Levothyroxine
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Bioequivalence trial of new levothyroxine formulation vs. old formulation

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EMR 200125-001

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
	0.604	0.511	0.578	0.625	0.610
	1.090	0.968	0.849	1.090	0.967
	0.973	1.300	0.745	0.976	1.010
	0.644	0.595	0.681	0.665	0.593
	0.782	0.778	0.785	0.746	0.736
	0.658	0.638	0.676	0.613	0.630
	0.416	0.500	0.545	0.525	0.405
	0.714	0.648	0.584	0.534	0.470
	0.871	0.911	0.909	0.939	0.901
	0.593	0.688	0.572	0.642	0.634
	0.590	0.533	0.784	0.716	0.878
	0.544	0.573	0.511	0.545	0.449
	0.838	0.861	0.790	0.703	0.790
	0.627	0.625	0.598	0.554	0.519
	0.955	0.893	0.880	1.080	0.738
	0.756	0.685	0.702	0.642	0.559
	0.623*	0.680	0.651	0.643	0.677
	0.573*	0.637	0.727	0.501	0.604

CI: Confidence Interval; CV%: 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)				
	6	8	10	12	18
	0.792	0.743	0.765	0.609	0.668
/	0.762	0.595	0.738	0.537	0.584
/	0.884	0.837	0.785	0.831	0.808
	0.673	0.714	0.694	0.645	0.620
	0.681	0.783	0.916	0.733	0.708
	0.789*	0.842	0.953	0.808	0.793
	0.514*	0.592	0.576	0.604	0.622
	0.849	0.694	0.753	0.592	0.864
	0.527	0.543	0.591	0.626	0.611
	1.070	1.100	1.040	1.020	1.020
	0.525	0.474	0.421	0.403	0.548
	0.718	0.683	0.710	0.786	0.642
	0.670	0.908	0.735	0.805	0.681
	0.742	0.730	0.796	0.860	0.788
	0.614*	0.702	0.534	0.692	0.501
;	0.475	0.671	0.547	0.431	0.451
	0.674	0.637	0.653	0.620	0.597
	0.553	0.587	0.594	0.522	0.541

CI: Confidence Interval; CV%: 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)		
	6	8	10	12	18
5	1.130	0.927	1.260	1.070	0.987
	1.020	0.885	0.932	0.945	0.968
	0.932	0.942	0.969	0.905	0.893
	1.230	0.921	1.110	0.919	1.000
	0.789	0.757	0.736	0.785	0.619
	0.537	0.645	0.502	0.611	0.596
	0.625	0.590	0.589	0.580	0.759
	0.601	0.472	0.484	0.537	0.506
	0.939	1.020	0.991	0.952	0.950
	0.810	0.979	0.760	0.553	0.651
	1.030	1.010	0.946	0.955	1.090
	0.794	0.924	1.000	1.010	1.010
	0.804	0.913	0.920	0.664	0.752
	0.516	0.553	0.549	0.757	0.528
	0.752	0.683	0.814	0.759	0.576
	0.739	0.698	0.743	0.708	0.619
	0.779	0.721	0.645	0.804	0.755
	0.472	0.479	0.478	0.467	0.503

CI: Confidence Interval; CV%: 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)				
	6	8	10	12	18
1	0.596	0.508	0.648	0.613	0.567
	0.618	0.550	0.638	0.721	0.572
	0.646	0.538	0.624	0.850	0.521
	0.661	0.653	0.616	0.778	0.892
	0.497	0.449	0.485	0.628	0.530
	0.746	0.680	0.783	0.670	0.598
	0.661	0.650	0.691	0.605	0.648
	0.657	0.629	0.891	0.767	0.667
	0.776	0.842	0.959	0.685	0.731
	0.776	0.771	0.894	0.762	0.848
	0.504	0.507	0.526	0.498	0.472
	0.746	0.715	0.946	0.566	0.706
	0.673	0.776	0.622	0.626	0.631
	0.667	0.703	0.936	0.541	0.761
	0.754	0.547	0.756	0.809	0.841
	0.435	0.478	0.497	0.431	0.521
	0.582	0.590	0.575	0.580	0.552
	0.775	0.843	0.890	0.954	0.892

CI: Confidence Interval; CV%: 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

	Sample Times (h)				
Subject Number/ Random Number	6	8	10	12	18
	0.650	0.907	0.633	0.684	0.582
	0.654	0.642	0.622	0.467	0.557
	0.658	0.509	0.548	0.565	0.646
	0.664	0.748	0.728	0.605	0.640
	0.576	0.500	0.519	0.569	0.472
	0.536	0.606	0.636	0.553	0.547

CI: Confidence Interval; CV%: 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
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	0.8013 (0.17664)	0.8014 (0.17407)	0.7810 (0.16963)	0.7673 (0.16938)	0.7476 (0.15749)
GeoMean	0.7817	0.7821	0.7617	0.7476	0.7307
(95% CI)	(0.7578;0.8064)	(0.7582;0.8067)	(0.7381;0.7862)	(0.7240;0.7721)	(0.7091;0.7529)
GeoCV(CV%)	22.8 (22.0)	22.8 (21.7)	23.2 (21.7)	23.6 (22.1)	22.0 (21.1)
SEM	0.01237	0.01219	0.01188	0.01186	0.01103
Median	0.7845	0.8055	0.7845	0.7795	0.7515
Min; Max	0.404;1.360	0.368;1.300	0.363;1.260	0.389;1.130	0.379;1.200

CI: Confidence Interval; CV%: 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)			
	24	36	48	72
?	0.884	0.818	0.625	0.848
?	0.995	0.745	0.709	0.828
	1.080	1.210	1.000	0.900*
	0.770	1.010	0.952	1.100
	0.843	0.752	0.700	1.020
	0.837	0.660	0.743	0.723
	0.995	1.110	1.080	1.110
	1.190	1.160	1.140	1.120
	0.968	0.800	0.697	0.862
	0.939	0.682	0.887	1.050
	0.836	0.824	0.785*	0.719
	0.865	0.809	0.885	0.923
	0.962	0.915	0.884	0.887
	1.020	1.030	1.040	1.080
	0.779	0.786	0.819	1.010
	0.808	0.790	0.856	0.827
	0.949	0.886	0.953	0.967
	0.971	0.975	0.881	0.849

CI: Confidence Interval; CV%: 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 mber	Sample Times (h)			
	24	36	48	72
	1.150	1.020	0.903	0.917
	0.858	0.762	1.200	1.000
	1.090	0.964	1.110	1.080
	0.941	0.974		0.920
	0.792	0.911	0.840	0.829*
	0.986	0.969	0.988	1.000
	0.842	0.853	0.864	0.831
	0.723	0.821	0.768	0.793
	0.951*	0.879	0.930	1.020
	0.867	0.976	0.903	0.908
	0.775	0.652	0.787	0.686
	0.939	0.927	0.924	1.060
	0.837	0.696	0.751	0.648*
	0.480	0.761	0.705	0.914
	0.907	0.844	0.746	0.902
	1.140	0.960	0.957	1.040
	0.812	0.990	0.916	0.923
	0.881	0.782	1.020*	0.958

CI: Confidence Interval; CV%: 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)			
	24	36	48	72
	0.721	0.846	1.000	0.875
	0.893	0.825	0.886	0.882
	0.743	0.804	0.906	0.733*
	0.919	0.784	1.020*	0.966*
	0.924	0.975	0.923	0.903*
	0.681	0.617	0.836	0.655
	0.754	0.984	0.867*	0.929*
	0.694	1.030	0.925	0.893
	0.854	0.869	1.010	1.030
	0.687	0.873	0.774	0.993
	0.939	1.070	1.210	1.240
	1.090	1.150	1.340	1.060
	0.554	0.859	1.010	1.080*
	0.698	0.773	0.778	1.030
	0.956	1.240	1.060	1.180
	1.060	1.110	1.090	1.150
	1.010	0.932	0.807	0.824
	1.050	0.974	1.080	1.070

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 concentrations at
cific 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)			
	24	36	48	72
	0.747	0.834	0.853	0.988
	0.762	0.970	0.823	0.850
	0.931	1.070	0.922	0.996
	0.887	0.892	0.874	0.776
	1.020	1.100	1.030	1.300
	0.891	0.839	1.150	0.784
	0.805	0.973	1.060*	0.996*
	0.732	0.853	0.866	0.901
	0.825	0.894	0.681	0.820
	0.894	1.060	0.997	1.100
	0.920	0.920	0.975	1.050
	0.871	0.893	1.030	0.932
	0.901	0.801	0.900	0.857
	0.963	0.984	1.050	1.260
	0.697	0.679	0.721	0.852
	0.965	0.942	0.784	0.983
	0.820	0.818	0.832	0.855
	0.777	0.842	0.966	1.050

CI: Confidence Interval; CV%: 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 Numb ··	Sample Times (h)			
	24	36	48	72
	0.664	0.729	0.710	0.851
	1.020	0.958	0.908	1.090
	0.752	0.680	0.825	0.695
	0.964	1.020	0.981	0.821
	0.882	0.949	0.939*	0.913*
	0.881	0.816	0.848*	0.872
	0.787	0.787	0.696	0.713*
	0.767	0.716	0.833	0.894
	0.938	1.090	1.030	1.110
	0.695	0.665	0.744	0.740
	0.710	0.812	0.855	1.070
	0.847	0.940	1.630	1.070
	0.994	0.998	1.090	0.979
	0.932	1.080	0.862	0.821
	0.842	0.860	0.992	0.734
	0.868	0.860	0.850	0.934
	0.962	0.828	0.623	0.853
	0.903	0.813	1.020	0.884

CI: Confidence Interval; CV%: 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)			
	24	36	48	72
	0.815	0.780	0.755	0.806
	0.776	0.696	0.787	0.710
	0.691	0.735	0.825	0.690*
	0.913	1.060	1.030	1.130
	0.976	0.851	0.759	0.957
	1.060	0.979	0.811	0.958
	1.120	1.060	1.020	1.080
	0.958	1.010	1.030	0.969
	0.741	0.573	0.441	1.020
	0.571	0.519	0.688	0.691
	0.673	0.599	0.689	0.720
	0.838	0.707	0.667	0.763
	0.753	0.571	0.610	0.562
	0.755*	0.604	0.805	0.625
	1.140	0.868	1.060*	1.100
	0.764	0.855	0.882	1.130
	0.473	0.593	0.588	0.739
	0.733	0.686	0.782	0.654

CI: Confidence Interval; CV%: 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)			
	24	36	48	72
	0.725*	0.673	0.687	0.792
	0.920	0.886	1.020*	0.795
	0.947	0.907	0.856	0.861
	0.723*	0.688	0.560*	0.802
	0.708	0.617	0.661*	0.825
	0.664	0.509	0.811	0.861
	0.693	0.775	0.872	0.756
	0.847	0.882	0.838	0.855
	0.605	0.630	0.723	0.632
	0.774	0.723	0.769	0.936
	0.575	0.670	0.728	0.628
	0.858	0.798	0.952	1.000
	0.992	1.120	1.040	1.160
	0.660	0.651	0.683	0.650
	0.676	0.759	0.564	0.759
	0.706	0.847	0.735	0.773
	1.030	1.210	1.220	1.140
	0.730	0.813	0.739	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.
*: Measurement taken outside the allowed windows allowance.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.1.1.3.sas

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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)			
	24	36	48	72
	0.667	0.449	0.584	0.649
	0.981	1.020	1.160	1.230
	1.070	1.200	1.090	1.190
	0.587	0.565	0.655	0.765
	0.924*	0.780	0.882	0.750*
	0.748	0.565	0.665	0.601
	0.601	0.563	0.744	0.690
	0.555	0.603	0.642	0.517
	0.993	1.180	0.973*	0.921
	0.694	0.793	0.826	0.758
	0.602	0.593	0.645	0.994
	0.684	0.560	0.546	0.768
	0.837	1.010	0.902	0.817
	0.550	0.494	0.612	0.670
	0.998	1.100	0.913	0.626
	0.820	0.653	0.765	0.733
	0.627	0.545	0.526	0.686
	0.703	0.737	0.678	0.729

CI: Confidence Interval; CV%: 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

	Sample Times (h)			
Subject Number/ Random N r	24	36	48	72
	0.832	0.715	0.757	0.717
	0.723	0.689	0.692	0.567
	0.820	1.020	0.887	0.921
	0.727	0.810	0.614	0.755
	0.847	0.609	0.687	0.745
	0.736	0.755	0.897	0.782
	0.483	0.590	0.668*	0.751*
	0.864	0.702	0.687	0.736
	0.633	0.648	0.782	0.584
	1.030	1.170	1.210	1.170
	0.440	0.625	0.655	0.496
	0.857	0.805	0.745	0.736*
	0.758	0.659	0.744	0.656
	0.751	0.844	0.903	0.772
	0.823*	0.614	0.664	0.953
	0.561	0.493	0.602	0.335
	0.672	0.610	0.631	0.752
	0.627	0.517	0.492	0.657

CI: Confidence Interval; CV%: 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 ⌐er	Sample Times (h)			
	24	36	48	72
	0.994	1.010	0.953	1.070
	0.829	0.737	0.860	0.832
	0.974	1.010	0.994	0.952
	1.140	0.995	1.150	1.200*
	0.756	0.667	0.692	0.662
	0.604	0.741	0.676*	0.664
	0.914	0.657	0.682	0.598
	0.609	0.588	0.558	0.626
	0.648	0.950	0.698	1.080
	0.815	0.807	0.863	0.770
	1.070	1.220	1.380	1.300
	0.997	0.999	0.872	0.853
	0.960	0.908	0.825	0.871
	0.627	0.602	0.512	0.587
	0.780	0.548	0.579	0.671
	0.743	0.859	0.751	0.828
	0.901	0.762	0.836	0.743
	0.536	0.535	0.627*	0.523

CI: Confidence Interval; CV%: 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 ·ber_	Sample Times (h)			
	24	36	48	72
	0.670	0.625	0.695	0.716
	0.647	0.585	0.702*	0.747
	0.637	0.595	0.665	0.717
	0.652	0.709	0.633	0.844
	0.651	0.576	0.611	0.650
	0.717	0.826	0.863	0.795
	0.653	0.625	0.619	0.677
	0.676	0.728	0.723	0.682
	0.845	0.633	0.794	0.668
	0.870	0.775	0.904	0.728
	0.469	0.471	0.544	0.603
	0.711	0.861	0.711	0.819
	0.668	0.631	0.735	0.816
	0.527	0.630	0.733	0.711
	0.727	0.698	0.755	0.731
	0.549	0.531	0.550	0.499*
	0.536	0.461	0.676	0.605
	0.797	0.791	0.755	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)

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Treatment: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
	0.655	0.669	0.569	0.649
	0.669	0.600	0.776	0.832
	0.927	0.638	0.937	0.806
	0.696*	0.653	0.691	0.624
	0.556	0.689	0.720*	0.690*
	0.685	0.637	0.652	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.
*: 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: Reference

Subject Number/ Random Number	Sample Times (h)			
	24	36	48	72
n(missing)	204 (0)	204 (0)	203 (0)	204 (0)
Mean(SD)	0.8098 (0.15679)	0.8079 (0.17964)	0.8313 (0.17921)	0.8504 (0.17680)
GeoMean	0.7941	0.7879	0.8129	0.8317
(95% CI)	(0.7724;0.8165)	(0.7636;0.8129)	(0.7894;0.8371)	(0.8076;0.8567)
GeoCV(CV%)	20.3 (19.4)	22.9 (22.2)	21.4 (21.6)	21.6 (20.8)
SEM	0.01098	0.01258	0.01258	0.01238
Median	0.8150	0.8045	0.8250	0.8300
Min; Max	0.440;1.190	0.449;1.240	0.441;1.630	0.335;1.300

CI: Confidence Interval; CV%: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	34.96	53.87	0.858	72.55
	41.19	60.96	1.260	0.00
	44.26	63.28*	1.290	0.00
	44.27	67.51*	1.070	0.50
	36.49	52.70	1.150	0.00
	36.93	55.77*	0.937	0.00
	43.13	67.51*	1.020	47.18
	54.62	80.91*	1.410	18.02
	44.31	65.45*	1.240	8.00
	39.75	59.54*	1.290	1.50
	39.15	59.25	1.060	10.00
	37.71	57.34	1.100	0.00
	43.27	65.54	1.110	0.00
	47.95	72.64	1.090	35.47
	37.77	57.20*	1.100	0.50
	38.25	56.98	0.928	35.32
	48.53	68.65*	1.270	8.00
	40.56	64.07	1.170	72.80
	39.88	60.13	0.964	4.07
	41.92	64.49	1.110	24.08
	38.60	58.56*	0.922	2.57

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	47.29	71.93	1.100	35.93
	39.45	58.66	1.080	2.63
	44.79	64.69	1.090	1.50
	43.77	66.82*	0.980	1.00
	43.11	63.67*	1.090	35.82
	41.13	63.56	0.985	2.50
	47.18	69.79	1.030	23.88
	35.18	54.11	0.931	8.03
	47.09	71.57*	1.370	2.00
	37.14	54.60	0.924	6.05
	33.58	54.04	0.933	1.50
	42.44	67.40	1.170	2.00
	49.01	75.41	1.160	2.00
	46.62	69.60	1.310	4.00
	39.71	64.92	1.210	1.50
	36.16	55.82*	0.874	71.50
	41.62	65.36*	1.070	47.53
	42.19	64.31	1.130	23.95
	43.94	67.70	1.150	1.00
	41.81	64.57*	1.060	71.02
	38.24	58.40	0.931	4.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	42.87	70.73	1.180	47.82
	39.04	61.51	0.982	72.77
	39.72	63.33*	0.997	47.28
	35.16	54.73*	1.200	0.00
	47.91	74.92*	1.190	48.57
	50.14	77.16*	1.230	71.53
	45.21	68.96	1.140	12.00
	34.48	56.26*	1.050	47.63
	36.48	56.35	0.979	3.00
	48.11	72.97*	1.410	2.50
	38.78	59.76	0.933	2.00
	47.44	70.19	1.090	23.97
	42.26	67.49*	1.150	48.33
	39.15	57.56*	1.000	1.50
	37.91	57.05*	0.941	10.02
	41.13	61.75	1.130	3.00
	48.62	73.67	1.150	3.02
	40.48	60.72	0.974	24.02
	41.00	63.23*	1.070	8.00
	37.50	58.12*	0.937	71.88
	36.44	54.92	0.904	73.50

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	50.28	76.79	1.160	18.00
	50.38	74.34*	1.200	12.00
,	42.97	66.53*	1.070	24.08
'	40.69	60.40*	0.995	23.90
.	45.67	70.35	1.120	36.33
:	40.88	60.16	1.030	2.50
	44.89	70.08	1.060	47.35
	38.53	57.95	0.960	0.52
	40.46	59.18*	1.000	2.50
	35.56	54.22*	0.971	10.00
	51.15	76.66*	1.230	35.75
	34.75	53.61*	0.856	2.00
	41.65	65.91*	1.020	48.65
	45.11	68.45	1.080	1.00
	42.52	63.52*	1.200	0.50
	38.04	59.53*	1.020	0.00
	36.38	54.66	1.080	1.50
	53.31	83.40	1.300	1.00
	31.36	47.95*	0.834	1.52
	44.32	68.04*	1.090	23.98
	44.54	75.00	1.310	72.20

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	43.32	70.42	1.270	2.02
	44.43	66.78	1.170	2.50
	43.21	66.37*	0.989	47.97
	36.73	57.36	0.909	2.50
	38.62	56.85*	0.891	35.45
	40.57	60.07*	0.954	10.00
	43.07	66.64*	1.080	48.58
	33.81	48.49	0.863	2.02
	32.16	49.38*	0.896	71.18
	46.07	70.45	1.070	35.72
	46.32	65.58*	1.220	18.03
	42.63	60.77	1.230	23.88
	49.51	76.87	1.240	10.00
	45.70	72.20	1.200	0.50
	24.51	38.84	0.812	0.00
	27.23	42.99*	0.689	47.50
	29.72	47.66*	0.833	71.15
	35.72	52.83*	0.927	35.77
	30.46	46.61*	0.742	35.80
	35.79	52.17*	0.929	1.00
	47.49	74.94	1.290	48.68

CI: Confidence Interval; CV%: 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; T3: Triiodothyronine.
*: AUC(0-tlast) was used. Normalization to exactly 72 hours was not possible because of invalid Lambda_z.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	37.08	56.98*	0.901	71.85
	27.58	41.46	0.666	48.47
	32.08	48.61*	0.738	4.03
	34.28	53.09	0.852	10.02
	38.68	65.88	1.370	72.27
	37.65	56.34*	0.910	69.78
	31.58	49.93	0.817	4.00
	30.06	48.48	0.917	2.00
	35.24	52.10	0.871	4.02
	38.45	58.96	0.863	1.00
	38.89	57.76	0.963	2.50
	26.90	40.96*	0.725	0.50
	31.80	49.31*	0.857	47.63
	30.57	46.31*	0.771	2.50
	42.19	61.88*	1.070	1.50
	51.60	78.48	1.190	35.38
	30.49	47.74*	0.823	47.50
	33.60	51.42	0.888	3.02
	37.38	54.25*	0.969	8.02
	51.09	75.33	1.200	36.08
	37.47	54.63*	0.918	35.82

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Levothyroxine
EMR 200125-001

Bioequivalence trial of new levothyroxine formulation vs. old formulation

Merck Serono
EMR 200125-001
Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	27.86	40.72	0.795	2.53
	52.47	83.14	1.410	48.78
	37.87	58.47*	0.900	71.92
	31.08	47.32	0.820	18.07
	35.92	55.86	0.919	2.50
	31.83	48.73*	0.806	23.88
	25.40	39.21*	0.687	4.00
	28.73	42.36	0.781	2.50
	52.66	77.18	1.210	2.03
	36.44	56.13	0.866	48.63
	30.00	48.58	0.889	72.13
	30.10	45.75*	0.730	35.57
	46.40	67.90*	1.140	35.60
	26.85	41.55	0.667	48.40
	44.25	66.81*	1.080	35.32
	33.52	49.98*	0.811	23.92
	29.58	45.72	0.807	1.50
	29.88	46.51	0.800	4.00
	30.68	47.38	0.943	4.02
	30.23	45.45*	0.824	2.52
	42.04	61.46*	1.000	2.52

