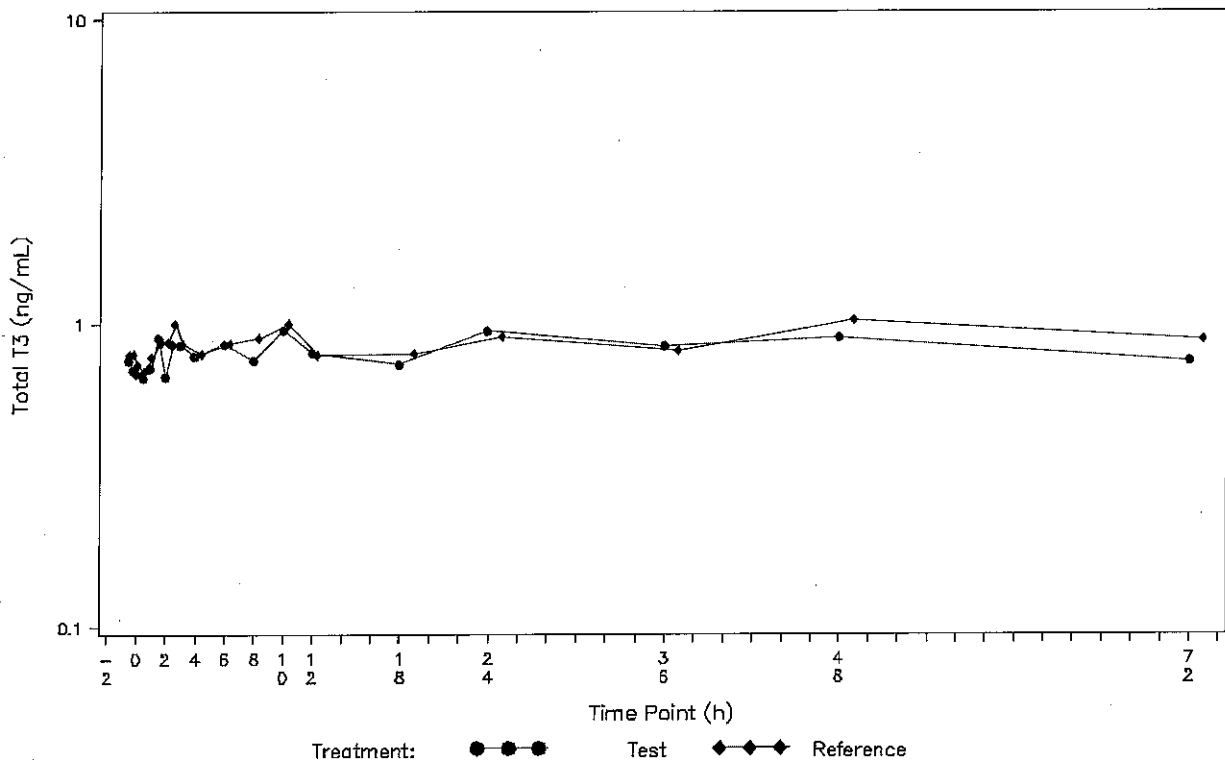


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



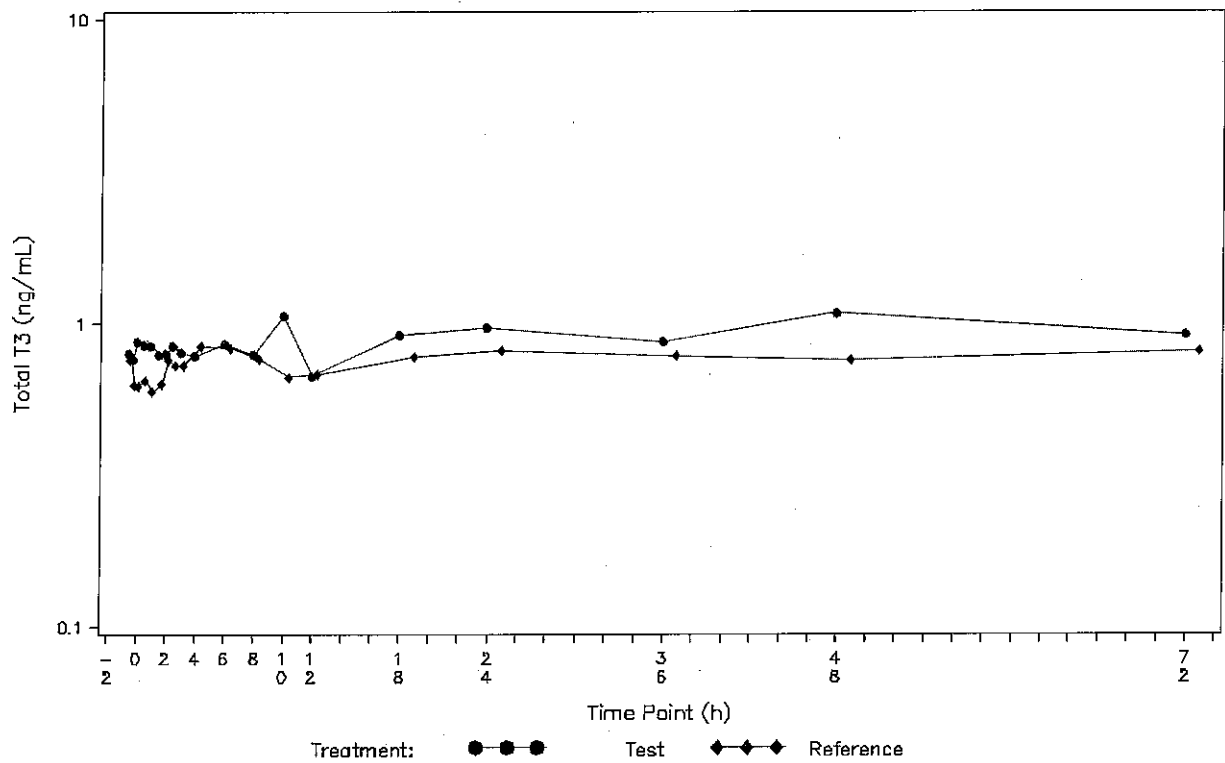
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

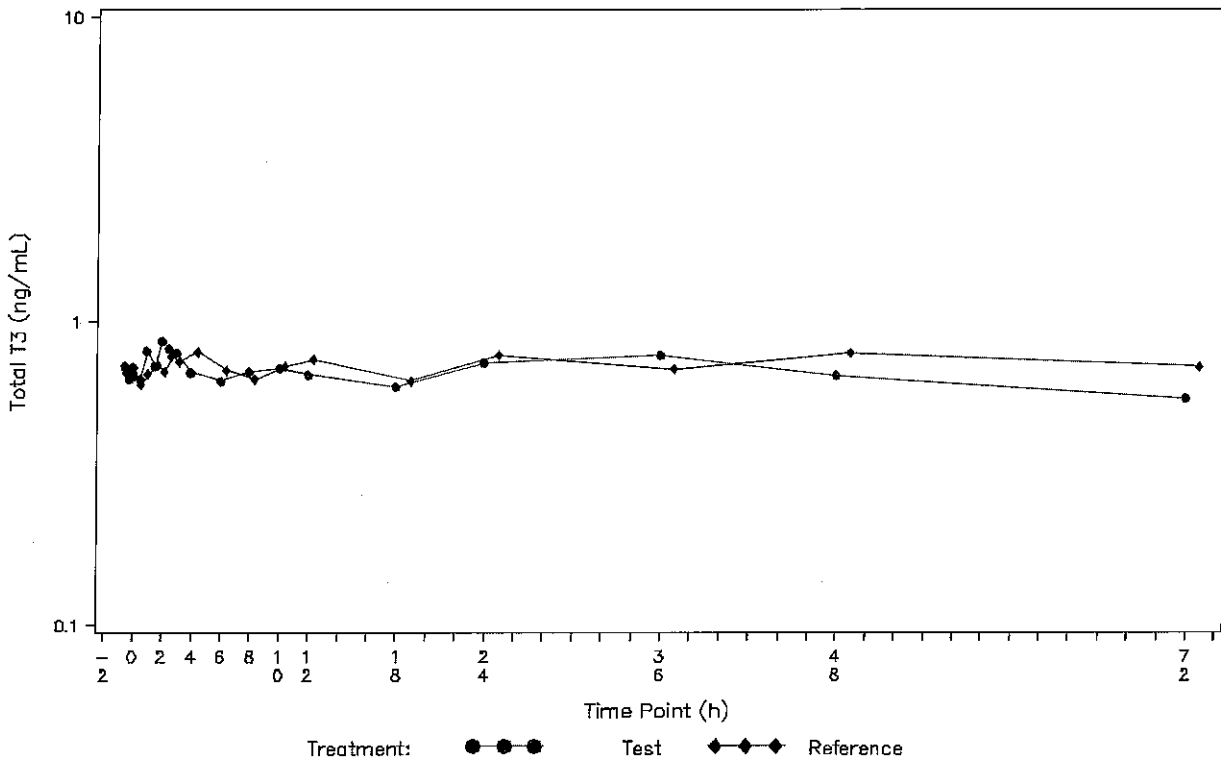
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



0: Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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15.4.2.12.sas



Levothyroxine
EMR 200125-001

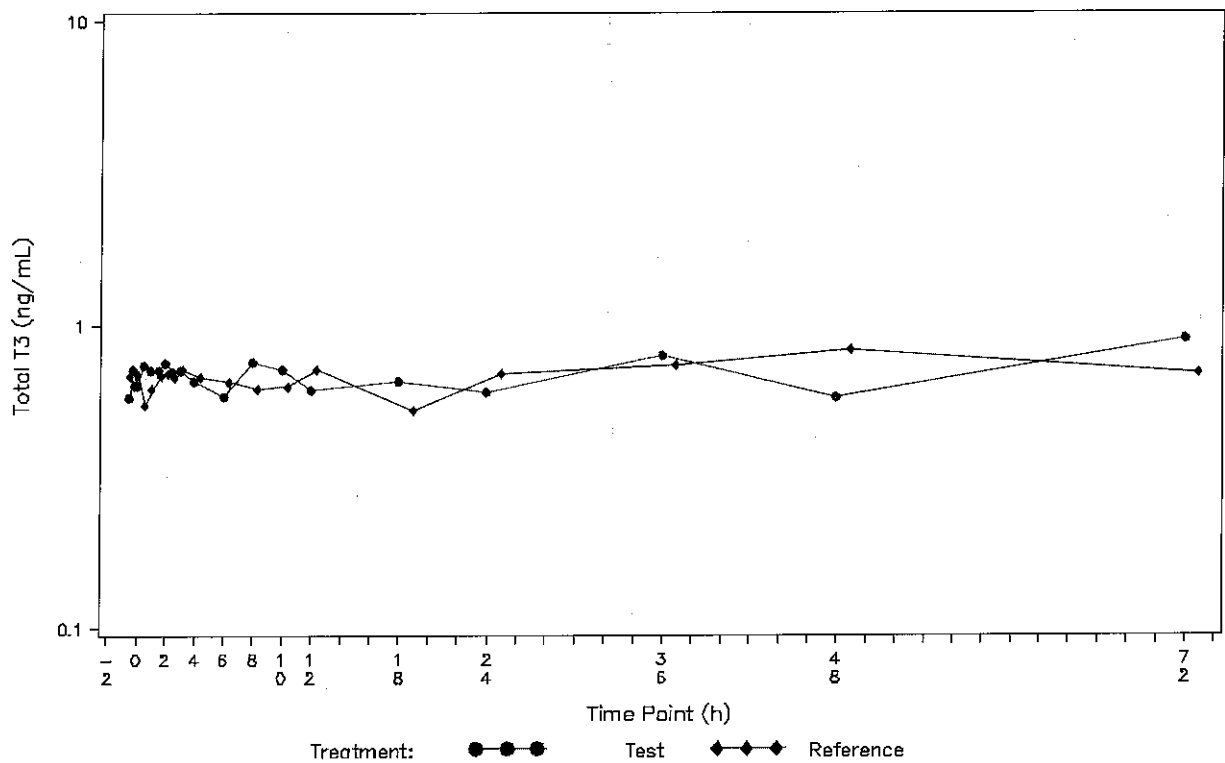
Bioequiv EMR200125-001 Page 1504 of 1628 ulation vs. old formulation

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



⊖: Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

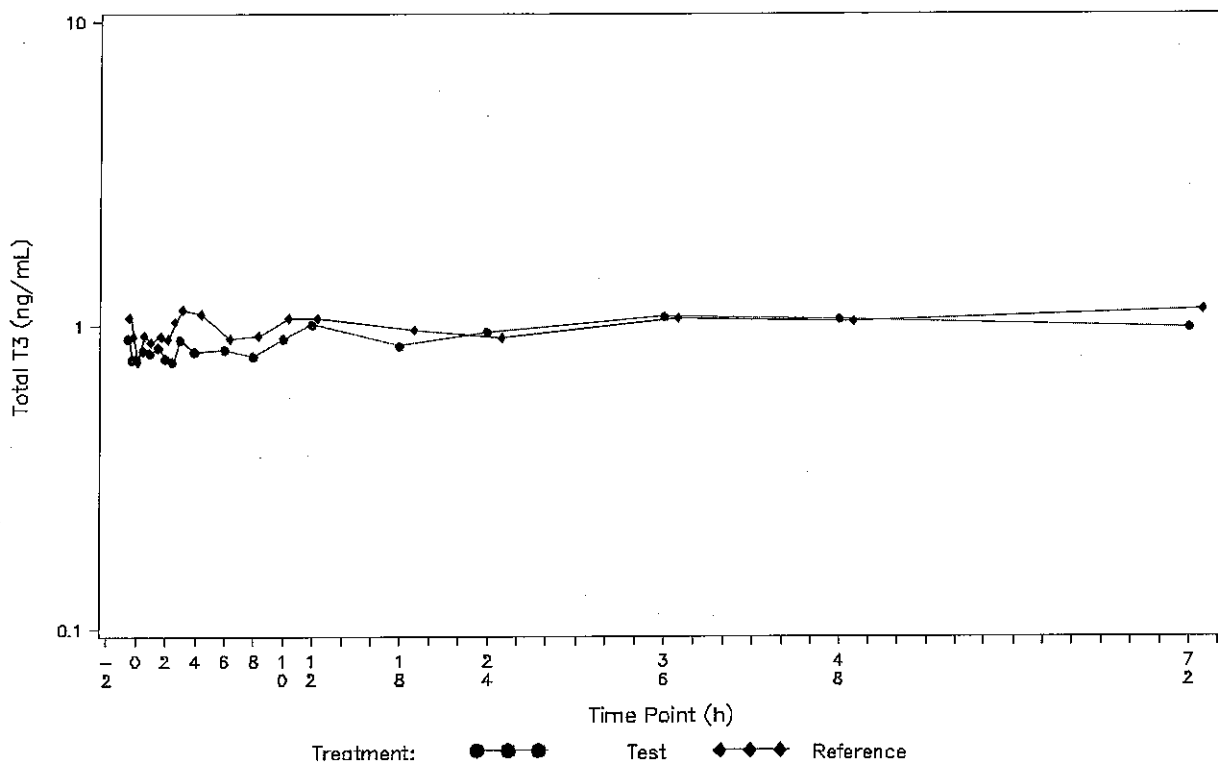
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



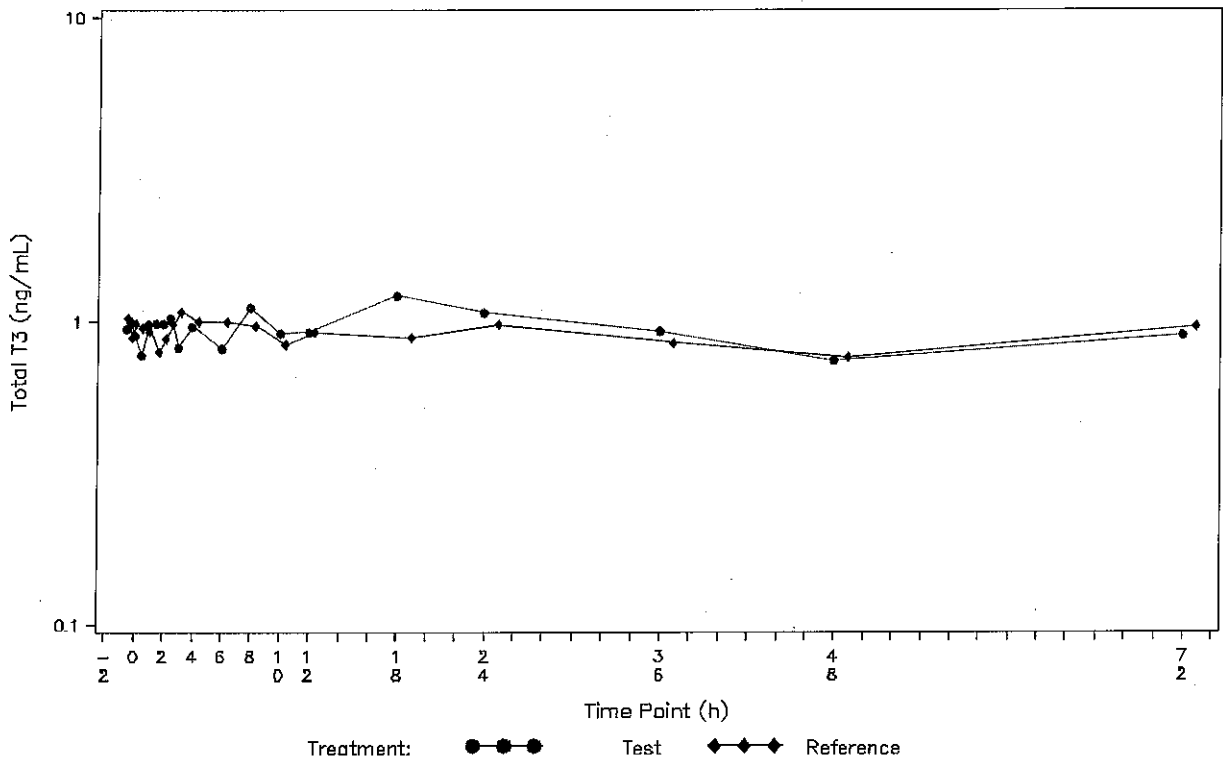
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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



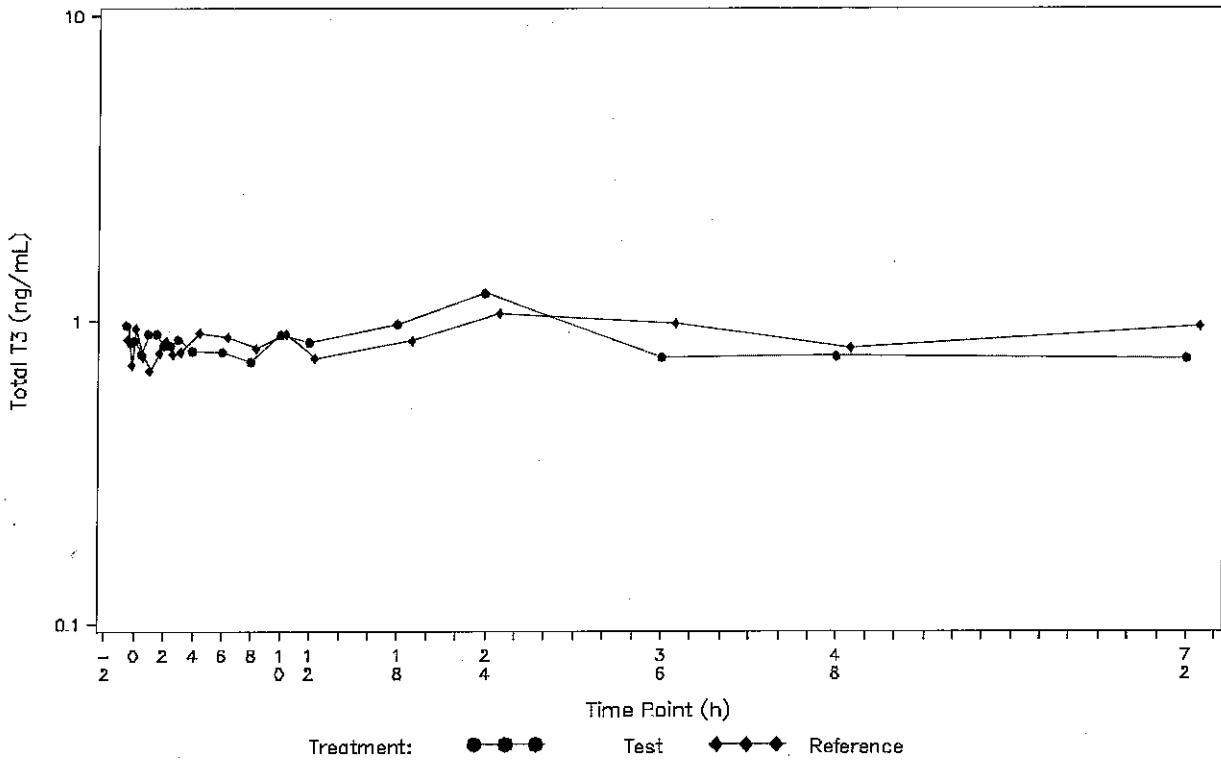
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



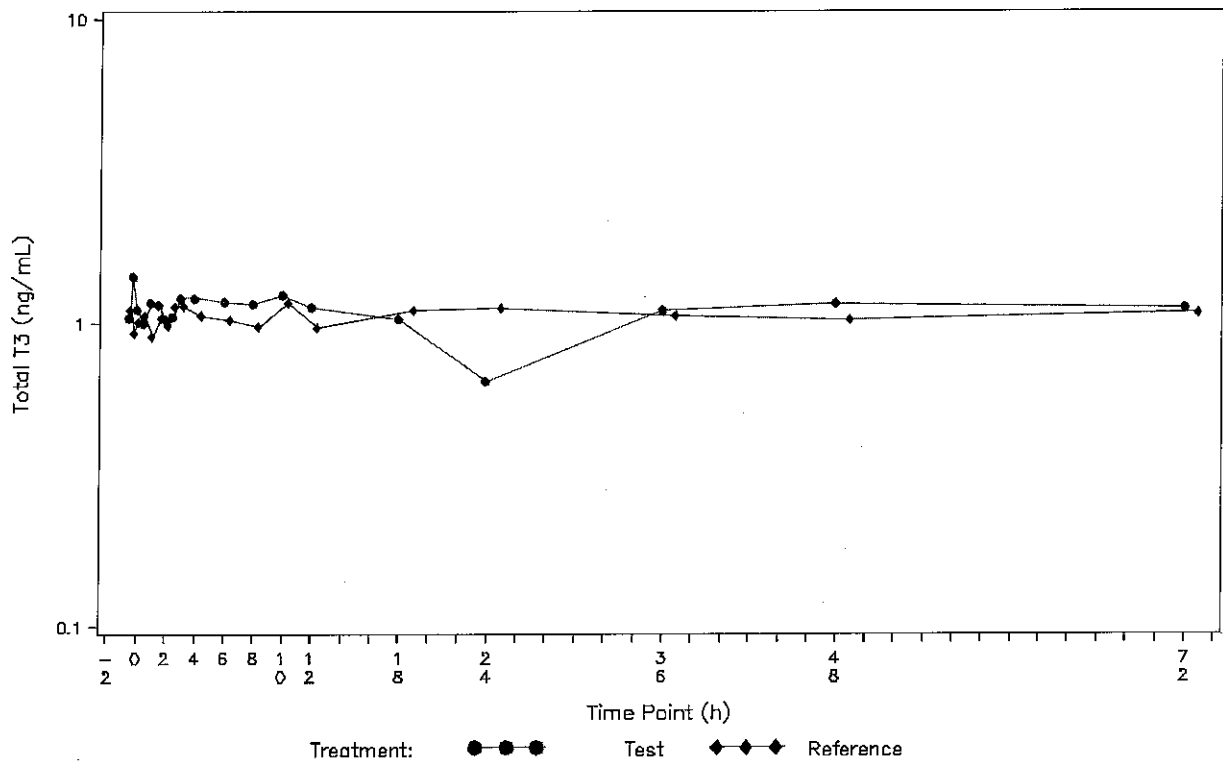
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

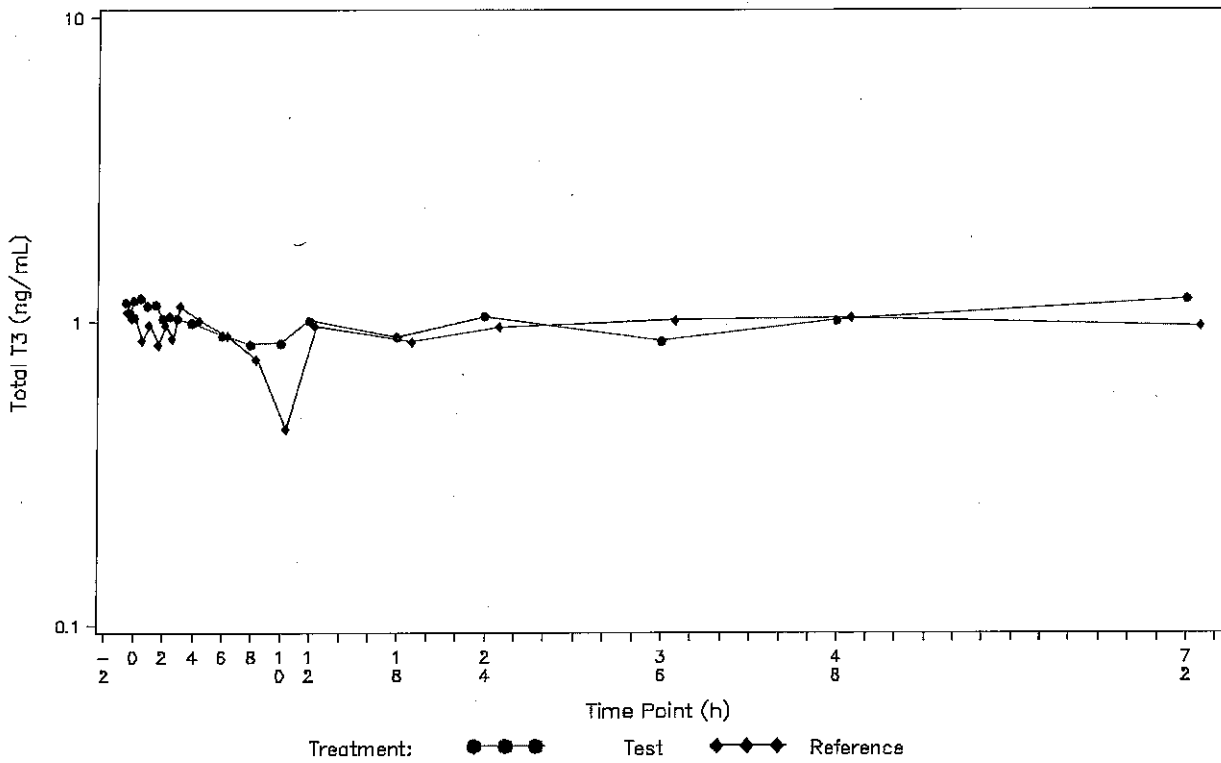
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



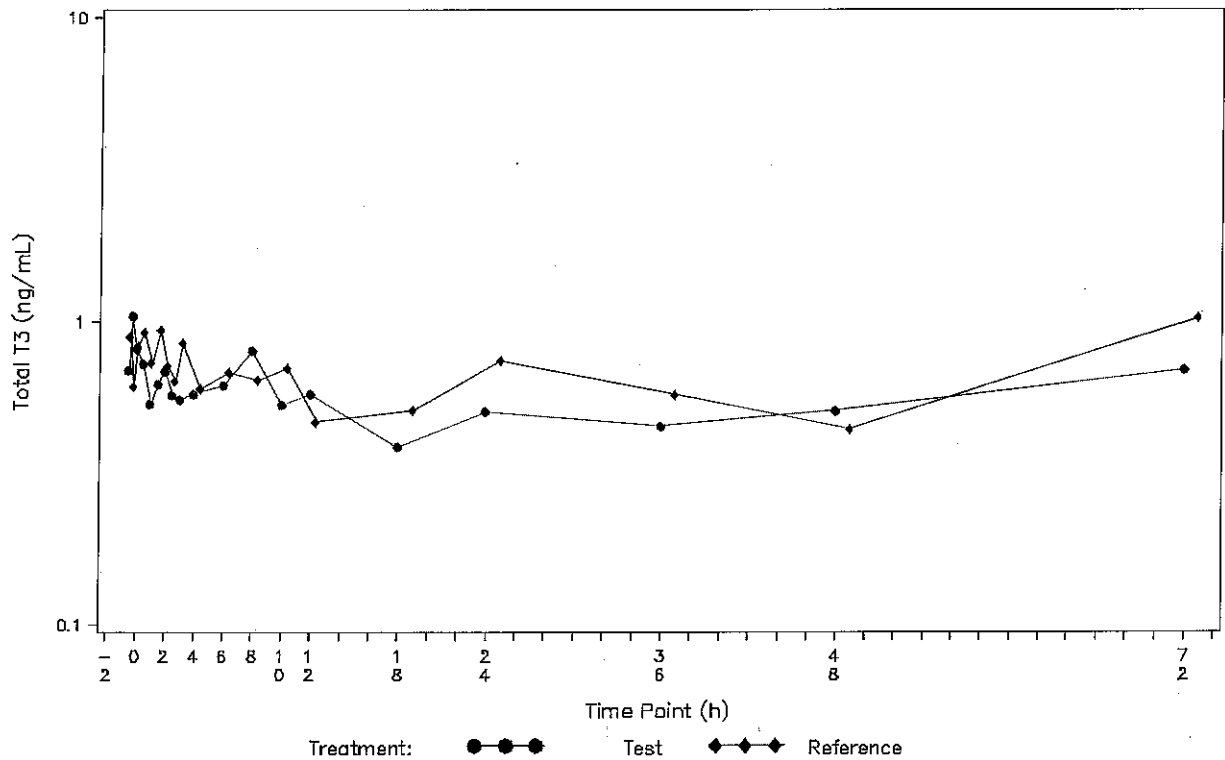
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



