 (100)		0
Single Dose Hour 4	Low	0	0	0	0		0
	Normal	0	2 (100)	0	2 (100)		9
	High	0	0	0	0		1
	Total	0	2 (100)	0	2 (100)		10
Single Dose Hour 8	Low	0	0	0	0		0
	Normal	0	0	0	0		11
	High	0	0	0	0		1
	Total	0	0	0	0		12

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Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Diastolic BP (mmHg)							
Single Dose							
Hour 12	Low	0	0	0	0		0
	Normal	0	0	0	0		11
	High	0	0	0	0		1
	Total	0	0	0	0		12
Multiple Dose							
Hour 0	Low	0	0	0	0		0
	Normal	0	10 (90.9)	0	10 (90.9)		1
	High	0	0	1 (9.1)	1 (9.1)		0
	Total	0	10 (90.9)	1 (9.1)	11 (100)		1
Multiple Dose							
Hour 4	Low	0	0	0	0		0
	Normal	0	10 (90.9)	0	10 (90.9)		1
	High	0	1 (9.1)	0	1 (9.1)		0
	Total	0	11 (100)	0	11 (100)		1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	9 (90.0)	0	9 (90.0)	2	
	High	0	1 (10.0)	0	1 (10.0)	0	
	Total	0	10 (100)	0	10 (100)	2	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	

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		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	1 (9.1)	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	1 (9.1)	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	9 (90.0)	0	9 (90.0)	2	
	High	0	1 (10.0)	0	1 (10.0)	0	
	Total	0	10 (100)	0	10 (100)	2	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Early Termination	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	0	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Diastolic BP (mmHg)						
Blinded Follow-up	Low	0	0	0	0	0
	Normal	0	8 (100)	0	8 (100)	0
	High	0	0	0	0	0
	Total	0	8 (100)	0	8 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	25 (96.2)	0	25 (96.2)	0	
	High	0	0	1 (3.8)	1 (3.8)	0	
	Total	0	25 (96.2)	1 (3.8)	26 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	9 (100)	0	9 (100)	16	
	High	0	0	0	0	1	
	Total	0	9 (100)	0	9 (100)	17	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	4 (100)	0	4 (100)	21	
	High	0	0	0	0	1	
	Total	0	4 (100)	0	4 (100)	22	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Single Dose							
Hour 12	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	24	
	High	0	0	0	0	1	
	Total	0	1 (100)	0	1 (100)	25	
Multiple Dose							
Hour 0	Low	0	0	0	0	0	
	Normal	0	24 (96.0)	0	24 (96.0)	1	
	High	0	0	1 (4.0)	1 (4.0)	0	
	Total	0	24 (96.0)	1 (4.0)	25 (100)	1	
Multiple Dose							
Hour 4	Low	0	0	0	0	0	
	Normal	0	24 (96.0)	0	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	25 (100)	0	25 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	22 (91.7)	1 (4.2)	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	23 (95.8)	1 (4.2)	24 (100)	2	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	24 (96.0)	0	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	24 (96.0)	0	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	25 (100)	0	25 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 20	Low	0	0	0	0		0
	Normal	0	24 (96.0)	0	24 (96.0)		1
	High	0	1 (4.0)	0	1 (4.0)		0
	Total	0	25 (100)	0	25 (100)		1
Multiple Dose Hour 24	Low	0	0	0	0		0
	Normal	0	23 (92.0)	1 (4.0)	24 (96.0)		1
	High	0	1 (4.0)	0	1 (4.0)		0
	Total	0	24 (96.0)	1 (4.0)	25 (100)		1
Multiple Dose Hour 28	Low	0	0	0	0		0
	Normal	0	23 (95.8)	0	23 (95.8)		2
	High	0	1 (4.2)	0	1 (4.2)		0
	Total	0	24 (100)	0	24 (100)		2

