

Levothyroxine
EMR 200125-001

Bioequivalence trial of new levothyroxine formulation vs. old formulation

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EMR 200125-001

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	71.42	99.87*	118.40	108.00
	53.94	55.88	88.91	103.40
	65.69	59.19	92.21	109.60
	56.36	61.46	72.84	90.50
	71.41	65.58	71.08	91.79
	70.57	69.44*	92.73	103.80
	57.32	59.81	59.56	66.84
	54.47	54.08	75.42	93.96
	55.77	51.07	76.66	104.50
	81.84	82.55	110.10	146.40
	54.33	62.57	93.05	116.40
	65.75	67.88	80.71	93.96
	52.93	49.81	64.53	74.57
	63.61	64.39	69.17	83.79
	66.19	106.50	97.57	101.60
	62.90	72.36	98.10	101.90
	51.99	57.81	68.24	71.50
	55.76	66.66*	99.04	119.90

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

*: Measurement taken outside the allowed windows allowance.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	71.27	77.37	92.61	95.02
	69.41	73.23	80.93	88.35
	72.23	70.56	105.80	101.40
	54.05	60.98	86.84	97.97
	67.83	75.59	100.90	115.40
	53.66	46.04	60.37	86.89
	80.83	77.38	80.89	133.70
	72.41	63.30	87.83	114.80
	80.20	75.14	119.20	128.30
	59.24	63.77	78.32	82.00
	54.58	59.70	98.00	114.20
	61.39	69.81	94.12	115.40
	63.50	66.56	75.74	83.79
	56.38	62.44	101.20	116.20
	74.25	75.47*	105.90	145.00
	63.45	61.86	97.62	96.70
	62.79	67.26	92.61	111.20
	61.95	77.45	93.69	119.90

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.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	64.12	67.33	97.48	104.10
	64.34	57.74	66.28	97.01
	54.98	59.05	74.83	89.09
	59.21	61.29	80.99	104.10
	89.75	109.00	119.60	117.70
	60.86	71.22	98.21	119.80
	70.84	78.66	91.81	97.71
	55.73	66.76	70.57	87.53
	58.80	59.51	89.55	109.70
	59.75	65.68	106.90	135.30
	73.20	72.97	98.75	113.50
	53.57	49.49	65.21	82.64
	47.57	57.82	81.22	94.47
	58.93	67.62	91.27	109.90
	66.66	68.53	89.13	111.80
	91.06	86.28	94.59	102.00
	65.59	87.76	108.40	113.30
	55.39	66.47	98.44	101.90

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.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	48.77	52.01	54.83	71.32
	67.26	68.79	82.07	88.64
	52.15	68.61	119.50	108.20
	62.73	66.88	99.29	101.10
	55.58	50.37	64.28	77.05
	55.02	61.78	74.14	76.90
	61.52	68.69	94.81	102.00
	67.46	70.04	106.70	132.40
	76.23	81.33	79.10	98.72
	70.10	85.42	107.00	113.40
	58.43	74.57	94.79	101.80
	68.87	76.13	113.10	129.20
	57.69	64.69	111.60	114.80
	54.43	68.90	80.57	102.00
	60.24	80.60	96.65	126.40
	50.23	50.55	59.51	64.61
	55.33	61.03	97.07	99.16
	60.09	39.95	58.66	85.69

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

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	49.64	65.01	71.26	85.37
	69.89	69.27	82.60	87.98
	77.30	83.00	108.30	113.30
	62.58	73.83	101.60	94.68
	51.25	72.97	118.30	101.10
	53.33	74.11	102.80	98.20

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	59.499 (10.2182)	64.683 (12.7371)	85.169 (17.6716)	97.782 (19.0136)
GeoMean	58.602	63.368	83.260	95.851
(95% CI)	(57.186;60.054)	(61.564;65.225)	(80.800;85.796)	(93.187;98.592)
GeoCV(CV%)	17.9 (17.2)	21.2 (19.7)	22.0 (20.7)	20.6 (19.4)
SEM	0.7154	0.8918	1.2373	1.3312
Median	59.422	64.125	83.355	99.275
Min; Max	29.11; 91.06	20.25; 109.00	41.78; 125.50	51.72; 148.50

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	93.60	77.48	93.66	85.68
	82.03	96.86	85.55	69.09
	110.20	111.10	102.70	107.90
	84.49	80.43	83.39	77.23
	92.53	104.00	112.30	111.00*
	94.65	80.57	78.31	82.86
	89.49	86.23	101.00	79.30
	128.90	129.00	150.80	131.80
	97.84	116.30	106.90	100.90
	126.60	131.80	125.20	122.90
	83.28	82.49	86.02	84.89
	103.10	92.06	114.70	110.30
	104.80	117.20	110.00	123.30
	116.40	89.99	82.51	120.10
	97.39	96.47	94.77	83.41
	84.72	72.36	71.42	77.74
	132.60	115.00	112.60	108.60
	106.30	118.90*	107.00	97.44

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Table 15.4.1.1.1 Individual Data and Summary Statistics of Concentrations for Total T4 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	61.42	65.56	70.22	83.43
	113.40	120.80	109.40	100.00
	142.50	149.40	152.40	153.30
	104.90	107.00	102.90	112.20
	72.01	106.00*	126.30	83.18
	112.90	101.00	123.30	111.80
	111.20	113.50	110.10	112.40
	92.83	90.19	89.56	90.97
	96.42	103.70*	85.97	103.80
	89.19	80.86	77.03	79.25
	81.58	81.69*	87.09	83.02
	118.50	122.60	112.90	110.90
	95.04	87.79	105.60	103.90
	87.21	103.40	83.45	63.65
	116.20	86.78	114.00	115.70
	112.40	112.70	111.40	121.80
	107.80	107.00	103.60	77.61
1.	65.76	70.00	85.57	55.32

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	79.47*	70.66	90.41	84.79
	103.10	109.70	96.52	91.70
	100.00	99.56	100.50	99.13
	85.42	89.57	85.27	65.52
	69.40	83.37	79.65	87.56
	102.50	105.70	88.15	77.42
	82.87*	92.90	86.33	92.28
	93.25	75.74	92.14	86.50
	115.10	117.80	133.00	99.88
	83.66	90.21	72.75	15.62
	107.20	103.00	93.53	105.40
	90.05	99.66	115.40	134.50
	68.57*	75.10	81.63	59.78
	118.80	100.70	99.10	96.53
	89.99	83.14	106.20	108.80
	109.70	97.01	117.90	134.30
	107.40	83.83	116.60	109.40
	113.30	122.90	115.10	114.90

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	88.89	96.44	91.78	99.82
	104.70	110.70	107.00	102.20
	97.25*	95.01	84.33	77.49
	96.87	85.41	137.60	122.90
	88.64	105.30	99.84	82.12
	76.02	97.31	77.87	94.61
	107.10	110.50	113.30	96.13
	80.43	80.11	84.76	79.08
	85.00	81.04	76.60	78.89
	72.39	77.16	88.62	102.00
	117.20*	111.50	109.60	105.40
	120.20	115.20	112.30	112.00
	114.20	112.50	110.80	119.20
	87.59	88.74	90.39	96.67
	105.60	100.70	106.50	101.20
	109.70	120.10	111.70	104.50
	88.32	76.82	86.82	88.97
	73.99	81.48	89.00	92.89

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

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	76.71	62.59	74.13	70.63
	92.29	105.80	110.20	110.60
	58.56	66.72	68.65	74.20
	121.70	155.70	98.22	129.20
	90.30	90.82	81.55	94.63
	116.40	115.10	118.60	112.40
	74.18	100.40	103.20	99.15
	90.99	51.50	93.79	93.15
	96.92	105.80	103.30	96.60
	82.95	87.53	94.90	72.48
	83.46	104.10	93.51	90.45
	118.50	117.80	106.20	113.60
	133.00	124.10	108.90	114.20
	96.57	89.29	94.31	93.40
	91.82	114.00	92.96	108.10
	94.68	77.15	88.87	72.44
	72.11	74.94	84.07	75.29
	74.23	101.70	85.18	95.24

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	85.89	89.49	83.60	83.48
	111.60*	113.00	114.80	115.60
	69.17	58.85	60.31	56.81
	103.50	103.00	101.70	105.80
	118.60	112.60	97.73	106.40
	88.49	81.93	84.77	86.63
	97.97	133.50	128.60	127.60
	120.00	103.90	105.90	105.00
	100.30	85.16	100.50	125.30
	102.90	102.70	100.10	108.60
	62.29	58.08	71.00	72.18
	71.96	71.73	93.15	86.39
	90.10	102.00	113.60	110.40
	84.92	83.61	95.28	88.26
	93.97	99.32	93.84	89.65
	121.60	140.60	148.80	119.00
	73.24	87.15	71.50	55.13
	101.40	106.10	109.50	105.10

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;

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	97.59	94.60	107.90	98.81
	88.45	125.10	131.60	110.90
	98.47	92.11	93.13	94.01
	87.39	81.70	99.85	96.99
	82.66	90.80	98.95	89.65
	89.23	90.01	83.15	81.07
	109.20	111.60	111.30	100.80
	117.10	116.40	102.50	105.00
	76.38	109.70	108.00	101.70
	121.00	133.30	127.90	129.50
	131.10	114.50	124.10	125.60
	116.60	130.10	116.10	120.40
	115.60	117.30	117.30	106.80
	105.50	110.50	108.70	108.30
	87.14	85.13	88.81	108.40
	88.07	99.74	99.17	120.70
	106.70	100.90	104.30	110.10
	102.90	114.30	86.59	108.60

