

Levothyroxine
EMR 200125-001

Bioequivalence trial of new levothyroxine formulation vs. old formulation

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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(0-48) (hr*ng/mL)	tmax (hr)	AUCextra,adj (hr*ng/mL) #	AUC0-∞,adj (hr*ng/mL) #
	5048.0	2.52	NE	NE
	4690.2	3.00	NE	NE
	4923.7	12.03	NE	NE
	4536.9	2.00	NE	NE
	5333.0	1.50	NE	NE
	3500.5	4.00	NE	NE
	4386.9	1.50	NE	NE
	4283.5	2.02	NE	NE
	4412.0	10.03	NE	NE
	3767.2	3.00	NE	NE
	3871.9	3.00	NE	NE
	4817.4	3.00	NE	NE
	5827.5	10.00	NE	NE
	4996.8	2.03	NE	NE
	4551.4	4.00	NE	NE
	4341.1	2.00	NE	NE
	3969.8	3.00	NE	NE
	4938.0	1.50	NE	NE
	4805.5	2.00	NE	NE
	4107.1	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.

#: 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) #
	3804.2	10.03	NE	NE
	4045.4	1.50	NE	NE
	4152.3	1.50	NE	NE
	5951.0	6.00	NE	NE
	4659.1	2.48	NE	NE
	3859.6	1.50	NE	NE
	3758.4	10.00	NE	NE
	4648.9	4.00	NE	NE
	4318.2	2.50	NE	NE
	4433.1	12.10	NE	NE
	3322.1	2.50	NE	NE
	4756.3	4.00	NE	NE
	3803.5	2.02	NE	NE
	5035.9	10.02	NE	NE
	4791.0	8.00	NE	NE
	5213.9	48.32	NE	NE
	3202.3	1.50	NE	NE
	4676.5	1.50	NE	NE
	4535.2	1.50	NE	NE
	3393.9	10.00	NE	NE

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GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
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(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) #
	4548.1	1.50	NE	NE
	3977.9	10.00	NE	NE
	3464.2	1.50	NE	NE
	3879.1	8.02	NE	NE
	4010.7	1.50	NE	NE
	3830.3	3.02	NE	NE
	5354.0	4.02	NE	NE
	6186.7	23.92	NE	NE
	4339.2	4.05	NE	NE
	4125.5	1.00	NE	NE
	4529.6	2.00	NE	NE

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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) #
n(missing)	204 (0)	204 (0)		
Mean(SD)	4286.84 (630.777)			
GeoMean (95% CI)	4239.73 (4152.55;4328.75)			
GeoCV(CV%)	15.1 (14.7)			
SEM	44.163			
Median	4325.12	3.000		
Min; Max	2381.0; 6186.7	1.00; 48.98		

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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	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.005	NE	NE
	NE	0.002	NE	NE
	NE	0.017	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	NE
	NE	0.005	NE	NE
	NE	0.001	NE	NE
	NE	0.008	NE	NE
	NE	0.004	NE	NE
	NE	0.005	NE	NE
	NE	NE	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.008	NE	NE
	NE	0.006	NE	NE
	NE	NE	NE	NE
	NE	0.007	NE	NE
	NE	NE	NE	NE
	NE	0.004	NE	NE
	NE	0.007	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	t1/2 (hr) #	λz (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.010	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	0.014	NE	NE
	NE	0.002	NE	NE
	NE	0.005	NE	NE
	NE	0.000	NE	NE
	NE	0.003	NE	NE
	NE	0.007	NE	NE
	NE	0.007	NE	NE
	NE	0.003	NE	NE
	NE	0.005	NE	NE
	NE	0.008	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.008	NE	NE

Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
 Mean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
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(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	t1/2 (hr) #	λz (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.002	NE	NE
	NE	0.019	NE	NE
	NE	0.000	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	NE	NE	NE
	NE	0.004	NE	NE
	NE	0.001	NE	NE
	NE	0.006	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.004	NE	NE
	NE	0.005	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	NE
	NE	0.001	NE	NE
	NE	0.001	NE	NE
	NE	0.004	NE	NE
	NE	0.007	NE	NE

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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	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.010	NE	NE
	NE	0.001	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.000	NE	NE
	NE	NE	NE	NE
3	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	NE	NE	NE
	NE	0.003	NE	NE
	NE	0.009	NE	NE
0	NE	NE	NE	NE
	NE	0.001	NE	NE
	NE	0.002	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.

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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	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.008	NE	NE
	NE	0.006	NE	NE
	NE	0.004	NE	NE
	NE	0.007	NE	NE
	NE	0.005	NE	NE
	NE	0.005	NE	NE
	NE	0.002	NE	NE
	NE	0.001	NE	NE
	NE	NE	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.011	NE	NE
	NE	NE	NE	NE
	NE	0.003	NE	NE
	NE	0.009	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.001	NE	NE
	NE	0.003	NE	NE
	NE	0.004	NE	NE

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(Pharmacokinetic Population)
Treatment: Reference

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Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CI/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.001	NE	NE
	NE	0.012	NE	NE
	NE	0.004	NE	NE
e	NE	0.006	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.006	NE	NE
	NE	0.000	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	0.001	NE	NE
	NE	0.001	NE	NE

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(Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	t1/2 (hr) #	λ_z (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.001	NE	NE
	NE	0.003	NE	NE
	NE	0.007	NE	NE
	NE	0.002	NE	NE
	NE	0.002	NE	NE
	NE	NE	NE	NE
	NE	0.010	NE	NE
	NE	0.004	NE	NE
	NE	NE	NE	NE
	NE	NE	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.012	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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(Pharmacokinetic Population)
Treatment: Reference

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

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(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	t1/2 (hr) #	λz (1/hr) ^	Vz/F (L) #	CL/P (L/hr) #
	NE	0.009	NE	NE
	NE	0.005	NE	NE
	NE	0.003	NE	NE
	NE	0.008	NE	NE
	NE	NE	NE	NE
	NE	0.005	NE	NE
	NE	0.005	NE	NE
	NE	0.001	NE	NE
	NE	0.002	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	0.000	NE	NE
	NE	0.009	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	0.003	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	0.001	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
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/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table
15.4.1.1.2.sas

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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	t1/2 (hr)#	λ_z (1/hr)^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.002	NE	NE
	NE	0.008	NE	NE
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.007	NE	NE
	NE	0.004	NE	NE
	NE	0.001	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	0.006	NE	NE
	NE	0.003	NE	NE
	NE	0.003	NE	NE
	NE	NE	NE	NE
	NE	NE	NE	NE
	NE	0.003	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.

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

Subject Number/ Random Number	t1/2 (hr) #	λz (1/hr) ^	Vz/F (L) #	CL/F (L/hr) #
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.001	NE	NE
	NE	0.003	NE	NE
0	NE	NE	NE	NE
	NE	0.005	NE	NE
	NE	0.004	NE	NE
	NE	0.004	NE	NE
	NE	0.006	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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.683	0.721	0.726	0.787
	1.217	1.150	1.070	1.000
	1.097	1.040	1.070	0.917
	0.863	1.070	0.730	0.901
	0.977	0.822	0.815	0.794
	0.762	0.770	0.753	0.794
	0.828	0.858	0.708	0.806
	0.862	0.913	0.937	0.952
	0.937	0.516	1.190	0.594
	0.956	0.974	0.827	1.290
	0.874	0.732	0.569	0.866*
	0.891	0.836	0.779	0.668
	0.936	0.855	0.851	0.781
	0.839	0.923	1.070	1.030
	0.850	1.100	0.845	0.941
	0.756	0.744	0.755	0.796
	0.795	0.892	0.864	0.942
	0.950	0.720	0.891	0.801

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.849	0.834	0.836	0.836
	0.797	0.777	0.742	0.855
	0.815	0.865	0.857	0.820
	0.729	0.688	0.823	0.892
	0.912	0.926	0.993	0.996
	0.971	1.070	1.000	1.090
	0.964	0.900	0.980	0.961
	0.724	0.826	0.773	0.798
	0.934	0.950	0.911	0.817
	0.979	0.949	1.000	0.871
	0.730	0.676	0.749	0.874
	1.016	1.010	0.930	1.140
	0.795	0.645	0.766	0.859
	0.769	0.740	0.847	0.933
	1.040	1.160	1.030	1.140
	1.111	1.100	1.060	1.070
	1.100	1.180	1.020	0.940
	0.885	1.010	0.857	1.210

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.566	0.615	0.661	0.662
	0.760	0.745	0.793	0.960
	0.926	1.080	0.903	0.824
	0.782	0.803	1.150	0.900
	0.718	0.817	0.858	0.822
	0.811	0.814	0.809	0.779
	0.713	0.732	0.776	0.897
	0.666	0.611	0.839	0.885
	0.774	0.877	0.733	0.736
	1.167	1.190	1.020	0.785
	0.916	0.920	0.943	1.090
	0.906	0.896	0.924	1.020
	0.871	1.040	0.894	0.901
	0.757	0.792	0.921	0.798
	0.837	0.819	0.780	0.898
	0.900	0.864	1.040*	0.955
	0.724	0.758	0.809	0.774
	0.915	0.943	0.925	0.922

