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14.1.1.1 Subject Disposition

	BP3304 n (%)	Placebo n (%)	Overall n (%)
Enrolled			xx
Withdrew Before Randomization			xx (xx.x)
Exclusionary Laboratory Values			xx (xx.x)
Non-Laboratory Safety Exclusions			xx (xx.x)
Excluded Concomitant Medication			xx (xx.x)
Other			xx (xx.x)
Randomized	xx	xx	xx
Completed Treatment Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued Treatment Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative Reasons by Sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did Not Meet Inclusion Criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-compliance	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawn by Investigator	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient Withdrew Consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listings 16.2.1 and 16.2.2
Note: Percentages for reasons withdrawn before randomization are based on the number of enrolled subjects.
All other percentages are based on the number of randomized subjects.

14.1.1.1 Subject Disposition

	BP3304 n (%)	Placebo n (%)	Overall n (%)
Randomized	xx	xx	xx
Entered Follow-up Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Follow-up Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued Follow-up Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative Reasons by Sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did Not Meet Inclusion Criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-compliance	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawn by Investigator	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient Withdrew Consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listings 16.2.1 and 16.2.2
Note: Percentages are based on the number of randomized subjects.

14.1.1.2 Subject Disposition by Site

Site: xxx

	BP3304 n (%)	Placebo n (%)	Overall n (%)
Enrolled			xx
Withdrew Before Randomization			xx (xx.x)
Exclusionary Laboratory Values			xx (xx.x)
Non-Laboratory Safety Exclusions			xx (xx.x)
Excluded Concomitant Medication			xx (xx.x)
Other			xx (xx.x)
Randomized	xx	xx	xx
Completed Treatment Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued Treatment Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative Reasons by Sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did Not Meet Inclusion Criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-compliance	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawn by Investigator	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient Withdrew Consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listings 16.2.1 and 16.2.2
Note: Percentages for reasons withdrawn before randomization are based on the number of enrolled subjects.
All other percentages are based on the number of randomized subjects.

14.1.1.2 Subject Disposition by Site

Site: xxx

	BP3304 n (%)	**Placebo n (%)**	**Overall n (%)**
Randomized	xx	xx	xx
Entered Follow-up Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Follow-up Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued Follow-up Phase	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative Reasons by Sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did Not Meet Inclusion Criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-compliance	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawn by Investigator	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient Withdrew Consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listings 16.2.1 and 16.2.2
Note: Percentages are based on the number of randomized subjects.

14.1.2.1 Subject Demographics and Baseline Characteristics
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Age (years)			
N	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Gender [n (%)][a]			
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity [n (%)][a]			
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race [n (%)][a]			
White	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaskan Native	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.4.1
[a] Percentages are based on the number of subjects in the population.
Note: SD = standard deviation, Min = Minimum, Max = Maximum.

14.1.2.1 Subject Demographics and Baseline Characteristics
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Height (cm)			
N	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Weight (kg)			
N	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Body Mass Index (kg/m^2)			
N	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Reference: Listing 16.2.4.1
Note: SD = standard deviation, Min = Minimum, Max = Maximum.

14.1.2.1 Subject Demographics and Baseline Characteristics
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Alcohol History [n (%)][a]			
Never Consumed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Previously Consumed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Currently Consumes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tobacco History [n (%)][a]			
Never Consumed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Previously Consumed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Currently Consumes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Duration of Hypertension (years)			
N	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
≤10 years	xx (xx.x)	xx (xx.x)	xx (xx.x)
>10 years	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.4.1
[a] Percentages are based on the number of subjects in the population.
Note: SD = standard deviation, Min = Minimum, Max = Maximum.

The following tables will be identical in format to Table 14.1.2.1, but will summarize data for the MITT population.

