



## **AutoPilot™ Toolkit for Phoenix®**

### **Examples of Generated Tables and Graphs**

#### **Disclaimer**

This document displays a number of examples of tables and graphs generated by AutoPilot Toolkit. The output was created using hypothetical study data that are not related to any real drug development. The names of the drug and any related names or identifiers are fictitious.

The underlying study was a non-randomized, single-dose crossover study with 12 subjects that received two treatments for a test of drug interaction for the fictitious drugs called Carterolol and Rifampin.

**AutoPilot™ Toolkit for Phoenix®: Sample Output**

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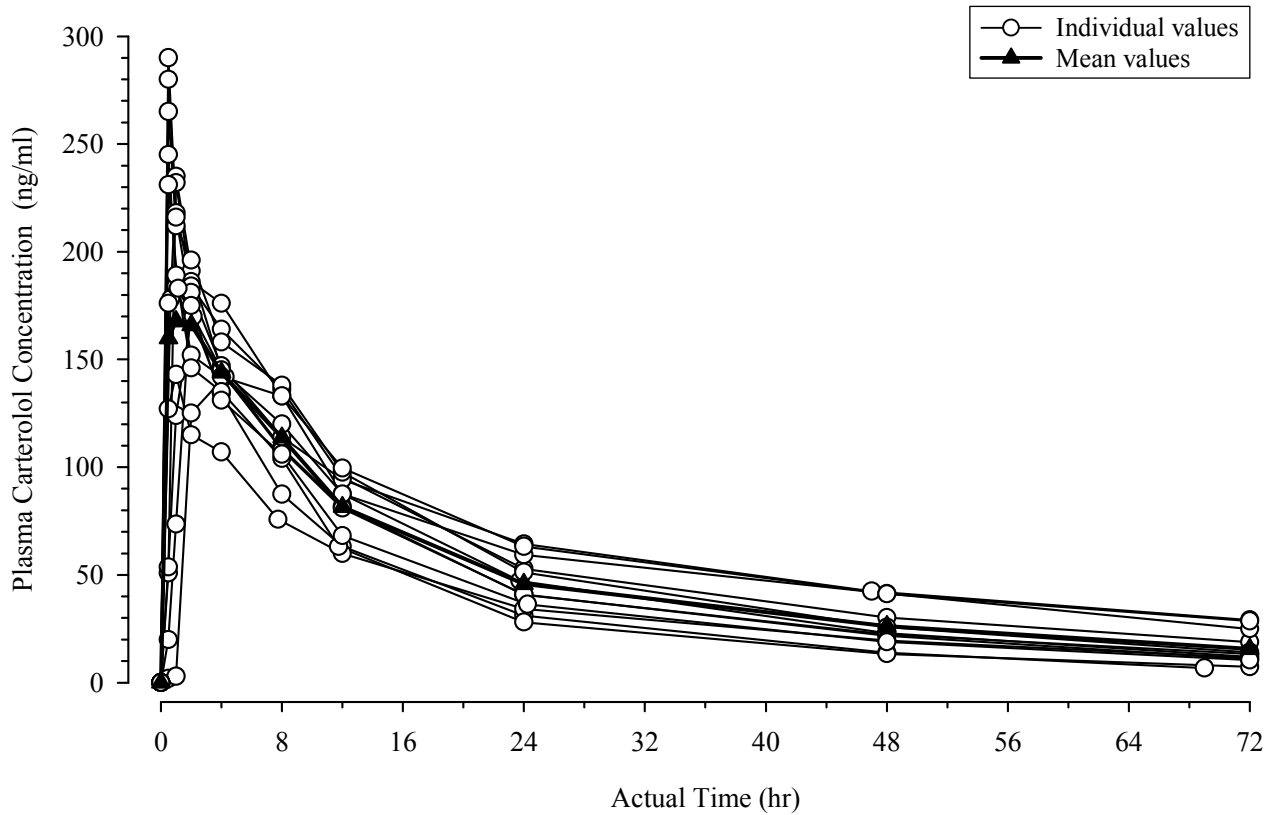
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AutoPilot™ Toolkit for Phoenix®: Sample Output

Spaghetti Individual Time Concentration Graph (linear)

Treatment = Carterolol

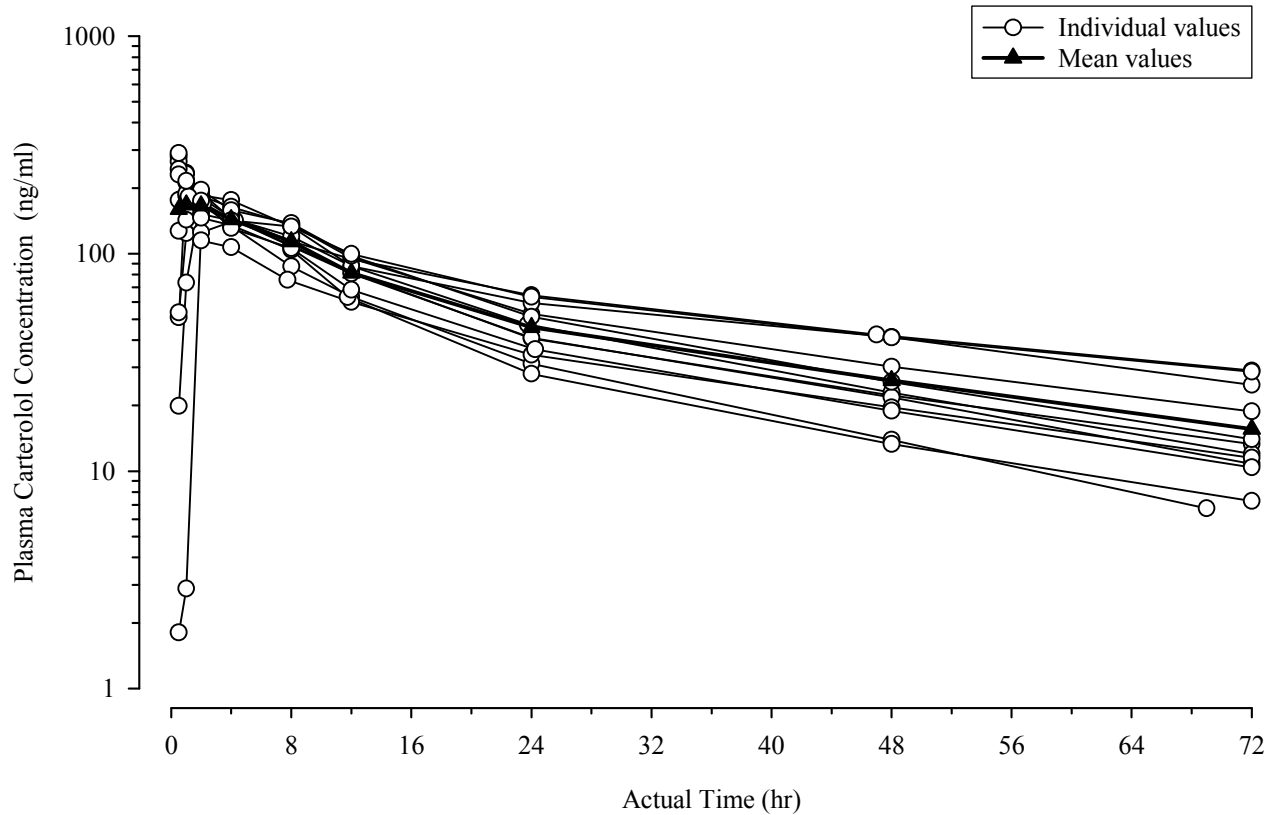


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AutoPilot™ Toolkit for Phoenix®: Sample Output

Spaghetti Individual Time Concentration Graph (logarithmic)

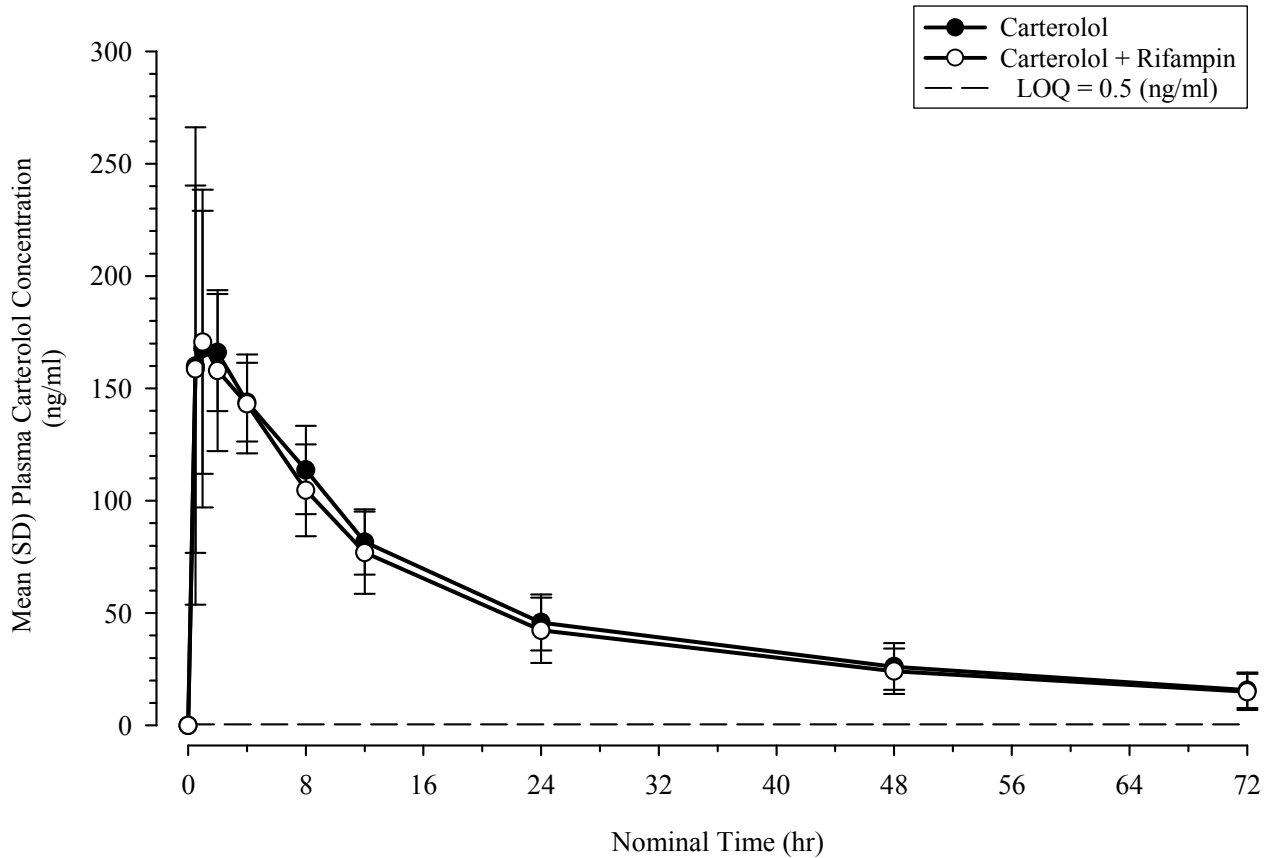
Treatment = Carterolol



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AutoPilot™ Toolkit for Phoenix®: Sample Output

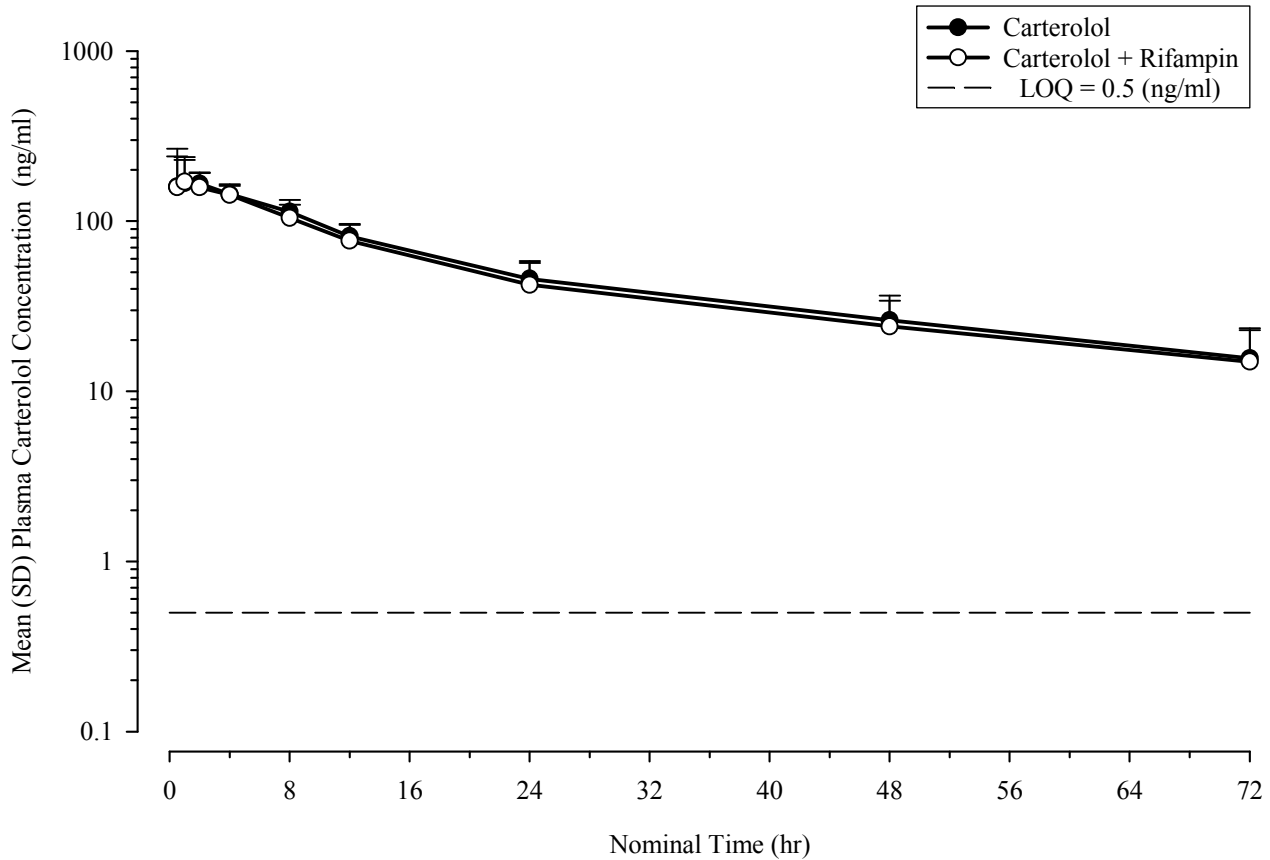
Summary Time Concentration Graph with LOQ value (Error bars in both directions)



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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Summary Time Concentration Graph with LOQ value (logarithmic, only upwards error bar)**



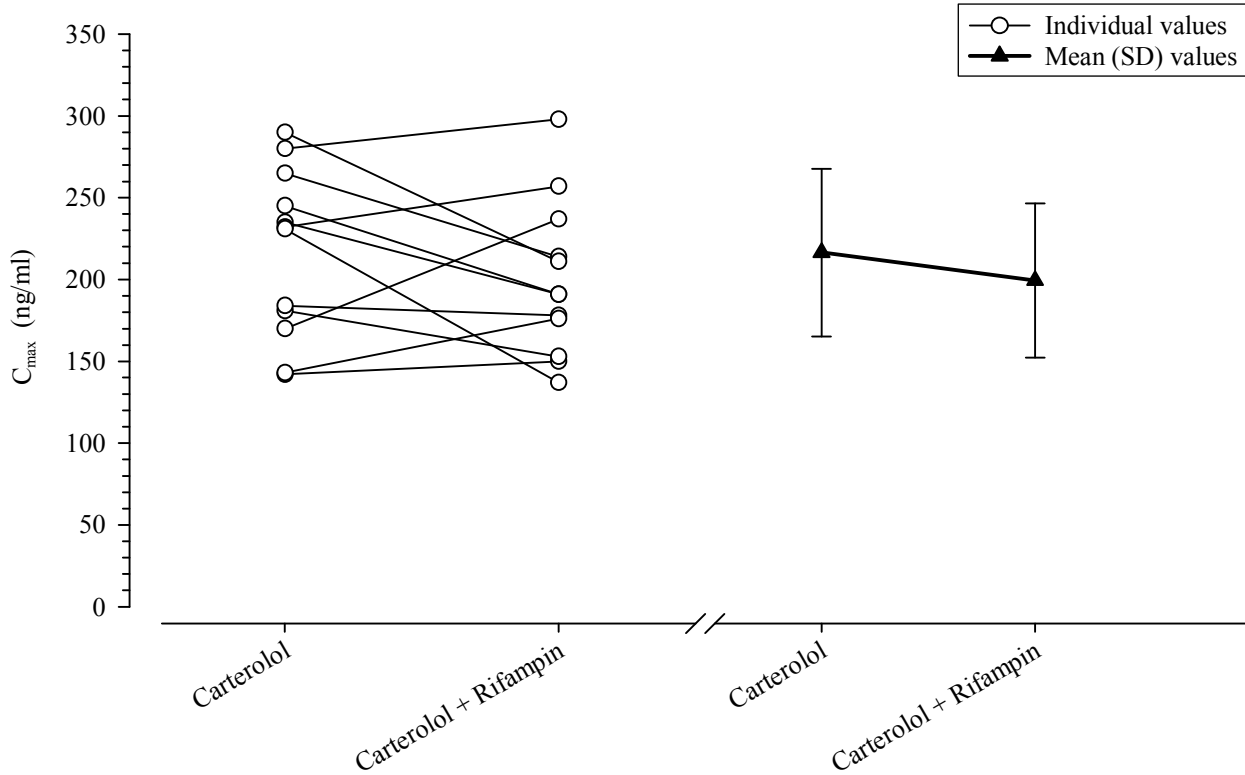
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AutoPilot™ Toolkit for Phoenix®: Sample Output

PK Parameter Categorical Standard Graph (Split graph)

Analyte = Carterolol

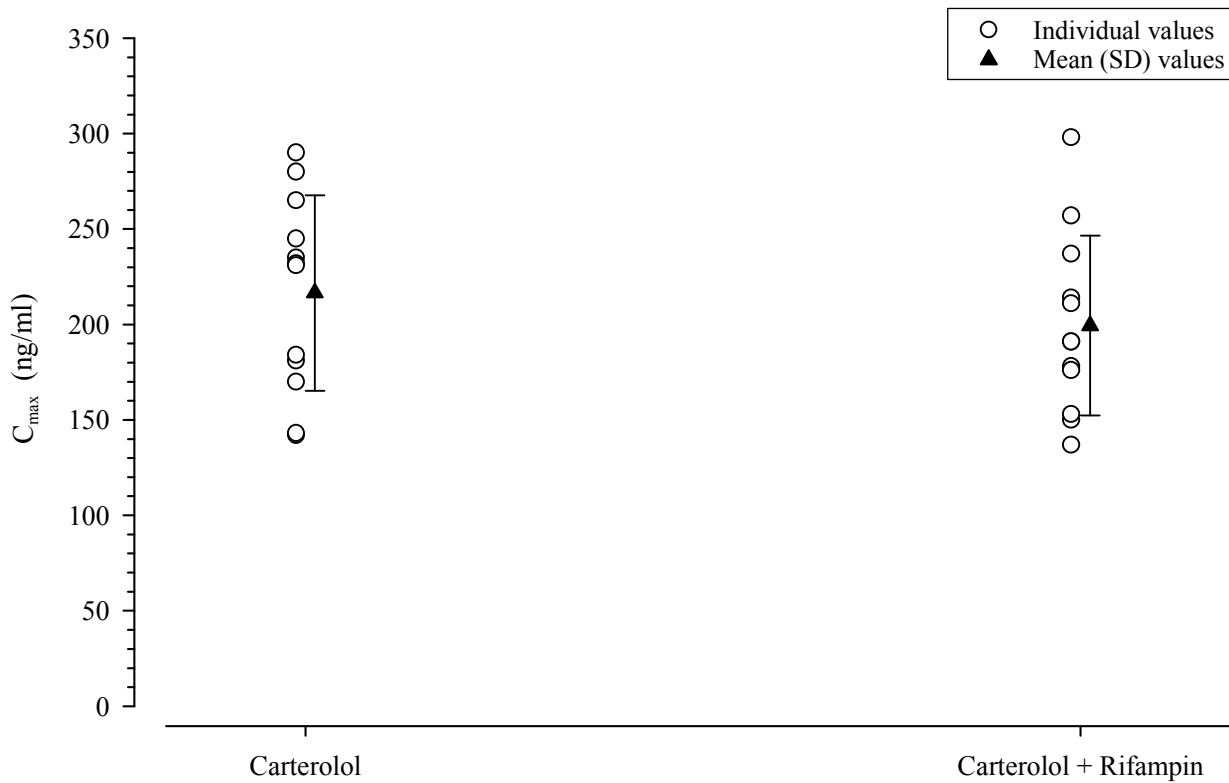


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AutoPilot™ Toolkit for Phoenix®: Sample Output

PK Parameter Categorical Standard Graph (Offset graph)

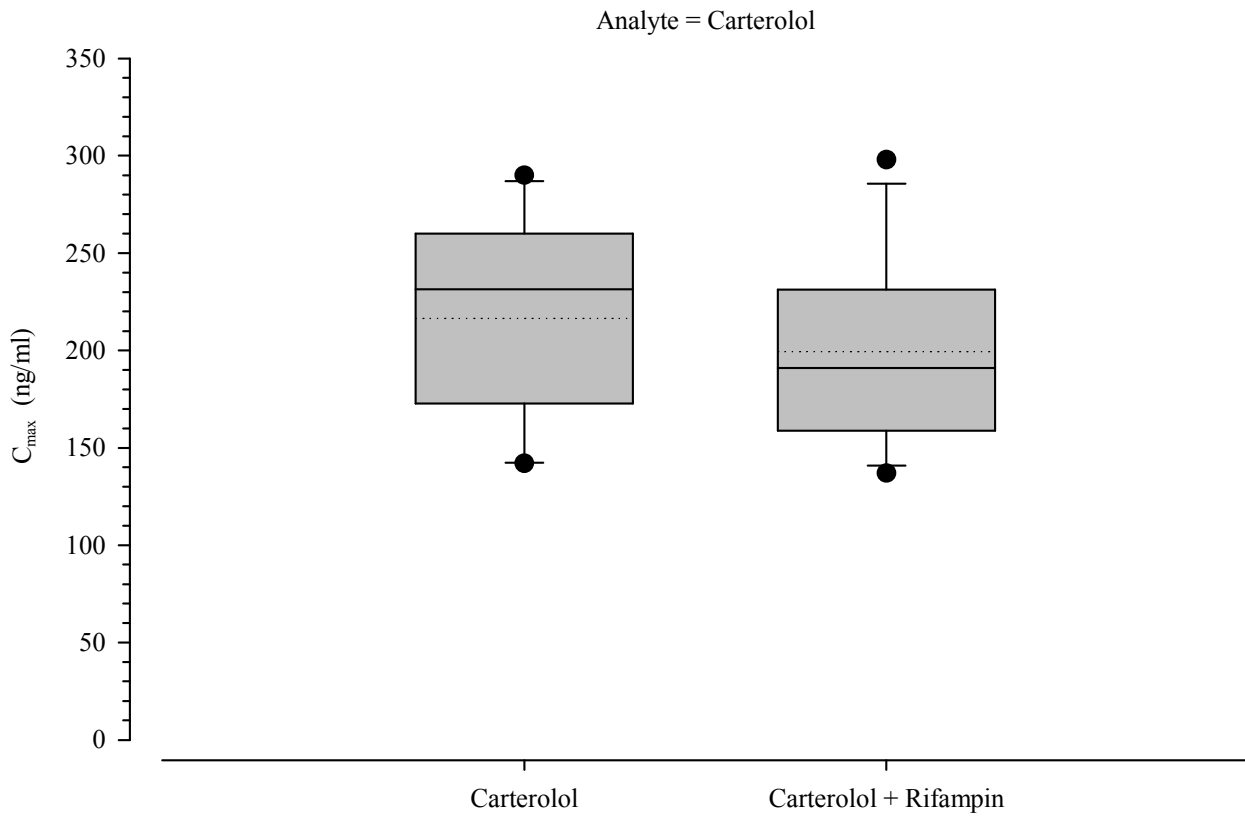
Analyte = Carterolol



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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

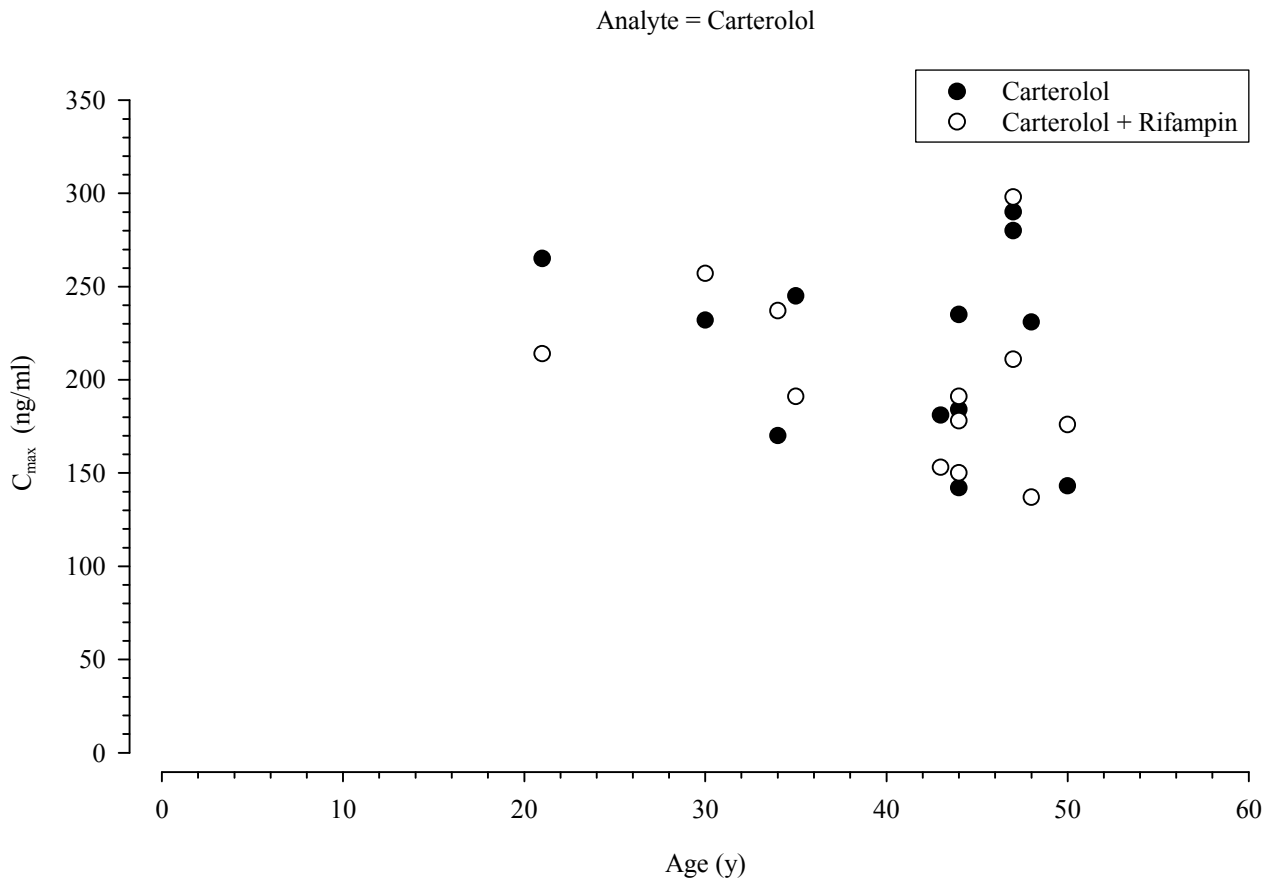
**PK Parameter Categorical Box & Whisker Graph**



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AutoPilot™ Toolkit for Phoenix®: Sample Output

PK Parameter vs. Continuous Demographic Graph



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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Time Concentration Table with LOQ value**

Treatment = Carterolol										
Plasma Carterolol										
Subject	Concentration (ng/ml) over Nominal Time (hr)									
	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
1	<0.5	50.9	235	191	145	109	81.8	40.8	22.3	13.3
2	<0.5	53.6	124	170	134	87.4	63.2	31.2	13.9	6.74
3	<0.5	280	218	186	176	133	87.6	47.2	23.0	12.0
4	<0.5	1.81	2.88	125	142	108	80.9	40.9	21.8	10.8
5	<0.5	178	232	184	164	136	95.3	52.8	30.2	18.8
6	<0.5	19.9	73.5	181	147	114	94.2	64.3	42.4	29.0
7	<0.5	176	184	170	145	120	87.5	59.2	41.3	24.9
8	<0.5	265	212	196	158	138	97.7	51.2	25.7	14.0
9	<0.5	127	143	115	107	75.7	59.9	34.2	19.6	11.5
10	<0.5	245	189	152	142	133	99.5	63.2	41.1	28.6
11	<0.5	231	183	146	135	104	63.1	28.0	13.3	7.28
12	<0.5	290	216	175	131	106	68.2	36.3	18.9	10.4
N	12	12	12	12	12	12	12	12	12	12
Mean	0.00	160	168	166	144	114	81.6	45.8	26.1	15.6
SD	0.00	106	70.7	26.1	17.5	19.6	14.5	12.5	10.4	7.87
SE	0.00	30.7	20.4	7.52	5.04	5.65	4.20	3.60	3.00	2.27
Min	0.00	1.81	2.88	115	107	75.7	59.9	28.0	13.3	6.74
Median	0.00	177	187	173	144	112	84.7	44.1	22.7	12.7
Max	0.00	290	235	196	176	138	99.5	64.3	42.4	29.0
CV%	NA	66	42	16	12	17	18	27	40	50
Geometric Mean	NA	94.0	124	164	143	112	80.3	44.2	24.3	14.0

< 0.5 = Below limit of quantification (ng/ml)

NA = Not Applicable

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Demographics Table**

Subject	Gender	Race	Smoke	Age (y)	Weight (kg)	Height (cm)	BMI (kg/m <sup>2</sup> )	BSA (m <sup>2</sup> )	CrCL (mL/min)
1	Female	Hispanic	No	44	72.7	158	29.3	1.81	74.0
2	Male	Hispanic	No	34	88.6	178	28.0	2.11	170
3	Female	Hispanic	No	47	65.6	158	26.4	1.72	72.0
4	Male	Hispanic	No	44	76.4	173	25.6	1.93	102
5	Female	Hispanic	No	30	70.9	158	28.6	1.79	74.0
6	Male	Hispanic	No	43	80.5	178	25.5	2.01	130
7	Female	Black	Yes	44	85.9	173	28.8	2.05	88.0
8	Male	Hispanic	Yes	21	60.0	170	20.7	1.69	109
9	Male	Caucasian	Yes	50	88.6	180	27.3	2.12	122
10	Male	Black	Yes	35	76.8	168	27.3	1.91	134
11	Male	Caucasian	Yes	48	90.0	170	31.1	2.09	150
12	Female	Caucasian	Yes	47	65.0	160	25.4	1.72	64.0
N				12	12	12	12	12	12
Mean				41	76.8	168	27.0	1.91	107
SD				9	10.2	8	2.6	0.16	34.3
SE				3	2.9	2	0.8	0.05	9.90
Min				21	60.0	158	20.7	1.69	64.0
Median				44	76.6	170	27.3	1.92	106
Max				50	90.0	180	31.1	2.12	170
CV%				21	13	5	10	9	32
Geometric Mean				40	76.1	168	26.9	1.90	102

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Actual Times Table**

Treatment = Carterolol										
Plasma Carterolol										
Subject	Actual Time (hr) over Nominal Time (hr)									
	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
1	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
2	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	69.00
3	0.00	0.50	1.00	2.00	4.00	8.00	12.00	23.75	48.00	72.00
4	0.00	0.50	1.00	2.00	4.25	8.00	12.00	24.00	48.00	72.00
5	0.00	0.65	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
6	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	47.00	72.00
7	0.00	0.50	1.00	2.15	4.00	8.00	12.00	24.00	48.00	72.00
8	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
9	0.00	0.50	1.00	2.00	4.00	7.75	12.00	24.00	48.00	72.00
10	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
11	0.00	0.50	1.15	2.00	4.00	8.00	11.75	24.00	48.00	72.00
12	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.25	48.00	72.00
N	12	12	12	12	12	12	12	12	12	12
Mean	0.00	0.51	1.01	2.01	4.02	7.98	11.98	24.00	47.92	71.75
SD	0.00	0.04	0.04	0.04	0.07	0.07	0.07	0.11	0.29	0.87
SE	0.00	0.01	0.01	0.01	0.02	0.02	0.02	0.03	0.08	0.25
Min	0.00	0.50	1.00	2.00	4.00	7.75	11.75	23.75	47.00	69.00
Median	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
Max	0.00	0.65	1.15	2.15	4.25	8.00	12.00	24.25	48.00	72.00
CV%	NA	8	4	2	2	1	1	0	1	1
Geometric Mean	NA	0.51	1.01	2.01	4.02	7.98	11.98	24.00	47.92	71.75

NA = Not Applicable

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Actual Times Deviation Table**

Treatment = Carterolol										
Plasma Carterolol										
Subject	Actual Time Deviation (%) from Nominal Time (hr)									
	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
1	NS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2	NS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-4.17
3	NS	0.00	0.00	0.00	0.00	0.00	0.00	-1.04	0.00	0.00
4	NS	0.00	0.00	0.00	6.25	0.00	0.00	0.00	0.00	0.00
5	NS	*30.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
6	NS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-2.08	0.00
7	NS	0.00	0.00	7.50	0.00	0.00	0.00	0.00	0.00	0.00
8	NS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
9	NS	0.00	0.00	0.00	0.00	-3.13	0.00	0.00	0.00	0.00
10	NS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
11	NS	0.00	15.00	0.00	0.00	0.00	-2.08	0.00	0.00	0.00
12	NS	0.00	0.00	0.00	0.00	0.00	0.00	1.04	0.00	0.00
N	0	12	12	12	12	12	12	12	12	12
Mean	NC	2.50	1.25	0.63	0.52	-0.26	-0.17	0.00	-0.17	-0.35
SD	NC	8.66	4.33	2.17	1.80	0.90	0.60	0.44	0.60	1.20
SE	NC	2.50	1.25	0.63	0.52	0.26	0.17	0.13	0.17	0.35
Min	NC	0.00	0.00	0.00	0.00	-3.13	-2.08	-1.04	-2.08	-4.17
Median	NC	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Max	NC	30.00	15.00	7.50	6.25	0.00	0.00	1.04	0.00	0.00
CV%	NC	346	346	346	346	-346	-346	NA	-346	-346
Geometric Mean	NC	NA	NA	NA	NA	NA	NA	NA	NA	NA

\* = Actual sampling time exceeds ±15% of nominal sampling time threshold.

NS = No Sample

NC = Not Calculated

NA = Not Applicable

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**PK Parameter A Table**

Treatment = Carterolol					
Plasma Carterolol					
Subject	T <sub>max</sub> (hr)	C <sub>max</sub> (ng/ml)	AUC <sub>last</sub> (ng•hr/ml)	AUC <sub>∞</sub> (ng•hr/ml)	AUC % Extrap (%)
1	1.00	235	3370	3940	14
2	2.00	170	2510	2710	7
3	0.50	280	3800	4220	10
4	4.25	142	3020	3400	11
5	1.00	232	4150	5030	17
6	2.00	181	4450	6200	28
7	1.00	184	4410	5790	24
8	0.50	265	4010	4530	11
9	1.00	143	2620	3130	16
10	0.50	245	4660	6400	27
11	0.50	231	2640	2900	9
12	0.50	290	3110	3500	11
N	12	12	12	12	12
Mean	1.23	217	3560	4310	16
SD	1.09	51.2	782	1290	7
SE	0.32	14.8	226	372	2
Min	0.50	142	2510	2710	7
Median	1.00	232	3590	4080	13
Max	4.25	290	4660	6400	28
CV%	89	24	22	30	46
Geometric Mean	0.95	211	3480	4140	14

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**AutoPilot™ Toolkit for Phoenix®: Sample Output****PK Parameter B Tables (stratified by Race)**

Treatment = Carterolol (Race = Hispanic)

Subject	Plasma Carterolol				
	t <sub>1/2</sub> (hr)	T <sub>lag</sub> (hr)	CL/F (ml/hr)	V <sub>z</sub> /F (ml)	AUC <sub>0-24</sub> (ng•hr/ml)
1	29.68	0.00	7610	326000	2220
2	20.36	0.00	11100	326000	1790
3	24.42	0.00	7110	251000	2590
4	24.99	0.00	8810	318000	1910
5	32.22	0.00	5970	277000	2600
6	41.83	0.00	4840	292000	2360
8	25.66	0.00	6620	245000	2660
N	7	7	7	7	7
Mean	28.45	0.00	7440	291000	2300
SD	7.03	0.00	2040	34300	349
SE	2.66	0.00	770	13000	132
Min	20.36	0.00	4840	245000	1790
Median	25.66	0.00	7110	292000	2360
Max	41.83	0.00	11100	326000	2660
CV%	25	NA	27	12	15
Geometric Mean	27.78	NA	7210	289000	2280

NA = Not Applicable

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**PK Parameter B Tables, continued (stratified by Race)**

Treatment = Carterolol (Race = Black)

Plasma Carterolol					
Subject	t <sub>1/2</sub> (hr)	T <sub>lag</sub> (hr)	CL/F (ml/hr)	V <sub>z</sub> /F (ml)	AUC <sub>0-24</sub> (ng•hr/ml)
7	38.42	0.00	5180	287000	2440
10	41.96	0.00	4690	284000	2600
N	2	2	2	2	2
Mean	40.19	0.00	4940	286000	2520
SD	2.51	0.00	348	2320	118
SE	1.77	0.00	246	1640	83.4
Min	38.42	0.00	4690	284000	2440
Median	40.19	0.00	4940	286000	2520
Max	41.96	0.00	5180	287000	2600
CV%	6	NA	7	1	5
Geometric Mean	40.15	NA	4930	286000	2520

NA = Not Applicable

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Treatment = Carterolol (Race = Caucasian)

Plasma Carterolol					
Subject	t <sub>1/2</sub> (hr)	T <sub>lag</sub> (hr)	CL/F (ml/hr)	V <sub>z</sub> /F (ml)	AUC <sub>0-24</sub> (ng•hr/ml)
9	30.53	0.00	9600	423000	1630
11	24.70	0.00	10400	369000	1920
12	26.48	0.00	8560	327000	2120
N	3	3	3	3	3
Mean	27.24	0.00	9510	373000	1890
SD	2.99	0.00	901	47900	250
SE	1.72	0.00	520	27600	144
Min	24.70	0.00	8560	327000	1630
Median	26.48	0.00	9600	369000	1920
Max	30.53	0.00	10400	423000	2120
CV%	11	NA	9	13	13
Geometric Mean	27.13	NA	9480	371000	1880

NA = Not Applicable

Source =

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Lambda Z Table**

Treatment = Carterolol				
Plasma Carterolol				
Regression Points Used in Lambda Z Calculation				
Subject	$\lambda_z$ Lower (hr)	$\lambda_z$ Upper (hr)	Number of Points	R <sup>2</sup>
1	24.00	72.00	3	0.998
2	24.00	69.00	3	1.00
3	23.75	72.00	3	0.999
4	24.00	72.00	3	0.999
5	24.00	72.00	3	0.998
6	24.00	72.00	3	0.997
7	24.00	72.00	3	0.991
8	24.00	72.00	3	0.999
9	24.00	72.00	3	1.00
10	24.00	72.00	3	0.998
11	24.00	72.00	3	0.996
12	24.25	72.00	3	0.999
N	12	12	12	12
Mean	24.00	71.75	3	0.998
SD	0.11	0.87	0	0.00251
SE	0.03	0.25	0	0.000724
Min	23.75	69.00	3	0.991
Median	24.00	72.00	3	0.998
Max	24.25	72.00	3	1.00
CV%	0	1	0	0
Geometric Mean	24.00	71.75	3	0.998

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Cumulative AUC Table**

Treatment = Carterolol										
Plasma Carterolol										
Subject	AUC (ng•hr/ml) over Nominal Time (hr)									
	0.00	0.50	1.00	2.00	4.00	8.00	12.00	24.00	48.00	72.00
1	0.00	12.73	84.20	296.44	630.33	1134.91	1513.91	2221.22	2956.20	3374.14
2	0.00	13.40	57.80	204.80	507.37	943.56	1242.15	1786.14	2299.67	2507.40
3	0.00	70.00	193.85	395.43	757.34	1371.33	1806.23	2573.87	3390.19	3795.97
4	0.00	0.45	1.63	65.57	365.94	831.79	1206.98	1910.71	2639.23	3015.10
5	0.00	57.85	129.60	336.67	684.29	1282.54	1740.33	2603.98	3574.86	4152.09
6	0.00	4.98	28.33	155.58	482.40	1001.60	1416.74	2356.35	3565.98	4447.90
7	0.00	44.00	134.00	337.44	628.21	1156.63	1568.21	2437.38	3630.52	4408.40
8	0.00	66.25	185.01	388.90	741.54	1332.64	1799.41	2662.97	3550.89	4013.16
9	0.00	31.75	99.25	227.74	449.65	788.83	1075.67	1625.94	2255.37	2619.97
10	0.00	61.25	169.15	338.97	632.86	1182.66	1644.43	2604.21	3836.85	4664.20
11	0.00	57.75	191.69	330.93	611.78	1087.09	1394.04	1923.23	2397.15	2636.89
12	0.00	72.50	198.09	392.87	696.75	1168.99	1511.85	2131.51	2764.70	3106.20
N	12	12	12	12	12	12	12	12	12	12
Mean	0.00	41.08	122.72	289.28	599.04	1106.88	1493.33	2236.46	3071.80	3561.79
SD	0.00	27.04	68.45	104.27	122.09	185.77	236.85	358.25	582.97	781.61
SE	0.00	7.81	19.76	30.10	35.25	53.63	68.37	103.42	168.29	225.63
Min	0.00	0.45	1.63	65.57	365.94	788.83	1075.67	1625.94	2255.37	2507.40
Median	0.00	50.88	131.80	333.80	629.27	1145.77	1512.88	2288.79	3173.19	3585.06
Max	0.00	72.50	198.09	395.43	757.34	1371.33	1806.23	2662.97	3836.85	4664.20
CV%	NA	66	56	36	20	17	16	16	19	22
Geometric Mean	NA	24.02	81.74	262.81	586.40	1091.75	1475.33	2208.83	3019.01	3481.10

NA = Not Applicable

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**AutoPilot™ Toolkit for Phoenix®: Sample Output****Intext PK Parameter Table**

Mean ± SD	Plasma Carterolol	
	Carterolol	Carterolol + Rifampin
N	12	12
t <sub>1/2</sub> (hr)	30.10 ± 7.18	30.25 ± 4.87
T <sub>max</sub> <sup>a</sup> (hr)	1.23 (0.50 - 4.25)	1.10 (0.50 - 4.00)
C <sub>max</sub> (ng/ml)	217 ± 51.2	199 ± 47.1
AUC <sub>last</sub> (ng•hr/ml)	3560 ± 782	3350 ± 853
AUC <sub>∞</sub> (ng•hr/ml)	4310 ± 1290	4040 ± 1280
CL/F (ml/hr)	7540 ± 2170	8090 ± 2410
V <sub>z</sub> /F (ml)	310000 ± 49900	344000 ± 83300
<sup>a</sup> Mean (Min - Max) Source = C:\TestingAndSupport\AP_Testing_Results\AP_Sample_OUTPUT Date/Time = 7/6/2010 4:28:19 PM		

**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**Intext PK Parameter Table (Stratified by Gender)**

Mean ± SD	Plasma Carterolol			
	Female		Male	
	Carterolol	Carterolol + Rifampin	Carterolol	Carterolol + Rifampin
N	5	5	7	7
t <sub>1/2</sub> (hr)	30.24 ± 5.46	29.64 ± 2.18	30.00 ± 8.65	30.69 ± 6.31
T <sub>max</sub> <sup>a</sup> (hr)	0.80 (0.50 - 1.00)	0.75 (0.50 - 1.00)	1.54 (0.50 - 4.25)	1.36 (0.50 - 4.00)
C <sub>max</sub> (ng/ml)	244 ± 42.5	227 ± 49.7	197 ± 50.0	180 ± 36.6
AUC <sub>last</sub> (ng•hr/ml)	3770 ± 537	3460 ± 567	3410 ± 932	3280 ± 1050
AUC <sub>∞</sub> (ng•hr/ml)	4500 ± 911	4030 ± 658	4180 ± 1560	4050 ± 1640
CL/F (ml/hr)	6890 ± 1330	7620 ± 1430	8000 ± 2620	8430 ± 2990
V <sub>z</sub> /F (ml)	294000 ± 32800	326000 ± 62100	322000 ± 58600	357000 ± 98400

<sup>a</sup> Mean (Min - Max)

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**AutoPilot™ Toolkit for Phoenix®: Sample Output****PK Ratios Table**

PK Parameter Ratios (Test/Reference)			
Subject	C <sub>max</sub> (ng/ml)	AUC <sub>last</sub> (ng•hr/ml)	AUC <sub>∞</sub> (ng•hr/ml)
1	0.813	1.04	1.09
2	1.39	0.924	0.940
3	1.06	1.05	1.08
4	1.06	0.852	0.846
5	1.11	0.950	0.907
6	0.845	0.945	0.923
7	0.967	0.590	0.519
8	0.808	1.05	1.08
9	1.23	0.920	0.938
10	0.780	1.01	1.03
11	0.593	0.948	0.977
12	0.728	1.05	1.08
N	12	12	12
Mean	0.949	0.944	0.950
SD	0.230	0.129	0.158
SE	0.0664	0.0372	0.0455
Min	0.593	0.590	0.519
Median	0.906	0.949	0.958
Max	1.39	1.05	1.09
CV%	24	14	17
Geometric Mean	0.924	0.934	0.934

Test = Carterolol + Rifampin

Reference = Carterolol

Values are calculated by division (Test/Ref)

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Sample\_OUTPUT

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**AutoPilot™ Toolkit for Phoenix®: Sample Output**

**PK Statistics Table**

PK Stats: Statistical Comparison for a (Single-Dose) Crossover Design

Factor	P-Values from Log-Transformed Analysis of Variance		
	C <sub>max</sub> (ng/ml)	AUC <sub>last</sub> (ng•hr/ml)	AUC <sub>∞</sub> (ng•hr/ml)
Treatment	0.426	0.501	0.588
Intrasubject CV%	24.3	24.6	31.0

	Pair-wise Comparison: Carterolol + Rifampin (Test) vs. Carterolol (Ref)		
	92	93	93
Ratio of Least Square Geometric Means (%)	92	93	93
90% Confidence Interval around Ratio	78-109	79-111	76-116
Probability < 80%	0.0778	0.0656	0.111
Probability > 125%	0.00265	0.00383	0.0140
Total Probability (<80%,>125%)	0.0805	0.0695	0.125
Statistical Power (%)	71.1	70.1	53.5

Treatments = [Carterolol, Carterolol + Rifampin]

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