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Bioequivalence trial of new levothyroxine formulation vs. old formulation

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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	31.92	47.73*	0.780	2.00
	32.53	50.14	0.785	10.00
	45.46	71.38*	1.210	48.32
	26.75	41.03*	0.884	1.50
	35.06	56.54*	0.989	71.40
	33.61	54.29*	0.899	18.02
	48.80	74.24*	1.280	6.00
	29.25	45.33	0.721	47.35
	30.07	51.00	0.949	72.78
	33.87	51.41*	0.825	71.83
	39.26	57.62*	0.916	3.02
	34.12	54.35	1.010	1.50
	25.71	38.59*	0.620	8.02
	29.93	45.76*	1.020	1.02
	24.48	37.27*	0.633	70.38
	45.16	70.35	1.160	72.80
	42.68	62.32*	1.120	6.08
	47.51	71.94	1.490	2.50
	48.61	74.00	1.250	3.00
	34.30	51.60*	0.817	2.50
	27.18	41.15*	0.795	1.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Bioequivalence trial of new levothyroxine formulation vs. old formulation

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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	32.69	49.97*	0.762	47.08
	24.64	38.50	0.602	72.57
	44.79	67.18	1.180	1.52
	38.83	58.87	0.978	72.12
	54.53	84.00*	1.340	3.00
	43.82	68.50	1.130	72.10
	40.55	61.65	1.030	72.65
	26.37	41.49	0.641	47.68
	34.61	50.86	1.060	1.50
	34.13	52.39	0.822	0.00
	38.83	59.00*	0.931	23.88
	26.60	40.70	0.637	35.90
	27.92	43.06*	0.713	10.00
	36.53	51.69*	1.290	23.87
	27.85	46.41	0.848	72.23
	28.46	46.39	0.804	72.10
	26.28	39.98*	0.641	4.00
	39.30	58.19*	0.914	35.80
	31.14	45.73*	0.923	1.50
	34.01	51.44	0.839	10.03
	33.06	49.31*	0.973	4.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	38.077 (7.1285)	58.130 (10.7231)	0.9891 (0.18755)	
GeoMean(95% CI)	37.402 (36.428;38.402)	57.137 (55.679;58.634)	0.9713 (0.9457;0.9975)	
GeoCV(CV%)	19.3 (18.7)	18.9 (18.4)	19.5 (19.0)	
SEM	0.4991	0.7508	0.01313	
Median	38.140	57.591	0.9735	10.000
Min; Max	24.48; 54.62	37.27; 84.00	0.602; 1.490	0.00; 73.50

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Bioequivalence trial of new levothyroxine formulation vs. old formulation

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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Test

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	34.64	52.01	0.836	10.07
	27.30	41.78	0.722	2.58
	30.33	46.57*	0.817	1.50
	34.02	52.49	0.807	35.77
	32.15	49.59*	0.800	8.00
	30.02	47.23*	0.744	1.00
	27.51	41.50*	0.711	1.50
	27.03	42.97	0.680	48.92
	42.12	62.70	1.100	2.02
	29.30	45.36	0.718	2.00
	29.86	48.65	0.843	72.52
	35.90	56.57	0.939	2.53
	31.92	47.05*	0.784	10.00
	29.09	45.61	0.778	73.07
	31.70	47.50*	0.773	4.00

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Bioequivalence trial of new levothyroxine formulation vs. old formulation

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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

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Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	38.77	55.97*	0.954	3.02
	36.80	55.21	0.995	24.02
	50.95	72.28*	1.210	35.72
	42.63	66.52*	1.100	71.25
	38.91	59.31	1.110	8.03
	36.76	54.36	0.903	4.00
	46.72	72.98	1.110	35.08
	53.65	80.77	1.200	18.10
	42.31	61.03	1.290	8.02
	39.82	63.08	1.170	2.50
	39.08	57.07	0.984	3.00
	40.20	61.91	0.961	0.00
	42.03	63.28	0.962	24.02
	47.16	72.61	1.220	1.00
	36.27	58.24	1.010	72.27
	37.34	57.55	0.856	48.88
	46.70	69.04*	1.200	2.50
	45.18	65.43*	1.310	2.67
	48.61	70.45	1.150	24.10
	44.80	71.19	1.200	48.30
	50.33	76.62	1.230	1.50

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Bioequivalence trial of new levothyroxine formulation vs. old formulation

Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	43.40	65.91	1.020	8.03
	39.93	59.97	1.130	3.00
	47.57	71.42	1.220	1.50
	39.92	60.27	0.962	1.50
	37.67	56.40	0.921	1.50
	42.35	65.75	1.020	72.25
	42.83	64.57	0.992	2.00
	34.88	52.51	1.070	1.50
	42.34	65.58*	1.060	71.40
	35.86	52.79	0.837	24.03
	33.43	52.89	1.050	1.00
	41.55	61.30	1.210	0.50
	49.16	73.04*	1.200	0.50
	45.49	67.05*	1.510	0.50
	41.23	65.00	1.170	4.00
	39.72	61.83*	1.000	47.67
	41.17	62.39	1.080	8.00
	41.57	61.34	1.140	1.50
	42.48	66.37	1.020	49.28
	41.08	62.00*	0.975	35.62
	32.78	50.62	0.836	48.10

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Bioequivalence trial of new levothyroxine formulation vs. old formulation

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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	41.44	62.93	0.984	35.83
	40.74	61.98*	1.030	36.23
	43.09	67.09*	1.040	3.02
	37.79	58.97	1.110	2.50
	50.18	78.93*	1.240	71.47
	53.09	81.13*	1.340	48.37
	38.50	62.34*	1.080	70.82
	33.25	54.47*	1.030	71.38
	49.24	75.54*	1.240	35.28
	50.16	77.05	1.330	6.05
	40.28	59.20*	1.010	24.00
	47.71	73.52	1.080	48.37
	39.27	61.30	1.210	4.00
	40.52	60.45*	1.030	2.50
	44.79	67.78	1.070	35.87
	40.58	60.42	1.000	3.00
	49.22	77.18	1.300	72.22
	41.52	64.55	1.150	47.83
	43.24	67.99	1.060	3.00
	38.64	59.83	0.936	2.02
	37.71	55.63	0.894	36.42

CI: Confidence Interval; CV%: 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; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	44.39	69.49	1.100	72.63
	46.54	70.81	1.340	1.53
	44.34	67.51*	1.140	10.02
	40.97	61.61*	0.930	10.02
	48.91	76.51	1.270	1.00
	35.58	54.10*	0.985	12.07
	43.13	63.76*	1.010	6.02
	40.45	60.24*	1.100	1.50
	39.92	63.63*	1.050	71.50
	34.42	53.15	0.885	0.50
	45.81	69.38*	1.090	71.58
	33.80	52.05	0.881	4.00
	44.96	66.57	1.190	2.50
	42.98	65.24	0.949	35.15
	41.46	62.08	1.070	1.52
	37.58	53.77*	1.010	0.00
	37.83	58.14*	1.080	10.00
	48.73	73.58*	1.170	1.00
	32.43	50.24	0.835	1.50
	36.28	59.36	1.070	72.32
	47.91	80.07	1.630	48.40

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Bioequivalence trial of new levothyroxine formulation vs. old formulation

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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

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Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	46.96	71.76	1.100	4.00
	46.00	66.21	1.130	3.00
	41.15	61.79*	0.992	48.98
	39.15	60.33*	0.934	71.75
	39.93	57.56*	0.962	23.97
	41.52	64.33	1.020	47.83
	36.73	55.45	0.838	4.00
	34.62	52.59	0.797	4.00
	33.02	51.75	0.825	48.62
	47.96	73.86	1.130	3.00
	42.86	63.27*	1.080	3.00
	43.49	64.66*	1.060	23.87
	50.94	76.11	1.170	10.00
	45.01	69.01	1.130	3.00
	28.72	46.11	1.020	72.47
	27.12	43.36*	0.691	71.55
	29.46	45.81*	0.738	0.00
	35.82	52.56*	0.944	3.00
	32.45	46.25*	1.090	4.02
	31.70	48.82	0.805	48.13
	46.06	71.95	1.200	8.02

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	37.69	61.79	1.130	72.70
	23.76	39.31*	0.739	71.38
	32.87	49.61*	0.782	47.30
	31.58	49.25	0.792	72.82
	43.42	65.27	1.050	12.00
	41.48	62.08	0.947	23.98
	32.12	48.22	0.802	72.78
	32.63	50.17*	0.836	1.00
	30.06	49.63*	0.861	71.40
	35.07	54.61	0.872	48.47
	39.67	59.65*	0.918	0.50
	29.83	46.06	0.897	0.00
	35.40	55.61*	0.936	71.63
	31.69	47.90	0.860	8.32
	39.78	62.43*	1.000	71.20
	46.97	72.82*	1.160	71.47
	31.70	47.69	0.866	0.00
	32.14	48.00*	0.774	6.00
	37.72	55.79	0.997	1.50
	52.18	79.92*	1.220	48.93
	36.18	54.87	0.853	2.02

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
7	27.53	42.28	0.743	2.52
	48.94	77.60	1.420	1.50
	51.40	77.78*	1.300	8.02
	29.21	46.17*	0.767	3.00
	39.16	58.84	0.943	1.50
	30.90	46.10	0.826	2.52
	26.64	43.84	0.744	47.45
	28.12	42.03	0.728	3.00
	48.03	70.81	1.180	35.25
	34.14	53.14	0.826	47.67
	31.76	51.26	0.994	72.47
	27.55	43.05*	0.780	4.02
	41.63	61.55*	1.010	35.57
	26.79	42.13	0.746	4.00
	46.29	64.57	1.150	0.50
	33.38	50.74*	0.820	23.87
	29.17	43.63	0.758	1.00
	31.75	48.08*	0.737	35.05
	35.68	53.15*	1.030	2.52
	32.27	46.66*	0.768	0.00
	42.25	63.95	1.020	35.50

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Levothyroxine
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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	33.70	50.10	0.810	35.75
	34.67	51.81	0.916	10.02
	38.16	58.12*	0.953	10.00
	27.96	43.89*	0.771	1.50
	36.61	53.34*	1.560	0.00
	30.77	46.79*	0.782	47.48
	52.61	81.18	1.210	48.18
	25.52	38.84*	0.655	47.63
	36.41	54.19	0.908	3.00
	34.62	51.24*	0.908	8.00
	38.74	58.66*	0.903	48.15
	31.70	51.12*	0.953	71.95
	25.25	35.88*	0.689	4.00
	30.55	46.99*	0.781	2.05
	26.55	40.31	0.713	1.50
	49.42	73.61	1.310	4.00
	41.65	61.95	1.120	2.50
	46.69	70.06	1.160	1.50
	50.54	78.69	1.240	1.52
	34.43	50.17*	1.020	0.00
	30.54	46.61	0.741	35.72

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	33.95	49.15*	0.914	23.87
	27.06	41.26	0.648	2.00
	41.73	63.13*	1.170	3.00
	37.10	56.37*	0.979	8.03
	53.89	85.45*	1.380	47.20
	46.27	66.72*	1.010	12.00
	41.52	61.86	1.010	2.52
	28.34	41.41*	0.757	12.00
	32.08	47.07	1.050	1.50
	36.19	55.13	0.911	1.50
	38.16	56.39*	0.908	0.48
	25.19	39.03	0.627	49.18
	29.78	46.70	0.716	72.77
	30.15	46.96*	0.747	71.17
	29.84	46.41	0.850	12.05
	33.73	51.38	0.892	18.02
	27.59	42.72	0.651	23.90
	35.77	55.68	0.863	48.38
	30.97	46.28*	0.791	4.00
	34.12	50.76*	0.891	10.02
	36.52	54.06	0.978	1.50

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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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Levothyroxine   **Bioequivalence trial of new levothyroxine formulation vs. old formulation**
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Table 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
	39.47	58.59*	0.904	48.32
	23.89	37.20*	0.646	2.00
	36.21	54.55	0.946	10.00
	31.92	50.51	0.816	72.47
	31.44	48.76	0.936	10.00
	35.38	53.21	0.841	18.00
	24.91	37.53	0.641	1.50
	26.29	41.46*	0.676	47.82
	39.77	57.63	0.996	3.02
	31.63	46.03*	0.907	8.00
	29.91	48.80*	0.832	71.52
	34.12	54.75*	0.937	47.35
	31.83	47.61	0.748	8.00
	28.66	45.61	0.720	49.18
	29.25	44.68	0.685	23.87

CI: Confidence Interval; CV%: 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; T3: Triiodothyronine.
*: 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 15.4.1.1.4 Individual Data and Summary Statistics of Total T3 Pharmacokinetic Parameters
(Pharmacokinetic Population)
Treatment: Reference

Subject Number/ Random Number	AUC0-48 (hr*ng/mL)	AUC0-72 (hr*ng/mL)	Cmax (ng/mL)	tmax (hr)
n(missing)	204 (0)	204 (0)	204 (0)	204 (0)
Mean(SD)	38.282 (7.0973)	58.281 (10.7196)	0.9893 (0.18680)	
GeoMean(95% CI)	37.616 (36.644;38.613)	57.295 (55.841;58.788)	0.9719 (0.9468;0.9976)	
GeoCV(CV%)	19.1 (18.5)	18.8 (18.4)	19.1 (18.9)	
SEM	0.4969	0.7505	0.01308	
Median	38.330	58.189	0.9920	9.159
Min; Max	23.76; 53.89	35.88; 85.45	0.627; 1.630	0.00; 72.82

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; GeoCV: Geometric Coefficient of Variation;
GeoMean: Geometric Mean; Max: Maximum Value; Min: Minimum Value; n: The number of subjects with specific parameter
calculable; SD: Standard Deviation; SEM: Standard Error of the Mean; T3: Triiodothyronine.
*: 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.
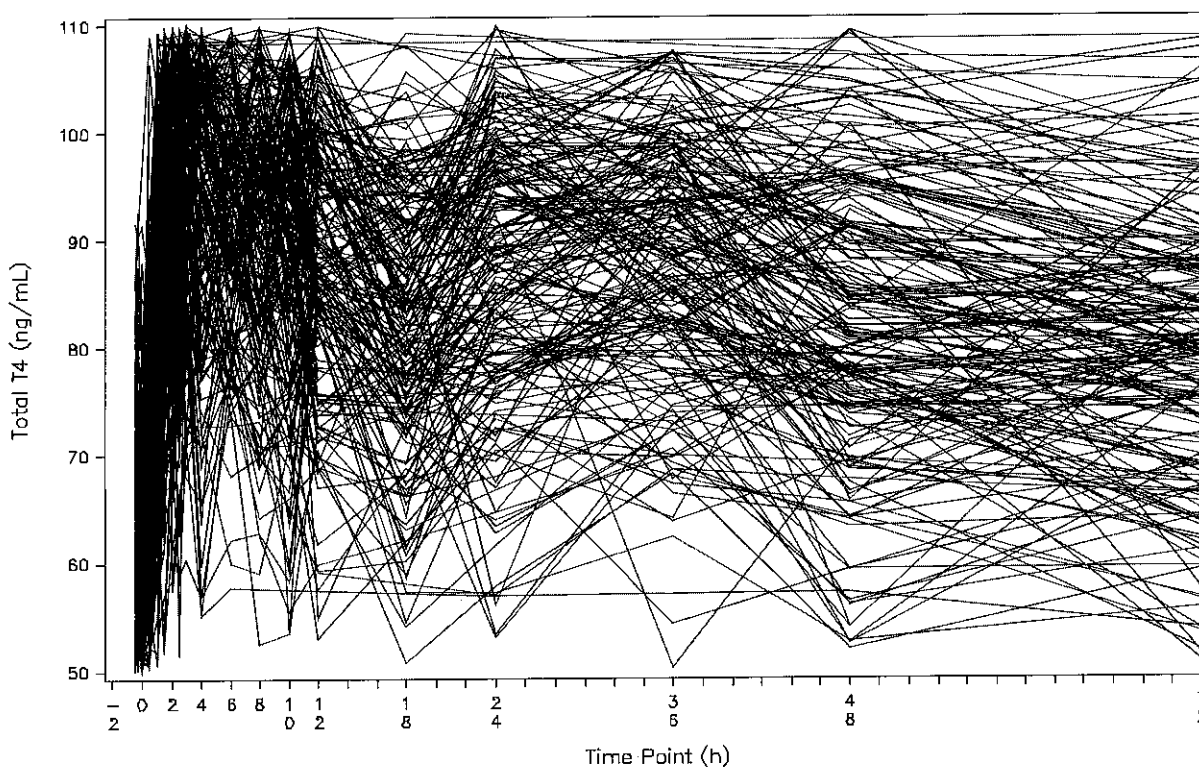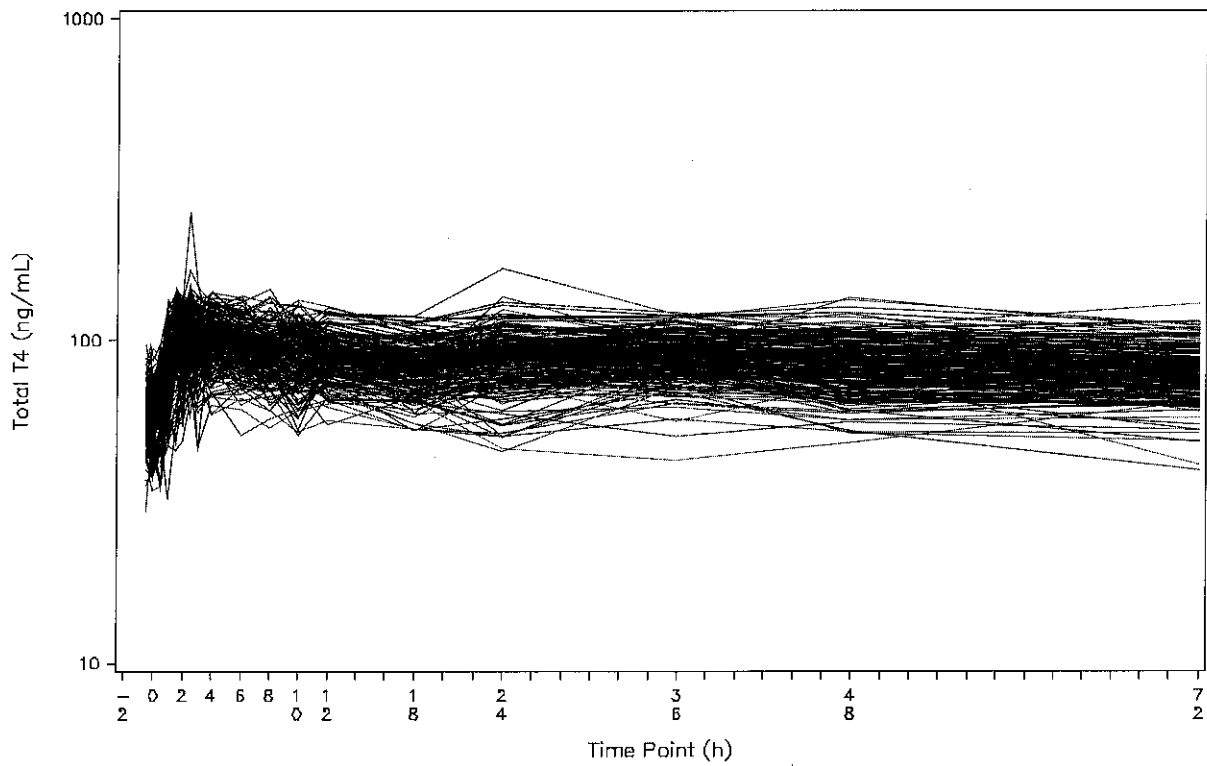Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.4.3.1 Summary of ANOVA of Primary Pharmacokinetic Parameters for T4 (Pharmacokinetic Population)

Parameter	Treatment	N	Geo-LSMean	Ratio (Test/Ref) (%)	90% CI of Ratio	Intra-CV (%)
AUC0-72,adj (hr*ng/mL)	Test	204	1852.079	99.3	95.6 - 103.2	23.7
	Reference	204	1864.359			
Cmax,adj (ng/mL)	Test	204	53.5473	101.7	98.8 - 104.6	17.7
	Reference	204	52.6736			