14.1.2.2 Subject Demographics – Modified Intent-to-Treat Population
14.1.2.3 Subject Demographics – Per Protocol Population

14.1.3 Subject Evaluability

	BP3304 n (%)	Placebo n (%)	Overall n (%)
Randomized	xx	xx	xx
Safety Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Safety Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did Not Receive Study Medication	xx (xx.x)	xx (xx.x)	xx (xx.x)
MITT Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not MITT Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not in Safety Population	xx (xx.x)	xx (xx.x)	xx (xx.x)
No Baseline Diastolic Blood Pressure	xx (xx.x)	xx (xx.x)	xx (xx.x)
No Post-Baseline Diastolic Blood Pressure	xx (xx.x)	xx (xx.x)	xx (xx.x)
Per Protocol Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Per Protocol Evaluable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not in MITT Population	xx (xx.x)	xx (xx.x)	xx (xx.x)
Received <80% of Scheduled Doses	xx (xx.x)	xx (xx.x)	xx (xx.x)
Major Protocol Violations	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Appendices 16.2.1 and 16.2.2
Note: Percentages are based on the number of randomized subjects.

14.1.4.1 Prior Medications
Safety Population

Therapeutic Class Generic Name	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Prior Medication	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic Class I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic Class II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.4.4
Note: Prior medications include all recorded medications taken prior to the date of the first injection of study drug. Percentages are based on the number of subjects in each population. Subjects taking a medication more than once are only counted once for that medication.

14.1.4.2 Concomitant Treatment Phase Medications
Safety Population

Therapeutic Class Generic Name	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Concomitant Treatment Phase Medication	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic Class I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic Class II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.4.4
Note: Concomitant Treatment Phase medications include all recorded medications which were taken prior to and continue after Day 1 and those that start on or after Day 1 up until the last dose date plus 1 day, inclusive. Percentages are based on the number of subjects in each population. Subjects taking a medication more than once are only counted once for that medication.

14.1.4.3 Concomitant Follow-up Phase Medications
Safety Population

Therapeutic Class Generic Name	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Concomitant Follow-up Phase Medication	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic Class I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic Class II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generic Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.4.4

Note: Concomitant Follow-up Phase medications include all recorded medications which were taken prior to and continue after the last dose day plus 1 and those that start after the last dose day plus 1. Percentages are based on the number of subjects in each population. Subjects taking a medication more than once are only counted once for that medication.

14.1.5.1 Exposure to Study Medication
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Duration of Exposure (weeks)			
N	xx	xx	xx
Mean (SD)	xx,xx (xx.xxx)	xx,xx (xx.xxx)	xx,xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Total Number of Doses Taken			
N	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Reference: Appendix 16.2.5
Note: Exposure to study drug in weeks is computed for each patient as the date of last dose minus the date of first dose, plus 1 day divided by 7 days per week. SD = standard deviation, Min = Minimum, Max = Maximum.

The following table will be identical in format to Table 14.1.5.1, but will summarize data for the MITT population.

14.1.5.2 Exposure to Study Medication – Modified Intent-to-Treat Population
14.1.5.3 Exposure to Study Medication – Per Protocol Population

14.1.6.1 Treatment Compliance
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Compliance (%)			
N	xx	xx	xx
Mean (SD)	xx,xx (xx.xxx)	xx,xx (xx.xxx)	xx,xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
<80% [n (%)]	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥80% [n (%)]	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Appendix 16.2.5
Note: Compliance with study drug dosing is computed for each patient as the exposure to study drug in days minus the number of Treatment Phase days on which study drug was not administered, divided by exposure to study drug in days, multiplied by 100%. SD = standard deviation, Min = Minimum, Max = Maximum.

The following table will be identical in format to Table 14.1.6.1, but will summarize data for the MITT population.

14.1.6.2 Treatment Compliance – Modified Intent-to-Treat Population

14.2.1.1 Diastolic Blood Pressure
Modified Intent-to-Treat Population

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Baseline				
N	XX		XX	
Mean (SD)	XXX.XX (XX.XXX)		XXX.XX (XX.XXX)	
Median	XXX.XX		XXX.XX	
Min, Max	XXX.X, XXX.X		XXX.X, XXX.X	
Week 4				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

14.2.1.1 Diastolic Blood Pressure
Modified Intent-to-Treat Population

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Week 8				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

14.2.1.1 Diastolic Blood Pressure
Modified Intent-to-Treat Population

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Week 16				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)
Week 20				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

14.2.1.1 Diastolic Blood Pressure
Modified Intent-to-Treat Population

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Week 24				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)
End of Study				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

The following tables will be identical in format to Table 14.2.1.1, but will summarize different parameters for different populations.