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	22 (91.7)	1 (4.2)	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	23 (95.8)	1 (4.2)	24 (100)	2	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	22 (91.7)	1 (4.2)	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	23 (95.8)	1 (4.2)	24 (100)	2	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	23 (95.8)	0	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	24 (100)	0	24 (100)	2	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Diastolic BP (mmHg)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	20 (90.9)	1 (4.5)	21 (95.5)	4	
	High	0	1 (4.5)	0	1 (4.5)	0	
	Total	0	21 (95.5)	1 (4.5)	22 (100)	4	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	21 (87.5)	2 (8.3)	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	22 (91.7)	2 (8.3)	24 (100)	2	
Early Termination	Low	0	0	0	0	0	
	Normal	0	2 (100)	0	2 (100)	0	
	High	0	0	0	0	0	
	Total	0	2 (100)	0	2 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Diastolic BP (mmHg)							
Blinded Follow-up	Low	0	0	0	0	0	
	Normal	0	16 (100)	0	16 (100)	0	
	High	0	0	0	0	0	
	Total	0	16 (100)	0	16 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Systolic BP (mmHg)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	13 (92.9)	0	13 (92.9)	0	
	High	0	0	1 (7.1)	1 (7.1)	0	
	Total	0	13 (92.9)	1 (7.1)	14 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	6 (85.7)	0	6 (85.7)	7	
	High	0	1 (14.3)	0	1 (14.3)	0	
	Total	0	7 (100)	0	7 (100)	7	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	3 (75.0)	0	3 (75.0)	10	
	High	0	0	1 (25.0)	1 (25.0)	0	
	Total	0	3 (75.0)	1 (25.0)	4 (100)	10	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Single Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	12	
	High	0	0	0	0	1	
	Total	0	1 (100)	0	1 (100)	13	
Multiple Dose Hour 0	Low	0	0	0	0	0	
	Normal	0	12 (85.7)	1 (7.1)	13 (92.9)	0	
	High	0	1 (7.1)	0	1 (7.1)	0	
	Total	0	13 (92.9)	1 (7.1)	14 (100)	0	
Multiple Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	12 (85.7)	1 (7.1)	13 (92.9)	0	
	High	0	1 (7.1)	0	1 (7.1)	0	
	Total	0	13 (92.9)	1 (7.1)	14 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	13 (92.9)	0	13 (92.9)	0	
	High	0	1 (7.1)	0	1 (7.1)	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	12 (85.7)	1 (7.1)	13 (92.9)	0	
	High	0	1 (7.1)	0	1 (7.1)	0	
	Total	0	13 (92.9)	1 (7.1)	14 (100)	0	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	1 (7.1)	10 (71.4)	2 (14.3)	13 (92.9)	0	
	High	0	1 (7.1)	0	1 (7.1)	0	
	Total	1 (7.1)	11 (78.6)	2 (14.3)	14 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	13 (92.9)	0	13 (92.9)	0	
	High	0	1 (7.1)	0	1 (7.1)	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	12 (85.7)	1 (7.1)	13 (92.9)	0	
	High	0	0	1 (7.1)	1 (7.1)	0	
	Total	0	12 (85.7)	2 (14.3)	14 (100)	0	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	12 (92.3)	0	12 (92.3)	1	
	High	0	1 (7.7)	0	1 (7.7)	0	
	Total	0	13 (100)	0	13 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