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; Geo-LSMean: Geometric Least Square Mean;
N: Number of subjects included in the analysis.
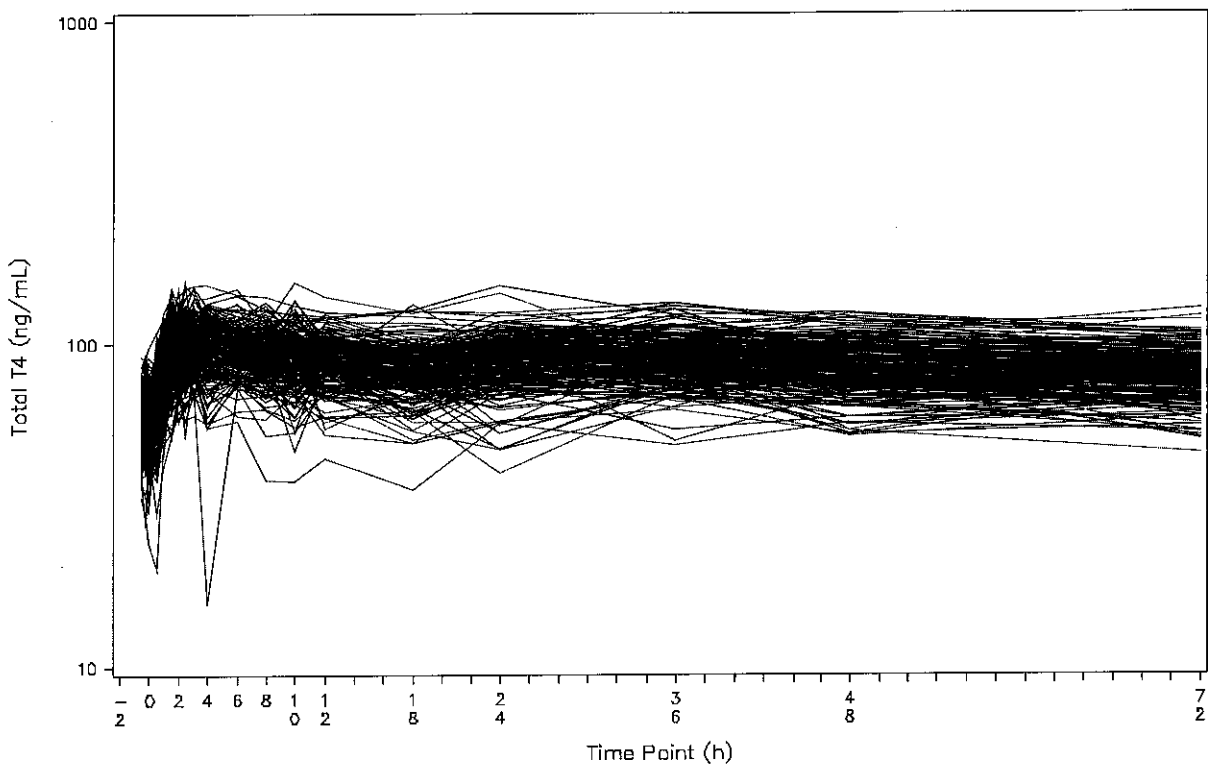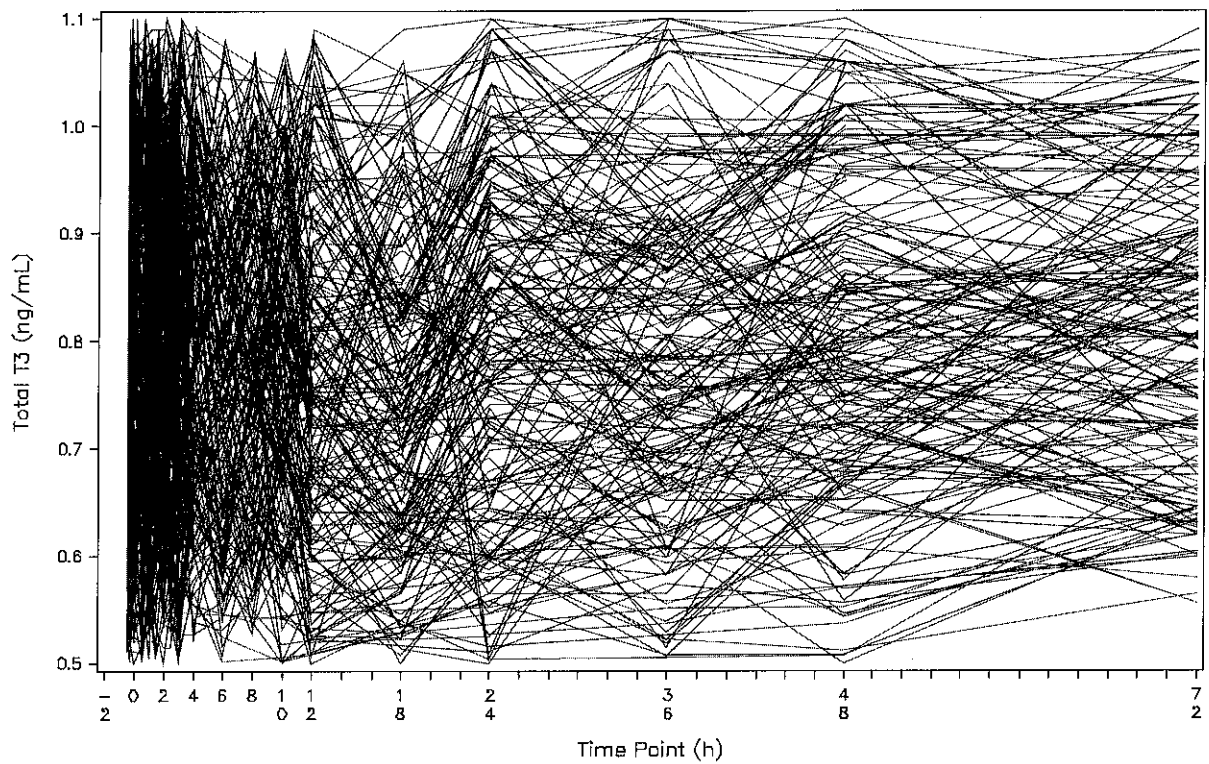Subjects 1028,1037,1185,1219,1238,1247,1385,1396,1541,1629,1632 and 1737 were excluded from the PK Population.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Appendix 16.1.9.1

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.4.3.1.sas

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Table 15.4.3.2   Summary of ANOVA of Secondary Pharmacokinetic Parameters for T4 and T3 (Pharmacokinetic Population)

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Analyte	Parameter	Treatment	N	Geo-LSMean	Ratio (Test/Ref) (%)	90% CI of Ratio	Intra-CV (%)
T3	AUC0-72 (hr*ng/mL)	Test	204	57.1222	99.7	98.8 - 100.6	5.5
		Reference	204	57.2855			
	Cmax (ng/mL)	Test	204	0.9711	99.9	98.5 - 101.3	8.6
		Reference	204	0.9718			
T4	AUC0-72 (hr*ng/mL)	Test	204	6169.484	99.7	98.8 - 100.6	5.5
		Reference	204	6190.588			
	Cmax (ng/mL)	Test	204	113.0876	100.6	99.2 - 102.0	8.5
		Reference	204	112.4192			

CI: Confidence Interval; CV%: Coefficient of Variation Percentage; Geo-LSMean: Geometric Least Square Mean;
N: Number of subjects included in the analysis.
Subjects 1028,1037,1185,1219,1238,1247,1385,1396,1541,1629,1632 and 1737 were excluded from the PK Population.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Appendix 16.1.9.2

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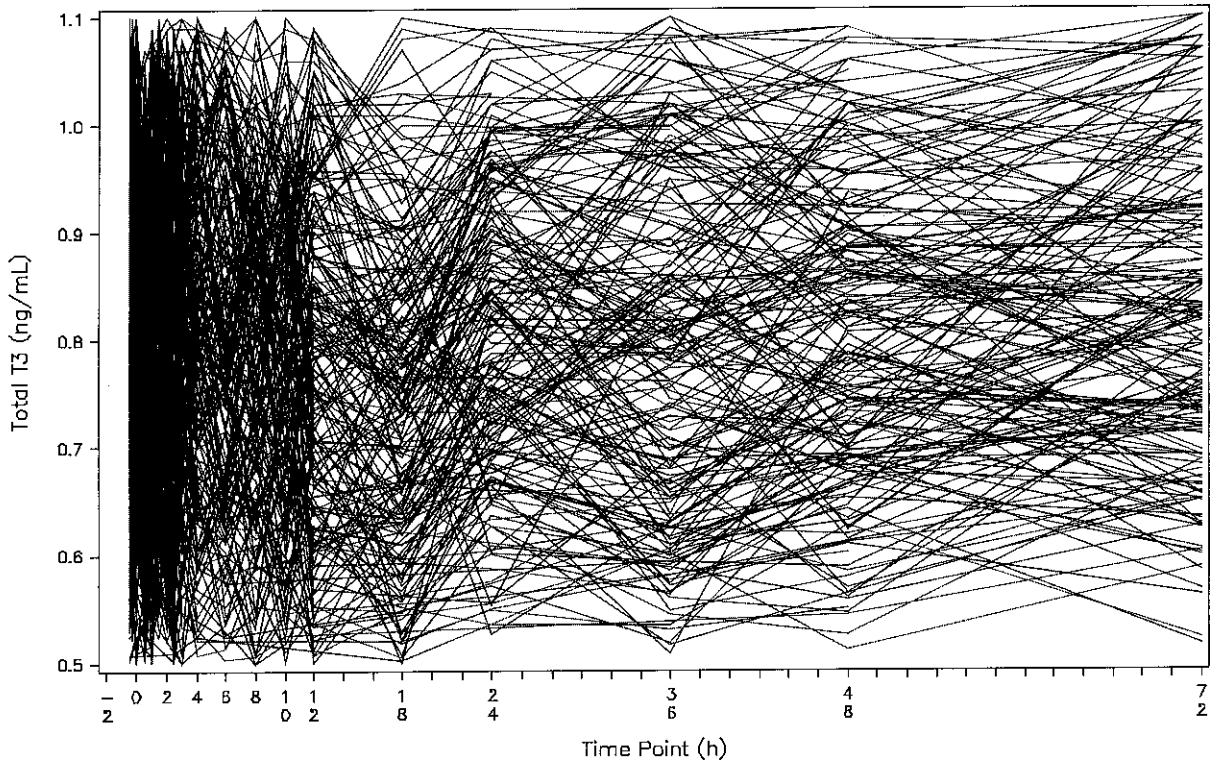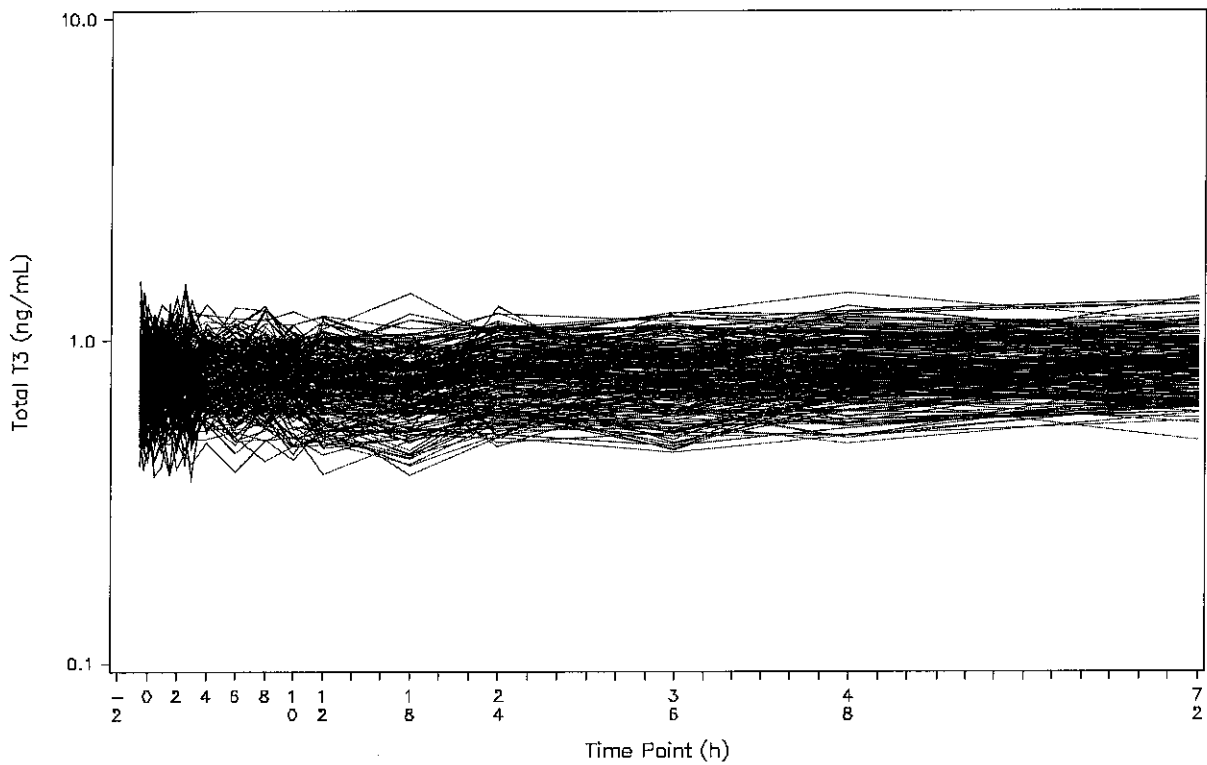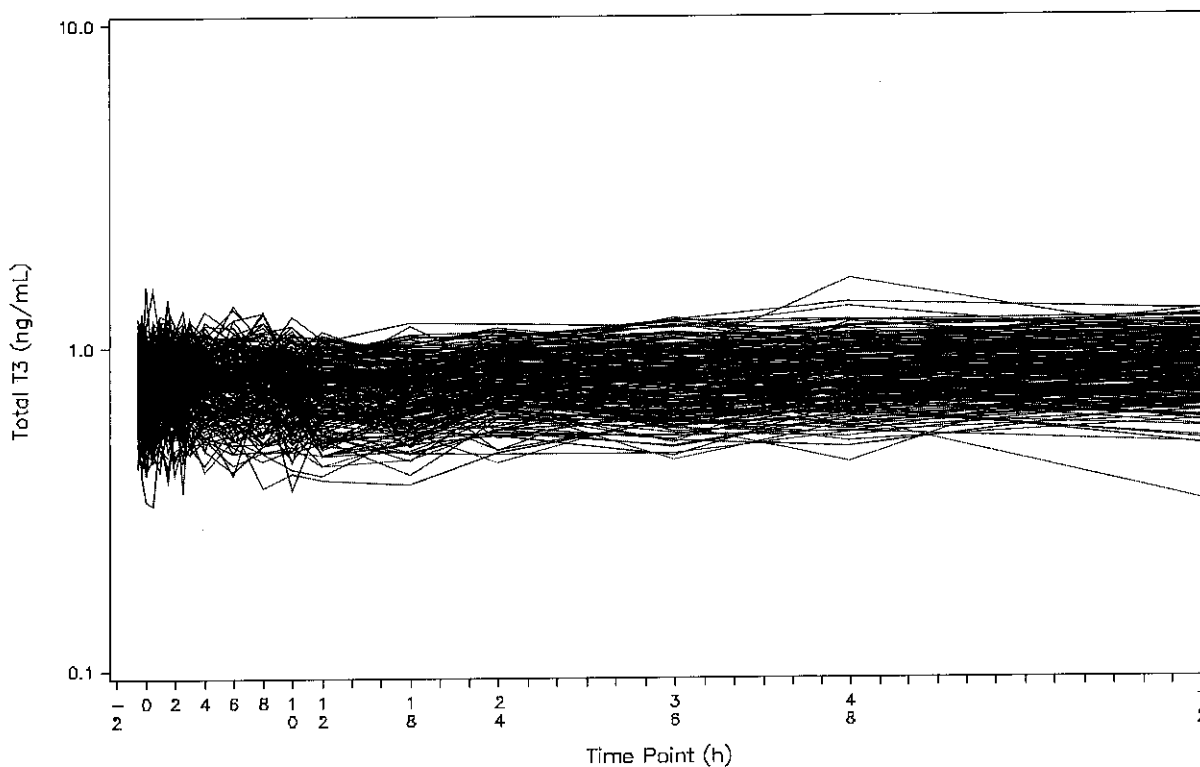15.4.3.2.sas

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15.4.2 Graphs

Figure 15.4.2.1   Concentration-Time Profiles: Arithmetic Mean (± SD) versus Scheduled Sampling Time in Linear Scale (for Total T4 Values) (Pharmacokinetic Population)

Figure 15.4.2.2   Concentration-Time Profiles: Arithmetic Mean versus Scheduled Sampling Time in Semi-Logarithmic Scale (For Total T4 Values)(Pharmacokinetic Population)

Figure 15.4.2.3   Concentration-Time Profiles: Arithmetic Mean (± SD) versus Scheduled Sampling Time in Linear Scale (for Total T3 Values)(Pharmacokinetic Population)

Figure 15.4.2.4   Concentration-Time Profiles: Arithmetic Mean (± SD) versus Scheduled Sampling Time in Semi-Logarithmic Scale (For Total T3 Values)(Pharmacokinetic Population)

Figure 15.4.2.5   Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (Spaghetti Plots) (for Total T4 Values)(Pharmacokinetic Population)

Figure 15.4.2.6   Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (Spaghetti Plots) (for Total T4 Values)(Pharmacokinetic Population)

Figure 15.4.2.7   Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (Spaghetti Plots) (for Total T3 Values)(Pharmacokinetic Population)

Figure 15.4.2.8   Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (Spaghetti Plots)(for Total T3 Values)(Pharmacokinetic Population)
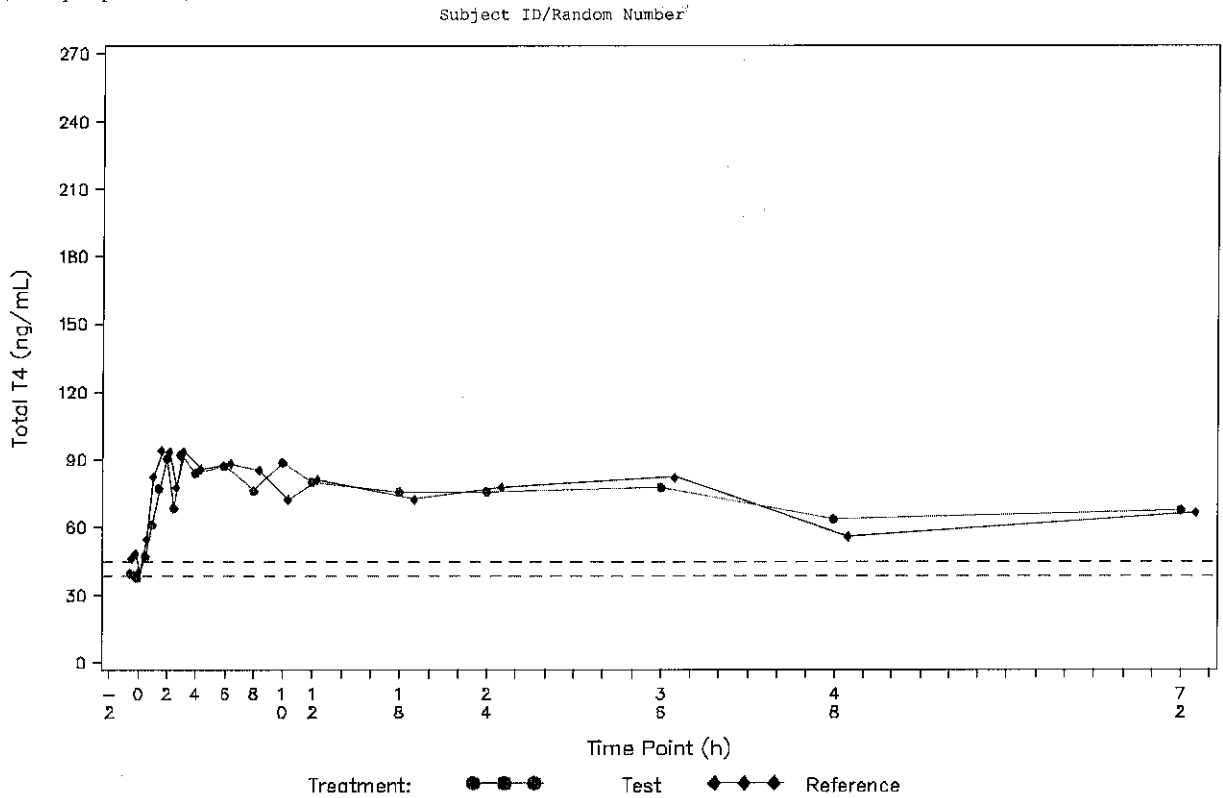
Figure 15.4.2.9   Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Figure 15.4.2.10   Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (for Total T4 Values) (Safety Population)

Figure 15.4.2.11   Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T3 Values) (Safety Population)
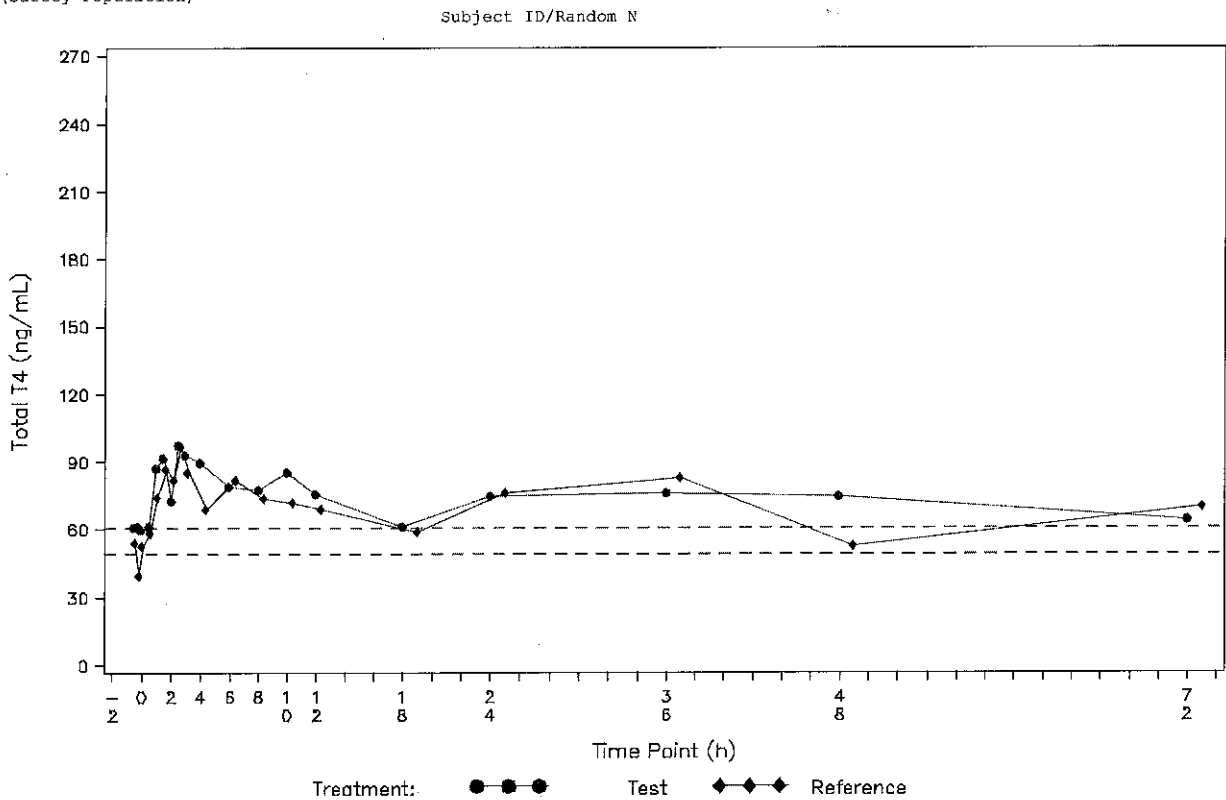
Levothyroxine

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Figure 15.4.2.1 Concentration-Time Profiles: Arithmetic Mean (± SD) versus Scheduled Sampling Time in Linear Scale
(for Total T4 Values) (Pharmacokinetic Population)

Subjects 1 _____ ___, were excluded from the PK Population.