14.2.1.2 Diastolic Blood Pressure – Per Protocol Population

14.2.2.1 Systolic Blood Pressure – Modified Intent-to-Treat Population

14.2.2.2 Systolic Blood Pressure – Per Protocol Population

14.2.3.1 Diastolic Blood Pressure by Age Group
Modified Intent-to-Treat Population

Age: >65 Years Old

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Baseline				
N	XX		XX	
Mean (SD)	XXX.XX (XX.XXX)		XXX.XX (XX.XXX)	
Median	XXX.XX		XXX.XX	
Min, Max	XXX.X, XXX.X		XXX.X, XXX.X	
Week 4				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

14.2.3.1 Diastolic Blood Pressure by Age Group
Modified Intent-to-Treat Population

Age: >65 Years Old

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Week 8				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

14.2.3.1 Diastolic Blood Pressure by Age Group
Modified Intent-to-Treat Population

Age: >65 Years Old

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Week 16				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)
Week 20				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

14.2.3.1 Diastolic Blood Pressure by Age Group
Modified Intent-to-Treat Population

Age: >65 Years Old

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	**Change From Baseline**	**Observed**	**Change From Baseline**
Week 24				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)
End of Study				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X	XXX.X, XXX.X
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
LS Mean Difference (SE)				XX.X (XX.XXX)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2

Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure.. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

Repeat for Age <=65 Years Old.

The following tables will be identical in format to Table 14.2.3.1, but will summarize diastolic blood pressure for different populations and subgroups.

14.2.3.2 Diastolic Blood Pressure by Age Group – Per Protocol Population (>65, <= 65 Years Old)

14.2.4.1 Diastolic Blood Pressure by Duration of Hypertension – Modified Intent-to-Treat Population (<10 Years, >=10 Years)

14.2.4.2 Diastolic Blood Pressure by Duration of Hypertension – Per Protocol Population (<10 Years, >=10 Years)

14.2.5.1 Time to Achievement of Diastolic Blood Pressure ≤ 90 mmHg
Modified Intent-to-Treat Population

	BP3304 (N = xx)	**Placebo (N = xx)**
	n (%)	**n (%)**
N	xx	xx
No. with DBP ≤ 90 mmHg	xx (xx.x)	xx (xx.x)
No. of Censored	xx (xx.x)	xx (xx.x)
Time to DBP ≤ 90 mmHg (Weeks)		
Median	xx.xx	xx.xx
95% CI of Median	(xx.xx, xx.xx)	(xx.xx, xx.xx)
25-75%ile	xx.xx – xx.xx	xx.xx – xx.xx
Min, Max	xx.x, xx.x+	xx.x, xx.x+

Reference: Listing 16.2.6.2
Note: Time to diastolic blood pressure ≤ 90 mmHg is calculated using Kaplan-Meier methods. 95% CI for median is computed using Brookmeyer and Crowley's method.
+ = censored value, C.I. = Confidence interval, DBP = diastolic blood pressure.

The following table will be identical in format to Table 14.2.5.1, but will summarize data for the Per Protocol population.

14.2.5.2 Time to Achievement of Diastolic Blood Pressure ≤ 90 mmHg – Per Protocol Population

14.2.6.1 Proportion of Patients Achieving Diastolic Blood Pressure ≤ 90 mmHg
Modified Intent-to-Treat Population

	BP3304 (N = xx)	Placebo (N = xx)
	n (%)	n (%)
At Any Time During the Study	XX/XX (XX.X)	XX/XX (XX.X)
Week 20	XX/XX (XX.X)	XX/XX (XX.X)
Odds Ratio Versus Placebo	X.XX	
95% Confidence Interval	(X.XX, X.XX)	
p-value	0.XXX	
Week 24	XX/XX (XX.X)	XX/XX (XX.X)
Odds Ratio Versus Placebo	X.XX	
95% Confidence Interval	(X.XX, X.XX)	
p-value	0.XXX	

Reference: Listing 16.2.6.2
Note: Odds ratios, 95% confidence intervals, and p-values come from a logistic regression analyses will be used with a covariate for baseline blood pressure to compare treatment groups.