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.870	0.923	0.758	0.813
	0.884	0.881	0.823	1.000
	0.694	0.675	0.688	0.690
	0.743	0.878	0.749	0.809
	0.934	1.010	0.859	0.872
	0.791	0.731	0.794	0.755
	0.883	0.815	0.840	0.813
	0.771	0.668	0.723*	0.931
	0.804	0.806	0.748	0.748
	0.900	0.942	1.080	0.743
	1.086	0.906	1.040	1.030
	0.855	0.925	0.819	0.929
	0.763	0.721	0.801	0.781
	0.915	1.000	1.020	1.030
	0.804	0.854	0.922	0.961
	0.883	0.826	0.897	0.828
	0.914	0.960	0.953	0.875
	0.798	0.814	0.768	0.794

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.894	0.818	0.808	0.736
	1.003	1.030	0.915	1.130
	0.735	0.635	0.846	0.764
	0.665	0.690	0.772	0.761
	0.985	0.904	1.080	0.978
	1.027	1.200	0.972	0.946
	0.849	0.910	0.792	0.937
	0.771	0.864	0.996	1.080
	1.270	1.110	1.300	1.230
	0.687	0.644	0.774	0.834
	0.895	0.777	0.836	0.857
	0.868	0.797	0.830	1.130
	0.845	0.845	0.853	1.140
	0.977	0.919	0.876	1.020
	0.823	0.844	0.872	0.809
	0.616	0.637	0.744	0.759
	0.747	0.849	0.855	0.774
	0.713	0.664	0.712	0.895

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.809	0.849	0.842	0.790
	0.688	0.647	0.798	0.715
	0.641	0.735	0.707	0.710
	0.820	0.830	0.814	0.851
	0.947	0.772	0.972	0.984
	0.893	0.777	0.904	0.903
	1.190	1.000	1.170	1.150
	1.137	1.200	1.130	1.140
	0.847	0.723	0.534	0.620
	0.493	0.521	0.456	0.563
	0.618	0.620	0.576	0.786
	0.822	0.922	0.571	0.543
	0.706	0.685	0.630	0.641
	0.774	0.810	0.929	0.794
	0.971	0.981	1.140	0.760
	0.667	0.705	0.729	0.745
	0.537	0.382	0.407	0.560
	0.642	0.513	0.551	0.640

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; T3: Triiodothyronine.

*: Measurement taken outside the allowed windows allowance.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.707	0.667	0.718	0.747
	0.978	0.789	0.678	0.821
	0.694	0.763	0.713	0.742
	0.678	0.647	0.646	0.623
	0.840	0.728	0.730	0.622
	0.731	0.746	0.603	0.711
	0.812	0.769	0.863	0.837
	0.775	0.830	0.654	0.774
	0.566	0.725	0.610*	0.505
	0.639	0.591	0.609	0.686
	0.686	0.650	0.721	0.744
	0.819	0.893	0.849	1.070
	0.936	1.060	0.996	0.983
	0.592	0.557	0.666	0.800
	0.696	0.637	0.717	0.684
	0.881	0.727	0.945	0.765
	0.998	0.944	0.945	0.946
	0.738	0.602	0.624	0.679

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.516	0.502	0.578	0.633
	1.113	1.140	0.945	1.170
	0.720	0.682	0.802	0.647
	0.673	0.704	0.657	0.691
	0.657	0.708	0.610	0.706
	0.671	0.723	0.709	0.674
	0.537	0.423	0.483	0.481
	0.632	0.619	0.733	0.725
	0.988	1.050	0.903	1.070*
	0.666	0.694*	0.636	0.816
	0.727	0.470	0.568	0.650
	0.541	0.723	0.527	0.608
	0.854	0.772	0.902	0.798
	0.571	0.614	0.576	0.625
	0.842	0.794	0.880	0.782
	0.691	0.688	0.658	0.729
	0.679	0.679	0.578	0.807
	0.639	0.669	0.614	0.584

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.601	0.637	0.560	0.612
	0.727	0.793	0.735	0.728
	0.730	0.503	0.556	0.764
	0.655	0.529	0.612	0.767
	0.659	0.640*	0.603	0.599
	0.835	0.664	0.731	0.782
	0.584	0.551	0.729	0.884
	0.663	0.784	0.616	0.745
	0.730	0.675	0.608	0.613
	1.023	1.060	1.080	1.110
	0.612	0.602	0.547	0.395
	0.553	0.569	0.505	0.653
	0.615	0.663	0.764	0.730
	0.763	0.799	0.754	0.815
	0.743	0.756	0.697	1.010
	0.458	0.510	0.578	0.538
	0.668	0.677	1.020	0.754*
	0.499	0.489	0.532	0.542

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; T3: Triiodothyronine.

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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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
1	0.939	1.130	1.020	1.150
	0.881	0.868	0.785	1.000
	1.097	1.120	1.090	1.140
	1.041	0.933	1.160	1.060
	0.796	0.802	0.708	0.815
	0.686	0.507	0.795	0.593
	0.661	0.720	0.642	0.698
	0.528	0.549	0.548	0.549
	1.022	1.030	1.070	1.180
	0.820	0.725	0.749	0.830
	1.073	0.915	1.010	0.880
	0.826	0.717	0.827	0.823
	0.935	0.818	0.939	0.775
	0.575	0.591	0.558	0.506
	0.754	0.754	0.628	1.060
	0.691	0.648	0.719	0.781
	0.699	0.586	0.758	0.608
	0.459	0.602	0.473	0.387

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
1	0.571	0.604	0.583	0.554
2	0.607	0.661	0.774	0.660
3	0.585	0.667	0.582	0.510
4	0.644	0.576	0.730	0.590
5	0.468	0.558	0.607	0.535
6	0.716	0.683	0.857	0.728
7	0.749	0.779	0.824	0.923
8	0.651	0.678	0.671	0.740
9	0.741	0.571	0.812	0.936
10	0.748	0.697	0.731	0.738
11	0.610	0.659*	0.573	0.630
12	0.644	0.734	0.694	0.817
13	0.727	0.739	0.639	0.688
14	0.742	0.713	0.746	0.698
15	0.695	0.701	0.744	0.641
16	0.569	0.587	0.657	0.711
17	0.501	0.545	0.620	0.657
18	0.891	0.965	1.060	1.030

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.549	0.637	0.485	0.644
	0.637	0.574	0.736	0.714
	0.797	0.796	0.659	0.591
	0.551	0.497	0.498	0.556
	0.493	0.432	0.494	0.521
	0.533	0.526	0.477	0.495

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; T3: Triiodothyronine.

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

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean (SD)	0.7856 (0.16163)	0.7788 (0.17288)	0.7891 (0.17117)	0.8116 (0.17488)
GeoMean	0.7691	0.7597	0.7705	0.7926
(95% CI)	(0.7473;0.7915)	(0.7365;0.7837)	(0.7472;0.7944)	(0.7687;0.8171)
GeoCV(CV%)	21.1 (20.6)	22.8 (22.2)	22.4 (21.7)	22.4 (21.5)
SEM	0.01132	0.01210	0.01198	0.01224
Median	0.7710	0.7605	0.7750	0.7950
Min; Max	0.458;1.270	0.382;1.200	0.407;1.300	0.387;1.290

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.683	0.629	0.738	0.745
	0.581	1.040	1.030	1.070
	0.926	0.874	0.996	1.010
	0.885	0.789	0.950	0.791
	0.775	0.633	0.854	0.937
	0.835	0.767	0.836	0.742
	0.821	0.874*	0.817	0.726
	0.909	1.040	1.050	0.997
	0.977	0.998	0.972	0.815
	0.912	1.040	0.959	0.675
	0.660	0.719	0.850	0.726
	0.762	0.690	0.742	0.785
	0.907	0.808	1.060	0.962
	0.972	0.812	0.878	0.986
	0.979	0.876	0.892	0.809
	0.660	0.802	0.677	0.715
	0.988	1.040	0.831	1.140
	0.908	0.807	0.918	0.910

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.915	0.854	0.827	0.964
	0.824	0.707	0.817	0.807
	0.870	0.922*	0.859	0.830
	0.696	0.795	0.757	0.772
	0.895	1.080*	1.070	0.965
	0.952	0.933	0.914	1.020
	0.866	0.913	0.876	0.968
	0.854	0.807	0.729	1.010
	0.845	0.985	0.967	0.897
	0.948	0.828	0.876	1.020
	0.723	0.723*	0.798	0.782
	1.370	1.050	1.160	0.997
	0.716	0.701	0.740	0.743
	0.646	0.729	0.813	0.728
	1.170	0.883	1.040	0.987
	1.160	1.060	1.090	1.150
	1.120	0.934	1.100	1.310
	0.916	0.934	0.741	0.897