Test: 600 µg (3*200 µg _____, levothyroxine new formulation.

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

Source: Table 15.4.1.1.1

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Figure 15.4.2.2 Concentration-Time Profiles: Arithmetic Mean versus Scheduled Sampling Time in Semi-Logarithmic Scale
(For Total T4 Values)(Pharmacokinetic Population)

Subjects   were excluded from the PK Population.
Test: 600 µg (3*2∪∪ µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.1

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Figure 15.4.2.3 Concentration-Time Profiles: Arithmetic Mean (± SD) versus Scheduled Sampling Time in Linear Scale
(for Total T3 Values)(Pharmacokinetic Population)

Subjects `[...]` [were excluded from the PK Population.
Test: 600 μg (3·200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.3

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Figure 15.4.2.4 Concentration-Time Profiles: Arithmetic Mean versus Scheduled Sampling Time in Semi-Logarithmic Scale (For Total T3 Values)(Pharmacokinetic Population)

Subjects 1 ....1.. .... \ '. were excluded from the PK Population.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.3

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Figure 15.4.2.5 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (Spaghetti Plots)
(for Total T4 Values)(Pharmacokinetic Population)

Treatment: Test

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.1

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Figure 15.4.2.5 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (Spaghetti Plots)
(for Total T4 Values)(Pharmacokinetic Population)

Treatment: Reference

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.1
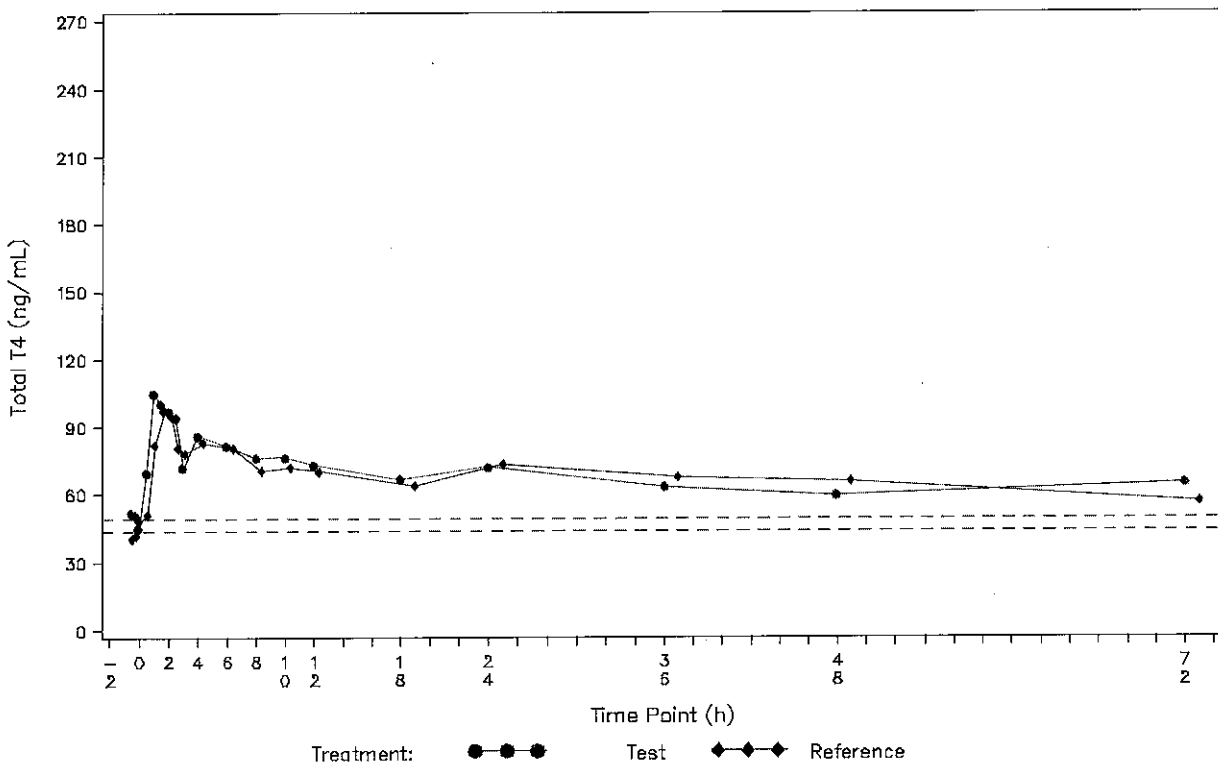
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Figure 15.4.2.6 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(Spaghetti Plots)(For Total T4 Values)(Pharmacokinetic Population)

Treatment: Test

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.1

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Figure 15.4.2.6 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(Spaghetti Plots)(For Total T4 Values)(Pharmacokinetic Population)

Treatment: Reference

Test: 600 μg (3*200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.1

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Figure 15.4.2.7 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (Spaghetti Plots)
(for Total T3 Values)(Pharmacokinetic Population)

Treatment: Test

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.3

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Figure 15.4.2.7 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (Spaghetti Plots) (for Total T3 Values)(Pharmacokinetic Population)

Treatment: Reference

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.3

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Figure 15.4.2.8 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(Spaghetti Plots)(For Total T3 Values)(Pharmacokinetic Population)

Treatment: Test

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.3

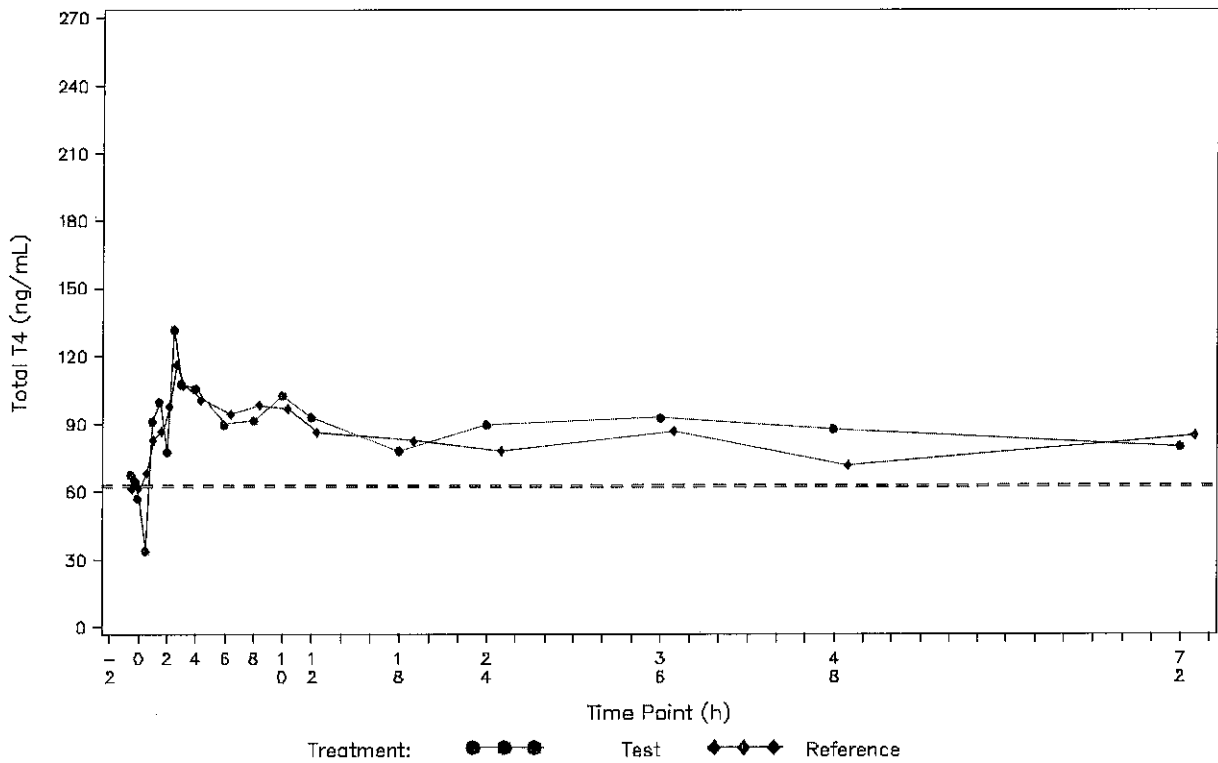/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.8 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (Spaghetti Plots)(For Total T3 Values)(Pharmacokinetic Population)

Treatment: Reference

Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.1.1.3

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
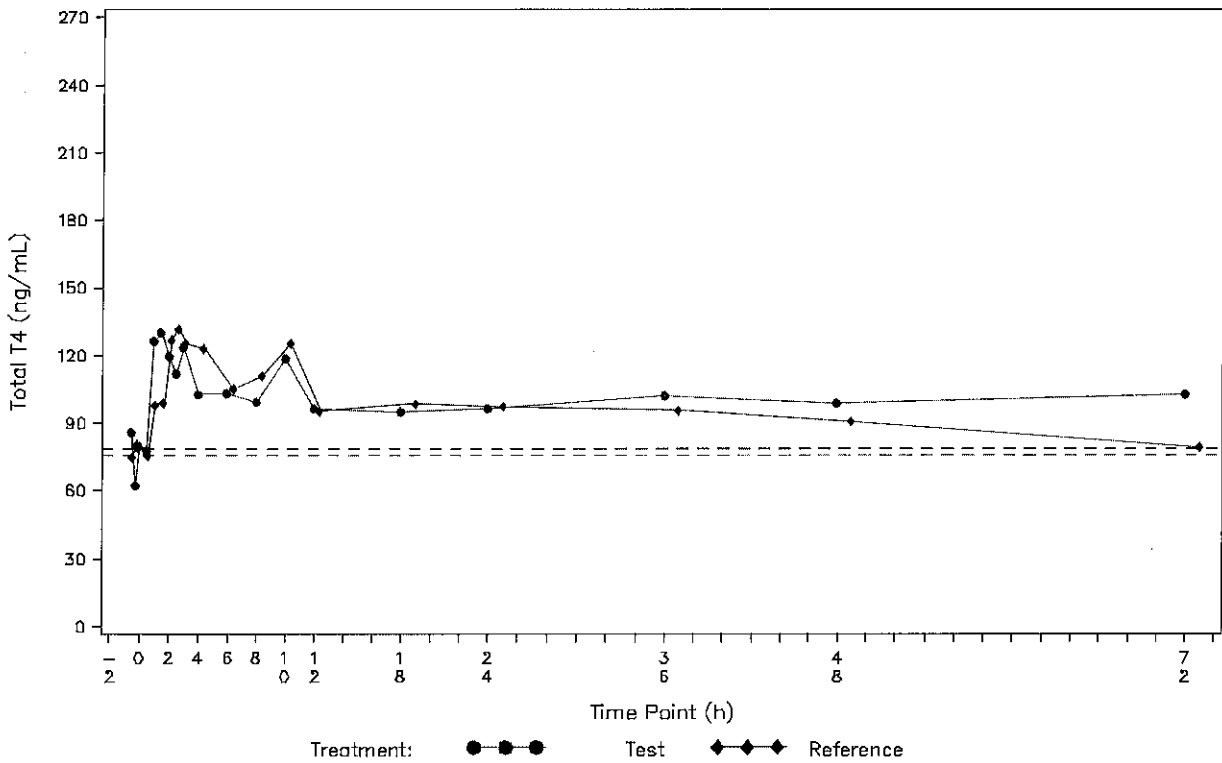(Safety Population)

Subject ID/Random Number

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
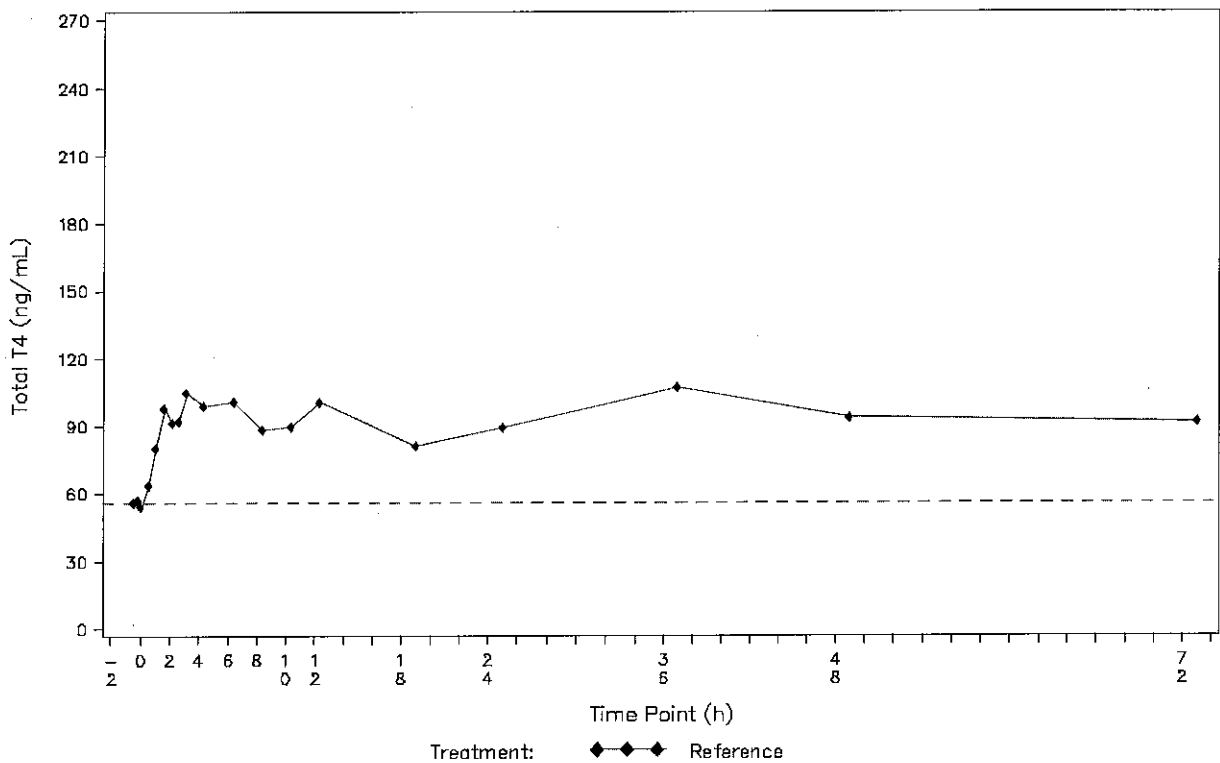Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random N

Time Point (h)

Treatment: ●●● Test ◆◆◆ Reference

θ:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
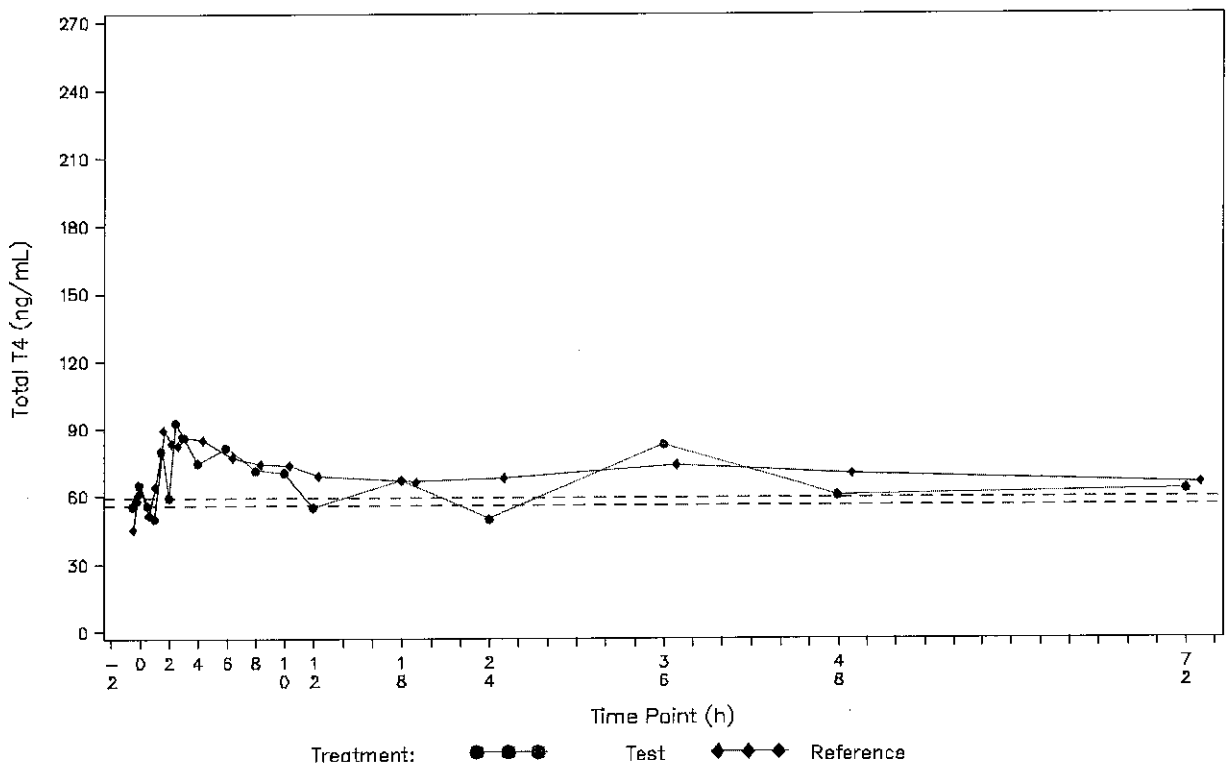
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:
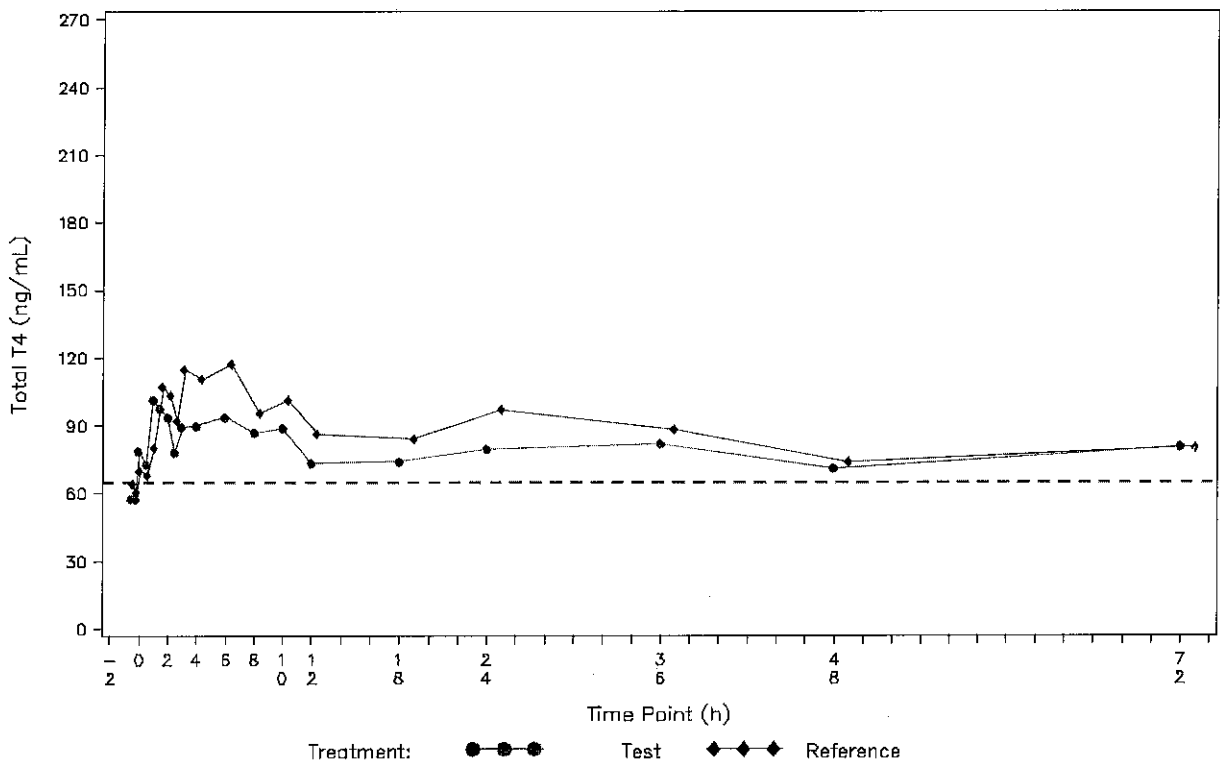