The following table will be identical in format to Table 14.2.6.1, but will summarize data for the Per Protocol population.

14.2.6.2 Proportion of Patients Achieving Diastolic Blood Pressure ≤ 90 mmHg – Per Protocol Population

14.3.1.1.1 Overall Summary of Treatment-Emergent Adverse Events
Safety Population

	BP3304 (N =xx)		Placebo (N =xx)		Overall (N =xx)	
	n (%)	**Events**	**n (%)**	**Events**	**n (%)**	**Events**
Treatment-Emergent Adverse Events (TEAE)						
Any TEAE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Severe TEAE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Any Treatment-Related TEAE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Resulting in Study Drug Discontinuation	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Treatment-Related Resulting in Study Drug Discontinuation	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Any TEAE by Maximum Severity						
Mild	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Moderate	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Severe	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Treatment-Related TEAE by Maximum Severity						
Mild	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Moderate	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Severe	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

Reference: Listing 16.2.7
Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Treatment-related TEAEs are AEs considered to be possibly or probably related to study drug. Percentages are based on the number of subjects in each population. Subjects reporting more than one adverse event in any category are counted only once for that category.

14.3.1.1.1 Overall Summary of Treatment-Emergent Adverse Events
Safety Population

	BP3304 (N =xx)		Placebo (N =xx)		Overall (N =xx)	
	n (%)	**Events**	**n (%)**	**Events**	**n (%)**	**Events**
Serious Adverse Events (SAE)						
Any SAE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Any Treatment-Related SAE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Deaths						
SAE Resulting in Death	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Treatment-Related SAE Resulting in Death	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

Reference: Listing 16.2.7
Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Treatment-related TEAEs are AEs considered to be possibly or probably related to study drug. Percentages are based on the number of subjects in each population. Subjects reporting more than one adverse event in any category are counted only once for that category.

14.3.1.1.2.1 Treatment-Emergent Adverse Events by System Organ Class
Safety Population

System Organ Class Preferred Term	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Treatment-Emergent Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.7
Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

Programming note: Terms should be sorted in descending order (based on the overall incidence) within a SOC.

The following tables will be the same in format as Table 14.3.1.1.2.1:

14.3.1.1.2.2 Treatment Related Treatment Emergent Adverse Events by System Organ Class – Safety Population

Note: Related TEAEs are AEs considered to be possibly or probably related to study drug. A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.1.3.1 Severe Treatment Emergent Adverse Events by System Organ Class – Safety Population

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.1.3.2 Treatment Related Severe Treatment Emergent Adverse Events by System Organ Class – Safety Population

Note: Related TEAEs are AEs considered to be possibly or probably related to study drug. A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.1.4.1 Treatment Emergent Adverse Events Reported by $\geq$ 5% of BP3304 Patients by System Organ Class – Safety Population

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.1.4.2 Treatment Related Treatment Emergent Adverse Events Reported by $\geq$ 5% of BP3304 Patients by System Organ Class – Safety Population

Note: Related TEAEs are AEs considered to be possibly or probably related to study drug. A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.1.5.1 Treatment Emergent Adverse Events Resulting in Study Drug Discontinuation by System Organ Class – Safety Population

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.1.5.2 Treatment Related Treatment Emergent Adverse Events Resulting in Study Drug Discontinuation by System Organ Class – Safety Population

Note: Related TEAEs are AEs considered to be possibly or probably related to study drug. A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.2.1 Serious Treatment Emergent Adverse Events by System Organ Class – Safety Population

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.2.2 Treatment Related Serious Treatment Emergent Adverse Events by System Organ Class – Safety Population

Note: Related TEAEs are AEs considered to be possibly or probably related to study drug. A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.2.3 Treatment Emergent Adverse Events Resulting in Death by System Organ Class – Safety Population

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.2.4 Treatment Related Treatment Emergent Adverse Events Resulting in Death by System Organ Class – Safety Population

Note: Related TEAEs are AEs considered to be possibly or probably related to study drug. A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.1.3 Treatment-Emergent Adverse Events by Maximum Severity and System Organ Class
Safety Population

