Figure 1. Patient Disposition (ITT: intention to treat, PP: Per Protocol)

Screened subjects
(n = 187)

Excluded
(n = 38)

Randomized subjects
(n = 149)

Amlodipine
(n = 75)

Amlodipine/Losartan
(n = 74)

Safety population &
ITT population
(n = 73)

Completers
(n = 65)

PP population
(n = 64)

Did not take study drug (n = 1)
Discontinued - Other

Discontinued (n = 8)
Withdrawn consent: 3
Adverse event: 2
Other: 3

Protocol Deviation (n = 1)

Discontinued (n = 5)
Withdrawn consent: 1
Inclusion/exclusion: 1
Investigator discretion: 1
Other: 2

Completers
(n = 70)

Safety population &
ITT population
(n = 75)

PP population
(n = 67)

Discontinued (n = 8)
Withdrawn consent: 3
Adverse event: 2
Other: 3

Protocol Deviation (n = 1)

Discontinued (n = 5)
Withdrawn consent: 1
Inclusion/exclusion: 1
Investigator discretion: 1
Other: 2

Completers
(n = 70)

Safety population &
ITT population
(n = 75)

PP population
(n = 67)

Discontinued (n = 5)
Withdrawn consent: 1
Inclusion/exclusion: 1
Investigator discretion: 1
Other: 2

Completers
(n = 70)

Safety population &
ITT population
(n = 75)

PP population
(n = 67)