Treatment: ●─●─● Test   ◆─◆─◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
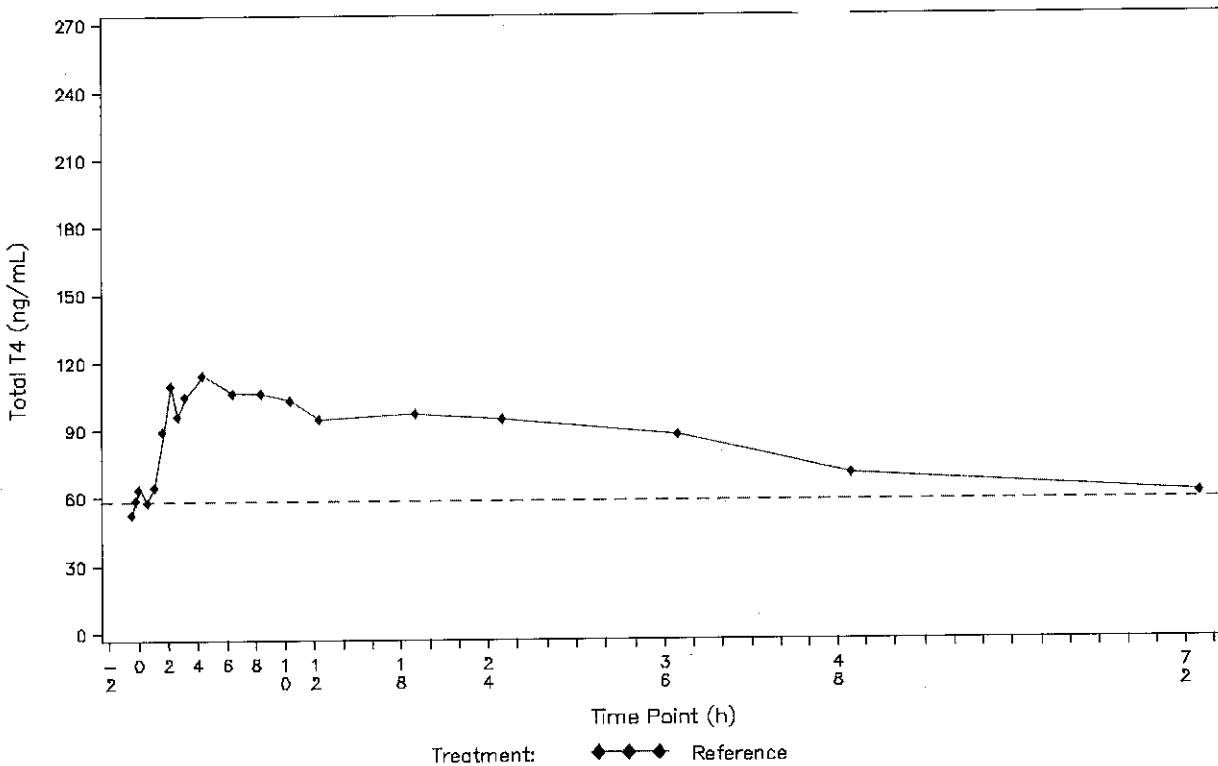Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number
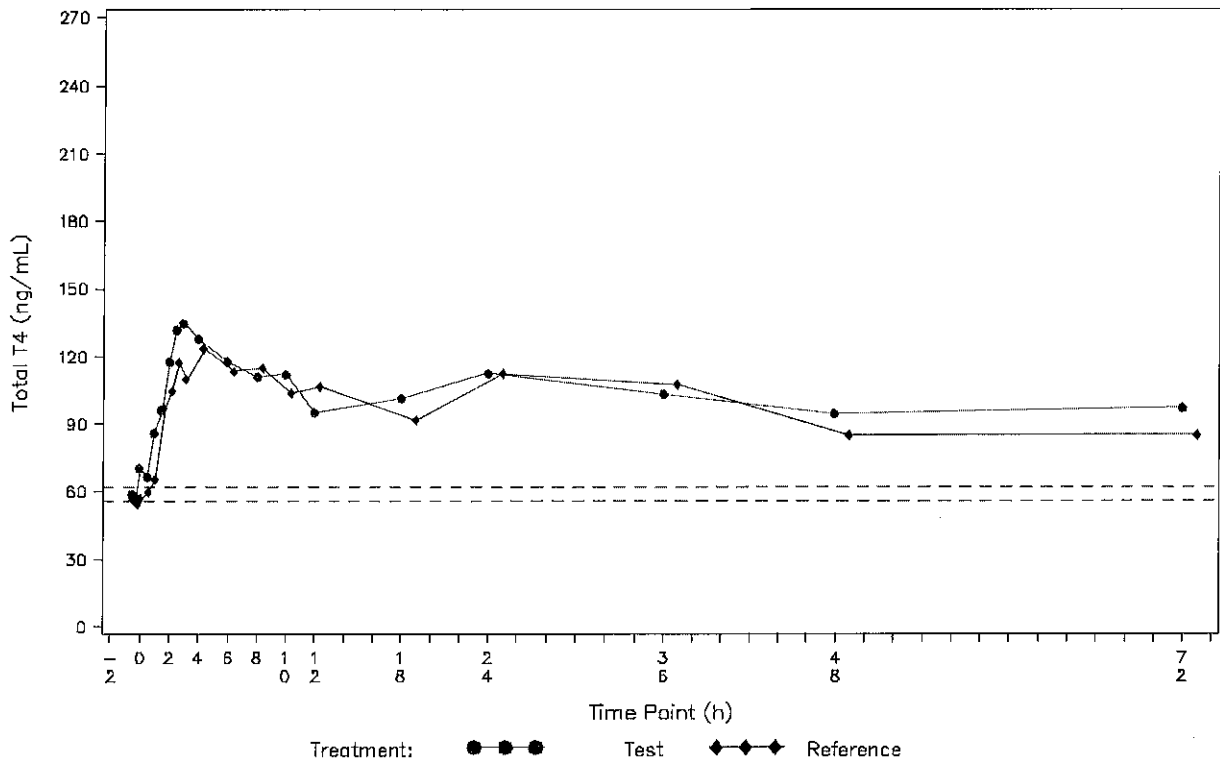

Treatment: ●─●─● Test ◆─◆─◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)
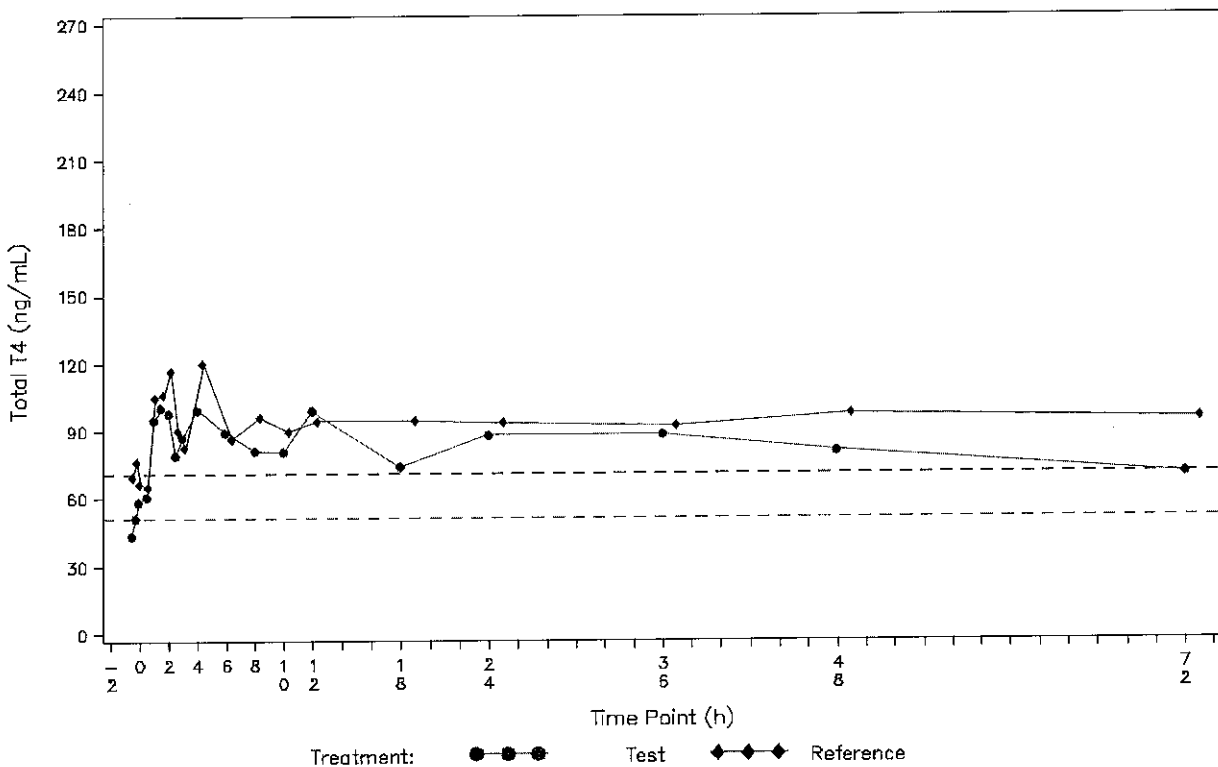
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
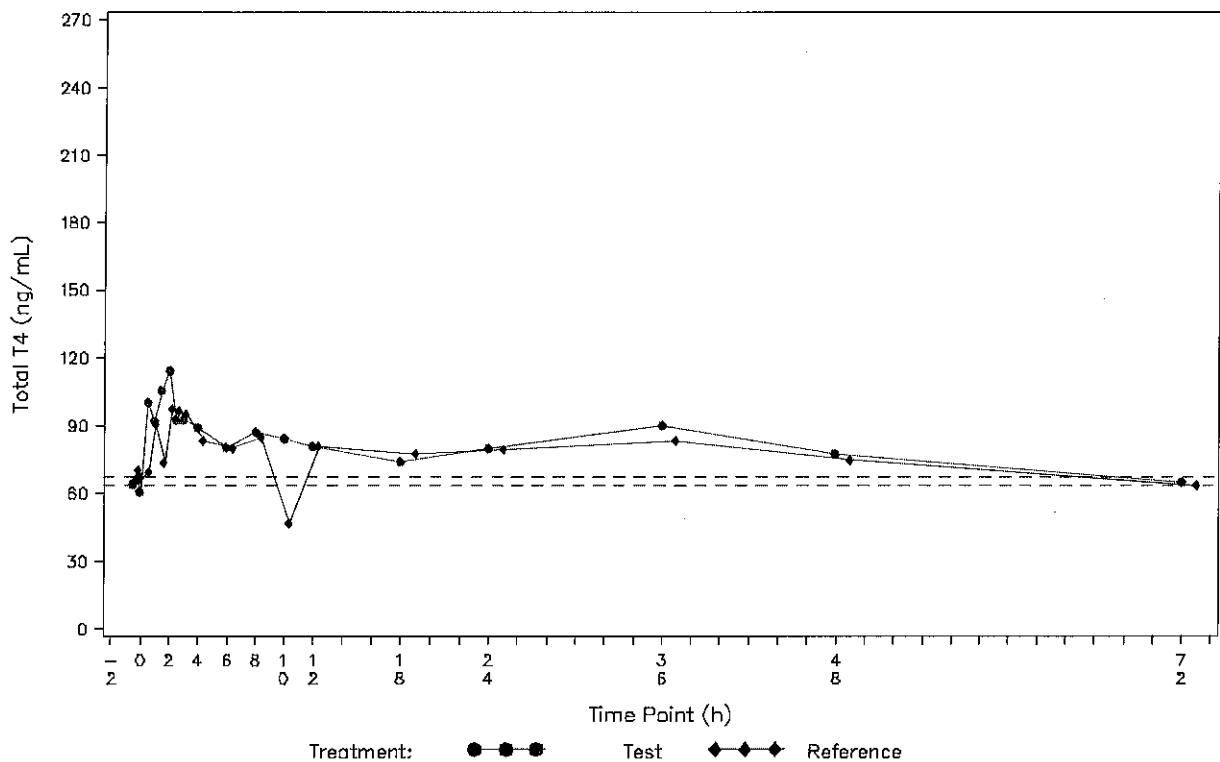
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)
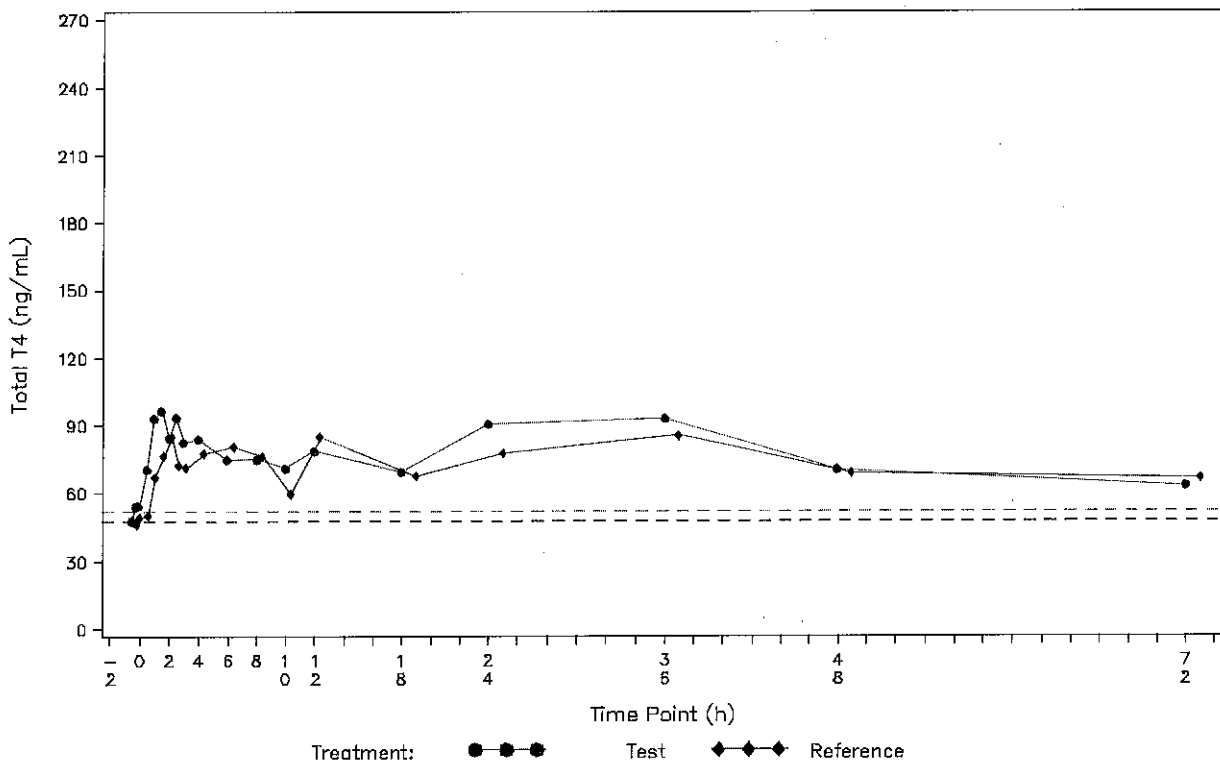
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Time Point (h)

Treatment: ◆—◆—◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
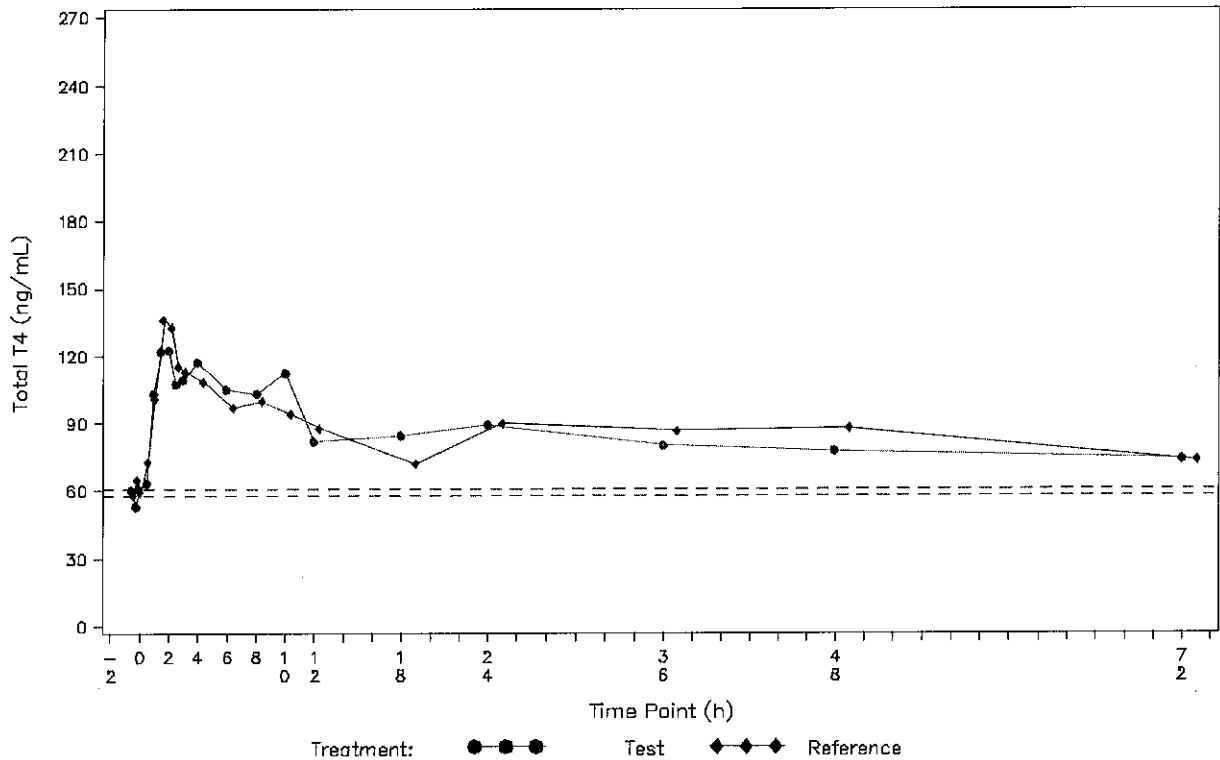(Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)
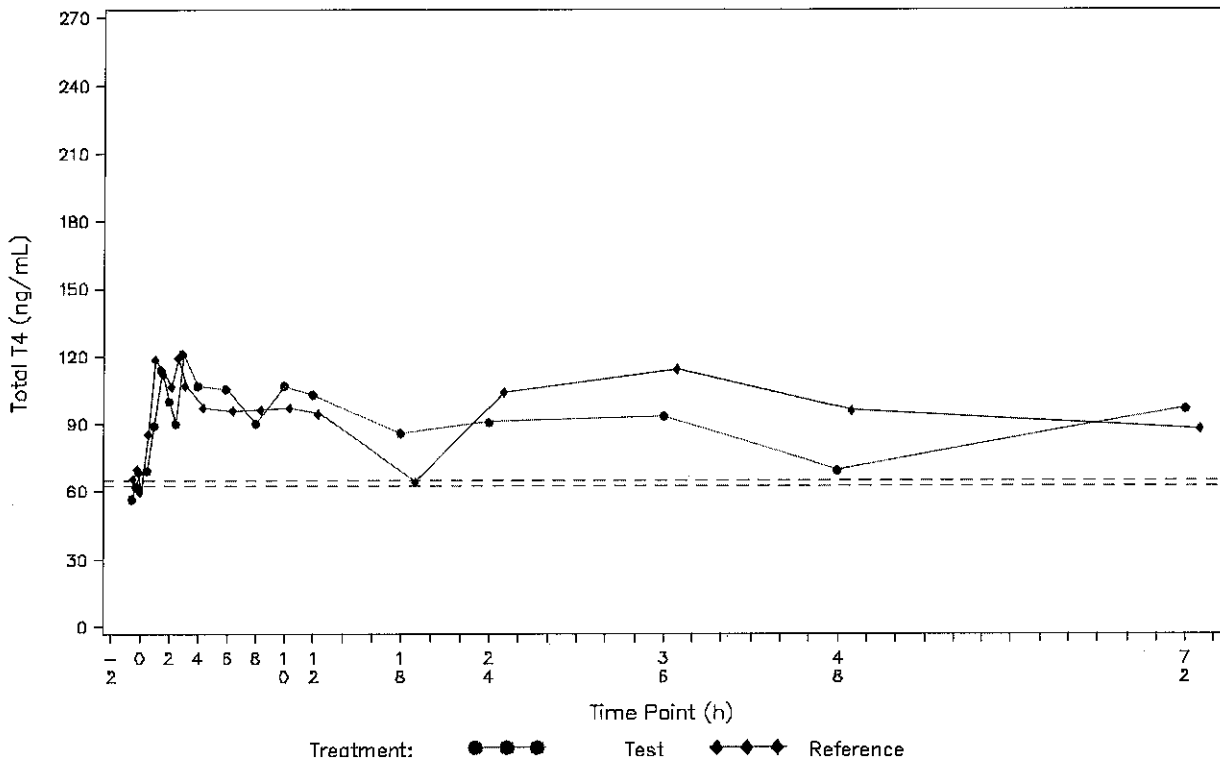
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number: ''^^^θ

$@$:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

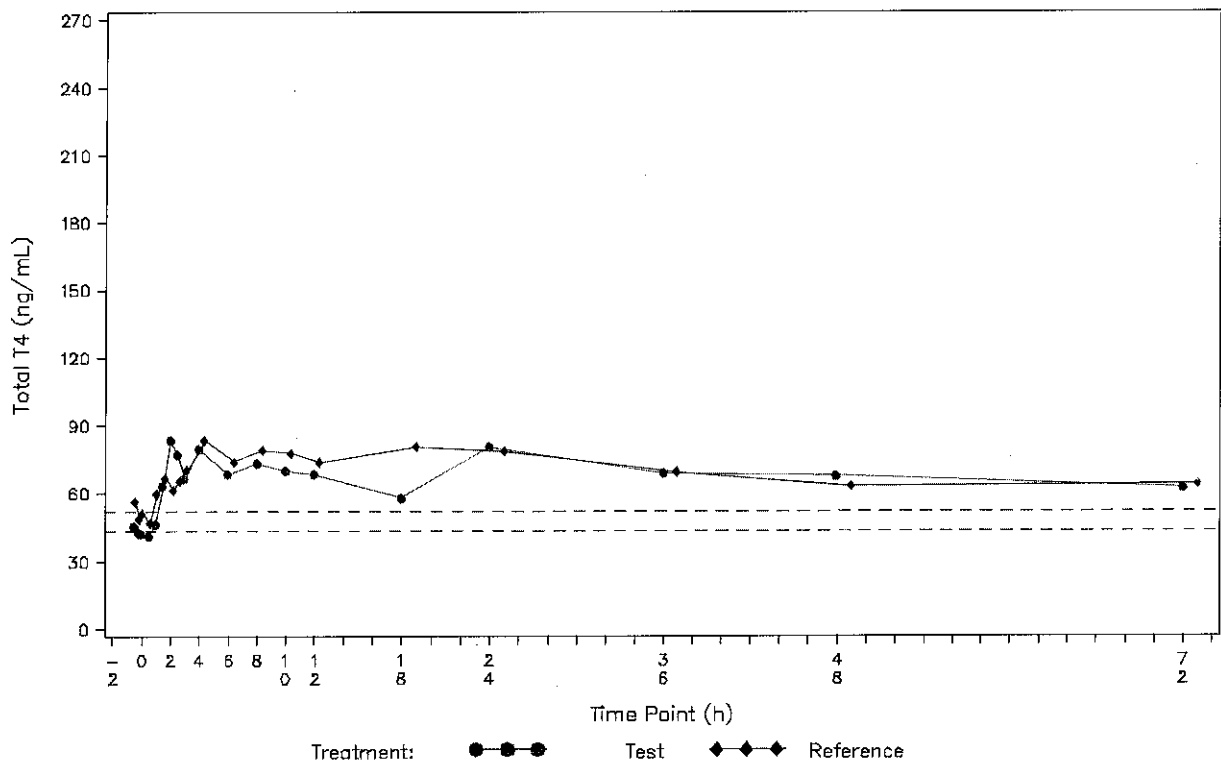/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