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Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	12 (92.3)	0	12 (92.3)	1	
	High	0	1 (7.7)	0	1 (7.7)	0	
	Total	0	13 (100)	0	13 (100)	1	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	12 (92.3)	0	12 (92.3)	1	
	High	0	1 (7.7)	0	1 (7.7)	0	
	Total	0	13 (100)	0	13 (100)	1	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	12 (92.3)	0	12 (92.3)	1	
	High	0	1 (7.7)	0	1 (7.7)	0	
	Total	0	13 (100)	0	13 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	11 (91.7)	0	11 (91.7)	2	
	High	0	1 (8.3)	0	1 (8.3)	0	
	Total	0	12 (100)	0	12 (100)	2	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	10 (76.9)	2 (15.4)	12 (92.3)	1	
	High	0	1 (7.7)	0	1 (7.7)	0	
	Total	0	11 (84.6)	2 (15.4)	13 (100)	1	
Early Termination	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	0	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Systolic BP (mmHg)						
Blinded Follow-up	Low	0	0	0	0	0
	Normal	0	7 (87.5)	0	7 (87.5)	0
	High	0	1 (12.5)	0	1 (12.5)	0
	Total	0	8 (100)	0	8 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Single Dose Hour 1	Low	0	0	0	0		0
	Normal	0	10 (83.3)	0	10 (83.3)		0
	High	0	1 (8.3)	1 (8.3)	2 (16.7)		0
	Total	0	11 (91.7)	1 (8.3)	12 (100)		0
Single Dose Hour 4	Low	0	0	0	0		0
	Normal	0	2 (100)	0	2 (100)		8
	High	0	0	0	0		2
	Total	0	2 (100)	0	2 (100)		10
Single Dose Hour 8	Low	0	0	0	0		0
	Normal	0	0	0	0		10
	High	0	0	0	0		2
	Total	0	0	0	0		12

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Systolic BP (mmHg)							
Single Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	0	0	0	10	
	High	0	0	0	0	2	
	Total	0	0	0	0	12	
Multiple Dose Hour 0	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	1 (9.1)	1 (9.1)	2 (18.2)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	8 (72.7)	1 (9.1)	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	1 (9.1)	1 (9.1)	2 (18.2)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	1 (9.1)	1 (9.1)	2 (18.2)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	1 (9.1)	1 (9.1)	2 (18.2)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	2 (18.2)	7 (63.6)	0	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	2 (18.2)	9 (81.8)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	8 (80.0)	0	8 (80.0)	2	
	High	0	2 (20.0)	0	2 (20.0)	0	
	Total	0	10 (100)	0	10 (100)	2	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	0	9 (81.8)	1	
	High	0	2 (18.2)	0	2 (18.2)	0	
	Total	0	11 (100)	0	11 (100)	1	
Early Termination	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	0	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Systolic BP (mmHg)							
Blinded Follow-up	Low	0	0	0	0	0	
	Normal	0	7 (87.5)	0	7 (87.5)	0	
	High	0	0	1 (12.5)	1 (12.5)	0	
	Total	0	7 (87.5)	1 (12.5)	8 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Single Dose Hour 1	Low	0	0	0	0	0	0
	Normal	0	23 (88.5)	0	23 (88.5)	0	0
	High	0	1 (3.8)	2 (7.7)	3 (11.5)	0	0
	Total	0	24 (92.3)	2 (7.7)	26 (100)	0	0
Single Dose Hour 4	Low	0	0	0	0	0	0
	Normal	0	8 (88.9)	0	8 (88.9)	15	15
	High	0	1 (11.1)	0	1 (11.1)	2	2
	Total	0	9 (100)	0	9 (100)	17	17
Single Dose Hour 8	Low	0	0	0	0	0	0
	Normal	0	3 (75.0)	0	3 (75.0)	20	20
	High	0	0	1 (25.0)	1 (25.0)	2	2
	Total	0	3 (75.0)	1 (25.0)	4 (100)	22	22