System Organ Class Preferred Term	Maximum Severity	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Treatment Emergent Adverse Event	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class I	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.7
Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

14.3.2.1 Adverse Events Resulting in Death
Safety Population

Treatment Group:

V: Verbatim Term P: Preferred Term S: System Organ Class	Start Date Day*	Days Since Last Study Drug Dose	Death Date Day*	Treatment Duration (Days)	Causal Relationship	S: Severity A: Action T: Treatment O: Outcome

Subject Number: xxx, <Center Number>, Age: xx Years, Gender: xxxxxx, Race: xxxxx, Weight: xx.x kg, Concomitant Medication: Yes or No

Reference: CRF Pages ##, ##, and ##
* Study days are calculated from the date of the first dose of study medication.
+ Treatment-emergent adverse event.

14.3.2.2 Non-fatal Serious Adverse Events
Safety Population

Treatment Group:

V: Verbatim Term **P: Preferred Term** **S: System Organ Class**	**Start Date Day***	**Days Since Last Study Drug Dose**	**Stop Date Day***	**Treatment Duration (Days)**	**Causal Relationship**	**S: Severity** **A: Action** **T: Treatment** **O: Outcome**

Subject Number: xxx, <Center Number>, Age: xx Years, Gender: xxxxxx, Race: xxxxx, Weight: xx.x kg, Concomitant Medication: Yes or No

Reference: CRF Pages ##, ##, and ##
* Study days are calculated from the date of the first dose of study medication.
+ Treatment-emergent adverse event.

14.3.2.3 Adverse Events Resulting in Study Discontinuation
Safety Population

Treatment Group:

V: Verbatim Term P: Preferred Term S: System Organ Class	Start Date Day*	Days Since Last Study Drug Dose	Stop Date Day*	Treatment Duration (Days)	Causal Relationship	S: Severity A: Action T: Treatment O: Outcome	Serious?

Subject Number: xxx, <Center Number>, Age: xx Years, Gender: xxxxxx, Race: xxxxx, Weight: xx.x kg, Concomitant Medication: Yes or No

Reference: CRF Pages ##, ##, and ##
* Study days are calculated from the date of the first dose of study medication.
+ Treatment-emergent adverse event.

14.3.4.1 Serum Chemistry Laboratory Parameters
Safety Population

<Blood Chemistry Parameter (Units)>

Visit	BP33404 (N=xx) Actual	BP33404 (N=xx) Change From Baseline	Placebo (N=xx) Actual	Placebo (N=xx) Change From Baseline	Overall (N=xx) Actual	Overall (N=xx) Change From Baseline
Baseline						
N	xx		xx		xx	
Mean (SD)	xx,x (xx.xx)		xx,x (xx.xx)		xx,x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Reference: Appendices 16.2.8.1.1-16.2.8.1.4

Note: SD = standard deviation, Min = Minimum, Max = Maximum. Baseline is defined as the last value collected before the first dose of study drug.

Programming note: The number of significant digits will vary by parameter. Parameters should not be sorted alphabetically, but rather placed in logical groups.

Repeat for Week 8, 12, 16, 20 and 24 visits.

14.3.4.2 Hematology Laboratory Parameters
Safety Population

<Blood Chemistry Parameter (Units)>

	BP33404 (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Visit	**Actual**	**Change From Baseline**	**Actual**	**Change From Baseline**	**Actual**	**Change From Baseline**
Baseline						
N	xx		xx		xx	
Mean (SD)	xx,x (xx.xx)		xx,x (xx.xx)		xx,x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Reference: Appendices 16.2.8.1.1-16.2.8.1.4
Note: SD = standard deviation, Min = Minimum, Max = Maximum. Baseline is defined as the last value collected before the first dose of study drug.

Programming note: The number of significant digits will vary by parameter. Parameters should not be sorted alphabetically, but rather placed in logical groups.

Repeat for Week 8, 12, 16, 20 and 24 visits.