Time Point (h)

Treatment: ●—●—● Test   ◆—◆—◆ Reference

θ:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
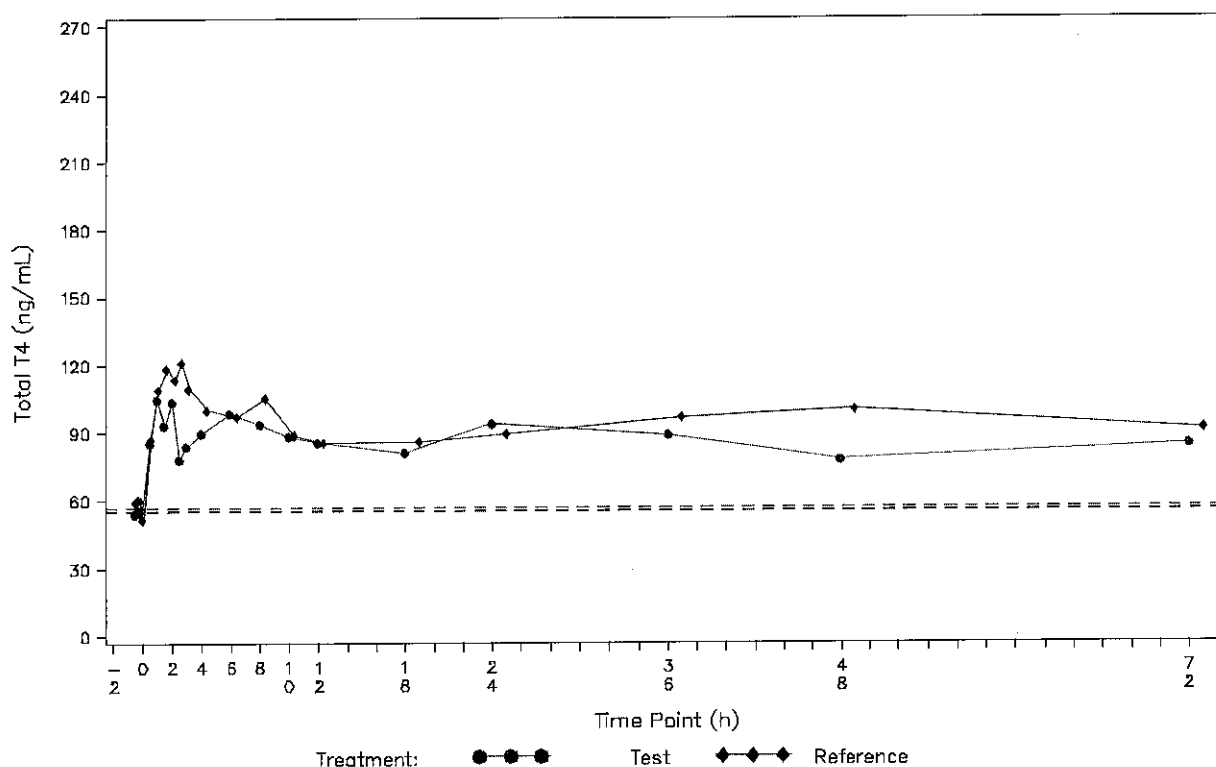Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
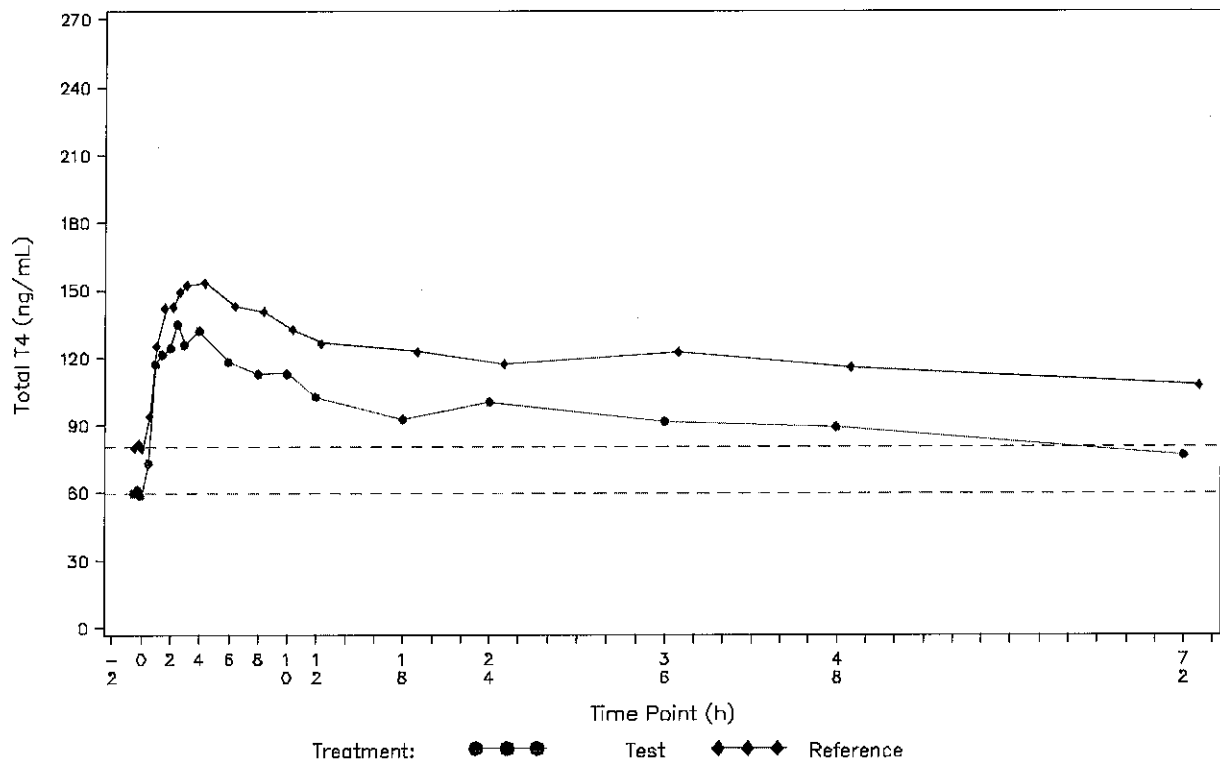
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

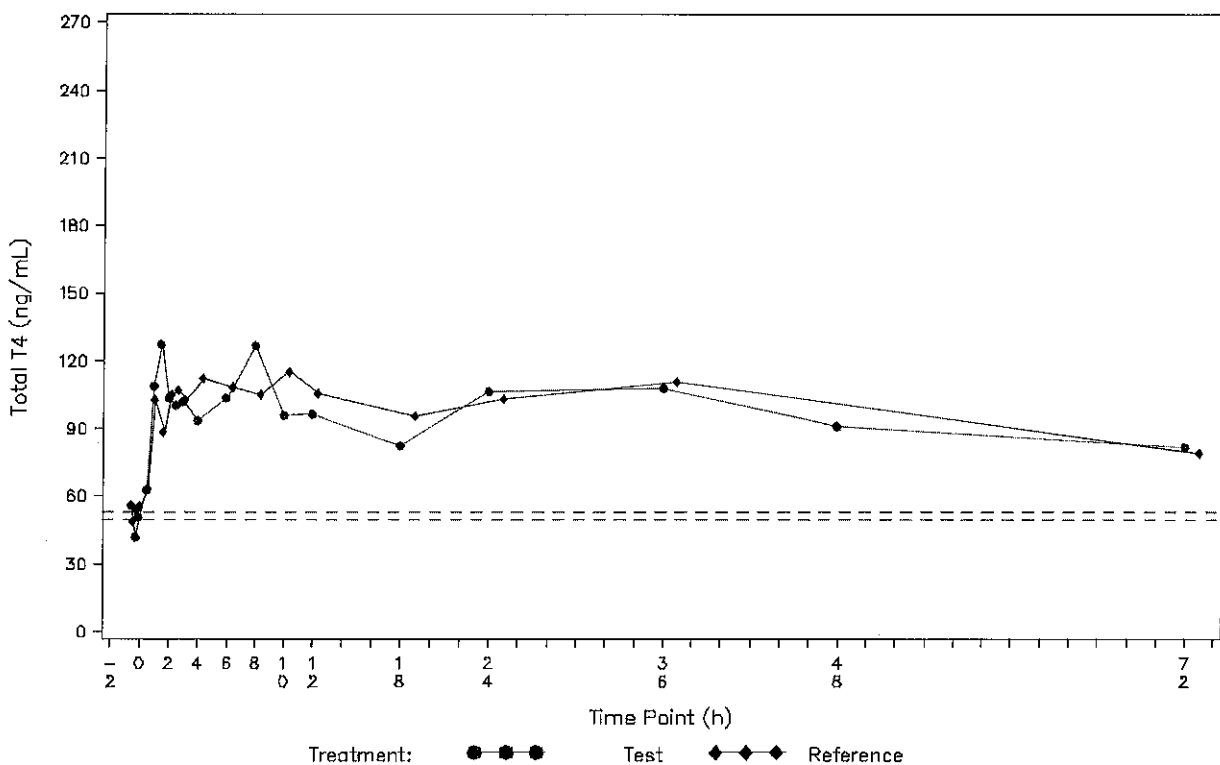

Time Point (h)

Treatment: ●─●─● Test   ◆─◆─◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

Time Point (h)

Treatment: ●─●─● Test   ◆─◆─◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
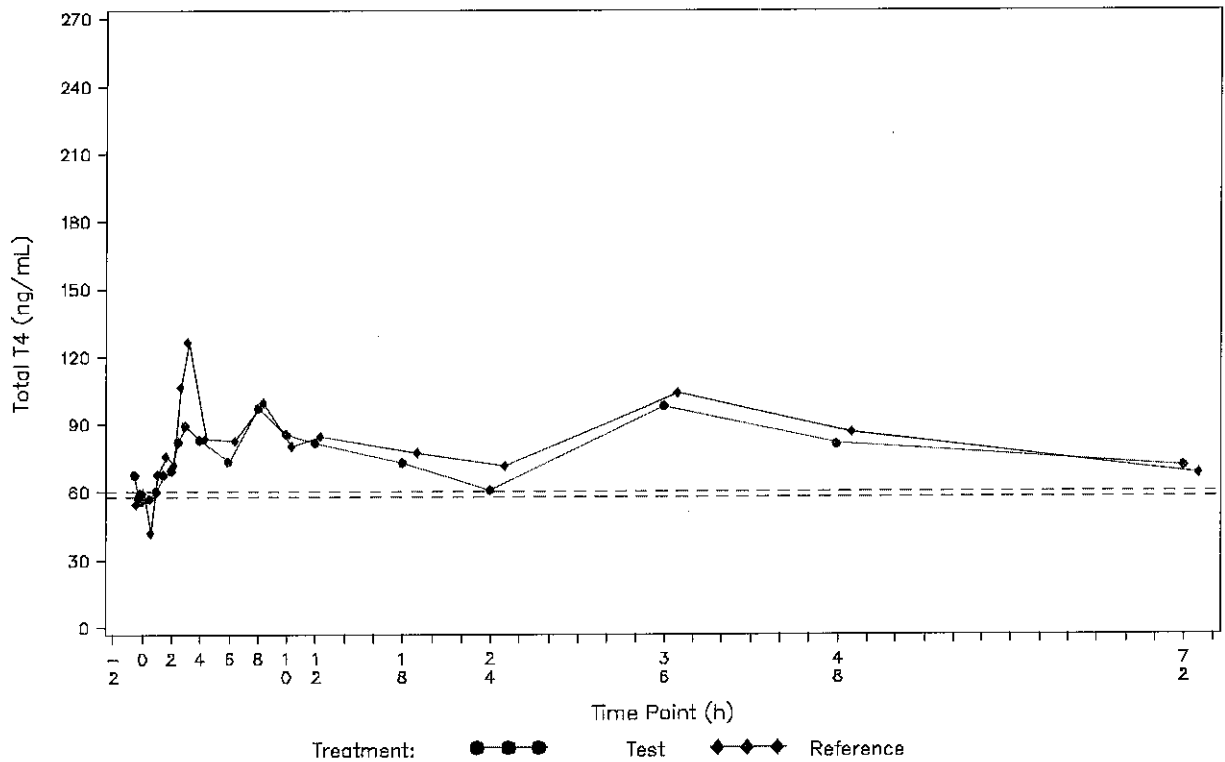Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

Time Point (h)

Treatment: ●—●—● Test ◆—◆—◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
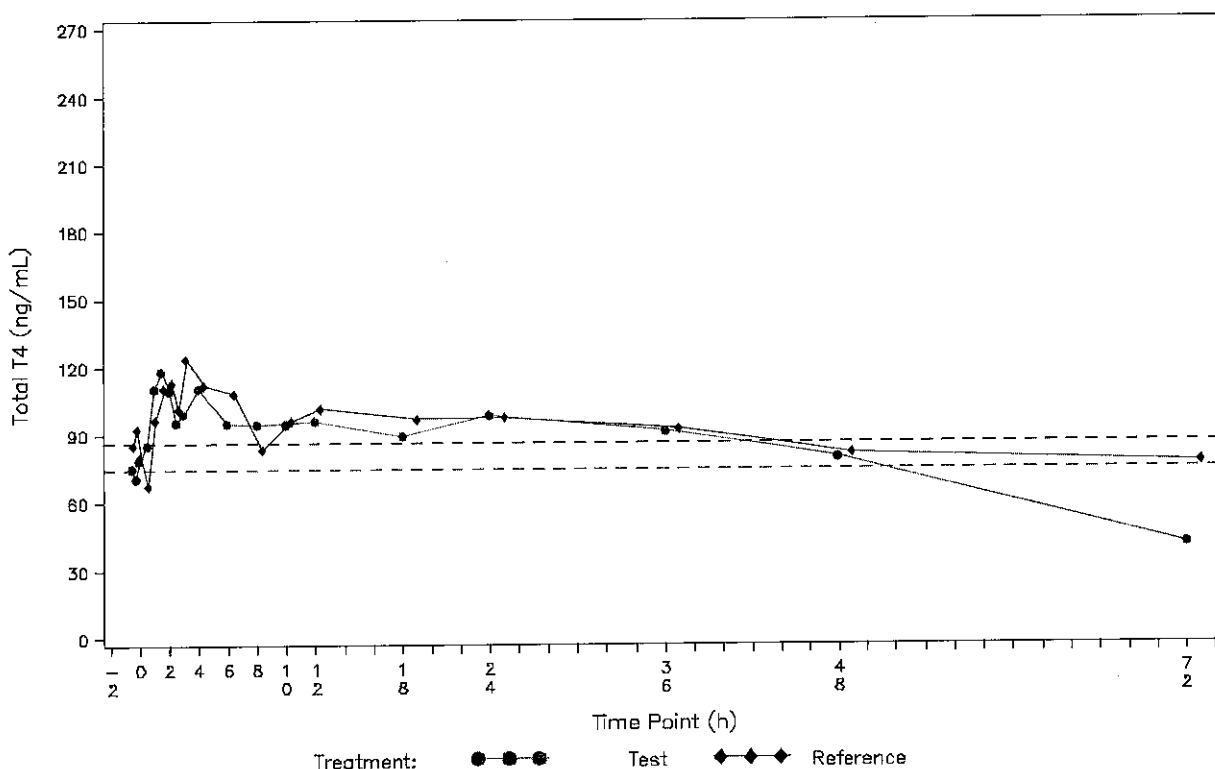Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
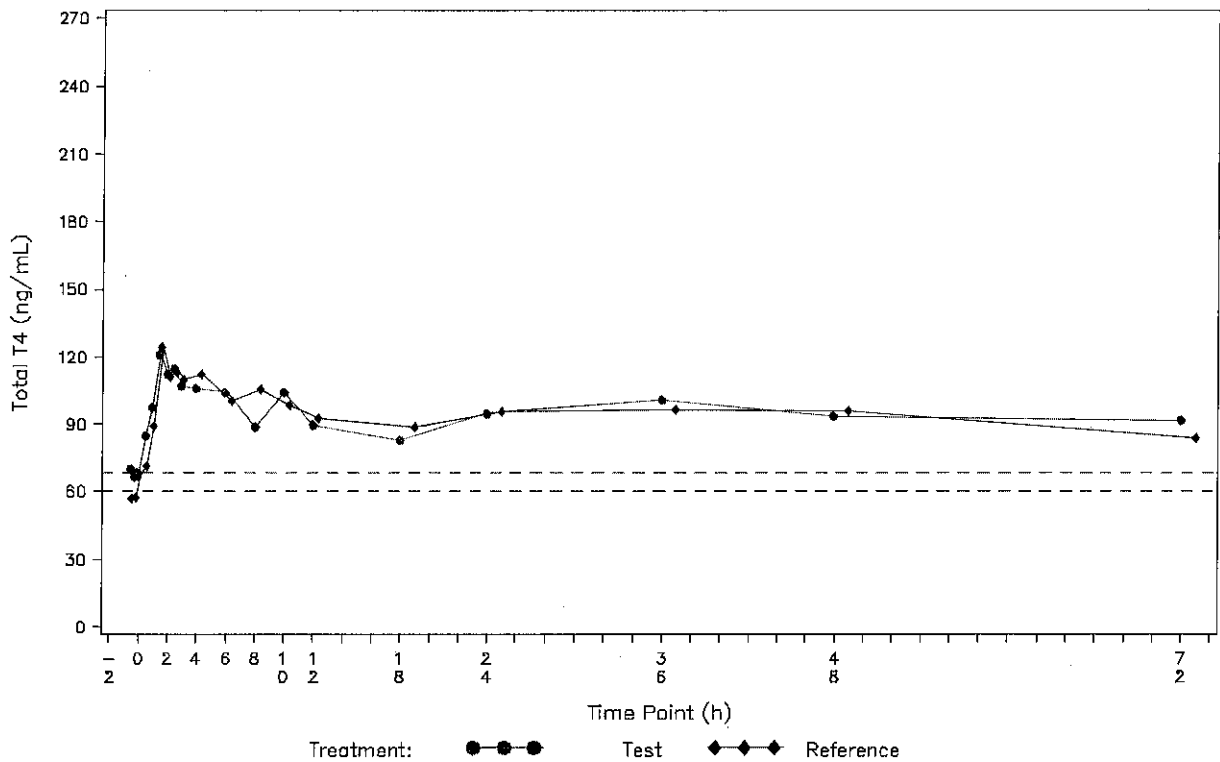
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
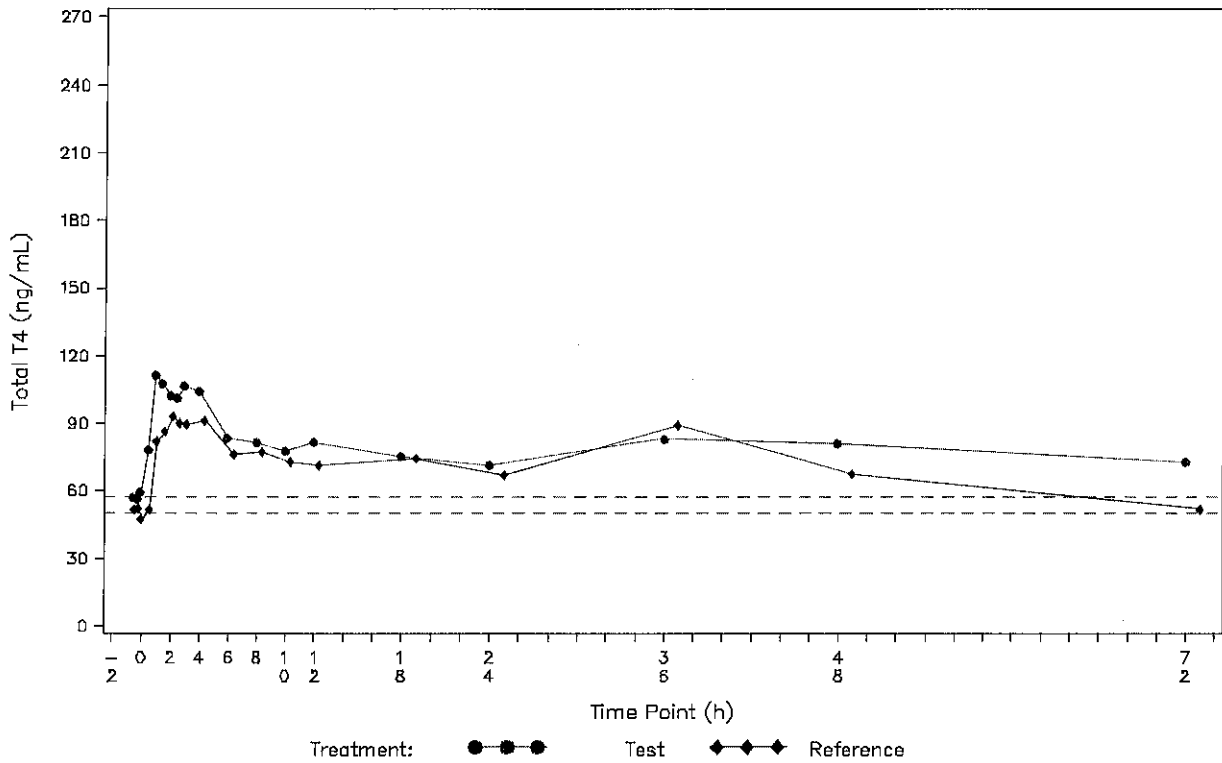
Subject ID/Random Number: 1