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.778	0.745	0.662	0.785
	0.820	0.853	0.783	0.698
	0.880	0.813	0.965	0.814
	0.997	0.914	0.723	0.874
	0.861	0.980	0.783	0.904
	0.696	0.777	0.650	0.931
	0.800	0.846	0.654	0.912
	0.700	0.784	0.724	0.712
	0.866	0.838	0.783	0.820
	0.903	0.932	0.906	0.796
	0.867	0.868	0.962	0.910
	0.968	1.010	0.834	1.090
	1.010	0.960	0.956	0.928
	0.720	0.724	0.675	0.678
	0.897*	0.924	0.979	0.930
	0.921	1.410	1.100	1.020
	0.933	0.499	0.882	0.797
	0.949	0.905	0.976	1.040

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.897	0.922	0.777	0.769
	0.799	0.986	0.831	0.994
	0.744	0.626	0.697	0.704
	0.533	0.976	1.130	0.932
	0.891	0.710	1.150	0.826
	0.740	0.920	0.742	0.782
	0.964	0.844	0.913	0.783
	0.790	0.897	0.768	0.710
	0.775	0.873	0.669	0.871
	1.010	0.967	0.741	0.907
	1.110	0.998	1.060	1.070
	0.907	0.850	0.872	0.880
	0.853	0.718	0.895	0.831
	0.956	0.933	0.908	0.861
	0.995	1.030	0.924	0.965
	0.807	0.846	0.944	0.945
	0.956	0.877	0.829	0.910
	0.837	1.000	0.875	0.853

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.683	0.805	0.722	0.746
	1.070	1.080	0.870	1.010
	0.856	0.777	0.730	0.521
	0.668	0.747	0.951	0.805
	1.020	1.010	0.950	0.879
	0.888	0.985	0.935	1.090
	0.728	0.816	0.840	0.943
	0.907	0.899	0.947	0.894
	1.050	1.140	1.060	1.090
	0.643	0.787	0.831	0.686
	0.938	0.936	0.898	0.859
	1.170	0.874	0.937	0.783
	1.270	0.993	0.875	0.911
	0.811	1.170	0.927	0.936
	0.871	0.885	0.879	0.862
	0.608	0.909	0.784	0.699
	0.776	0.872	0.730	0.752
	0.668	0.857	0.850	0.782

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.791	0.840	0.800	0.781
	0.863	0.815	0.787	0.681
	0.748	0.700	0.706	0.652
	0.782	0.760	0.896	0.821
	0.982	1.020	0.823	0.962
	0.828	0.827	0.871	0.794
	1.030	1.050	1.210	1.210
	1.020	1.040	1.020	0.992
	0.687	0.571	0.551	0.578
	0.609	0.580	0.494	0.494
	0.537	0.554	0.701	0.615
	0.652	0.878	0.706	0.696
	0.588	0.701	0.680	0.533
	0.822*	0.848	0.819	0.617
	0.959	0.891	0.876	0.995
	0.598	0.747	0.819	0.825
	0.562	0.614	0.522	0.656
	0.632	0.630	0.733	0.738

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.709	0.613	0.604	0.658
	0.812	0.921	0.821	0.755
	0.732	0.683	0.693	0.777
	0.722	0.563	0.781	0.817
	0.917	0.774	0.469	0.599
	0.698	0.733	0.473	0.871
	0.782	0.818	0.826	0.844
	0.686	0.963	0.814	0.730
	0.555	0.458	0.522	0.683
	0.665	0.644	0.709	0.662
	0.753	0.771	0.638	0.612
	0.875	0.873	0.815	0.916
	1.070	0.968	1.040	0.973
	0.656	0.730	0.579	0.554
	0.628	0.741	0.888	0.663
	0.799	0.830	0.807	0.951
	0.641	1.040	0.887	1.020
	0.817	0.899	0.692	0.745

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.641	0.795	0.644	0.704
	1.240	1.030	0.887	0.911
	0.771	0.731	0.628	0.768
	0.540	0.717	0.627	0.637
	0.540	0.919	0.628	0.717
	0.695	0.667	0.691	0.661
	0.485	0.542	0.503	0.687
	0.643	0.781	0.761	0.632
	1.210	1.190	1.070	0.940
	0.743	0.601	0.811	0.747
	0.690	0.647	0.609	0.693
	0.665	0.544	0.717	0.603
	0.842	1.110	0.937	0.825
	0.545	0.560	0.557	0.592
	0.986	0.743	0.784	0.826
	0.774*	0.728	0.713	0.672
	0.746	0.600	0.684	0.744
	0.495	0.531	0.378	0.800

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.687	0.642	0.658	0.943
	0.760	0.824	0.768	0.722
	0.789	1.000	0.850	0.666
	0.780	0.631	0.639	0.642
	0.663	0.659	0.637	0.657
	0.811	0.878	0.828	0.882
	0.585	0.639	0.604	0.620
	0.700	0.595	0.626	0.919
	0.474	0.776	0.532	0.706
	1.130	0.979	1.200	0.956
	0.645	0.418	0.570	0.564
	0.626	0.710	0.561	0.729
	0.710	0.760	0.779	0.700
	0.753*	0.798	0.916	0.823
	0.781	0.832	0.783	0.780
	0.501	0.550	0.485	0.603
	0.661	0.703	0.719	0.703
	0.496	0.430	0.528	0.527

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	1.070	1.080	1.150	0.874
	0.926	0.866	1.090	0.933
	1.090	1.490	1.150	0.979
	0.997	0.999	1.250	1.200
	0.782	0.817	0.751	0.742
	0.544	0.586	0.651	0.598
	0.692	0.718	0.745	0.676
	0.402	0.447	0.414	0.486
	1.090	1.040	0.906	1.050
	0.779	0.915	0.651	0.948
	1.190	1.110	1.340	0.974
	0.969	1.010	0.786	0.902
	0.767	0.934	0.737	0.955
	0.538	0.543	0.504	0.573
	0.664	0.717	0.816	0.887
	0.778	0.555	0.819	0.636
	0.630	0.615	0.740	0.675
	0.474	0.556	0.511	0.566

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.633	0.632	0.548	0.657
	0.632	0.614	0.595	0.691
	0.614	0.586	0.508	0.665
	0.623	0.615	0.540	0.634
	0.515	0.515	0.573	0.641
	0.703	0.756	0.811	0.694
	0.705	0.653	0.663	0.793
	0.804	0.629	0.604	0.665
	0.702	0.738	0.727	0.973
	0.721	0.700	0.774	0.735
	0.577	0.722*	0.470	0.598
	0.671	0.664	0.620	0.702
	0.731	0.756	0.744	0.702
	0.685	0.621	0.642	0.657
	0.456	0.586	0.733	0.605
	0.614	0.576	0.545	0.601
	0.540	0.584	0.627	0.541
	1.100	1.080	1.010	0.976

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.718	0.574	0.556	0.677
	0.614	0.707	0.708	0.729
	0.619	0.939	0.596	0.752
	0.603	0.626	0.597	0.711
	0.466	0.659	0.602	0.539
	0.606	0.562	0.553	0.773

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.740	0.747	0.806	0.720	0.726
	0.799	1.040	0.983	0.720	0.730
	0.949	0.909	0.899	0.858	0.749
	0.950	0.777	0.901	1.040	0.767
	0.761	0.848	0.798	0.785	0.702
	0.726	0.761	0.764	0.737	0.791
	0.815	0.707	0.835	0.810	0.815
	1.000	1.010	0.938	1.090*	1.410
	0.874	1.240	0.755	1.180	0.945
	0.766	0.962	0.860	1.080	0.709
	0.820	0.770	1.060	0.902	1.060
	0.910	0.701	0.794	0.682	0.699
	0.987	0.860	0.884	0.723	0.826
	0.915	0.889	0.907	1.040	0.837
	0.798	0.815	0.735	0.751	0.732
	0.674	0.689	0.745	0.753	0.630
	0.880	1.270	0.992	1.150	0.826
	1.010	1.030	0.935	0.944	0.838

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
n (missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean (SD)	0.7913 (0.17880)	0.8079 (0.17682)	0.7912 (0.17643)	0.8039 (0.15450)
GeoMean	0.7714	0.7885	0.7713	0.7893
(95% CI)	(0.7475;0.7960)	(0.7646;0.8132)	(0.7473;0.7961)	(0.7685;0.8106)
GeoCV (CV%)	23.1 (22.6)	22.6 (21.9)	23.2 (22.3)	19.5 (19.2)
SEM	0.01252	0.01238	0.01235	0.01082
Median	0.7780	0.8075	0.7840	0.7840
Min; Max	0.402;1.370	0.418;1.490	0.378;1.340	0.486;1.310

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; T3: Triiodothyronine.

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

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.643	0.775	0.777	0.871	0.650
	0.743	0.787	0.856	0.843	0.728
	0.761	0.885	0.859	0.753	0.823
	0.900	0.961	0.857	0.955	0.822
	0.867	1.010	0.815	0.795	0.636
	0.889	0.946	0.942	0.976*	0.841
	0.896	0.949	0.942	0.907	0.797
	0.838	0.927	0.836	0.709	0.940
	0.788	0.758	0.899	0.883	0.753
	0.926	1.010	1.020	0.947	0.925
	0.864	0.931	0.815	0.643	0.726
	1.140	0.926	0.901	0.850	0.779
	0.924	0.792	0.713	0.734	0.634
	0.759	0.715	0.861	0.747	0.626
	0.839	0.917	0.873	0.749	0.702
	1.140	1.040	0.988	1.010	0.996
	1.030	0.918	1.120	0.914	0.750
	1.010	0.907	0.828	0.635	0.979

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; T3: Triiodothyronine.