14.3.5.1 Shifts from Baseline in Serum Chemistry Laboratory Parameters
Safety Population

[Laboratory Parameter Name, Unit]

	BP3304 (N=xx)			Placebo (N=xx)		
	Baseline			Baseline		
	Low	**Normal**	**High**	**Low**	**Normal**	**High**
Week 4 [n (%)]		(N = XX)			(N = XX)	
Low	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Week 8 [n (%)]		(N = XX)			(N = XX)	
Low	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Week 12 [n (%)]		(N = XX)			(N = XX)	
Low	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

Reference: Listing 16.2.8.1.2
Note: Baseline is defined as the last value collected before the first dose of study drug. .

Repeat for Week 16, 20 and 24 visits.

14.3.5.2 Shifts from Baseline in Hematology Laboratory Parameters
Safety Population

[Laboratory Parameter Name, Unit]

	BP3304 (N=xx)			Placebo (N=xx)		
	Baseline			Baseline		
	Low	**Normal**	**High**	**Low**	**Normal**	**High**
Week 4 [n (%)]		(N = XX)			(N = XX)	
Low	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Week 8 [n (%)]		(N = XX)			(N = XX)	
Low	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Week 12 [n (%)]		(N = XX)			(N = XX)	
Low	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

Reference: Listing 16.2.8.1.2
Note: Baseline is defined as the last value collected before the first dose of study drug. .

Repeat for Week 16, 20 and 24 visits.

14.3.5.3 Shifts from Baseline in Urinalysis Laboratory Parameters
Safety Population

[Laboratory Parameter Name, Unit]

	BP3304 (N=xx)			Placebo (N=xx)		
	Baseline			Baseline		
	Low	**Normal**	**High**	**Low**	**Normal**	**High**
Week 4 [n (%)]		(N = XX)			(N = XX)	
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Abnormal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Week 8 [n (%)]		(N = XX)			(N = XX)	
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Abnormal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Week 12 [n (%)]		(N = XX)			(N = XX)	
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Abnormal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

Reference: Listing 16.2.8.1.2
Note: Baseline is defined as the last value collected before the first dose of study drug. .

Repeat for Week 16, 20 and 24 visits. This table will be similar in structure to 14.3.5.3.1 and 14.3.5.3.2, but will use appropriate shift categories (such as “Normal” and “Abnormal”) for the following parameters: Color, pH, Specific Gravity, Glucose, Protein, Ketones, Blood, and Microscopy (RBC, WBC, Epithelial Cells, Casts, and Crystals).

14.3.5.4 Clinically Significant Laboratory Results During Treatment Phase
Safety Population

Laboratory Type Laboratory Parameter [n (%)]	BP3304 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Chemistry			
Parameter 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parameter 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parameter 3	XX (XX.X)	XX (XX.X)	XX (XX.X)
.	.	.	.
.	.	.	.
.	.	.	.
Hematology			
Parameter 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parameter 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parameter 3	XX (XX.X)	XX (XX.X)	XX (XX.X)
.	.	.	.
.	.	.	.
.	.	.	.
Urinalysis			
Parameter 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parameter 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parameter 3	XX (XX.X)	XX (XX.X)	XX (XX.X)
.	.		.
.	.		.
.	.		.

Reference: Listings 16.2.8.1.3, 16.2.8.2.2, and 16.2.8.3.2

14.3.6.1 Vital Signs
Safety Population

<Vital Signs Parameter (Units)>

	BP33404 (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Visit	**Actual**	**Change From Baseline**	**Actual**	**Change From Baseline**	**Actual**	**Change From Baseline**
Baseline						
N	xx		xx		xx	
Mean (SD)	xx,x (xx.xx)		xx,x (xx.xx)		xx,x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Reference: Listings 16.2.8.1.1-16.2.8.1.4
Note: SD = standard deviation, Min = Minimum, Max = Maximum. Baseline is defined as the last measurement before the first dose of study drug.

Programming note: The number of significant digits will vary by parameter.

Repeat for Week 8, 12, 16, 20 and 24 visits. Display for heart rate, weight and body mass index.