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	105.40	115.20	114.20	109.40
	88.25	86.22	120.30	87.80
	79.76	113.20	81.57	86.88*
	96.16	106.20	109.90	98.92
	93.54	103.70	91.47	95.64
	118.00	130.10	112.30	117.60
	67.29	86.48	90.73	81.06
	98.03	94.47	96.52	88.49
	125.50	96.86	97.40	131.40
	133.70	129.60	107.50	114.70
	114.70	128.20	108.90	107.70
	101.50	105.80	108.80	99.81
	102.20	117.80	101.10	88.12
	108.30	115.40	120.60	121.00
	116.20	107.90	99.80	106.00
	118.00	105.60	109.70	107.60
	68.91	69.03	71.26	96.05
	121.20	118.90	112.00	106.50

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

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	103.60	153.70	143.40	117.40
	82.53	102.30	122.20	115.60
	107.30	100.20	114.70	108.60
	96.39	113.90	107.40	87.24
	147.60	104.00*	118.10	125.90
	66.08	77.34	106.00	108.40
	110.00	99.33	105.20	102.40
	122.60*	114.70	130.00	124.70
	118.70	117.50	127.70	126.40
	91.26	101.40	99.63	104.60
	123.00	123.60	114.00	118.40
	123.50	109.60	127.40	119.60
	93.06	116.30	106.10	111.10
	121.20	103.80	108.70	96.49
	118.80	114.10	101.80	114.10
	104.30*	102.50	92.78	110.00
	106.90	89.96	96.08	80.80
	128.90	95.48	94.19	79.10

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;

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	107.10	104.50	98.00	94.65
	73.16	96.07	105.70	92.56
	90.79	88.99	97.46	94.28
	103.90	116.20	120.70	94.76
	95.46	122.50	139.40	140.20
	121.90	102.10	109.60	107.40
	98.40	100.10	104.70	110.10
	111.20	75.84	97.25	101.80
	112.50	96.55	114.40	104.50
	122.70	125.40	122.10	117.50
	120.00	110.70	99.46	110.40
	84.70	97.87	84.64	89.26
	83.38	88.53	84.54	91.39
	99.14	104.50	99.22	98.62
	108.50	107.90	98.45	94.89
	118.80	112.60	117.30	134.60
	122.20	130.30	125.10	119.70
	92.09	100.00	100.40	101.50

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;
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	91.68	95.53	93.81	93.87
	104.70	107.90	113.60	115.10
	98.46	120.50	108.90	95.76
	100.30	89.66	88.36	92.49
	79.86	86.64	76.91	78.22
	88.10	93.73	99.42	115.90
	110.30	108.90	101.60	102.10
	137.10	129.40	121.50	116.60
	93.33	107.40	108.20	111.30
	115.00	116.10	105.40	108.60
	100.40	70.98	81.37	56.96
	104.20	128.00	110.10	110.80
	96.44	102.70	101.90	107.90
	57.38	64.62	72.90	70.82
	116.10	104.30	105.80	105.50
	78.81	86.72	88.37	91.36
	87.85	94.82	68.15	65.61
	93.40	94.57	95.20	77.06

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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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	93.24	74.30	105.50	86.86
	96.36	97.15	114.10	132.60
	120.50	126.00	123.40	134.30
	92.31	114.20	96.28	123.60
	103.60	104.70	97.48	109.70
	110.30	104.10	108.60	110.20

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

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
n (missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean (SD)	99.443 (17.3658)	101.099 (18.0259)	101.852 (16.3456)	100.216 (18.6843)
GeoMean (95% CI)	97.879 (95.462;100.357)	99.433 (96.913;102.018)	100.540 (98.309;102.821)	98.081 (95.056;101.202)
GeoCV (CV%)	18.3 (17.5)	18.8 (17.8)	16.4 (16.0)	23.0 (18.6)
SEM	1.2159	1.2621	1.1444	1.3082
Median	98.430	102.400	101.750	101.900
Min; Max	57.38; 147.60	51.50; 155.70	60.31; 152.40	15.62; 153.30

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	88.21	85.39	72.12	81.11	72.55
	81.79	73.84	71.79	69.03	58.95
	102.00	84.46	97.49	98.16	79.77
	81.99	77.64	85.60	75.18*	66.77
	97.50	95.79	93.82	97.61	84.47
	80.36	70.21	71.98	70.08	63.55
	93.82	85.35	88.66	89.76	81.45
	127.40	122.50	109.30	122.00	127.70
	94.59	98.13	96.94	86.11	82.67
	105.10	110.90	125.20	95.14	98.50
	77.21	74.06	73.83	68.97	66.22
	116.90	95.34	101.30	86.13	84.12
	113.50	114.60	103.40	106.30	91.71
	86.50	95.80	89.71	94.16	94.30
	80.25	84.62	46.87	80.97	77.50
	80.32	76.35	59.84	84.74	67.35
	97.02	99.62	93.87	87.48	71.97
	95.88	96.33	97.47	94.72	64.30

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;
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	73.94	79.09	77.86	73.73	80.29
	96.97	105.00	88.73	85.36*	85.84
	143.00	140.80	132.40	126.50	122.60
	108.50	104.90	115.40*	105.50*	95.41
	82.53	99.34	80.10	84.36	77.22
	108.20	83.27	95.84	101.40	96.64
	100.30	105.60	98.27	92.53	88.62
	76.18	77.12	72.91	71.48	74.13
	87.04	86.79	84.68	78.94	77.56
	90.37	81.12	63.57	77.99	75.29
	77.31	70.08	65.21	59.26	60.11
	103.20	105.80	106.20	98.89	89.49
	100.00	100.80	90.96	83.67	90.39
	101.00	76.10	84.93	86.93	81.18
	129.40	104.70	106.00	98.49	75.55
	135.20	110.30	95.41	84.34	91.85
	103.10	95.25	91.32	74.69	81.26
	77.68	71.74	76.87	83.94	60.76

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

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	91.08	117.40	97.26	87.57	88.55
	78.16	98.47	90.42	95.93	88.07
	87.69	90.69	84.15	91.61	73.09
	73.65	69.98	66.75	84.49	81.29
	89.17	87.02	75.96	74.33	82.13
	97.79	83.68	79.91	95.55	91.64
	98.01	77.17	64.45	87.99	82.20
	76.37	72.06	59.10	83.32	72.43
	111.10	111.50	95.83	109.20	81.29
	72.80	73.21	68.94	57.51	68.83
	95.77	107.50	92.04	99.66	98.34
	110.90*	125.20	88.85	109.90	115.00
	79.17	62.58	55.51	59.89	62.06
	95.92	89.07	83.88	87.80	58.59
	114.90	98.68	85.54	99.76	94.23
	117.20	98.85	90.10	95.30	81.44
	88.22	88.13	77.27	84.76	77.13
	102.30	102.80	95.73	97.02	97.79

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

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	92.18	84.01	85.23	72.63	67.64
	87.61	79.59	99.03	85.69	76.42
	88.81	80.47	88.20	93.65	73.84
	89.30	78.51	70.96	87.23	91.00
	103.10	98.85	78.93	104.10	88.42
	87.16	85.07	79.35	66.98	68.16
	79.59	82.45	84.79	83.95	80.80
	79.79	70.84	70.91	71.81	69.40
	85.63	85.37	75.99	81.79	61.37
	110.40	101.20	95.86	96.88	95.93
	97.50	92.73	96.20	102.20	85.10
	99.28	94.74	98.58	104.30	89.06
	105.40	95.75	105.20	97.20	86.74
	90.12	80.18	87.71	84.19	74.42
	102.90	102.30	98.30	100.50	73.61
	102.30	92.42	99.06	100.90	84.61
	80.85	83.04	89.44	75.26	74.92
	79.91	80.04	76.52	84.22	71.22

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	77.31	68.87	75.14	81.67	57.34
	100.80	89.86	91.71	86.57	84.34
	68.11	69.83	74.70	59.18	49.49
	115.30	127.90	125.90	122.50	101.10
	93.78	82.18	87.54	84.66	74.45
	109.10	109.70	112.80	108.90	83.32
	97.72	103.10	91.04	72.73	69.21
	96.07	97.37	89.72	71.28	77.25
	98.96	100.90	86.36	82.37	78.71
	80.73	78.70	70.94	52.94	49.47
	82.72	90.65	82.67	73.70	80.68
	124.10	115.40	107.00	93.95	97.45
	120.70	135.30	112.80	104.90	111.60
	88.90	82.16	75.52	87.28	75.78
	94.27	89.36	83.29	68.45	79.95
	84.12	73.60	75.37	75.82	74.21
	76.49	74.68	75.76	85.74	61.62
	97.63	85.16	103.00	83.77	77.40

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	76.32	83.38	86.97	72.59	78.51
	88.03	98.74	97.53	99.43	94.44
	62.21	62.80	58.36	70.41	50.77
	90.28	92.19	101.30	102.20	77.58
	97.86	97.10	86.86	93.90	96.09
	80.42	77.89	79.12	75.34	72.96
	111.10	107.00	104.40	104.10	100.40
	84.44	100.70	53.49	95.81	91.99
	109.50	106.40	127.60	90.81	93.17
	98.89	90.90	71.79	74.28	72.98
	59.99	59.01	71.00	61.80	68.17
	73.69	52.49	53.44	72.31	63.04
	95.47	84.29	72.43	86.53	133.30
	95.68	98.86	84.89	101.30	83.73*
	102.70	105.60	89.35	72.89	69.25
	123.30	105.10	119.50	102.70	91.46
	57.77	38.21	37.81	44.44	35.51
	94.81	89.72	100.00	89.20	105.70

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: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	92.72	97.21	86.88	96.99	81.31*
	93.77	97.63	106.90	95.17	96.91
	87.05	82.98	98.76	86.58	79.31
	78.01	77.82	76.76	86.78	75.95*
	80.28	85.44	82.89	74.96	74.54
	77.36	94.16	86.39	85.60	80.19
	98.65	96.92	91.31	90.28	91.26
	96.79	101.60	89.92	110.40	84.30
	98.79	99.17	93.64	90.16	84.49
	130.00	128.60	112.70	112.40	109.30
	133.30	120.60*	99.31	112.60	101.40
	118.90	132.20	104.60	114.30	97.94
	103.50	101.20	83.80	95.10	91.82
	100.70	101.30*	92.65	88.49	88.34
	99.17	89.52	88.39	93.31	83.44
	104.70	109.90	102.60	97.26	91.97
	100.70	106.60	102.60	106.40	95.02
	105.20	99.63	87.55	85.93	78.39

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

*: Measurement taken outside the allowed windows allowance.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
-	101.70	90.72	94.48	83.39	86.04
-	115.40	86.95	88.54	96.57	86.51
-	93.41	98.29	86.74	93.51	96.62
-	93.84	95.37	94.74	87.50	79.19
-	96.69	109.00	110.10	96.44	97.30
-	112.20	111.70	103.20	87.26	94.93
-	91.98	92.54	88.21	89.79	79.50
-	94.22	90.39	83.49	83.16	74.26
-	108.40	113.70	110.20	109.90	97.00
-	110.90	99.95	89.49	116.90	98.37
-	99.22	98.07	107.50	98.37	87.36
-	107.50	113.30	80.05	94.47	85.60
-	92.65	98.35	95.35	83.32	77.74
-	104.40	105.00	106.80	97.63	85.01
-	106.30	86.93	83.53	98.11	79.22
-	114.10	98.36	91.91	93.10	76.50
-	87.63*	77.77	69.80	87.86	74.07
-	105.30*	96.65	105.60	86.12	82.83

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

*: Measurement taken outside the allowed windows allowance.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	108.90	105.30	105.00	99.08	90.37
	101.10	92.41	95.34	89.61	83.30
	108.60	90.75	90.85	87.46	93.78
	91.52	109.70	81.26	80.24	87.20
	94.49	105.50	136.50	105.20	93.50
	104.30*	103.10	104.10	89.94	84.00
	110.60*	108.70	95.31	105.50	108.10
	106.70	104.10	105.10	103.60	91.10
	110.50	112.10	129.80	100.70	97.14
	92.12	93.69	112.10	86.74	88.54
	109.10	114.80	105.40	111.50	94.61
	111.80	107.90	115.10	100.10	99.40
	105.60	101.00	111.30	124.60	104.70
	90.15	96.12	91.28	104.60	95.80
	111.80*	101.80	118.20	119.50	97.85
	81.27	82.31	80.25	69.83	66.32
	93.14	97.01	96.15	84.61	80.38
	83.94	97.71	99.21	88.85	91.29

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.
 Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
 Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	88.41	98.98	124.10	89.93	84.06
	88.66	86.57	92.90	74.95	77.95
	89.69	80.76	79.53	89.48	78.56
	107.00	92.60	106.20	109.00	89.67
	148.70	116.10	156.50	141.10	125.50
	119.50	106.90	105.10	106.50	94.00
	99.57	97.30	92.56	91.41	95.84
	93.60	91.60	92.08	93.13	73.74
	104.00	93.22	102.50	96.34	91.11
	112.80	118.00	103.00	93.97	94.44
	100.10	98.50	96.78	84.68	93.39
	86.87	82.13	83.06	69.28	89.19
	75.16	78.96	99.74	75.59	75.64
	90.77	82.73	88.72	78.18	77.73
	88.41	101.90	96.38	90.38	83.37
	142.00	129.40	124.20	120.20	127.60
	113.30	112.70	108.80	99.37	96.38
	90.36	88.44	83.24	87.84	65.51

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.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	85.46	87.68	104.80	82.51	66.27
	110.10	98.84	94.70	98.29	87.90
	87.40	97.05	85.48	107.90	76.79
	91.70	88.05	94.54	107.30	82.29
	75.34	79.11	76.34	81.95	54.46
	111.10	95.54	103.20	100.60	75.06
	92.22	94.96	109.50	91.36	87.55
	121.00	82.65	138.10	101.20	103.30
	110.80	120.50	106.70	102.10	93.39
	100.50	103.00	117.40	100.90	95.48
	75.25	64.24	66.03	68.83	54.14
	99.70	102.10	109.30	96.21	84.99
	95.72	108.50	90.27	90.18	94.25
	82.57	69.20	103.70	54.92	72.90
	96.97	91.70	101.20	96.01	103.90
	92.34	82.20	106.70	82.61	84.12
	78.77	66.76	75.51	73.76	74.04
	81.78	95.58	77.54	87.80	93.13

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

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	91.56	74.88	101.50	77.00	85.21
	124.00	118.60	120.60	118.30	117.40
	128.00	124.70	117.00	122.00	128.30
	85.03	103.50	100.50	89.45	87.57
	87.68	91.01	87.81	83.60	71.78
	109.90	92.38	105.40	85.24	99.21

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

*: Measurement taken outside the allowed windows allowance.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)	204 (0)
Mean (SD)	96.816 (15.2584)	94.041 (15.5969)	92.322 (17.1616)	90.227 (14.6833)	84.145 (14.9115)
GeoMean (95% CI)	95.637 (93.585;97.735)	92.684 (90.475;94.948)	90.660 (88.247;93.139)	88.993 (86.939;91.095)	82.798 (80.731;84.918)
GeoCV(CV%)	15.8 (15.8)	17.6 (16.6)	19.7 (18.6)	17.0 (16.3)	18.5 (17.7)
SEM	1.0683	1.0920	1.2016	1.0280	1.0440
Median	95.900	95.455	91.810	89.545	83.865
Min; Max	57.77; 148.70	38.21; 140.80	37.81; 156.50	44.44; 141.10	35.51; 133.30

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

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	77.50	82.14	56.03	66.58
	76.30	82.91	52.48	69.88
	87.80	89.19	77.19	50.76*
	74.05	76.43	68.63	67.19
	82.10	93.39	70.51	95.64
	73.34	67.37	65.55	56.42
	84.49	82.15	91.38	78.82
	125.50	134.70	113.20	100.10
	78.14	86.78	71.62	84.68
	97.17	95.68	90.40	78.99
	68.08	73.63	69.73*	65.43
	96.89	88.29	73.67	80.27
	112.10	107.40	84.69	85.01
	93.41	92.13	97.47	94.90
	79.53	83.26	74.89	63.56
	77.59	85.56	68.82	66.34
	89.89	86.46	87.82	73.19
	103.90	114.30	96.16	87.57

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

*: Measurement taken outside the allowed windows allowance.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	78.49	69.23	63.30	64.22
	89.04	96.55	99.98	90.98
	117.20	122.20	115.70	107.70
	103.00	110.80		79.20
	71.28	103.40	86.19	67.98*
	97.27	92.28	81.29	76.94
	95.28	96.31	95.93	83.92
	66.97	89.10	67.46	51.82
	85.09*	84.28	79.18	78.07
	79.42	80.23	59.31	59.46
	70.47	69.74	77.31	68.23
	100.10	106.00	98.36	93.80
	100.00	67.71	78.15	60.79*
	53.35	74.59	78.21	59.89
	92.76	92.94	68.62	89.68
	87.64	82.47	75.25	69.02
	67.52	92.05	77.45	68.70
	75.88	77.05	52.54*	76.22

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

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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	76.63	88.18	94.63	81.01
	76.80	86.14	87.35	66.73
	47.28	64.07	92.63	76.08*
	81.39	77.90	72.68*	67.17*
	93.52	88.09	77.49	61.31*
	90.64	91.93	96.02	87.20
	82.51	95.64	83.70*	79.93*
	63.38	72.18	65.51	71.76
	107.00	112.90	125.40	104.60
	63.96	70.53	56.40	64.11
	96.53	105.80	103.30	96.53
	106.00	107.40	113.90	106.60
	39.89	69.87	80.00	75.84*
	84.34	94.28	85.43	83.23
	93.09	123.80	94.14	121.40
	91.03	98.53	97.54	88.91
	113.40	96.54	81.44	72.44
	102.00	99.29	112.20	96.43

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	70.11	80.42	81.80	75.15
	81.31	87.65	90.64	73.26
	85.90	79.23	74.36	80.76
	91.13	98.87	90.34	51.32
	97.18	107.50	94.95	99.08
	81.25	72.73	78.57	63.44
	79.55	79.68	94.47*	84.09*
	75.43	72.28	56.07	61.11
	82.82	85.30	66.25	81.10
	103.50	99.77	91.11	79.32
	83.14	86.42	79.10	75.24
	107.80	93.13	91.12	84.42
	105.80	94.10	85.04	77.98
	88.86	80.52	74.52	68.63
	76.83	86.54	66.55	79.24
	104.80	99.29	65.75	96.72
	72.21	75.72	69.68	67.74
	69.45	82.50	77.38	78.99

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	57.24	62.35	52.71	55.72
	85.16	105.60	95.60	89.52
	56.98	68.66	63.88	53.35
	87.14	107.60	81.32	76.26
	79.65	93.00	78.33*	73.49*
	94.24	89.01	80.16*	89.69
	77.23	81.69	79.71	63.69*
	76.14	85.10	73.83	70.74
	87.00	89.88	88.92	76.44
	71.08	54.26	59.38	66.81
	74.76	78.00	76.61	83.12
	98.97	93.35	124.90	100.90
	110.20	97.81	107.10	90.99
	75.57	85.17	68.83	81.42
	71.86	94.37	75.88	63.11
	77.98	75.60	80.07	88.98
	72.56	69.99	69.25	62.21
	77.77	87.36	77.26	63.52

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.

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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	81.12	78.96	74.25	75.19
	93.90	88.62	85.35	78.87
	57.81	68.24	52.02	59.26*
	89.28	80.91	78.04	80.40
	96.00	82.05	77.00	85.76
	83.57	66.40	64.07	68.69
	109.60	115.10	93.88	95.89
	92.94	95.89	88.94	87.71
	91.88	77.07	80.01	86.07
	86.10	77.43	74.59	74.24
	84.27	68.68	67.73	66.22
	47.60	74.04	54.01	46.00
	94.45	85.22	75.36	76.57
	83.98*	95.26	84.18	85.29
	96.16	84.57	104.00*	79.29
	113.50	113.60	109.10	91.72
	56.95	48.73	57.18	53.77
	99.42	88.93	97.57	87.11

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

*: Measurement taken outside the allowed windows allowance.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	94.36*	89.54	85.76	78.32
	86.91	92.68	99.01*	90.05
	96.72	87.63	80.57	80.81
	80.72*	81.44	70.68*	79.91
	79.44	78.99	79.33*	75.39
	83.18	75.87	83.44	77.61
	100.40	96.23	85.67	83.11
	87.65	82.06	91.08	80.18
	103.80	89.37	85.04	87.39
	111.30	108.20	107.40	98.25
	117.50	103.50	100.40	101.40
	101.10	99.70	100.80	96.03
	95.32	94.74	96.26	86.34
	89.41	90.62	93.82	72.85
	91.14	93.48	80.87	83.14
	85.37	91.59	95.14	89.24
	104.30	114.20	101.50	97.63
	83.96	97.32	76.09	65.78

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

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	110.00	79.66	79.22	88.29
	98.29	90.54	96.75	97.15
	88.45	114.80	119.70	103.00
	93.57	93.62	82.47	83.29
	102.00*	107.40	104.90	94.85*
	99.17	90.47	80.79	80.78
	77.15	82.53	79.25	74.96
	82.76	81.68	73.26	53.67
	100.50	114.20	90.45*	82.93
	118.10	131.20	122.10	108.50
	90.49	91.17	81.96	82.29
	105.10	88.44	95.60	86.50
	84.73	102.40	84.34	79.10
	89.38	90.13	83.89	85.76
	98.86	88.00	75.65	78.86
	103.10	85.48	89.79	89.81
	73.83	73.12	59.20	69.66
	99.28	84.92	82.00	81.94

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	103.90	94.88	91.00	83.77
	98.25	83.23	77.47	69.76
	97.46	128.60	84.35	79.82
	97.70	98.66	72.47	75.06
	115.60	97.84	96.18	104.50
	96.71	81.37	100.70	57.29
	101.10	134.50	116.90*	118.10*
	103.50	102.50	95.26	90.68
	99.31	96.06	109.50	98.87
	89.02	93.28	95.93	79.42
	91.30	120.90	96.03	85.96
	101.60	84.34	93.08	78.95*
	99.70	104.70	88.21	87.94
	89.93	98.38	84.78	74.32
	126.50*	107.30	105.80	129.00
	72.44	68.08	64.34	56.65
	90.61	100.00	89.82	82.90
	95.72	86.07	77.95	94.63

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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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	88.20	97.96	81.08	83.24
	78.48	79.64	64.15	75.69
	80.52	77.52	76.29	68.86
	109.60	106.00	83.48	105.90*
	145.00	93.41	109.40	81.67
	111.40	100.60	103.30*	87.79
	92.69	97.19	89.50	83.36
	93.59	94.88	91.46	83.64
	56.14	97.03	54.01	84.87
	106.90	106.90	89.40	90.01
	110.40	101.40	98.80	104.70
	96.42	88.51	77.57	81.00
	87.87	74.40	74.54	77.55
	75.28	92.08	81.05	68.17
	89.49	82.88	74.05	78.95
	122.40	128.50	117.40	110.30
	96.38	99.33	69.31	77.40
	77.60	85.47	66.61*	75.18

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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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	81.98	73.92	74.72	74.83
	99.18	98.90	91.59*	88.15
	85.13	88.31	94.89	83.81
	89.61	100.10	84.45	87.00
	73.84	63.75	69.46	61.87
	95.05	112.80	102.50	90.12
	92.27	50.23	71.22	80.41
	106.60	101.70	97.84	92.07
	105.40	98.78	84.57	87.80
	117.90	106.90	121.20	86.73
	47.29	76.48	77.69	79.02
	98.84	98.61	91.56	87.11
	88.51	96.30	95.05	88.02
	53.08	72.82	83.94	64.67
	88.32	94.22	86.90	81.87
	81.76	82.78	77.86	71.11*
	62.79	72.15	78.10	73.25
	79.19	82.54	64.00	80.02

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

*: Measurement taken outside the allowed windows allowance.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	64.73	85.67	74.61	71.42
	114.00	106.60	104.70	96.67
	152.80	123.40	126.00	108.80
	84.97*	90.33	86.53	73.30
	86.62	83.76	91.15*	76.02*
	82.33	100.60	88.08	87.12

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

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
n(missing)	204 (0)	204 (0)	203 (0)	204 (0)
Mean (SD)	89.183 (16.6346)	90.416 (14.9052)	84.320 (15.4659)	80.400 (13.7604)
GeoMean	87.552	89.185	82.907	79.218
(95% CI)	(85.198;89.970)	(87.147;91.270)	(80.806;85.063)	(77.339;81.144)
GeoCV(CV%)	19.9 (18.7)	16.9 (16.5)	18.7 (18.3)	17.5 (17.1)
SEM	1.1647	1.0436	1.0855	0.9634
Median	89.330	89.455	83.440	80.100
Min; Max	39.89; 152.80	48.73; 134.70	52.02; 126.00	46.00; 129.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with concentrations at
specific sampling time; SD: Standard Deviation; SEM: Standard Error of the Mean; T4: Tetraiodothyronine;
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	5217.6	2445.6	92.19	53.690
	5275.6	916.9	97.28	36.743
	5856.2	330.2	113.10	36.350
	5140.4	1476.6	93.62	42.733
	6179.1	1671.2	107.40	44.790
	4825.8	1287.7	104.60	55.460
	6343.2	2618.4	123.10	71.367
	8145.5	3351.0	141.00	74.410
	6332.3	1793.4	131.40	68.360
	7251.1	1815.8	130.00	54.510
	4704.4	425.7	92.69	33.263
	5654.1	1018.3	101.20	36.813
	7333.1	2851.6	134.60	72.357
	5927.9	2248.9	100.30	49.203
	5707.6	1123.5	114.40	50.733
	5527.7	1775.3	96.22	44.103
	6046.2	1868.2	122.50	64.473
	6368.2	1858.1	121.00	58.360
	4892.6	1773.6	83.53	40.210
	6148.9	2063.4	104.50	47.757

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.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

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

Treatment: Test

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	6751.4	2444.6	135.10	75.283
	6875.5	3310.8	127.40	77.890
	5671.4	1332.0	97.62	37.350
	5848.4	457.8	118.30	43.430
	6809.0	1887.1	121.20	52.840
	5727.1	1589.0	111.20	53.727
	5677.3	1467.2	92.76	34.287
	5108.7	1425.2	90.96	39.800
	5008.3	1628.7	104.30	57.360
	7427.5	2000.7	135.90	60.527
	5305.2	1204.8	105.10	48.150
	4640.4	1246.5	100.40	53.263
	7262.4	2442.2	128.60	61.653
	6012.4	1984.0	136.00	80.050
	5635.8	1006.4	122.30	58.003
	5792.5	1605.2	99.39	41.233
	5899.3	2515.8	100.20	53.207
	6158.9	2018.9	129.00	71.500
	5844.3	1365.9	112.40	50.200
	5737.2	2476.8	98.22	52.937

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.

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	5879.5	2047.7	118.60	65.380
	6332.5	1912.7	106.10	44.713
	6338.3	2432.1	104.80	50.547
	5250.2	2472.0	98.87	60.283
	8205.4*	3075.1*	133.70	62.197
	4324.2*	140.4*	93.56	35.263
	7022.7	2532.8	110.80	48.440
	8120.6	3068.2	128.30	58.127
	5643.7	1792.2	98.62	45.127
	6650.7	2421.6	137.10	78.363
	7158.3	2664.3	134.00	71.583
	6599.6	2310.8	250.80	191.233
	5908.2	2285.8	116.90	66.590
	7447.5	2299.3	128.40	56.897
	5620.9	1830.3	106.00	53.353
	5601.9	1113.4	104.20	41.860
	5076.9	2045.0	85.64	43.530
	6443.7	2313.8	129.20	71.840
	6058.3	2532.4	99.25	50.280
	5759.4	2343.0	112.70	65.250

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.

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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters

(Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	5786.3	1583.6	104.20	45.830
	4434.2	1422.3	86.29	44.457
	5181.5	904.7	97.53	38.130
	5262.4	1611.1	90.93	40.217
	8341.4	3377.7	142.30	73.360
	5722.0	996.4	114.30	48.667
	6498.5	1259.9	106.70	33.943
	7219.3	3023.1	134.90	76.620
	4995.1	1279.4	88.58	36.973
	6107.5	1634.6	126.20	64.077
	7430.7	2727.1	141.30	75.973
	5119.3	1576.1	96.55	47.340
	5174.3	1722.4	100.60	52.657
	4245.3	938.8	77.84	31.917
	6994.6	2264.4	113.00	47.303
	4337.1	1752.1	74.61	38.707
	6661.2	3749.7	125.80	85.363
	5783.5	1924.1	94.12	40.517
	6893.1	1933.2	123.80	54.913
	5935.4	1977.6	121.30	66.330

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	5218.1	1474.8	101.20	49.210
	6072.2	1946.6	99.74	42.440
	4148.1	1212.7	75.82	35.050
	5948.5	1854.1	99.83	42.963
	7658.5	3198.3	135.70	73.753
	7217.5	2793.6	144.80	83.357
	5409.7	1565.6	97.98	44.590
	5953.8	2196.1	113.40	61.210
	5332.8	2383.0	110.80	69.830
	4918.1	1666.1	94.03	48.863
	6417.3	2904.4	120.40	71.610
	5801.5	2006.2	107.70	54.987
	6677.3	2272.6	135.70	74.523
	3980.2	923.6	74.27	31.817
	5707.6	1791.3	87.64	33.247
	5901.2	1584.8	108.00	48.050
	6061.8	1445.9	106.20	42.090
	7598.8	2296.0	134.20	60.550
	6143.8	1599.4	119.40	56.283
	5907.9	1308.1	101.80	37.913

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

Treatment: Test

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	6308.9	1957.2	111.10	50.660
	5144.3	2032.9	94.82	51.607
	3617.3	827.8	75.77	37.027
	3948.6	617.9	73.78	27.520
	5862.8*	2235.4*	93.47	42.937
	6383.3	1529.8	133.60	66.190
	5970.3	2409.9	111.30	61.850
	7066.0	2342.3	122.50	56.893
	3839.7	999.8	77.41	37.967
	6445.4	2270.8	108.80	50.820
	6409.8	1753.3	107.10	42.427
	5896.6	1633.0	114.30	55.083
	5092.1	1593.6	95.58	46.990
	5675.1	1613.6	100.60	44.190
	5724.4	1555.4	95.26	37.357
	6119.2	1904.8	98.98	40.447
	7021.9	1571.7	133.00	57.303
	6922.2	2226.6	125.80	60.583
	6201.9	2226.3	108.10	52.883
	7395.9	2281.3	129.90	58.863

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	7985.5	2818.6	137.90	66.137
	7503.9	2834.7	146.30	81.450
	6737.8	1996.6	123.00	57.150
	6234.8*	1820.7*	104.70	43.350
	6621.4	2350.6	112.70	53.383
	7408.1	2311.0	136.90	66.107
	6410.1	2074.4	109.10	48.883
	6503.8	1957.2	130.20	67.053
	6336.6	1826.5	140.50	77.860
	7195.9	3367.7	114.60	61.430
	5241.3	1609.9	99.76	49.323
	6161.6	1846.0	111.40	51.460
	7903.3	2347.5	147.60	70.437
	6804.6	1522.7	139.80	66.440
	5637.5	1779.2	96.12	42.533
	5796.0	1175.1	101.70	37.520
	7238.6	2921.9	132.20	72.247
	8366.9	2916.0	142.40	66.693
	6396.1	2261.9	113.90	56.480
	6517.3	2399.8	114.20	57.013

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.

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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters

(Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	6294.8	2297.4	124.30	68.780
	6037.2	1883.5	106.80	49.110
	6572.0*	1920.3*	113.30	48.287
	6657.1	2095.1	126.90	63.540
	5396.4	1369.9	106.50	50.577
	6124.5	2017.8	121.80	64.763
	6400.7	1827.1	116.70	53.177
	6526.0	1254.7	145.60	72.387
	7013.0	2704.5	136.30	76.460
	5878.3	1795.4	115.50	58.793
@	5810.4	964.8	112.00	44.700
	7255.1	2275.8	131.90	62.743
	6171.0	2452.5	111.60	59.953
	6915.3	2651.4	117.10	57.880
	6561.9	2284.2	127.00	67.587
	7613.5	2402.9	140.30	67.930
	6369.9	2047.1	114.40	54.360
	7515.9	3242.2	134.20	74.843
	6430.4	1955.4	107.50	45.347
	7364.5	2629.8	126.60	60.840

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.

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

Treatment: Test

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	6999.9	2338.2	137.20	72.453
	8694.1	2208.3	146.90	56.820
	5759.0	1805.3	133.30	78.387
	7182.8	2918.9	121.70	62.480
	7384.0	2327.4	125.50	55.270
	5555.1	1730.9	97.40	44.287
	5470.9	1295.1	101.00	43.003
	5762.2	1606.4	94.57	36.850
@	6014.0	2053.3	122.90	67.890
@	5965.3	1093.3	129.90	62.233
	6218.1	1512.9	102.10	36.750
/?	7815.3	1477.0	136.90	48.867
	7339.6	3005.7	129.40	69.207
	6495.7*	1941.7*	103.50	39.823
	6402.0	2227.2	120.00	62.017
	6232.2	1780.2	115.10	53.267
	7601.6	3118.2	133.10	70.830
	7482.7	1988.9	120.40	44.097
	6343.1	2324.7	112.10	56.290
	5941.7	2228.6	95.01	43.440

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	5083.3	992.0	93.17	36.347
	6161.4	1964.6	106.30	48.010
	8513.3	2234.7	138.30	51.097
	7709.9	3113.4	132.10	68.260
	5472.3	1586.6	100.40	46.433
	5156.3	1596.1	97.27	47.823
	6953.2	2242.9	137.10	71.680
	6228.0	1745.8	119.40	57.147
	6434.0	1482.8	112.60	43.833
	5381.4	1472.3	98.49	34.197
	6792.9	2209.6	119.90	56.243
	5960.3	1304.1	118.30	53.630
	6223.3	1333.1	121.60	53.680
	6741.8	2051.7	114.60	49.460
	6802.1	1707.2	111.90	41.137
	4917.2	770.7	112.30	54.710
	6293.1	1768.6	112.00	49.160
	6997.4	2359.7	124.90	60.487
	5552.3	1577.4	99.98	44.773
	6615.5	2365.9	119.40	60.377

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.

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	6099.8	1936.2	96.37	38.543
	5407.8	1802.2	110.00	59.923
	5318.7	1034.7	113.50	54.000
	5193.8	1781.0	89.10	41.700
	6930.4	2367.6	127.30	63.927
	9155.7	3367.1	167.20	86.803
	7118.9	2632.8	136.30	73.993
	6574.1	2633.6	106.50	51.770
	6758.3	2861.7	118.50	64.380

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.

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	6241.58 (943.948)	1975.81 (626.137)	114.633 (19.6367)	55.3788 (15.93241)
GeoMean (95% CI)	6169.49 (6039.61;6302.16)	1851.94 (1751.43;1958.22)	113.091 (110.567;115.672)	53.5498 (51.7064;55.4589)
GeoCV(CV%)	15.5 (15.1)	42.1 (31.7)	16.5 (17.1)	25.8 (28.8)
SEM	66.090	43.838	1.3748	1.11549
Median	6190.50	1944.15	113.050	53.6550
Min; Max	3839.7; 9155.7	140.4; 3749.7	73.78; 250.80	27.520; 191.233

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra, adj (hr*ng/mL) #	AUC0-∞, adj (hr*ng/mL) #
	3646.6	3.00	NE	NE
	3607.3	2.50	NE	NE
	4313.7	4.00	NE	NE
	3496.1	2.52	NE	NE
	4296.8	2.00	NE	NE
	3339.7	1.00	NE	NE
	4380.9	2.57	NE	NE
	5474.4	1.50	NE	NE
	4321.1	2.50	NE	NE
	4832.6	1.50	NE	NE
	3232.4	2.52	NE	NE
	3842.1	1.02	NE	NE
	5035.0	3.00	NE	NE
	4113.0	1.50	NE	NE
	4006.4	2.02	NE	NE
	3928.1	1.52	NE	NE
	4230.4	2.02	NE	NE
	4375.9	3.00	NE	NE
	3330.9	2.02	NE	NE
	4204.9	1.00	NE	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.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	4774.1	2.57	NE	NE
	4803.1	1.50	NE	NE
	3842.2	36.02	NE	NE
	4457.3	1.50	NE	NE
	4590.7	1.50	NE	NE
	3887.4	1.00	NE	NE
	3911.4	6.03	NE	NE
	3565.0	2.00	NE	NE
	3418.6	3.00	NE	NE
	5107.1	2.50	NE	NE
	3651.9	6.05	NE	NE
	3161.6	6.02	NE	NE
	4941.4	6.03	NE	NE
	4236.3	6.00	NE	NE
	3956.2	6.07	NE	NE
	3633.6	6.00	NE	NE
	4211.2	6.02	NE	NE
	4048.1	1.50	NE	NE
	4220.4	2.00	NE	NE
	3760.7	2.00	NE	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
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	4087.0	1.50	NE	NE
	4245.3	1.52	NE	NE
	4232.7	2.02	NE	NE
	3487.3	2.52	NE	NE
	5320.0	47.28	NE	NE
	2814.7	3.02	NE	NE
	4620.2	2.50	NE	NE
	5503.9	23.93	NE	NE
	3770.6	36.00	NE	NE
	4475.6	1.50	NE	NE
	4772.8	2.07	NE	NE
	4642.5	2.50	NE	NE
	4019.2	3.02	NE	NE
	5071.3	4.02	NE	NE
	3768.5	1.52	NE	NE
	3857.9	1.50	NE	NE
	3503.3	2.00	NE	NE
	4336.1	2.50	NE	NE
	4110.3	6.00	NE	NE
	3991.1	1.50	NE	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.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	3927.9	6.00	NE	NE
	3024.2	1.50	NE	NE
	3665.6	8.00	NE	NE
	3625.1	2.50	NE	NE
	5716.3	1.50	NE	NE
	3968.8	2.03	NE	NE
	4399.7	3.03	NE	NE
	4992.1	4.02	NE	NE
	3460.8	3.02	NE	NE
	4398.2	1.50	NE	NE
	5169.0	4.03	NE	NE
	3493.3	2.00	NE	NE
	3872.6	2.50	NE	NE
	3045.8	10.00	NE	NE
	4715.3	2.50	NE	NE
	2968.5	10.00	NE	NE
	4512.0	3.00	NE	NE
	3901.3	2.50	NE	NE
	4678.4	4.07	NE	NE
	4046.1	1.50	NE	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.

*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_Z.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra, adj (hr*ng/mL) #	AUC0-∞, adj (hr*ng/mL) #
	3460.9	1.02	NE	NE
	4079.7	2.00	NE	NE
	2849.5	2.50	NE	NE
	3984.6	2.50	NE	NE
	4749.9	48.32	NE	NE
	4852.7	1.50	NE	NE
	3709.9	2.50	NE	NE
	3955.7	2.53	NE	NE
	3521.7	2.50	NE	NE
	3502.1	2.00	NE	NE
	4407.1	1.50	NE	NE
	4094.6	10.02	NE	NE
	4617.8	2.50	NE	NE
	2738.3	2.00	NE	NE
	3790.5	47.87	NE	NE
	4164.0	1.02	NE	NE
	4307.4	1.00	NE	NE
	5137.3	10.00	NE	NE
	4069.0	2.02	NE	NE
	3955.1	6.00	NE	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.

*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0--∞,adj (hr*ng/mL) #
	4259.6	3.00	NE	NE
	3540.5	4.02	NE	NE
	2452.3	2.00	NE	NE
	2864.9	2.52	NE	NE
	3993.7	35.80	NE	NE
	4444.2	2.50	NE	NE
	3889.7	4.00	NE	NE
	4793.4	2.50	NE	NE
	2495.9	2.50	NE	NE
	4318.6	2.00	NE	NE
	4303.0	10.02	NE	NE
	4044.0	2.50	NE	NE
	3508.7	6.00	NE	NE
	3866.2	1.50	NE	NE
	3858.2	3.00	NE	NE
	4279.8	2.50	NE	NE
	4965.6	2.50	NE	NE
	4700.2	2.00	NE	NE
	4352.2	3.00	NE	NE
	5014.9	1.50	NE	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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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	5448.3	2.00	NE	NE
	5276.8	2.52	NE	NE
	4643.0	2.03	NE	NE
	4052.7	1.50	NE	NE
	4465.2	2.00	NE	NE
	5079.5	8.02	NE	NE
	4473.2	2.00	NE	NE
	4617.4	2.50	NE	NE
	4538.3	2.53	NE	NE
	4657.3	48.78	NE	NE
	3604.1	1.00	NE	NE
	4362.1	4.00	NE	NE
	5223.8	2.50	NE	NE
	4821.3	2.53	NE	NE
	3817.1	2.52	NE	NE
	3969.2	4.00	NE	NE
	5145.3	2.03	NE	NE
	5619.3	4.00	NE	NE
	4466.2	2.00	NE	NE
	4462.7	1.50	NE	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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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Test

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	4386.3	2.52	NE	NE
	4168.3	2.52	NE	NE
	4710.1	35.32	NE	NE
	4618.8	2.07	NE	NE
	3708.1	10.02	NE	NE
	4263.7	4.00	NE	NE
	4382.3	4.02	NE	NE
	4474.9	2.52	NE	NE
	4981.4	2.52	NE	NE
	4139.0	2.00	NE	NE
	4084.2	3.00	NE	NE
	4871.6	10.00	NE	NE
	3974.1	2.50	NE	NE
	4613.7	1.50	NE	NE
	4351.0	1.50	NE	NE
	5104.3	1.50	NE	NE
	4431.5	1.50	NE	NE
	5122.8	2.55	NE	NE
	4409.9	3.00	NE	NE
	5079.2	12.00	NE	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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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra, adj (hr*ng/mL) #	AUC0-∞, adj (hr*ng/mL) #
	4942.9	1.50	NE	NE
	5820.2	2.50	NE	NE
	3921.6	1.02	NE	NE
	4719.7	1.60	NE	NE
	4903.2	1.50	NE	NE
	3844.1	2.00	NE	NE
	3853.7	4.00	NE	NE
	3916.3	2.50	NE	NE
	4251.2	2.52	NE	NE
	4466.3	1.50	NE	NE
	4270.5	8.00	NE	NE
	5399.6	3.00	NE	NE
	5105.3	1.00	NE	NE
	4181.6	71.52	NE	NE
	4385.4	2.03	NE	NE
	4246.9	2.50	NE	NE
	5080.2	4.00	NE	NE
	5005.4	3.00	NE	NE
	4373.3	2.00	NE	NE
	4093.8	2.50	NE	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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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	3530.6	4.00	NE	NE
	4170.1	1.50	NE	NE
	5789.6	3.00	NE	NE
	5271.5	6.03	NE	NE
	3921.5	2.00	NE	NE
	3568.6	1.50	NE	NE
	4884.8	23.87	NE	NE
	4239.9	2.52	NE	NE
	4444.1	2.02	NE	NE
	3623.1	2.00	NE	NE
	4617.8	1.50	NE	NE
	4079.6	2.00	NE	NE
	4471.2	10.03	NE	NE
	4704.9	2.50	NE	NE
	4515.4	10.07	NE	NE
	3226.1	2.58	NE	NE
	4304.2	2.50	NE	NE
	4681.8	3.00	NE	NE
	3631.2	2.02	NE	NE
	4591.6	4.00	NE	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.
*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	4255.9	2.50	NE	NE
	3555.4	2.52	NE	NE
	3843.4	2.50	NE	NE
	3478.5	10.00	NE	NE
	4788.3	4.00	NE	NE
	6296.7	23.92	NE	NE
	4917.2	4.00	NE	NE
	4401.0	3.00	NE	NE
	4605.6	1.50	NE	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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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
n(missing)	204 (0)	204 (0)		
Mean(SD)	4270.49 (635.849)			
GeoMean	4222.26			
(95% CI)	(4134.18;4312.22)			
GeoCV(CV%)	15.4 (14.9)			
SEM	44.518			
Median	4267.10	2.500		
Min; Max	2495.9; 6296.7	1.00; 71.52		

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 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.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.005	NE	NE
	NE	0.008	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.004	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.009	NE	NE
	NE	0.008	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	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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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.005	NE	NE
	NE	0.006	NE	NE
	NE	NE	NE	NE
	NE	0.023	NE	NE
	NE	0.002	NE	NE
	NE	0.004	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.008	NE	NE
	NE	0.009	NE	NE
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.002	NE	NE
	NE	NE	NE	NE
	NE	0.008	NE	NE
	NE	0.002	NE	NE
	NE	0.009	NE	NE
	NE	0.002	NE	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.
*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	$t_{1/2}$ (hr) #	λ_z (1/hr) ^	V_z/F (L) #	CL/F (L/hr) #
	NE	0.005	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.000	NE	NE
	NE	NE	NE	NE
	NE	NE	NE	NE
	NE	0.000	NE	NE
	NE	0.000	NE	NE
	NE	NE	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	0.002	NE	NE
	NE	0.001	NE	NE
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.004	NE	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.
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#: Due to unreliable λ_z , All λ_z dependent parameters are not estimated.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.001	NE	NE
	NE	0.003	NE	NE
3	NE	0.006	NE	NE
	NE	0.002	NE	NE
	NE	0.005	NE	NE
	NE	0.002	NE	NE
	NE	0.002	NE	NE
	NE	0.006	NE	NE
	NE	0.002	NE	NE
	NE	0.007	NE	NE
	NE	0.005	NE	NE
	NE	0.001	NE	NE
	NE	0.013	NE	NE
	NE	0.010	NE	NE
	NE	0.006	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	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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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.000	NE	NE
	NE	0.004	NE	NE
	NE	0.001	NE	NE
	NE	NE	NE	NE
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.001	NE	NE
	NE	0.001	NE	NE
	NE	0.011	NE	NE
	NE	0.002	NE	NE
	NE	0.008	NE	NE
	NE	0.003	NE	NE
	NE	0.004	NE	NE
	NE	NE	NE	NE
	NE	0.005	NE	NE
	NE	0.007	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	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.

*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters

(Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.011	NE	NE
	NE	0.015	NE	NE
	NE	NE	NE	NE
	NE	0.005	NE	NE
	NE	0.000	NE	NE
	NE	0.001	NE	NE
	NE	0.001	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.004	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.005	NE	NE
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.002	NE	NE
	NE	0.006	NE	NE
	NE	0.002	NE	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.

*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_Z.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λz (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.003	NE	NE
	NE	0.007	NE	NE
	NE	0.005	NE	NE
	NE	NE	NE	NE
	NE	0.001	NE	NE
	NE	0.006	NE	NE
	NE	0.009	NE	NE
	NE	0.004	NE	NE
	NE	0.009	NE	NE
	NE	NE	NE	NE
	NE	0.004	NE	NE
	NE	0.006	NE	NE
	NE	0.000	NE	NE
	NE	0.007	NE	NE
	NE	0.002	NE	NE
	NE	0.002	NE	NE
	NE	0.010	NE	NE
	NE	0.002	NE	NE
	NE	0.005	NE	NE
	NE	0.001	NE	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.

*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old Formulation.

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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters

(Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.009	NE	NE
	NE	0.004	NE	NE
	NE	NE	NE	NE
	NE	0.004	NE	NE
	NE	0.005	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.012	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	0.001	NE	NE
	NE	0.001	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	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.

*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	t1/2 (hr) #	λz (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.005	NE	NE
	NE	0.001	NE	NE
	NE	0.005	NE	NE
	NE	0.000	NE	NE
	NE	0.001	NE	NE
	NE	0.006	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.005	NE	NE
	NE	0.013	NE	NE
	NE	0.006	NE	NE
	NE	0.004	NE	NE
	NE	0.006	NE	NE
	NE	NE	NE	NE
	NE	0.006	NE	NE
	NE	0.003	NE	NE
	NE	0.001	NE	NE
	NE	0.001	NE	NE
	NE	0.004	NE	NE
	NE	0.005	NE	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.
*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.005	NE	NE
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.007	NE	NE
	NE	0.004	NE	NE
	NE	0.007	NE	NE
	NE	0.002	NE	NE
	NE	0.006	NE	NE
	NE	0.002	NE	NE
	NE	0.005	NE	NE
	NE	0.003	NE	NE
	NE	0.012	NE	NE
	NE	0.004	NE	NE
	NE	0.000	NE	NE
	NE	0.000	NE	NE
	NE	0.004	NE	NE
	NE	0.002	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	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.
*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.001	NE	NE
	NE	0.007	NE	NE
	NE	0.001	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	NE
	NE	0.007	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	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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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	5143.7	1904.9	94.05	49.067
	4913.4	1393.6	96.86	47.973
	5752.7	1076.5	111.10	46.153
	5203.2	1404.9	91.08	38.327
	6224.1	1871.2	112.30	51.843
	4826.1	1682.8	96.82	53.163
	6165.3	2453.7	123.60	72.050
	8554.4	3349.0	150.80	78.503
	5937.8	1450.2	116.30	53.973
	6805.3	1159.5	131.80	53.387
@	6758.9	2751.6	106.90	51.243
	5045.6	1037.3	89.19	33.520
	6175.7	1502.7	116.90	51.997
@	5944.8	1734.7	114.00	55.527
	6969.2	2942.5	123.30	67.373
	6826.6	1740.0	120.10	49.453
	5452.7	589.3	97.39	29.843
	5295.0	1856.8	85.56	37.807
	6195.7	1828.9	136.10	75.450
	6919.8	2237.9	118.90	53.873

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.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	5028.0	1266.2	83.43	31.183
	6811.9	2838.0	120.80	65.607
	8664.1	2861.4	153.30	72.707
	7129.4	3326.9	115.40	62.587
	5998.2	1850.5	126.30	68.693
	6447.7	253.5	123.30	37.270
	6782.4	2432.2	124.30	63.880
	5092.4	1470.3	92.83	42.523
	5866.0	1709.6	103.80	46.073
	5040.0	2114.7	90.37	49.740
	5069.9	1682.0	87.09	40.037
	7171.8	1914.8	122.60	49.587
	5768.1	1594.3	105.60	47.630
	5232.0	2162.6	103.40	60.770
	6292.4	1402.4	129.40	61.483
	6063.8	2374.0	135.20	83.953
	5740.0	1523.2	107.80	49.233
	4899.7	776.2	85.57	28.300
	6290.5	2969.1	117.40	71.270
	5981.1	2394.8	109.70	59.890

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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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Treatment: Reference

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	5583.2	1014.8	102.50	39.050
	5419.3	1828.7	98.26	48.390
	5673.2	1858.1	93.52	40.533
	6591.3	1295.0	107.70	34.140
	6116.4	1915.9	98.01	39.670
	5047.6	2598.1	95.21	61.190
	7906.1	2690.2	133.00	60.557
	4536.6	937.6	90.21	40.223
	7200.6	2824.2	107.50	46.717
	7846.8	3466.1	134.50	73.657
	4775.0*	1271.7*	81.63	32.160
	6041.2	2001.7	129.10	72.997
	6165.4	2416.6	136.90	84.833
	7427.9*	2610.0*	123.80	56.417
	6848.2	2687.3	134.30	76.510
	6277.8	2845.1	116.60	68.923
	6116.6*	1804.5*	102.00	42.067
	7415.8	2220.8	122.90	50.747
	5624.2	2091.9	99.82	50.760
	6119.1	1651.7	111.10	49.053

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.

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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	5752.3	2709.4	97.25	54.987
	6118.9	2134.5	137.60	82.260
	7023.8	2908.8	126.40	69.247
	5376.3	2025.4	102.90	56.360
	8354.5	3088.2	140.90	67.757
	6197.2	1586.5	113.30	49.263
	4787.1	1445.5	84.76	38.350
	5518.8	2666.7	107.60	67.987
	6702.6	1916.0	110.40	43.920
	6121.0	1029.2	123.50	52.780
	6797.8	1771.2	120.20	50.387
	6564.9	2428.3	119.20	61.747
	5653.8	1635.0	96.67	40.853
	5778.0	1836.0	106.50	51.750
	6468.2	2146.5	120.10	60.077
	5302.5	1655.5	104.00	53.347
	5578.4	1963.8	92.89	42.687
	4317.3	1195.2	81.67	38.307
	6730.2	2339.4	110.60	49.617
	4395.9	1405.9	74.70	33.173

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.

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.

Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	6828.8	3022.2	155.70	102.830
	5842.0	2125.8	94.63	43.017
	6558.0	1468.8	118.60	47.917
	5565.7	1051.1	103.20	40.497
	5602.3	1774.8	97.37	44.210
	6202.2	1598.3	105.80	41.857
	4484.0	1906.4	94.90	59.100
	5699.0	1374.0	104.10	44.030
	7621.3	2998.4	124.90	60.693
	7521.1	2921.5	135.30	71.417
	5640.9	1984.3	99.39	48.603
	5662.7	2038.2	114.00	63.660
	5677.9*	2214.8*	94.68	46.413
	5004.4	1426.7	85.74	36.050
	5681.0	2476.5	103.00	58.493
	5566.3	1906.5	94.07	43.240
	6440.3	2114.8	115.60	55.523
	4192.8	1596.5	78.83	42.770
	6045.9	1903.7	105.80	48.270
	6280.6	1984.2	118.60	58.927

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	5136.8	1316.6	88.49	35.433
	7410.8	2490.3	133.50	65.160
	6537.6	1933.0	120.00	56.047
	6315.5	1509.0	127.60	60.843
	5672.2	1329.7	108.60	48.287
	4917.3	1673.7	84.27	39.220
	4220.3	1267.1	93.15	52.133
	6255.3	2540.1	133.30	81.700
@	7813.4	3524.2	138.10	78.527
	6335.9	1334.7	101.30	31.840
	6422.4	2980.6	105.60	57.797
	7675.2	2919.6	148.80	82.750
	3710.1	1614.2	87.15	58.040
	6791.1	2372.3	109.50	48.127
	6310.3	1150.8	107.90	36.240
	6827.7	2397.4	131.60	70.067
	6134.9	1857.9	104.60	45.197
	5626.8	1603.2	100.10	44.217
	5646.8	1702.4	98.95	44.167
	5834.8	1948.2	94.16	40.180

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

Treatment: Reference

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	6584.4	1876.1	112.20	46.807
	6417.4	1411.8	117.10	47.577
	6482.6	1998.5	109.70	47.420
	7852.3	1989.9	133.30	51.877
	7689.7	2476.2	148.50	76.090
	7396.3	2677.9	132.20	66.667
	6758.5	1754.3	117.30	47.797
	6400.3	1804.5	110.50	46.670
	6265.6	1495.1	108.40	42.143
	6715.2	2179.2	120.70	57.700
	7363.1*	3114.1*	114.20	54.760
	5933.0	1419.3	114.30	51.610
	6373.6	1231.6	118.40	46.983
	6807.2	2923.7	120.30	66.363
	7425.4*	2749.4*	119.70	54.010
	6301.3	2243.6	109.90	53.543
	7288.3	2146.6	110.10	38.687
	6505.2	1424.2	130.10	59.530
	5762.4	1635.1	92.54	35.217
	5424.2	1502.4	98.03	43.560

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	7103.5	3087.9	131.40	75.627
	8367.1	2474.6	146.40	64.560
	6413.5	2501.5	128.20	73.867
	6718.4	1984.4	113.30	47.550
	6242.6	2431.4	117.80	64.867
	6464.2	1884.5	121.00	57.393
	6178.1	1412.2	116.20	50.007
	6585.0	2056.4	118.00	55.103
	5084.0	1340.7	96.05	44.060
	6332.7	2318.2	121.20	65.443
	6849.2	1717.6	153.70	82.427
	6031.4	1033.8	122.20	52.790
	6873.2	1672.5	128.60	56.367
	6116.2	2224.8	113.90	59.853
	7407.6	2523.8	147.60	79.770
	6207.1	2343.6	108.40	54.740
	8052.2*	2362.9*	134.50	53.667
	7107.1	1893.3	130.00	57.587
	7446.9*	1696.7*	129.80	49.603
	6526.5	2261.0	112.10	52.857

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.

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	7223.8	3293.8	123.60	69.017
	6758.2	2338.4	127.40	66.013
	7037.3	2465.6	124.60	61.103
	6443.2	2383.6	121.20	64.817
	8149.3*	2807.3*	145.00	70.753
	4948.4	380.0	110.00	46.550
	6457.2	1936.1	111.20	48.407
	6351.2	1890.6	128.90	66.947
	6382.6	1766.0	124.10	59.980
	5446.0	813.5	105.70	41.360
	5616.0	1657.5	97.46	42.480
	7068.7	2805.8	120.70	61.493
	8103.3	1641.1	156.50	66.747
	7280.9	2898.9	121.90	61.040
	8625.5	1525.3	110.10	39.263
	6442.1	2429.3	111.20	55.467
	5647.6	1414.2	114.40	55.603
	7090.7	2788.9	135.30	75.553
	7250.4	1979.8	120.00	46.797
	6009.4	2152.6	97.87	44.303

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

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72,adj (hr*ng/mL)	Cmax (ng/mL)	Cmax,adj (ng/mL)
	5628.0	2203.2	99.74	52.173
	5830.4	1587.7	109.90	50.973
	5987.7	1187.9	111.80	45.137
	8682.5	2126.1	142.00	50.940
	6422.1	1699.6	130.30	64.710
	5554.9	1566.9	101.90	46.510
	5552.9	2041.5	104.80	56.030
	6801.9	1959.0	115.10	47.837
	6463.9	2708.9	120.50	68.347
	6489.7	1973.4	107.30	44.573
	4896.7	894.9	86.64	31.060
	7068.8	3107.1	115.90	60.877
	5624.5	1194.9	110.30	48.777
	7311.6	2454.5	138.10	70.640
	6858.4	1369.6	120.50	44.267
	7638.4*	2627.7*	121.20	51.103
	5018.1*	859.6*	101.80	43.367
	6820.5	1861.9	129.20	60.330
	6743.6	2590.2	114.80	57.113
	5162.4	1243.4	103.70	49.270

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.

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

Treatment: Reference

Subject Number/ Random Number	AUC0-72 (hr*ng/mL)	AUC0-72, adj (hr*ng/mL)	Cmax (ng/mL)	Cmax, adj (ng/mL)
	6573.7	2236.2	126.40	66.157
	5769.7	2153.1	106.70	56.470
	5278.4	1294.8	99.16	43.833
	5606.2	1279.5	95.58	35.487
3	6070.8*	1857.0*	91.66	32.630
	5582.7	2008.7	105.50	55.860
	7768.6	2736.6	132.60	62.710
	8991.9	3426.0	152.80	75.497
	6255.3	1749.8	123.60	61.023
	6143.5	2453.7	118.30	67.053
	6632.0	2792.4	110.30	56.973

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.

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

Subject Number/ Random Number	AUC ₀₋₇₂ (hr*ng/mL)	AUC _{0-72,adj} (hr*ng/mL)	C _{max} (ng/mL)	C _{max,adj} (ng/mL)
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	6258.71 (922.975)	1976.87 (619.892)	113.635 (16.6874)	54.1358 (12.72064)
GeoMean (95% CI)	6190.28 (6063.65;6319.55)	1865.11 (1772.77;1962.25)	112.415 (110.143;114.733)	52.6806 (50.9997;54.4170)
GeoCV(CV%)	15.1 (14.7)	38.1 (31.4)	14.9 (14.7)	23.8 (23.5)
SEM	64.621	43.401	1.1683	0.89062
Median	6271.72	1915.95	113.300	52.4765
Min; Max	3710.1; 8991.9	253.5; 3466.1	74.70; 156.50	28.300; 102.830

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.

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

Treatment: Reference

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	3672.8	1.52	NE	NE
	3449.7	2.50	NE	NE
	4254.1	2.53	NE	NE
	3574.4	1.50	NE	NE
	4249.4	3.00	NE	NE
	3363.4	1.50	NE	NE
	4118.7	1.50	NE	NE
	5999.0	3.00	NE	NE
	4060.8	2.50	NE	NE
	4777.2	2.50	NE	NE
	4536.7	36.00	NE	NE
	3427.0	1.50	NE	NE
	4326.0	6.02	NE	NE
	4371.1	4.00	NE	NE
	4932.9	4.00	NE	NE
	4519.2	4.00	NE	NE
	3796.1	2.02	NE	NE
	3671.7	35.42	NE	NE
	4274.8	1.50	NE	NE
	4723.5	2.67	NE	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
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	3498.0	4.00	NE	NE
	4519.3	2.50	NE	NE
	5980.6	4.03	NE	NE
	4995.5	10.22	NE	NE
	4128.6	3.00	NE	NE
	4549.1	3.00	NE	NE
	4621.8	1.50	NE	NE
	3666.3	2.03	NE	NE
	3978.9	4.03	NE	NE
	3614.7	5.98	NE	NE
	3327.2	3.00	NE	NE
	4868.8	2.50	NE	NE
	4081.5	3.00	NE	NE
	3587.9	2.52	NE	NE
	4396.1	6.02	NE	NE
	4335.0	6.02	NE	NE
	3993.6	2.00	NE	NE
	3371.5	3.00	NE	NE
	4191.5	8.05	NE	NE
	4139.5	2.50	NE	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.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters

(Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	3548.9	1.50	NE	NE
	3734.4	1.50	NE	NE
	4022.0	23.90	NE	NE
	4392.6	1.50	NE	NE
	4148.8	6.02	NE	NE
	3398.6	1.52	NE	NE
	5159.5	3.02	NE	NE
	3091.4	2.50	NE	NE
	4807.8	8.00	NE	NE
	5201.9	4.00	NE	NE
	2997.4	2.98	NE	NE
	4006.2	2.02	NE	NE
	4143.4	1.50	NE	NE
	4901.7	35.28	NE	NE
	4613.6	4.02	NE	NE
	4437.4	3.02	NE	NE
	3988.0	4.02	NE	NE
	4911.4	2.50	NE	NE
	3738.8	4.00	NE	NE
	4156.6	1.50	NE	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.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	3892.7	2.07	NE	NE
	4435.9	3.00	NE	NE
	4695.4	1.50	NE	NE
	3674.3	1.50	NE	NE
	5629.6	8.00	NE	NE
	4042.6	3.00	NE	NE
	3382.3	3.00	NE	NE
	3760.0	1.00	NE	NE
	4653.5	6.00	NE	NE
	4267.9	1.53	NE	NE
	4693.4	2.00	NE	NE
	4614.6	4.02	NE	NE
	3933.8	4.03	NE	NE
	4032.5	3.00	NE	NE
	4513.3	2.50	NE	NE
	3653.7	1.50	NE	NE
	3701.3	4.02	NE	NE
	3016.1	12.03	NE	NE
	4511.3	4.00	NE	NE
	2988.5	10.00	NE	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
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#: 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.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	4937.2	2.50	NE	NE
	4014.5	4.03	NE	NE
	4524.8	3.00	NE	NE
	3865.0	3.00	NE	NE
	3869.2	8.02	NE	NE
	4222.1	2.50	NE	NE
	2973.4	3.00	NE	NE
	3782.7	2.50	NE	NE
	4912.2	48.40	NE	NE
	5149.2	8.03	NE	NE
	3843.1	1.50	NE	NE
	3992.8	2.50	NE	NE
	3671.0	2.02	NE	NE
	3426.9	12.00	NE	NE
	3997.3	10.02	NE	NE
	3773.2	1.50	NE	NE
	4469.1	4.00	NE	NE
	2889.7	1.50	NE	NE
	4145.1	4.00	NE	NE
	4327.3	2.02	NE	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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Table 15.4.1.1.2 Individual Data and Summary Statistics of Total T4 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	3542.0	2.00	NE	NE
	5134.6	2.52	NE	NE
	4417.5	2.00	NE	NE
	4324.0	10.00	NE	NE
	3887.0	4.00	NE	NE
	3311.1	23.87	NE	NE
	3029.0	3.00	NE	NE
	4432.4	18.13	NE	NE
	5492.3	2.00	NE	NE
	4302.5	12.00	NE	NE
	4220.7	8.02	NE	NE
	5268.4	3.00	NE	NE
	2381.0	2.50	NE	NE
	4583.9	3.00	NE	NE
	4337.3	3.00	NE	NE
	4553.4	3.00	NE	NE
	4198.4	1.50	NE	NE
	3828.5	1.50	NE	NE
	3788.8	3.00	NE	NE
	3905.4	8.02	NE	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.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	4558.3	1.00	NE	NE
	4366.6	2.02	NE	NE
	4413.4	2.52	NE	NE
	5391.1	2.50	NE	NE
	5267.8	1.52	NE	NE
	5037.1	8.00	NE	NE
	4574.5	2.50	NE	NE
	4413.4	2.52	NE	NE
	4297.4	3.98	NE	NE
	4499.8	4.00	NE	NE
	5023.1	35.73	NE	NE
	4231.7	2.50	NE	NE
	4369.5	1.00	NE	NE
	4480.4	3.00	NE	NE
	4840.6	48.98	NE	NE
	4312.3	3.00	NE	NE
	4882.5	10.02	NE	NE
	4566.3	2.52	NE	NE
	3913.0	8.03	NE	NE
	3905.1	2.00	NE	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.

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

Subject Number/ Random Number	AUC(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	5016.1	4.00	NE	NE
	5601.7	1.50	NE	NE
	4442.6	2.50	NE	NE
	4539.1	8.00	NE	NE
	4286.4	2.52	NE	NE
	4429.7	4.00	NE	NE
	4324.3	2.00	NE	NE
	4432.4	2.00	NE	NE
	3543.0	4.00	NE	NE
	4368.3	2.00	NE	NE
	4754.8	2.52	NE	NE
	4273.3	3.00	NE	NE
	4903.4	35.50	NE	NE
	4346.3	2.50	NE	NE
	5005.5	2.02	NE	NE
	4356.0	4.00	NE	NE
	5421.5	35.28	NE	NE
	4878.5	3.00	NE	NE
	4982.6	10.05	NE	NE
	4424.1	10.00	NE	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
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