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
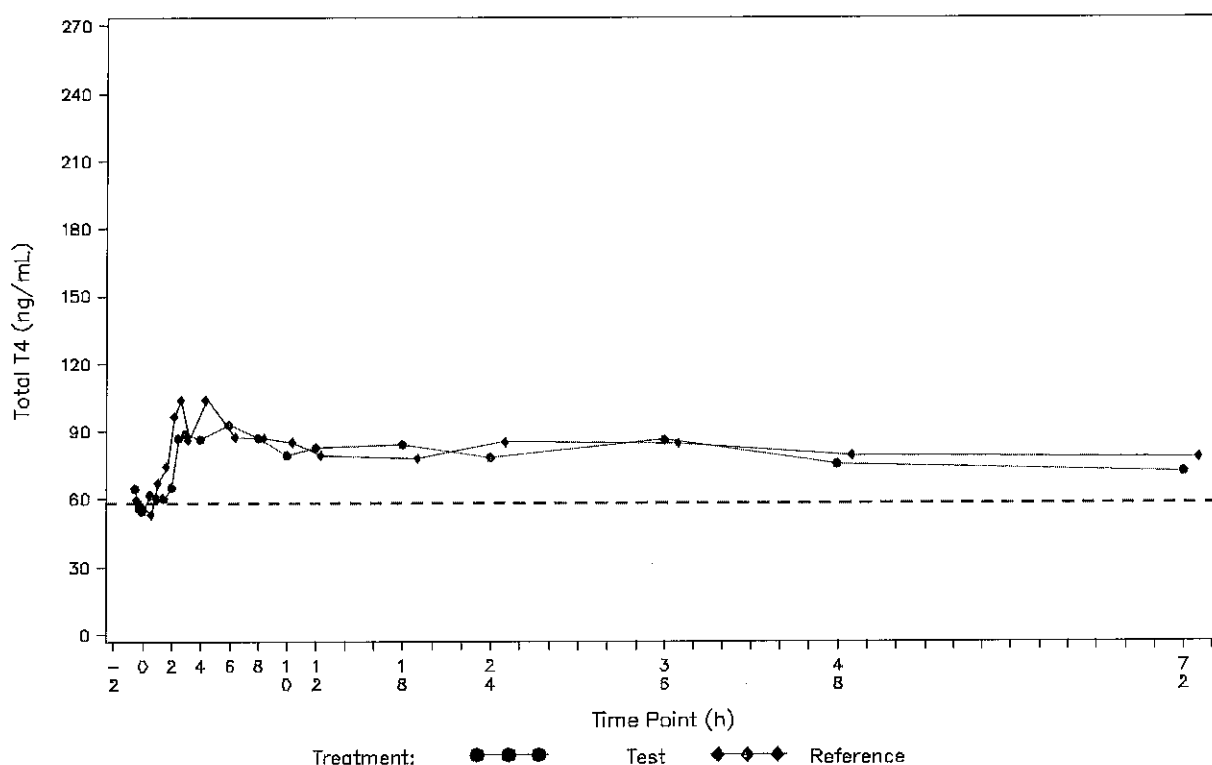
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)
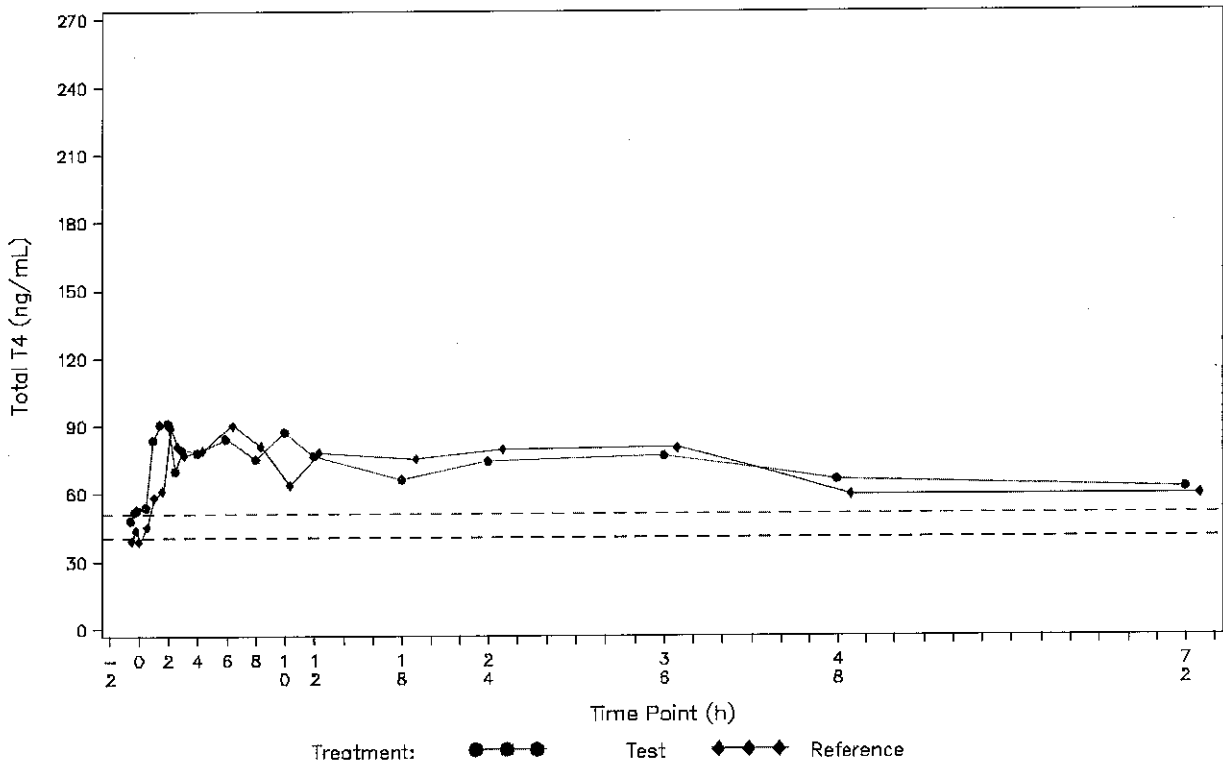
Subject ID/Random Number·

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
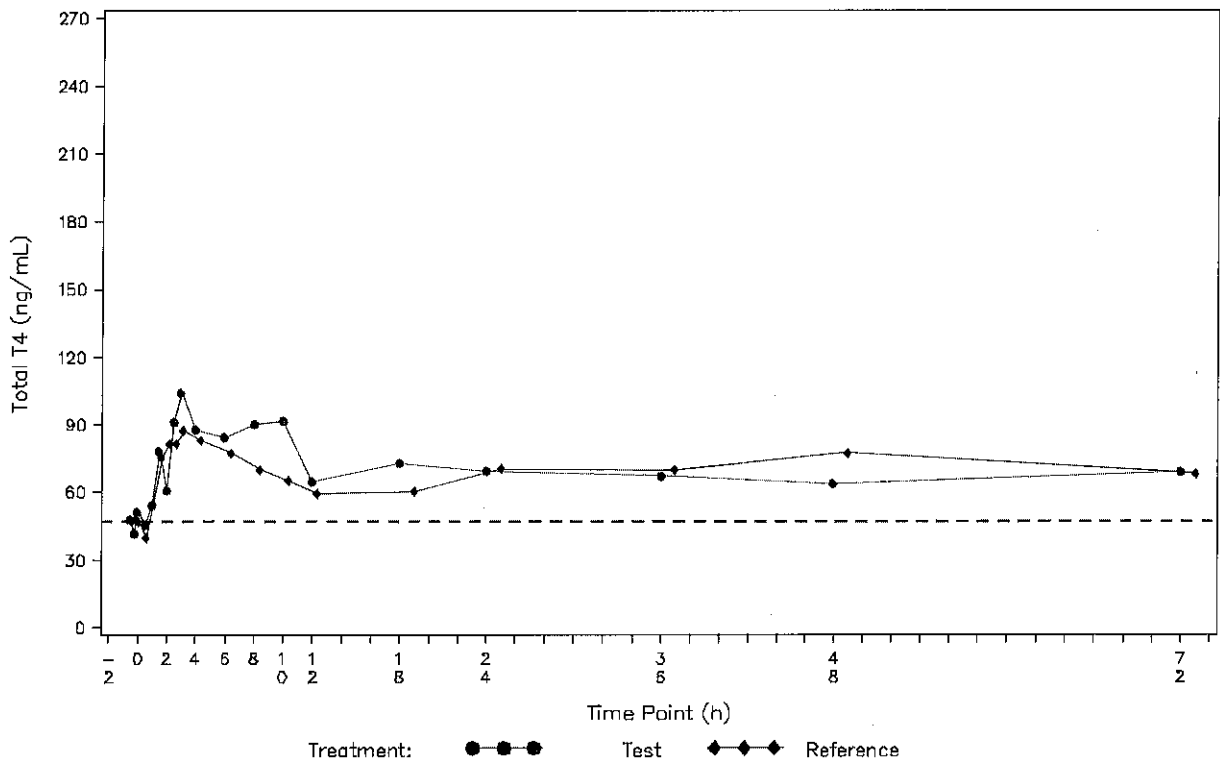
Subject ID/Random Number: :

Time Point (h)

Treatment: ●—●—● Test ◆—◆—◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:
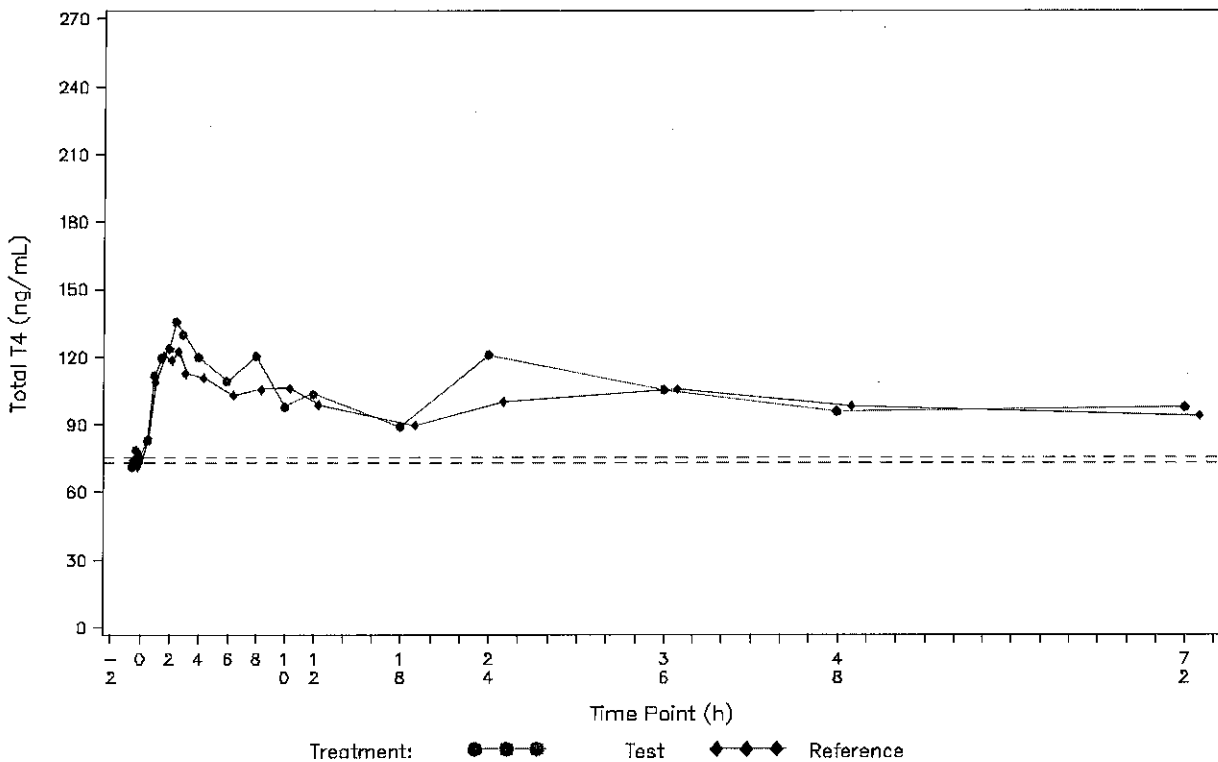

Treatment: ●─●─● Test ◆─◆─◆ Reference

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)
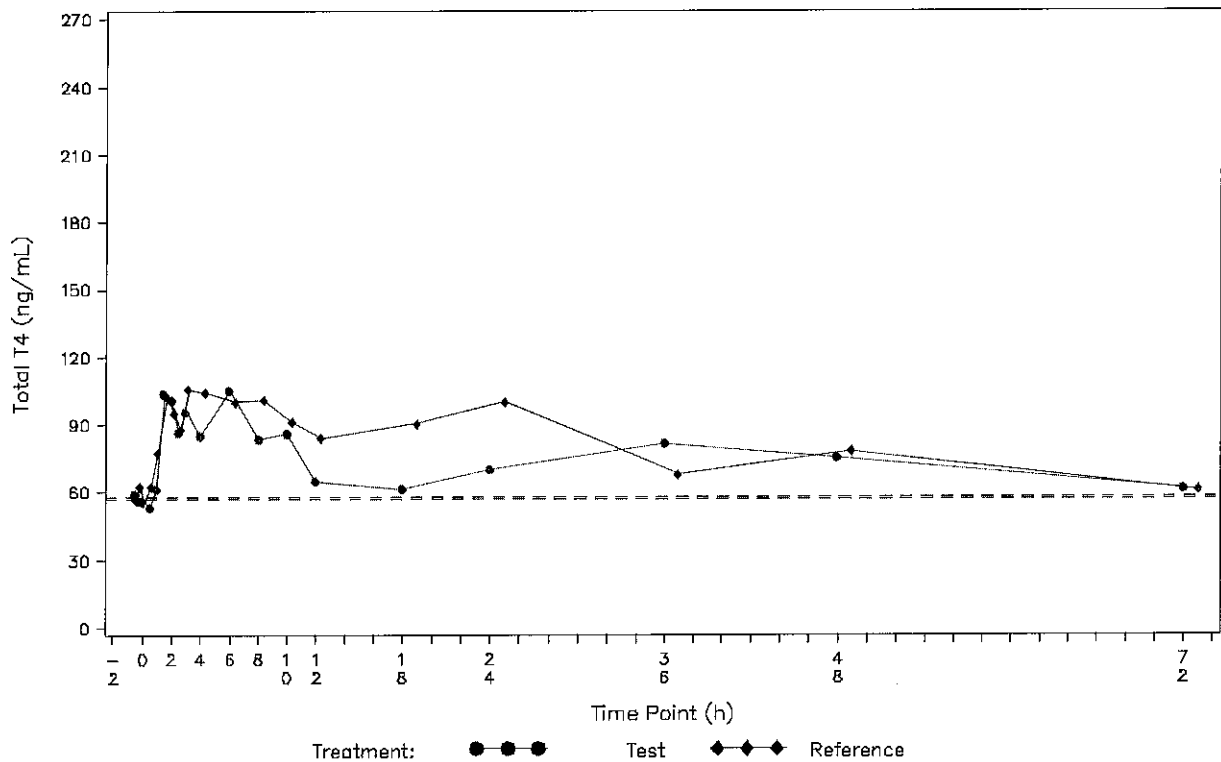
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
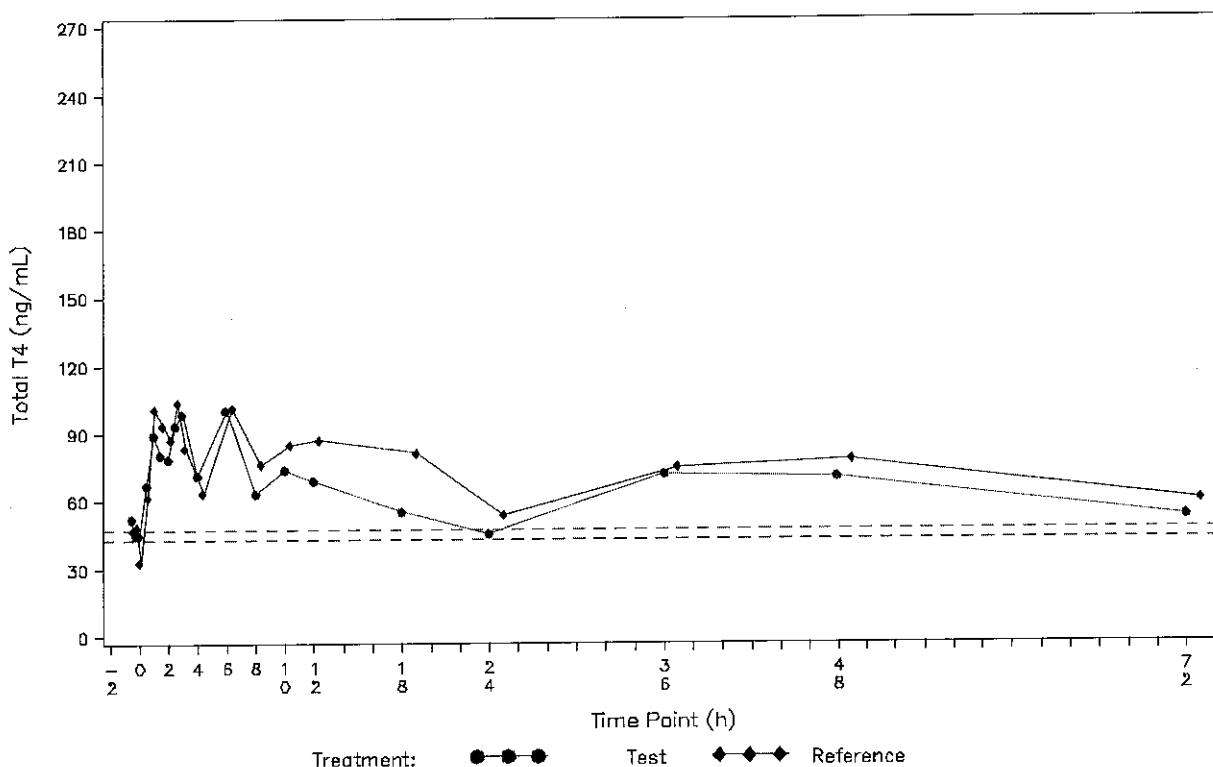
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
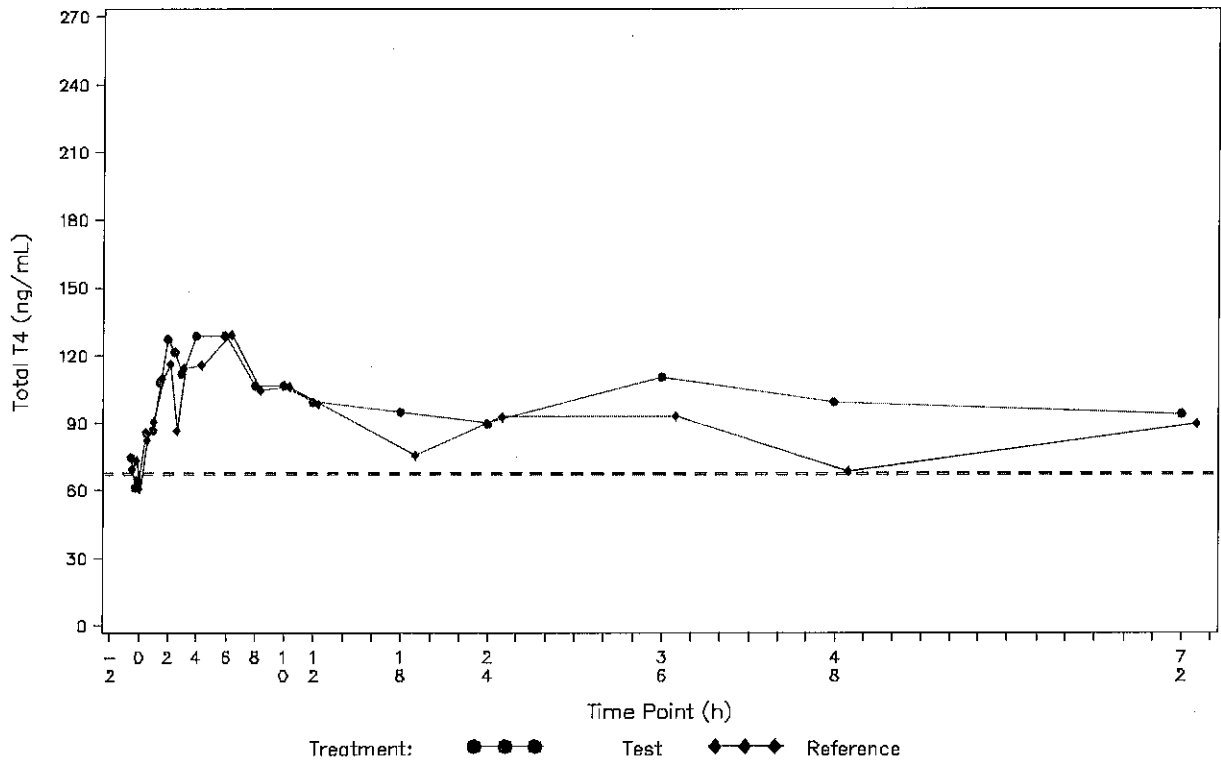(Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
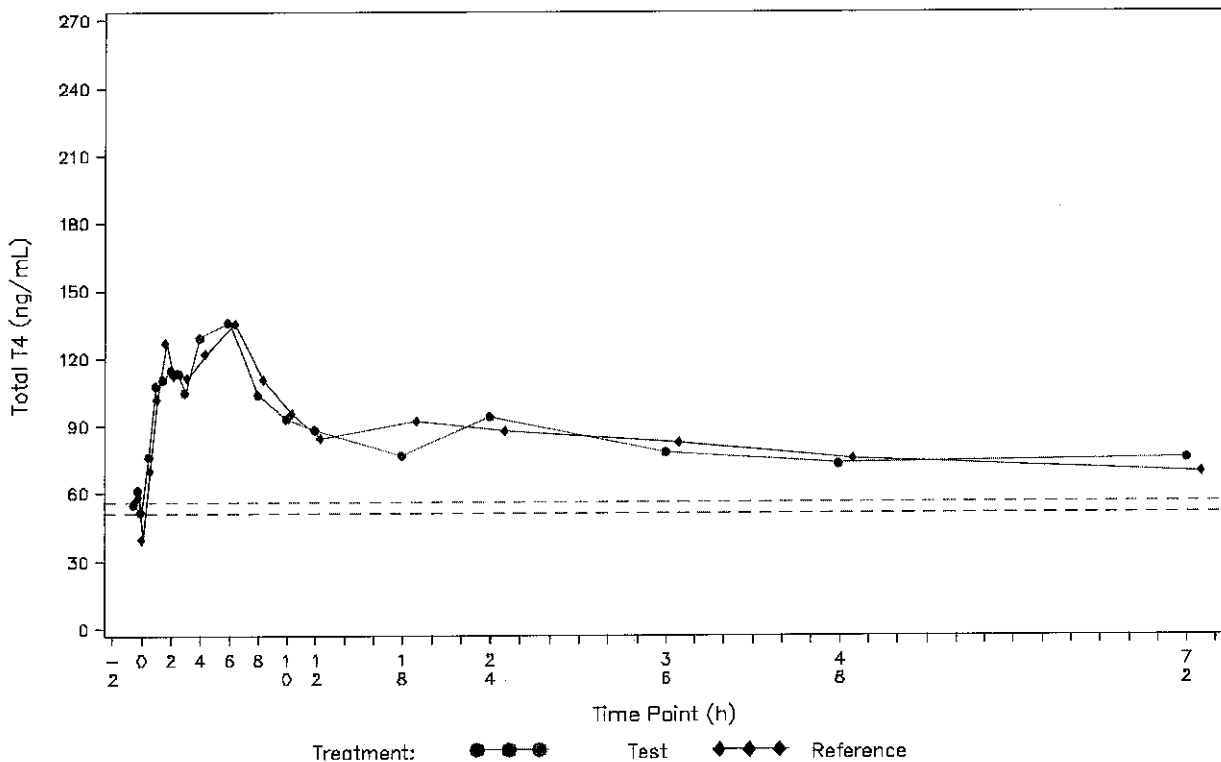Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
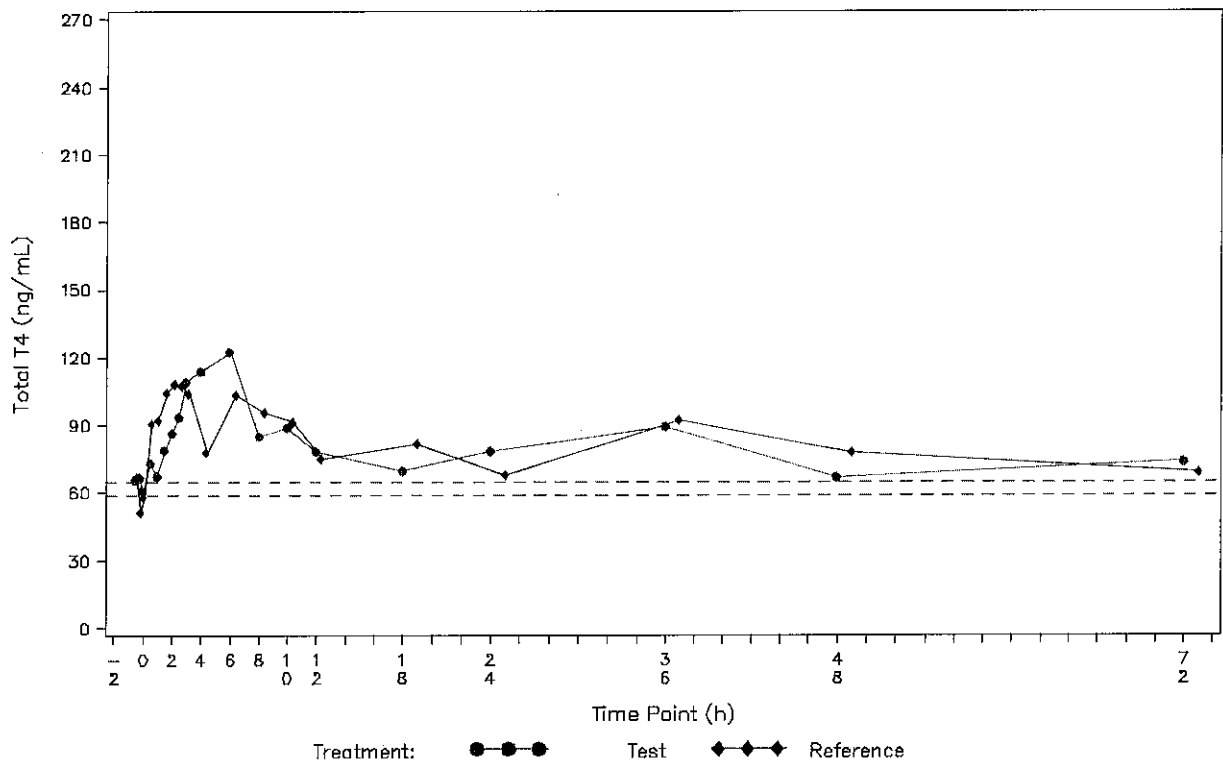
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)
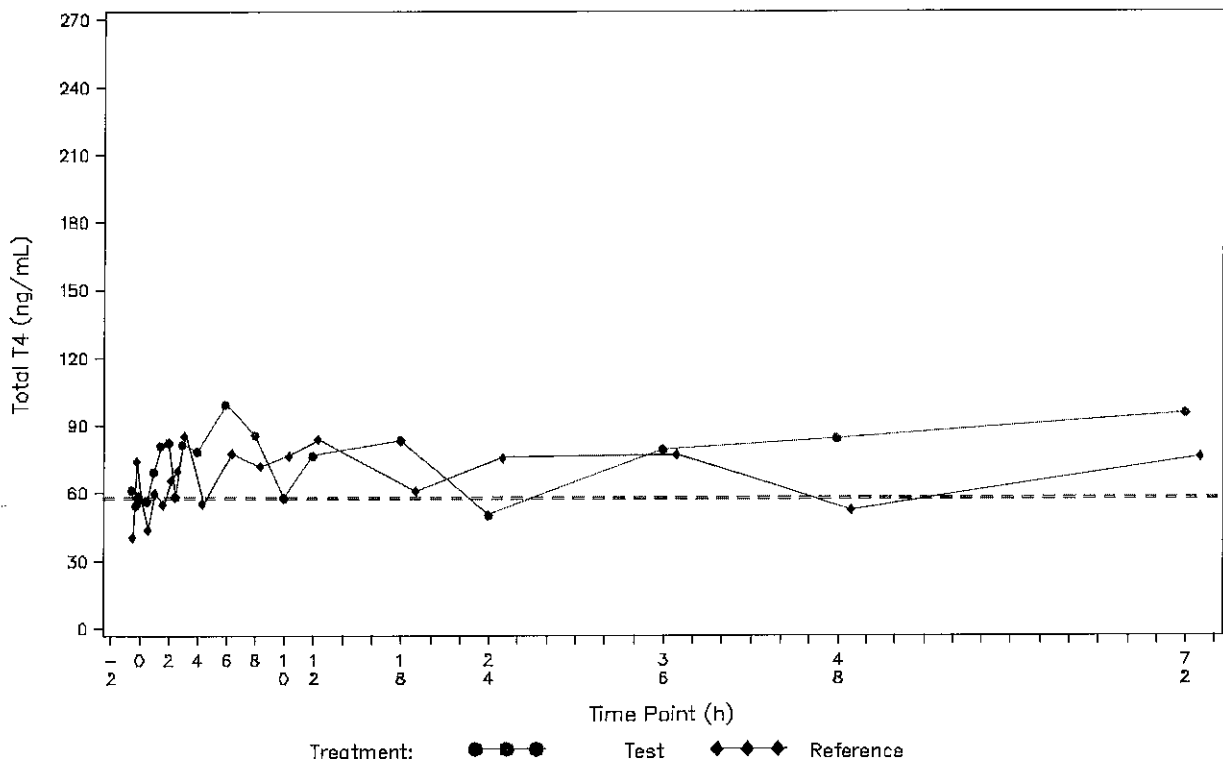
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
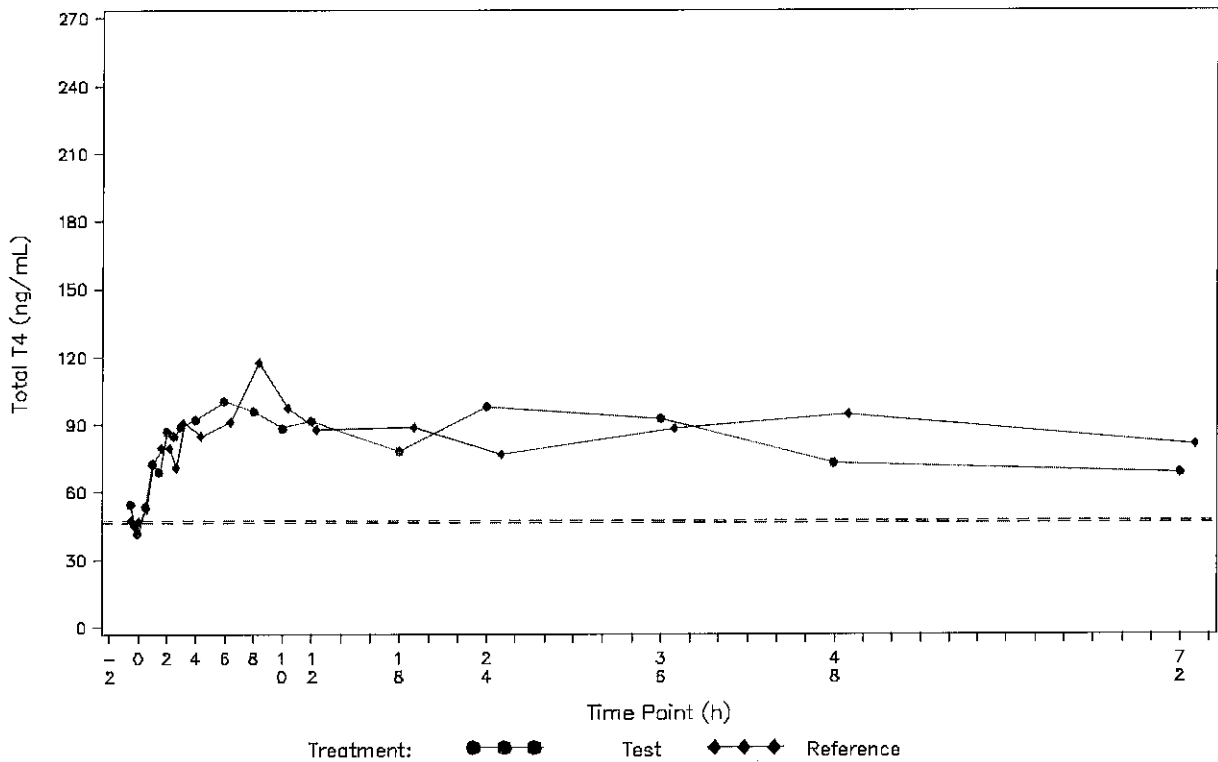(Safety Population)