14.3.6.2 Clinically Significant Vital Signs During Treatment Phase
Safety Population

	BP3304 (N=xx) n (%)	Placebo (N=xx) n (%)	Overall (N=xx) n (%)
Diastolic Blood Pressure			
<40 mmHg	XX (XX.X)	XX (XX.X)	XX (XX.X)
>130 mmHg	XX (XX.X)	XX (XX.X)	XX (XX.X)
Systolic Blood Pressure			
<80 mmHg	XX (XX.X)	XX (XX.X)	XX (XX.X)
>210 mmHg	XX (XX.X)	XX (XX.X)	XX (XX.X)
Heart Rate			
<40 beats per minute	XX (XX.X)	XX (XX.X)	XX (XX.X)
>150 beats per minute	XX (XX.X)	XX (XX.X)	XX (XX.X)
Temperature			
<32 C	XX (XX.X)	XX (XX.X)	XX (XX.X)
>40 C	XX (XX.X)	XX (XX.X)	XX (XX.X)

Reference: Listings 16.2.8.1.1-16.2.8.1.4

14.3.7.1 Electrocardiogram Overall Results
Safety Population

	BP33404 (N=xx)			Placebo (N=xx)		
n (%) of Patients	**N**	**Normal**	**Abnormal**	**N**	**Normal**	**Abnormal**
Screening 1	xx	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)
Screening 2	xx	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)
Screening 3	xx	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)
Week 24	xx	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.9.1
Note: N = Number of patients with results at the indicated visit (this number is used as the denominator for computing percentages).

14.3.7.2 Electrocardiogram Results by Parameter
Safety Population

<Electrocardiogram Parameter (Units)>

	BP33404 (N=xx)		Placebo (N=xx)		Overall (N=xx)	
Visit	**Actual**	**Change From Baseline**	**Actual**	**Change From Baseline**	**Actual**	**Change From Baseline**
Baseline						
N	xx		xx		xx	
Mean (SD)	xx,x (xx.xx)		xx,x (xx.xx)		xx,x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
>450 ms [n (%)]	xx (xx.x)		xx (xx.x)		xx (xx.x)	
>480 ms [n (%)]	xx (xx.x)		xx (xx.x)		xx (xx.x)	
>500 ms [n (%)]	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Week 24						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)	xx,x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
>450 ms [n (%)]	xx (xx.x)		xx (xx.x)		xx (xx.x)	
>480 ms [n (%)]	xx (xx.x)		xx (xx.x)		xx (xx.x)	
>500 ms [n (%)]	xx (xx.x)		xx (xx.x)		xx (xx.x)	
>30 ms Increase [n (%)]		xx (xx.x)		xx (xx.x)		xx (xx.x)
>60 ms Increase [n (%)]		xx (xx.x)		xx (xx.x)		xx (xx.x)

Reference: Appendices 16.2.8.1.1-16.2.8.1.4

Note: Baseline value is mean of 3 tracings collected during screening period. The change from baseline value is calculated using this mean baseline value. SD = Standard Deviation, Min = Minimum, Max = Maximum.

Display for PR, QT, QTcB, QTcF, QRS, and RR intervals.

14.3.8.1 Screening Physical Examination
Safety Population

	BP33404 (N=xx)				Placebo (N=xx)			
			Abnormal				Abnormal	
Body System [n (%)]	**N**	**Normal**	**NCS**	**CS**	**N**	**Normal**	**NCS**	**CS**
Body as a Whole	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Head, Eyes, Ears, Nose, Throat	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neck/Thyroid	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Back	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Breasts/Gynecological	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lungs	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Heart	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Skin	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abdomen	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Extremities/Musculoskeletal	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neurological	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Urological	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.11
Note: N = Number of patients with results for the indicated body system (this number is used as the denominator for computing percentages), NCS = Not Clinically Significant, CS = Clinically Significant.

14.3.8.2 Follow-up Physical Examination
Safety Population

Body System Visit [n (%)]	BP33404 (N=xx) N	No Change	Change NCS	CS	Placebo (N=xx) N	No Change	Change NCS	CS
Body as a Whole								
Baseline	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 12	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 24	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Early Termination	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Head, Eyes, Ears, Nose, Throat								
Baseline	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 12	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 24	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Early Termination	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)

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.
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Reference: Listing 16.2.11
Note: This table summarizes change from the previous visit (not change from baseline). N = Number of patients with results for the indicated body system (this number is used as the denominator for computing percentages), NCS = Not Clinically Significant, CS = Clinically Significant.

Additional pages will show the result for each body system.