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Single Dose Hour 12	Low	0	0	0	0		0
	Normal	0	1 (100)	0	1 (100)		22
	High	0	0	0	0		3
	Total	0	1 (100)	0	1 (100)		25
Multiple Dose Hour 0	Low	0	0	0	0		0
	Normal	0	21 (84.0)	1 (4.0)	22 (88.0)		1
	High	0	2 (8.0)	1 (4.0)	3 (12.0)		0
	Total	0	23 (92.0)	2 (8.0)	25 (100)		1
Multiple Dose Hour 4	Low	0	0	0	0		0
	Normal	0	21 (84.0)	1 (4.0)	22 (88.0)		1
	High	0	3 (12.0)	0	3 (12.0)		0
	Total	0	24 (96.0)	1 (4.0)	25 (100)		1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 8	Low	0	0	0	0		0
	Normal	0	21 (84.0)	1 (4.0)	22 (88.0)		1
	High	0	3 (12.0)	0	3 (12.0)		0
	Total	0	24 (96.0)	1 (4.0)	25 (100)		1
Multiple Dose Hour 12	Low	0	0	0	0		0
	Normal	0	21 (84.0)	1 (4.0)	22 (88.0)		1
	High	0	2 (8.0)	1 (4.0)	3 (12.0)		0
	Total	0	23 (92.0)	2 (8.0)	25 (100)		1
Multiple Dose Hour 16	Low	0	0	0	0		0
	Normal	1 (4.0)	19 (76.0)	2 (8.0)	22 (88.0)		1
	High	0	3 (12.0)	0	3 (12.0)		0
	Total	1 (4.0)	22 (88.0)	2 (8.0)	25 (100)		1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	22 (88.0)	0	22 (88.0)	1	
	High	0	3 (12.0)	0	3 (12.0)	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	21 (84.0)	1 (4.0)	22 (88.0)	1	
	High	0	2 (8.0)	1 (4.0)	3 (12.0)	0	
	Total	0	23 (92.0)	2 (8.0)	25 (100)	1	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	21 (87.5)	0	21 (87.5)	2	
	High	0	3 (12.5)	0	3 (12.5)	0	
	Total	0	24 (100)	0	24 (100)	2	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 32	Low	0	0	0	0	0	0
	Normal	0	21 (87.5)	0	21 (87.5)	2	2
	High	0	2 (8.3)	1 (4.2)	3 (12.5)	0	0
	Total	0	23 (95.8)	1 (4.2)	24 (100)	2	2
Multiple Dose Hour 36	Low	0	0	0	0	0	0
	Normal	0	21 (87.5)	0	21 (87.5)	2	2
	High	0	2 (8.3)	1 (4.2)	3 (12.5)	0	0
	Total	0	23 (95.8)	1 (4.2)	24 (100)	2	2
Multiple Dose Hour 40	Low	0	0	0	0	0	0
	Normal	2 (8.3)	19 (79.2)	0	21 (87.5)	2	2
	High	0	3 (12.5)	0	3 (12.5)	0	0
	Total	2 (8.3)	22 (91.7)	0	24 (100)	2	2