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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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random	Sample Times (h)				
	6	8	10	12	18
	0.766	0.742	0.744	0.693	0.665
	0.804	0.918	0.672	0.891	0.951
	1.010	0.906	0.846	0.962	0.843
	0.859	0.881	0.788	1.050	0.768
	0.843	0.803	0.744	0.840	0.964
	0.734	0.796	0.774	0.760	0.783
	0.827	0.725	0.663	0.813	0.819
	0.642	0.889	0.712	0.926	0.792
	0.881	0.743	0.724	0.731	0.704
	0.780	0.758	0.664	0.675	0.733
	0.962	1.050	0.914	0.871	0.888
	0.962	1.060	0.977	1.070	0.952
	0.877	0.979	0.743	1.140	0.960
	0.622	0.745	0.676	0.566	0.508
	0.825	0.760	0.872	0.813	0.768
	0.908	0.818	0.891	0.887	0.975
	0.740	0.865	0.780	0.757	0.767
	1.020	0.968	0.924	0.916	1.000

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; T3: Triiodothyronine.

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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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random	Sample Times (h)				
	6	8	10	12	18
	0.887	0.847	0.683	0.807	0.728
	0.887	0.887	1.000	0.793	0.712
	0.759	0.665	0.941	0.703	0.742
	0.771	0.933	0.789	0.890	0.740
	1.010	0.950	0.882	0.966	0.932
	0.877	0.800	0.843	0.712	0.729
	0.861	1.070	0.746	0.749	0.694
	0.820*	0.680	0.733	0.844	0.734
	0.785	0.784	0.673	0.732	0.679
	1.030	0.791	0.930	0.940	1.160
	0.950	1.140	1.130	1.200	1.090
	0.863	1.010	1.000	0.915	0.860
	0.771	0.786	0.832	0.783	0.824
	0.983	0.967	0.913	0.828	0.862
	0.807	1.010	0.898	0.907	0.840
	0.929	0.826	1.000	0.986	0.994
	0.861	0.775	0.848	0.818	0.763
	0.731	0.876	0.700	0.808	0.769

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; T3: Triiodothyronine.

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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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.763	0.835	0.971	0.753	0.681
	0.935	0.967	1.000	0.872	1.050
	0.751	0.722	0.820	0.597	0.680
	0.920	0.980	0.861	0.813	0.837
	0.903	0.950	0.927	0.871	0.855
	0.862	0.899	0.924	0.915	0.825
	0.912	0.746	0.901	0.831	0.680
	0.974	0.882	0.960	0.759	0.675
	1.120	1.270	1.040	1.030	1.050
	0.676	0.760	0.669	0.674	0.671
	0.764	0.768	0.815	0.740	0.937
	0.952	0.897	0.953	0.680	0.957
	1.080	0.964	1.070	0.960	0.918
	0.825	0.959	0.993	1.060	0.824
	0.899	0.840	0.795	0.853	0.810
	0.688	0.765	0.590	0.666	0.741
	0.767	0.845	0.716	0.810	0.850
	0.858	0.753	0.954	0.802	0.734

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.854	0.787	1.060	0.670	0.912
	0.638	0.682	0.700	0.670	0.608*
	0.579	0.754	0.712	0.611	0.652
	0.833	0.794	0.905	1.010	0.857
	0.811	1.110	0.910	0.924	1.220
	0.786	0.729	0.901	0.845	0.972
	1.180	1.160	1.240	1.130	1.030
	0.901	0.843	0.851	1.010	0.888
	0.616	0.799	0.532	0.576	0.385
	0.525	0.491	0.502	0.444	0.528
	0.686	0.604	0.680	0.629	0.486
	0.692	0.654	0.634	0.749	0.612
	0.638	0.728	0.701	0.602	0.514
	0.696	0.814	0.797	0.743	0.759
	0.849	1.250	1.060	0.855	0.822*
	0.793	0.649	0.769	0.758	0.756
	0.580	0.541	0.471	0.476	0.556
	0.540	0.669	0.606	0.594	0.600

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; T3: Triiodothyronine.

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

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.704	0.625	0.852	0.743	0.680
	0.759	0.845	0.991	0.757	0.782
	0.907	0.744	0.750	0.687	0.709
	0.640	0.634	0.614	0.699	0.602
	0.648	0.709	0.595	0.693	0.590*
	0.705	0.722	0.695	0.635	0.785
	0.773	0.838	0.807	0.773	0.846
	0.769	0.778	0.698	0.720	0.715
	0.707	0.559	0.687	0.509	0.529
	0.722	0.759	0.630	0.547	0.625
	0.549	0.681	0.690	0.468	0.622
	0.945*	0.958	0.833	0.821	0.845
	0.929	0.894	0.983	1.020	1.020
	0.447	0.539	0.501	0.524	0.565
	0.762	0.658	0.707	0.643	0.679
	0.901	0.969	0.953	0.807	0.653
	0.872	0.935	1.050	1.020	0.986
	0.803	0.794	0.817	0.750	0.720

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; T3: Triiodothyronine.

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

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.731	0.784	0.588	0.652	0.500
	1.070	0.946	1.130	1.190	0.953
	0.619	0.748	0.841	0.862	0.835
	0.718	0.779	0.680	0.664	0.820
	0.688	0.648	0.590	0.739	0.753
	0.609	0.645	0.585	0.526	0.567
	0.669	0.578	0.446	0.628	0.537
	0.596	0.568	0.682	0.616	0.606
	1.110	0.999	0.932	0.971	1.160
	0.807	0.808	0.704	0.794	0.635
	0.560	0.617	0.610	0.561	0.631
	0.649	0.567	0.661	0.526	0.524
	0.833	0.913	0.882	0.826	0.842
	0.610	0.601	0.622	0.466	0.498
	0.790	0.911	0.925	0.942	0.805
	0.724	0.584	0.735	0.522	0.585
	0.727	0.725	0.693	0.790	0.675
	0.734	0.600	0.798	0.681	0.639

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.857	0.774	0.670	0.498	0.661
	0.669	0.709	0.584	0.529	0.591
	0.741	0.849	0.863	0.926	0.816
	0.585*	0.612	0.729	0.685	0.638
	0.710	0.615	0.785	0.730	0.604
	0.793	0.943	0.711	0.890	0.889
	0.562	0.637	0.542	0.533	0.528
	0.574	0.759	0.778	0.537	0.620
	0.608	0.690	0.564	0.689	0.899
	1.280	1.250	1.000	1.080	0.918
	0.477	0.639	0.478	0.579	0.460
	0.667	0.630	0.581	0.601	0.523
	0.652	0.739	0.817	0.776	0.640
	0.798	0.757	0.697	0.814	0.826
	0.785	0.759	0.697	0.665	0.621
	0.591	0.620	0.595	0.500	0.431
	0.673*	0.663	0.665	0.576	0.610
	0.543	0.612	0.503	0.489	0.416

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; T3: Triiodothyronine.

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

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EMR 200125-001

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.945	0.922	1.020	1.030	0.828
	1.120	0.681	0.910	0.861	0.853
	1.170	1.060	0.779	1.010	0.781
	1.060	1.180	0.960	1.010	1.000
	0.664	0.647	0.698	0.611	0.678
	0.640	0.583	0.468	0.520	0.440
	0.745	0.641	0.632	0.608	0.595
	0.394	0.489	0.542	0.523	0.411
	0.960	1.030	0.956	0.991	0.701
	0.936	0.747	0.746	0.822	0.884
	1.120	1.290	0.922	1.020	1.040
	0.794	0.816	0.809	0.753	0.912
	0.801	0.883	0.888	0.841	0.846
	0.621	0.550	0.518	0.387	0.490
	0.591	1.010	0.706	0.683	0.584
	0.589	0.751	0.729	0.703	0.624
	0.642	0.726	0.832	0.784	0.833
	0.502	0.423	0.474	0.508	0.436

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.491	0.528	0.713	0.557	0.447
	0.625	0.694	0.628	0.678	0.533
	0.566	0.560	0.607	0.547	0.491
	0.795	0.584	0.702	0.595	0.597
	0.489	0.494	0.428	0.546	0.637
	0.744	0.864	0.795	0.841	0.725*
	0.601	0.542	0.729	0.621	0.665
	0.658	0.720	0.839	0.753	0.753
	0.649	0.700	0.703	0.652	0.702
	0.705	0.808	0.836	0.747	0.620
	0.620	0.707	0.502	0.563	0.444
	0.689	0.643	0.621	0.599	0.539
	0.598	0.765	0.743	0.675	0.598
	0.715	0.800	0.737	0.723	0.717
	0.686	0.534	0.595	0.651	0.695
	0.507	0.630	0.542	0.476	0.498
	0.557	0.615	0.476	0.490	0.546
	0.971	0.957	0.816	0.774	0.997

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)	204 (0)
Mean (SD)	0.7837 (0.16078)	0.8023 (0.16836)	0.7847 (0.15542)	0.7663 (0.17124)	0.7448 (0.16817)
GeoMean	0.7671	0.7851	0.7687	0.7471	0.7259
(95% CI)	(0.7453;0.7896)	(0.7627;0.8081)	(0.7470;0.7910)	(0.7239;0.7710)	(0.7033;0.7493)
GeoCV(CV%)	21.1 (20.5)	21.2 (21.0)	20.9 (19.8)	23.1 (22.3)	23.2 (22.6)
SEM	0.01126	0.01179	0.01098	0.01199	0.01177
Median	0.7765	0.7815	0.7865	0.7530	0.7335
Min; Max	0.394;1.280	0.423;1.290	0.428;1.240	0.387;1.200	0.385;1.410

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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Treatment: Test

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.668	0.594	0.603	0.679	0.686
	0.604	0.764	0.764	0.614	0.748
	0.782	0.803	0.646	0.507	0.780
	0.635	0.653	0.784	0.651	0.570
	0.531	0.559	0.643	0.600	0.638
	0.516	0.568	0.685	0.641	0.641

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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.729	0.719	0.722	0.858
	0.869	0.834	0.899	0.750
	1.010	1.040	0.749	0.858
	0.938	0.974	0.978	1.040
	0.780	0.807	0.558	0.809
	0.749	0.785	0.772	0.861
	1.010	0.925	1.020	1.020
	1.010	1.230	1.210	1.000
	0.972	0.813	0.911	0.868
	1.040	0.607	0.863	0.794
	0.509	0.892	0.838	0.837*
	0.849	0.849	0.719	0.923
	0.973	0.873	1.010	0.856
	1.000	1.090	1.080	0.975
	0.782	0.782	0.798	0.863
	0.913	0.928	0.732	0.830
	1.040	1.120	0.876	0.844
	0.866	0.741	0.799	1.170

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
1	0.927	0.844	0.882	0.805
	1.110	0.820	0.954	0.926
	0.796	0.726	0.906	0.819
	1.080	1.100	1.060	0.994
	0.706	0.937	0.776	0.824
	1.020	0.884	0.920	0.746
	0.872	0.949	0.974	0.971
	0.840	1.090	0.785	0.961
	0.818	0.895	0.925	0.944
	1.030	1.010	0.972	0.909
	0.749	0.696	0.689	0.885
	1.090	0.945	1.090	1.040
	0.795	0.834	0.776*	0.669
	0.587	0.690	0.809	0.901
	0.889	0.876	1.040	1.040
	1.140	0.855	1.110	1.090
	0.948	1.120	0.799	1.120
	0.504	0.857*	0.949	1.150

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.873	0.726	0.797	0.874
	0.707	0.907	1.070	0.923
	1.130	0.598	1.060	0.794
	0.881	0.972	1.020*	0.950*
	0.922	0.816	0.912	1.060
	0.866	0.731	0.888	0.793
	0.968	0.868	1.180	1.140*
	0.767	0.847	0.893	0.982
	0.818	0.864	0.997	0.991
	0.602	0.749	0.786	0.859
	1.070	0.986	1.190	1.110
	1.120	1.070	1.060	1.230
	0.809	1.060	0.855	1.120
	0.595	0.798	1.050	0.818
	0.671	0.705	0.776	0.881
	0.976	1.100	1.050	1.070
	0.835	0.824	0.843	0.903
	1.090	0.935	1.020	0.878

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.766	0.991	1.150	0.990
	0.764	0.787	0.876	0.703
	0.813	0.846	0.829	0.806
	0.920	0.881	0.827	0.892
	1.110	1.070	1.020	1.070
	0.974	0.853	0.893	0.792
	0.944	0.869	0.901	1.020
	0.807	0.785	0.790	0.937
	0.870	0.762	0.664*	0.904*
	1.090	1.100	1.090	1.120
	1.100	0.973	0.976	1.030
	1.070	0.728	0.964	1.030
	0.995	0.820	0.847	0.801
	0.844	1.120	0.957	1.110
	0.787	0.846	0.804	0.803
	0.827	0.924	1.060	1.040
	0.847	0.759	0.748*	0.878
	0.934	0.913	0.763	0.807

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.634	0.768	0.761	0.823
	0.994	1.230	1.140	0.990
	0.806	0.670	0.825	0.778
	0.866	0.838	1.020	1.010
	0.972	0.974	0.955*	0.993*
	0.929	0.803	0.918	0.856
	0.829	0.744	0.803*	1.010
	0.664	0.743	0.694	0.832
	1.110	1.090	1.210	1.300*
	0.547	0.607	0.754	0.656
	1.090	0.904	1.010	1.020
	0.894	0.888	1.230	1.310
	0.774	0.772	1.120	1.140
	0.920	0.902	0.980	0.879*
	0.981	0.901*	0.989	0.956
	0.851	0.762	0.852	0.868
	0.761	0.891	0.705	0.842
	0.946	0.839	0.898	0.749

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.963	0.867	1.080	0.911
	0.729*	0.773	0.664	0.556
	0.600	0.795	0.577	0.896
	0.951	1.070	1.050	0.981
	1.070	0.927	0.742	0.898
	1.230	0.756	0.764	0.747
	0.646	1.100	1.160	1.120
	1.040	0.864	1.010*	1.190
	0.504	0.452	0.507	0.692
	0.558	0.622	0.689	0.646
	0.633	0.598	0.712	0.833
	0.653	0.927	0.771	0.705
	0.500	0.742	0.716	0.645
	0.874		0.583	0.783
	1.000*	0.977	1.290	0.992
	0.818	0.779	0.768	0.901
	0.598	0.582	0.666	0.491
	0.679	0.737	0.704	0.701

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.832	0.606	0.811	0.756
	0.810	0.755	0.891	1.370
	0.766	0.868	0.809	0.910*
	0.576	0.675	0.750	0.780
	0.660*	0.497*	0.811*	0.718*
	0.669	0.806	0.751	0.656
	0.796	0.754	0.849	0.860
	0.867	0.891	0.818	0.755
	0.606	0.479	0.608	0.579
	0.599	0.642	0.857	0.660
	0.587	0.675	0.723	0.626
	0.783	0.885	1.020	0.675
	1.080	1.190	1.130	1.110
	0.712	0.628	0.823	0.630
	0.670	0.713	0.767	0.717
	0.741	0.747	0.785	0.637
	1.100	1.200	1.060	0.954
	0.763	0.918	0.656	0.802

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
.	0.615	0.523	0.512	0.564
.	0.828	1.220	1.410	1.140
.	0.778	0.786	0.825	0.900
.	0.720	0.483	0.628	0.729
.	0.839	0.737	0.795	0.868
.	0.806	0.661*	0.653	0.771
.	0.516	0.474	0.537	0.643
.	0.583	0.610	0.500	0.639
.	1.060	1.200	1.100*	0.934
.	0.761	0.759	0.866	0.770*
.	0.553	0.685	0.667	0.889
.	0.565	0.730	0.684	0.662
.	1.010	1.140	0.959	0.865
.	0.601	0.507	0.667	0.556
.	0.838	1.080	0.960	0.956
.	0.811	0.717	0.745	0.649
.	0.484	0.519	0.670	0.675
.	0.632	0.471	0.772	0.620

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.691	0.529	0.673	0.722
	0.720	0.626	0.499	0.773
	0.844	0.980	0.929	0.756
	0.726	0.652	0.652	0.684
	0.602	0.699	0.782	0.687
	0.973	0.965	1.210	0.958
	0.536	0.551	0.552	0.645
	0.931	0.659	0.843	0.989
	0.724	0.583	0.842	0.898
	1.150	0.866	1.000	1.120
	0.671	0.656	0.721	0.622
	0.738	0.515	0.798	0.949
	0.755	0.689	0.642	0.825
	0.827	0.833	0.836	0.726
	0.779	0.687	0.678	1.010
	0.581	0.558	0.481	0.598
	0.667	0.555	0.608	0.731
	0.558	0.508	0.508	0.633*

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.969	0.896	0.952	1.160
	0.889	0.914	0.848	0.804
	0.883	1.120	0.977	1.060
	1.090	0.899	1.010	1.110
	0.658	0.804	0.724	0.725
	0.525	0.674	0.546	0.620
	0.706	0.686	0.762	0.710
	0.511	0.574	0.556*	0.602
	0.916	1.020	0.851	1.020
	0.829	0.801	0.703	0.978
	1.220	1.150	1.240	1.340*
	0.902	1.040	0.931	1.130
	0.817	0.898	0.748*	1.030
	0.546	0.584	0.641	0.619
	0.849	0.665	0.698	0.651*
	0.707	0.742	0.783	0.735*
	0.931	0.769	0.906	0.829
	0.634	0.637	0.543	0.634

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.643	0.593	0.605	0.700
	1.290	0.667	0.734	0.601*
	0.552	0.583	0.698	0.848
	0.632	0.457	0.690	0.804
	0.527	0.537	0.571	0.619
	0.782	0.914	0.846	0.735
	0.617	0.677	0.582	0.643
	0.658	0.698	0.730	0.722*
	0.731	0.623	0.682	0.682
	0.758	0.718	0.686	0.764
	0.578	0.609	0.544	0.665
	0.645	0.620	0.677	0.725
	0.614	0.807	0.790	0.748
	0.469	0.696	0.744	0.756
	0.565	0.565	0.741*	0.721
	0.600	0.620	0.569	0.604
	0.595	0.522	0.680	0.646*
	0.880	0.782	0.873	0.842

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.599	0.539	0.632	0.708
	0.595	0.464	0.726	0.843
	0.878	0.681	0.861	0.862
	0.698	0.718	0.643	0.631
	0.645	0.606	0.611	0.778*
	0.666	0.695	0.724	0.628

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Test

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
n(missing)	204 (0)	203 (1)	204 (0)	204 (0)
Mean (SD)	0.8069 (0.17957)	0.7991 (0.18094)	0.8336 (0.17921)	0.8536 (0.17281)
GeoMean (95% CI)	0.7868 (0.7625;0.8118)	0.7785 (0.7540;0.8039)	0.8146 (0.7906;0.8393)	0.8366 (0.8136;0.8602)
GeoCV(CV%)	23.0 (22.3)	23.4 (22.6)	21.9 (21.5)	20.4 (20.2)
SEM	0.01257	0.01270	0.01255	0.01210
Median	0.8080	0.7860	0.8090	0.8425
Min; Max	0.469;1.290	0.452;1.230	0.481;1.410	0.491;1.370

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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.774	0.915	0.798	0.881
	0.815	0.587	0.854	0.853
	1.035	0.879	1.080	1.020
	0.904	1.010	0.821	0.731
	0.858	0.810	0.814	0.628
	0.782	0.824	0.758	0.703
	0.799	0.747	0.813	0.910
	0.947	0.903	0.955	0.953
	0.964	1.050	0.922	0.794
	0.928	0.922	0.836	0.698
	0.835	0.839	0.781	0.744
	0.873	0.768	0.786	0.836
	0.849	0.929	0.750	0.862
	1.038	0.966	1.220	1.060
	0.914	0.862	0.934	0.714
	0.753	0.766	0.773	0.783
	0.982	0.967	0.800	1.030
	0.909	0.896	0.907	1.090

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.915	0.776	1.060	1.070
	0.836	0.793	0.894	0.930
	1.016	1.070	1.060	1.230
	0.733	0.664	0.844	0.690
	0.814	0.831	0.860	0.860
	1.137	0.864	1.210	1.220
	0.827	0.796	0.888	0.962
	0.633	0.770	0.784	0.921
	0.894	0.741	0.765	1.010
	0.748	0.673	0.854	0.812
	0.734	0.689	0.745	1.070
	0.847	0.827	0.854	0.892
	0.729	0.704	0.748	0.793
	0.599	0.994	1.050	0.664
	0.957	1.210	1.140	0.890
	0.982	1.200	0.937	1.170
	1.127	1.510	1.080	1.150
	1.023	0.690	0.901	1.110

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.697	0.881	0.748	0.786
	0.783	0.861	0.875	0.823
	0.968	0.727	0.654	1.140
	0.924	0.793	0.785	0.898
	0.724	0.706	0.810	0.752
	0.797	0.739	0.643	0.713
	0.867	0.728	0.836	0.870
	0.654	0.671	0.758	0.876
	0.873	0.948	0.893	0.877
	0.940	0.979	1.080	0.915
	1.042	0.988	0.984	0.968
	0.955	0.942	0.863	0.922
	0.890	0.936	0.854	0.871
	0.785	0.665	0.789	0.738
	0.933	0.897	0.877	0.923
	0.911	0.974	1.070	1.020
	0.743	0.817	0.756	0.724
	0.974	0.873	0.891	0.934

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.882	0.908	0.883	0.837
	0.795	1.020	0.843	0.983
	0.822	0.577	0.807	0.797
	0.827	0.730	0.772	0.816
	0.985	0.990	1.010	0.995
	0.724	0.827	0.784	0.714
	0.950	1.020	0.902	0.913
	0.891	0.795	0.761	0.766
	0.630	0.678	0.757	0.718
	0.903	0.844	0.908	0.961
	1.082	1.000	0.984	1.340
	0.964	0.850	0.917	0.918
	0.726	0.665	0.831	0.782
	1.080	1.060	1.270	1.240
	0.726	0.718	0.805	0.856
	0.802	0.788	0.821	0.781
	0.913	0.854	0.974	1.100
	0.771	0.814	0.792	0.702

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.809	0.885	0.717	0.705
	0.957	0.900	0.908	0.938
	0.655	0.591	0.741	0.615
	0.763	0.687	0.909	0.859
	0.863	0.937	0.817	0.878
	0.961	0.921	1.010	1.070
	0.939	0.791	0.723	0.716
	0.839	0.867	1.020	0.875
	1.100	1.130	1.170	0.991
	0.606	0.595	0.752	0.835
	0.861	0.871	0.923	0.920
	0.860	0.931	0.927	1.100
	0.947	0.794	0.903	0.985
	0.867	0.959	0.924	1.060
	0.791	0.760	0.772	0.870
	0.693	0.746	0.733	0.761
	0.852	0.807	0.826	0.939
	0.770	0.697	0.774	0.872

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.667	0.648	0.593	0.630
	0.670	0.618	0.672	0.720
	0.665	0.542	0.615	0.677
	0.916	0.928	0.881	0.923
	0.961	0.951	0.926	0.795
	0.841	0.764	0.687	0.778
	1.014	1.060	0.907	1.040
	1.043	0.870	0.973	0.843
	0.774	0.921	0.729	0.933
	0.606	0.527	0.536	0.417
	0.657	0.470	0.543*	0.639
	0.736	0.833	0.751	0.739
	0.656	0.542	0.747	0.781
	0.601	0.597	0.662	0.570
	0.877	0.850	0.989	1.120
	0.694	0.631	0.729	0.667
	0.437	0.326	0.541	0.389
	0.575	0.577	0.759	0.617

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.735	0.630	0.664	0.762
	0.954	0.830	0.948	0.954
	0.836	0.785	0.830	0.842
	0.685	0.684	0.562	0.637
	0.695	0.630	0.836	0.687
	0.588	0.613	0.608	0.736
	0.679	0.617	0.763	0.638
	0.730	0.918	0.827	0.834
	0.750	0.614	0.716	0.618
	0.805	0.759	0.770	0.903
	0.616	0.560	0.778	0.659
	0.745	0.821	0.883	0.924
	0.887	0.828	0.836	0.907
	0.787	0.513	0.634	0.792
	0.640	0.746	0.611	0.691
	0.767	0.765	0.820*	0.997
	0.897	0.967	0.917	0.975*
	0.729	0.695	0.756	0.710

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.646	0.584*	0.735	0.603
	1.011	0.898	0.896	1.420
	0.961	0.875	1.090	1.010
	0.583	0.557	0.647	0.701
	0.828	0.871	0.782	0.943
	0.598	0.699*	0.645	0.638
	0.500	0.448	0.447	0.554
	0.564	0.482	0.683	0.678
	0.864	0.833	0.773	0.913
	0.750	0.692	0.633	0.717
	0.621	0.943	0.792	0.647
	0.670	0.673	0.501	0.693
	0.710	0.720	0.712	0.778
	0.557	0.645	0.629	0.588
	0.753	1.150	0.899	0.930
	0.630	0.669	0.670	0.634
	0.643	0.591	0.758	0.601
	0.656	0.677*	0.601	0.552

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
1	0.756	0.896	0.837	0.822
	0.709	0.740	0.665	0.630
	0.913	0.871	0.738	0.978
	0.651	0.649	0.711	0.753
	0.686	0.716	0.643	0.628
	0.796	0.691	0.695	0.862
	0.685	0.587	0.686	0.771
	1.085	0.793	0.765	0.606
	0.563	0.774	0.687	0.479
	1.019	1.110	1.120	1.080
	0.502	0.528	0.486	0.430
	0.595	0.604	0.720	0.667
	0.650	0.649	0.616	0.679
	0.685	0.685	0.820	0.669
	0.664	0.742*	0.673	0.918
	0.561	0.478	0.418	0.603
	0.658	0.686	0.767	0.632
	0.605	0.546	0.591	0.713

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; T3: Triiodothyronine.

*: 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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EMR 200125-001

Biocquivalence trial of new levothyroxine formulation vs. old formulation

Merck Serono
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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	1.063	0.958	1.140	1.210
	0.998	0.933	0.915	1.020
	0.995	0.945	0.831	1.160
	0.983	0.963	0.963	1.240
	0.872	0.962	0.865	0.853
	0.580	0.564	0.540	0.525
	0.703	0.712	0.649	0.616
	0.586	0.452	0.610	0.593
	0.987	1.020	0.963	1.030
	0.752	0.810	0.736	0.751
	1.002	0.898	1.060	0.999
	0.857	0.791	0.924	0.999
	0.753	0.928	0.836	0.796
	0.558	0.520	0.611	0.666
	0.833	0.700	0.848	1.050
	0.767	0.677	0.781	0.911
	0.797	0.908	0.810	0.695
	0.467	0.460	0.492	0.462

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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
3	0.547	0.479	0.552	0.568
	0.664	0.618	0.600	0.617
	0.613	0.533	0.514	0.560
	0.663	0.657	0.695	0.558
	0.543	0.453	0.517	0.586
	0.643	0.650	0.681	0.651
	0.672	0.656	0.770	0.634
	0.722	0.781	0.659	0.773
	0.767	0.825	0.812	0.978
	0.797	0.824	0.813	0.778
	0.552	0.588	0.590	0.544
	0.732	0.720	0.863	0.929
	0.640	0.632	0.738	0.772
	0.669	0.795	0.598	0.764
	0.705	0.781	0.757	0.624
	0.478	0.457	0.508	0.641
	0.546	0.506	0.580	0.558
	0.781	0.876	0.946	0.820

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	Predose (Mean)	0.5	1	1.5
	0.681	0.568	0.737	0.695
	0.531	0.466	0.557	0.611
	0.558	0.661	0.621	0.562
	0.519	0.563	0.532	0.567
	0.456	0.453	0.453	0.576
	0.456	0.460	0.587	0.533

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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)	0.7809 (0.15527)	0.7705 (0.17513)	0.7921 (0.15835)	0.8149 (0.18665)
GeoMean (95% CI)	0.7651 (0.7437;0.7871)	0.7502 (0.7262;0.7750)	0.7761 (0.7544;0.7984)	0.7936 (0.7685;0.8195)
GeoCV(CV%)	20.8 (19.9)	23.9 (22.7)	20.7 (20.0)	23.6 (22.9)
SEM	0.01087	0.01226	0.01109	0.01307
Median	0.7725	0.7750	0.7840	0.7945
Min; Max	0.437;1.137	0.326;1.510	0.418;1.270	0.389;1.420

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.811	0.742	0.954	0.808
	0.772	0.994	0.843	0.914
	0.885	1.020	0.929	0.935
	0.874	0.791	0.848	0.866
	0.951	0.844	1.040	0.982*
	0.798	0.852	0.805	0.903
	0.777	0.795	0.878	0.839
	0.922	1.020	1.050	0.996
	0.939	0.794	0.801	0.701
	0.714	1.170	0.902	0.999
	0.967	0.688	0.984	0.840
	0.798	0.793	0.772	0.807
	0.808	0.813	0.796	0.861
	1.030	1.030	0.854	1.030
	0.956	0.869	0.907	0.827
	0.664	0.659	0.697	0.754
	1.140	1.200	1.130	0.969
	1.120	1.310*	0.990	0.980

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
1	1.010	0.971	0.890	0.952
	0.954	1.010	0.993	0.961
	1.090	1.120	1.100	1.110
	0.714	0.696	0.754	0.817
	0.773	0.928*	1.130	0.857
	1.070	1.010	1.080	1.180
	0.837	0.883	0.901	0.947
	0.742	0.809	0.818	0.804
	0.889	0.960*	0.901	0.929
	0.992	0.750	0.902	0.857
	0.833	0.870*	0.843	0.849
	0.870	0.861	0.857	0.892
	0.648	0.700	0.712	0.822
	0.585	0.755	0.848	0.699
	1.040	0.839	0.885	1.100
	1.120	1.040	1.020	1.020
	1.110	1.020	0.957	1.030
	0.784	0.810	0.778	1.170

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; T3: Triiodothyronine.

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

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.775*	0.650	0.793	0.795
	0.868	0.972	0.836	0.785
	0.772	1.060	0.856	1.050
	0.808	0.965	0.966	0.788
	0.827	0.748	0.841	0.825
	0.775	0.776	0.692	0.608
	0.902*	0.898	0.925	0.833
	0.666	0.638	0.764	0.734
	0.872	0.789	1.040	0.797
	1.090	1.110	0.810	0.480
	1.000	0.922	0.873	1.020
	0.842	0.956	0.912	1.120
	1.070*	0.945	0.921	0.768
	0.800	0.692	0.683	0.649
	1.050	0.860	0.958	1.010
	0.996	0.552	0.999	1.080
	0.770	0.359	0.751	0.701
	0.942	0.997	0.988	0.945

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.796	0.993	0.917	1.210
	0.866	1.030	0.821	0.717
	0.958*	0.825	0.813	0.836
	0.763	0.501	1.000	0.979
	0.814	1.090	1.180	0.953
	0.785	0.755	0.782	0.889
	0.959	0.966	1.060	0.916
	0.936	0.861	0.833	0.782
	0.747	0.773	0.658	0.849
	0.913	0.834	0.842	0.805
	1.180*	1.110	1.030	1.130
	1.080	1.040	0.943	0.790
	0.839	0.806	0.828	0.862
	1.100	1.090	1.210	1.090
	0.861	0.833	0.794	0.809
	0.935	0.897	0.894	0.918
	0.885	0.863	0.853	0.895
	0.863	0.812	0.840	0.846

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.649	0.600	0.655	0.738
	0.827	1.050	0.942	0.948
	0.798	0.619	0.687	0.881
	0.842	1.190	0.814	0.950
	0.872	0.932	0.858	0.890
	0.980	0.961	0.966	0.939
	0.826	0.861	0.889	0.855
	0.888	0.712	1.020	0.904
	1.050	1.050	0.855	1.090
	0.702	0.683	0.832	0.705
	0.955	1.060	0.756	0.814
	1.010	0.917	1.000	0.931
	1.060	0.970	0.960	1.100
	0.960	1.080	1.130	1.020
	0.790	0.841	0.862	0.947
	0.769	0.678	0.908	0.790
	0.841	0.870	0.931	0.784
	0.869	1.000	0.857	0.792

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.753	0.723	0.728	0.838
	0.687*	0.769	0.735	0.797
	0.690	0.673	0.711	0.675
	0.902	1.030	1.130	1.090
	0.876	0.981	1.080	0.999
	0.852	0.772	0.785	0.914
	0.984	1.130	1.140	1.060
	0.977	0.882	1.130	1.010
	0.716	0.634	0.849	0.600
	0.581	0.520	0.525	0.576
	0.588	0.589	0.611	0.670
	0.835	0.807	0.944	0.750
	0.702	0.674	0.899	1.090
	0.535	0.660	0.547	0.526
	1.020	0.998	0.956	0.763
	0.774	0.804	0.836	0.773
	0.570	0.616	0.498	0.435
	0.721	0.568	0.678	0.667

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.559	0.576	0.644	0.686
	0.778	0.980	0.912	0.866
	0.720	0.840	0.895	0.783
	0.604	0.682	0.762	0.666
	0.725	0.792	0.770	0.670
	0.633	0.605	0.687	0.590
	0.796	0.742	0.699	0.724
	0.780	0.762	0.862	0.733
	0.623	0.699	0.699	0.801
	0.809	0.856	0.790	0.770
	0.712	0.592	0.667	0.725
	0.791	0.893	0.785	0.929
	0.780	0.891	0.925	0.889
	0.628	0.740	0.704	0.767
	0.702	0.739	0.645	0.633
	0.758	0.755	0.806	0.758
	1.180	1.050	0.986	1.040
	0.853	0.759	0.686	0.803

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.673	0.743	0.623	0.631
	0.901	0.951	1.230	0.825
	0.923	1.050	0.855	0.992*
	0.611	0.582	0.767	0.606
	0.864	0.793	0.846	0.763
	0.736	0.826	0.686	0.592
	0.522	0.538	0.575	0.483
	0.630	0.575	0.728	0.649
	0.958	0.946	0.810	0.991
	0.605	0.705	0.643	0.647
	0.791	0.874	0.635	0.543
	0.584	0.706	0.617	0.780
	0.977	0.881	0.821	0.828
	0.602	0.614	0.625	0.746
	0.895	0.961	0.796	0.904
	0.726	0.538	0.730	0.734
	0.570	0.641	0.671	0.692
	0.646	0.570	0.577	0.663

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.683	1.030	0.865	0.708
	0.722	0.718	0.704	0.700
	0.948	0.837	0.852	0.733
	0.656	0.677	0.693	0.632
	0.860	0.742*	0.831	0.801
	0.603	0.598	0.892	0.907
	0.540	0.520	0.593	0.508
	0.683*	1.020	0.834	0.850
	0.564	0.561	0.670	0.595
	1.050	1.110	1.100	1.090
	0.483	0.503	0.548	0.414
	0.809	0.618	0.908	0.586
	0.752	0.848	0.874	0.631
	0.799	0.731	0.845	0.733
	0.707	0.772	0.693	0.636
	0.579*	0.553	0.508	0.689
	0.781	0.690	0.726	0.633
	0.553	0.611	0.643	0.568

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; T3: Triiodothyronine.

*: 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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	1.120	1.130	1.070	1.310
	0.922	1.120	0.909	1.010
	0.895	1.070	1.120	1.070
	1.200	0.987	1.180	1.020
	0.686	0.678	0.763	0.835
	0.566	0.483	0.470	0.651
	0.565	0.782	0.700	0.711
	0.648	0.629	0.492	0.607
	1.060	1.010	1.170	0.952
	0.655	0.738	0.689	0.716
	1.070	1.040	0.979	0.935
	0.840	1.000	0.918	0.958
	0.979	1.010	0.944	0.967
	0.607	0.547	0.573	0.658
	0.784	0.772	0.785	0.842
	0.759	0.760	0.788	0.758
	0.668	0.832	0.726	0.802
	0.458	0.510	0.471	0.525

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.582	0.526	0.563	0.556
	0.575	0.735	0.603	0.611
	0.613	0.630	0.616	0.573
	0.643	0.616	0.747	0.641
	0.408	0.518	0.501	0.591
	0.677	0.655	0.726	0.768
	0.718	0.725	0.683	0.791
	0.755	0.684	0.699	0.673
	0.838	0.896	0.873	0.890
	0.826	0.742	0.782	0.784
	0.646	0.456	0.612	0.533
	0.751	0.857	0.778	0.768
	0.677	0.641	0.661	0.730
	0.539	0.705	0.745	0.611
	0.667	0.707	0.742	0.719
	0.449	0.509	0.591	0.522
	0.543	0.608	0.534	0.531
	0.977	0.858	0.996	0.811

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	2	2.5	3	4
	0.755	0.767	0.762	0.811
	0.575	0.552	0.708	0.644
	0.665	0.595	0.561	0.585
	0.561	0.643	0.581	0.709
	0.545	0.564	0.638	0.588
	0.467	0.444	0.501	0.514

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

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)	0.7985 (0.16743)	0.8069 (0.18199)	0.8189 (0.16327)	0.8097 (0.16807)
GeoMean (95% CI)	0.7806 (0.7577;0.8043)	0.7858 (0.7608;0.8116)	0.8023 (0.7798;0.8253)	0.7919 (0.7688;0.8157)
GeoCV(CV%)	21.9 (21.0)	23.7 (22.6)	20.8 (19.9)	21.7 (20.8)
SEM	0.01172	0.01274	0.01143	0.01177
Median	0.7910	0.7935	0.8245	0.8025
Min; Max	0.408;1.200	0.359;1.310	0.470;1.230	0.414;1.310

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 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.845	0.873	0.801	0.848	0.777
	0.642	0.725	0.767	0.493	0.714
	1.040	0.862	1.100	1.070	0.944
	0.926	0.945	0.936	0.930*	0.709
	1.050	1.110	0.785	0.825	0.744
	0.874	0.743	0.758	0.789	0.813
	0.900	0.844	0.893	0.840	0.857
	0.985	1.010	0.956	1.050	1.200
	1.230	1.290	0.866	1.020	0.835
	1.020	0.748	0.954	0.727	0.832
	0.946	0.757	0.643	0.802	0.818
	0.954	0.800	0.871	0.852	0.781
	0.931	0.775	0.826	0.857	0.742
	0.741	0.960	0.890	0.907	0.912
	0.759	0.798	0.363	0.621	0.724
	0.664	0.805	0.773	0.817	0.673
	1.070	1.060	1.090	1.080	0.991
	0.871	0.841	0.933	0.894	0.932

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	1.060	0.985	0.961	0.906	1.030
	0.886	0.981	1.020	0.830*	1.170
	1.020	1.120	1.110	0.953	1.080
	0.739	1.020	0.923*	0.804*	0.853
	0.717	0.843	0.766	0.816	0.751
	1.160	0.904	1.050	1.010	0.894
	0.789	0.868	0.876	0.755	0.721
	0.783	0.806	0.877	0.766	0.785
	0.875	0.850	0.751	0.834	0.817
	0.888	0.949	0.768	0.901	0.816
	0.763	0.932	0.697	0.646	0.634
	0.839	0.926	0.791	0.853	0.730
	0.723	0.822	0.775	0.751	0.691
	0.716	0.622	0.758	0.794	0.766
	1.050	0.876	0.965	0.741	0.832
	1.090	1.060	0.945	1.020	1.030
	1.070	1.160	0.966	0.885	0.903
	0.879	0.862	0.895	1.010	0.658

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
100	0.757	0.929	0.862	0.820	0.803
	0.774	1.080	0.982	0.830	0.790
	0.949	0.920	0.932	0.958	0.955
	0.856	0.898	0.818	0.930	0.950
	0.717	0.899	0.829	0.672	0.661
	0.716	0.625	0.573	0.696	0.699
	0.945	0.733	0.743	0.914	0.808
	0.847	0.717	0.628	0.877	0.861
	0.893	0.872	0.808	1.030	0.879
	0.859	0.772	0.722	0.814	0.738
	0.998	1.200	1.040	0.951	1.070
	0.974*	1.280	0.873	1.010	1.040
	0.843	0.860	0.827	0.818	0.759
	0.580	0.718	0.556	0.706	0.495
	1.030	0.949	0.801	0.898	0.905
	1.330	1.060	1.070	0.875	0.908
	0.761	0.733	0.684	0.672	0.787
101	0.942	1.000	0.856	0.997	0.969

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	1.060	0.810	0.761	0.706	0.736
	0.748	0.769	0.852	0.794	0.816
	0.872	0.871	0.936	0.983	0.788
	0.745	0.734	0.695	0.834	0.796
	1.050	1.020	0.931	1.050	0.914
	0.786	0.851	0.798	0.735	0.774
	0.973	0.883	0.804	0.808	0.758
	0.850	0.798	0.820	0.794	0.734
	0.780	0.885	0.722	0.757	0.641
	0.837	0.824	0.815	0.781	0.867
	0.968	1.040	0.968	1.130	0.902
	1.060	0.974	1.140	0.869	0.866
	0.800	0.861	0.930	0.880	0.842
	1.080	1.130	1.170	0.948	0.981
	0.799	0.820	0.841	0.985	0.667
	1.010	0.945	0.932	0.878	0.813
	0.877	0.870	0.797	0.853	0.868
	0.812	0.875	0.768	0.831	0.762

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; T3: Triiodothyronine.

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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.840	0.721	0.731	0.773	0.695
	1.050	0.891	0.902	1.040	0.862
	0.632	0.736	0.804	0.590	0.592
	0.852	0.986	0.928	0.783	0.842
	0.910	0.858	0.843	0.835	0.839
	0.973	0.912	1.010	0.881	0.757
	0.937	0.975	0.972	0.708	0.700
	0.800	0.935	1.080	0.662	0.760
	1.030	1.100	0.899	1.010	0.943
	0.787	0.730	0.685	0.485	0.634
	0.759	0.956	0.661	0.616	0.579
	1.360	1.030	0.832	0.881	0.773
	1.020	0.858	0.958	0.957	0.836
	0.885	0.847	0.889	0.927	0.904
	0.816	0.826	0.832	0.836	0.798
	0.769	0.761	0.674	0.851	0.707
	0.914	0.907	0.792	0.938	0.761
	0.859	0.898	0.999	0.785	0.791

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.830	0.763	0.665	0.680	0.776
	0.693	0.645	0.712	0.749	0.638
	0.649	0.616	0.628	0.713	0.522
	0.902	0.928	1.060	1.060	0.968
	0.995	0.966	0.838	0.917	0.880
	0.884	0.809	0.905	0.749	0.858
	1.020	0.974	1.170	0.963	1.100
	0.899	0.751	0.443	0.968	0.858
	0.677	0.640	0.699	0.467	0.508
	0.620	0.662	0.476	0.508	0.549
	0.712	0.591	0.676	0.467	0.529
	0.763	0.633	0.704	0.801	0.751
	0.834	0.587	0.448	0.604	0.823
	0.565	0.645	0.523	0.707	0.626*
	1.110	1.200	0.935	0.937	0.738
	0.807	0.714	0.826	0.706	0.663
	0.574	0.368	0.408	0.389	0.379
	0.612	0.663	0.694	0.513	0.677

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
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Table 15.4.1.1.3 Individual Data and Summary Statistics of Concentrations for Total T3 (ng/mL) (Pharmacokinetic Population)

Treatment: Reference

Subject Number/ Random Number	Sample Times (h)				
	6	8	10	12	18
	0.616	0.691	0.658	0.508	0.625*
	0.963	0.723	0.818	1.050	0.794
	0.744	0.905	0.936	0.722	0.814
	0.686	0.692	0.626	0.655	0.664*
	0.635	0.644	0.599	0.737	0.779
	0.404	0.773	0.567	0.662	0.638
	0.656	0.709	0.782	0.611	0.660
	0.782	0.909	0.602	0.878	0.730
	0.625	0.734	0.726	0.462	0.481
	0.788	0.819	0.687	0.637	0.663
	0.757	0.860*	0.649	0.701	0.562
	0.846	0.962	0.872	0.668	0.730
	0.993	0.842	0.869	0.839	0.875
	0.684	0.839*	0.650	0.491	0.668
	0.774	0.639	0.562	0.589	0.664
	0.647	0.799	0.849	0.880	0.784
	1.020	1.010	1.000	1.090	0.928
	0.755	0.798	0.726	0.734	0.694

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