15.3.6 Other Displays of Safety Data

Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Table 16.3.6.2.1 Summary of Electrocardiogram Evaluations by Treatment and Time Point (Safety Population)

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Supine Systolic Blood Pressure (mmHg)	Screening	n (missing)					216 (0)	
		Mean (SD)					116.1 (9.41)	
		Median					116.0	
		Min; Max					97; 140	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	114.1 (10.65)		114.1 (10.33)			
		Median	113.0		113.0			
		Min; Max	86; 156		87; 173			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	112.6 (11.06)		112.5 (10.89)			
		Median	111.0		112.0			
		Min; Max	86; 147		86; 147			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Supine Systolic Blood Pressure (mmHg)	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	112.2 (9.58)	-0.5 (7.28)	112.5 (10.84)	0.0 (6.99)		
		Median	111.0	-1.0	111.0	0.0		
		Min; Max	93; 141	-21; 26	86; 156	-22; 18		
	Day 1/ 3 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	113.2 (10.43)	0.6 (7.01)	114.0 (11.19)	1.5 (7.57)		
		Median	113.0	0.0	112.0	2.0		
		Min; Max	89; 147	-23; 24	84; 147	-20; 23		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	111.2 (9.83)	-1.4 (7.75)	111.5 (10.44)	-0.9 (7.68)		
		Median	111.0	-1.0	110.0	-1.0		
		Min; Max	86; 144	-23; 19	89; 142	-33; 24		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Supine Systolic Blood Pressure (mmHg)	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	113.5 (11.15)	0.9 (8.58)	113.5 (11.67)	1.0 (8.71)		
		Median	112.0	0.0	112.0	1.0		
		Min; Max	82; 152	-29; 29	88; 152	-27; 27		
	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	113.1 (10.11)	0.5 (7.96)	113.1 (9.78)	0.6 (7.49)		
		Median	113.0	1.0	112.0	0.0		
		Min; Max	88; 141	-24; 18	93; 141	-27; 22		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	112.7 (9.90)	0.1 (9.07)	113.3 (9.99)	0.8 (9.42)		
		Median	112.0	0.0	112.5	0.0		
		Min; Max	93; 167	-25; 39	93; 147	-27; 24		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Supine Systolic Blood Pressure (mmHg)	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	113.1 (9.82)	0.5 (8.77)	114.3 (10.71)	1.8 (9.76)		
		Median	112.0	1.0	113.0	2.0		
		Min; Max	91; 151	-24; 23	83; 151	-24; 30		
	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					115.7 (11.52)	-0.4 (8.99)
		Median					114.5	0.0
		Min; Max					89; 151	-20; 20
Supine Diastolic Blood Pressure (mmHg)	Screening	n (missing)					216 (0)	
		Mean (SD)					71.0 (7.55)	
		Median					71.5	
		Min; Max					50; 89	

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Supine Diastolic Blood Pressure (mmHg)	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	69.0 (8.31)		68.5 (7.20)			
		Median	69.0		68.0			
		Min; Max	47; 91		50; 95			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	66.9 (7.54)		67.7 (7.97)			
		Median	67.0		68.0			
		Min; Max	51; 91		46; 91			
	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	66.4 (7.41)	-0.5 (5.16)	66.8 (7.80)	-1.0 (5.58)		
		Median	66.0	-1.0	66.0	-1.0		
		Min; Max	47; 87	-14; 13	46; 92	-26; 18		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Supine Diastolic Blood Pressure (mmHg)	Day 1/ 3 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	67.4 (7.55)	0.5 (4.89)	68.2 (8.21)	0.5 (5.48)		
		Median	67.0	0.0	68.0	0.0		
		Min; Max	49; 95	-14; 20	47; 90	-19; 15		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	64.5 (6.87)	-2.3 (5.15)	64.7 (7.55)	-3.1 (6.34)		
		Median	65.0	-2.0	64.0	-3.0		
		Min; Max	48; 88	-19; 14	48; 91	-21; 18		
	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	65.3 (7.36)	-1.6 (5.96)	65.5 (7.21)	-2.2 (6.14)		
		Median	65.0	-1.0	65.0	-3.0		
		Min; Max	48; 89	-20; 15	50; 95	-30; 16		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Supine Diastolic Blood Pressure (mmHg)	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	67.1 (7.76)	0.2 (5.46)	67.4 (7.39)	-0.3 (5.54)		
		Median	67.0	0.0	67.0	0.0		
		Min; Max	49; 92	-14; 18	49; 92	-24; 16		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	68.3 (7.75)	1.4 (7.02)	68.6 (7.24)	0.8 (6.84)		
		Median	68.0	2.0	69.0	1.0		
		Min; Max	51; 101	-17; 20	51; 95	-24; 18		
	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	68.5 (7.63)	1.6 (6.59)	69.3 (8.34)	1.6 (7.12)		
		Median	68.0	2.0	69.0	1.0		
		Min; Max	50; 93	-16; 22	52; 92	-20; 18		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Supine Diastolic Blood Pressure (mmHg)	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					70.6 (8.03)	-0.4 (6.48)
		Median					70.0	-1.0
		Min; Max					53; 102	-19; 19
Supine Pulse Rate (beats/min)	Screening	n (missing)					216 (0)	
		Mean (SD)					62.7 (8.77)	
		Median					62.0	
		Min; Max					45; 87	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	61.3 (8.93)		62.2 (8.92)			
		Median	60.0		62.0			
		Min; Max	40; 89		44; 91			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Supine Pulse Rate (beats/min)	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	57.2 (8.08)		57.3 (8.06)			
		Median	56.0		57.0			
		Min; Max	41; 84		40; 91			
	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	57.1 (8.25)	-0.0 (5.24)	57.5 (8.08)	0.2 (5.91)		
		Median	56.0	0.0	57.0	0.0		
		Min; Max	42; 95	-17; 21	42; 85	-20; 29		
	Day 1/ 3 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	56.6 (8.18)	-0.6 (5.62)	57.0 (7.47)	-0.3 (5.42)		
		Median	55.0	0.0	56.0	0.0		
		Min; Max	41; 87	-19; 18	40; 76	-19; 16		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Supine Pulse Rate (beats/min)	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	63.7 (8.68)	6.5 (6.12)	64.5 (8.23)	7.2 (6.23)		
		Median	64.0	7.0	64.0	7.0		
		Min; Max	44; 100	-20; 25	47; 88	-13; 36		
	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	63.4 (8.83)	6.2 (6.60)	63.5 (8.39)	6.2 (6.46)		
		Median	62.0	6.0	63.0	6.0		
		Min; Max	40; 93	-20; 21	46; 88	-21; 28		
	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	60.6 (8.70)	3.5 (6.21)	61.0 (9.63)	3.7 (7.00)		
		Median	60.0	4.0	60.0	3.0		
		Min; Max	40; 81	-21; 21	43; 94	-33; 36		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Supine Pulse Rate (beats/min)	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	63.9 (8.16)	6.7 (6.99)	63.5 (8.65)	6.3 (7.32)		
		Median	64.0	6.0	63.5	6.0		
		Min; Max	43; 84	-14; 26	43; 86	-12; 27		
	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	63.5 (9.43)	6.3 (7.97)	63.9 (9.11)	6.6 (8.28)		
		Median	63.0	6.0	64.0	6.0		
		Min; Max	44; 101	-18; 27	45; 89	-22; 28		
	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					61.8 (10.28)	-1.0 (9.52)
		Median					62.0	-1.0
		Min; Max					43; 108	-28; 30

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Temperature (C)	Screening	n (missing)					216 (0)	
		Mean (SD)					36.28 (0.265)	
		Median					36.20	
		Min; Max					36.0; 37.0	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	36.38 (0.264)		36.38 (0.281)			
		Median	36.40		36.40			
		Min; Max	35.9; 37.1		36.0; 37.3			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	36.29 (0.271)		36.32 (0.277)			
		Median	36.20		36.30			
		Min; Max	35.7; 37.1		36.0; 37.0			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Temperature (C)	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	36.42 (0.295)	0.13 (0.253)	36.43 (0.270)	0.11 (0.270)		
		Median	36.40	0.10	36.40	0.10		
		Min; Max	35.9; 38.0	-0.9; 1.0	35.9; 37.1	-0.6; 0.8		
	Day 1/ 3 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	36.47 (0.293)	0.18 (0.250)	36.44 (0.301)	0.12 (0.284)		
		Median	36.50	0.20	36.40	0.10		
		Min; Max	35.8; 37.7	-0.6; 0.9	35.8; 37.3	-0.7; 1.0		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	36.56 (0.329)	0.27 (0.354)	36.58 (0.278)	0.26 (0.316)		
		Median	36.60	0.30	36.60	0.30		
		Min; Max	35.8; 38.4	-0.8; 1.5	36.0; 37.3	-0.9; 1.3		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.6.1.1.sas

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Temperature (C)	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	36.55 (0.299)	0.26 (0.356)	36.52 (0.289)	0.20 (0.366)		
		Median	36.50	0.30	36.50	0.20		
		Min; Max	36.0; 37.8	-0.7; 1.4	35.9; 37.3	-0.7; 1.3		
	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	36.37 (0.312)	0.08 (0.286)	36.40 (0.312)	0.08 (0.313)		
		Median	36.40	0.10	36.40	0.10		
		Min; Max	35.5; 37.7	-1.0; 1.2	35.5; 37.8	-0.9; 1.8		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	36.37 (0.287)	0.08 (0.336)	36.37 (0.293)	0.05 (0.363)		
		Median	36.40	0.10	36.40	0.00		
		Min; Max	35.6; 37.2	-0.9; 1.1	36.0; 38.0	-0.9; 2.0		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.1.1 Summary and Change from Baseline of Safety Vital Signs Measurements by Treatment and Time Point (Safety Population)

Vital Sign (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Temperature (C)	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	36.38 (0.288)	0.09 (0.350)	36.35 (0.287)	0.03 (0.355)		
		Median	36.40	0.10	36.30	0.00		
		Min; Max	36.0; 37.3	-0.8; 1.1	35.9; 37.1	-1.0; 1.1		
	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					36.33 (0.294)	0.05 (0.337)
		Median					36.30	0.00
		Min; Max					35.6; 37.1	-1.0; 0.8

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific vital signs results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
PR Interval (msec)	Screening	n (missing)					216 (0)	
		Mean (SD)					159.0 (20.95)	
		Median					156.0	
		Min; Max					120; 216	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	157.2 (20.76)		157.0 (20.78)			
		Median	154.0		154.0			
		Min; Max	116; 216		110; 210			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	163.2 (22.11)		162.8 (21.13)			
		Median	162.0		160.0			
		Min; Max	120; 214		120; 218			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
PR Interval (msec)	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	161.1 (21.26)	-2.1 (8.96)	161.1 (21.98)	-1.7 (8.41)		
		Median	160.0	-2.0	158.0	-2.0		
		Min; Max	120; 222	-32; 26	114; 232	-24; 24		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	156.3 (19.90)	-6.9 (9.83)	156.7 (20.53)	-6.1 (9.51)		
		Median	156.0	-6.0	154.0	-6.0		
		Min; Max	110; 208	-44; 24	112; 226	-38; 24		
	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	158.0 (20.14)	-5.2 (10.26)	158.5 (21.00)	-4.3 (11.00)		
		Median	156.0	-6.0	156.0	-4.0		
		Min; Max	120; 202	-42; 26	122; 212	-40; 32		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
PR Interval (msec)	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	158.2 (20.72)	-5.0 (9.55)	158.6 (21.24)	-4.2 (9.24)		
		Median	154.0	-4.0	156.0	-4.0		
		Min; Max	112; 210	-38; 24	108; 218	-30; 26		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	160.9 (20.64)	-2.2 (9.74)	161.2 (21.75)	-1.8 (10.01)		
		Median	160.0	-2.0	160.0	-2.0		
		Min; Max	120; 210	-34; 38	118; 218	-34; 22		
	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	157.3 (20.42)	-5.9 (9.45)	158.4 (21.54)	-4.4 (10.37)		
		Median	156.0	-4.0	156.0	-4.0		
		Min; Max	106; 208	-32; 20	116; 230	-42; 26		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
PR Interval (msec)	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					158.5 (20.30)	-0.5 (10.90)
		Median					157.0	0.0
		Min; Max					112; 218	-36; 36
QRS Interval (msec)	Screening	n (missing)					216 (0)	
		Mean (SD)					98.7 (9.42)	
		Median					98.0	
		Min; Max					78; 120	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	98.6 (9.68)		97.8 (9.81)			
		Median	98.0		98.0			
		Min; Max	78; 120		72; 134			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
QRS Interval (msec)	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	96.6 (9.34)		96.5 (9.36)			
		Median	96.0		96.0			
		Min; Max	68; 118		70; 120			
	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	96.3 (9.81)	-0.4 (4.01)	96.2 (9.74)	-0.3 (3.78)		
		Median	96.0	0.0	96.0	0.0		
		Min; Max	68; 120	-14; 12	68; 120	-14; 14		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	96.1 (9.83)	-0.5 (5.09)	95.8 (9.59)	-0.6 (4.45)		
		Median	96.0	-2.0	96.0	0.0		
		Min; Max	74; 120	-16; 16	72; 118	-16; 12		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
QRS Interval (msec)	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	97.4 (10.01)	0.8 (5.50)	97.2 (9.92)	0.8 (4.48)		
		Median	98.0	0.0	98.0	0.0		
		Min; Max	70; 120	-28; 18	72; 118	-14; 12		
	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	96.7 (9.54)	0.1 (4.33)	96.0 (9.39)	-0.5 (4.86)		
		Median	96.0	0.0	96.0	0.0		
		Min; Max	68; 120	-10; 16	72; 124	-16; 14		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	97.4 (9.23)	0.8 (4.50)	96.6 (9.66)	0.1 (4.45)		
		Median	96.0	0.0	96.0	0.0		
		Min; Max	76; 120	-8; 20	72; 120	-16; 16		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QRS Interval (msec)	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	97.0 (9.63)	0.4 (4.44)	96.8 (9.48)	0.3 (4.49)		
		Median	96.0	0.0	96.0	0.0		
		Min; Max	74; 122	-14; 20	74; 122	-14; 14		
	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					98.4 (9.62)	-0.3 (6.19)
		Median					98.0	0.0
		Min; Max					74; 120	-18; 18
QT Interval (msec)	Screening	n (missing)					216 (0)	
		Mean (SD)					398.0 (23.11)	
		Median					398.0	
		Min; Max					350; 462	

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
QT Interval (msec)	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	410.7 (25.42)		408.2 (23.39)			
		Median	412.0		408.0			
		Min; Max	354; 478		352; 480			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	417.2 (23.32)		416.6 (22.63)			
		Median	418.0		414.0			
		Min; Max	362; 488		366; 486			
	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	417.2 (23.47)	-0.0 (12.50)	417.4 (23.41)	0.7 (12.73)		
		Median	416.0	0.0	416.0	0.0		
		Min; Max	350; 486	-40; 44	366; 506	-30; 44		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QT Interval (msec)	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	395.3 (21.65)	-22.0 (15.70)	394.8 (20.55)	-21.9 (15.05)		
		Median	396.0	-20.0	396.0	-22.0		
		Min; Max	326; 474	-62; 34	344; 464	-54; 24		
	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	397.2 (23.24)	-20.0 (17.26)	397.0 (22.01)	-19.6 (16.75)		
		Median	398.0	-20.0	398.0	-20.0		
		Min; Max	328; 480	-76; 26	324; 460	-60; 30		
	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	409.5 (23.18)	-7.7 (14.96)	409.1 (24.57)	-7.5 (15.10)		
		Median	410.0	-8.0	408.0	-8.0		
		Min; Max	360; 510	-48; 26	330; 472	-68; 32		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
QT Interval (msec)	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	404.7 (23.36)	-12.5 (17.14)	404.6 (23.22)	-12.3 (16.69)		
		Median	402.0	-12.0	402.0	-10.0		
		Min; Max	356; 496	-58; 40	342; 490	-60; 46		
	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	407.5 (23.26)	-9.8 (18.50)	406.4 (23.39)	-10.2 (18.61)		
		Median	406.0	-10.0	404.0	-10.0		
		Min; Max	344; 480	-74; 56	348; 474	-86; 46		
	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					403.6 (26.82)	5.6 (20.42)
		Median					402.0	4.0
		Min; Max					342; 492	-52; 82

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QTcB - Bazett's Correction Formula (msec)	Screening	n (missing)					216 (0)	
		Mean (SD)					400.9 (19.33)	
		Median					401.0	
		Min; Max					349; 448	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	410.0 (20.62)		412.1 (19.92)			
		Median	410.0		412.0			
		Min; Max	354; 472		365; 463			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	406.3 (19.48)		406.5 (19.99)			
		Median	406.0		409.0			
		Min; Max	362; 459		356; 459			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QTcB - Bazett's Correction Formula (msec)	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	405.2 (19.92)	-1.2 (15.47)	405.0 (21.38)	-1.4 (16.33)		
		Median	404.0	0.0	406.0	0.0		
		Min; Max	356; 454	-43; 45	351; 458	-44; 39		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	408.9 (18.66)	2.6 (16.13)	407.5 (18.87)	1.0 (16.11)		
		Median	411.0	2.0	407.0	0.0		
		Min; Max	360; 456	-35; 42	360; 463	-53; 40		
	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	410.2 (18.92)	3.9 (15.72)	409.6 (17.71)	3.1 (16.10)		
		Median	411.0	3.0	411.0	2.0		
		Min; Max	344; 452	-52; 48	364; 448	-50; 45		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QTcB - Bazett's Correction Formula (msec)	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	407.1 (19.84)	0.8 (14.60)	406.7 (19.65)	0.2 (16.64)		
		Median	408.0	2.0	406.0	2.0		
		Min; Max	364; 462	-45; 51	356; 454	-63; 51		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	412.1 (20.78)	5.8 (18.19)	412.3 (19.13)	5.8 (17.22)		
		Median	413.0	6.0	414.5	6.0		
		Min; Max	356; 479	-43; 49	364; 459	-54; 54		
	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	411.5 (19.82)	5.2 (16.91)	412.5 (19.38)	6.0 (17.24)		
		Median	412.0	4.0	413.0	6.0		
		Min; Max	359; 469	-60; 54	361; 457	-47; 64		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QTcB - Bazett's Correction Formula (msec)	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					405.2 (20.49)	4.3 (18.07)
		Median					405.0	4.5
		Min; Max					352; 463	-52; 67
QTcF - Fridericia's Correction Formula (msec)	Screening	n (missing)					216 (0)	
		Mean (SD)					399.7 (16.28)	
		Median					400.0	
		Min; Max					359; 446	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	409.9 (16.65)		410.6 (15.46)			
		Median	410.0		411.0			
		Min; Max	370; 454		367; 447			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QTcF - Fridericia's Correction Formula (msec)	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	409.7 (15.54)		409.6 (16.67)			
		Median	410.0		410.0			
		Min; Max	363; 450		369; 447			
	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	409.0 (16.05)	-0.8 (11.47)	408.9 (17.85)	-0.7 (12.16)		
		Median	410.0	-1.0	411.0	0.0		
		Min; Max	365; 453	-35; 34	361; 449	-35; 35		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	404.1 (15.18)	-5.6 (12.83)	403.0 (15.27)	-6.6 (12.45)		
		Median	407.0	-5.0	404.0	-7.0		
		Min; Max	363; 447	-38; 31	362; 449	-48; 26		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
QTcF - Fridericia's Correction Formula (msec)	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	405.6 (15.39)	-4.1 (12.84)	405.1 (14.87)	-4.5 (12.86)		
		Median	407.0	-4.0	406.0	-5.0		
		Min; Max	363; 450	-49; 32	366; 438	-51; 29		
	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	407.7 (16.08)	-2.0 (11.43)	407.3 (16.09)	-2.4 (12.52)		
		Median	409.0	-1.0	408.0	-1.0		
		Min; Max	370; 448	-36; 26	364; 447	-49; 36		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	409.4 (16.96)	-0.3 (13.19)	409.5 (15.99)	-0.3 (12.81)		
		Median	410.0	0.0	411.0	0.0		
		Min; Max	366; 455	-37; 43	372; 448	-41; 37		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
QTcF - Fridericia's Correction Formula (msec)	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	409.9 (16.05)	0.2 (12.07)	410.2 (15.92)	0.6 (12.59)		
		Median	411.0	1.0	411.0	0.0		
		Min; Max	371; 450	-46; 35	372; 445	-38; 33		
	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					404.4 (17.63)	4.7 (14.40)
		Median					405.0	4.0
		Min; Max					364; 448	-47; 47
RR Interval (msec)	Screening	n (missing)					216 (0)	
		Mean (SD)					993.5 (133.54)	
		Median					977.0	
		Min; Max					686; 1326	

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
RR Interval (msec)	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	1014.0 (156.64)		990.6 (144.46)			
		Median	1012.0		982.0			
		Min; Max	676; 1504		650; 1362			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	1063.9 (151.14)		1059.2 (140.35)			
		Median	1054.0		1052.0			
		Min; Max	758; 1550		778; 1502			
	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	1070.4 (151.99)	6.5 (102.69)	1070.9 (141.42)	11.7 (104.17)		
		Median	1060.0	6.0	1070.0	10.0		
		Min; Max	664; 1536	-378; 390	760; 1438	-268; 312		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
RR Interval (msec)	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	941.8 (124.28)	-122.2 (105.24)	945.5 (119.78)	-113.7 (104.39)		
		Median	922.0	-122.0	946.0	-114.0		
		Min; Max	600; 1358	-492; 140	670; 1304	-428; 190		
	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	946.2 (135.69)	-117.8 (111.31)	946.4 (123.87)	-112.8 (110.00)		
		Median	946.0	-110.0	938.0	-112.0		
		Min; Max	628; 1520	-444; 352	656; 1280	-452; 232		
	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	1020.8 (143.00)	-43.2 (104.09)	1021.7 (147.84)	-37.5 (109.26)		
		Median	1018.0	-44.0	1024.0	-42.0		
		Min; Max	684; 1526	-464; 290	630; 1338	-376; 272		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
RR Interval (msec)	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	972.9 (136.28)	-91.1 (127.59)	970.6 (130.53)	-89.4 (122.82)		
		Median	952.0	-88.0	950.0	-89.0		
		Min; Max	708; 1374	-446; 356	738; 1306	-432; 292		
	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	989.1 (138.46)	-74.9 (133.41)	979.2 (134.81)	-80.0 (134.44)		
		Median	978.0	-76.0	974.0	-80.0		
		Min; Max	638; 1508	-430; 516	650; 1350	-516; 330		
	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					1001.3 (149.74)	7.8 (126.12)
		Median					997.0	9.0
		Min; Max					644; 1416	-384; 356

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Heart Rate (beats/min)	Screening	n (missing)					216 (0)	
		Mean (SD)					61.0 (8.24)	
		Median					60.5	
		Min; Max					45; 87	
	Day -1/ 24 H Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	60.1 (9.32)		61.3 (9.27)			
		Median	59.0		61.0			
		Min; Max	42; 88		44; 92			
	Day 1/ 0 H 50 Min Predose	n (missing)	209 (0)		211 (0)			
		Mean (SD)	57.1 (8.14)		57.2 (7.36)			
		Median	56.0		56.0			
		Min; Max	38; 78		42; 77			

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Heart Rate (beats/min)	Day 1/ 2 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	56.7 (8.00)	-0.4 (5.27)	56.6 (7.68)	-0.6 (5.43)		
		Median	56.0	0.0	55.0	-1.0		
		Min; Max	38; 89	-18; 18	41; 78	-16; 16		
	Day 1/ 6 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	64.3 (8.63)	7.3 (6.03)	63.9 (8.09)	6.7 (6.00)		
		Median	64.0	7.0	63.0	7.0		
		Min; Max	44; 99	-11; 24	45; 89	-9; 21		
	Day 1/ 12 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	64.2 (9.15)	7.1 (6.37)	64.0 (8.38)	6.8 (6.52)		
		Median	63.0	7.0	63.0	7.0		
		Min; Max	39; 95	-16; 27	46; 91	-12; 25		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Test (N=209) Observed	Test (N=209) Change	Reference (N=211) Observed	Reference (N=211) Change	Total (N=216) Observed	Total (N=216) Change
Heart Rate (beats/min)	Day 2/ 24 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	59.4 (8.15)	2.4 (5.49)	59.5 (8.93)	2.3 (6.49)		
		Median	58.0	2.0	58.0	2.0		
		Min; Max	39; 87	-13; 23	44; 94	-20; 35		
	Day 3/ 48 H Postdose	n (missing)	209 (0)	209 (0)	210 (0)	210 (0)		
		Mean (SD)	62.3 (8.49)	5.2 (7.42)	62.4 (8.30)	5.2 (7.02)		
		Median	62.0	5.0	63.0	6.0		
		Min; Max	43; 84	-17; 24	46; 81	-16; 25		
	Day 4/ 72 H Postdose	n (missing)	209 (0)	209 (0)	211 (0)	211 (0)		
		Mean (SD)	61.3 (8.64)	4.2 (7.72)	62.0 (8.78)	4.8 (7.78)		
		Median	60.0	4.0	61.0	4.0		
		Min; Max	39; 93	-18; 29	44; 92	-16; 31		

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Test (N=209)		Reference (N=211)		Total (N=216)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Heart Rate (beats/min)	Follow-Up	n (missing)					216 (0)	216 (0)
		Mean (SD)					60.8 (9.25)	-0.2 (7.90)
		Median					60.0	-0.5
		Min; Max					42; 93	-22; 23

Baseline is defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific ECG results.
Subject is excluded in summary statistics when subject is discontinued without receiving the treatment.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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15.4 Pharmacokinetic Data

15.4.1 Tables

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	38.50	47.20	61.14	76.97
	60.54	61.15	87.30	91.81
	76.75	76.91	108.60	110.90
	50.89	58.94	49.76	62.73
	62.61	77.65	90.21	104.50
	49.14	69.27	104.60	100.30
	51.73	59.32	58.38	91.95
	66.59	77.00	126.50	141.00
	63.04	33.98	91.28	99.58
	75.49	77.68	126.30	130.00
	59.43	55.85	50.07	79.98*
	64.39	72.61	101.20	97.35
	62.24	66.47	85.63	95.76
	51.10	60.76	95.05	100.30
	63.67	100.10	92.10	105.70
	52.12	70.54	93.27	96.22
	58.03	63.19	103.30	121.80
	62.64	69.37	89.12	113.60

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.1.sas

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	43.32	40.93	46.48	63.41
	56.74	85.13	104.50	93.16
	59.82	73.26	117.30	121.30
	49.51	62.54	109.00	127.40
	60.27	56.96	60.43	67.62
	74.87	85.51	110.40	118.30
	68.36	84.82	97.61	121.20
	57.47	77.88	111.20	107.60
	58.47	61.59	60.20	60.38
	51.16	53.98	83.81	90.42
	46.94	45.14	53.85	78.31
	75.37	82.88	111.70	119.70
	56.95	52.95	61.20	103.70
	47.14	67.25	89.22	80.40
	66.95	85.80	87.01	108.00
	55.95	76.31	107.40	110.50
	64.30	72.86	66.91	78.61
	58.16	56.24	69.28	81.02

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	46.99	53.38	72.38	69.09
	57.50	72.80	102.30	129.00
	62.20	77.56	89.12	100.80
	45.28	51.01	96.32	97.45
	53.22	62.04	106.20	118.60
	61.39	66.72	91.94	106.10
	54.25	62.52	92.39	103.00
	38.59	51.40	71.84	89.60
	71.50	93.21	101.10	116.60
	58.30	56.97	59.73	50.32
	62.36	63.19	75.75	89.12
	70.17	72.04	88.64	103.80
	53.49	58.57	55.31	57.98
	58.74	80.05	108.60	137.10
	62.42	67.09	85.76	126.00
	59.57	55.11	95.95*	121.20
	50.31	60.73	78.43	94.53
	71.50	82.88	100.00	110.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	52.65	77.94	91.10	106.00
	62.34	85.39	100.60	104.20
	42.11	46.20	71.40	69.45
	57.36	54.44	73.25	86.95
	48.97	60.42	87.17	94.71
	47.45	53.13	99.02	112.70
	58.37	64.38	84.52	91.44
	41.83	41.64	69.57*	86.29
	50.71	55.77	79.70	80.22
	68.94	65.77	102.10	142.30
	65.63	69.36	89.41	98.94
	72.76	76.49	78.58	90.56
	58.28	66.81	85.35	87.34
	51.61	57.59	72.91	78.83
	62.12	76.92	117.90	126.20
	65.33	66.11	86.08	89.21
	49.21	68.72	90.66	93.60
	47.94	69.93	89.02	98.04

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	45.92	45.73	47.34	45.61
	65.70	64.58	77.36	102.00
	35.90	35.32	51.34	57.10
	40.44	51.50	82.60	89.17
	53.60	47.49	66.32	77.37
	68.89	82.12	87.13	98.40
	54.97	68.44	61.25	121.30
	51.99	72.46	101.20	98.01
	57.30	57.16	78.82	96.93
	40.77	48.03	69.86	70.49
	56.87	55.38	68.11	78.57
	61.95	67.49	73.90	115.80
	61.44	62.26	103.90	144.80
	53.39	66.29	84.32	90.68
	52.19	56.55	77.96	93.83
	40.97	45.08	58.19	81.41
	45.17	54.92	80.37	88.90
	48.79	61.46	83.67	120.40

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	52.71	52.37	75.97	87.94
	61.18	65.81	111.60	96.32
	42.45	54.41	66.98	59.21
	54.39	52.22	78.40	87.33
	59.95	70.69	108.00	103.40
	64.11	77.52	106.20	99.28
	73.65	71.96	98.90	108.40
	63.12	64.54	103.10	117.20
	63.89	67.29	77.25	95.48
	60.44	60.10	91.22	97.41
	43.21	44.90	48.86	53.99
	46.26	50.36	32.23	56.31
	50.53	49.49	69.26	79.23
	67.41	69.38	110.40	118.20
	49.45	52.39	66.00	76.13
	65.61	79.40	114.80	105.60
	39.44	37.14	51.98	62.75
	57.98	64.78	91.83	98.78

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	64.67	64.85	81.73	102.80
	59.22	67.05	90.40	84.40
	48.59	61.80	83.03	80.29
	56.41	57.69	77.77	100.60
	57.90	65.57	76.06	72.71
	58.53	56.52	67.60	85.28
	75.70	78.38	107.30	121.30
	65.22	69.86	108.90	105.50
	55.22	70.93	95.77*	107.50
	71.04	79.88	115.90	129.90
	71.76	83.27	94.25	120.20
	64.85	72.87	108.80	144.40
	65.85	64.26	87.41	106.00
	61.35	63.75	86.75	104.70
	59.32	70.86	100.20	100.90
	70.79	87.88	130.50	126.50
	60.22	62.89	76.62	89.63
	63.15	62.90	77.11	97.09

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	62.64	84.87	114.80	124.00
	53.17	59.89	55.65	86.00
	50.44	50.24	99.76	94.23
	59.94	67.13	85.06	89.09
	77.16	78.23	101.90	129.90
	73.36	77.11	105.60	124.90
	53.59	58.16	85.95	93.80
	64.18	59.63	83.14	87.97
	59.95	67.66	95.77	101.70*
	75.71	79.97*	90.55	122.90
	57.42	58.36	88.80	95.07
	57.19	64.92	79.05	114.20
	55.52	49.56	85.37	106.20
	57.69	59.71	66.98	95.40
	65.01	62.61	98.55	93.79
	63.36	64.04	81.48	109.20
	55.92	62.74	93.56	101.20
	57.04	91.86	112.60	109.10

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	63.52	64.47	107.80	103.10
	73.21	89.86	108.20	112.60
	59.84	60.13	61.84	98.82
	56.71	57.33	85.14	96.02
	69.16	78.31*	100.20	112.30
	51.65	35.60	60.59	47.91
	59.22	59.73	88.35	117.10
	59.41	68.17	96.75	127.00
	72.37	77.95	107.40	140.30
	60.04	70.48	96.85	114.40
	59.36	63.27	92.60	130.30
	62.15	62.05	88.09	98.30
	65.76	68.28	96.22	105.20
	64.75	99.95	127.60	137.20
	90.08	84.98	120.30	138.30
	54.91	78.95	133.30	120.00
	59.22	65.58	90.70	121.70*
	70.23	85.38	113.90	125.50

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	53.11	63.30	76.21	87.86
	58.00	56.52	64.04	91.83
	57.72	55.03	61.96	63.67
	65.35	64.25	85.20	88.88
	88.03	98.70	102.10	115.30
	60.19	88.10	129.40	125.80
	63.68	72.18	83.71	89.39
	57.98	74.43	72.11	92.60
	61.83	66.98	100.30	108.90
	62.27	68.08	101.70	132.50
	76.30	87.17	106.50	115.00
	55.81	69.50	91.89	99.77
	51.57	55.68	61.59	89.63
	56.82	62.91	68.77	87.05
	58.29	62.98	88.09	106.30
	87.20	90.93	101.70	121.90
	63.84	61.33	78.28	89.98
	53.97	66.61	94.37	89.76

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	49.45	62.60	61.61	97.27
	65.42	68.03	90.71	111.10
	62.25	66.57	110.70	116.00
	68.77	90.38	101.20	109.80
	54.29	60.87	66.73	81.63
	63.66	82.44	108.30	119.90
	64.67	63.67	80.99	111.00
	67.92	87.58	118.30	119.80
	65.14	68.21	79.42	95.12
	70.76	66.06	91.10	107.40
	57.59	69.92*	86.10	87.26
	62.84	72.92	101.00	109.40
	64.41	70.12	93.80	109.30
	55.21	66.46	83.90	87.06
	59.02	63.95	102.90	103.20
	57.83	63.92	82.88	90.89
	50.08	56.66	66.44	85.23
	59.50	50.45	94.30	88.69

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	47.40	51.27	52.10	54.65
	63.37	72.41	101.90	115.40
	80.40	87.67	115.80	129.60
---	62.31	82.23	102.40	110.60
	54.73	52.83	87.01	87.37
	54.12	85.34	116.60	118.50

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	59.254 (9.2426)	66.308 (12.6102)	88.180 (18.9283)	100.143 (20.0550)
GeoMean	58.528	65.081	85.966	97.945
(95% CI)	(57.260;59.825)	(63.338;66.873)	(83.239;88.783)	(95.037;100.942)
GeoCV(CV%)	16.0 (15.6)	19.9 (19.0)	23.7 (21.5)	22.1 (20.0)
SEM	0.6471	0.8829	1.3252	1.4041
Median	59.269	65.575	89.070	99.675
Min; Max	35.90; 90.08	33.98; 100.10	32.23; 133.30	45.61; 144.80

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.1.sas

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	90.59	68.33	92.19	84.01
	72.64	97.28	92.99	89.51
	112.80	104.40	108.90	113.10
	80.76	93.62	81.13	80.31
	107.40	76.10	102.60	97.30
	96.71	93.78	71.70	85.99
	110.40	123.10*	89.92	81.19
	124.20	140.80	135.40	129.60
	77.74	131.40	107.30	105.80
	119.30	111.60	123.40	102.90
	59.10	92.69	86.40	74.87
	93.50	77.88	88.97	89.87
	117.50	131.60	134.60	127.70
	97.89	78.85	87.08	99.53
	114.40	92.45	92.78	89.32
	84.17	93.34	82.55	83.83
	122.50	107.50	109.40	116.90
	100.50	90.35	121.00	107.10

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.1.sas

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	83.53	77.00	66.37	79.60
	103.60	78.31	83.98	89.51
	124.50	135.10*	125.70	131.90
	103.40	100.50	101.90	93.40
	69.50	82.06*	89.17	82.97
	109.60	95.59	99.36	110.20
	112.30	114.80	106.80	105.90
	102.20	101.30	106.60	104.00
	65.03	86.81	88.57	86.19
	90.96	70.03	79.75	78.00
	60.86	90.95*	104.30	87.61
	123.70	135.90	130.00	119.80
	100.60	86.53	95.65	84.98
	78.60	93.75	98.69	71.15
	127.00	121.60	111.70	128.50
	114.80	113.20	104.70	129.40
	86.14	93.43	109.10	113.80
	82.67	58.29	81.63	78.53

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
[illegible]	86.76	84.62	88.87	92.16
	96.37	105.30	101.70	75.56
	112.40	83.96	102.10	99.33
	98.22	86.88	65.14	84.90
	105.00	108.10	101.20	107.10
	94.90	85.59	68.23	96.65
	104.80	104.80	81.40	95.70
[illegible]	89.09	98.87	79.52	74.67
	120.20	133.10	127.40	130.00
	61.11	69.96	93.56	58.93
	89.33	110.80	102.70	99.32
	97.85	124.70	99.59	113.70
	80.22	76.23	77.24	87.29
	133.20	125.30	109.40	105.60
	134.00*	123.10	127.70	110.30
	139.50	250.80	144.20	112.20
	112.50	106.80	116.90	113.30
	116.60	120.60	117.60	128.40

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.1.sas

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	100.30	91.78	93.50	88.53
	95.77	94.28	93.77	96.67
	85.64	84.71	81.84	76.64
	54.08	129.20	45.20	123.40
	86.65	79.47	89.55	78.28
	103.20	107.10	93.11	93.12
	98.00	96.47	102.10	89.60
	75.31	68.34	79.22	69.31
	83.14	90.93	81.41	87.44
	131.40	135.70	117.30	141.20
	114.30	97.34	103.90	85.89
	100.10	102.20	106.70	104.60
	103.70	107.40	106.90	134.90
	73.13	73.26	88.58	81.74
	122.80	116.60	108.50	109.50
	105.30	108.10	117.80	141.30
	96.55	94.85	84.62	83.89
	98.01	100.60	95.63	90.46

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	48.99	64.33	73.13	66.96
	104.20	113.00	107.60	106.80
	64.99	67.43	63.94	67.88
	106.30	111.80	125.80	113.80
	89.07	94.12	87.02	90.03
	102.80	115.30	117.20	123.80
	70.60	79.20	90.93	104.10
	89.47	92.12	92.99	86.56
	99.74	88.78	94.69	97.46
	69.03	75.82	69.52	75.06
	82.42	99.83	94.85	91.41
	128.30	108.70	106.60	102.30
	135.50	115.70	106.50	107.40
	78.79	97.98	93.06	90.40
	89.08	113.40	106.00	79.42
	68.39	110.80	90.48	76.28
	94.03	86.86	80.40	86.36
	112.70	117.50	119.00	106.80

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	95.23	102.10	99.70	97.63
	117.90	135.70	128.00	120.10
	74.27	69.95	62.34	67.24
	77.03	78.70	86.25	79.87
	97.86	101.50	102.10	93.37
	105.20	99.19	95.52	92.02
	123.80	129.80	130.60	123.10
	119.40	116.90	105.60	106.60
	95.45	94.96	99.22	99.09
	104.90	109.60	111.10	98.60
	56.01	68.89	68.99	94.82
	67.58	73.78	61.70	69.07
	67.91	82.44	92.71	82.04
	130.30*	133.60	115.50	105.30
	70.07	72.45	72.98	111.30
	79.62	122.50	116.40	119.10
	74.67	77.41	46.46	62.98
	108.80	102.00	103.40	104.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	91.63	90.52	94.04	95.14
	109.10	114.30	107.50	99.75
	82.02	83.33	81.83	73.14
	83.12	81.50	77.01	98.59
	79.45	93.27	95.26	94.24
	91.70	98.98	90.93	98.00
	122.30	133.00	109.60	124.60
	125.80	123.50	124.10	109.30
	107.60	98.89	108.10	97.66
	111.40	119.80	120.80	117.00
	137.90	131.00	132.20	128.50
	121.90	146.30	137.00	125.50
	123.00	116.10	113.60	111.90
	92.64	97.34	88.78	87.70
	112.70	97.91	102.80	101.20
	133.20	132.40	118.70	120.70
	109.10	94.40	86.85	91.16
	112.50	130.20	93.02	113.90

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
[redacted]	130.70	140.50	108.00	114.00
	91.68	101.60	83.82	96.35
	80.88	80.47	79.34	70.71
	94.93	110.90	107.50	111.40
	114.20	147.60	115.90	110.00
	113.90	139.80	119.70	129.80
	89.34	96.12	87.17	87.10
	80.30	92.49	99.75	101.70
	132.20	125.70	129.30	92.68
	109.80	115.50	127.20	142.40
	113.90	106.90	99.02	112.10
	108.50	110.40	100.20	104.50
	94.68	124.30	94.26	84.90
	96.90	106.80	103.00	105.00
	106.70	98.68	93.27	97.49
	126.90*	124.20	116.70	123.60
	104.50	79.00	87.69	79.67
	106.20	115.00	104.70	121.80

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	103.10	92.98	99.48	116.70
	109.70	145.60	105.00	118.20
	91.33	136.30	106.30	90.19
	115.50	114.10	105.30	92.02
	118.80	108.90	106.30	112.20
	71.41	111.60	107.70	102.90
	99.53	97.87	93.34	89.82
	108.90	110.10	104.60	116.60
	113.30	134.60	126.60	122.50
	105.50	104.80	110.10	103.20
	120.00	134.20	102.60	114.10
	107.40	102.20	107.50	103.90
	109.30	125.20	121.60	115.20
	129.70*	125.20	115.90	116.00
	111.10	146.90	115.10	141.00
	98.11	117.70	102.00	92.96
	116.20	102.70	105.10	103.60
	99.72	104.00	107.60	113.40

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	97.40	92.99	83.64	86.92
	80.18	83.21	85.81	101.00
	80.16	94.57	90.34	90.66
	89.00	99.55	91.78	94.66
	116.50	126.60	136.90	135.40
	118.10	117.60	117.90	113.30
	100.40	102.60	102.90	94.13
	120.00	105.50	95.78	97.88
	113.80	115.10	102.40	96.76
	126.00	128.80	122.90	133.10
	107.60	119.60	120.40	107.90
	112.10	101.90	96.18	104.00
	75.71	95.01	92.30	91.88
	84.19	86.78	88.29	93.17
	100.70	98.40	105.30	92.87
	133.60	117.10	138.30	123.30
	116.20	103.20	118.30	119.20
	100.40	94.26	95.13	85.65

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	94.89	92.23	93.85	72.73
	111.80	116.80	113.40	90.78
	115.80	119.40	100.30	86.44
	112.60	108.40	98.14	108.30
	88.49	80.28	77.57	80.12
	113.70	115.10	105.70	95.35
	118.30	113.10	110.90	107.80
	118.30	111.90	114.40	89.45
	103.10	114.60	107.20	114.40
	101.00	92.99	107.00	100.30
	92.37	112.30*	65.37	84.70
	103.20	112.00	108.60	96.06
	112.80	116.10	124.90	112.80
	99.98	98.34	75.28	59.32
	111.70	101.40	113.40	119.40
	85.65	96.37	93.14	93.85
	78.17	110.00	94.58	83.72
	93.20	113.50	102.50	92.81

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	63.83	68.89	59.56	67.99
	124.80	119.00	119.40	127.30
	135.90	164.60	146.70	130.50
	116.20	128.70	126.10	136.30
	81.33	101.60	106.50	101.30
	92.25	100.90	112.60	113.30

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

	Sample Times (h)			
Subject Number/ Random Number	2	2.5	3	4
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	100.658 (18.9149)	105.133 (21.9397)	100.721 (17.8540)	100.291 (17.8335)
GeoMean	98.742	103.029	99.021	98.690
(95% CI)	(96.030;101.531)	(100.216;105.920)	(96.454;101.655)	(96.248;101.193)
GeoCV(CV%)	20.4 (18.8)	20.2 (20.9)	19.2 (17.7)	18.3 (17.8)
SEM	1.3243	1.5361	1.2500	1.2486
Median	102.500	102.650	102.100	98.595
Min; Max	48.99; 139.50	58.29; 250.80	45.20; 146.70	58.93; 142.40

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	87.05	76.38	88.59	80.08	75.76
	79.18	77.50	85.15	75.54	61.23
	106.00	97.33	92.20	99.47	83.53
	85.70	74.47	79.66	84.30	64.90
	97.86	96.53	93.22	100.00	82.20
	81.59	76.01	76.39	73.02	66.64
	92.81	90.69	95.01	95.71	92.16
	123.90	122.70	119.50	121.70*	118.90
	89.87	91.63	102.60	92.86	77.96
	103.20	99.35	118.50	96.31	94.93
	81.36	71.60	70.42	54.91	66.82
	93.76	86.75	88.58	73.32	73.98
	117.70	110.70	112.00	95.08	101.00
	89.25	80.76	80.60	98.83	73.66
	80.65	87.18	84.42	80.79	74.12
	74.62	74.93	71.04	78.83	69.30
	105.20	103.30	112.50	81.82	84.15
	105.50	90.17	107.00	103.20	85.72

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.1.sas

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	68.30	73.34	70.04	68.61	58.07
	98.42	93.40	88.18	85.53	81.14
	117.90	112.90	113.00	102.60	92.34
	103.50	126.60	95.97	96.34	82.31
	73.21	97.04	85.13	81.60	72.64
	95.00	94.39	94.71	96.02*	89.27
	104.30	88.67	104.00	89.51	82.88
	83.54	81.60	77.61	81.25	75.32
	92.76	86.84	79.18	82.48	83.69
	84.39	75.00	87.04	76.66	66.04
	84.26	89.98	91.71	64.43	72.91
	109.50	120.50	98.07	103.80	88.95
	105.10	83.18	85.88	64.48	61.28
	100.40	63.26	73.55	68.80	55.16
	128.60	106.30	106.40	99.53	94.84
	136.00	103.40	93.00	88.28	76.76
	122.30	84.67	88.80	78.15	69.35
	99.39	85.63	57.65	76.82	83.55

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	100.20	95.91	88.43	91.57	77.99
	89.74	85.63	73.22	83.08	86.73
	80.66	69.54	70.88	93.69	82.43
	63.12	70.31	57.63	88.95	72.46
	91.85	83.48	85.62	72.01	81.02
	97.82	92.24	76.88	92.86	83.93
	86.09	79.38	60.82	88.02	81.71
	73.62	69.34	72.59	81.28	67.26
	111.60	89.51	95.39	93.26	80.14
	65.81	60.81	51.83	56.71	53.24
	99.56	104.20	103.90	89.97	88.50
	114.40	112.20	104.20	117.00	113.00
	79.61	80.32	57.90	82.32	67.30
	96.95	103.30	96.77	100.80	88.82
	96.55	98.52	97.97	99.09	98.68
	97.61	81.12	94.39	89.50	86.41
	94.40	94.66	91.79	89.57	83.19
	117.00	104.60	108.40	105.70	101.80

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	90.21	74.97	75.48	74.99	68.14
	94.53	84.07	90.55	79.48	70.38
	79.72	80.00	82.93	73.76	68.56
	93.71	101.30	83.99	95.71	86.36
	99.25	80.44	85.68	86.99	88.86
	90.77	88.12	82.16	81.55	73.85
	104.20	95.12	91.07	80.26	77.09
	72.73*	64.56	63.61	74.13	59.30
	76.92	80.27	75.91	67.50	74.57
	135.40	106.10	128.90	119.90	118.00
	106.40	95.42	92.15	100.10	80.10
	96.43	104.10	92.31	89.05	89.51
	116.70	106.60	112.00	102.20	88.78
	75.23	71.53	69.96	67.83	68.25
	113.80	98.48	96.58	102.90	87.25
	118.50	110.60	113.80	114.70	98.94
	85.90	77.27	75.28	74.72	63.96
	86.28	82.99	52.92	89.69	79.91

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	71.51	69.39	77.84	66.23	65.73
	109.50	83.86	105.80	84.28	97.01
	70.63	60.54	74.61	65.52	65.09
	108.00	120.70	109.90	78.40	98.20
	83.78	86.46	82.72	82.45	78.01
	107.70	102.90	102.40	96.66	86.48
	98.31	86.69	98.03	84.49	64.25
	89.52	93.01	93.22	75.44	52.29
	92.27	96.12	89.82	93.92	74.74
	72.41	70.06	50.90	66.82	64.51
	77.51	97.18	83.53	76.69	84.91
	128.90	98.28	99.83	84.52	89.86
	122.20	116.60	115.30	104.00	104.40
	81.31	80.18	75.57	82.22	66.36
	92.19	94.21	63.94	78.54	82.09
	76.38	84.52	63.05	71.65	69.67
	75.18	74.59	74.70	70.67	65.84
	107.00	96.95	113.90	93.03	86.96

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	90.83	86.48	107.70	89.99	70.80
	107.20	101.60	90.33	102.60	84.93*
	65.17	67.12	69.38	62.24	52.98
	83.04	82.25	80.29	79.56	70.14
	91.02	93.52	93.64	89.27	91.22
	102.80	84.31	88.43	84.13	88.15
	116.30	116.70	134.20	127.50	108.80
	99.83	88.52	72.81	93.31	80.56
	101.80	101.20	97.13	81.09	82.03
	107.40	88.29	91.86	81.71	79.97
	73.77	69.36	77.04	78.17	67.90
	50.57	57.20	61.74	65.56	52.85
	88.74	78.05	85.31	85.14	75.48
	110.50	109.10	104.10	103.10	90.50
	85.00	100.80	80.59	90.82	69.61*
	110.50	99.73	107.80	96.99	92.81
	60.92	53.65	60.58	63.51	64.98
	70.30	96.47	91.78	92.26	90.48

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	93.53	98.41	107.10	105.70	85.58
	94.78	95.92	97.18	88.43	82.39
	95.58	76.58	70.77	76.87	63.14
	83.80	77.04	76.24	86.15	81.77
	83.41	84.78	78.14	88.53	75.07*
	89.37	93.35	93.01	89.79	93.63
	109.10	112.60	114.70	99.79	102.40
	105.90	93.25	112.80	96.73	85.20
	97.99	91.56	90.68	86.62	84.56
	122.20	123.30	118.70	99.42	94.55
	123.00	135.50	95.31	112.40	113.90
	132.10*	144.20	103.80	120.70	114.40
	108.20	94.62	92.90	90.51	87.64
	94.34	71.04	78.20	78.36	79.67
	101.30	94.94	91.18	91.36	88.55
	121.00	136.90	115.80	106.20	89.23
	86.15	83.29	93.20	87.31	83.05
	100.10	96.92	105.70	96.32	88.55

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	112.60	91.12	81.96	91.00	79.02
	97.65	86.11	113.30	84.20	90.62
	77.40	74.30	76.20	89.77	74.25
	98.80	97.57	97.34	90.70	91.94
	109.20	123.40	103.40	120.80	105.40
	86.80	105.10	73.48	86.29	84.99
	87.46	83.95	79.19	78.00	74.48
	93.27	83.14	83.67	78.19	80.46
	118.80	114.90	118.60	107.90	100.60
	118.00	136.20	96.77	123.40	105.40
	100.80	92.68	102.60	88.33	83.05
	106.10	102.80	86.34	88.07	88.92
	81.40	89.90	84.97	85.60	82.05
	99.06	95.84	94.59	81.71	83.96
	96.93	91.31	108.60	96.62	78.06
	108.10	98.57	97.71	93.64	90.89
	93.07	80.47	106.50	87.01	102.10
	103.30	90.69	104.10	82.07	80.91

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	103.70	104.50	94.21	88.89	86.22
	98.72	103.10	106.90	90.70	90.60
	101.80	92.16	97.16	104.80	92.37
	97.29*	93.16	98.05	100.50	78.51
	107.30	90.91	131.90	103.40	103.50
	105.40	82.21	68.03	91.03	86.06
	103.10	97.15	100.70	101.00	95.41
	101.70	98.95	94.43	86.54	82.10
	122.80	115.10	127.50	104.00	97.04
	93.00	89.34	92.08	101.30	86.50
	112.60	110.60	109.10	102.60	103.80
	88.52	97.77	98.20	95.45	82.31
	111.20	104.40	107.20	126.60	108.90
	112.00	109.50	102.50	115.30	102.60
	119.40	131.90	119.20	122.50	113.40
	84.51	84.37	99.45	79.53	70.11
	95.75*	98.06	110.00	95.93	89.01
	98.25	106.20	113.80	107.90	90.70

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	81.37	81.73	79.16	78.23	77.74
	91.92	77.47	85.28	73.20	83.97
	88.31	85.06	74.90	80.99	77.26
	95.26	102.10	92.05	89.48	72.22
	133.60	94.02	111.90	113.00	112.10
	122.50	111.30	111.00	105.20	99.60
	90.36	92.41	81.46	82.32	83.70
	93.85	87.91	87.37	88.43	83.06
	100.90	105.70	104.80	98.76	59.79
	120.10	111.20	107.10	113.50	100.10
	107.00	99.00	100.30	103.50	101.30
	93.56	93.60	96.36	77.72	89.19
	92.52	87.68	94.53	86.66	79.19
	88.75	70.03	79.91	77.82	82.41
	91.89	100.40	91.00	83.74	72.87
	137.60	130.50	127.50	122.80	114.70
	132.10	120.30	118.50	112.90	99.17
	82.52	73.33	84.88	73.80	82.40

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	97.025 (15.9780)	93.013 (16.1570)	92.386 (16.7332)	89.794 (14.2100)	83.302 (13.6973)
GeoMean (95% CI)	95.684 (93.476;97.945)	91.628 (89.449;93.860)	90.806 (88.462;93.213)	88.678 (86.752;90.647)	82.172 (80.300;84.087)
GeoCV(CV%)	17.0 (16.5)	17.6 (17.4)	19.1 (18.1)	16.0 (15.8)	16.8 (16.4)
SEM	1.1187	1.1312	1.1716	0.9949	0.9590
Median	96.940	92.980	92.950	89.375	83.050
Min; Max	50.57; 137.60	53.65; 144.20	50.90; 134.20	54.91; 127.50	52.29; 119.40

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	75.79	77.49	63.73	67.29
	74.58	76.08	74.80	64.29
	97.99	87.29	65.21	63.44
	76.94	70.49	65.53	71.40
	86.78	96.78	69.48	88.59
	72.03	63.29	59.30	64.41
	99.24	84.38	93.39	71.88
	108.40	108.70	107.70	114.80
	89.71	92.71	87.88	80.12
	96.52	102.20	98.74	102.80
	49.88	83.02	60.09	62.80*
	79.66	82.01	70.92	80.38
	112.50	103.30	94.32	97.08
	87.91	88.01	80.72	70.39
	79.89	90.18	77.55	65.04
	90.78	93.06	70.27	63.08
	89.14	80.21	77.65	73.94
	90.80	93.47	69.65	97.07

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	80.28	68.72	67.69	62.42
	93.76	88.66	77.83	84.35
	100.10	91.51	89.13	76.71
	106.40	108.00	91.11	81.83
	60.69	97.62	81.24	71.49
	98.20	91.31	79.78	41.00
	94.64	100.70	93.50	91.44
	71.29	83.09	80.99	72.82
	78.07	86.00	75.14	71.99
	74.30	76.80	66.11	62.30
	69.34	67.23	63.56	68.83
	120.80	105.70	95.74	97.66
	69.75	81.58	75.15*	61.49
	45.12	71.66	70.53	52.68
	89.87	110.30	99.32	93.98
	93.82	78.13	73.01	75.02
	78.25	89.23	66.57	73.47
	50.40	79.70*	84.39	95.41

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	97.77	92.68	72.69	68.33
	63.48	94.95	89.60	86.39
	98.39	96.64	68.07	67.25
	76.79	81.63	86.91*	76.39*
	91.27	82.86	80.59	69.87
	92.74	87.99	85.76	88.20
	93.98	90.71	92.16	83.03*
	72.82	71.99	71.21	75.83
	118.20	117.00	133.70	110.70
	51.71	64.24	59.97	66.93
	100.80	93.14	105.90	94.47
	128.30	119.30	102.80	114.70
	74.94	98.62	67.76	88.01
	80.15	93.30	92.47	88.94
	98.29	96.87	100.70	98.08
	97.95	101.80	84.00	79.21
	79.46	72.67	85.14	72.99
	113.70	100.40	98.34	99.69

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.1.sas

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	79.30	77.95	80.07	74.37
	78.66	78.02	77.46	68.34
	74.62	71.94	69.11	62.29
	94.25	89.48	87.92	87.71
	92.22	82.97	78.75	83.81
	85.18	84.37	76.88	70.30
	79.18	78.27	78.27	76.62
	60.18	62.15	56.76	60.75
	81.36	77.54	62.52*	75.35*
	116.00	119.40	118.00	100.90
	76.02	76.34	73.95	72.12
	88.53	90.22	93.74	81.49
	108.80	103.60	106.10	80.63
	67.24	81.61	63.30	64.62
	80.13	98.83	67.98	74.71
	112.20	106.10	102.10	87.13
	73.21	70.04	68.46*	66.95
	84.39	87.68	60.76	48.59

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	54.69	72.45	51.39	48.73
	87.44	109.40	101.90	88.30
	54.43	65.38	56.40	57.62
	85.88	91.47	94.73	84.32
	85.94	78.74	80.56*	75.88*
	98.52	94.07	99.95	84.92
	89.92	91.76	69.60*	88.59
	73.27	67.52	65.57	81.16
	83.71	83.64	83.64	82.37*
	59.34	50.28	55.63	52.68
	89.03	81.54	77.61	85.78
	90.71	91.88	135.70	107.20
	96.41	88.96	105.40	91.51
	72.92	81.13	75.42	65.94*
	88.85	78.46*	81.60	84.91
	65.51	75.24	83.14	67.86
	66.67	83.30	63.43	55.00
	92.26	84.96	86.81	80.93

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	89.17	86.34	77.20	65.23
	100.90*	92.14	88.96	82.34
	50.40	57.19	51.99	51.66
	83.13	75.10	87.64	72.18
	89.17	84.60	70.65	74.04
	105.00	86.34	74.47	71.54
	69.01	119.00	105.60	99.49
	86.18	72.70	87.08*	85.88
	78.40	75.31	79.23	83.62
	85.94	91.77	87.73	83.25
	70.97	84.47	66.89	66.85
	56.90	69.29	52.39	39.45
	87.38	93.47	70.46	86.37
	101.40	85.32	64.84	96.31
	74.25*	81.65	89.63	83.45
	103.70	97.35	96.36	93.06
	46.30	42.42	48.20	64.60
	95.49	83.82	91.34	86.14

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	90.68	81.97	87.93	87.63
	79.62	81.01	76.25	78.11
	69.77	78.70	64.36	67.48*
	85.79	77.57	73.19	77.58
	71.62*	82.84*	84.57*	70.00*
	91.06	94.61	72.18	81.14
	110.60	100.20	88.26	83.15
	100.20	96.44	96.82	88.46
	98.75	89.24	83.32	71.20
	101.00	103.10	102.30	96.44
	120.90	110.50	101.70	109.50
	97.96	100.20	109.60	78.86
	104.50	95.72	93.62	81.03
	87.32	83.22	91.84	90.42
	93.09	93.92	90.70	88.93
	94.14	107.90	105.70	88.57
	100.20	103.20	87.31	73.55
	79.61	119.50	78.60	78.61

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	108.10	93.96	78.52	70.87
	92.55	103.60	114.60	96.41
	67.99	78.05	69.06	67.32
	93.47	87.18	81.23	68.66
	107.50	104.90	109.40	114.00
	124.40	97.72*	89.25	76.53
	82.05	79.71	73.57	78.17
	85.59	83.18	73.58	78.76
	105.30	114.70	94.40*	79.20
	119.30	117.10	121.50	106.80*
	95.04	98.08	83.37	77.31
	101.20	89.76	86.38	84.89
	93.72	103.80	86.39	73.48
	92.49	81.17	82.21	73.22
	100.20	113.30	90.45	68.30
	101.20	92.13	89.43	80.80
	73.36	56.27	73.78	66.84
	85.99	89.92	77.41	77.65

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
-----	92.64	89.13	83.08	85.22
	88.46	92.40	82.64	88.26
	114.10	115.50	96.02	75.38
	81.71	87.28	74.48	70.61
	95.68	97.84	102.70	95.96
	84.31	70.44	95.89	87.23
	93.96	95.21	99.27	92.83
	84.35	94.69	84.62	99.20
	107.40	99.65	105.10	104.10
	95.85	92.58	82.05	79.53
	111.20	105.90	104.30	95.37
	96.49	93.59	83.27	85.14
	97.62	107.70	96.04	94.47
	99.30	102.60	84.95	86.51
	131.30	121.80	109.60	130.00
	76.98	84.72	72.42	80.73
	102.50	96.72	102.40	102.90
	111.50	95.58	102.00	104.80*

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	79.12	82.76	76.53	65.65
	85.05	82.91	63.91	70.85
	83.13	84.76	78.49	75.30
	91.59	92.15	88.63	73.43
	108.80	106.70	121.20	82.38
	103.80	108.90	99.55	87.22
	90.86	82.00	92.90	103.50
	89.16	99.35	88.21*	79.35
	88.92	89.57	85.87	79.47
	91.80	107.80	106.60	103.40
	110.00	102.50	102.40	104.00*
	94.95	94.24	83.07	81.04
	88.50	85.41	82.00*	71.44
	64.38	71.26	67.29	62.21
	83.40	90.78	88.14	76.73*
	119.30	118.60	121.60	104.30*
	106.80	111.50	113.00	91.19
	87.37	86.89	65.77	63.43

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	77.00	78.86	60.95	71.14
	137.10	95.95	97.27	76.88*
	91.68	88.23	81.13	84.53
	90.89	90.07	91.62	74.81
	75.25	75.51	76.69	70.10
	84.17	102.60	97.06	84.51
	81.49	76.84	78.53	78.24
	88.17	94.54	85.71	60.17*
	101.40	96.44	86.72	82.98
	93.39	93.94	97.72	92.73
	50.45	74.89	68.49	72.51
	88.72	84.65	89.89	76.83
	91.96	97.74	100.50	92.37
	54.63	90.69	77.05	83.07
	92.37	92.49	84.32*	84.39
	90.22	86.99	78.99	74.74
	80.01	67.90	74.94	79.94*
	89.78	76.34	59.14	63.85

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	73.44	74.17	70.82	72.15
	94.24	95.96	93.58	84.82
	167.20	120.30	126.30	112.20
	101.20	100.90	103.70	81.38
	96.49	91.43	93.39	87.33*
	104.10	95.13	92.87	86.90

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h) 24	36	48	72
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	88.916 (17.2832)	89.503 (13.8167)	84.279 (15.9005)	80.197 (14.2479)
GeoMean	87.179	88.389	82.797	78.913
(95% CI)	(84.766;89.661)	(86.437;90.385)	(80.656;84.994)	(76.949;80.926)
GeoCV(CV%)	20.5 (19.4)	16.3 (15.4)	19.1 (18.9)	18.4 (17.8)
SEM	1.2101	0.9674	1.1133	0.9976
Median	89.745	89.840	83.345	79.500
Min; Max	45.12; 167.20	42.42; 121.80	48.20; 135.70	39.45; 130.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	44.98	54.65	82.59	94.05
	48.89	58.30	74.37	86.80
	64.95	63.54	90.67	105.00
	52.75	68.72	73.06	91.08
	60.46	63.00	90.13	111.50
	43.66	51.06	81.86	96.82
	51.55	71.69	101.00	123.60
	72.30	75.83	103.80	124.80
	62.33	68.35	83.16	86.55
	78.41	75.13	98.09	99.06
	55.67	51.79	64.33	89.19
	64.90	67.96	80.14	106.90
	55.93	59.69	65.60	96.77
	70.65	65.02	104.50	106.10
	67.55	69.57	90.76	73.94
	47.75	50.26	67.20	76.87
	60.65	72.62	100.60	136.10
	65.03	85.27	118.60	112.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	52.25	46.77	59.71	66.56
	55.19	86.87	108.70	118.30
	80.59	93.94	125.50	142.10
	52.81	63.02	102.60	88.51
	57.61	42.05	67.39	75.81
	86.03	67.51	96.46	110.50
	60.42	71.59	88.98	124.30
	50.31	51.62	81.99	86.11
	57.73	53.11	67.12	74.22
	40.63	45.46	58.16	61.19
	47.05	39.35	54.56	75.45
	73.01	83.65	109.00	120.30
	57.97	62.20	77.10	102.80
	42.63	61.55	100.80	93.67
	67.92	82.57	90.84	109.90
	51.25	69.83	101.80	126.60
	58.57	90.63	92.31	104.30
	57.27	44.12	59.72	54.80

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	46.13	52.45	72.60	79.34
	49.81	56.60	80.52	100.80
	63.45	56.93	95.45	102.50
	49.87	57.60	87.44	98.26
	52.99	53.64	60.02	61.36
	73.56	73.93	97.68	107.70
	58.34	64.80	86.18	94.93
	34.02	55.36	50.57	95.21
	72.44	83.81	112.30	107.50
	49.99	47.98	62.18	73.38
	60.78	62.21	89.62	95.30
	60.84	62.63	78.09	61.79
	49.47	58.00	58.92	69.04
	52.07	80.75	113.40	136.90
	67.38	62.93	65.52	86.74
	57.79	64.65	109.40	104.60
	47.68	58.83	79.76	101.70
	72.15	90.65	113.50	114.80

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	49.06	54.70	75.93	86.91
	62.05	75.77	89.35	111.10
	42.26	40.91	81.34	93.42
	55.34	63.97	81.93	100.20
	57.15	65.04	105.40	126.40
	46.54	58.10	80.71	102.90
	64.04	78.74	90.16	104.20
	46.41	52.26	51.79	67.97
	39.61	62.64	107.60	92.49
	66.48	60.58	63.16	69.07
	70.72	72.79	94.27	123.50
	69.81	74.92	99.77	109.40
	57.45	64.28	84.96	103.80
	55.82	56.13	72.86	84.64
	54.75	55.56	74.70	85.97
	60.02	76.19	101.30	106.20
	50.65	56.55	92.00	104.00
	50.20	57.34	63.75	51.72

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.1.sas

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	43.36	46.91	57.39	69.63
	60.98	69.55	84.07	86.08
	41.53	38.00	52.93	56.94
	52.87	53.90	94.94	122.00
	51.61	47.20	65.20	70.57
	70.68	74.02	92.80	118.00
	62.70	62.43	57.14	68.61
	53.16	58.99	75.75	91.64
	63.94	63.91	83.04	76.44
	35.80	43.36	59.51	76.30
	60.07	68.43	72.26	78.62
	64.21	60.68	76.47	106.60
	63.88	57.24	70.00	113.40
	50.79	50.53	77.17	99.39
	50.34	58.65	81.48	101.10
	48.27	47.28	66.78	75.97
	49.69	51.04	63.47	74.61
	44.51	57.62	75.85	90.72

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	50.83	57.06	67.02	94.07
	60.08	68.86	100.50	102.20
	36.06	41.74	45.10	78.83
	57.53	61.72	75.40	91.84
	59.67	76.19	99.16	110.60
	53.06	61.45	69.86	87.48
	68.34	65.55	78.82	103.30
	63.95	64.37	83.45	107.20
	66.76	70.32	71.99	87.64
	60.31	57.10	89.44	105.30
	45.05	29.95	41.78*	52.22
	41.02	58.27	63.32	66.47
	51.60	52.37	77.57	91.99
	69.46	67.45	98.98	90.22
	47.80	56.48	76.66	92.58
	66.05	72.48	100.10	102.30
	29.11	20.25	49.32	53.81
	61.37	65.62	83.26	88.81

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
[illegible]	71.66	65.25	93.38	99.90
	61.53	61.98	83.18	87.51
	59.40	58.93	82.09	104.60
	55.88	53.34	60.08	100.10
	54.78	52.77	65.64	77.48
	53.98	57.07	92.81	90.04
	65.39	74.32	112.20	111.30
	69.52	91.99	107.30	113.20
	62.28	62.83	75.22	77.75
	81.42	79.78	114.50	127.80
	72.41	87.25	112.80	148.50
	65.53	84.00	121.90	122.40
	69.50	67.44	72.89	85.53
	63.83	66.81	63.53	96.76
	66.26	69.39	77.97	77.65
	63.00	68.07	74.57*	100.90
	59.44	62.64	86.40	100.40*
	62.69	63.53	80.05	79.76

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation; GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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