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Systolic BP (mmHg)							
Multiple Dose Hour 44	Low	0	0	0	0	0	0
	Normal	0	19 (86.4)	0	19 (86.4)	4	4
	High	0	3 (13.6)	0	3 (13.6)	0	0
	Total	0	22 (100)	0	22 (100)	4	4
Multiple Dose Hour 48	Low	0	0	0	0	0	0
	Normal	0	19 (79.2)	2 (8.3)	21 (87.5)	2	2
	High	0	3 (12.5)	0	3 (12.5)	0	0
	Total	0	22 (91.7)	2 (8.3)	24 (100)	2	2
Early Termination	Low	0	0	0	0	0	0
	Normal	0	2 (100)	0	2 (100)	0	0
	High	0	0	0	0	0	0
	Total	0	2 (100)	0	2 (100)	0	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Systolic BP (mmHg)							
Blinded Follow-up	Low	0	0	0	0	0	
	Normal	0	14 (87.5)	0	14 (87.5)	0	
	High	0	1 (6.3)	1 (6.3)	2 (12.5)	0	
	Total	0	15 (93.8)	1 (6.3)	16 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	7 (100)	0	7 (100)	7	
	High	0	0	0	0	0	
	Total	0	7 (100)	0	7 (100)	7	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	4 (100)	0	4 (100)	10	
	High	0	0	0	0	0	
	Total	0	4 (100)	0	4 (100)	10	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Single Dose							
Hour 12	Low	0	0	0	0	0	0
	Normal	0	1 (100)	0	1 (100)	13	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	13	
Multiple Dose							
Hour 0	Low	0	0	0	0	0	0
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose							
Hour 4	Low	0	0	0	0	0	0
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 8	Low	0	0	0	0	0	0
	Normal	0	14 (100)	0	14 (100)	0	0
	High	0	0	0	0	0	0
	Total	0	14 (100)	0	14 (100)	0	0
Multiple Dose Hour 12	Low	0	0	0	0	0	0
	Normal	0	14 (100)	0	14 (100)	0	0
	High	0	0	0	0	0	0
	Total	0	14 (100)	0	14 (100)	0	0
Multiple Dose Hour 16	Low	0	0	0	0	0	0
	Normal	0	13 (92.9)	1 (7.1)	14 (100)	0	0
	High	0	0	0	0	0	0
	Total	0	13 (92.9)	1 (7.1)	14 (100)	0	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	13 (92.9)	1 (7.1)	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	13 (92.9)	1 (7.1)	14 (100)	0	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 32	Low	0	0	0	0	0	0
	Normal	0	13 (100)	0	13 (100)	1	1
	High	0	0	0	0	0	0
	Total	0	13 (100)	0	13 (100)	1	1
Multiple Dose Hour 36	Low	0	0	0	0	0	0
	Normal	0	13 (100)	0	13 (100)	1	1
	High	0	0	0	0	0	0
	Total	0	13 (100)	0	13 (100)	1	1
Multiple Dose Hour 40	Low	0	0	0	0	0	0
	Normal	0	13 (100)	0	13 (100)	1	1
	High	0	0	0	0	0	0
	Total	0	13 (100)	0	13 (100)	1	1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	12 (100)	0	12 (100)	2	
	High	0	0	0	0	0	
	Total	0	12 (100)	0	12 (100)	2	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	
Early Termination	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	0	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Heart Rate (BEATS/MIN)						
Blinded Follow-up	Low	0	0	0	0	0
	Normal	0	8 (100)	0	8 (100)	0
	High	0	0	0	0	0
	Total	0	8 (100)	0	8 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Heart Rate (BEATS/MIN)						
Single Dose Hour 1	Low	0	0	0	0	0
	Normal	0	11 (91.7)	0	11 (91.7)	0
	High	0	1 (8.3)	0	1 (8.3)	0
	Total	0	12 (100)	0	12 (100)	0
Single Dose Hour 4	Low	0	0	0	0	0
	Normal	0	2 (100)	0	2 (100)	9
	High	0	0	0	0	1
	Total	0	2 (100)	0	2 (100)	10
Single Dose Hour 8	Low	0	0	0	0	0
	Normal	0	0	0	0	11
	High	0	0	0	0	1
	Total	0	0	0	0	12

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Heart Rate (BEATS/MIN)							
Single Dose							
Hour 12	Low	0	0	0	0		0
	Normal	0	0	0	0		11
	High	0	0	0	0		1
	Total	0	0	0	0		12
Multiple Dose							
Hour 0	Low	0	0	0	0		0
	Normal	0	10 (90.9)	0	10 (90.9)		1
	High	0	1 (9.1)	0	1 (9.1)		0
	Total	0	11 (100)	0	11 (100)		1
Multiple Dose							
Hour 4	Low	0	0	0	0		0
	Normal	0	10 (90.9)	0	10 (90.9)		1
	High	0	1 (9.1)	0	1 (9.1)		0
	Total	0	11 (100)	0	11 (100)		1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	9 (81.8)	1 (9.1)	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	10 (90.9)	1 (9.1)	11 (100)	1	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	9 (90.0)	0	9 (90.0)	2	
	High	0	1 (10.0)	0	1 (10.0)	0	
	Total	0	10 (100)	0	10 (100)	2	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	10 (90.9)	0	10 (90.9)	1	
	High	0	1 (9.1)	0	1 (9.1)	0	
	Total	0	11 (100)	0	11 (100)	1	
Early Termination	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	0	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Heart Rate (BEATS/MIN)						
Blinded Follow-up	Low	0	0	0	0	0
	Normal	0	8 (100)	0	8 (100)	0
	High	0	0	0	0	0
	Total	0	8 (100)	0	8 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	25 (96.2)	0	25 (96.2)	0	
	High	0	1 (3.8)	0	1 (3.8)	0	
	Total	0	26 (100)	0	26 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	9 (100)	0	9 (100)	16	
	High	0	0	0	0	1	
	Total	0	9 (100)	0	9 (100)	17	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	4 (100)	0	4 (100)	21	
	High	0	0	0	0	1	
	Total	0	4 (100)	0	4 (100)	22	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Single Dose							
Hour 12	Low	0	0	0	0		0
	Normal	0	1 (100)	0	1 (100)		24
	High	0	0	0	0		1
	Total	0	1 (100)	0	1 (100)		25
Multiple Dose							
Hour 0	Low	0	0	0	0		0
	Normal	0	24 (96.0)	0	24 (96.0)		1
	High	0	1 (4.0)	0	1 (4.0)		0
	Total	0	25 (100)	0	25 (100)		1
Multiple Dose							
Hour 4	Low	0	0	0	0		0
	Normal	0	24 (96.0)	0	24 (96.0)		1
	High	0	1 (4.0)	0	1 (4.0)		0
	Total	0	25 (100)	0	25 (100)		1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	24 (96.0)	0	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	24 (96.0)	0	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	23 (92.0)	1 (4.0)	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	24 (96.0)	1 (4.0)	25 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	23 (92.0)	1 (4.0)	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	24 (96.0)	1 (4.0)	25 (100)	1	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	24 (96.0)	0	24 (96.0)	1	
	High	0	1 (4.0)	0	1 (4.0)	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	23 (95.8)	0	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	24 (100)	0	24 (100)	2	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Heart Rate (BEATS/MIN)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	23 (95.8)	0	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	24 (100)	0	24 (100)	2	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	22 (91.7)	1 (4.2)	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	23 (95.8)	1 (4.2)	24 (100)	2	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	23 (95.8)	0	23 (95.8)	2	
	High	0	1 (4.2)	0	1 (4.2)	0	
	Total	0	24 (100)	0	24 (100)	2	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

Table Generation: 10SEP2012 11:34

Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Heart Rate (BEATS/MIN)						
Multiple Dose Hour 44	Low	0	0	0	0	0
	Normal	0	21 (95.5)	0	21 (95.5)	4
	High	0	1 (4.5)	0	1 (4.5)	0
	Total	0	22 (100)	0	22 (100)	4
Multiple Dose Hour 48	Low	0	0	0	0	0
	Normal	0	23 (95.8)	0	23 (95.8)	2
	High	0	1 (4.2)	0	1 (4.2)	0
	Total	0	24 (100)	0	24 (100)	2
Early Termination	Low	0	0	0	0	0
	Normal	0	2 (100)	0	2 (100)	0
	High	0	0	0	0	0
	Total	0	2 (100)	0	2 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Heart Rate (BEATS/MIN)							
Blinded Follow-up	Low	0	0	0	0	0	
	Normal	0	16 (100)	0	16 (100)	0	
	High	0	0	0	0	0	
	Total	0	16 (100)	0	16 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	7 (100)	0	7 (100)	7	
	High	0	0	0	0	0	
	Total	0	7 (100)	0	7 (100)	7	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	4 (100)	0	4 (100)	10	
	High	0	0	0	0	0	
	Total	0	4 (100)	0	4 (100)	10	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Single Dose							
Hour 12	Low	0	0	0	0	0	0
	Normal	0	1 (100)	0	1 (100)	13	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	13	
Multiple Dose							
Hour 0	Low	0	0	0	0	0	0
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose							
Hour 4	Low	0	0	0	0	0	0
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	14 (100)	0	14 (100)	0	
	High	0	0	0	0	0	
	Total	0	14 (100)	0	14 (100)	0	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	13 (100)	0	13 (100)	1	
	High	0	0	0	0	0	
	Total	0	13 (100)	0	13 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 44	Low	0	0	0	0	0	0
	Normal	0	12 (100)	0	12 (100)	2	2
	High	0	0	0	0	0	0
	Total	0	12 (100)	0	12 (100)	2	2
Multiple Dose Hour 48	Low	0	0	0	0	0	0
	Normal	0	13 (100)	0	13 (100)	1	1
	High	0	0	0	0	0	0
	Total	0	13 (100)	0	13 (100)	1	1
Early Termination	Low	0	0	0	0	0	0
	Normal	0	1 (100)	0	1 (100)	0	0
	High	0	0	0	0	0	0
	Total	0	1 (100)	0	1 (100)	0	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	COV795 (N=14)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Respiratory Rate (BREATHS/MIN)						
Blinded Follow-up	Low	0	0	0	0	0
	Normal	0	8 (100)	0	8 (100)	0
	High	0	0	0	0	0
	Total	0	8 (100)	0	8 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	12 (100)	0	12 (100)	0	
	High	0	0	0	0	0	
	Total	0	12 (100)	0	12 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	2 (100)	0	2 (100)	10	
	High	0	0	0	0	0	
	Total	0	2 (100)	0	2 (100)	10	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	0	0	0	12	
	High	0	0	0	0	0	
	Total	0	0	0	0	12	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Single Dose							
Hour 12	Low	0	0	0	0		0
	Normal	0	0	0	0		12
	High	0	0	0	0		0
	Total	0	0	0	0		12
Multiple Dose							
Hour 0	Low	0	0	0	0		0
	Normal	0	11 (100)	0	11 (100)		1
	High	0	0	0	0		0
	Total	0	11 (100)	0	11 (100)		1
Multiple Dose							
Hour 4	Low	0	0	0	0		0
	Normal	0	11 (100)	0	11 (100)		1
	High	0	0	0	0		0
	Total	0	11 (100)	0	11 (100)		1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

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Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	10 (100)	0	10 (100)	2	
	High	0	0	0	0	0	
	Total	0	10 (100)	0	10 (100)	2	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	11 (100)	0	11 (100)	1	
	High	0	0	0	0	0	
	Total	0	11 (100)	0	11 (100)	1	
Early Termination	Low	0	0	0	0	0	
	Normal	0	1 (100)	0	1 (100)	0	
	High	0	0	0	0	0	
	Total	0	1 (100)	0	1 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

Program Name: T1403050302.SAS

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Placebo (N=12)				
		Low	Normal	High	Total	Missing
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]	n [2]
Respiratory Rate (BREATHS/MIN)						
Blinded Follow-up	Low	0	0	0	0	0
	Normal	0	8 (100)	0	8 (100)	0
	High	0	0	0	0	0
	Total	0	8 (100)	0	8 (100)	0

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

Cross-reference: Appendix 16.4-2

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Single Dose Hour 1	Low	0	0	0	0	0	
	Normal	0	26 (100)	0	26 (100)	0	
	High	0	0	0	0	0	
	Total	0	26 (100)	0	26 (100)	0	
Single Dose Hour 4	Low	0	0	0	0	0	
	Normal	0	9 (100)	0	9 (100)	17	
	High	0	0	0	0	0	
	Total	0	9 (100)	0	9 (100)	17	
Single Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	4 (100)	0	4 (100)	22	
	High	0	0	0	0	0	
	Total	0	4 (100)	0	4 (100)	22	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

[2] Number of subjects with missing observations

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Table 14.3.5-3.2
Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Single Dose							
Hour 12	Low	0	0	0	0		0
	Normal	0	1 (100)	0	1 (100)		25
	High	0	0	0	0		0
	Total	0	1 (100)	0	1 (100)		25
Multiple Dose							
Hour 0	Low	0	0	0	0		0
	Normal	0	25 (100)	0	25 (100)		1
	High	0	0	0	0		0
	Total	0	25 (100)	0	25 (100)		1
Multiple Dose							
Hour 4	Low	0	0	0	0		0
	Normal	0	25 (100)	0	25 (100)		1
	High	0	0	0	0		0
	Total	0	25 (100)	0	25 (100)		1

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

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Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 8	Low	0	0	0	0	0	
	Normal	0	25 (100)	0	25 (100)	1	
	High	0	0	0	0	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 12	Low	0	0	0	0	0	
	Normal	0	25 (100)	0	25 (100)	1	
	High	0	0	0	0	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 16	Low	0	0	0	0	0	
	Normal	0	25 (100)	0	25 (100)	1	
	High	0	0	0	0	0	
	Total	0	25 (100)	0	25 (100)	1	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 20	Low	0	0	0	0	0	
	Normal	0	25 (100)	0	25 (100)	1	
	High	0	0	0	0	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 24	Low	0	0	0	0	0	
	Normal	0	25 (100)	0	25 (100)	1	
	High	0	0	0	0	0	
	Total	0	25 (100)	0	25 (100)	1	
Multiple Dose Hour 28	Low	0	0	0	0	0	
	Normal	0	24 (100)	0	24 (100)	2	
	High	0	0	0	0	0	
	Total	0	24 (100)	0	24 (100)	2	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 32	Low	0	0	0	0	0	
	Normal	0	24 (100)	0	24 (100)	2	
	High	0	0	0	0	0	
	Total	0	24 (100)	0	24 (100)	2	
Multiple Dose Hour 36	Low	0	0	0	0	0	
	Normal	0	24 (100)	0	24 (100)	2	
	High	0	0	0	0	0	
	Total	0	24 (100)	0	24 (100)	2	
Multiple Dose Hour 40	Low	0	0	0	0	0	
	Normal	0	24 (100)	0	24 (100)	2	
	High	0	0	0	0	0	
	Total	0	24 (100)	0	24 (100)	2	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

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Missing values are not included in percents.

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Shift from Baseline to Double Blind Phase Time Points
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Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low	Normal	High	Total		
		n (%) [1]	n (%) [1]	n (%) [1]	n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Multiple Dose Hour 44	Low	0	0	0	0	0	
	Normal	0	22 (100)	0	22 (100)	4	
	High	0	0	0	0	0	
	Total	0	22 (100)	0	22 (100)	4	
Multiple Dose Hour 48	Low	0	0	0	0	0	
	Normal	0	24 (100)	0	24 (100)	2	
	High	0	0	0	0	0	
	Total	0	24 (100)	0	24 (100)	2	
Early Termination	Low	0	0	0	0	0	
	Normal	0	2 (100)	0	2 (100)	0	
	High	0	0	0	0	0	
	Total	0	2 (100)	0	2 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

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Vital Signs
Shift from Baseline to Double Blind Phase Time Points
Blinded Safety Population - Cohort 1

Measure (Unit) Time Point (Visit)	BL Ref Flag	Total (N=26)					Missing n [2]
		Low n (%) [1]	Normal n (%) [1]	High n (%) [1]	Total n (%) [1]		
Respiratory Rate (BREATHS/MIN)							
Blinded Follow-up	Low	0	0	0	0	0	
	Normal	0	16 (100)	0	16 (100)	0	
	High	0	0	0	0	0	
	Total	0	16 (100)	0	16 (100)	0	

Note: BL = baseline; BP = blood pressure; mmHg = millimeters mercury

[1] Percents are based on the number of subjects with a baseline and a value at the visit for each treatment.

Missing values are not included in percents.

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