Subject ID/Random Number: .

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas

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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
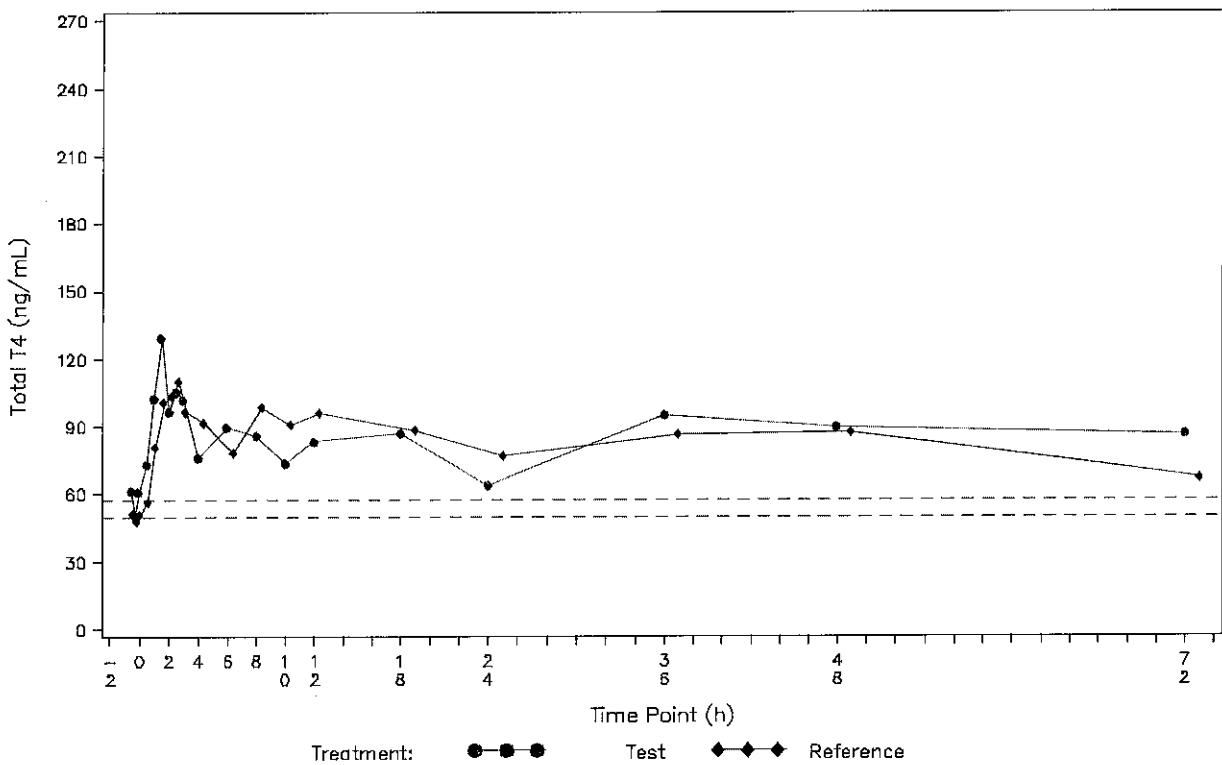(Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)
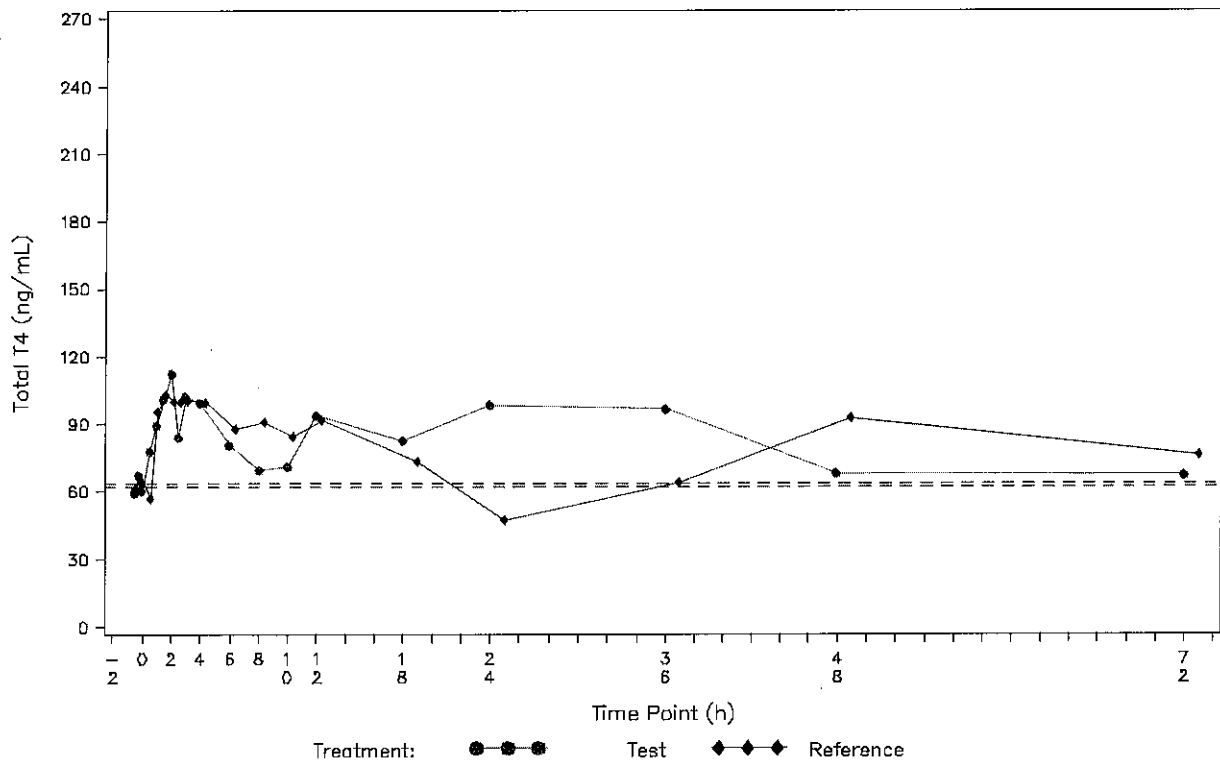
Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number: 1............

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas
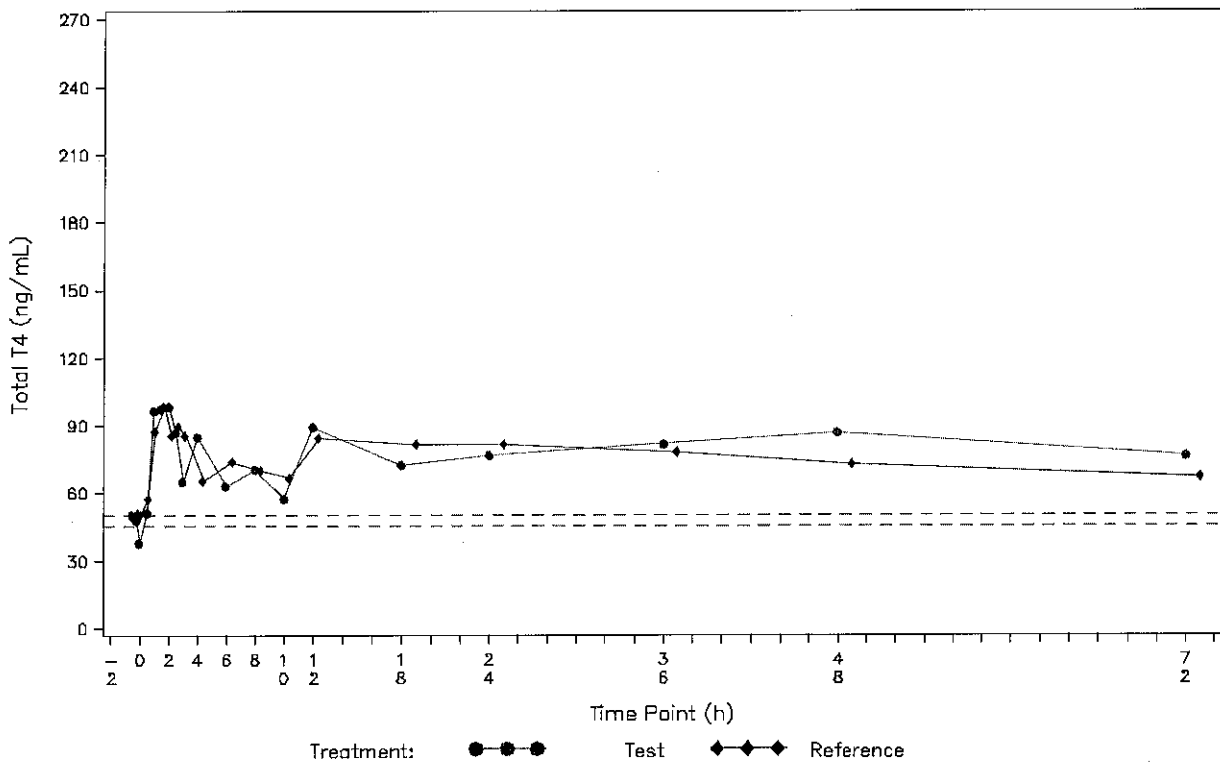
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
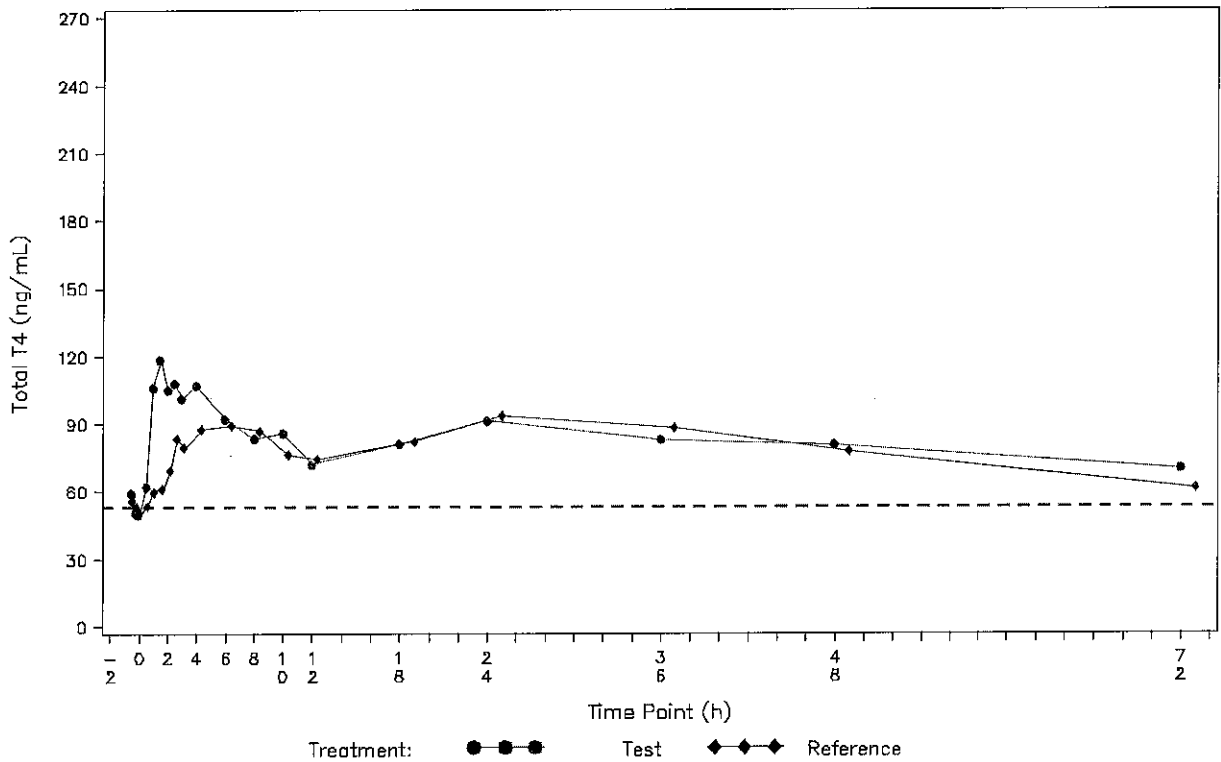(Safety Population)

Subject ID/Random Number:

@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas