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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Sodium (mmol/L)	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	137.30 (2.632)		136.92 (1.158)		137.75 (1.252)		137.29 (1.593)	
		Median	138.65		136.80		137.80		137.15	
		Min; Max	133.8; 139.8		135.5; 138.9		136.0; 139.1		133.8; 140.5	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	138.00 (1.686)	0.73 (1.268)	137.46 (2.276)	-0.50 (1.872)	139.84 (0.952)	1.10 (1.028)	138.58 (1.789)	0.34 (1.923)
		Median	137.80	0.60	137.60	0.00	140.10	1.50	138.65	0.10
		Min; Max	135.4; 140.6	-1.2; 2.5	133.6; 140.7	-4.4; 1.3	138.7; 141.0	-0.4; 2.3	133.6; 142.6	-4.4; 5.9
Thyrotropin (mU/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	2.116 (1.550)		1.180 (0.428)		1.570 (0.381)		1.506 (0.786)	
		Median	1.540		1.250		1.490		1.460	
		Min; Max	0.67; 4.46		0.48; 1.77		1.05; 2.24		0.48; 4.46	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=7)		Treatment Sequence 2 (N=7)		Treatment Sequence 3 (N=7)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Thyrotropin (mU/L)	Follow-Up	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	1.420 (0.524)		1.309 (0.546)		1.243 (0.539)	
		Median	1.540		1.460		1.080	
		Min; Max	0.89; 2.20		0.63; 2.00		0.68; 2.18	
Thyroxine (nmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	73.06 (6.900)		70.51 (3.017)		78.07 (6.462)	
		Median	76.30		71.40		76.10	
		Min; Max	62.8; 79.4		65.9; 73.4		68.9; 88.9	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	75.51 (8.393)		71.71 (4.482)		78.59 (8.170)	
		Median	71.10		72.90		77.40	
		Min; Max	67.4; 87.5		65.3; 77.8		68.1; 92.3	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Thyrotropin (mU/L)	Follow-Up	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	1.903 (1.343)		1.164 (0.377)		1.544 (0.340)		1.430 (0.699)	
		Median	1.460		1.180		1.390		1.420	
		Min; Max	0.23; 4.36		0.66; 1.62		1.29; 2.26		0.23; 4.36	
Thyroxine (nmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	78.10 (8.543)		75.80 (8.707)		76.86 (8.264)		75.40 (7.352)	
		Median	77.80		73.80		77.70		74.60	
		Min; Max	68.4; 94.2		65.2; 88.9		66.0; 91.3		62.8; 94.2	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	79.01 (9.804)		73.66 (6.871)		77.09 (6.124)		75.93 (7.515)	
		Median	75.40		73.30		76.80		74.90	
		Min; Max	69.8; 97.2		66.6; 86.2		69.0; 86.3		65.3; 97.2	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=7)		Treatment Sequence 2 (N=7)		Treatment Sequence 3 (N=7)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Thyroxine (nmol/L)	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	68.81 (9.641)		67.65 (7.055)		72.60 (7.323)	
		Median	65.30		66.75		70.30	
		Min; Max	54.4; 80.0		60.0; 79.4		66.0; 84.6	
	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	67.69 (9.534)		66.85 (6.580)		70.40 (5.536)	
		Median	66.70		67.20		68.60	
		Min; Max	56.8; 79.6		56.2; 76.1		65.1; 80.1	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	64.74 (6.101)	-8.31 (4.358)	63.27 (5.558)	-7.24 (6.515)	69.73 (7.555)	-8.34 (5.494)
		Median	66.60	-7.90	61.10	-9.20	65.40	-10.10
		Min; Max	55.5; 71.5	-14.1; -0.8	57.5; 70.3	-14.8; 3.9	64.0; 84.5	-16.5; 0.9

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Thyroxine (nmol/L)	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	74.97 (7.034)		73.32 (10.212)		75.63 (9.741)		72.09 (8.544)	
		Median	75.30		76.45		76.00		70.95	
		Min; Max	67.1; 82.8		55.3; 83.8		63.6; 91.8		54.4; 91.8	
	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	78.03 (11.160)		74.73 (9.086)		77.88 (8.261)		72.41 (9.145)	
		Median	79.80		76.90		76.55		72.10	
		Min; Max	62.3; 90.0		63.1; 83.1		67.1; 91.2		56.2; 91.2	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	69.40 (8.701)	-8.70 (5.582)	66.37 (12.985)	-9.43 (11.229)	67.80 (6.548)	-9.06 (4.513)	66.89 (8.124)	-8.51 (6.316)
		Median	65.20	-8.40	63.00	-8.30	70.00	-9.20	65.35	-8.60
		Min; Max	60.6; 85.4	-17.2; -0.8	47.0; 86.8	-25.9; 9.6	59.4; 77.2	-14.1; -2.2	47.0; 86.8	-25.9; 9.6

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Thyroxine, Free (pmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	13.024 (1.066)		13.074 (1.015)		13.936 (1.068)	
		Median	12.820		12.730		13.340	
		Min; Max	11.67; 14.31		11.70; 14.36		13.02; 15.57	
	Follow-Up	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	12.474 (0.960)		12.246 (0.585)		13.214 (1.057)	
		Median	12.650		12.270		13.050	
		Min; Max	10.99; 13.64		11.31; 13.16		12.29; 15.32	
Triacylglycerol Lipase (IU/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	22.31 (4.885)		24.14 (18.747)		18.91 (8.308)	
		Median	21.70		17.50		19.60	
		Min; Max	16.2; 28.3		14.9; 66.5		10.0; 32.5	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Thyroxine, Free (pmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	14.087 (1.473)		13.537 (0.980)		13.469 (0.954)		13.521 (1.112)	
		Median	13.820		13.100		13.610		13.475	
		Min; Max	12.25; 16.05		12.47; 14.80		11.82; 14.70		11.67; 16.05	
	Follow-Up	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	13.469 (1.494)		12.621 (1.169)		13.040 (0.888)		12.844 (1.086)	
		Median	12.880		12.700		12.810		12.700	
		Min; Max	11.90; 16.09		10.81; 13.93		12.07; 14.76		10.81; 16.09	
Triacylglycerol Lipase (IU/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	20.33 (9.094)		23.39 (9.461)		14.36 (7.016)		20.57 (10.419)	
		Median	20.00		23.70		13.60		19.45	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
		Min; Max	5.7; 34.8		12.6; 40.2		4.1; 23.1		4.1; 66.5	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Triacylglycerol Lipase (IU/L)	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	20.09 (4.611)		20.03 (8.527)		17.19 (7.521)	
		Median	20.70		18.10		15.30	
		Min; Max	14.9; 28.0		11.1; 33.6		10.0; 32.9	
	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	22.83 (4.635)		18.15 (5.704)		19.80 (8.270)	
		Median	22.60		17.25		18.40	
		Min; Max	15.9; 30.8		11.2; 26.1		8.1; 35.7	
	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	22.64 (4.461)		19.38 (5.364)		20.67 (9.331)	
		Median	23.40		19.75		15.90	
		Min; Max	14.6; 28.4		13.4; 25.4		11.2; 33.7	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Triacylglycerol Lipase (IU/L)	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	24.20 (9.655)		25.39 (3.632)		14.93 (7.870)		20.30 (7.764)	
		Median	29.10		26.20		12.10		18.60	
		Min; Max	8.5; 33.7		19.6; 30.1		4.0; 25.2		4.0; 33.7	
	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	22.93 (11.349)		24.45 (8.072)		16.87 (12.098)		20.86 (8.513)	
		Median	23.80		25.70		13.45		20.85	
		Min; Max	5.3; 37.9		12.3; 35.4		5.4; 32.8		5.3; 37.9	
	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	25.00 (10.083)		24.65 (5.253)		18.37 (10.682)		21.78 (7.767)	
		Median	25.15		24.95		14.55		23.00	
		Min; Max	9.7; 37.4		15.7; 31.8		8.6; 33.5		8.6; 37.4	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Treatment Sequence 1 (N=7) Change	Treatment Sequence 2 (N=7) Observed	Treatment Sequence 2 (N=7) Change	Treatment Sequence 3 (N=7) Observed	Treatment Sequence 3 (N=7) Change
Triacylglycerol Lipase (IU/L)	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	26.27 (9.193)	3.96 (7.706)	19.77 (10.338)	-4.37 (18.849)	19.36 (6.658)	0.44 (4.152)
		Median	24.70	0.80	17.80	-1.40	19.70	-0.50
		Min; Max	16.0; 45.1	-3.6; 18.2	10.8; 40.3	-41.1; 22.7	10.0; 29.5	-4.8; 7.2
Triiodothyronine (nmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	1.563 (0.187)		1.453 (0.110)		1.560 (0.186)	
		Median	1.530		1.460		1.530	
		Min; Max	1.27; 1.88		1.24; 1.59		1.32; 1.85	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	1.627 (0.325)		1.576 (0.172)		1.626 (0.114)	
		Median	1.760		1.510		1.670	
		Min; Max	0.96; 1.91		1.41; 1.93		1.42; 1.77	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Triacylglycerol Lipase (IU/L)	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	24.63 (12.688)	4.30 (6.126)	23.53 (7.969)	0.14 (11.976)	15.36 (6.929)	1.00 (2.997)	21.49 (9.401)	0.91 (9.973)
		Median	20.80	3.50	24.60	0.70	14.20	0.60	20.25	0.30
		Min; Max	5.0; 41.8	-1.1; 16.2	15.5; 37.0	-24.7; 12.1	7.2; 26.2	-4.1; 4.4	5.0; 45.1	-41.1; 22.7
Triiodothyronine (nmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	1.610 (0.187)		1.534 (0.150)		1.586 (0.087)		1.551 (0.155)	
		Median	1.620		1.480		1.580		1.530	
		Min; Max	1.36; 1.89		1.39; 1.82		1.50; 1.76		1.24; 1.89	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	1.641 (0.161)		1.650 (0.226)		1.644 (0.214)		1.627 (0.201)	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

		Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Visit/ Test (Unit) Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	1.640		1.650		1.600		1.635	
	Min; Max	1.41; 1.91		1.35; 1.92		1.35; 2.04		0.96; 2.04	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Treatment Sequence 1 (N=7) Change	Treatment Sequence 2 (N=7) Observed	Treatment Sequence 2 (N=7) Change	Treatment Sequence 3 (N=7) Observed	Treatment Sequence 3 (N=7) Change
Triiodothyronine (nmol/L)	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	1.639 (0.231)		1.508 (0.166)		1.660 (0.181)	
		Median	1.660		1.450		1.630	
		Min; Max	1.25; 1.86		1.40; 1.84		1.47; 2.00	
	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	1.589 (0.140)		1.862 (1.103)		1.523 (0.206)	
		Median	1.530		1.545		1.570	
		Min; Max	1.43; 1.78		1.04; 4.06		1.28; 1.75	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	1.569 (0.170)	0.006 (0.130)	1.544 (0.121)	0.091 (0.119)	1.541 (0.193)	-0.019 (0.199)
		Median	1.590	-0.020	1.510	0.090	1.500	-0.030
		Min; Max	1.25; 1.75	-0.18; 0.22	1.45; 1.81	-0.08; 0.26	1.25; 1.82	-0.22; 0.29

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Triiodothyronine (nmol/L)	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	1.603 (0.118)		1.597 (0.159)		1.617 (0.095)		1.606 (0.163)	
		Median	1.565		1.550		1.630		1.590	
		Min; Max	1.48; 1.78		1.45; 1.90		1.45; 1.71		1.25; 2.00	
	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	1.617 (0.285)		1.538 (0.133)		1.625 (0.086)		1.622 (0.449)	
		Median	1.625		1.525		1.640		1.560	
		Min; Max	1.14; 1.98		1.34; 1.73		1.52; 1.74		1.04; 4.06	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	1.606 (0.215)	-0.004 (0.136)	1.479 (0.292)	-0.056 (0.171)	1.529 (0.071)	-0.057 (0.125)	1.545 (0.183)	-0.006 (0.149)
		Median	1.520	-0.010	1.440	-0.070	1.520	-0.080	1.510	-0.015
		Min; Max	1.34; 1.88	-0.21; 0.14	1.17; 2.08	-0.24; 0.26	1.43; 1.66	-0.24; 0.14	1.17; 2.08	-0.24; 0.29

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Triiodothyronine, Free (pmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	4.417 (0.611)		4.149 (0.379)		4.489 (0.538)	
		Median	4.530		4.300		4.380	
		Min; Max	3.51; 5.18		3.49; 4.54		3.95; 5.61	
	Follow-Up	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	3.957 (0.532)		4.047 (0.286)		3.973 (0.429)	
		Median	3.810		4.120		3.930	
		Min; Max	3.09; 4.70		3.58; 4.50		3.44; 4.75	
Urea (mmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	3.711 (1.314)		3.894 (1.176)		3.530 (0.502)	
		Median	3.540		3.640		3.360	
		Min; Max	2.61; 6.45		2.10; 5.23		2.88; 4.44	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Triiodothyronine, Free (pmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	4.560 (0.323)		4.346 (0.373)		4.351 (0.459)		4.385 (0.449)	
		Median	4.640		4.430		4.130		4.385	
		Min; Max	3.95; 4.85		3.82; 4.82		3.98; 5.28		3.49; 5.61	
	Follow-Up	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	4.189 (0.582)		3.930 (0.645)		3.933 (0.187)		4.005 (0.452)	
		Median	4.130		3.780		4.030		3.935	
		Min; Max	3.38; 4.78		3.38; 5.31		3.60; 4.11		3.09; 5.31	
Urea (mmol/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	4.693 (0.892)		3.890 (1.072)		4.217 (1.183)		3.989 (1.062)	
		Median	4.660		3.510		3.730		3.670	
		Min; Max	3.21; 5.92		2.61; 5.38		2.80; 6.41		2.10; 6.45	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Urea (mmol/L)	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	3.670 (0.821)		4.363 (0.925)		3.423 (0.813)	
		Median	3.500		4.470		3.690	
		Min; Max	2.80; 5.27		2.96; 5.39		2.42; 4.48	
	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	4.279 (1.358)		5.027 (1.179)		4.099 (0.730)	
		Median	4.060		5.275		4.230	
		Min; Max	2.31; 6.52		3.52; 6.28		2.84; 4.94	
	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	3.816 (0.920)		4.765 (0.952)		4.017 (0.555)	
		Median	3.740		4.640		4.170	
		Min; Max	2.21; 5.03		3.87; 6.48		2.92; 4.65	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Urea (mmol/L)	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	4.696 (0.984)		4.064 (0.539)		4.720 (1.700)		4.156 (1.083)	
		Median	4.180		4.020		4.850		4.030	
		Min; Max	3.77; 6.47		3.19; 4.88		3.05; 7.86		2.42; 7.86	
	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	4.462 (0.551)		3.743 (0.726)		4.893 (1.237)		4.405 (1.042)	
		Median	4.570		3.640		4.900		4.400	
		Min; Max	3.71; 5.12		2.66; 4.63		3.08; 6.59		2.31; 6.59	
	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	4.502 (0.771)		3.387 (0.561)		4.818 (1.301)		4.202 (0.965)	
		Median	4.470		3.365		4.505		4.145	
		Min; Max	3.76; 5.87		2.61; 4.11		3.43; 7.03		2.21; 7.03	

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Urea (mmol/L)	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	4.166 (1.257)	0.454 (1.185)	4.309 (1.236)	0.414 (0.747)	3.477 (0.586)	-0.053 (0.512)
		Median	4.200	0.800	4.570	0.470	3.310	-0.220
		Min; Max	2.73; 6.14	-1.10; 1.82	2.40; 5.74	-0.49; 1.50	2.70; 4.22	-0.52; 0.90

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Urea (mmol/L)	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	4.889 (1.008)	0.196 (1.463)	3.813 (0.903)	-0.077 (1.090)	5.124 (1.900)	0.907 (1.259)	4.296 (1.279)	0.307 (1.077)
		Median	4.830	0.380	4.170	-0.470	5.420	0.660	4.210	0.340
		Min; Max	3.46; 6.71	-2.46; 2.05	2.61; 5.06	-1.11; 1.86	2.70; 7.95	-1.03; 3.10	2.40; 7.95	-2.46; 3.10

Baseline 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 in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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)

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	Treatment A (N=38) Observed	Change	Treatment B (N=40) Observed	Change	Treatment C (N=39) Observed	Change	Total (N=42) Observed	Change
Supine Systolic Blood Pressure (mmHg)	Screening	n (missing)							42 (0)	
		Mean (SD)							114.7 (10.04)	
		Median							114.5	
		Min; Max							95; 138	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	113.1 (13.86)		113.1 (10.34)		113.5 (11.10)			
		Median	111.0		112.0		112.0			
		Min; Max	87; 147		88; 139		92; 142			
	Day 1 0 H/ 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	111.2 (11.19)		110.4 (10.66)		112.8 (10.80)			
		Median	112.0		110.0		113.0			
		Min; Max	90; 142		87; 140		89; 135			

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Systolic Blood Pressure (mmHg)	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	110.9 (10.41)	-0.3 (8.58)	111.5 (11.09)	1.1 (7.11)	111.9 (9.36)	-0.9 (9.13)		
		Median	110.0	1.5	110.5	2.0	111.0	-1.0		
		Min; Max	95; 136	-23; 15	90; 133	-13; 18	88; 132	-30; 19		
	Day 1/ 3 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	112.7 (12.89)	1.5 (7.79)	113.1 (8.46)	2.7 (7.24)	113.8 (9.08)	1.0 (8.59)		
		Median	112.0	2.0	112.5	2.5	114.0	1.0		
		Min; Max	85; 148	-16; 19	97; 137	-15; 14	94; 136	-14; 25		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	110.9 (11.01)	-0.3 (7.86)	111.2 (10.72)	0.8 (6.46)	110.0 (8.53)	-2.8 (8.56)		
		Median	109.5	-1.0	111.0	1.0	111.0	-2.0		
		Min; Max	93; 139	-19; 19	92; 136	-12; 19	90; 125	-29; 25		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Systolic Blood Pressure (mmHg)	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	112.2 (10.03)	1.0 (5.52)	113.2 (11.07)	2.8 (8.33)	112.8 (10.08)	-0.0 (8.31)		
		Median	113.5	1.0	114.0	1.0	113.0	0.0		
		Min; Max	91; 135	-10; 13	92; 134	-12; 21	86; 133	-27; 18		
	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	110.4 (11.29)	-0.8 (8.88)	111.6 (11.81)	1.2 (7.30)	111.4 (9.52)	-1.4 (10.16)		
		Median	109.0	0.5	111.5	1.0	110.0	-5.0		
		Min; Max	86; 135	-21; 15	87; 137	-16; 15	92; 136	-23; 20		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	111.0 (10.61)	-0.2 (7.56)	112.2 (10.23)	2.4 (7.57)	110.6 (11.37)	-2.2 (10.27)		
		Median	111.0	-1.0	112.0	2.5	107.0	-4.0		
		Min; Max	90; 137	-18; 20	86; 134	-14; 20	92; 140	-26; 19		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
Supine Systolic Blood Pressure (mmHg)	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	111.9 (10.36)	0.2 (7.98)	110.2 (7.63)	0.4 (6.66)	111.6 (9.91)	-1.2 (10.17)		
		Median	112.0	0.0	110.5	1.0	111.0	0.0		
		Min; Max	90; 138	-16; 27	92; 126	-13; 14	91; 133	-31; 24		
	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							114.9 (11.43)	0.1 (8.60)
		Median							114.5	0.5
		Min; Max							86; 138	-16; 34
Supine Diastolic Blood Pressure (mmHg)	Screening	n (missing)							42 (0)	
		Mean (SD)							70.8 (7.78)	
		Median							70.0	
		Min; Max							55; 89	

Baseline defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Diastolic Blood Pressure (mmHg)	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	68.9 (8.38)		68.4 (6.99)		69.9 (7.98)			
		Median	69.0		68.0		70.0			
		Min; Max	51; 88		55; 84		53; 86			
	Day 1 0 H/ 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	67.2 (7.75)		66.8 (8.63)		67.5 (7.56)			
		Median	67.0		66.5		67.0			
		Min; Max	51; 87		51; 88		49; 84			
	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	65.6 (7.77)	-1.6 (5.40)	66.4 (8.18)	-0.4 (5.31)	66.8 (7.70)	-0.7 (5.69)		
		Median	64.5	-2.5	66.5	0.5	67.0	-1.0		
		Min; Max	54; 87	-12; 11	43; 83	-14; 9	53; 80	-16; 9		

Baseline 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.
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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Diastolic Blood Pressure (mmHg)	Day 1/ 3 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	65.7 (9.42)	-1.5 (5.43)	66.9 (8.45)	0.1 (5.86)	66.9 (7.59)	-0.6 (4.48)		
		Median	66.5	-1.0	67.5	0.0	67.0	-1.0		
		Min; Max	40; 88	-18; 9	49; 85	-12; 13	55; 90	-13; 10		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	65.0 (8.07)	-2.3 (6.33)	64.5 (7.01)	-2.3 (5.49)	64.0 (6.84)	-3.5 (5.94)		
		Median	63.0	-4.0	64.0	-2.0	63.0	-3.0		
		Min; Max	49; 83	-17; 16	49; 84	-15; 15	51; 85	-21; 10		
	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	64.9 (7.00)	-2.3 (4.24)	65.0 (8.03)	-1.8 (4.68)	64.8 (7.93)	-2.7 (5.27)		
		Median	65.5	-2.0	63.5	-2.0	66.0	-3.0		
		Min; Max	49; 83	-10; 11	41; 82	-13; 7	50; 85	-15; 7		

Baseline defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Diastolic Blood Pressure (mmHg)	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	67.0 (7.24)	-0.2 (4.96)	67.9 (8.21)	1.2 (4.68)	66.2 (7.47)	-1.4 (6.59)		
		Median	67.0	0.5	67.0	1.0	67.0	0.0		
		Min; Max	52; 82	-15; 9	45; 85	-8; 13	48; 82	-17; 12		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	68.4 (6.01)	1.2 (5.74)	68.8 (7.54)	2.6 (6.18)	67.8 (7.66)	0.3 (4.86)		
		Median	68.5	-0.5	68.0	3.0	68.0	0.0		
		Min; Max	54; 81	-14; 14	55; 85	-13; 18	53; 84	-10; 8		
	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	68.4 (7.81)	0.9 (7.09)	68.1 (7.23)	1.9 (6.38)	68.2 (6.77)	0.7 (5.45)		
		Median	68.0	1.0	68.0	2.0	66.0	1.0		
		Min; Max	55; 92	-13; 22	54; 83	-12; 14	59; 85	-10; 15		

Baseline defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Diastolic Blood Pressure (mmHg)	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							70.7 (7.06)	-0.1 (6.02)
		Median							71.0	1.0
		Min; Max							57; 91	-15; 10
Supine Pulse Rate (beats/min)	Screening	n (missing)							42 (0)	
		Mean (SD)							63.9 (7.40)	
		Median							62.0	
		Min; Max							47; 80	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	66.3 (10.22)		63.1 (9.93)		65.2 (11.25)			
		Median	67.5		63.5		64.0			
		Min; Max	44; 91		44; 82		45; 88			

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Pulse Rate (beats/min)	Day 1 0 H/ 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	59.4 (9.50)		58.0 (9.22)		59.8 (9.91)			
		Median	56.0		55.5		59.0			
		Min; Max	43; 82		40; 79		42; 82			
	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	58.7 (8.86)	-0.7 (6.04)	59.8 (9.45)	1.8 (5.10)	59.5 (9.68)	-0.3 (6.49)		
		Median	58.5	0.0	59.0	2.0	60.0	0.0		
		Min; Max	41; 83	-17; 14	43; 81	-6; 14	40; 76	-23; 12		
	Day 1/ 3 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	58.1 (7.75)	-1.3 (5.29)	57.2 (7.88)	-0.8 (5.24)	58.5 (8.17)	-1.3 (6.91)		
		Median	58.5	-1.0	57.0	-1.0	60.0	-1.0		
		Min; Max	41; 76	-14; 7	40; 74	-11; 10	42; 74	-24; 11		

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Pulse Rate (beats/min)	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	66.3 (8.90)	6.8 (6.15)	65.4 (8.27)	7.4 (5.12)	66.4 (9.92)	6.6 (7.70)		
		Median	66.5	8.5	66.5	7.0	68.0	7.0		
		Min; Max	43; 84	-10; 17	50; 81	-6; 16	43; 85	-23; 19		
	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	65.6 (10.31)	6.1 (6.35)	66.1 (8.89)	8.1 (6.55)	66.8 (9.43)	7.0 (7.60)		
		Median	65.0	4.5	66.0	7.0	67.0	8.0		
		Min; Max	45; 86	-4; 22	46; 88	-6; 24	44; 86	-19; 19		
	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	62.3 (9.45)	2.8 (5.47)	63.5 (10.17)	5.5 (6.14)	63.9 (12.46)	4.2 (10.58)		
		Median	63.0	2.5	62.0	5.5	62.0	5.0		
		Min; Max	42; 83	-9; 15	48; 86	-5; 20	46; 102	-22; 35		

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Supine Pulse Rate (beats/min)	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	65.7 (9.09)	6.3 (7.50)	66.8 (9.79)	9.0 (7.80)	65.5 (10.32)	5.7 (8.86)		
		Median	65.0	5.5	65.5	7.0	67.0	8.0		
		Min; Max	47; 81	-9; 26	48; 85	-8; 35	45; 86	-22; 22		
	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	66.5 (10.83)	7.0 (8.04)	63.8 (10.38)	6.0 (6.82)	65.4 (10.98)	5.6 (9.57)		
		Median	66.0	6.0	62.5	6.0	66.0	8.0		
		Min; Max	44; 86	-9; 30	49; 86	-8; 22	42; 88	-28; 26		
	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							63.1 (9.47)	-0.8 (6.06)
		Median							62.0	-1.0
		Min; Max							43; 83	-13; 16

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Temperature (C)	Screening	n (missing)							42 (0)	
		Mean (SD)							36.30 (0.251)	
		Median							36.30	
		Min; Max							36.0; 36.8	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	36.32 (0.266)		36.29 (0.296)		36.28 (0.267)			
		Median	36.30		36.30		36.30			
		Min; Max	35.8; 36.8		35.7; 36.8		36.0; 37.0			
	Day 1 0 H/ 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	36.25 (0.241)		36.25 (0.248)		36.24 (0.281)			
		Median	36.20		36.15		36.10			
		Min; Max	36.0; 36.7		36.0; 36.8		36.0; 37.1			

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Temperature (C)	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	36.39 (0.277)	0.14 (0.324)	36.38 (0.263)	0.13 (0.324)	36.37 (0.280)	0.13 (0.326)		
		Median	36.40	0.20	36.35	0.10	36.40	0.10		
		Min; Max	36.0; 36.9	-0.6; 0.8	36.0; 36.9	-0.5; 0.8	35.9; 37.3	-0.9; 0.6		
	Day 1/ 3 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	36.49 (0.264)	0.24 (0.307)	36.40 (0.284)	0.15 (0.294)	36.39 (0.323)	0.16 (0.375)		
		Median	36.50	0.20	36.40	0.10	36.40	0.10		
		Min; Max	36.0; 36.9	-0.5; 0.9	36.0; 37.1	-0.5; 0.8	35.9; 37.1	-0.9; 0.9		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	36.52 (0.267)	0.27 (0.299)	36.56 (0.287)	0.31 (0.310)	36.55 (0.325)	0.32 (0.327)		
		Median	36.50	0.30	36.60	0.30	36.50	0.30		
		Min; Max	36.0; 37.0	-0.4; 0.8	36.0; 37.0	-0.2; 1.0	36.0; 37.2	-0.4; 1.1		

Baseline defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
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Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
Vital Sign (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Temperature (C)	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	36.48 (0.337)	0.23 (0.383)	36.59 (0.303)	0.34 (0.338)	36.54 (0.306)	0.30 (0.453)		
		Median	36.45	0.30	36.60	0.30	36.50	0.40		
		Min; Max	36.0; 37.5	-0.7; 1.1	36.0; 37.2	-0.4; 1.1	36.0; 37.2	-0.7; 1.0		
	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	36.31 (0.244)	0.06 (0.282)	36.34 (0.267)	0.09 (0.289)	36.34 (0.307)	0.10 (0.346)		
		Median	36.30	0.00	36.40	0.00	36.30	0.00		
		Min; Max	36.0; 37.0	-0.5; 0.6	36.0; 36.9	-0.5; 0.6	36.0; 37.1	-1.0; 0.6		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	36.28 (0.234)	0.02 (0.287)	36.32 (0.258)	0.08 (0.307)	36.33 (0.278)	0.09 (0.408)		
		Median	36.25	0.00	36.40	0.00	36.40	0.10		
		Min; Max	36.0; 36.8	-0.5; 0.6	36.0; 36.9	-0.6; 0.9	36.0; 36.9	-0.8; 0.9		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
Temperature (C)	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	36.27 (0.231)	0.02 (0.290)	36.31 (0.269)	0.07 (0.367)	36.35 (0.268)	0.11 (0.397)		
		Median	36.20	0.00	36.30	0.00	36.30	0.10		
		Min; Max	36.0; 36.8	-0.7; 0.6	36.0; 36.8	-0.8; 0.8	36.0; 36.9	-1.1; 0.9		
	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							36.25 (0.244)	-0.04 (0.305)
		Median							36.20	0.00
		Min; Max							36.0; 36.7	-0.8; 0.6

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

/project24/ep/blinded/e210898_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.6.1.1.sas

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

ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Treatment A (N=38) Observed	Change	Treatment B (N=40) Observed	Change	Treatment C (N=39) Observed	Change	Total (N=42) Observed	Change
PR Interval (msec)	Screening	n (missing)							42 (0)	
		Mean (SD)							158.5 (22.46)	
		Median							151.0	
		Min; Max							128; 218	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	158.5 (21.98)		156.5 (24.07)		156.8 (23.73)			
		Median	153.0		151.0		150.0			
		Min; Max	132; 212		128; 220		126; 212			
	Day 1/ 0 H 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	159.9 (21.59)		161.5 (24.52)		162.2 (23.68)			
		Median	155.0		154.0		156.0			
		Min; Max	128; 220		120; 220		118; 214			

Baseline 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.
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Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
PR Interval (msec)	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	157.9 (23.93)	-1.9 (9.83)	159.3 (23.92)	-2.2 (7.44)	158.1 (22.99)	-4.1 (9.48)		
		Median	152.0	-2.0	153.0	-2.0	150.0	-2.0		
		Min; Max	124; 224	-26; 24	124; 220	-30; 10	126; 214	-28; 16		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	155.6 (22.57)	-4.3 (7.72)	156.1 (21.07)	-5.4 (7.70)	153.4 (20.77)	-8.7 (12.32)		
		Median	149.0	-5.0	151.0	-5.0	148.0	-10.0		
		Min; Max	124; 218	-22; 12	128; 208	-24; 14	120; 204	-36; 30		
	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	155.7 (23.58)	-4.2 (10.73)	155.7 (22.89)	-5.8 (9.52)	157.3 (24.51)	-4.8 (11.93)		
		Median	152.0	-5.0	150.0	-6.0	150.0	-4.0		
		Min; Max	118; 212	-30; 20	120; 212	-30; 16	128; 228	-28; 28		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
PR Interval (msec)	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	157.9 (22.95)	-1.9 (7.60)	158.0 (20.73)	-3.5 (9.56)	157.9 (21.59)	-4.3 (11.31)		
		Median	151.0	-1.0	150.0	-2.0	156.0	-2.0		
		Min; Max	126; 220	-24; 14	126; 208	-30; 14	106; 208	-30; 18		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	157.5 (23.06)	-2.4 (10.96)	158.3 (25.12)	-4.2 (10.07)	159.2 (23.88)	-2.9 (8.61)		
		Median	154.0	-1.0	150.0	-2.0	154.0	-4.0		
		Min; Max	126; 208	-28; 18	118; 218	-32; 10	108; 216	-22; 18		
	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	157.3 (23.94)	-3.1 (10.14)	156.4 (23.79)	-6.1 (8.03)	158.8 (23.54)	-3.3 (9.44)		
		Median	150.0	-2.0	150.0	-4.0	156.0	-6.0		
		Min; Max	126; 218	-26; 18	126; 210	-26; 12	126; 218	-26; 18		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
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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	Treatment A (N=38) Observed	Change	Treatment B (N=40) Observed	Change	Treatment C (N=39) Observed	Change	Total (N=42) Observed	Change
PR Interval (msec)	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							157.5 (22.68)	-1.0 (8.66)
		Median							149.0	0.0
		Min; Max							124; 206	-26; 18
QRS Interval (msec)	Screening	n (missing)							42 (0)	
		Mean (SD)							96.8 (9.62)	
		Median							97.0	
		Min; Max							78; 118	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	96.2 (9.71)		96.1 (9.06)		94.7 (8.88)			
		Median	96.0		96.0		94.0			
		Min; Max	80; 122		80; 118		76; 114			

Baseline 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.
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Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QRS Interval (msec)	Day 1/ 0 H 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	95.7 (9.38)		95.9 (8.53)		96.1 (8.83)			
		Median	94.0		95.0		98.0			
		Min; Max	82; 118		78; 116		78; 116			
	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	94.2 (9.26)	-1.6 (3.78)	94.2 (9.50)	-1.7 (4.16)	93.9 (8.34)	-2.1 (3.46)		
		Median	93.0	-1.0	92.0	-2.0	94.0	-2.0		
		Min; Max	80; 118	-8; 8	78; 116	-12; 12	80; 116	-12; 4		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	93.1 (9.45)	-2.6 (3.51)	93.5 (9.83)	-2.4 (4.71)	93.7 (8.81)	-2.4 (3.72)		
		Median	92.0	-2.0	92.0	-2.0	92.0	-2.0		
		Min; Max	78; 118	-10; 4	74; 120	-10; 10	78; 114	-8; 4		

Baseline 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.
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QRS Interval (msec)	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	94.9 (10.12)	-0.8 (4.66)	95.5 (9.62)	-0.4 (5.49)	94.7 (9.08)	-1.4 (5.27)		
		Median	94.0	0.0	95.0	0.0	94.0	-2.0		
		Min; Max	78; 120	-14; 8	74; 116	-10; 12	80; 120	-14; 10		
	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	94.2 (8.76)	-1.5 (3.98)	94.0 (9.27)	-1.9 (5.14)	94.8 (9.17)	-1.3 (4.41)		
		Median	94.0	-2.0	94.0	-2.0	94.0	-2.0		
		Min; Max	80; 116	-8; 6	78; 118	-10; 14	80; 120	-12; 8		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	95.1 (9.14)	-0.7 (4.14)	94.9 (9.39)	-1.2 (6.44)	95.2 (9.17)	-0.9 (4.61)		
		Median	94.0	0.0	96.0	-1.0	94.0	0.0		
		Min; Max	80; 118	-10; 8	80; 118	-14; 18	76; 114	-12; 6		

Baseline 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.
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Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QRS Interval (msec)	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	94.2 (9.82)	-1.4 (4.52)	95.6 (9.81)	-0.5 (5.45)	95.3 (8.61)	-0.8 (4.04)		
		Median	94.0	-2.0	96.0	0.0	96.0	-2.0		
		Min; Max	80; 116	-12; 10	76; 118	-10; 14	80; 116	-8; 8		
	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							95.0 (9.74)	-1.8 (7.84)
		Median							94.0	0.0
		Min; Max							76; 120	-14; 18
QT Interval (msec)	Screening	n (missing)							42 (0)	
		Mean (SD)							393.5 (23.05)	
		Median							393.0	
		Min; Max							354; 458	

Baseline 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.
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QT Interval (msec)	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	402.5 (27.93)		406.9 (25.89)		403.5 (26.70)			
		Median	399.0		404.0		402.0			
		Min; Max	354; 482		356; 468		364; 460			
	Day 1/ 0 H 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	413.5 (25.82)		415.7 (28.13)		415.4 (29.36)			
		Median	412.0		415.0		418.0			
		Min; Max	380; 496		368; 506		362; 514			
	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	413.4 (30.02)	-0.1 (12.57)	412.3 (27.31)	-3.4 (10.82)	409.7 (28.56)	-5.6 (13.44)		
		Median	413.0	-2.0	413.0	-3.0	410.0	-6.0		
		Min; Max	374; 526	-20; 30	364; 486	-22; 20	352; 494	-34; 30		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
QT Interval (msec)	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	391.8 (25.67)	-21.6 (12.61)	391.0 (24.63)	-24.7 (11.34)	390.7 (26.26)	-24.7 (13.78)		
		Median	386.0	-25.0	384.0	-25.0	392.0	-24.0		
		Min; Max	348; 478	-44; 10	348; 470	-46; 0	352; 494	-56; 10		
	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	392.7 (26.63)	-20.7 (13.16)	392.8 (22.95)	-22.9 (15.52)	391.4 (26.75)	-24.0 (15.59)		
		Median	391.0	-22.0	387.0	-21.0	388.0	-24.0		
		Min; Max	346; 488	-44; 12	350; 458	-50; 10	340; 488	-52; 8		
	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	407.2 (26.81)	-6.3 (13.76)	405.9 (25.30)	-9.8 (14.00)	406.7 (28.19)	-8.7 (15.00)		
		Median	404.0	-6.0	411.0	-9.0	406.0	-12.0		
		Min; Max	368; 490	-34; 30	358; 462	-44; 24	334; 478	-44; 36		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QT Interval (msec)	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	401.7 (27.27)	-11.7 (16.82)	400.5 (22.57)	-16.6 (15.77)	400.3 (30.33)	-15.1 (17.70)		
		Median	400.0	-13.0	397.0	-16.0	396.0	-16.0		
		Min; Max	350; 490	-42; 18	354; 460	-60; 14	358; 506	-46; 28		
	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	401.5 (27.56)	-12.6 (20.37)	405.5 (27.01)	-11.5 (14.85)	403.7 (30.88)	-11.6 (18.83)		
		Median	400.0	-16.0	405.0	-10.0	398.0	-14.0		
		Min; Max	348; 460	-48; 36	354; 504	-44; 18	354; 500	-40; 30		
	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							399.5 (28.38)	6.0 (17.28)
		Median							395.0	8.0
		Min; Max							362; 506	-36; 48

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Change	Treatment B (N=40) Observed	Change	Treatment C (N=39) Observed	Change	Total (N=42) Observed	Change
QTcB - Bazett's Correction Formula (msec)	Screening	n (missing)							42 (0)	
		Mean (SD)							401.9 (23.11)	
		Median							400.5	
		Min; Max							347; 463	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	417.6 (20.01)		415.4 (23.35)		414.7 (20.39)			
		Median	412.5		416.0		415.0			
		Min; Max	379; 472		369; 468		352; 459			
	Day 1/ 0 H 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	412.3 (21.09)		409.7 (23.21)		407.3 (17.52)			
		Median	410.0		404.5		409.0			
		Min; Max	373; 473		364; 462		360; 439			

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QTcB - Bazett's Correction Formula (msec)	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	409.3 (20.76)	-3.1 (17.96)	408.6 (22.85)	-1.1 (12.91)	407.2 (20.55)	-0.1 (15.73)		
		Median	407.0	-3.0	409.0	4.0	409.0	2.0		
		Min; Max	370; 448	-59; 22	358; 466	-31; 18	367; 462	-42; 35		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	408.5 (20.88)	-3.8 (17.30)	409.2 (18.88)	-0.5 (18.02)	408.4 (19.29)	1.1 (15.03)		
		Median	409.0	-1.0	410.5	1.0	408.0	2.0		
		Min; Max	366; 457	-48; 23	373; 451	-41; 34	368; 449	-39; 36		
	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	412.2 (19.49)	-0.2 (19.15)	412.3 (19.80)	2.6 (17.86)	411.9 (17.81)	4.6 (16.20)		
		Median	412.5	2.5	414.5	7.0	412.0	2.0		
		Min; Max	365; 445	-46; 31	382; 473	-45; 45	377; 448	-40; 34		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QTcB - Bazett's Correction Formula (msec)	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	411.7 (21.69)	-0.7 (22.42)	412.1 (20.86)	2.5 (15.53)	414.8 (19.77)	7.5 (17.85)		
		Median	412.5	-3.0	408.5	4.5	414.0	3.0		
		Min; Max	368; 460	-37; 66	373; 467	-32; 40	375; 450	-30; 60		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	417.0 (19.18)	4.6 (14.31)	414.3 (22.93)	3.8 (18.31)	411.4 (20.72)	4.0 (15.57)		
		Median	418.0	2.0	414.5	2.0	412.0	6.0		
		Min; Max	368; 453	-21; 47	372; 463	-31; 49	367; 461	-32; 36		
	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	412.3 (21.05)	-0.1 (15.35)	416.7 (20.23)	6.2 (17.82)	414.4 (19.69)	7.1 (19.78)		
		Median	408.0	2.0	419.0	7.0	420.0	8.0		
		Min; Max	372; 469	-39; 34	377; 455	-30; 43	373; 445	-45; 62		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Change	Treatment B (N=40) Observed	Change	Treatment C (N=39) Observed	Change	Total (N=42) Observed	Change
QTcB - Bazett's Correction Formula (msec)	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							404.5 (22.65)	2.7 (14.61)
		Median							406.0	1.0
		Min; Max							341; 463	-40; 43
QTcF - Fridericia's Correction Formula (msec)	Screening	n (missing)							42 (0)	
		Mean (SD)							398.9 (19.41)	
		Median							396.0	
		Min; Max							351; 444	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	412.2 (18.22)		412.2 (18.62)		410.6 (15.91)			
		Median	412.0		411.0		412.0			
		Min; Max	378; 466		381; 450		358; 438			

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QTcF - Fridericia's Correction Formula (msec)	Day 1/ 0 H 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	412.5 (18.07)		411.4 (20.09)		409.7 (14.98)			
		Median	411.5		409.0		412.0			
		Min; Max	379; 481		369; 461		366; 452			
	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	410.3 (18.82)	-2.2 (11.94)	409.6 (20.07)	-1.8 (9.10)	407.7 (16.77)	-1.9 (10.97)		
		Median	408.5	-1.0	407.0	-1.0	410.0	-1.0		
		Min; Max	381; 463	-33; 19	366; 453	-25; 11	366; 444	-25; 17		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	402.6 (17.98)	-9.9 (12.18)	402.7 (16.34)	-8.6 (14.18)	402.2 (16.29)	-7.5 (10.24)		
		Median	403.0	-8.5	404.5	-7.0	403.0	-6.0		
		Min; Max	366; 445	-36; 11	364; 435	-37; 23	370; 450	-30; 9		

Baseline 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.
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QTcF - Fridericia's Correction Formula (msec)	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	405.4 (15.91)	-7.2 (13.25)	405.5 (15.78)	-5.9 (13.71)	404.6 (15.84)	-5.1 (13.06)		
		Median	405.0	-5.0	404.0	-3.5	405.0	-8.0		
		Min; Max	368; 448	-33; 17	380; 441	-40; 22	376; 446	-29; 22		
	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	409.8 (16.08)	-2.7 (15.83)	409.8 (16.20)	-1.6 (12.33)	411.7 (15.90)	2.0 (13.66)		
		Median	411.5	-2.0	409.0	-2.0	412.0	0.0		
		Min; Max	373; 461	-32; 40	383; 455	-27; 28	370; 441	-20; 42		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	411.7 (17.71)	-0.8 (10.12)	409.4 (17.86)	-3.0 (14.47)	407.4 (18.08)	-2.3 (12.64)		
		Median	412.0	-2.5	409.5	-4.5	410.0	-2.0		
		Min; Max	369; 464	-20; 22	377; 446	-29; 35	365; 458	-23; 28		

Baseline defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
QTcF - Fridericia's Correction Formula (msec)	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	408.4 (17.26)	-4.3 (12.91)	412.8 (17.59)	0.4 (14.62)	410.5 (17.56)	0.8 (14.11)		
		Median	410.0	-5.0	415.5	2.0	411.0	2.0		
		Min; Max	374; 445	-39; 19	376; 465	-28; 34	370; 456	-25; 30		
	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							402.7 (19.61)	3.8 (12.86)
		Median							403.5	4.0
		Min; Max							348; 456	-37; 33
RR Interval (msec)	Screening	n (missing)							42 (0)	
		Mean (SD)							966.6 (126.04)	
		Median							975.0	
		Min; Max							736; 1234	

Baseline defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
RR Interval (msec)	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	936.8 (133.33)		970.7 (152.88)		957.7 (157.95)			
		Median	928.0		972.0		952.0			
		Min; Max	676; 1224		710; 1266		700; 1290			
	Day 1/ 0 H 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	1014.4 (141.34)		1039.2 (153.02)		1050.9 (175.22)			
		Median	1025.0		1057.0		1042.0			
		Min; Max	714; 1282		764; 1324		782; 1468			
	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	1029.8 (168.33)	15.4 (136.84)	1026.9 (147.41)	-12.3 (82.82)	1024.8 (178.55)	-26.2 (109.29)		
		Median	982.0	4.0	1020.0	-19.0	1000.0	-24.0		
		Min; Max	778; 1598	-202; 536	796; 1322	-190; 170	738; 1536	-292; 304		

Baseline defined as Day 1 (predose) in each treatment period; Baseline is defined as Screening for Follow-Up results.
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Table 15.3.6.2.1 Summary of ECG Evaluations by Treatment and Time Point (Safety Population)

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
RR Interval (msec)	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	927.9 (137.39)	-86.4 (112.27)	920.2 (130.44)	-119.0 (79.79)	923.9 (149.01)	-127.0 (107.71)		
		Median	904.0	-116.0	899.0	-111.0	894.0	-116.0		
		Min; Max	714; 1360	-294; 298	714; 1332	-266; 28	708; 1356	-352; 122		
	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	917.4 (152.24)	-97.0 (121.20)	915.5 (130.68)	-123.7 (104.21)	910.2 (138.51)	-140.7 (100.35)		
		Median	901.0	-120.0	908.0	-130.0	898.0	-144.0		
		Min; Max	674; 1342	-328; 280	652; 1280	-316; 144	686; 1308	-314; 158		
	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	991.6 (173.87)	-22.7 (120.52)	980.6 (156.96)	-58.6 (93.20)	972.7 (169.65)	-78.2 (104.77)		
		Median	994.0	-11.0	963.0	-50.0	950.0	-68.0		
		Min; Max	676; 1400	-274; 338	720; 1286	-280; 108	646; 1358	-268; 212		

Baseline 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.
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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
RR Interval (msec)	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	934.6 (130.09)	-79.7 (115.73)	944.2 (136.60)	-98.1 (99.92)	956.9 (161.76)	-94.0 (113.07)		
		Median	918.0	-81.0	951.0	-90.0	898.0	-120.0		
		Min; Max	710; 1222	-330; 148	718; 1242	-324; 98	686; 1348	-302; 216		
	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	958.8 (158.40)	-58.7 (122.25)	954.4 (137.17)	-87.8 (86.41)	959.7 (170.36)	-91.2 (147.30)		
		Median	968.0	-48.0	968.0	-86.0	928.0	-112.0		
		Min; Max	708; 1370	-380; 308	694; 1276	-286; 100	692; 1456	-508; 362		
	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							985.0 (157.76)	18.5 (94.05)
		Median							962.0	17.0
		Min; Max							738; 1438	-214; 270

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

/project24/ep/blinded/e210898_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.6.2.1.sas

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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	Treatment A (N=38) Observed	Change	Treatment B (N=40) Observed	Change	Treatment C (N=39) Observed	Change	Total (N=42) Observed	Change
Heart Rate (beats/min)	Screening	n (missing)							42 (0)	
		Mean (SD)							62.6 (8.39)	
		Median							61.0	
		Min; Max							48; 81	
	Day -1/ 24 H Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	64.9 (9.31)		62.7 (9.94)		63.8 (10.59)			
		Median	64.0		61.0		63.0			
		Min; Max	49; 88		47; 84		46; 85			
	Day 1/ 0 H 50 Min Predose	n (missing)	38 (0)		40 (0)		39 (0)			
		Mean (SD)	59.8 (8.54)		58.6 (8.74)		58.2 (9.40)			
		Median	58.0		56.0		57.0			
		Min; Max	47; 83		45; 78		40; 76			

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
Heart Rate (beats/min)	Day 1/ 2 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	59.0 (8.26)	-0.8 (5.90)	59.2 (8.34)	0.6 (5.31)	59.8 (9.53)	1.6 (6.39)		
		Median	61.0	-0.5	58.0	1.0	59.0	2.0		
		Min; Max	38; 76	-17; 9	45; 75	-11; 13	42; 81	-13; 20		
	Day 1/ 6 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	65.3 (8.73)	5.5 (5.99)	65.9 (8.57)	7.3 (4.96)	65.9 (9.47)	7.8 (6.81)		
		Median	66.0	7.5	66.0	7.0	66.0	7.0		
		Min; Max	44; 83	-11; 16	45; 84	-3; 16	44; 84	-8; 26		
	Day 1/ 12 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	66.3 (10.29)	6.5 (7.26)	66.0 (9.42)	7.4 (6.47)	66.7 (9.23)	8.5 (6.06)		
		Median	66.0	7.0	65.0	8.0	66.0	9.0		
		Min; Max	44; 88	-11; 25	47; 92	-5; 21	45; 87	-11; 19		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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

			Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
ECG Parameter (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Heart Rate (beats/min)	Day 2/ 24 H Postdose	n (missing)	38 (0)	38 (0)	40 (0)	40 (0)	39 (0)	39 (0)		
		Mean (SD)	61.9 (10.77)	2.1 (7.80)	62.2 (10.04)	3.6 (5.48)	62.8 (10.64)	4.7 (6.59)		
		Median	59.5	1.0	61.5	3.0	62.0	4.0		
		Min; Max	43; 88	-12; 26	47; 83	-5; 13	44; 92	-11; 19		
	Day 3/ 48 H Postdose	n (missing)	38 (0)	38 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	64.8 (8.80)	5.1 (7.19)	64.2 (9.46)	5.7 (6.00)	63.8 (10.03)	5.6 (6.66)		
		Median	64.5	6.0	62.0	5.0	66.0	7.0		
		Min; Max	49; 84	-9; 21	48; 83	-6; 22	44; 87	-10; 16		
	Day 4/ 72 H Postdose	n (missing)	37 (0)	37 (0)	38 (0)	38 (0)	39 (0)	39 (0)		
		Mean (SD)	63.7 (10.50)	4.1 (7.62)	63.5 (9.57)	5.0 (5.64)	63.8 (10.21)	5.6 (8.73)		
		Median	61.0	3.0	61.0	5.0	64.0	7.0		
		Min; Max	43; 84	-12; 25	46; 86	-6; 21	41; 86	-16; 28		

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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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	Treatment A (N=38) Observed	Treatment A (N=38) Change	Treatment B (N=40) Observed	Treatment B (N=40) Change	Treatment C (N=39) Observed	Treatment C (N=39) Change	Total (N=42) Observed	Total (N=42) Change
Heart Rate (beats/min)	Follow-Up	n (missing)							42 (0)	42 (0)
		Mean (SD)							61.6 (8.83)	-1.0 (5.08)
		Median							62.0	-1.0
		Min; Max							41; 80	-11; 11

Baseline 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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15.4 Pharmacokinetic Data

15.4.1 Tables

Merck Serono
EMR 200125-002

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

Treatment: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	49.90	63.57	107.80	124.50
	63.71	66.11	105.00	125.80
	68.74	82.70	112.30	114.90
	61.54	70.61	100.80	114.40
	73.90	109.10	133.20	140.10
	53.70	60.35	70.72	70.57
	58.35	64.86	109.00	104.00
	64.19	82.49	106.00	118.90
	67.89	69.11	87.28	107.50
	60.95	65.64	105.00	113.50
	58.24	65.50	94.39	106.50
	76.11	86.32	132.40	127.60
	73.64	93.83	134.60	136.50
	47.49	80.29	97.93	113.60
	62.03	69.69	86.23	83.99
	54.88	72.60	72.57	97.51
	78.18	88.70	114.00	103.00
	60.52	76.12	67.82	85.87
	55.95	69.88	98.52	112.70
1	60.10	73.66	110.20	102.30

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	60.17	70.48	96.54	108.20
	57.08	51.52	77.32	81.67
	58.20	67.34	113.10	104.20
	61.67	88.76	132.00	126.50
	44.10	59.26	104.20	104.30
	77.89	101.60	145.60	143.60
	58.80	71.28	82.44	126.10
	55.48	60.10	82.11	97.31*
	67.16	72.42	88.29	126.80
	63.60	75.97	72.52	86.11
	55.27	58.98	65.22	82.42
	67.59	89.86	114.60	139.60
[redacted]	74.16	73.93	55.48	93.67
	54.65	61.66	93.91	103.30
	74.41	75.40	100.80	115.10
	81.06	89.59	129.10	129.00
	59.62	78.43	107.40	132.80

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	62.728 (8.9020)	74.533 (12.5726)	100.173 (21.5679)	110.930 (18.2839)
GeoMean	62.116	73.551	97.812	109.395
(95% CI)	(59.239;65.133)	(69.642;77.679)	(90.727;105.449)	(103.303;115.847)
GeoCV(CV%)	14.3 (14.2)	16.5 (16.9)	22.8 (21.5)	17.3 (16.5)
SEM	1.4635	2.0669	3.5457	3.0059
Median	60.953	72.420	100.800	112.700
Min; Max	44.10; 81.06	51.52; 109.10	55.48; 145.60	70.57; 143.60

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
[illegible]2	139.40	129.60	134.70	132.70
[illegible]	127.10	122.20	118.60	123.00
[illegible]	111.10	120.40	114.00	100.60
[illegible]	119.70	121.80	121.70	121.50*
[illegible]	130.60	128.10	123.40	113.00
[illegible]	80.01	89.05	87.39	101.40
[illegible]	102.10	129.70	104.00	127.50
[illegible]	120.70	150.40	99.76	97.38
[illegible]	106.70	110.30	107.10	121.10
[illegible]	111.00	110.50	120.50	118.90
[illegible]	136.90	137.90	143.90	149.10
[illegible]	117.80	117.50	120.20	143.30
[illegible]	128.60	135.70	119.30	122.80
[illegible]	99.99	95.10	98.27	84.50
[illegible]	93.87	90.19	92.79	93.45
[illegible]	89.43	102.70	98.91	98.94
[illegible]	90.55	112.20	116.30	99.12
[illegible]	84.46	97.84	97.93	102.60
[illegible]	100.90	97.90	107.90	116.40
[illegible]	91.57	107.50	92.50	93.08

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
[illegible]	94.75	100.90	99.96	75.62
	82.28	109.50	129.80	111.20
	118.60	121.90	118.30	89.56
	108.90*	124.10	116.40	104.70
	96.21	89.26	73.93	87.50
	140.10	134.20	132.60	127.40
	108.30	137.60	100.60	118.30
	95.99	93.68	91.13	88.22
	123.10	118.40	121.40	123.80
	91.69	107.60	115.20	109.00
	96.52	109.00	88.28	100.80
	116.90	119.20	102.80	102.30
	107.00	111.90	141.00	101.80
	114.30	85.50	107.80	99.12
	123.40	128.30	118.80	122.20
	143.40	139.60	129.80	117.70
	113.10	108.30	112.90	99.73

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	109.649 (17.1326)	114.744 (16.3726)	111.347 (15.8954)	109.171 (16.4949)
GeoMean	108.350	113.594	110.212	107.967
(95% CI)	(102.831;114.166)	(108.247;119.205)	(104.951;115.736)	(102.660;113.549)
GeoCV(CV%)	15.8 (15.6)	14.5 (14.3)	14.7 (14.3)	15.2 (15.1)
SEM	2.8166	2.6916	2.6132	2.7117
Median	108.900	112.200	114.000	104.700
Min; Max	80.01; 143.40	85.50; 150.40	73.93; 143.90	75.62; 149.10

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	113.10	100.90	118.80	101.80	89.57
	107.80	109.00	109.00	98.89	87.53
	104.20	107.50	101.00	105.20	91.65
	107.40	124.90	106.80	107.10	94.09
	114.60*	119.90	128.90	113.40	99.03
	105.30	99.57	105.90	84.80	106.90
	110.90	101.10	96.47	93.73	100.40
	95.55	91.54	106.60	91.80	89.15
	103.90	95.99	99.46	98.06	97.09
	103.30	96.82	103.00	96.38	100.30
	119.10	117.40	117.30	110.00*	111.00
	144.20	144.90	136.80	119.20	116.80
	108.40	117.30	109.20	113.90	103.20
	87.41	86.69	106.10	86.38	86.94
	90.20	87.24	83.43	81.04	79.32
	98.84	91.25	90.98	90.84	89.25
	92.46	107.40	108.70	101.00	98.19
	93.85	88.53	83.93	86.67	75.19
	116.30	110.60	95.05	96.04	84.61
	88.36	89.15	95.14	92.37	68.29

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
[redacted]	87.39	85.72	88.22	89.63	73.85
	102.70	113.30	105.90	109.20	95.90
	98.71*	91.68	109.80	112.50	101.90
	97.23	94.45	92.27	90.39	84.84
	84.89	89.32	77.21	82.98	69.65
	128.30	115.00	134.40	113.50	101.40
	106.00	105.90	102.10	109.30	98.25
	89.41	87.68	95.42	94.57	80.71
	112.50	100.30	111.40	99.83	95.61
	99.76	93.07	87.00	94.57	73.98
	108.80	80.84	61.52	104.80	85.78
	97.16	107.60	99.23	97.85	100.50
	124.50	100.70	108.00	98.73	95.99
	91.33	83.12	80.59	87.72	76.01
	103.00	108.30	99.21	100.50	94.44
	105.00	121.20	131.40	112.90	122.60
	82.96	95.86	121.20	100.50	80.52

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

	Sample Times (h)				
Subject Number/ Random Number	6	8	10	12	18
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	103.373 (12.9370)	101.668 (13.8460)	102.904 (16.1012)	99.137 (9.9120)	91.904 (12.6390)
GeoMean	102.624	100.800	101.633	98.655	91.052
(95% CI)	(98.561;106.854)	(96.481;105.312)	(96.281;107.282)	(95.416;102.005)	(86.929;95.370)
GeoCV(CV%)	12.2 (12.5)	13.2 (13.6)	16.3 (15.6)	10.0 (10.0)	14.0 (13.8)
SEM	2.1268	2.2763	2.6470	1.6295	2.0778
Median	103.300	100.300	103.000	98.730	94.090
Min; Max	82.96; 144.20	80.84; 144.90	61.52; 136.80	81.04; 119.20	68.29; 122.60

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

/project24/ep/blinded/e210898_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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	88.05	90.53	86.56	89.13
	99.98	91.66	87.97	90.86
	85.90	101.20	106.40	87.72
	104.40	107.20	93.86	90.75
	122.10	106.70	104.00	104.90
	85.23	86.19	83.83	80.24
	102.60	97.39	100.60	99.04
	91.76	106.20	91.79	89.37
	95.27	119.30	92.42	93.60
	106.40	101.90	86.48	106.30
	118.70	101.80	101.90	98.29
	109.50	111.20	103.90	110.60
	109.60	122.90	110.90	110.20
	88.16	89.81	97.30	78.10
	77.60	94.58	73.71	70.75
	90.53	106.10	86.87	74.48
	104.10	87.96	96.77	90.05
	86.68	97.64	90.97	87.60*
	96.23	106.20	93.62	85.84
	77.35	89.20	80.01	68.84

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	81.50	86.97	76.80	78.82
	107.70	99.76	94.19	81.74
	98.60	94.21	82.40	106.00
	76.76	100.70	82.67	86.03
	82.50	86.53	80.17	68.06
	120.40	103.80	112.20	100.00
	98.73	95.43	90.23*	88.62
	96.45	93.92	80.08	83.86
	108.90	99.56	107.20	92.34
	86.02	99.15	93.65	90.33
	107.90	73.51	69.06	89.25
	95.32	110.70	110.60	87.61*
	97.70	98.09	92.27	91.56
	71.84	91.41	78.51	82.54
	109.70	110.70	92.66	98.18
	112.00	109.00	92.57	98.90
	104.10	84.06	77.40	79.51

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
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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: Treatment A

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	97.196 (12.9016)	98.734 (10.1940)	91.419 (10.9617)	89.460 (10.8160)
GeoMean	96.349	98.217	90.778	88.816
(95% CI)	(92.106;100.786)	(94.861;101.693)	(87.199;94.504)	(85.260;92.519)
GeoCV(CV%)	13.6 (13.3)	10.5 (10.3)	12.1 (12.0)	12.3 (12.1)
SEM	2.1210	1.6759	1.8021	1.7781
Median	97.700	99.150	92.270	89.250
Min; Max	71.84; 122.10	73.51; 122.90	69.06; 112.20	68.06; 110.60

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	53.10	66.01	79.90	90.84
	70.12	66.64	109.80	130.60
	65.69	76.53	93.07	106.10
	59.72	88.24	111.90	135.40
	66.92	77.22	91.96	135.00
	51.51	54.88	78.27	91.15
	53.51	62.75	79.73	88.53
	66.61	79.96	95.60	106.70
	58.04	59.63	75.23	86.71
	63.69	67.92	82.79	107.70
	59.55	71.51	110.10	125.20
	73.19	70.72	90.90	116.30
	73.61	83.48	136.30	158.90
	46.63	82.49	109.80	102.60
	63.28	63.94	64.52	65.40
	58.79	93.11*	100.50	94.38
	69.44	89.93*	90.62	113.70
	64.25	70.53	91.14	100.00
	56.30	80.88	101.30	107.10
	53.42	52.78	71.68	84.86

CI: (fidence 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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	63.12	66.54	94.91	107.60
	67.94	80.64	82.54	106.00
	57.48	65.49	98.94	117.70
	67.77	54.79	74.59	90.49
	50.83	77.71	104.70	98.43
	75.74	73.00	96.99	139.80
	54.60	66.19	94.04	93.50
	61.73	66.25	94.17	110.20
	72.04	75.10	116.00	128.60
	62.56	64.22	88.10	95.67
	52.66	49.15	59.75	79.52
	63.89	73.38	97.38	112.30
	72.99	91.60	130.30	152.80
	62.31	73.13	103.40	107.80
	75.92	74.39	90.77	144.40
	68.63	90.66	129.00	147.20
	61.99	87.01	118.30	136.50

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
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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: Treatment B

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	62.691 (7.6054)	72.659 (11.3041)	95.648 (17.4699)	111.235 (22.0145)
GeoMean	62.233	71.781	94.088	109.128
(95% CI)	(59.719;64.852)	(68.058;75.707)	(88.455;100.081)	(102.120;116.618)
GeoCV(CV%)	12.4 (12.1)	16.1 (15.6)	18.7 (18.3)	20.1 (19.8)
SEM	1.2503	1.8584	2.8720	3.6192
Median	63.120	73.000	94.170	107.600
Min; Max	46.63; 75.92	49.15; 93.11	59.75; 136.30	65.40; 158.90

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
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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: Treatment B

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	133.10	118.30	126.60	124.40
	128.20	140.30	160.70	131.90
	108.80	125.70	106.50	104.00
	130.50	141.50	121.10	129.20
	128.50	113.50	113.00	123.10
	91.16	85.25	76.80	87.39
	98.60*	108.10	99.21	125.90
	110.60	108.20	104.90	108.60
	85.46	83.80	103.70	103.70
	103.10	111.60	114.00	121.50*
	152.80	158.90	145.30	128.50
	110.40	104.60	101.20	133.10
	130.50	139.60	131.20	138.10
	91.65	101.70	101.60	82.55
	65.95	89.53	94.78	108.50
	101.40	90.33	91.35	86.59
	124.30	134.30	117.40	112.00
	103.40	104.00	96.08	109.40
	98.02	102.10	91.85	103.60
	126.80	94.71	104.50	106.40

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

Treatment: Treatment B

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	93.56	97.30	96.00	67.76
	121.60	112.10	122.90	121.20
	103.50	117.50	97.01	110.50
	96.75	127.30	117.20	101.40
	111.00	88.74	103.20	88.86
	140.00	161.50	142.40	153.80
	91.19	113.70	103.50	107.30
	110.40	103.60	95.57	107.30
	122.20	126.20	125.10	113.20
	99.56	96.39	100.80	122.50
	84.95	108.00	92.33	77.49
	108.30	126.20	99.31	105.10
	117.10	146.10	130.30	131.50
	86.02	91.88	98.22	79.78
	120.60	134.80	127.50	122.70
	136.60	124.60	141.60	124.60
	111.20	115.40	111.80	100.70

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;
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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: Treatment B

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	110.210 (18.4482)	114.793 (20.1892)	110.987 (18.1150)	110.922 (18.7415)
GeoMean	108.664	113.119	109.626	109.283
(95% CI)	(102.589;115.099)	(106.779;119.836)	(104.014;115.542)	(102.968;115.986)
GeoCV(CV%)	17.4 (16.7)	17.4 (17.6)	15.9 (16.3)	18.0 (16.9)
SEM	3.0329	3.3191	2.9781	3.0811
Median	110.400	112.100	104.500	109.400
Min; Max	65.95; 152.80	83.80; 161.50	76.80; 160.70	67.76; 153.80

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	113.70	106.80	121.00	113.80	88.30
	128.60*	133.40	144.90	113.70	118.30
	114.00	114.70	102.90	115.50	90.41
	122.70	111.60	130.80	114.30	105.40
	117.80	107.60	119.60	102.30	89.46
	101.20	99.05	95.49	91.63	88.80
	99.57	82.55	90.06	101.10	84.47
	109.30	107.00	110.90	92.58	93.37
	92.08	90.63	89.44	93.89	84.54
	98.91	98.32	112.90	117.40	93.65
	131.90	128.80	133.60	131.70	115.40
	140.10	133.70	130.10	130.90	87.03
	123.40	115.00	119.00	101.20	105.60
	98.21	80.52	78.46	86.97	89.09
	82.36	83.48	82.91	85.44	83.59
	81.90	86.51	109.20	82.33	85.54
	108.50	109.20	116.50	99.58	107.80
	89.67	91.98	90.29	83.72	81.88
	104.00	97.70	92.79	84.43	85.49
	77.84	79.26	91.14	82.73	66.32

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	100.00	102.90	89.66	90.60	64.86
	120.80	115.10	110.60	124.40	100.80
	109.80	98.84	84.66	122.00	103.80
	117.10	99.73	97.61	101.80	81.55
	93.60	89.59	92.91	75.74	81.63
	127.80	129.80	137.70	128.20	114.40
	90.42	91.46	88.90	96.16	95.03
	88.80	85.47	89.49	99.84	90.58
	106.00	106.80	103.10	96.89	91.22
	114.10	107.10	97.18	95.77	91.81
	84.24	91.03	97.70	85.77	78.36
	94.37	103.60	103.70	97.70	94.64
	133.90	152.30	118.60	115.60	117.80
	89.08	82.22	96.35	73.24	84.54
	113.10	114.30	109.10	102.70	102.70
	121.20	109.60	131.40	111.40	98.63
	99.75	105.60	98.40	89.87	81.97

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.
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Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

	Sample Times (h)				
Subject Number/ Random Number	6	8	10	12	18
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	106.481 (16.1498)	103.871 (16.7973)	105.650 (17.0778)	100.889 (15.5729)	92.399 (12.6976)
GeoMean	105.287	102.615	104.359	99.736	91.550
(95% CI)	(100.058;110.788)	(97.387;108.122)	(99.010;109.996)	(94.759;104.975)	(87.427;95.868)
GeoCV(CV%)	15.4 (15.2)	15.8 (16.2)	15.9 (16.2)	15.4 (15.4)	13.9 (13.7)
SEM	2.6550	2.7615	2.8076	2.5602	2.0875
Median	106.000	103.600	102.900	99.580	90.410
Min; Max	77.84; 140.10	79.26; 152.30	78.46; 144.90	73.24; 131.70	64.86; 118.30

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

Subject Number/ Parameter Number	Sample Times (h)			
	24	36	48	72
	84.84	89.04	86.66	82.46
	109.00	119.10	105.30	99.22
	104.80	102.70	98.84	93.24
	92.85	117.30	106.20	96.50
	100.90	101.40	91.84	97.84*
	79.65	82.93	78.48	61.70
	101.30	76.49	96.37	84.96
	90.75	101.70	84.69	74.97
	91.25	95.51	88.94	78.30
	123.50	115.40	96.98	85.15
	143.20	100.20	109.50	88.03
	118.40	120.90	124.10	109.80
	134.90	92.22	113.20	106.80
	97.89	93.12	78.58	90.22
	88.55	79.75	74.29	76.35
	87.55	79.68	89.55	91.95
	97.03	104.20	95.26	97.70
	79.07	86.61	84.11	74.28
	96.25	95.72	90.38	86.91
	80.50	81.50	78.47	70.20

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

Subject Number/ Parameter	Sample Times (h)			
	24	36	48	72
	71.28	82.76	77.42*	71.04
	103.40	101.70	98.41	116.20
	115.40	100.60	105.50	95.07
	100.50	94.32	84.53	86.15
	76.52	90.62	80.07	69.45
	126.90	105.80	94.42*	103.50*
	76.05	88.96	83.19	76.07
	95.91	107.50	87.96	78.32
	100.90	101.60	94.47	92.17
	98.65	112.20	107.40	91.62
	90.64	85.94	89.10	73.01
	101.80	102.50	91.47	90.50
	101.20	108.30	104.40	114.60
	73.38	84.05	78.26	76.14
	104.60	106.70	94.75	90.45
	110.40	108.40	109.90	100.00
	71.91	84.59	79.45	67.77

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment B

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	97.882 (17.1314)	97.352 (12.0502)	92.769 (11.8787)	87.531 (13.4668)
GeoMean	96.475	96.625	92.050	86.524
(95% CI)	(91.107;102.160)	(92.700;100.716)	(88.272;95.991)	(82.175;91.102)
GeoCV(CV%)	17.3 (17.5)	12.5 (12.4)	12.6 (12.8)	15.6 (15.4)
SEM	2.8164	1.9810	1.9528	2.2139
Median	97.890	100.200	91.470	88.030
Min; Max	71.28; 143.20	76.49; 120.90	74.29; 124.10	61.70; 116.20

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ [illegible] Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	63.97	64.33	90.09	114.20
	62.55	62.78	81.84	119.30
	67.17	70.94	86.31	95.48
	70.48	72.78*	70.31	85.80
	73.21	77.90	101.50	140.10
	55.05	58.41	61.25	82.05
	52.75	53.08	63.01	72.20
	63.72	71.09	101.70	119.00
	65.43	77.07	99.18	103.20
	66.36	80.15	121.70	127.50
	59.99	74.85	124.60	145.50
	65.26	71.94*	65.72	76.76
	80.84	98.88	130.30	141.80
	51.29	59.02	98.78	114.40
	61.28	73.58	76.79	102.60
	61.36	56.10	104.70	126.20
	74.61	88.91	128.20	119.40
	57.31	65.98	95.94	102.50
	56.15	78.28	95.74	99.71
	46.07	58.25	83.71	98.28

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	63.93	75.50	107.90	120.90
	56.25	61.00	92.00	107.80
	54.48	66.54	90.31	90.78
	65.21	75.64	99.18	115.70
	60.81	57.13	66.11	88.83
	75.43	83.90	105.80	130.40
	55.70	55.09	62.41	71.91
	63.42	66.17	85.75*	98.32
	68.24	68.46	78.60	84.34
	55.67	56.84	77.26	82.54
	48.26	61.51	76.50	86.89
	74.06	74.21	89.69	119.30
	68.74	78.22	120.70	137.80
	64.73	80.20	99.04	106.50
	72.03	83.58	123.20	130.60
	76.82	95.81	137.10	144.10
	60.09	68.54	102.60	146.50

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

	Sample Times (h)			
Subject Number/ Random Number	Predose (Mean)	0.5	1	1.5
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	63.209 (8.1873)	70.883 (11.1929)	94.474 (20.4620)	109.438 (21.8924)
GeoMean	62.686	70.045	92.302	107.257
(95% CI)	(59.998;65.494)	(66.498;73.781)	(85.766;99.336)	(100.155;114.862)
GeoCV(CV%)	13.2 (13.0)	15.7 (15.8)	22.3 (21.7)	20.8 (20.0)
SEM	1.3460	1.8401	3.3639	3.5991
Median	63.720	71.090	95.740	107.800
Min; Max	46.07; 80.84	53.08; 98.88	61.25; 137.10	71.91; 146.50

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	106.00	109.40	117.30	105.40
	118.80	112.60	119.40	119.20
	95.95	110.40	105.50	100.60
	114.70	125.90	126.30	118.20
	144.30	128.00	127.40	111.80
	85.39	96.99	95.85	80.29
	88.45	95.79	87.18	106.40
	128.00	102.10	108.40	105.10
	103.10	103.10	99.68	113.10
	120.30	102.10	112.20	107.40
	131.70	142.90	122.40	133.60
	69.14	68.42	77.35	120.20
	137.30	131.40	131.70	127.60
	108.60	104.10	104.10	107.80
	115.00*	105.80	97.27	93.45
	115.50	125.30	100.00	85.24*
	120.70	116.30	106.90	106.10
	99.86	88.97	97.13	102.60
	101.80	108.00	103.70	104.90
	104.10	104.50	93.95	93.27

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	111.60	105.90	100.90	111.70
	111.50	122.50	140.70	100.90
	107.80	138.10	129.60	124.40
	124.00	152.50	114.80	110.80
	97.78	112.40	109.80	110.90
	138.30	133.40	104.80	125.50
	82.76	98.53	104.10	97.65
	99.37	110.10	104.00	108.50
	92.56	98.16	96.94	109.80
	81.25	87.83	97.28	116.30
	112.60	114.70	91.13	79.34
	145.50	142.30	140.40	123.70
	145.40	135.60	130.30	148.40
	112.00	129.50	118.40	111.70
	110.50	125.30	111.10	144.10
	146.60	148.60	141.10	130.00
	126.90	108.80	110.30	112.30

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	112.300 (19.2894)	114.765 (18.4630)	110.253 (15.4714)	111.034 (15.1860)
GeoMean	110.640	113.278	109.211	110.015
(95% CI)	(104.294;117.372)	(107.187;119.715)	(104.243;114.416)	(105.052;115.213)
GeoCV(CV%)	17.9 (17.2)	16.7 (16.1)	14.0 (14.0)	13.9 (13.7)
SEM	3.1712	3.0353	2.5435	2.4966
Median	111.600	110.400	106.900	110.800
Min; Max	69.14; 146.60	68.42; 152.50	77.35; 141.10	79.34; 148.40

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Number	Sample Times (h)				
	6	8	10	12	18
	108.30	116.00	114.80	94.04	96.04
	117.20	114.70	136.00	98.60	101.00
	120.30	107.10	93.72	94.49	85.93
	114.60	110.30	98.24	104.20	104.40
	121.30	126.90	122.00	103.10	95.84
	91.31	94.21	105.10	96.48	91.03
	103.80	96.72	107.40	97.59	85.39
	101.60*	98.31	111.80	94.27*	80.13
	104.90	100.50	98.85	96.22	94.73
	105.10	101.60	89.79	108.60	86.51
	137.00	127.20	133.70	114.10	102.60
	112.10	116.70	92.19	114.20	100.90
	113.20	123.30	114.70	103.60	107.40
	92.66*	81.38	92.91	112.20*	93.17
	85.23	92.93	92.08	96.12	78.69
	97.03	100.10	107.10	94.83	101.10
	100.20	104.30	112.10	108.60	102.90
	98.68	101.60	84.51	86.87	83.68
	90.28	95.59	90.01	97.56	94.02
	82.74	81.80	100.50	95.63	81.31

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	88.49	99.64	112.50	89.49	80.35
	119.30	94.63	97.77	93.49	96.04
	116.40	98.03	100.10	116.80	107.20
	119.10	113.60	94.33	105.90	91.23
	104.40	98.94	106.90	101.30	94.27
	113.60	104.20	116.00	111.20	119.70
	93.44	85.99	92.82	99.13	93.13
	101.70	87.27	105.40	92.37	99.74
	99.12	92.13	114.90	98.55	98.01
	99.98	94.53	96.83	83.50	82.47
	76.03	90.92	78.30	80.05	70.01
	107.90	104.90	96.65	99.55	96.83
	135.90	142.50	110.50	125.50	115.00
	100.50	118.30	105.90	107.20	94.26
	112.30	105.70	110.20	106.60	83.47
	120.90*	118.90	122.80	103.60	111.90
	91.56	101.60	86.78	81.61	66.82

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	105.355 (13.8090)	103.865 (13.4433)	103.951 (13.0040)	100.193 (9.9076)	93.708 (11.6695)
GeoMean	104.473	103.053	103.175	99.717	92.982
(95% CI)	(99.976;109.172)	(98.809;107.478)	(99.005;107.521)	(96.475;103.067)	(89.106;97.026)
GeoCV(CV%)	13.3 (13.1)	12.7 (12.9)	12.4 (12.5)	9.9 (9.9)	12.8 (12.5)
SEM	2.2702	2.2101	2.1379	1.6288	1.9184
Median	104.400	101.600	105.100	98.600	94.270
Min; Max	76.03; 137.00	81.38; 142.50	78.30; 136.00	80.05; 125.50	66.82; 119.70

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	95.63	100.80	82.24	92.99
	112.60	107.20	96.22	81.43
	99.53	108.40	98.89	95.14
	98.80	110.20	98.38	93.08
	109.50	119.20	108.60	106.20
	77.05	85.68	84.31*	84.49
	101.00	99.33	96.98	67.53
	88.29	90.82	87.22	88.97
	102.70	103.50	91.15	87.02
	91.89	92.67	91.70	89.08
	122.00	112.40	112.10	110.60*
	104.60	110.00	106.70	101.50*
	119.30	116.50	116.20	111.80
	88.60	90.30	94.21	77.55
	91.44	87.32	84.83	72.40
	102.80	95.73	99.33	87.49
	117.90	96.11	114.00	90.78
	86.31	98.48	77.58	69.75*
	86.45	95.96	102.90	90.18
	86.92	90.17	69.26	62.62

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	89.37	87.21	73.21	85.83
	87.88	88.85	89.85	92.38
	113.30	106.00	98.27	93.68
	96.63	112.40	101.80	91.09
	92.08	101.80	95.58	93.46
	112.60	113.00	92.87	84.31
	99.54	86.27	82.71*	81.63
	99.81	116.30	103.90	83.50
	92.87	94.66	86.62	78.41
	65.82	110.90	87.69	74.14
	81.92	92.77	86.48	72.28
	110.30	111.60	94.24	95.91
	126.20	118.80	103.20	107.60
	102.70	105.00	105.10	69.11
	95.11	99.85	96.87	90.36
	122.70	119.70	109.20	93.94
	74.17	90.52	75.02	76.75

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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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: Treatment C

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	98.549 (14.0466)	101.795 (10.6151)	94.471 (11.4560)	87.162 (11.9705)
GeoMean	97.554	101.257	93.774	86.350
(95% CI)	(92.928;102.410)	(97.793;104.844)	(89.960;97.750)	(82.424;90.463)
GeoCV(CV%)	14.6 (14.3)	10.5 (10.4)	12.5 (12.1)	14.0 (13.7)
SEM	2.3092	1.7451	1.8834	1.9679
Median	98.800	100.800	95.580	88.970
Min; Max	65.82; 126.20	85.68; 119.70	69.26; 116.20	62.62; 111.80

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.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;

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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters (Pharmacokinetic Population)
Treatment: Treatment A

Subject Number/ adam Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	6710.0	3117.4	139.40	89.503
	6803.8	2216.9	127.10	63.393
	7010.7*	2061.4*	120.40	51.660
	7185.8*	2754.7*	124.90	63.357
	7878.3	2557.5	140.10	66.200
	6229.7*	2363.6*	106.90	53.203
	7222.8	3021.6	129.70	71.350
	6837.7	2215.8	150.40	86.207
	7156.0*	2268.2*	121.10	53.213
	7051.0*	2662.4*	120.50	59.547
	7724.5	3531.2	149.10	90.860
	8157.7	2677.8	144.90	68.790
	8128.4	2826.4	136.50	62.860
	6374.1*	2955.0*	113.60	66.113
	5775.8	1309.5	94.58	32.547
	6447.0	2495.4	106.10	51.217
	6894.0*	1265.0*	116.30	38.120
	6422.8	2065.4	102.60	42.080
	6830.1*	2801.7*	116.40	60.450
	5773.1*	1445.7*	110.20	50.097

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 specific parameter calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine; NE: Not Estimated.
^: Parameter values are presented but excluded from summary statistics.
#: Due to unreliable Lambda_Z, All Lambda_Z dependent parameters are not estimated.
*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine;
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters (Pharmacokinetic Population)
Treatment: Treatment A

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
[illegible]	5845.2*	1512.8*	108.20	48.027
	6895.4*	2785.6*	129.80	72.720
	6863.3*	2673.1*	121.90	63.703
	6339.2*	1898.9*	132.00	70.330
	5718.7	2543.7	104.30	60.203
	7977.1*	2368.8*	145.60	67.707
	6907.4	2673.6	137.60	78.797
	6271.7	2277.4	97.31	41.833
	7324.8*	2489.1*	126.80	59.637
	6508.2*	1928.8*	115.20	51.597
	6005.7*	2026.3*	109.00	53.730
	7374.9	2508.2	139.60	72.007
	6894.5*	1555.0*	141.00	66.840
	5903.9*	1969.1*	114.30	59.650
	7259.2*	1901.7*	128.30	53.890
	7668.9	1832.3	143.40	62.337
	6285.9	1993.4	132.80	73.183

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 specific parameter calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine; NE: Not Estimated.
^: Parameter values are presented but excluded from summary statistics.
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*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine;
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters (Pharmacokinetic Population)
Treatment: Treatment A

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
n(missing)	37 (0)	37 (0)	37 (0)	37 (0)
Mean(SD)	6828.58 (674.946)	2312.18 (525.549)	124.267 (15.2342)	61.5394 (13.24115)
GeoMean	6796.27	2249.63	123.343	60.0991
(95% CI)	(6576.12;7023.78)	(2073.95;2440.19)	(118.321;128.577)	(55.7575;64.7787)
GeoCV(CV%)	9.9 (9.9)	24.8 (22.7)	12.5 (12.3)	22.8 (21.5)
SEM	110.960	86.400	2.5045	2.17683
Median	6863.29	2363.56	124.900	62.3370
Min; Max	5718.7; 8157.7	1265.0; 3531.2	94.58; 150.40	32.547; 90.860

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 specific parameter calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine; NE: Not Estimated.
^: Parameter values are presented but excluded from summary statistics.
#: Due to unreliable Lambda_Z, All Lambda_Z dependent parameters are not estimated.
*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Treatment A

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	AUC(0-48,adj) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL)#
	4602.0	2207.0	2.00	NE
	4660.1	1602.1	2.00	NE
	4755.4	1455.9	2.53	NE
	5004.0	2049.9	8.02	NE
	5371.4	1824.2	1.50	NE
	4318.9	1741.5	18.00	NE
	4827.3	2026.5	2.50	NE
	4663.6	1582.3	2.50	NE
	4926.7	1668.2	4.00	NE
	4813.7	1888.0	3.00	NE
	5322.9	2527.4	4.00	NE
	5585.3	1932.1	8.02	NE
	5475.0	1940.3	1.50	NE
	4342.0	2062.6	1.50	NE
	4039.5	1061.9	36.52	NE
	4513.3	1878.9	35.07	NE
	4686.0	933.3	3.00	NE
	4276.3	1371.3	4.00	NE
	4744.0	2058.4	4.03	NE
	4029.9	1145.0	1.00	NE

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 specific parameter calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine; NE: Not Estimated.
^: Parameter values are presented but excluded from summary statistics.
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*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine;
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters (Pharmacokinetic Population)
Treatment: Treatment A

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	AUC(0-48,adj) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL)#
	3995.8	1107.5	1.52	NE
	4864.6	2124.7	3.02	NE
	4663.7	1870.2	2.52	NE
	4384.5	1424.3	1.00	NE
	3938.0	1821.3	1.52	NE
	5458.4	1719.5	1.00	NE
	4759.7	1937.1	2.50	NE
	4304.9	1642.1	1.55	NE
	4999.4	1775.6	1.50	NE
	4386.5	1333.6	3.00	NE
	4110.5	1457.5	2.50	NE
	4989.1	1744.6	1.50	NE
	4740.9	1181.2	3.00	NE
	4000.1	1376.9	2.02	NE
	5009.2	1437.5	2.50	NE
	5371.1	1480.0	2.00	NE
	4403.2	1541.6	1.50	NE

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 specific parameter calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine; NE: Not Estimated.
^: Parameter values are presented but excluded from summary statistics.
#: Due to unreliable Lambda_Z, All Lambda_Z dependent parameters are not estimated.
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Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
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