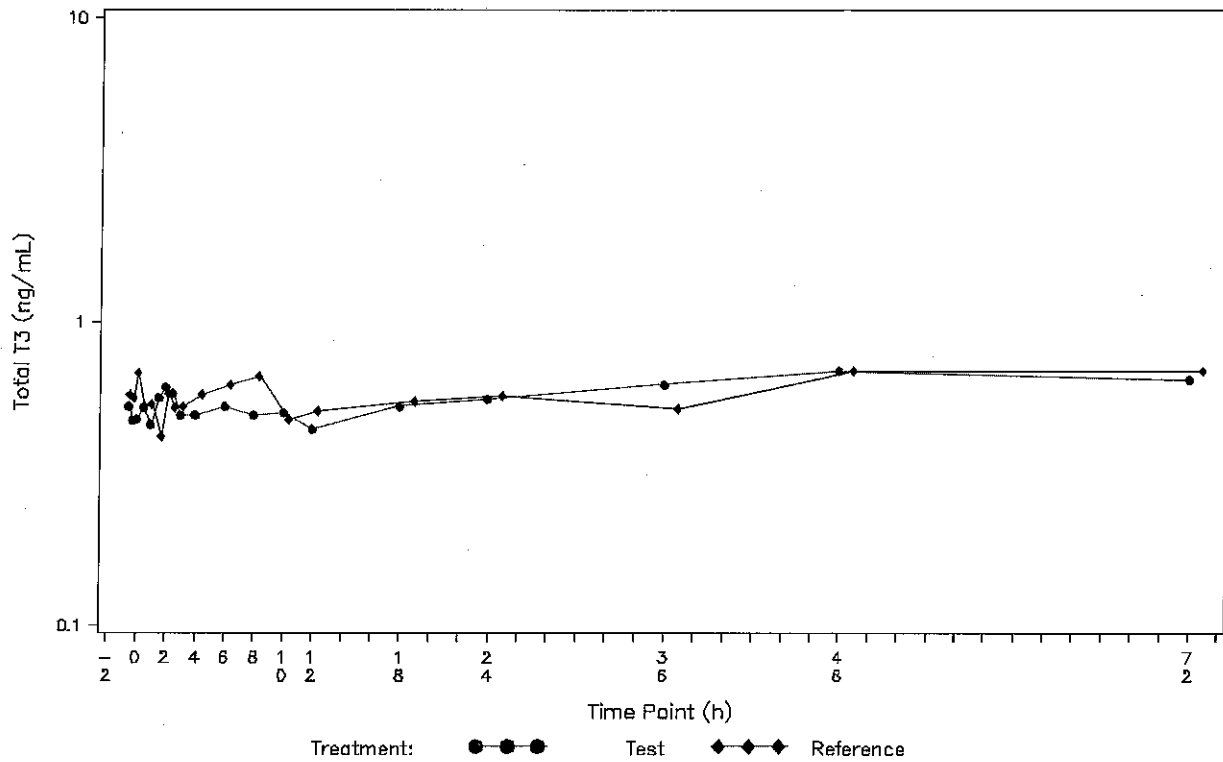
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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15.4.2.12.sas

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



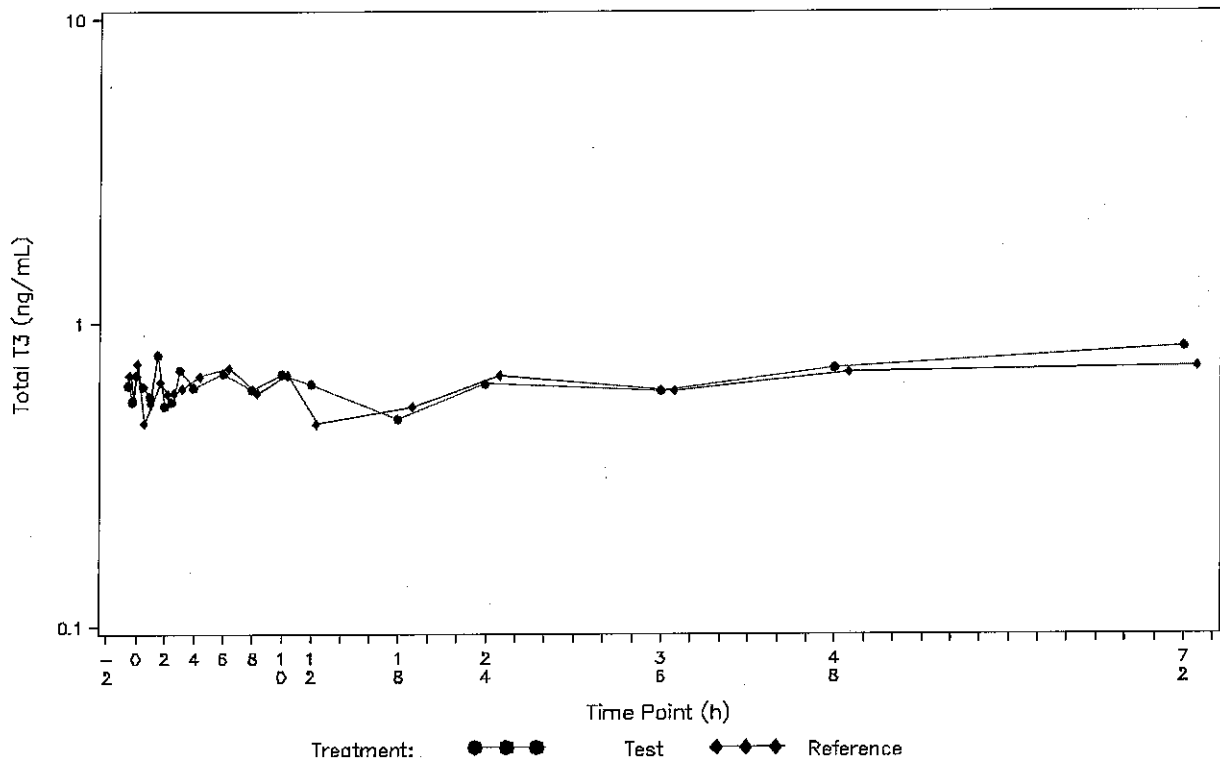
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

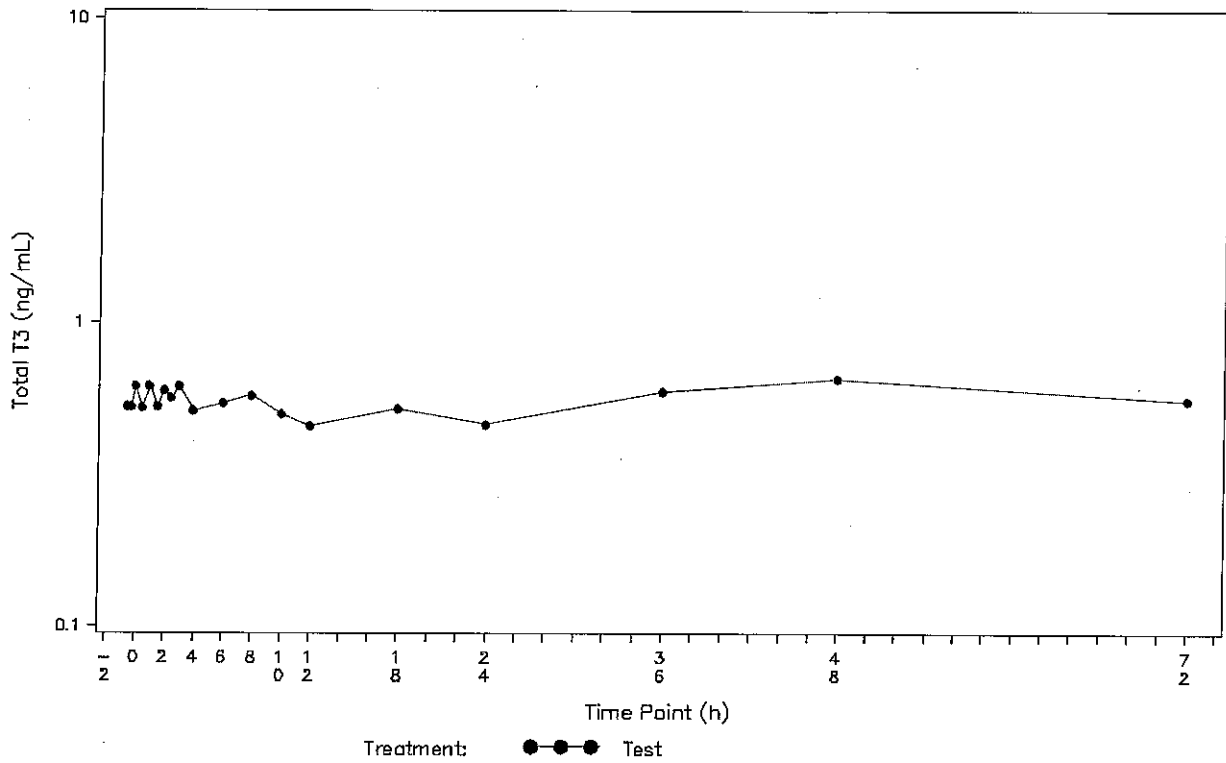


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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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15.4.2.12.sas

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: .



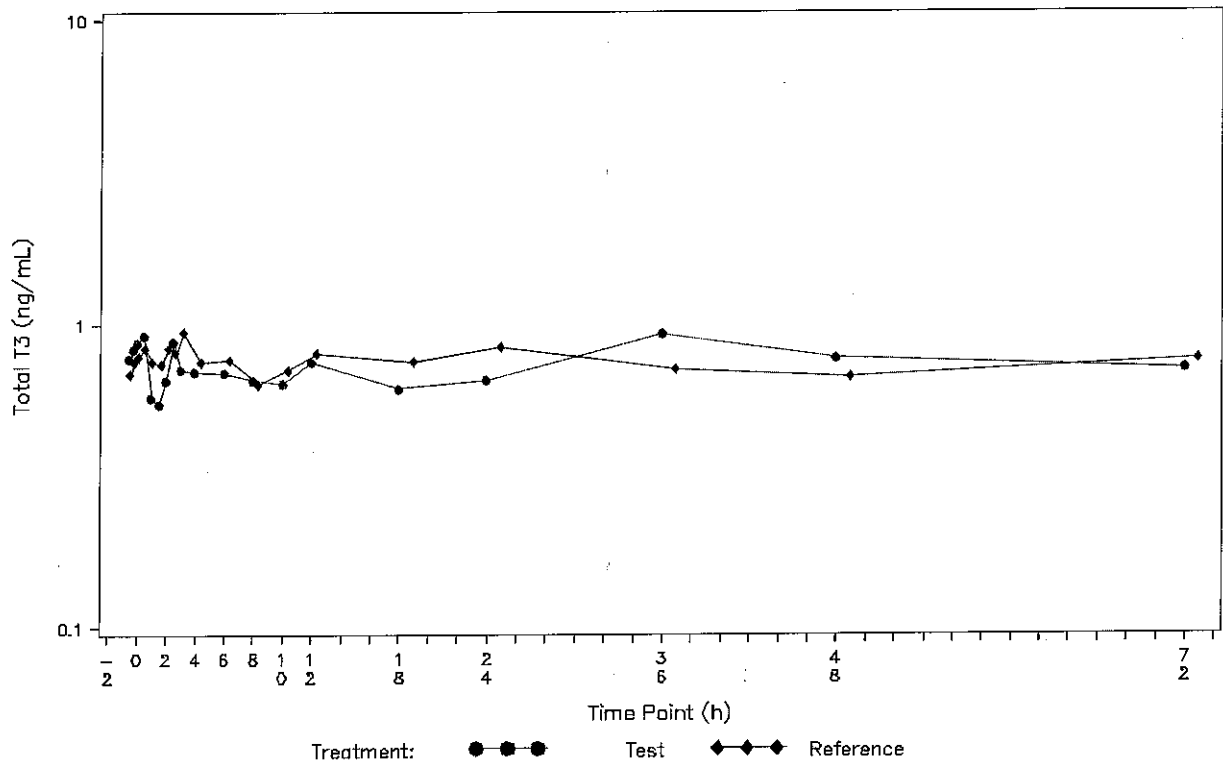
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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



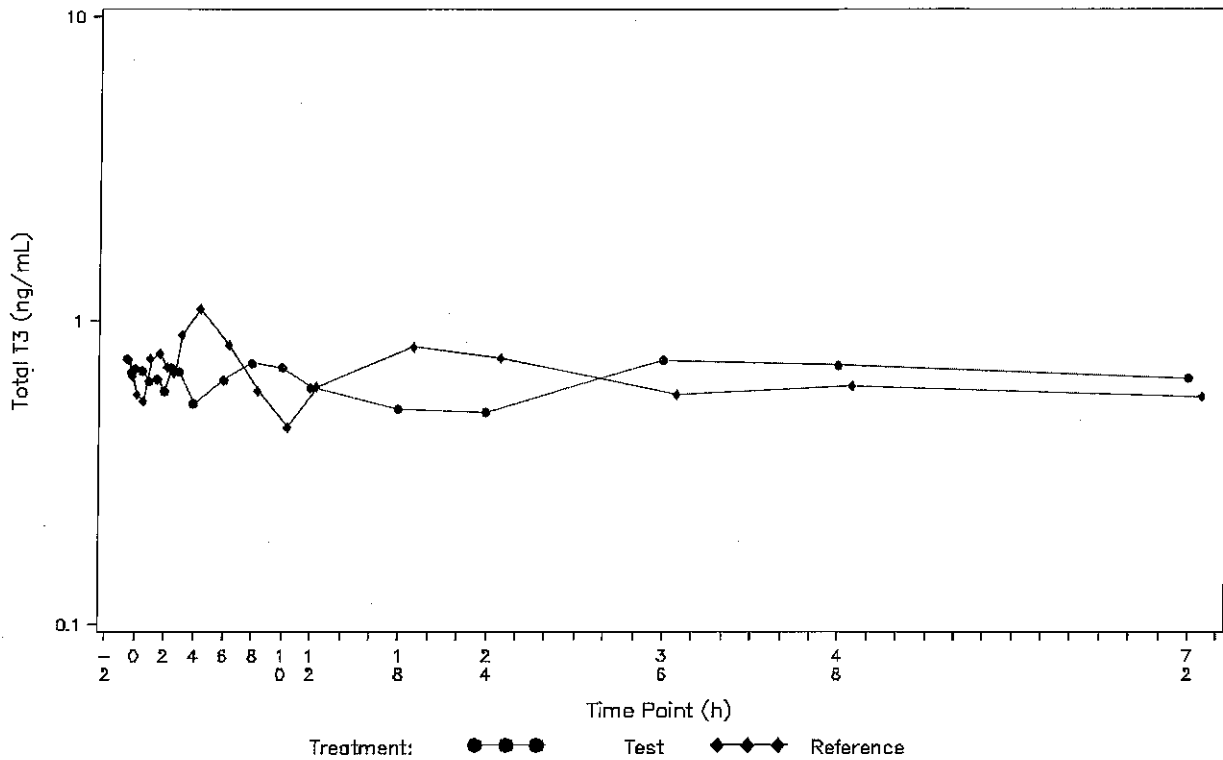
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: :



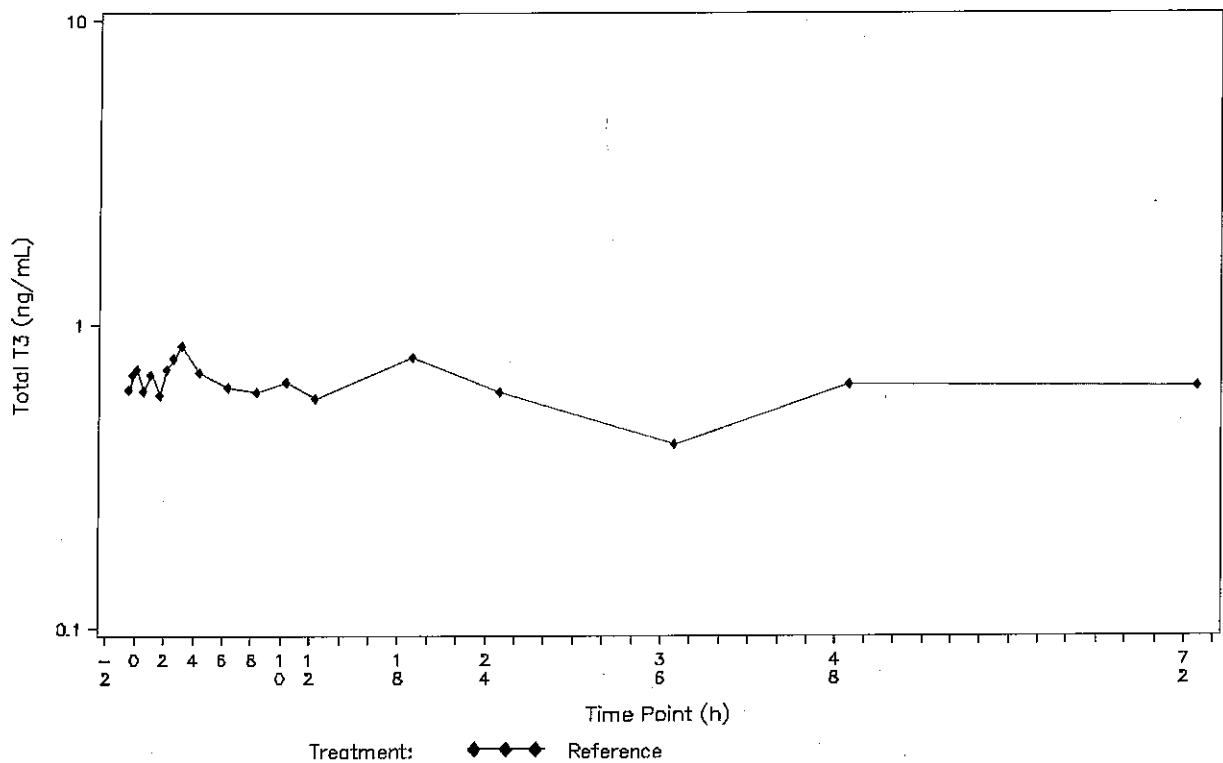
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



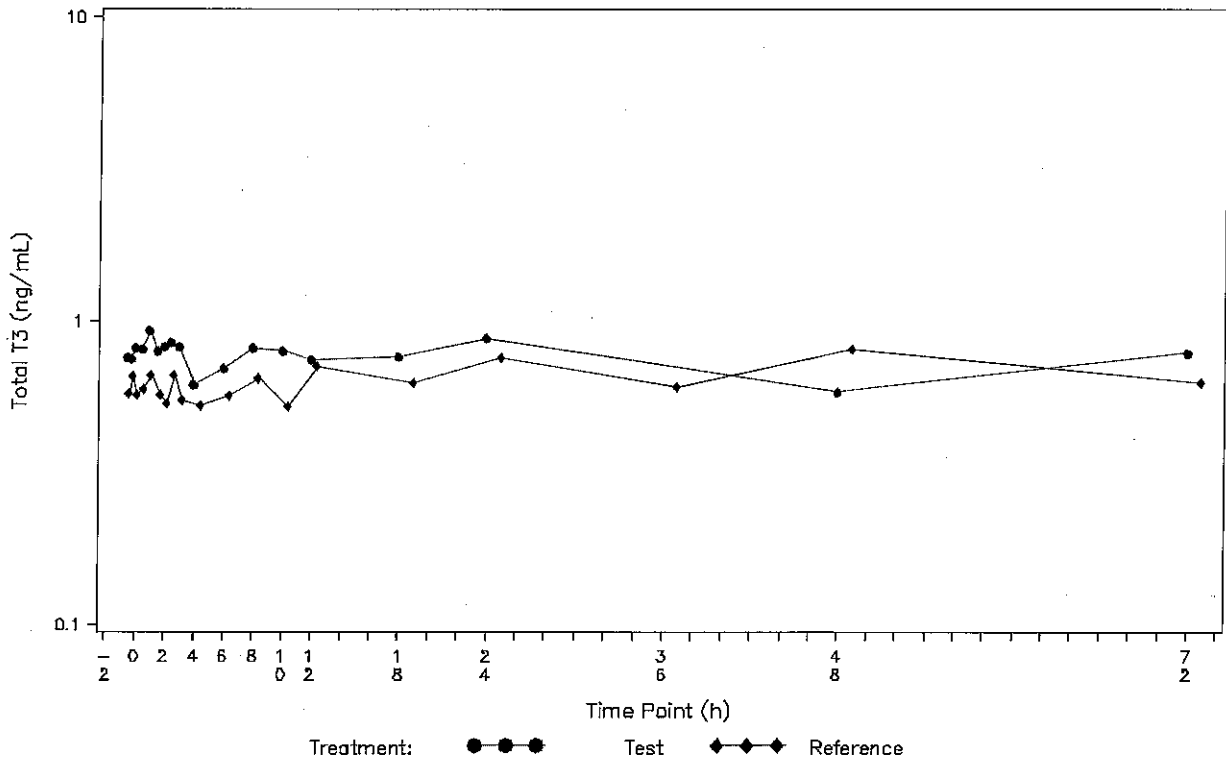
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



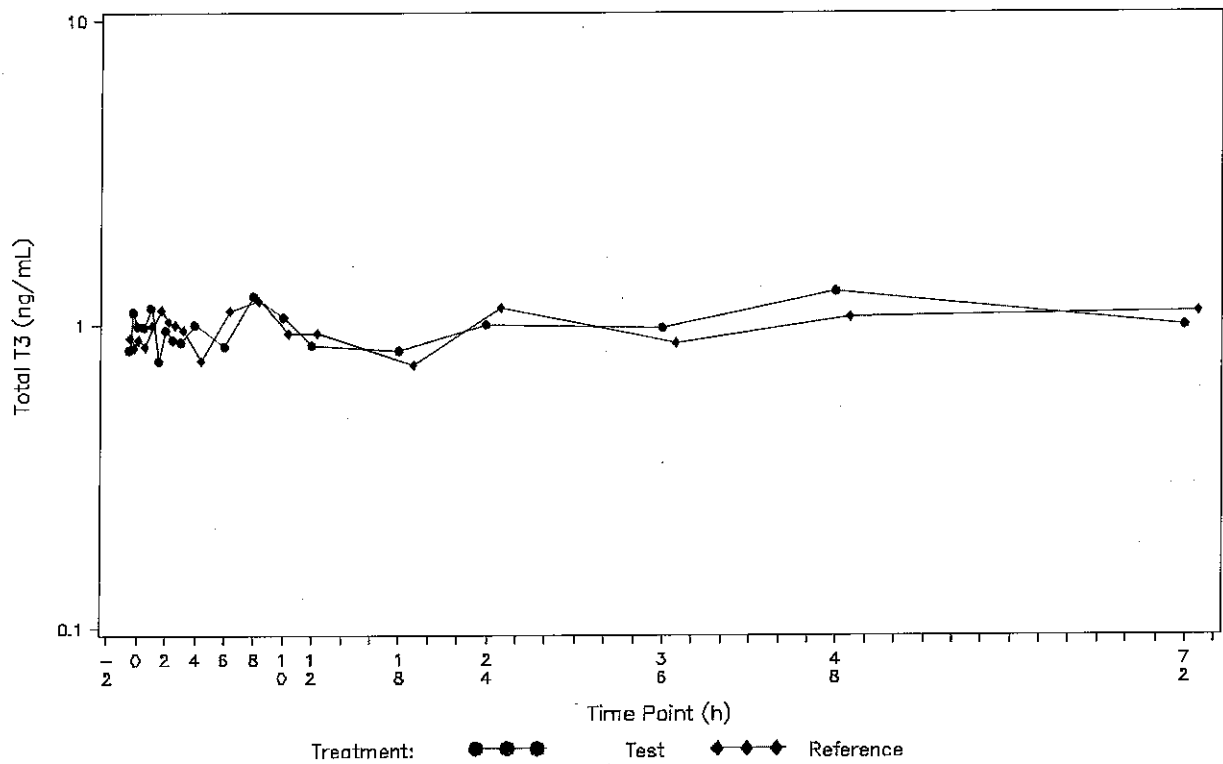
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



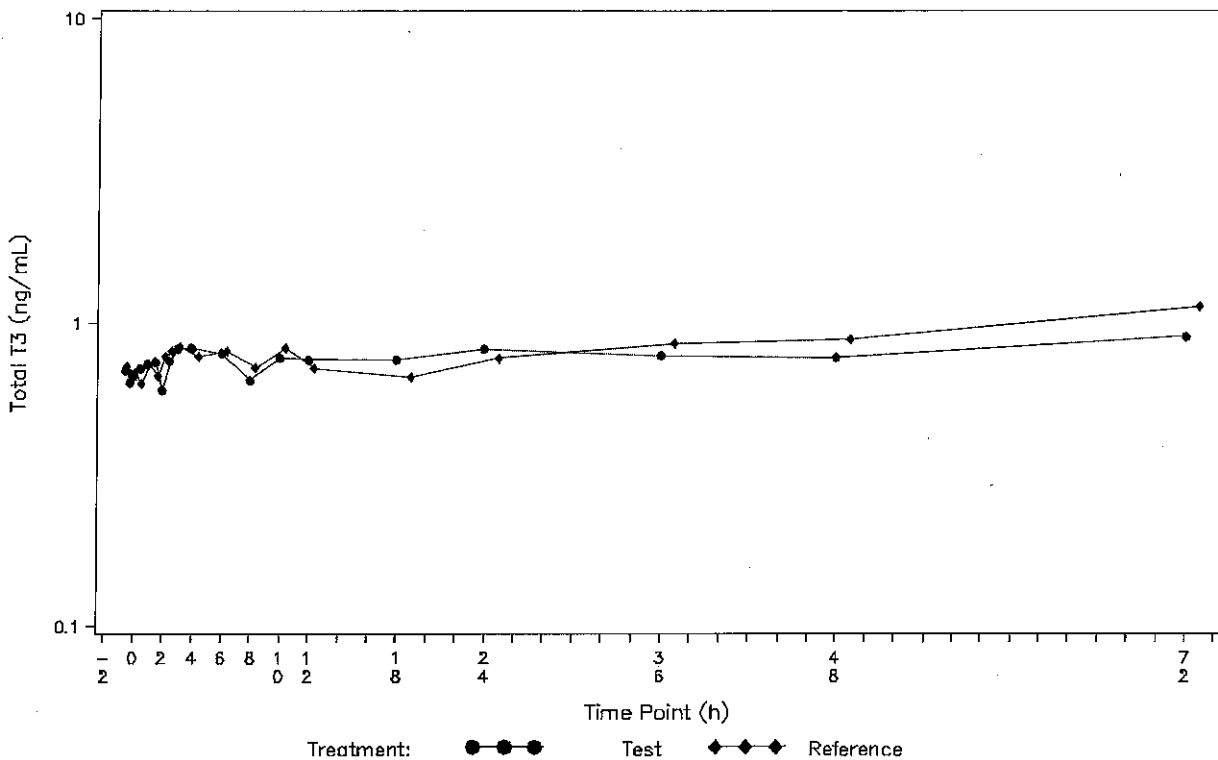
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



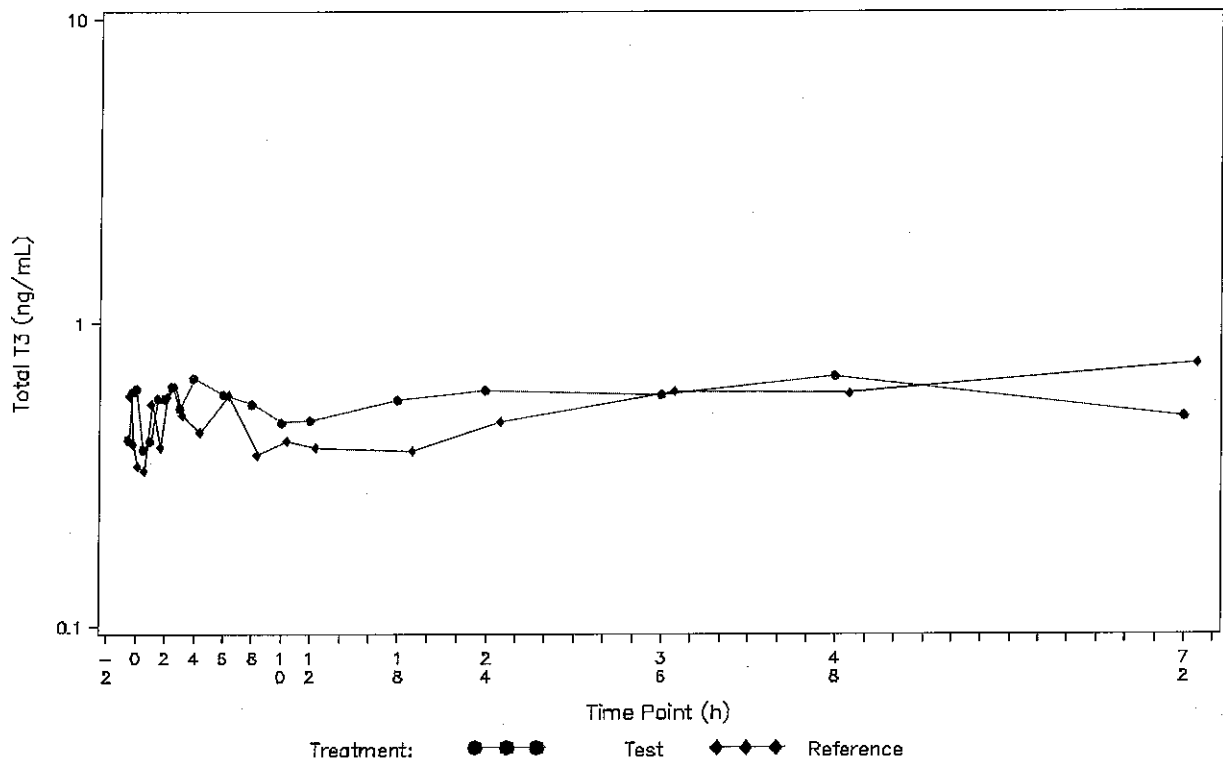
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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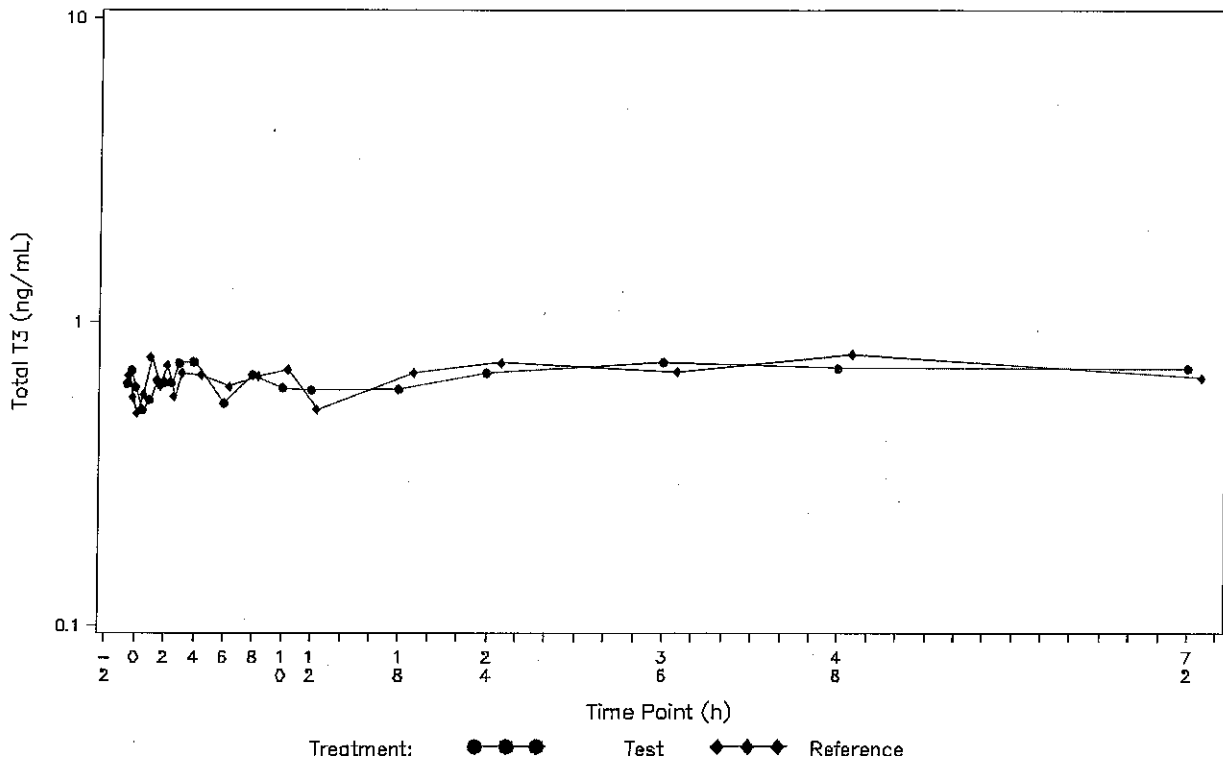
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



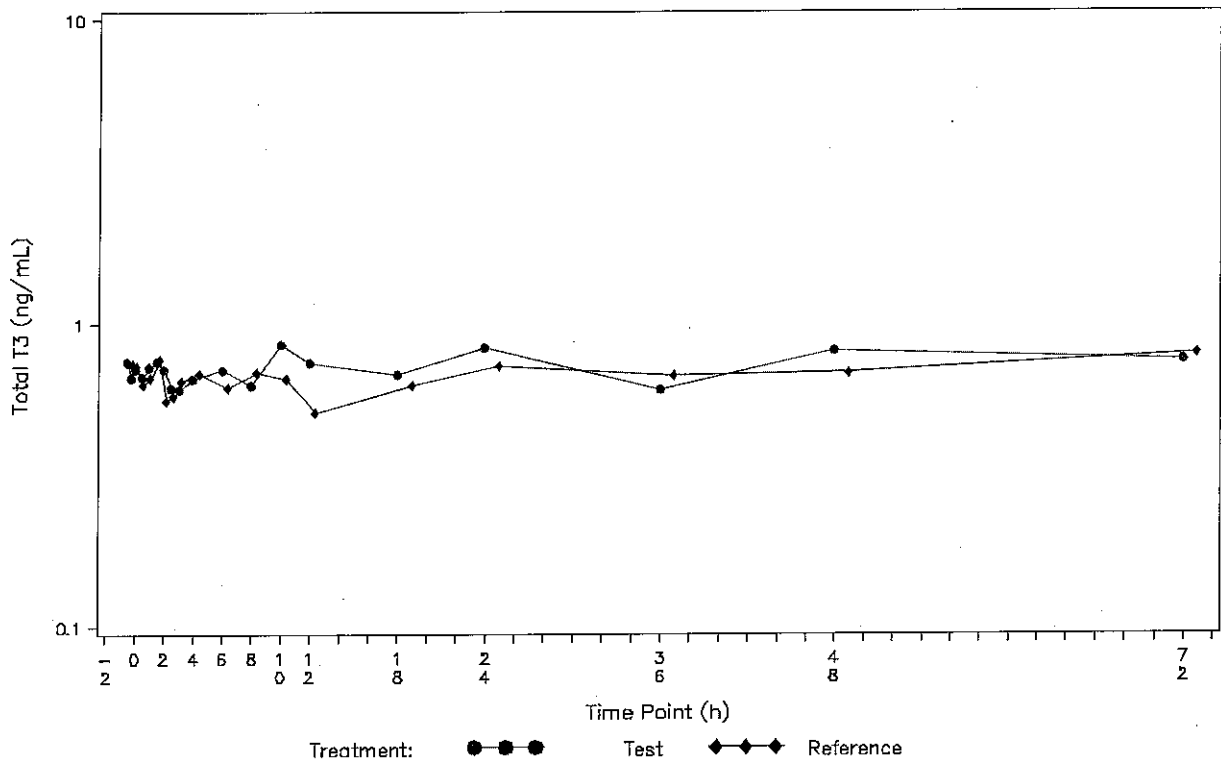
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale ;
(For Total T3 values) (Safety Population)

Subject ID/Random Number: .



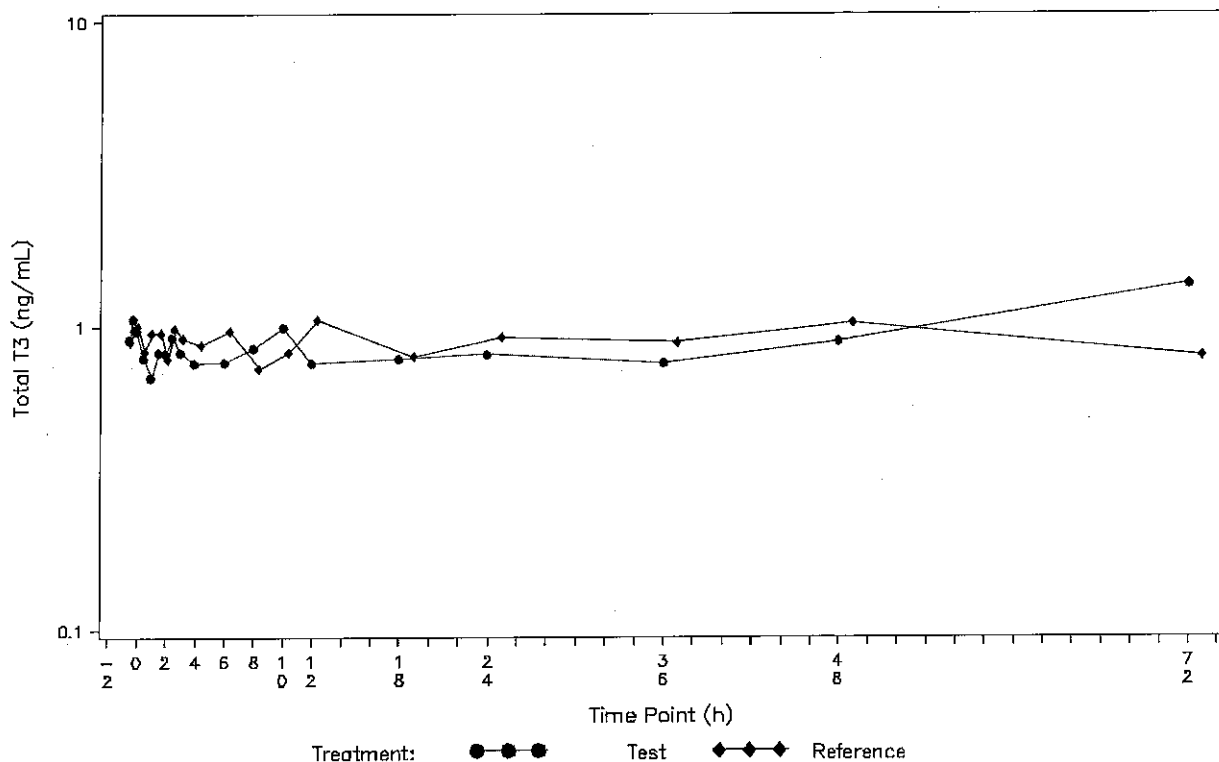
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



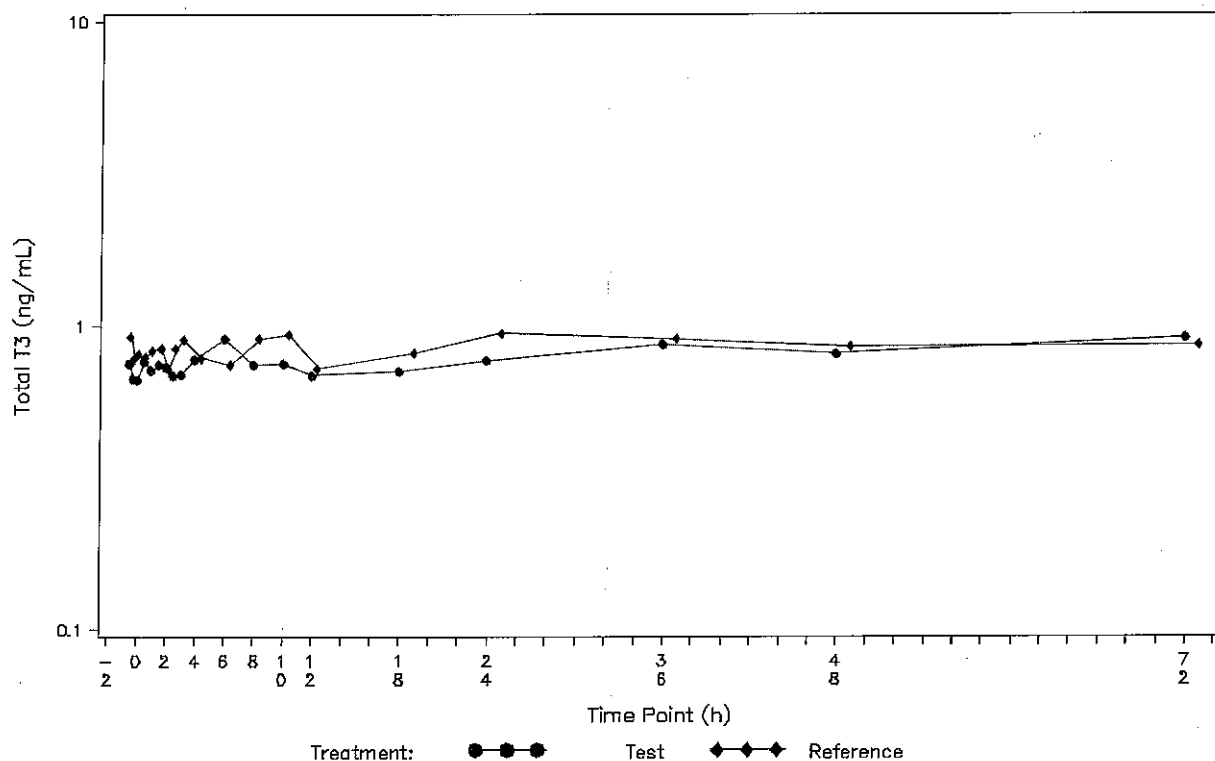
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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



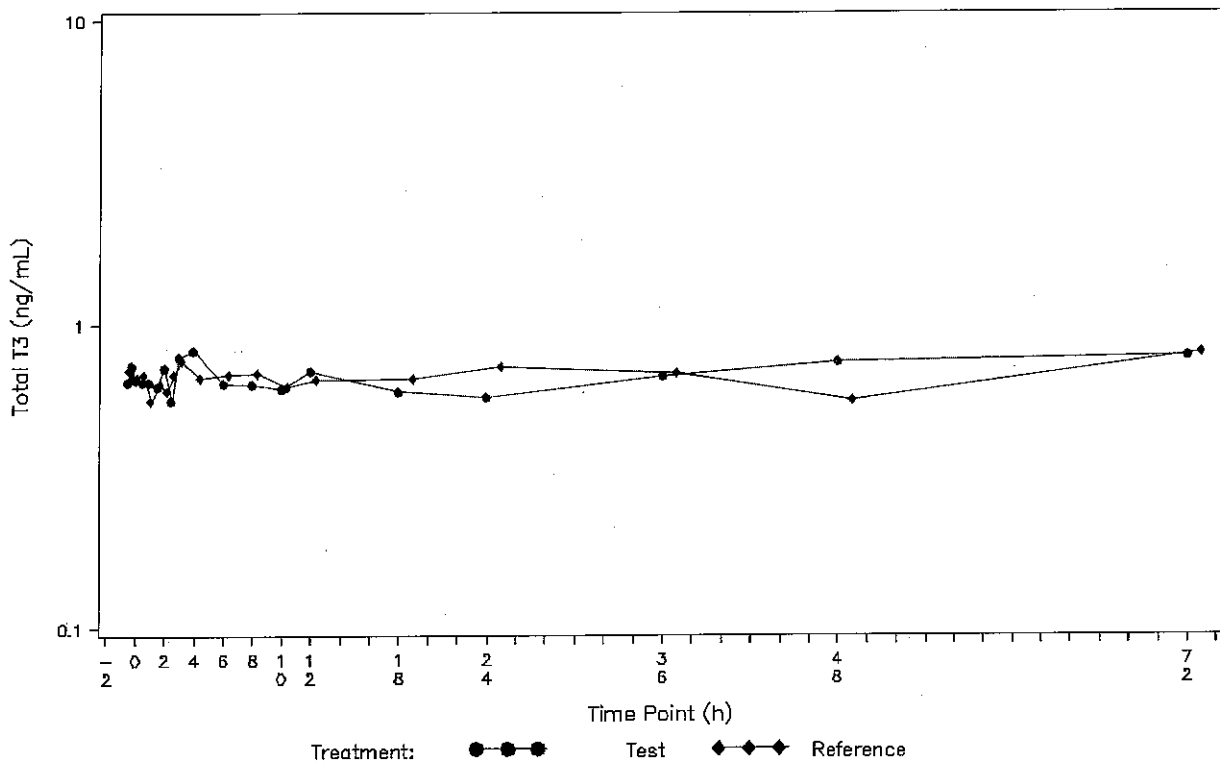
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EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

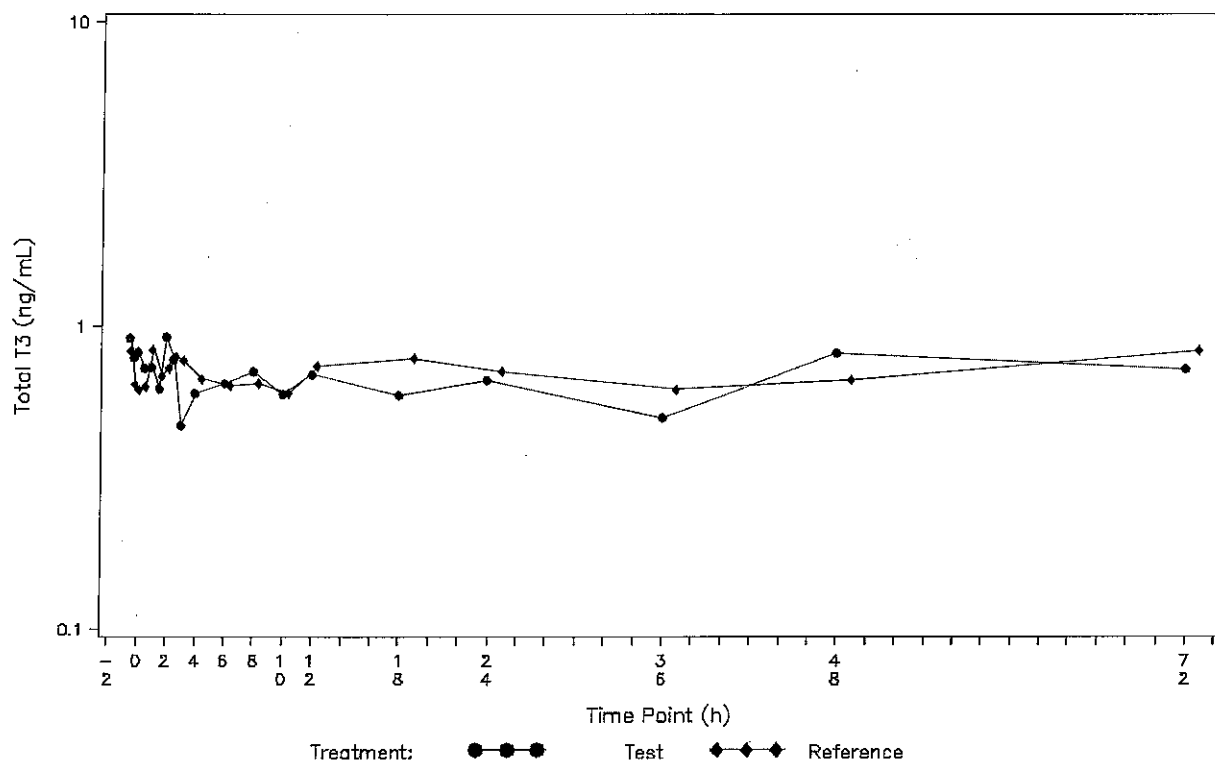


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

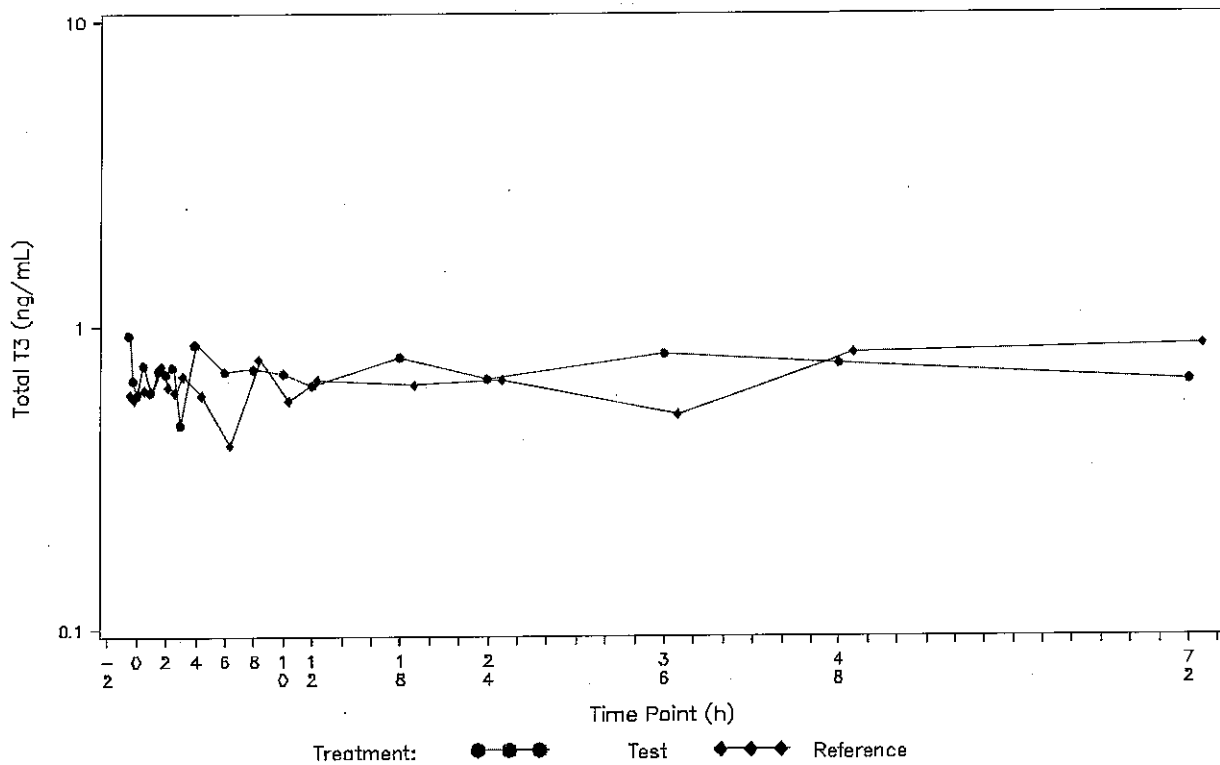


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Merck Serono
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

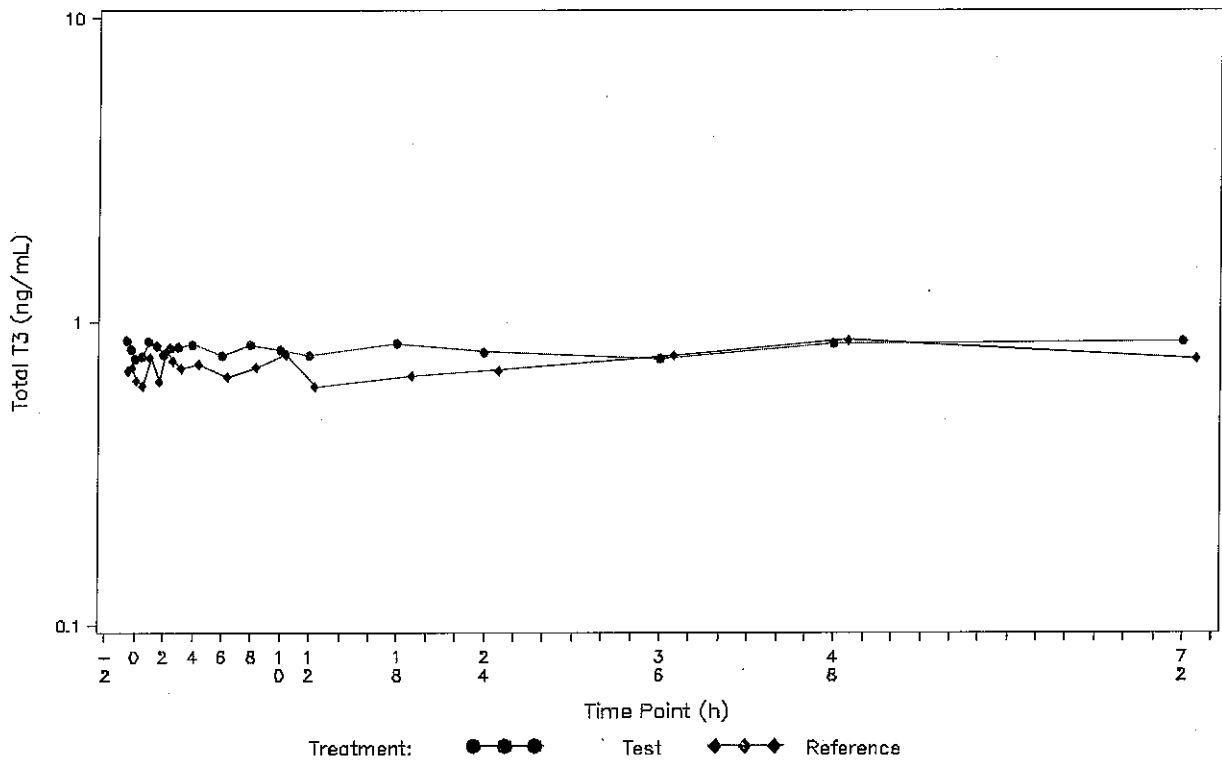


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: .



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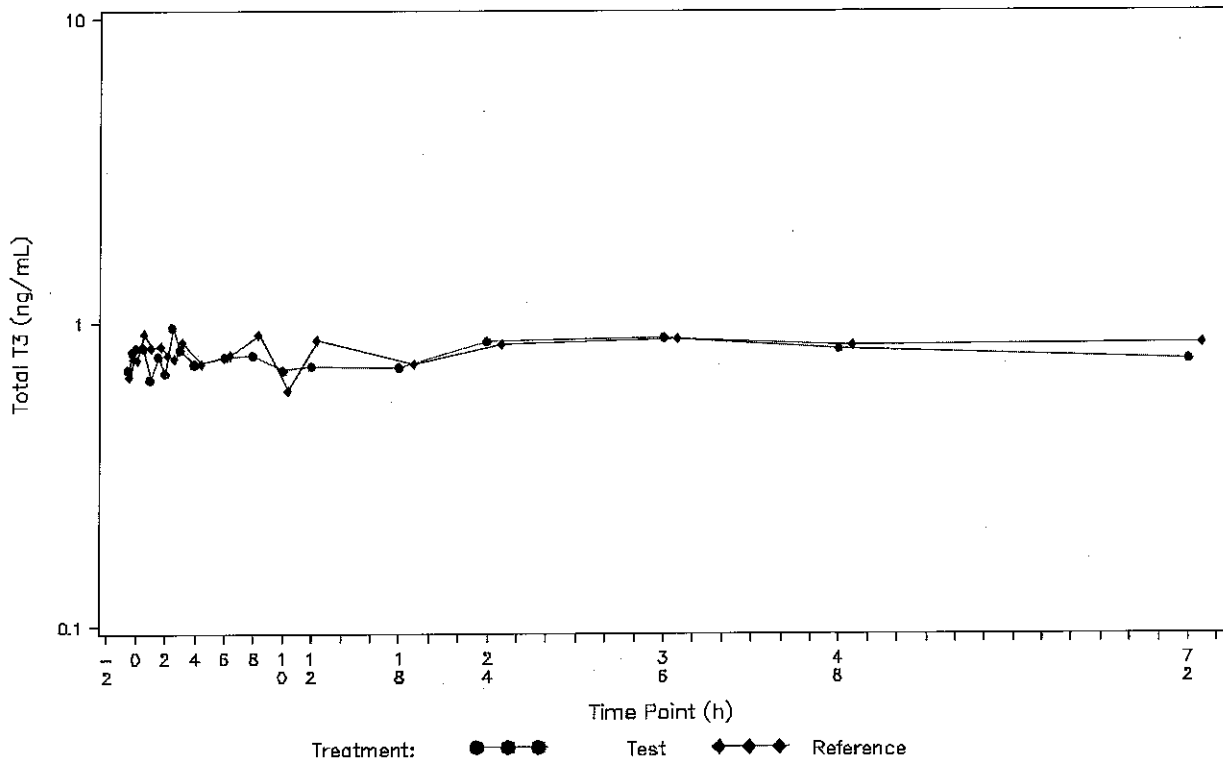
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



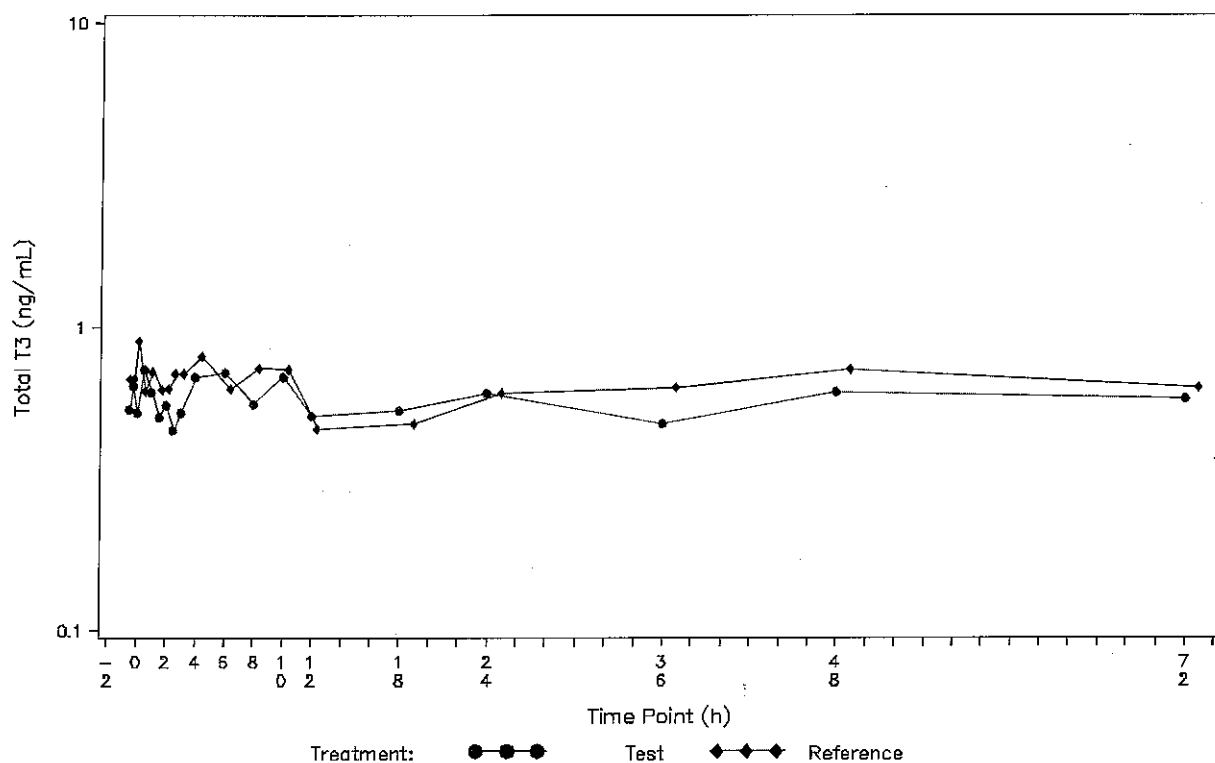
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



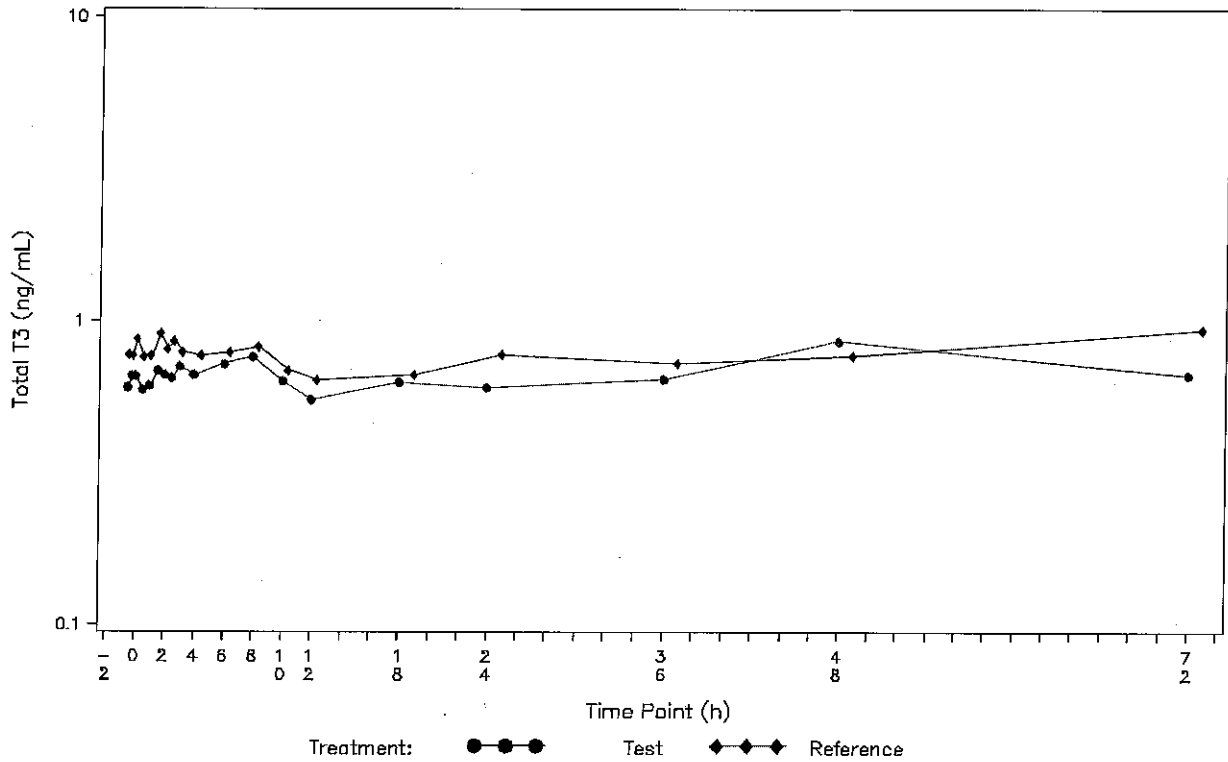
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



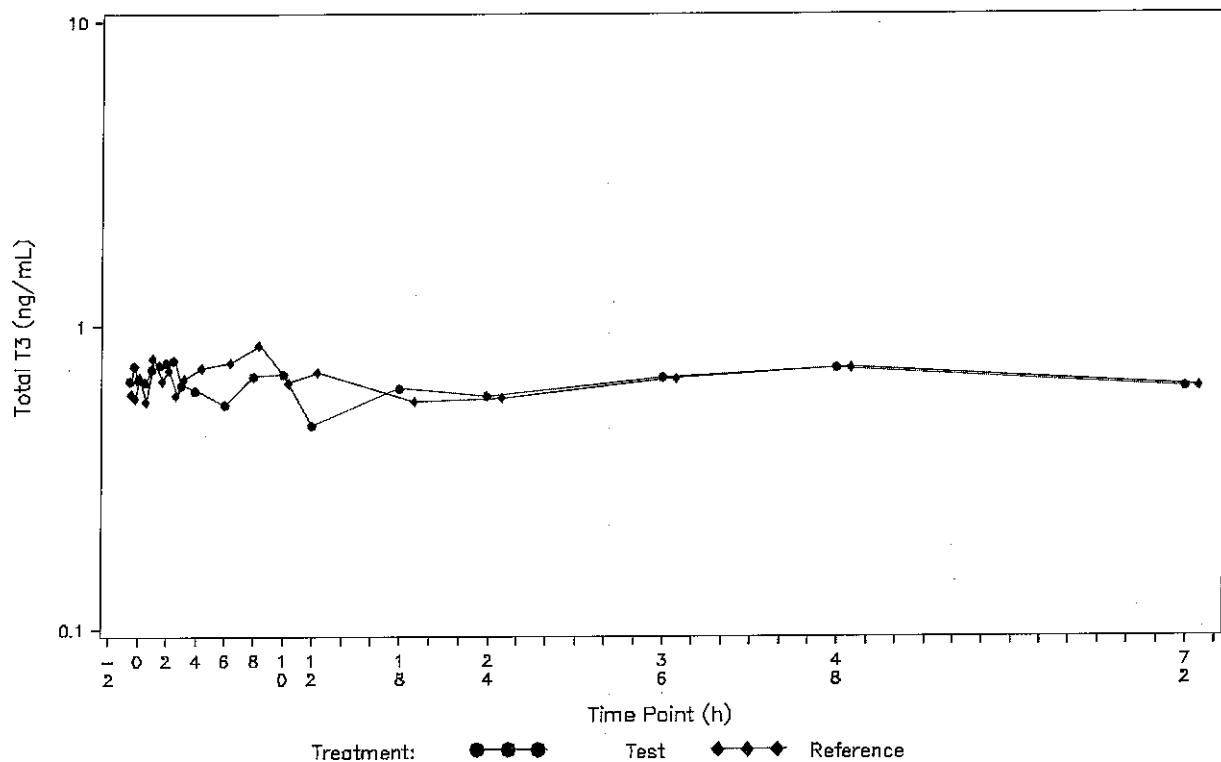
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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: . . .

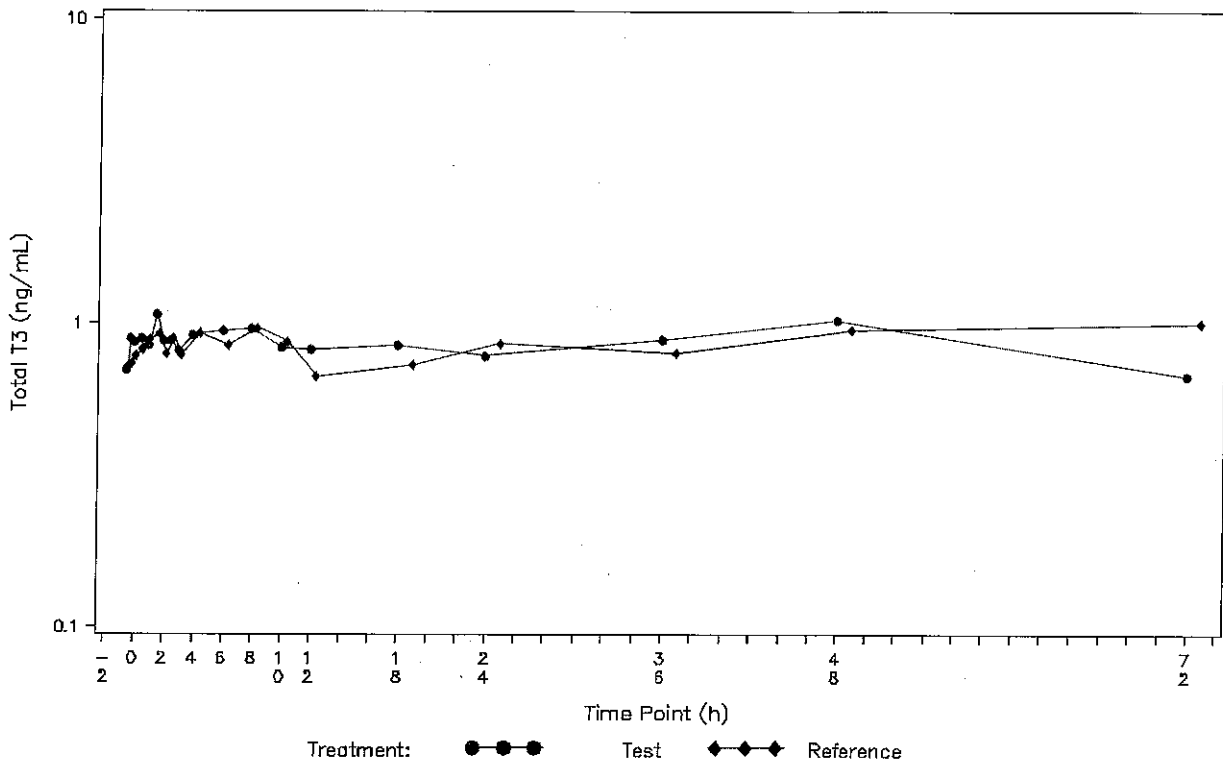


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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



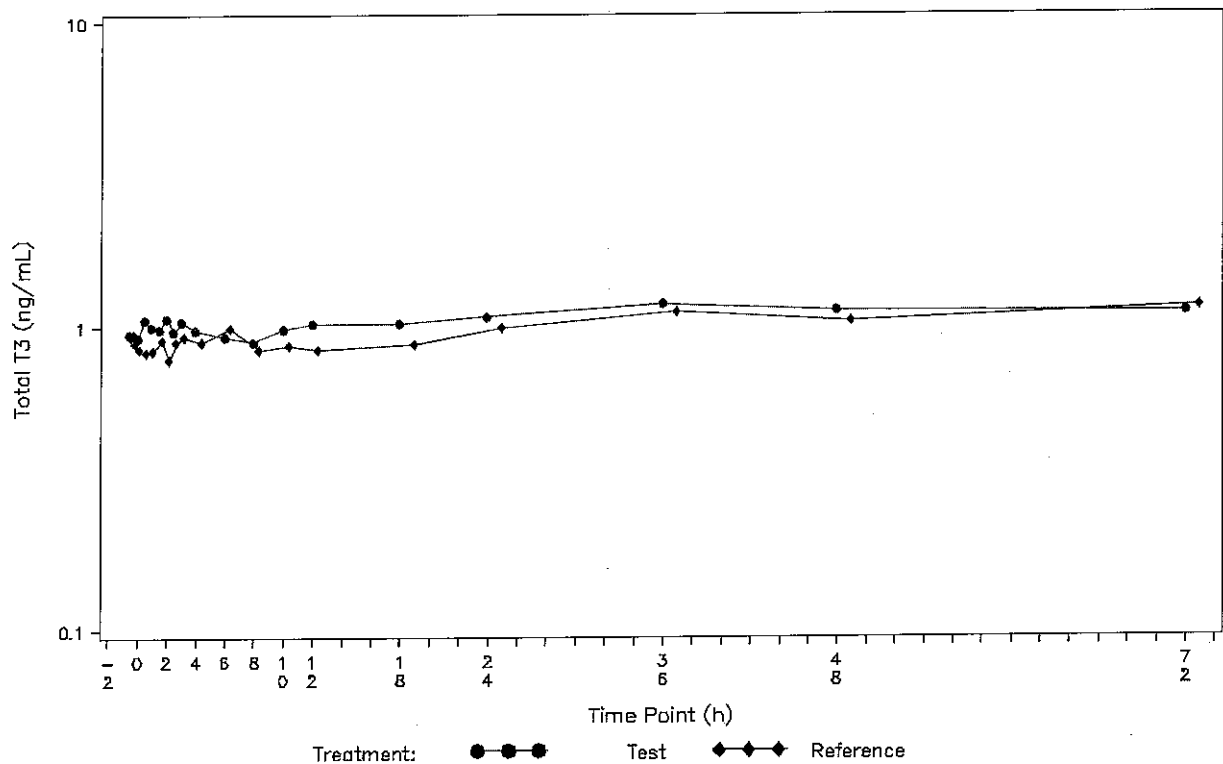
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



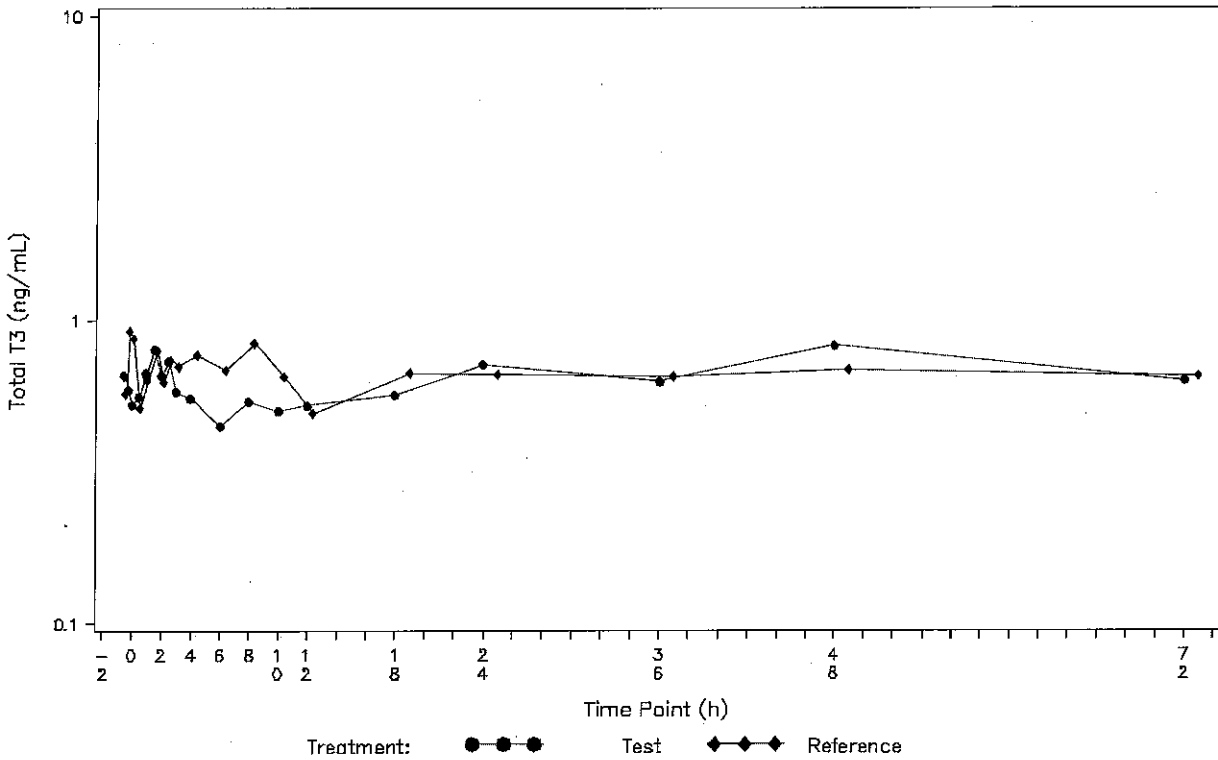
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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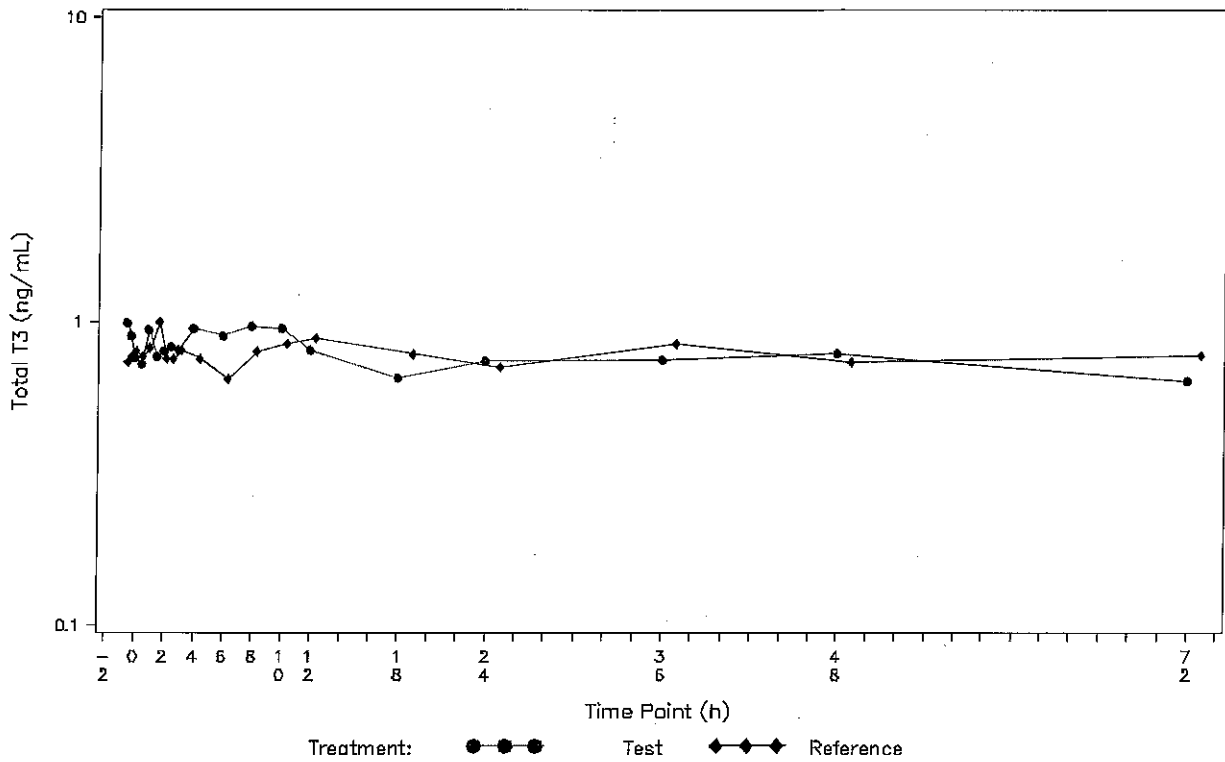
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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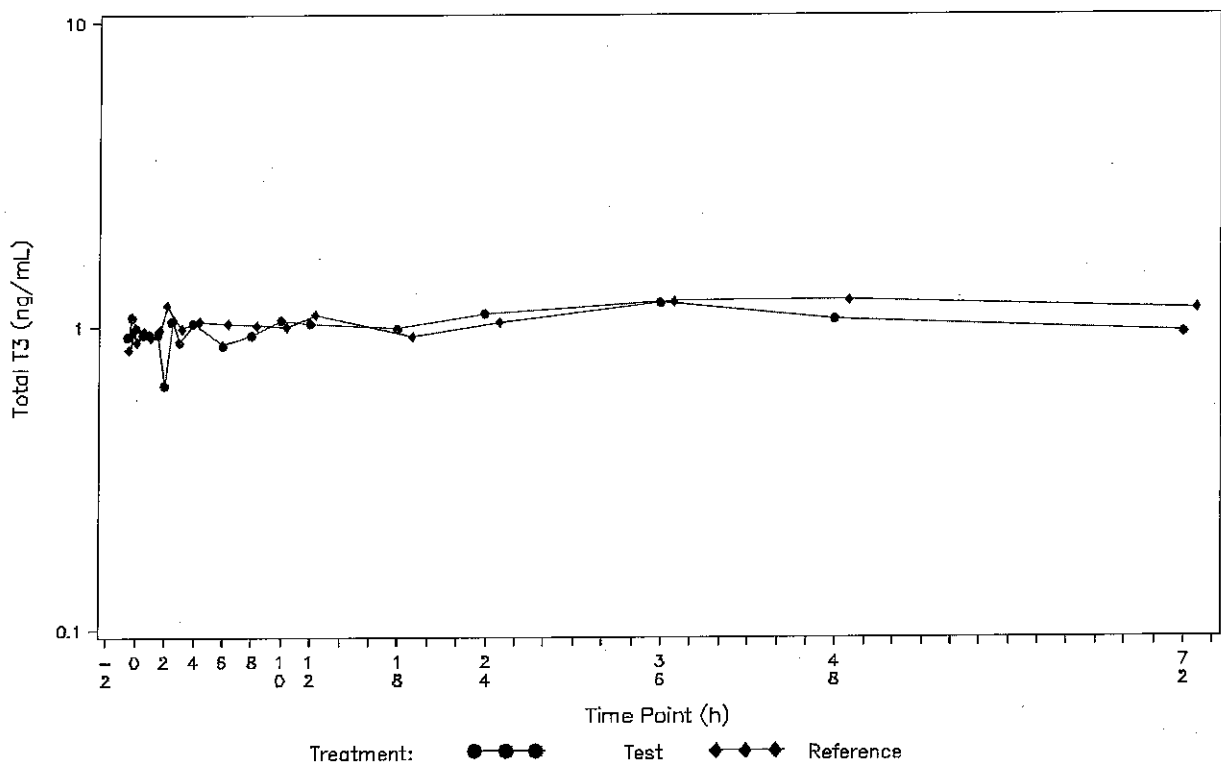


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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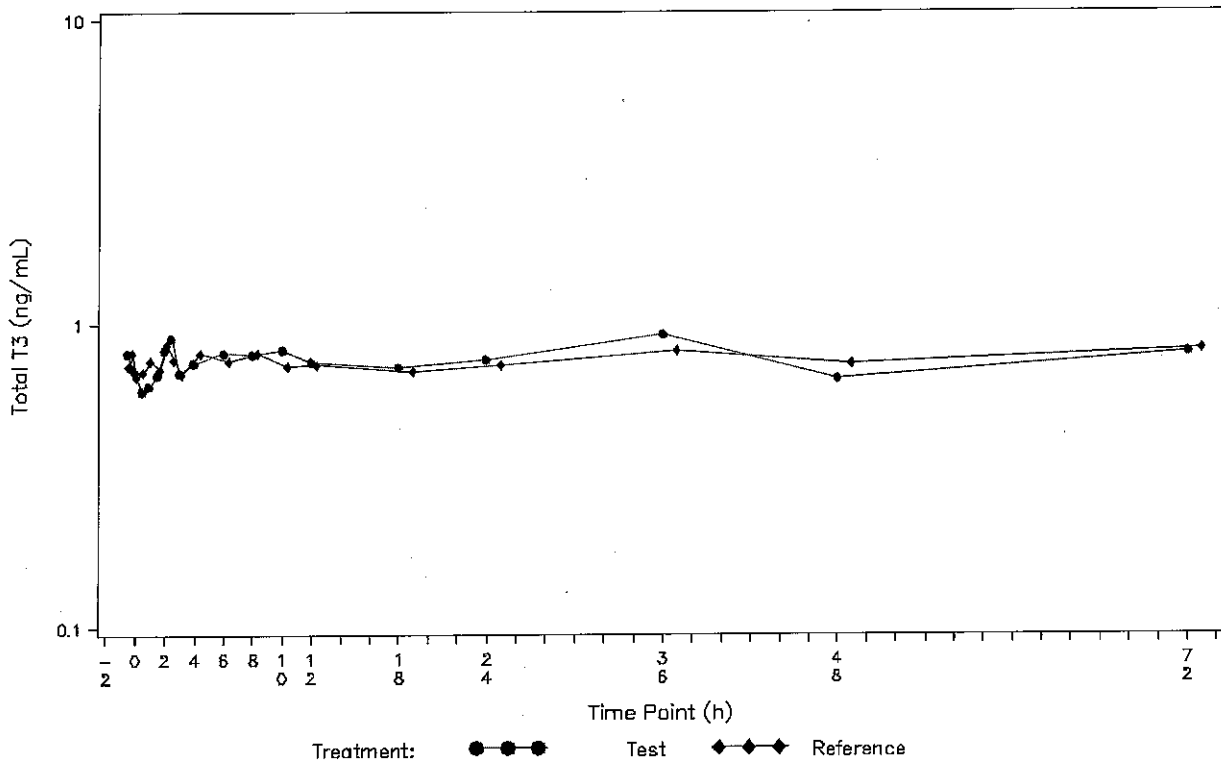
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



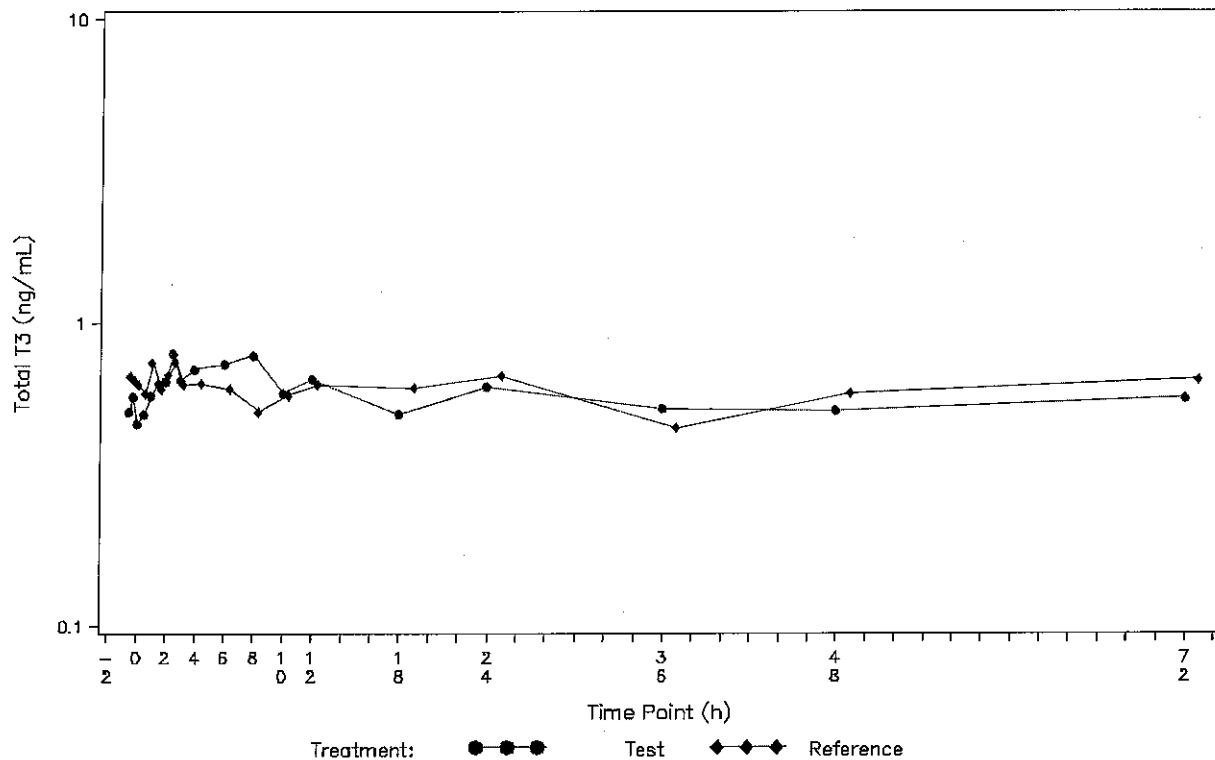
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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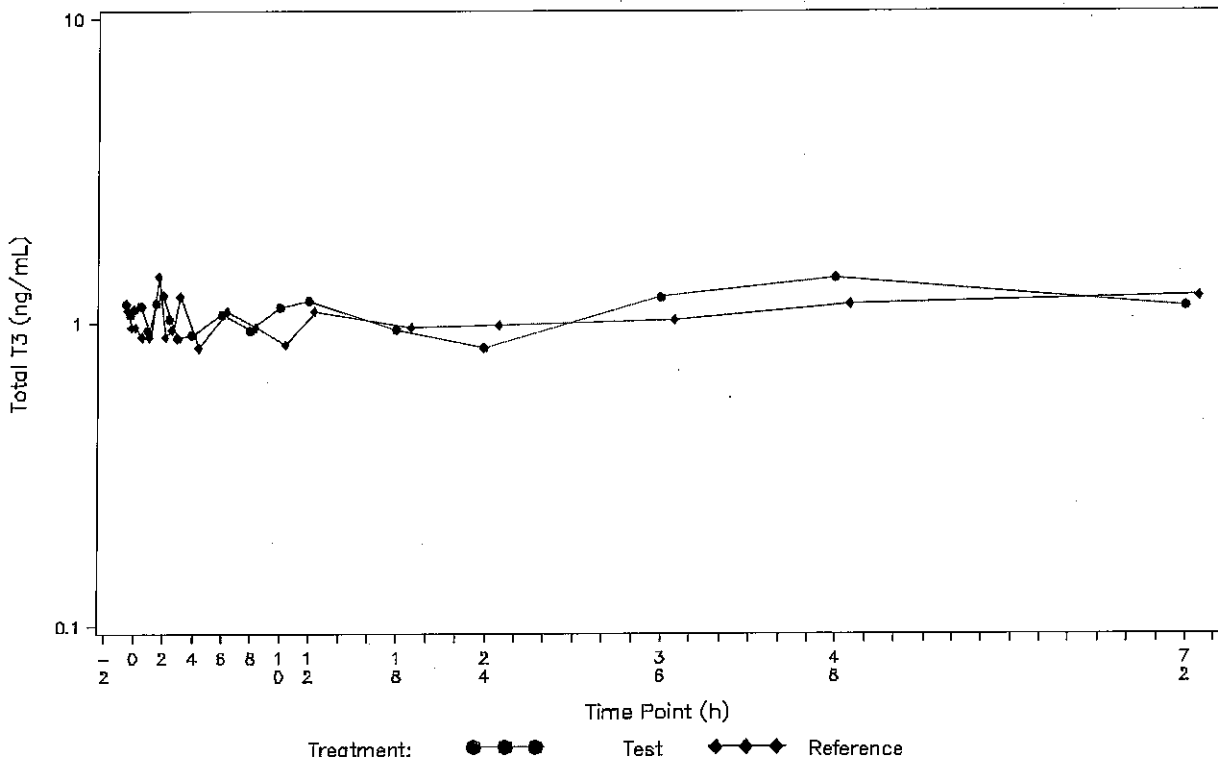
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



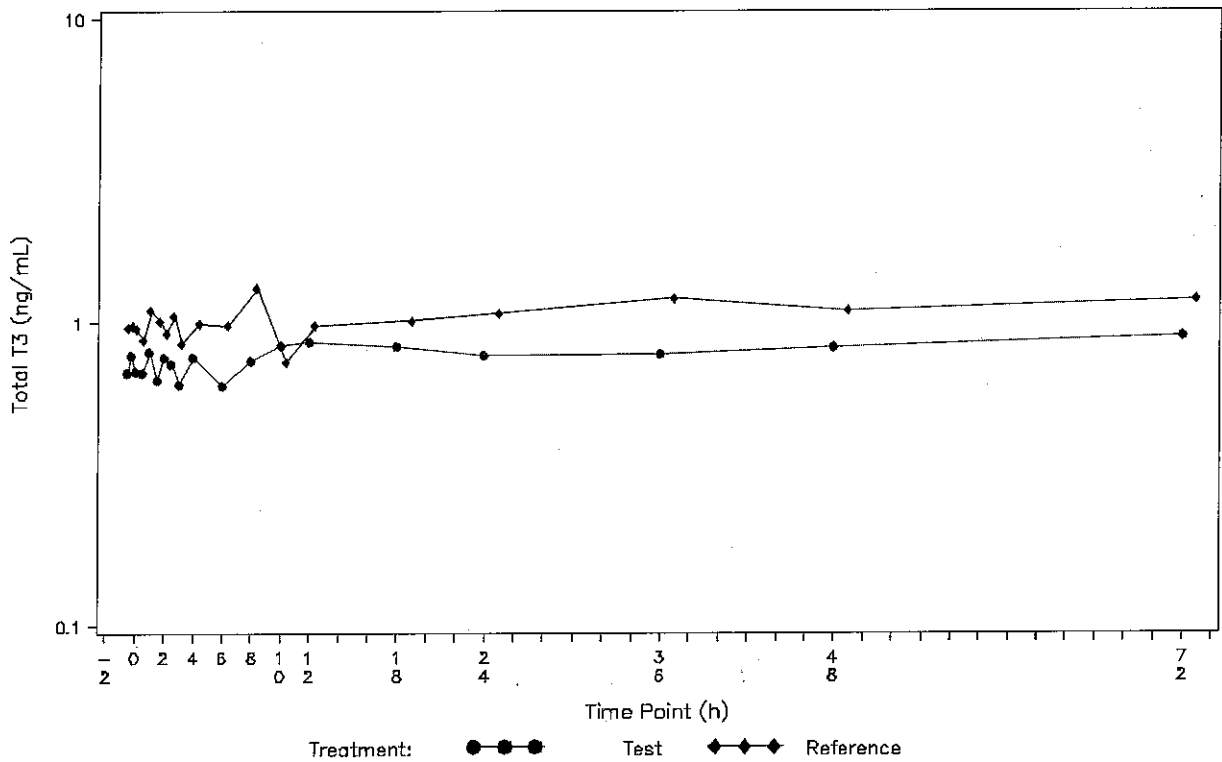
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



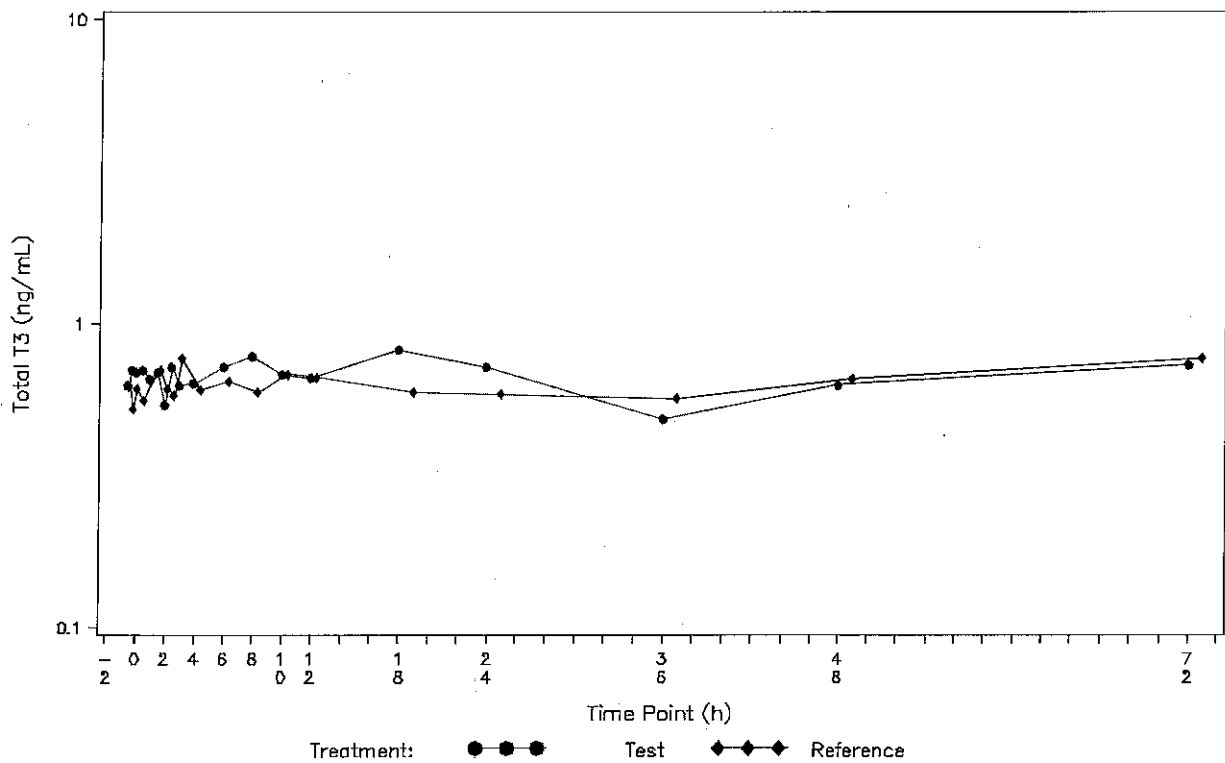
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



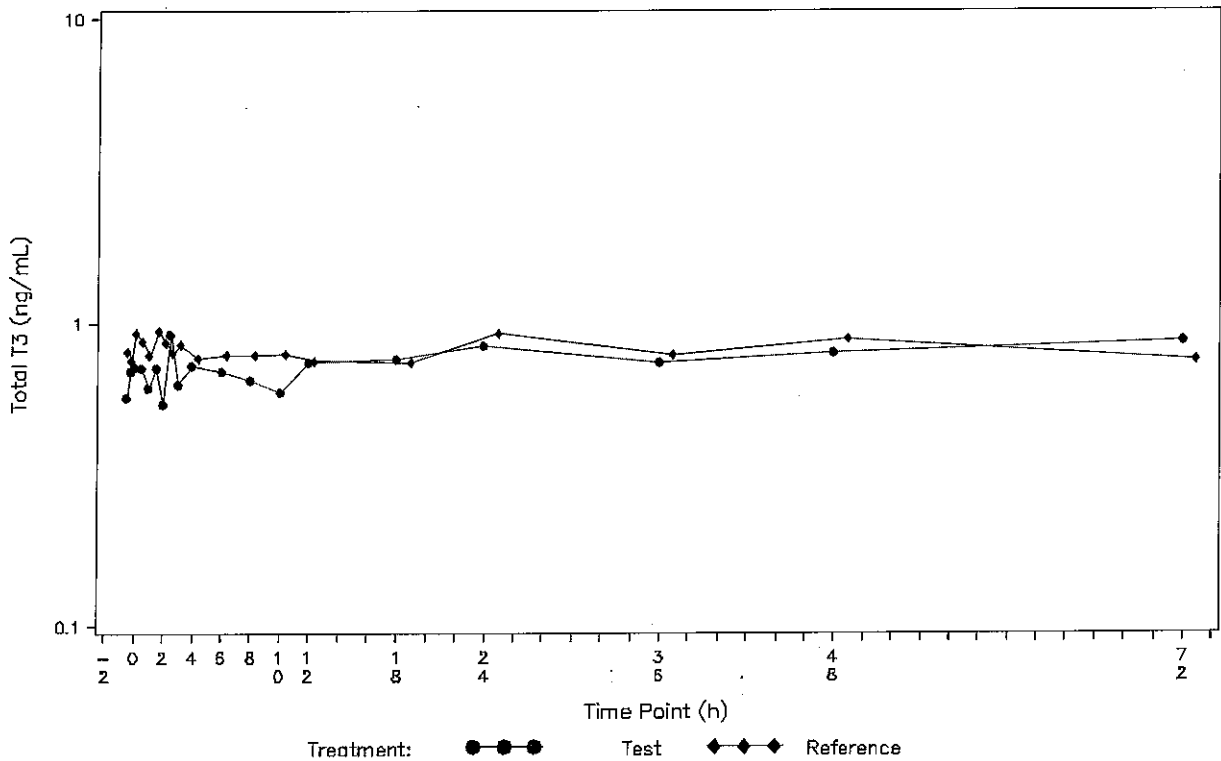
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



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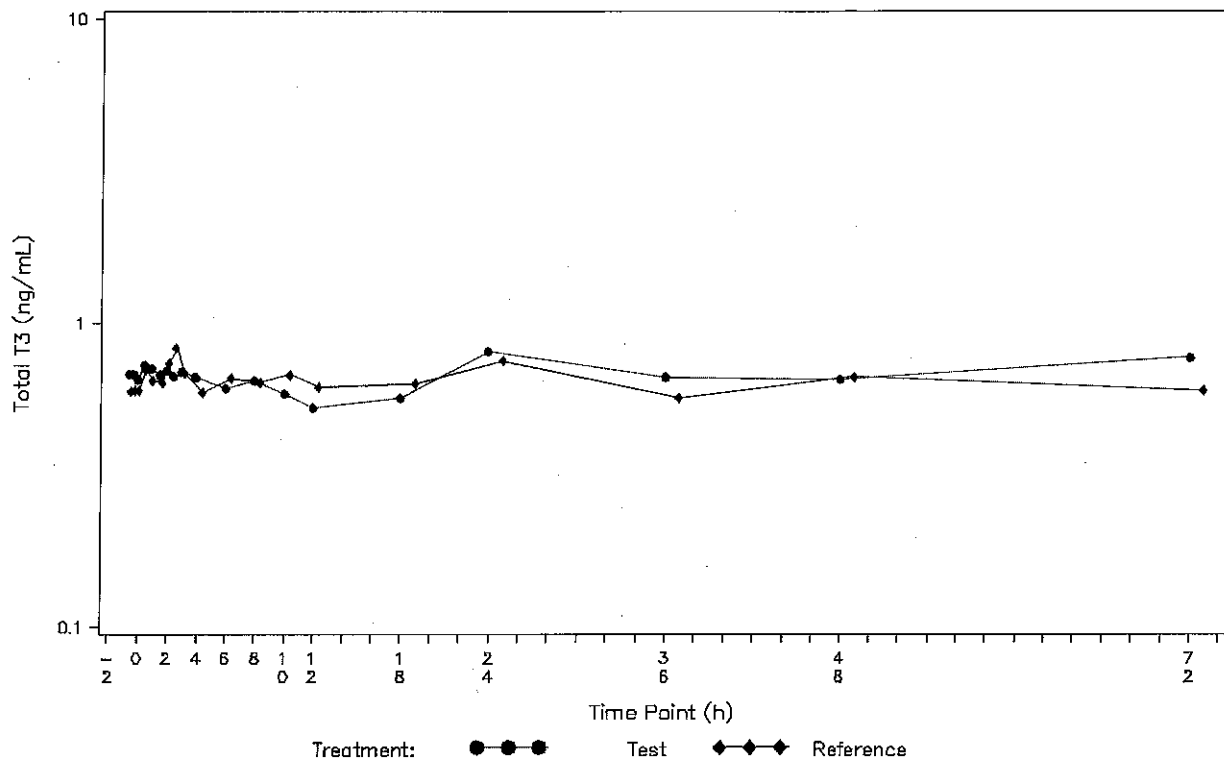
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



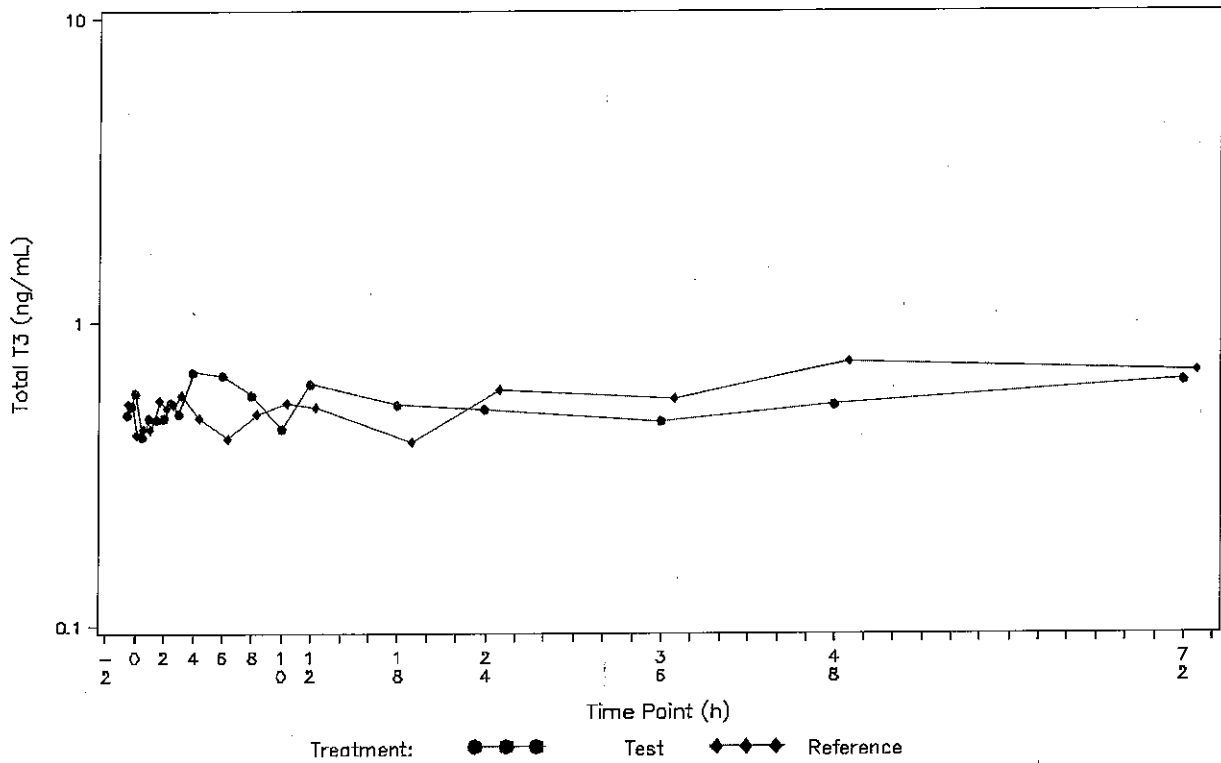
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: .

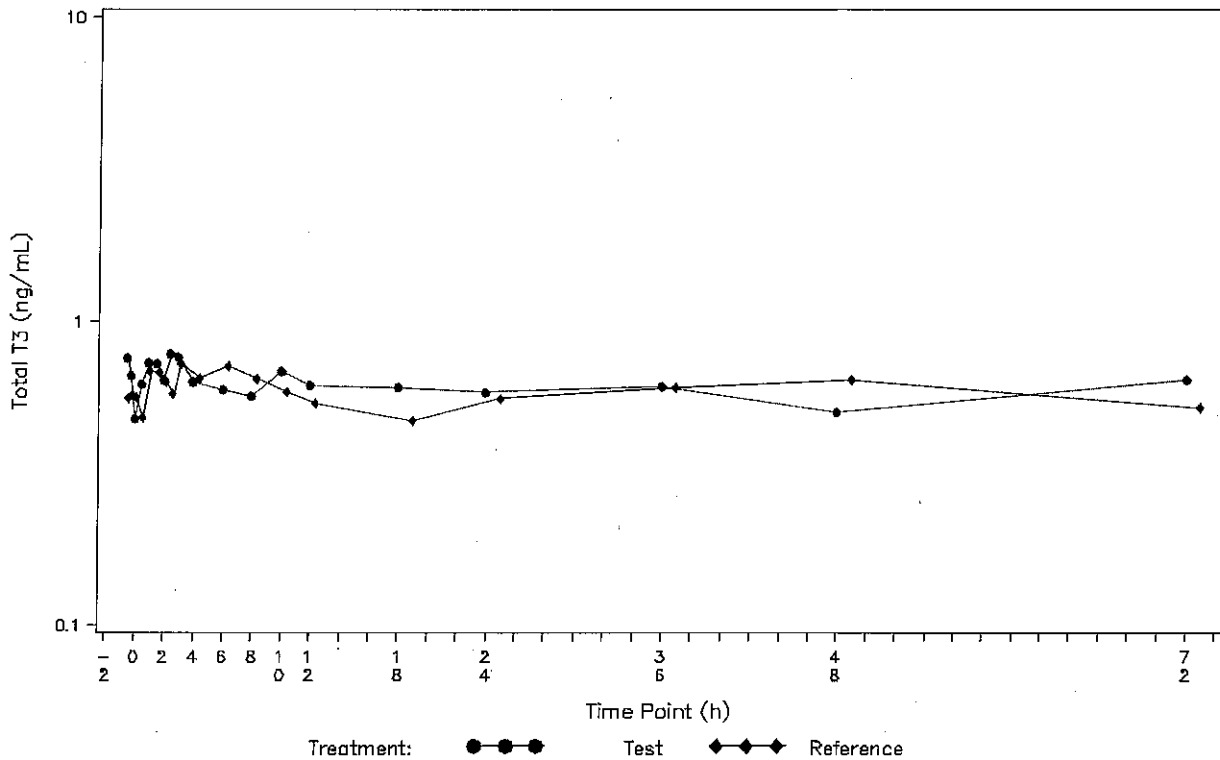


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



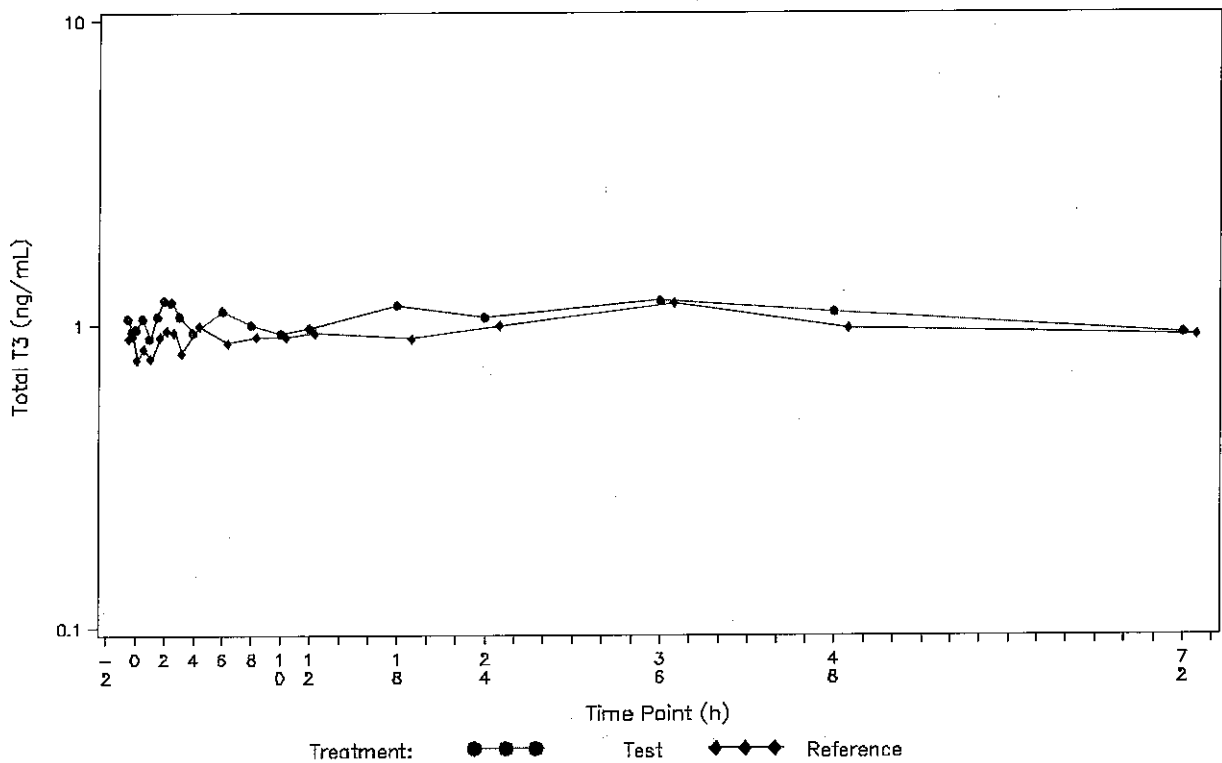
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(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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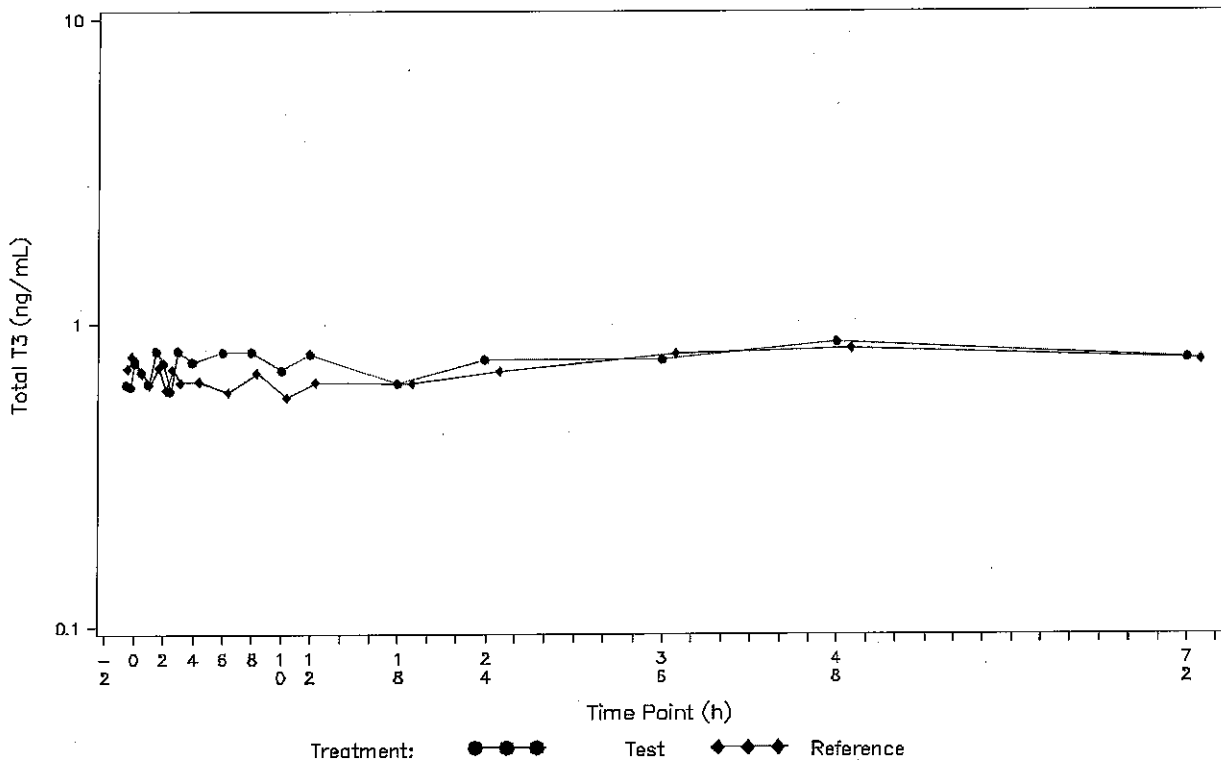
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



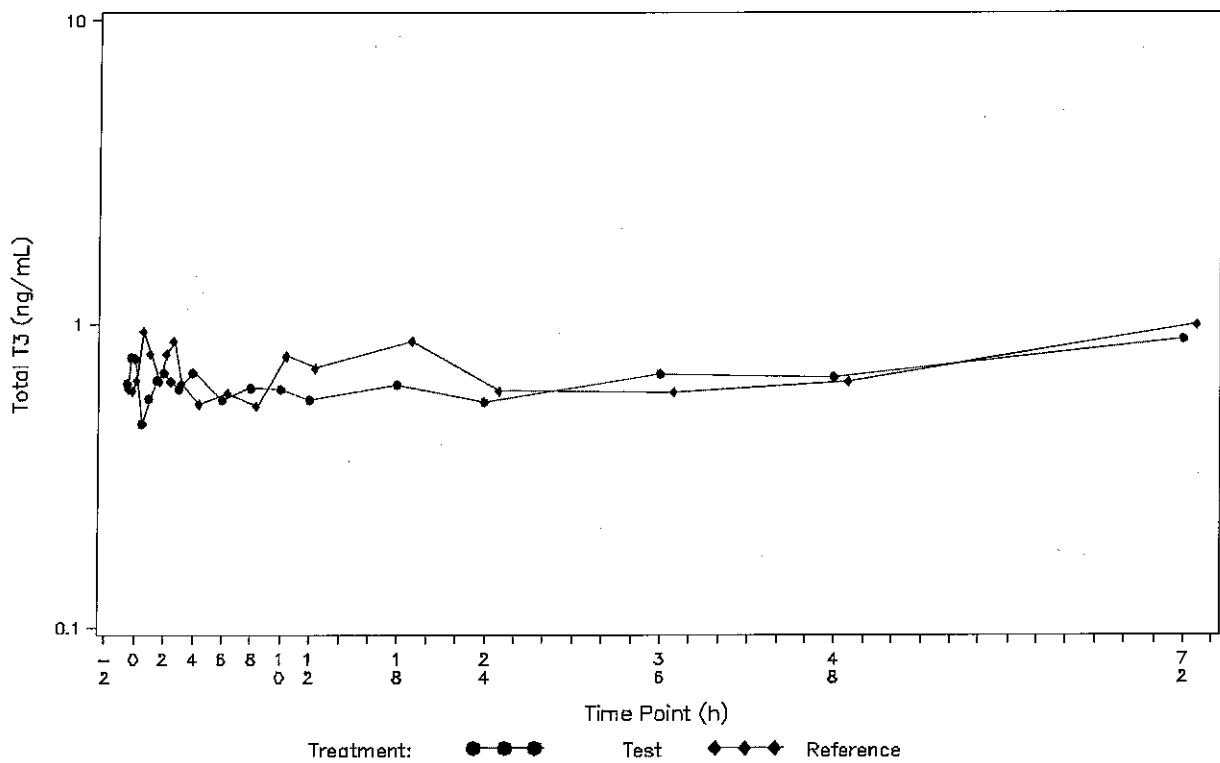
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

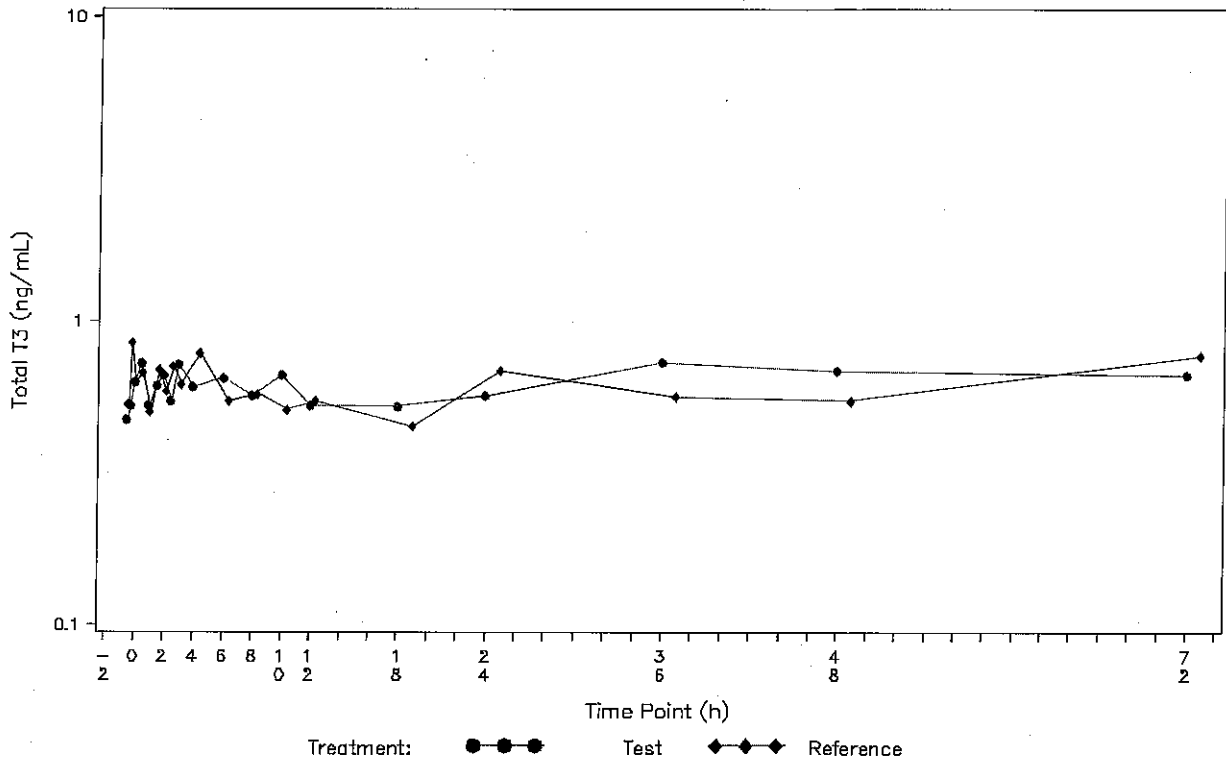


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: .



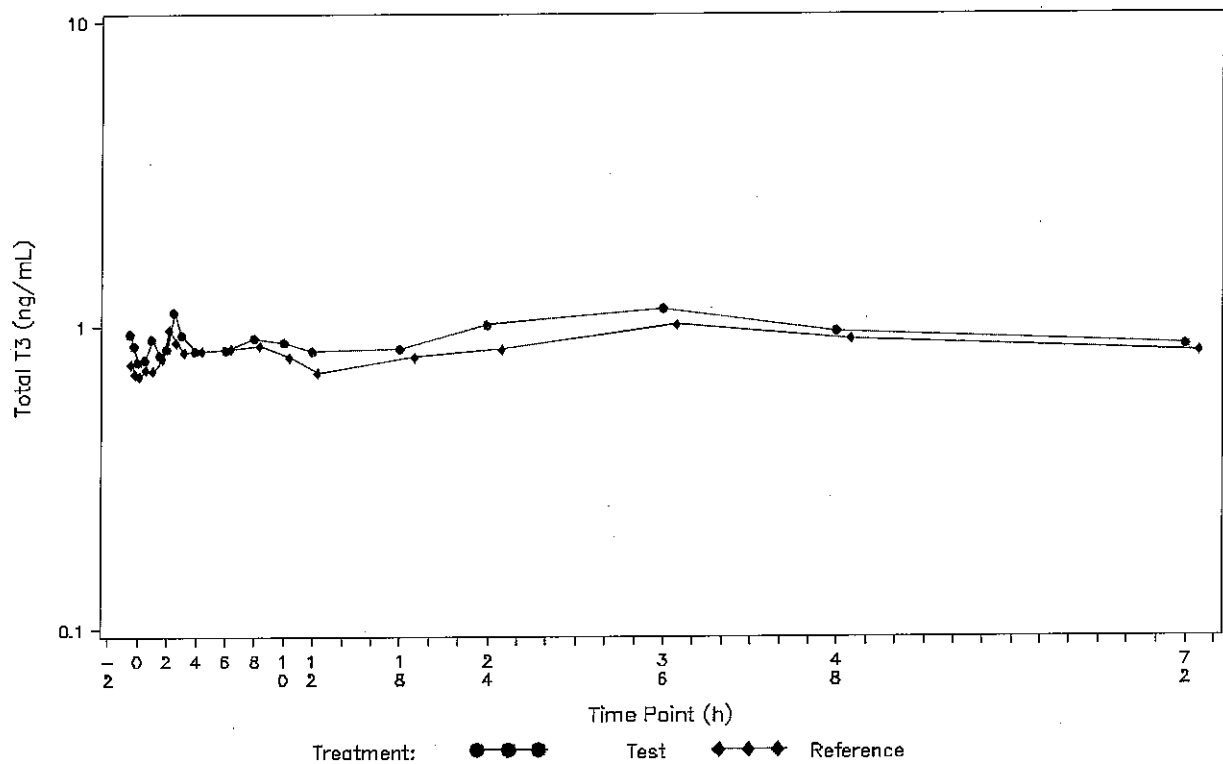
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:

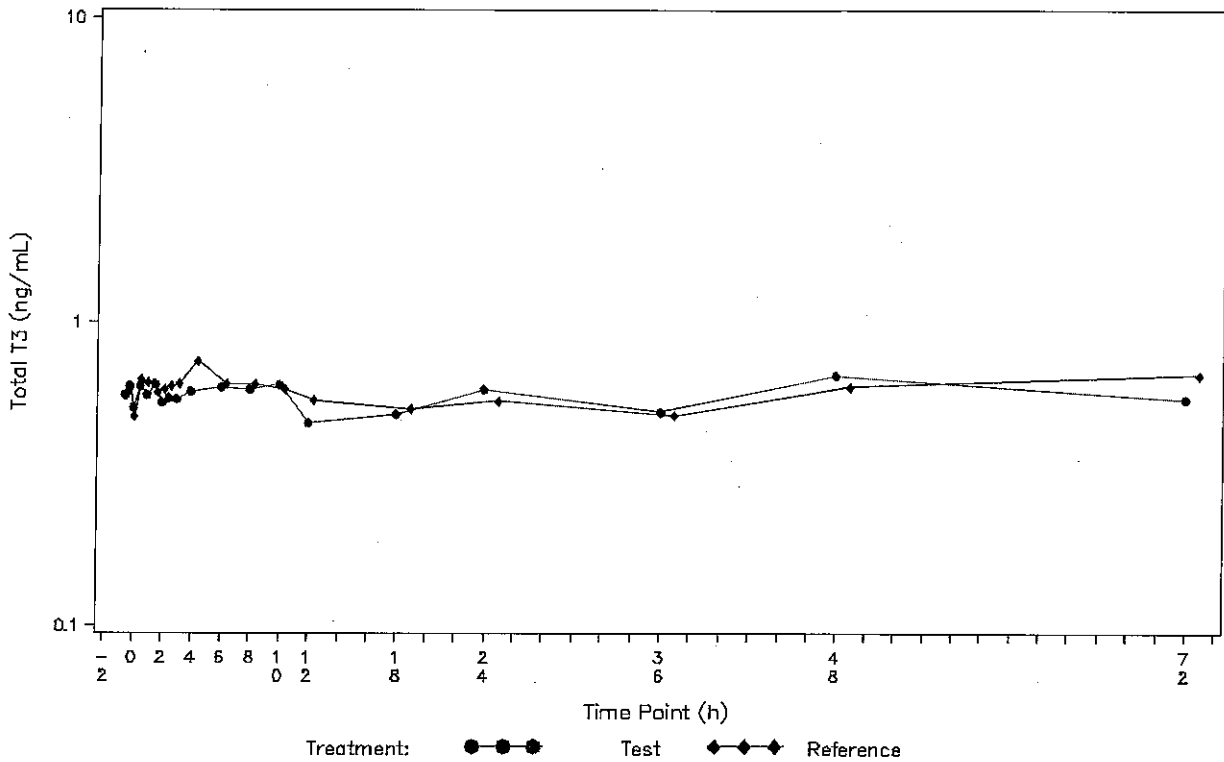


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

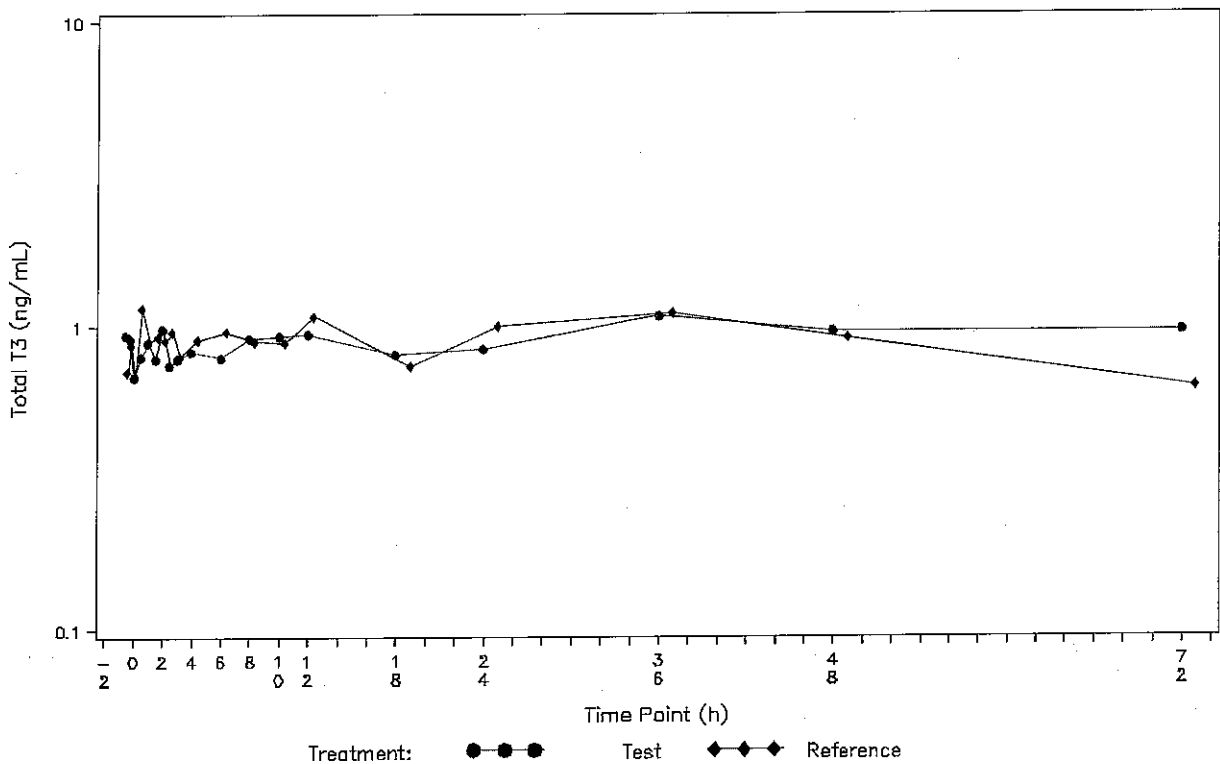


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Subject ID/Random Number:



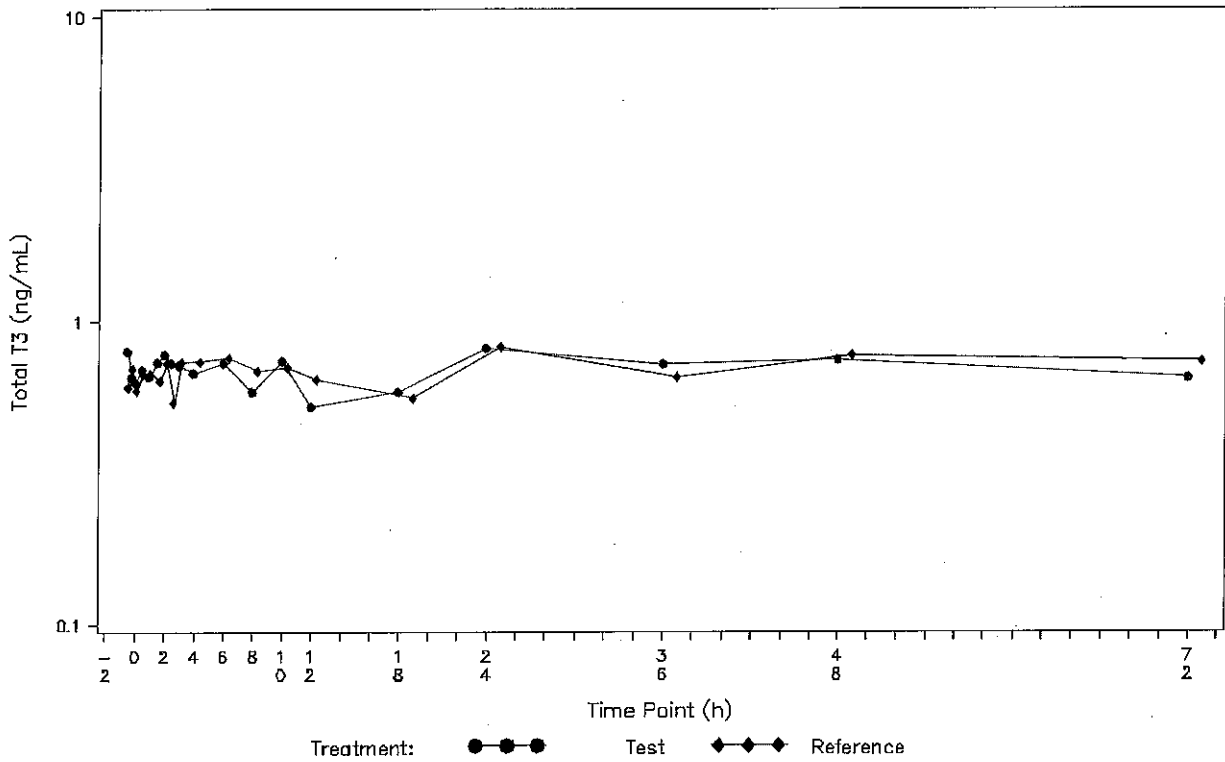
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

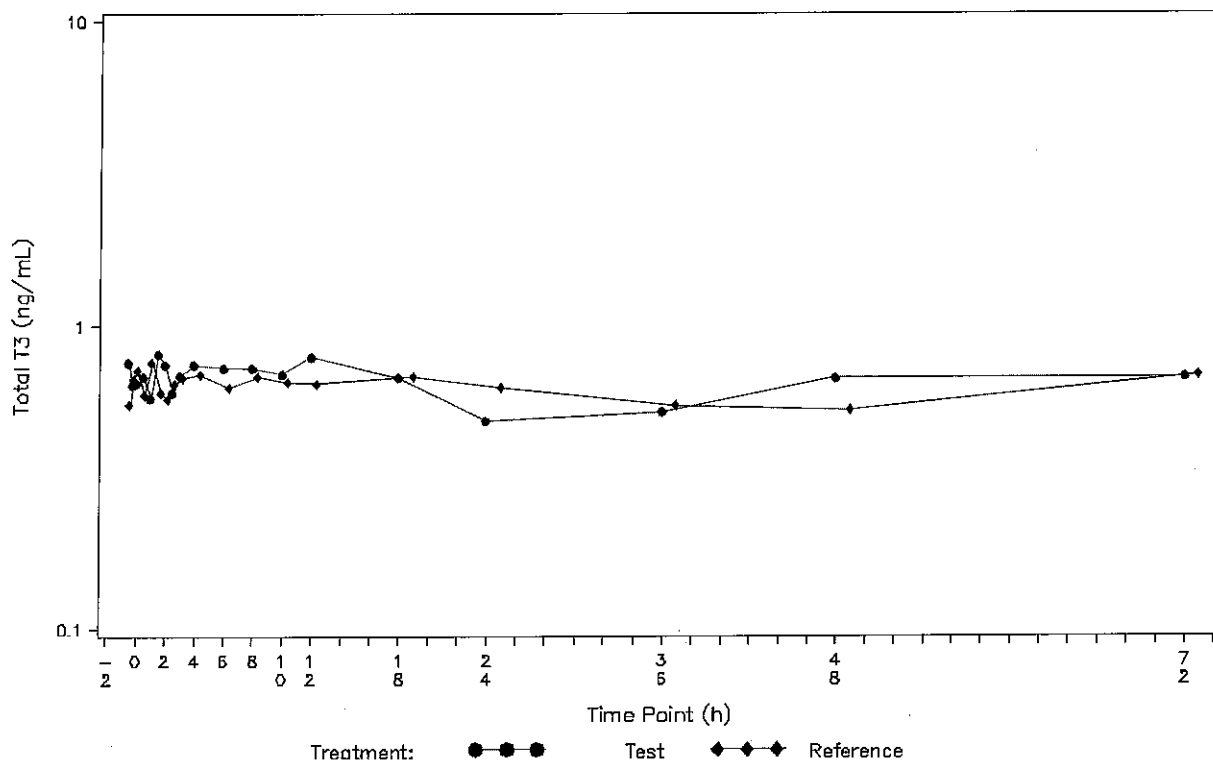


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: . . .



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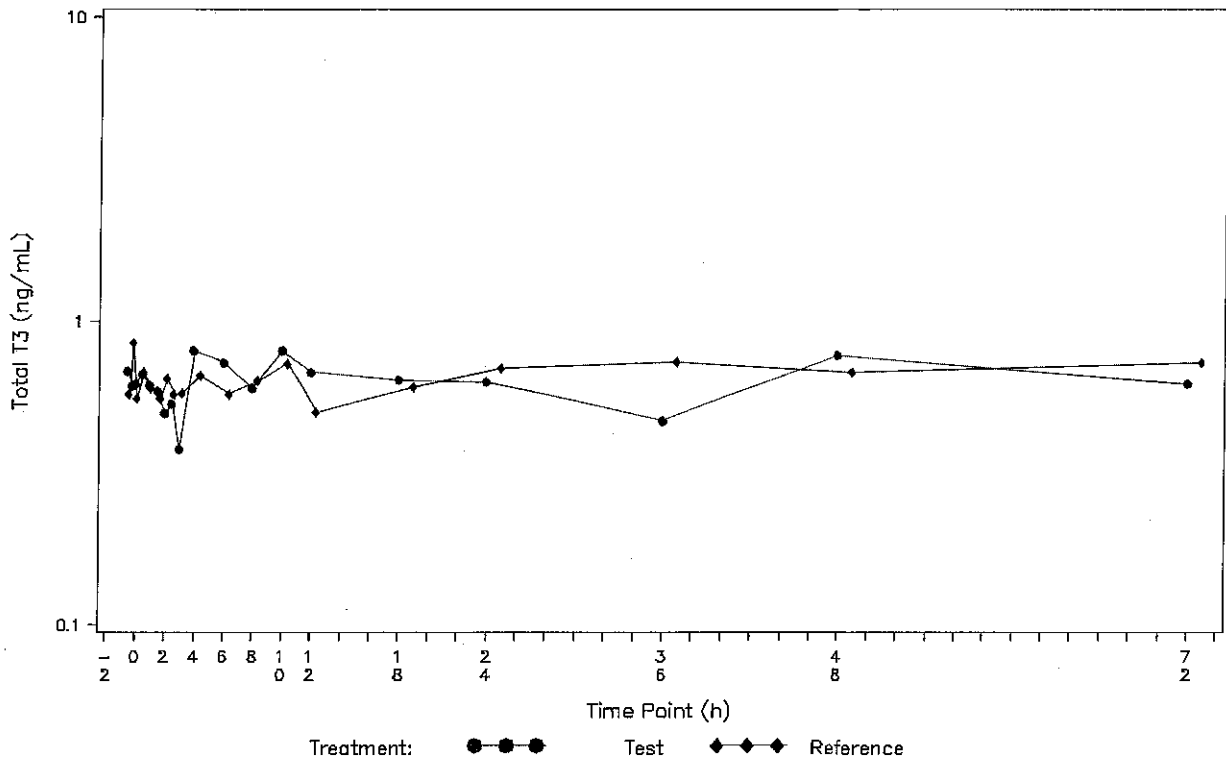
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



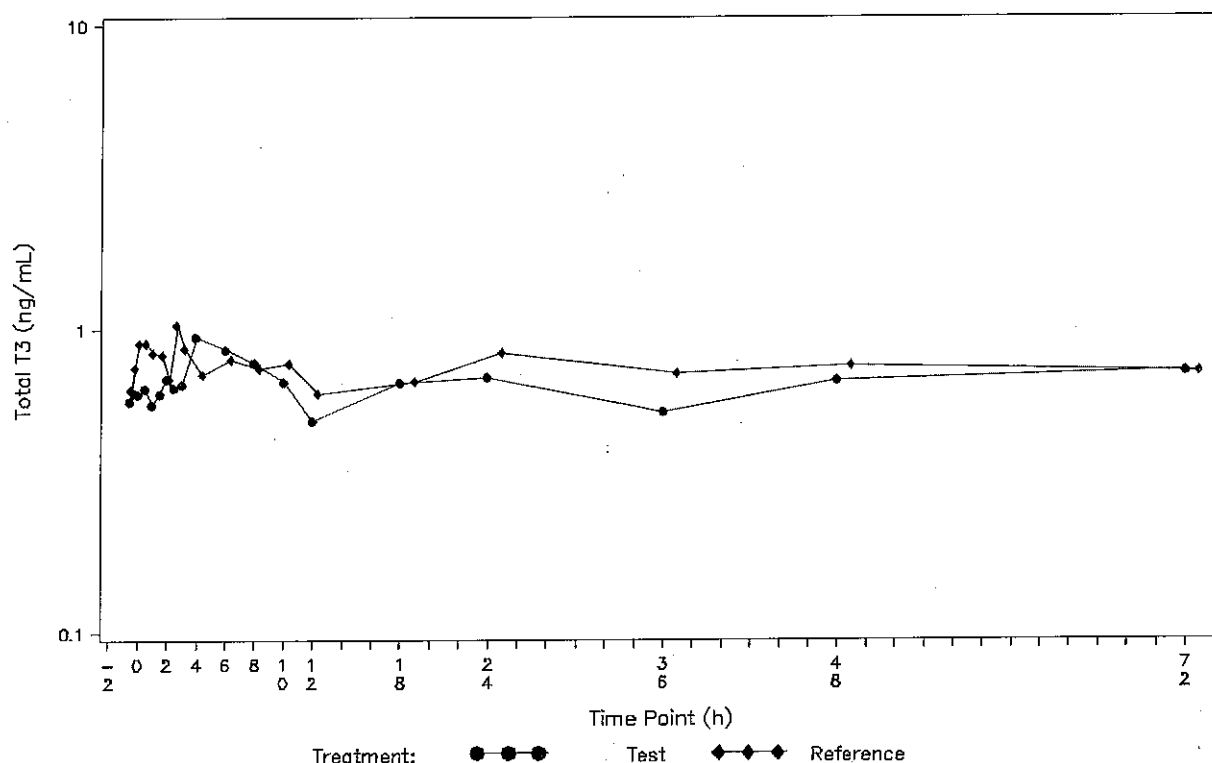
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(For Total T3 values) (Safety Population)

Subject ID/Random Number:



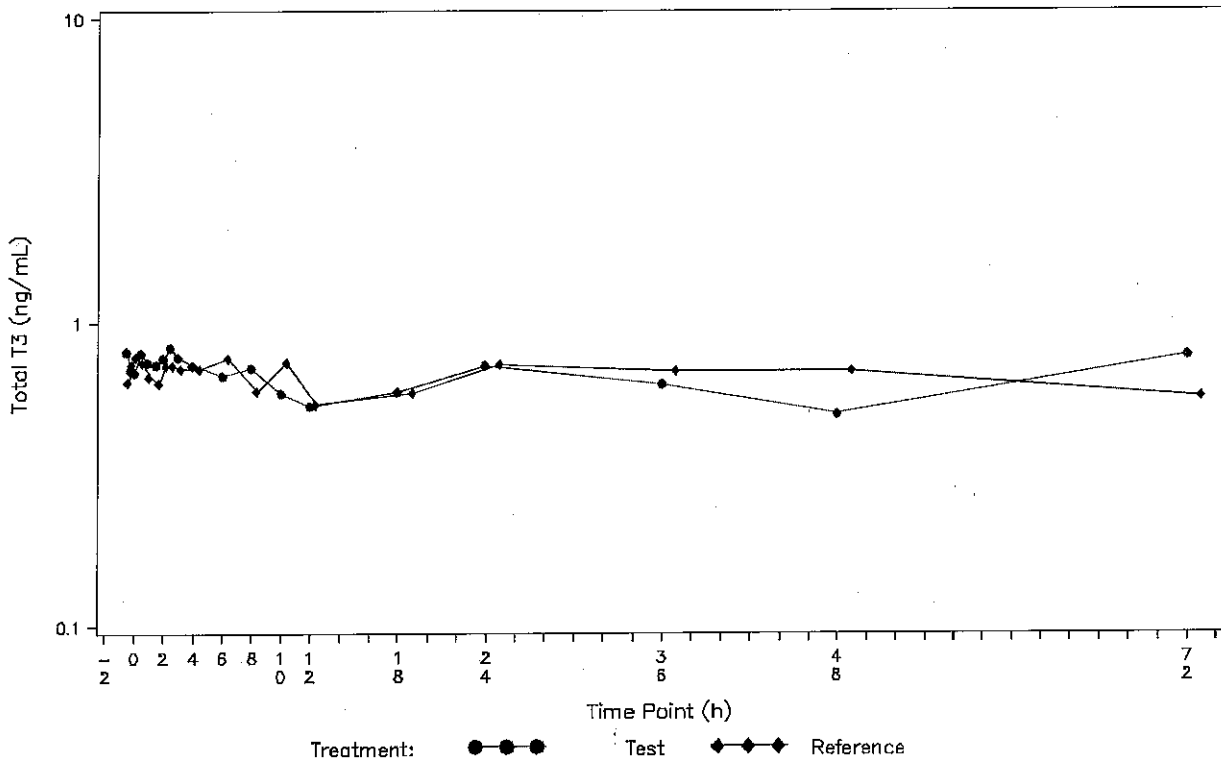
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(For Total T3 values) (Safety Population)

Subject ID/Random Number:



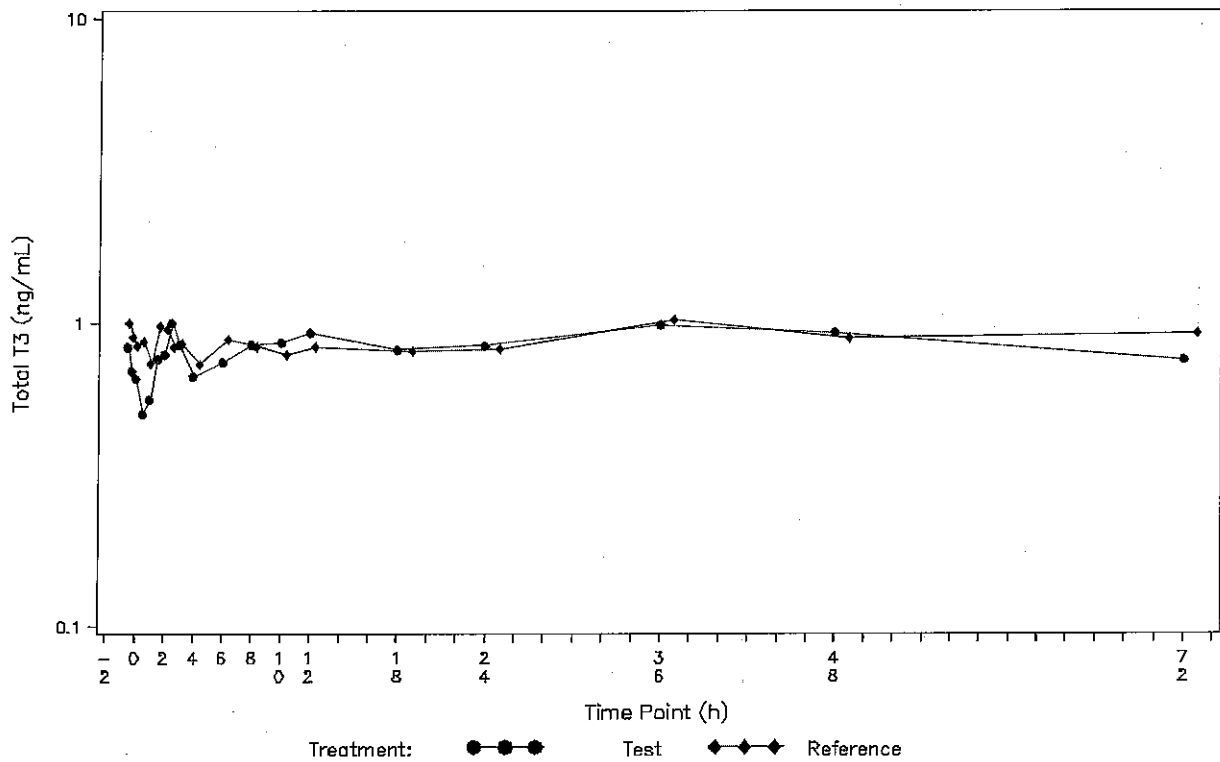
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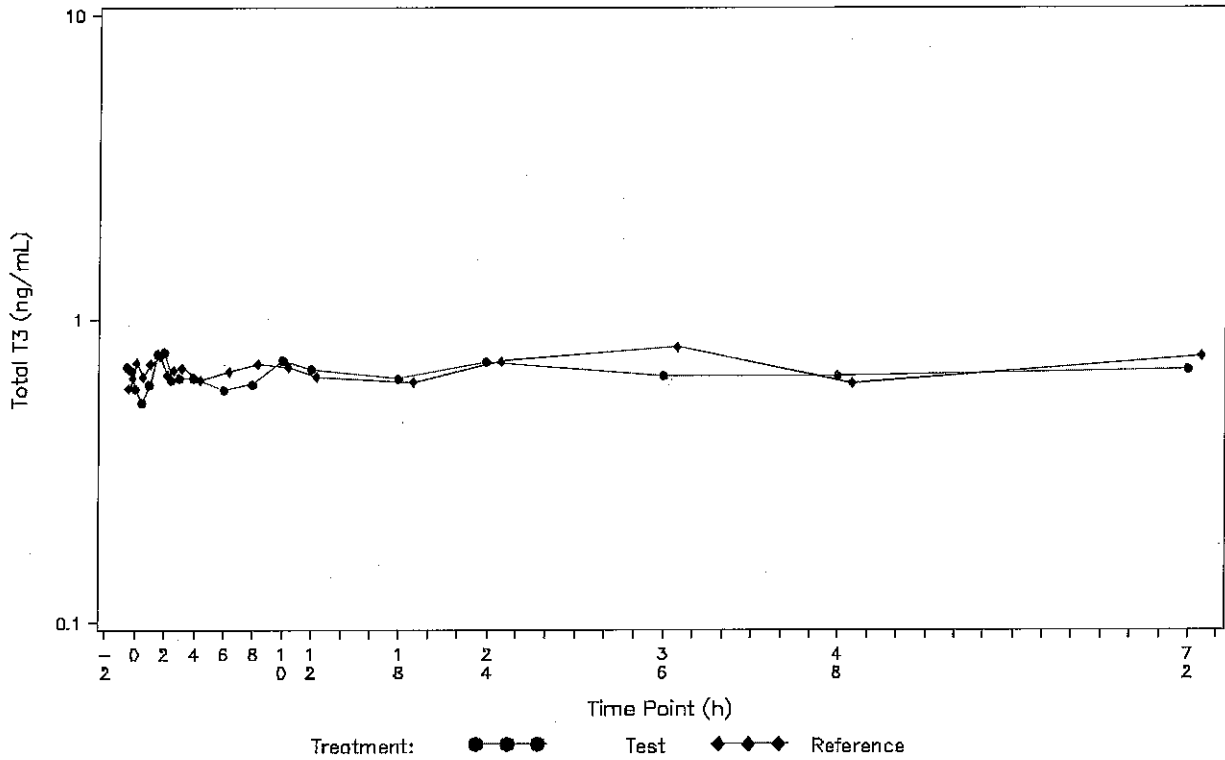
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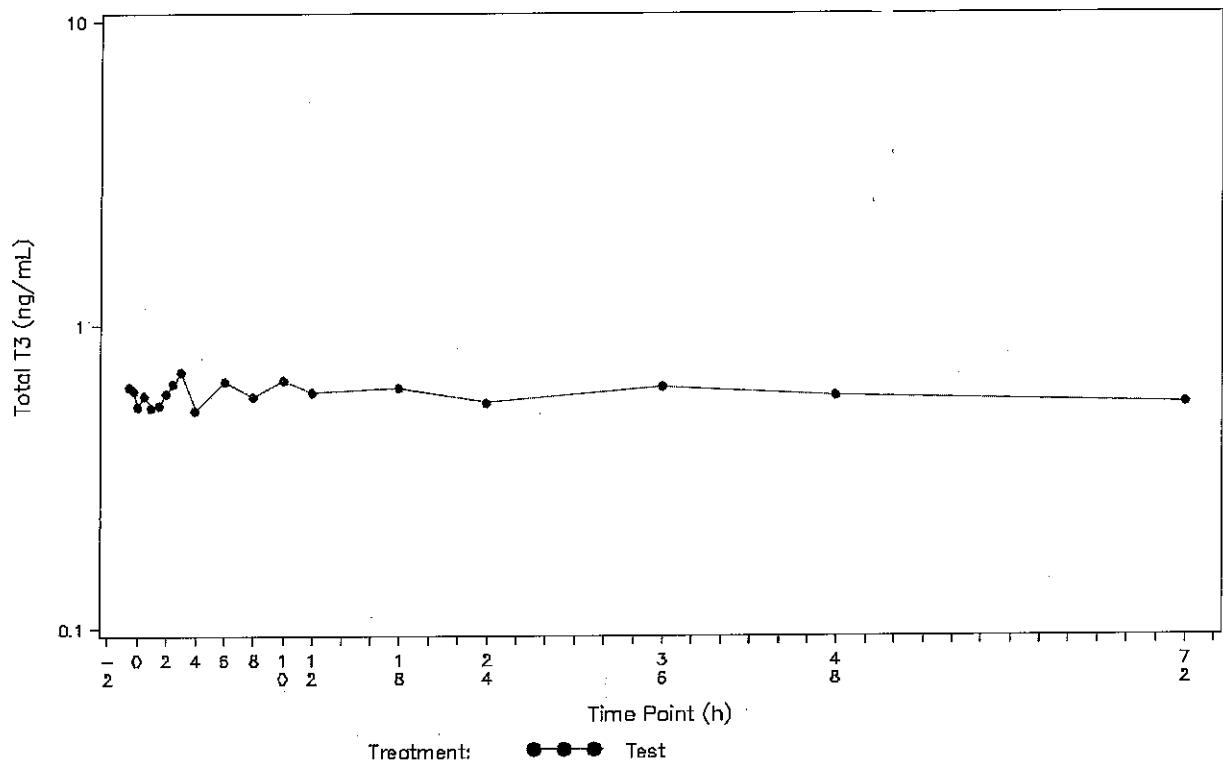


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



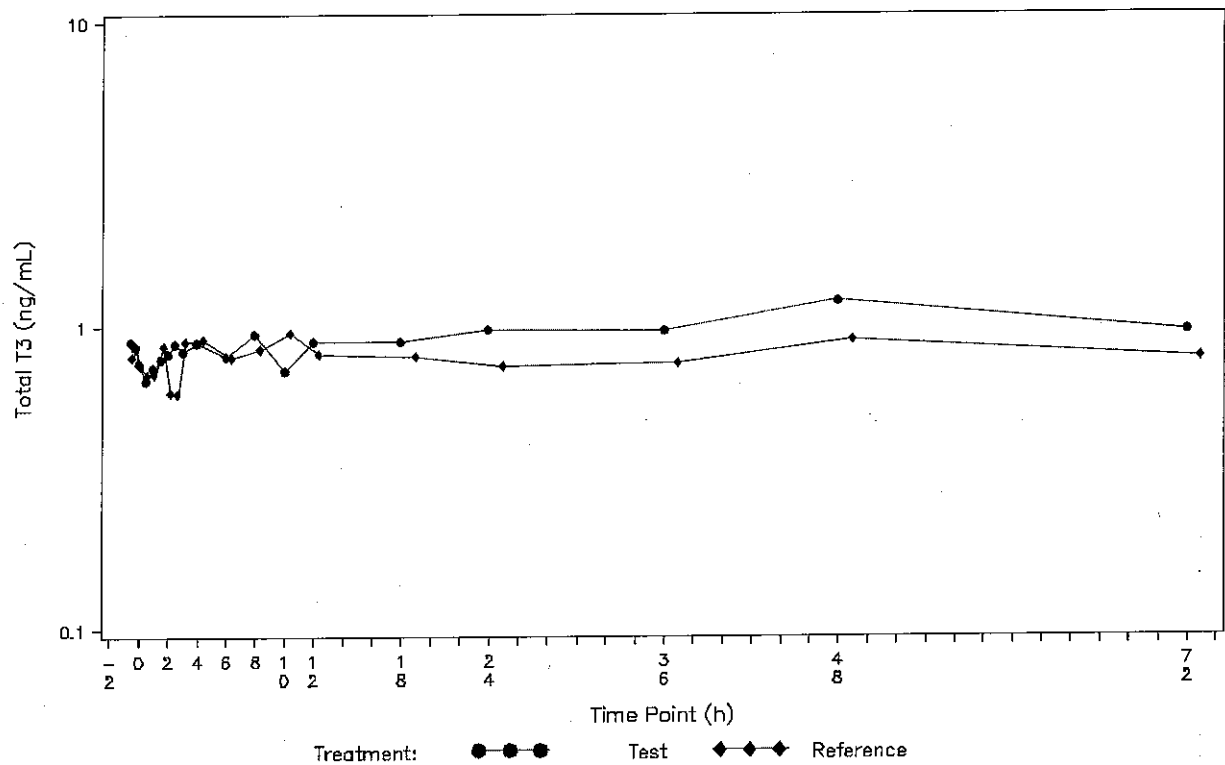
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



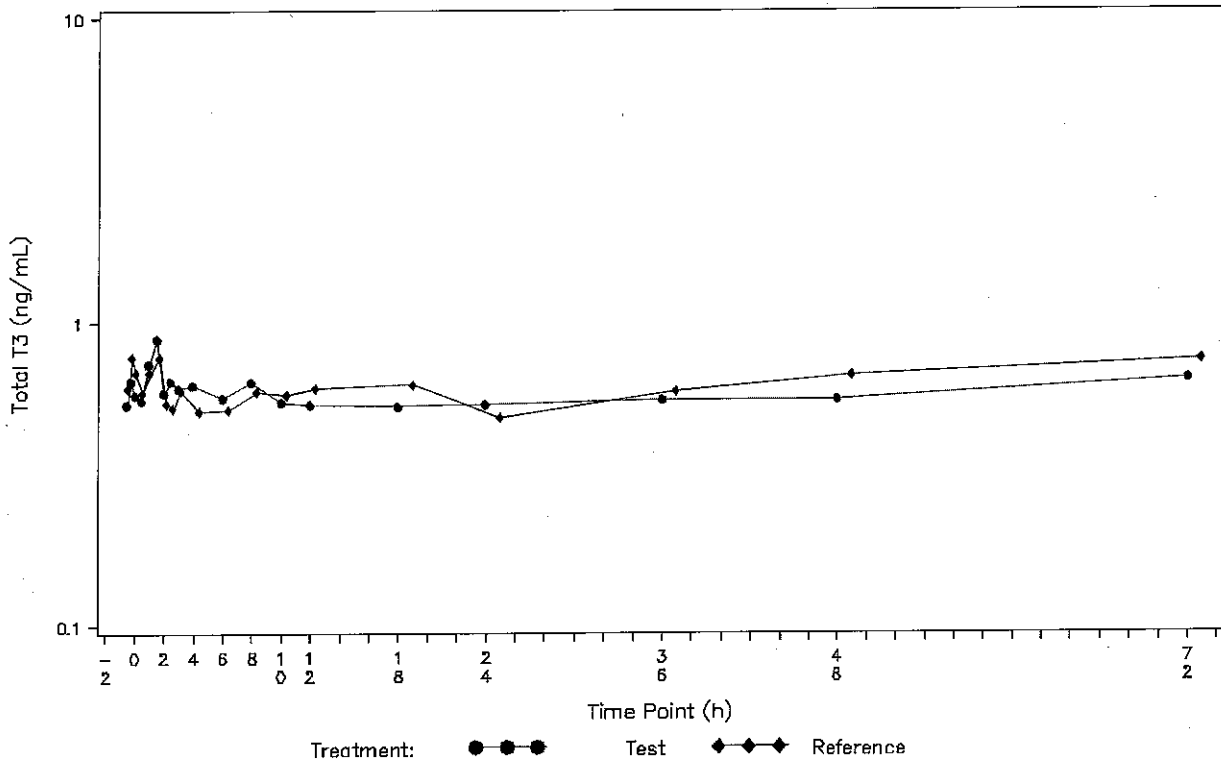
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



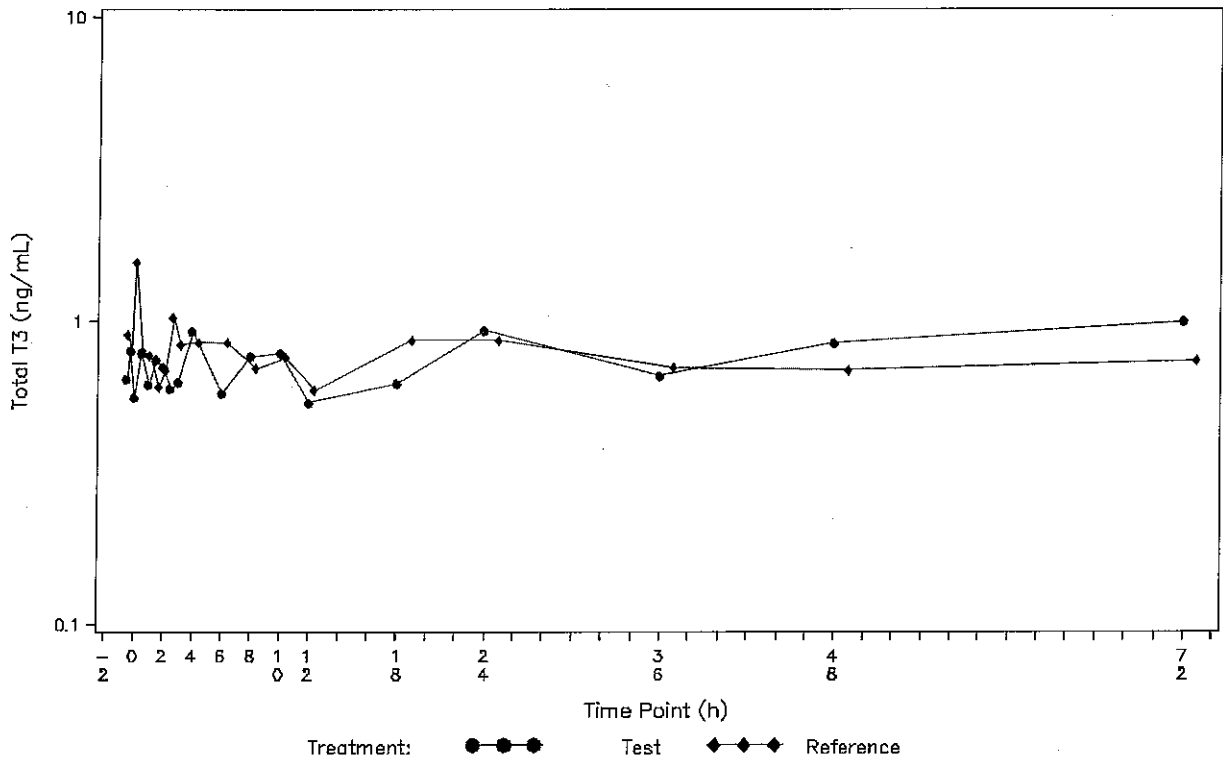
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

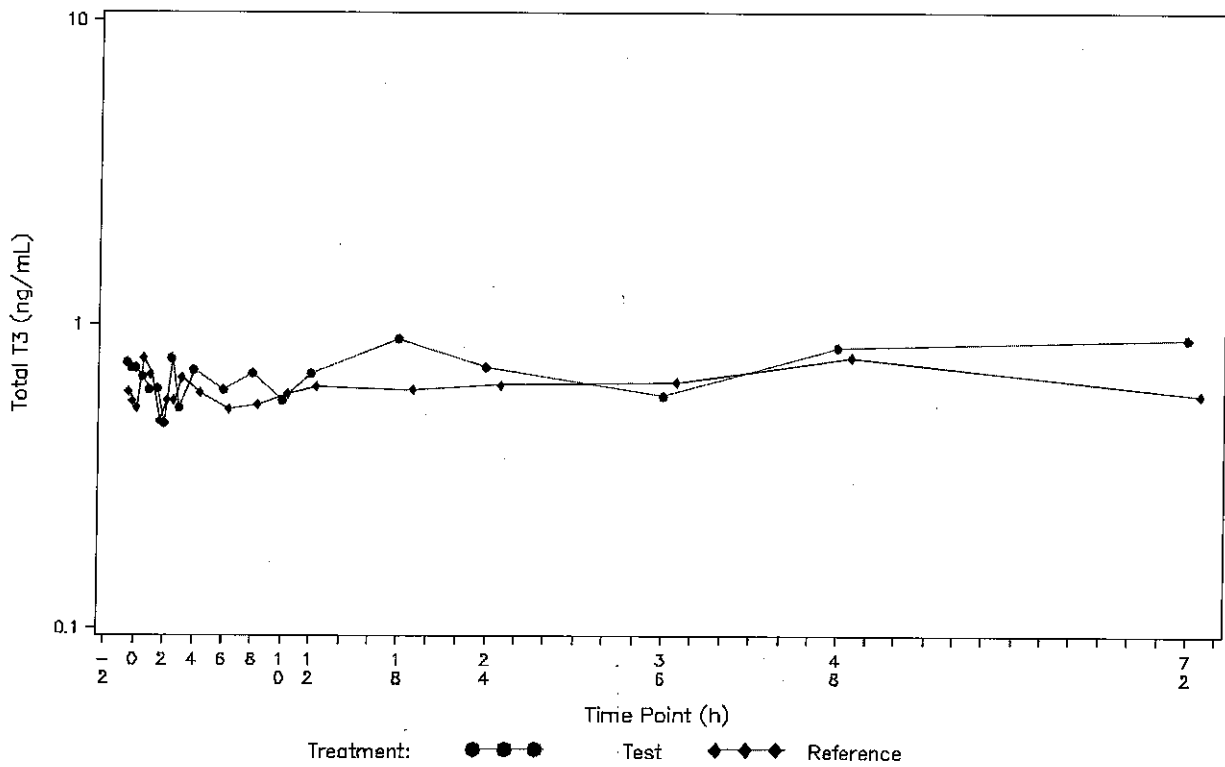
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15.4.2.12.sas



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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:

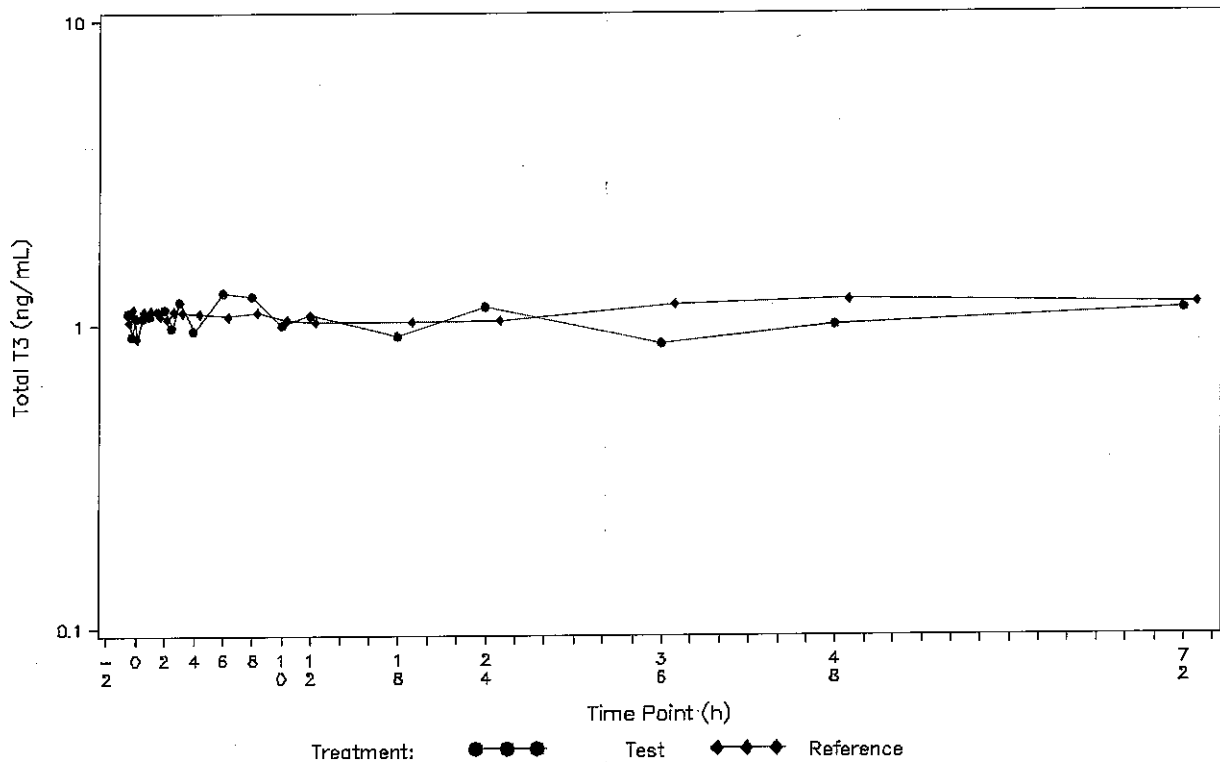


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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



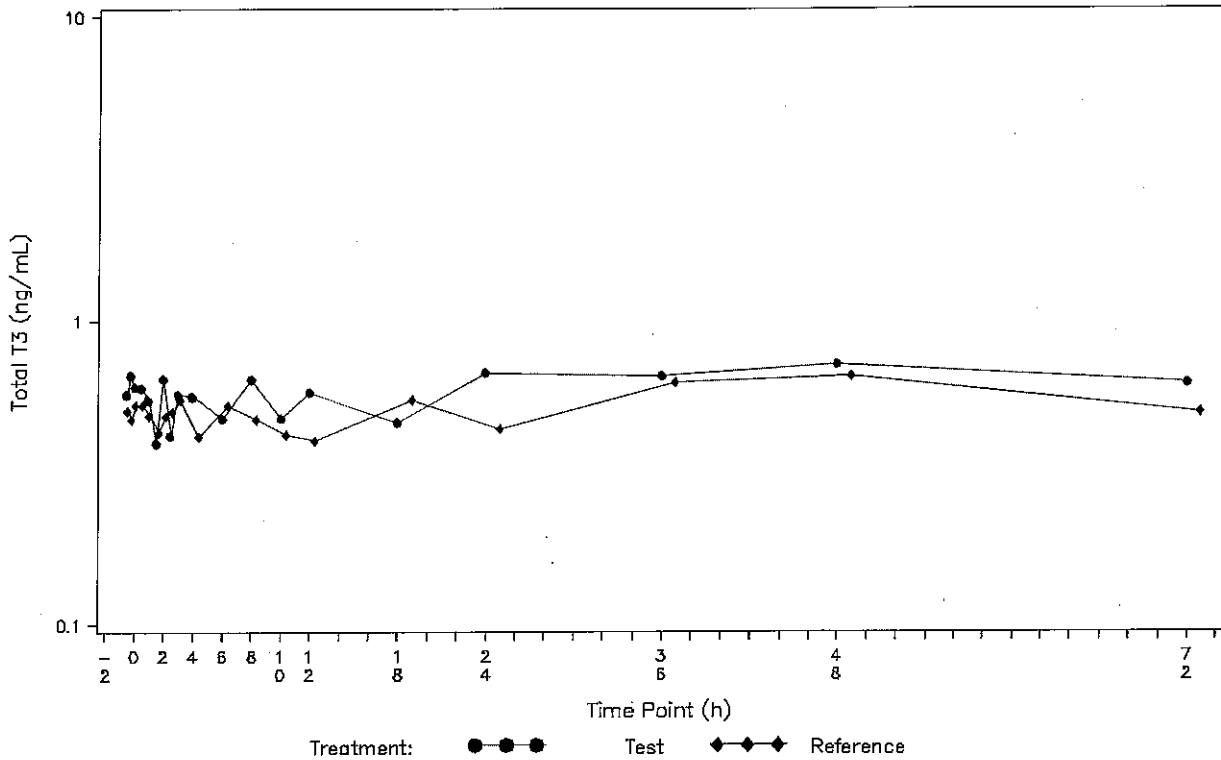
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



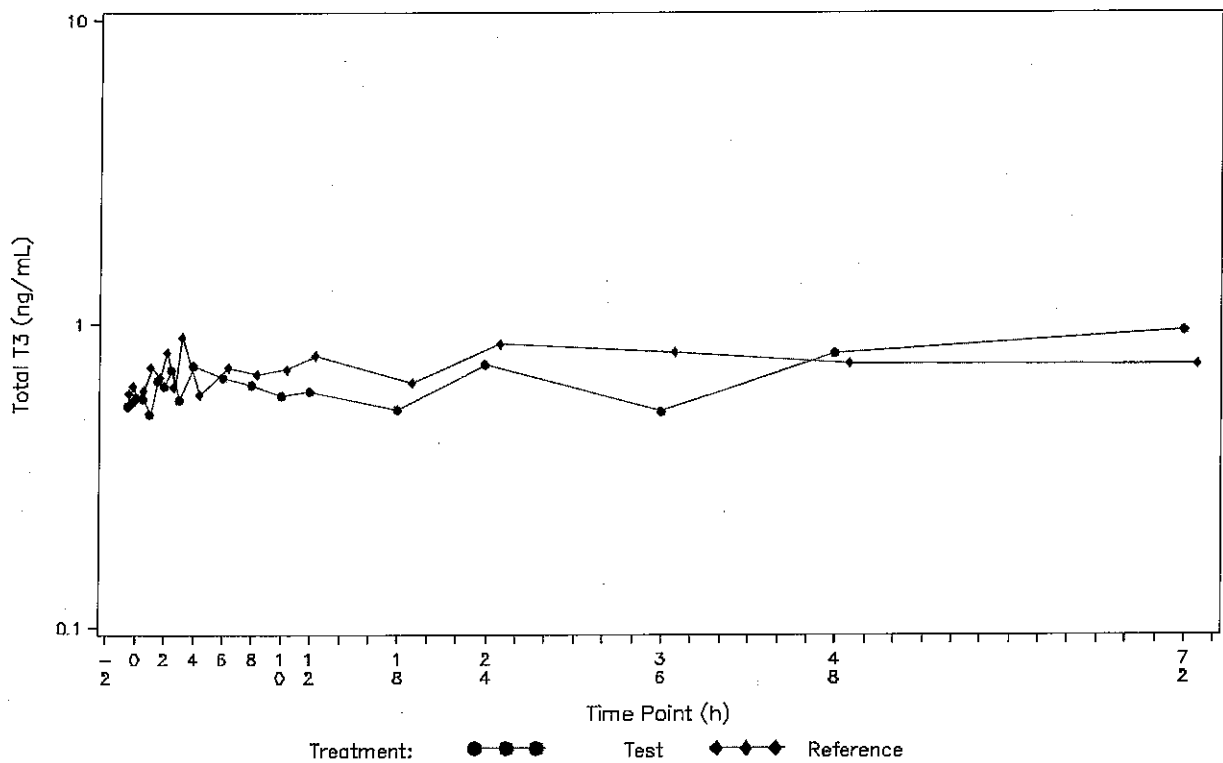
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



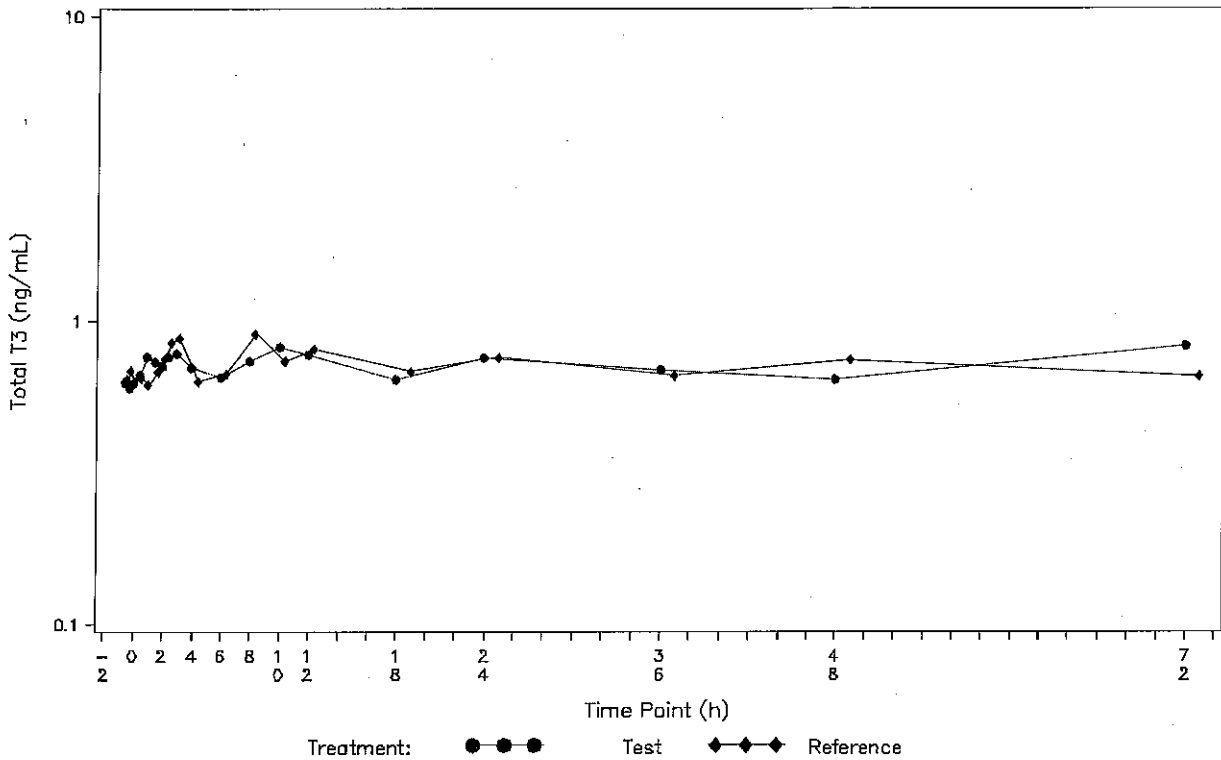
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



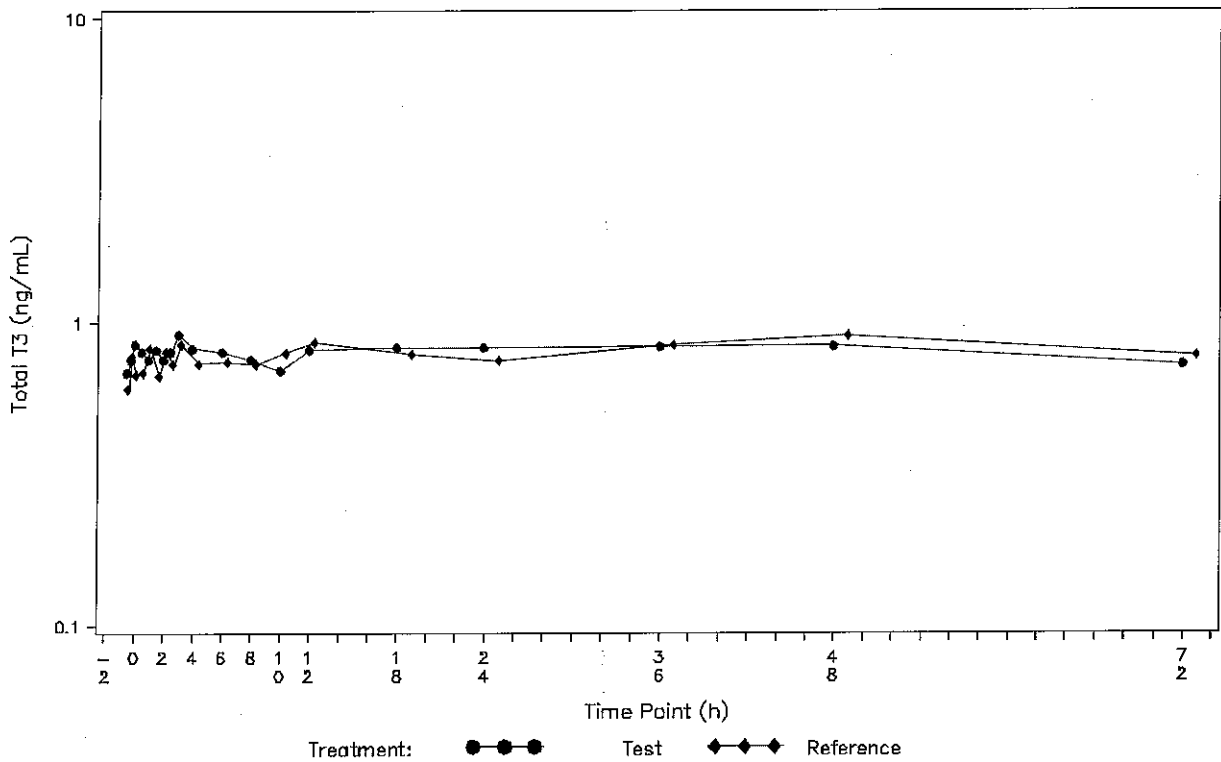
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Source: Table 16.2.5.3

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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

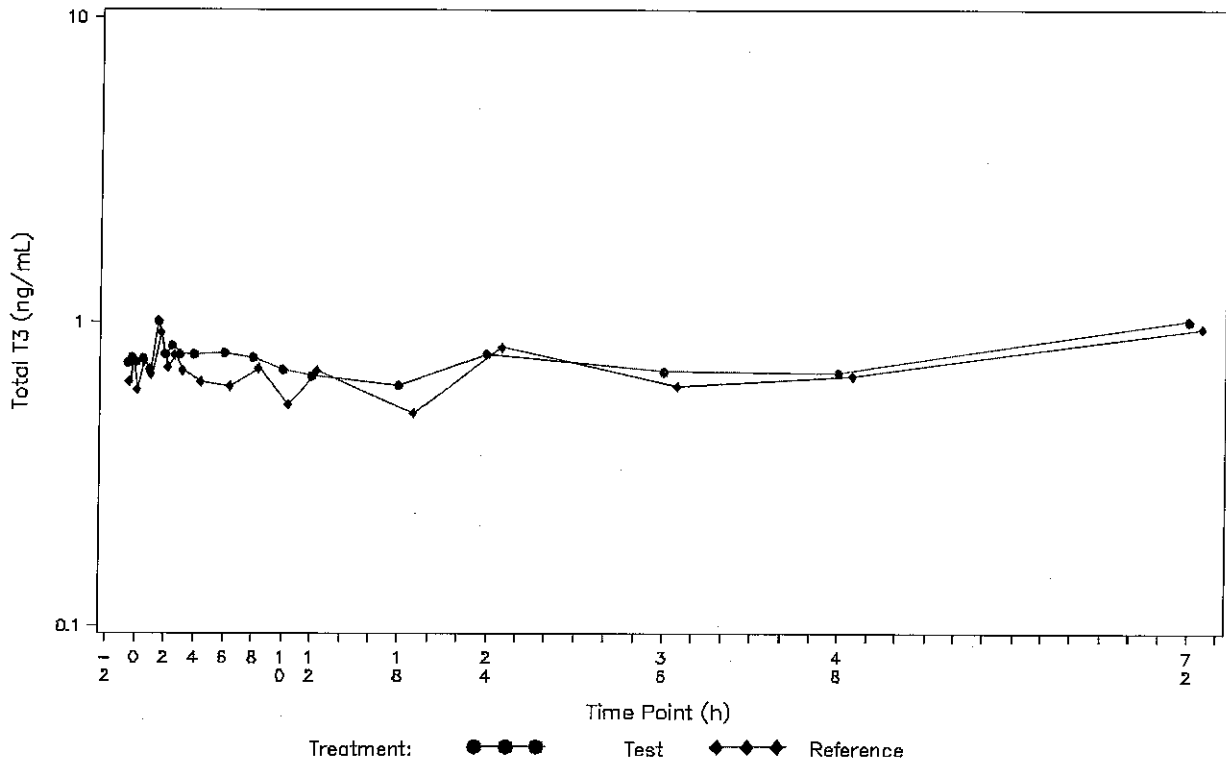


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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: .

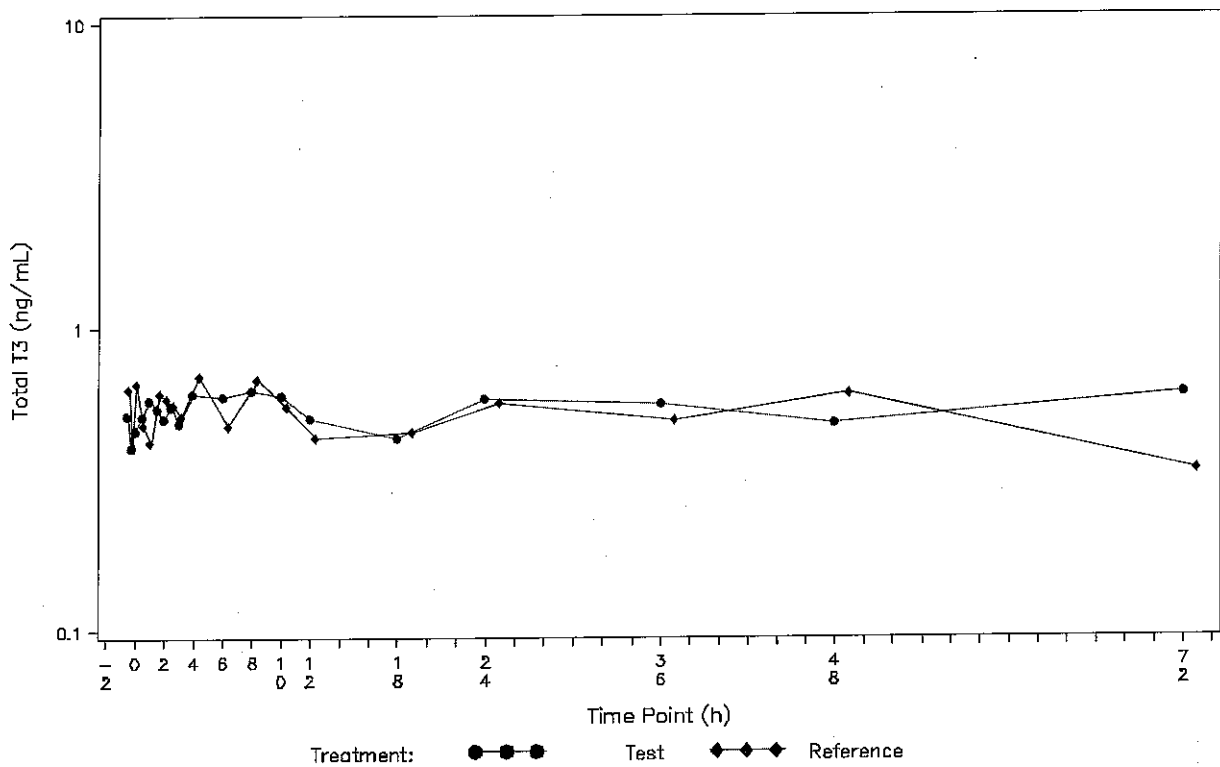


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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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15.4.2.12.sas

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: .



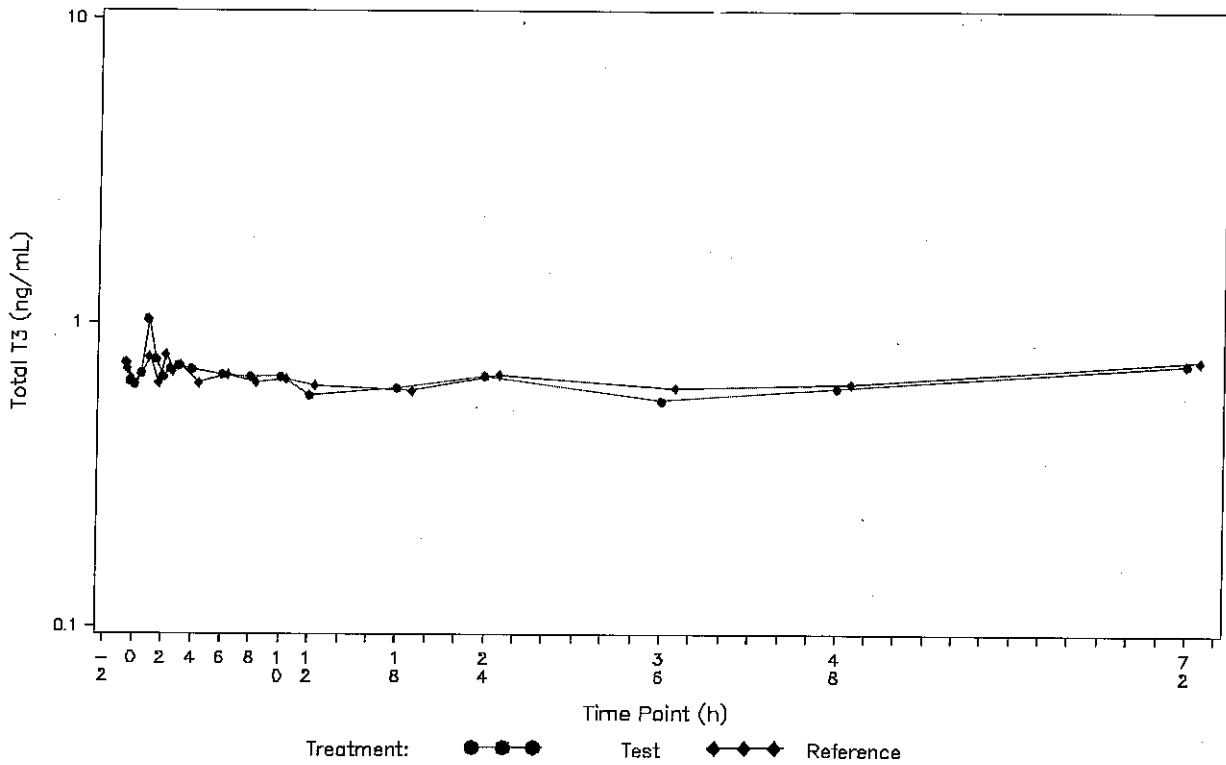
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



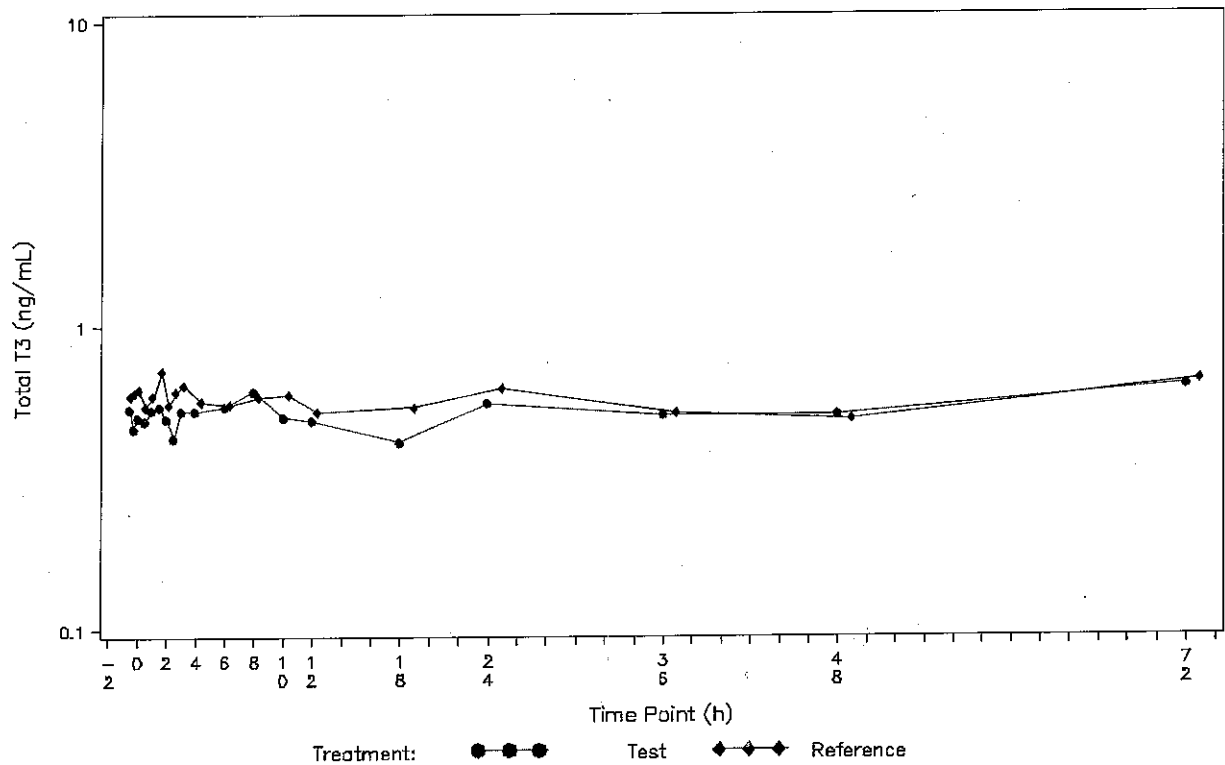
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



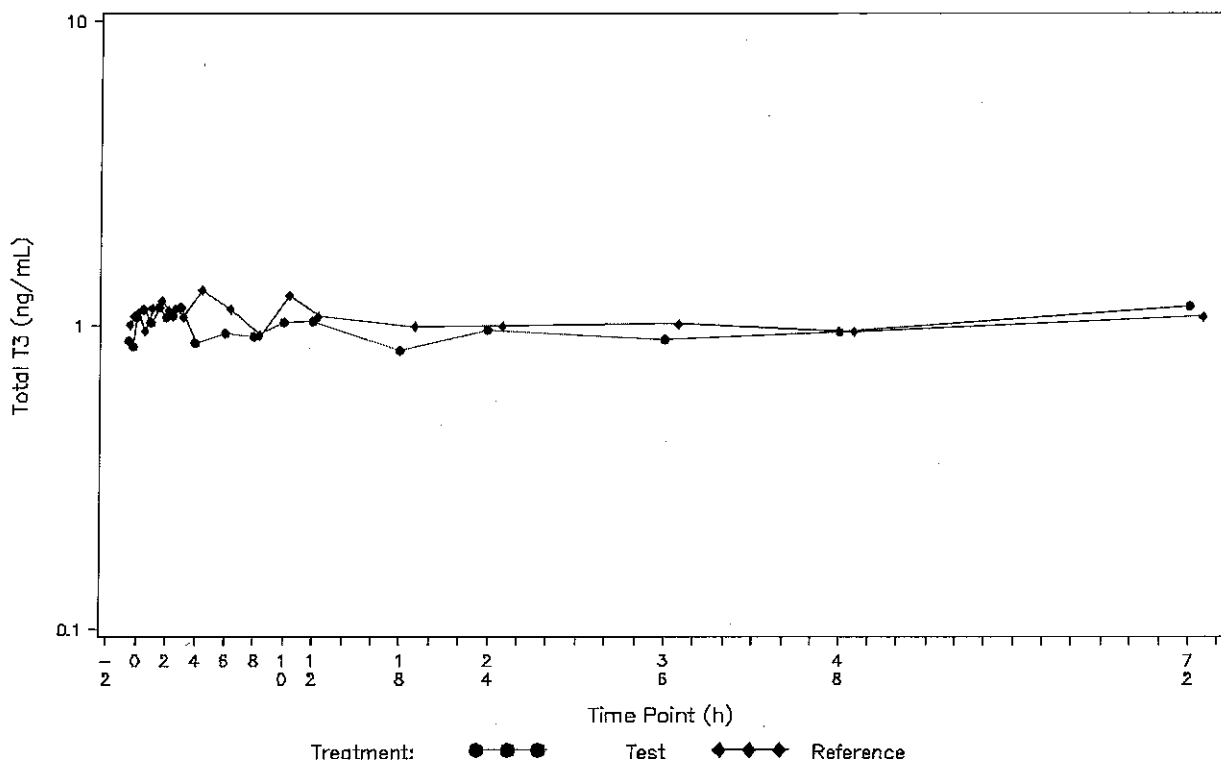
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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15.4.2.12.sas

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



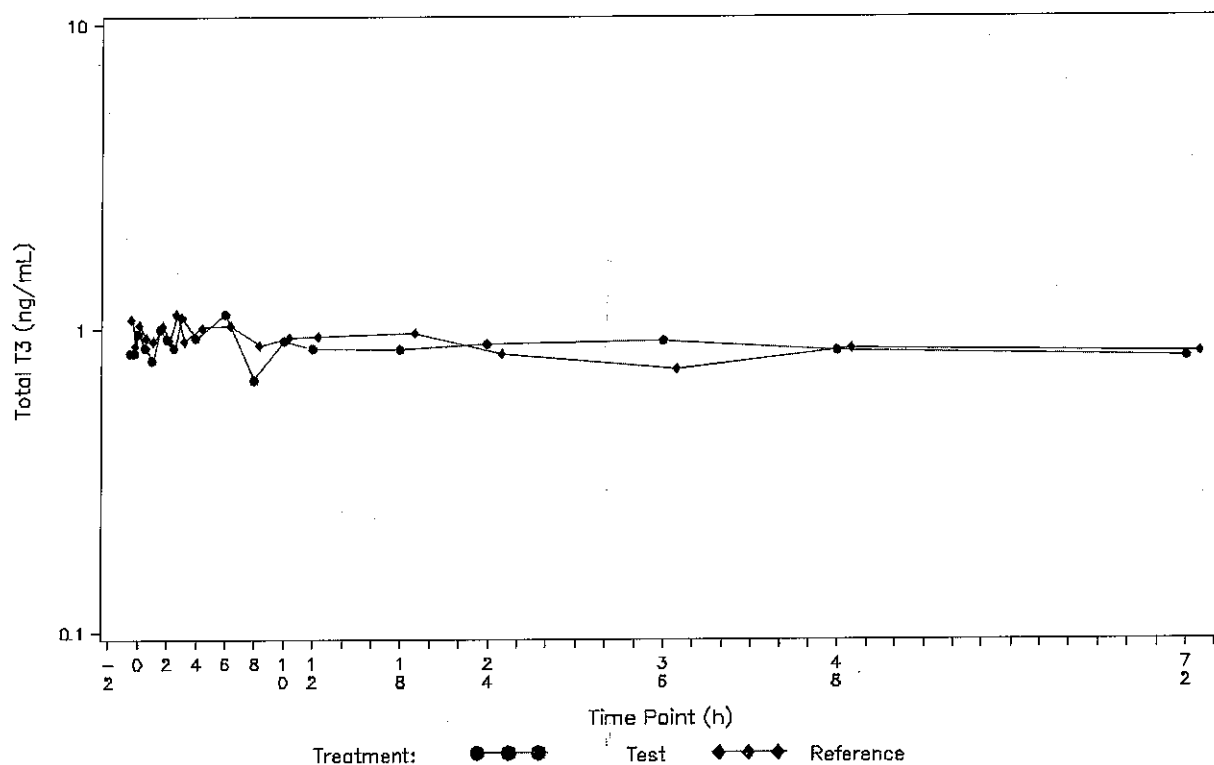
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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

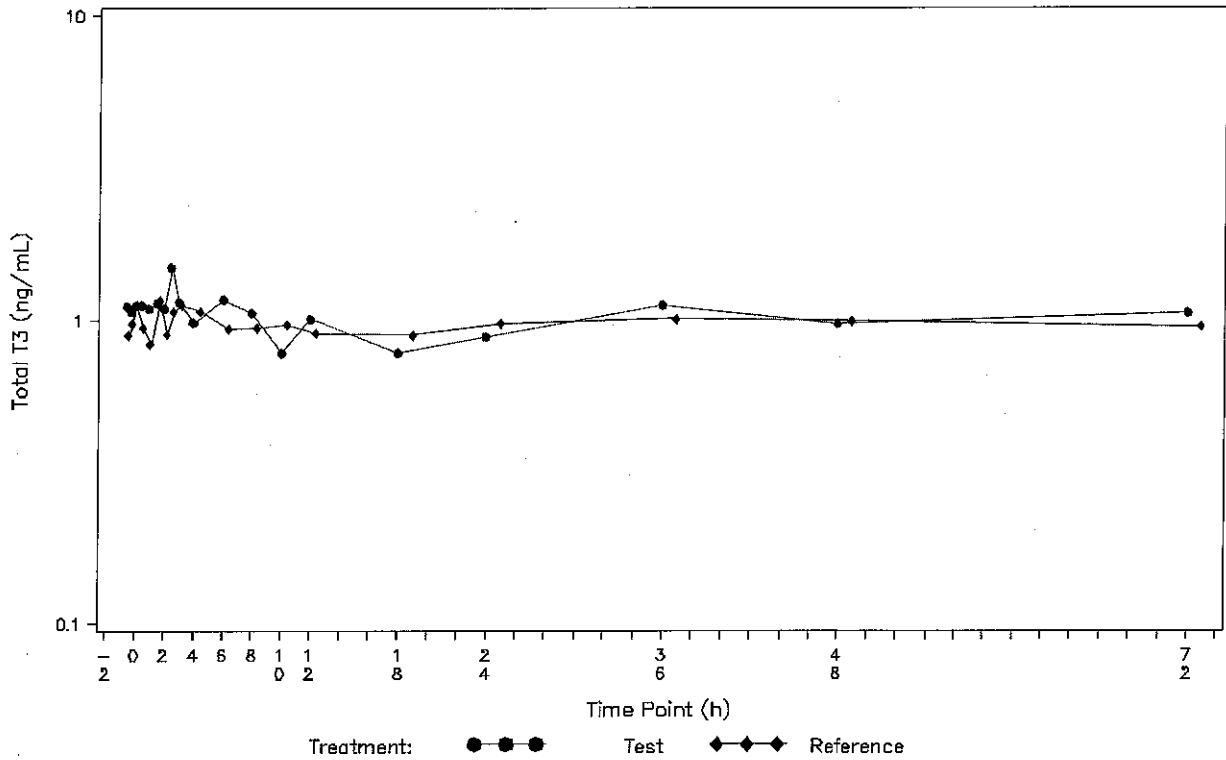
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

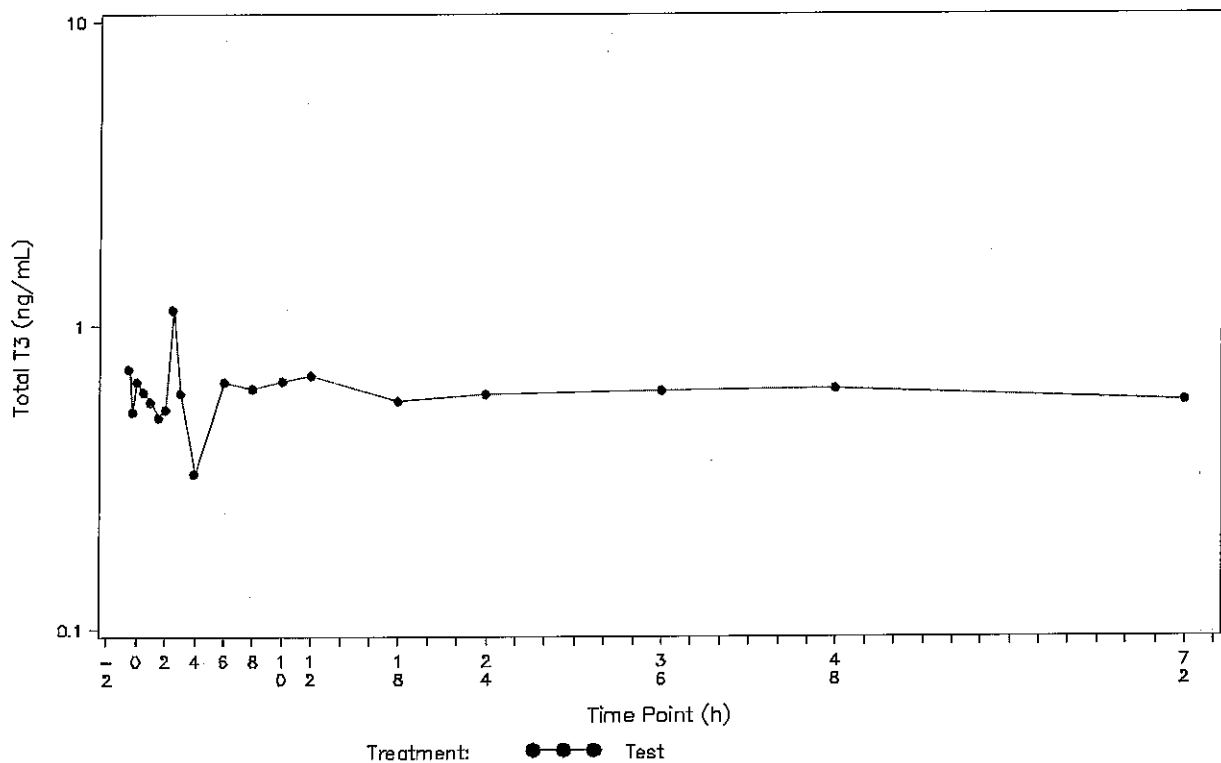


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

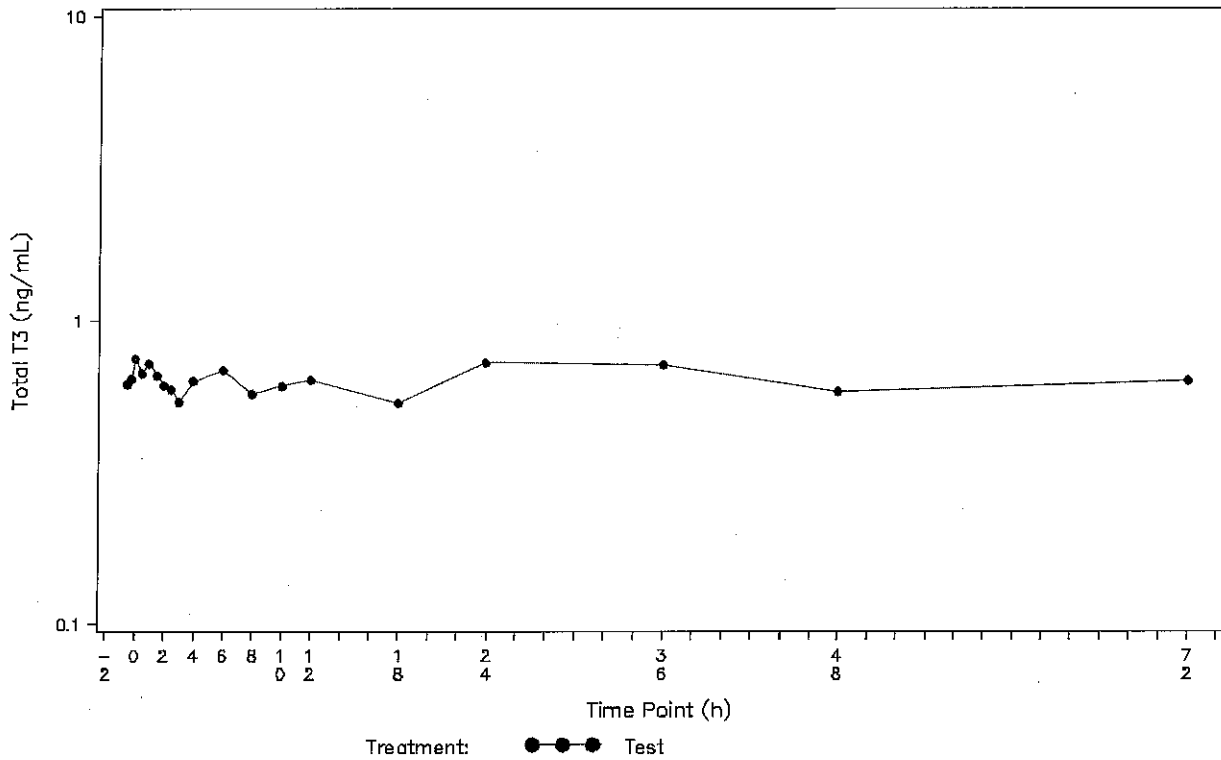
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



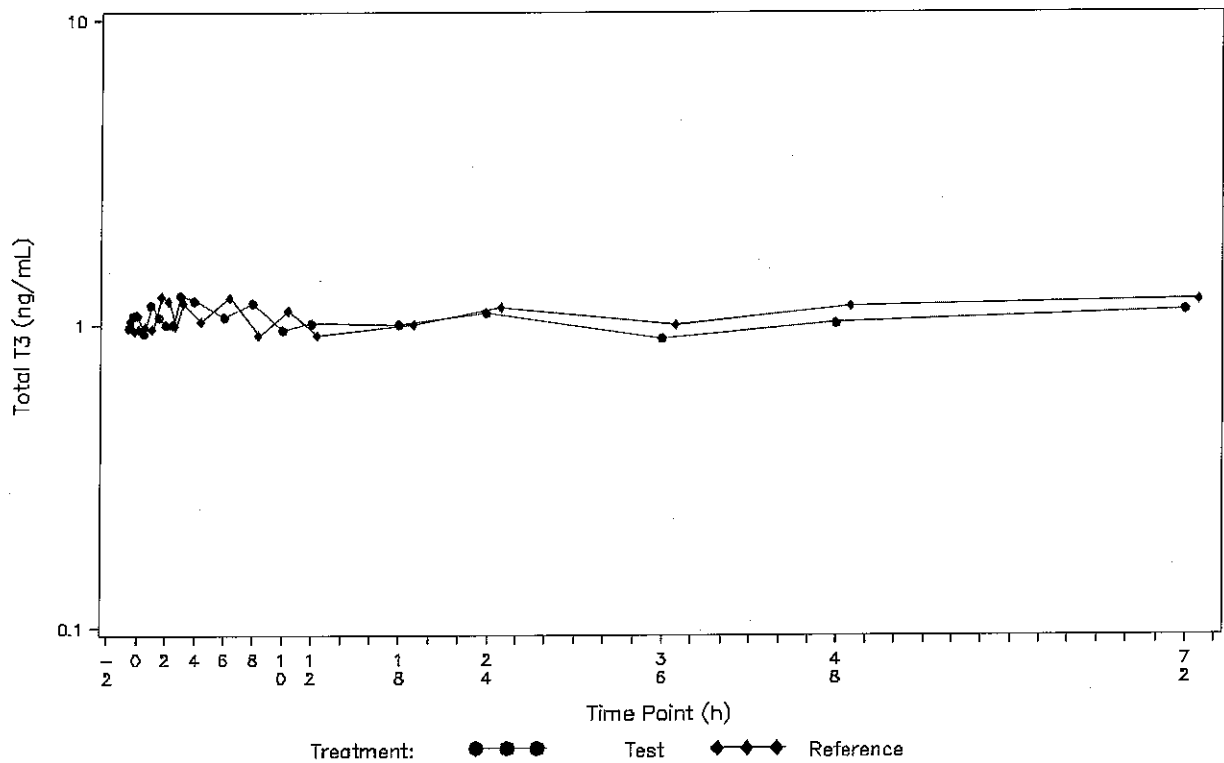
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15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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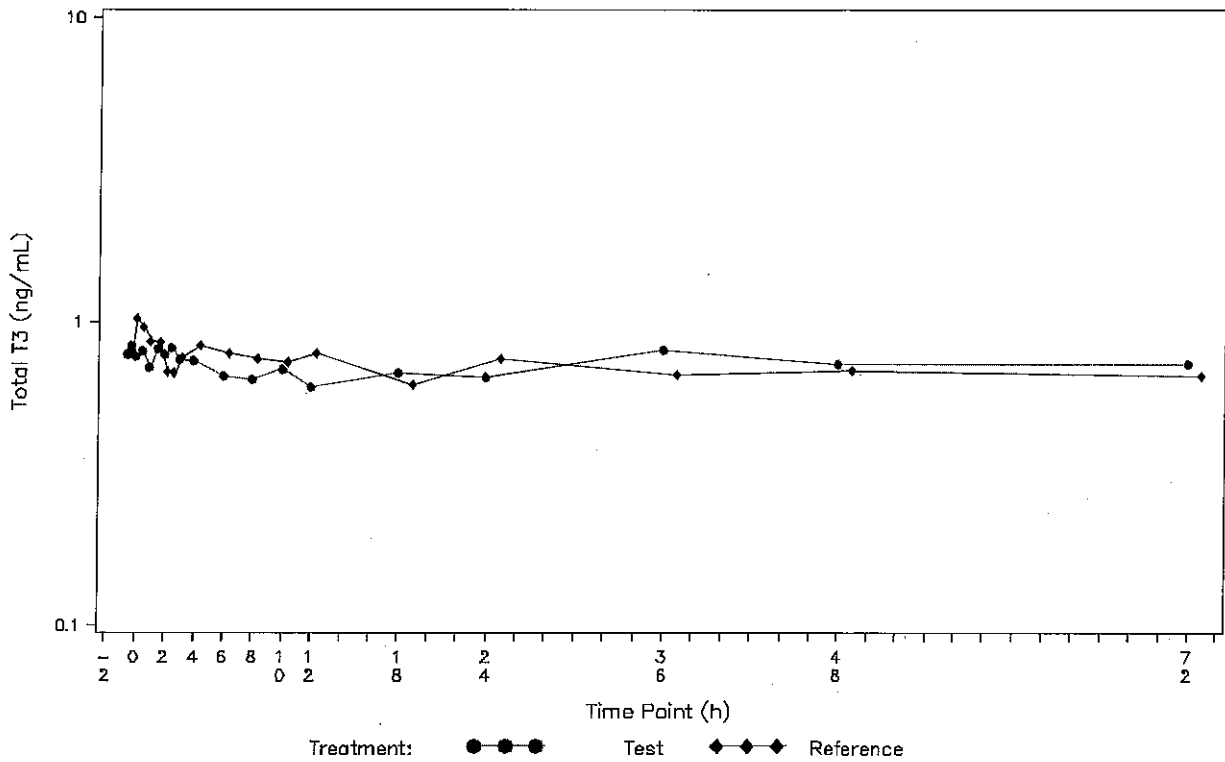
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



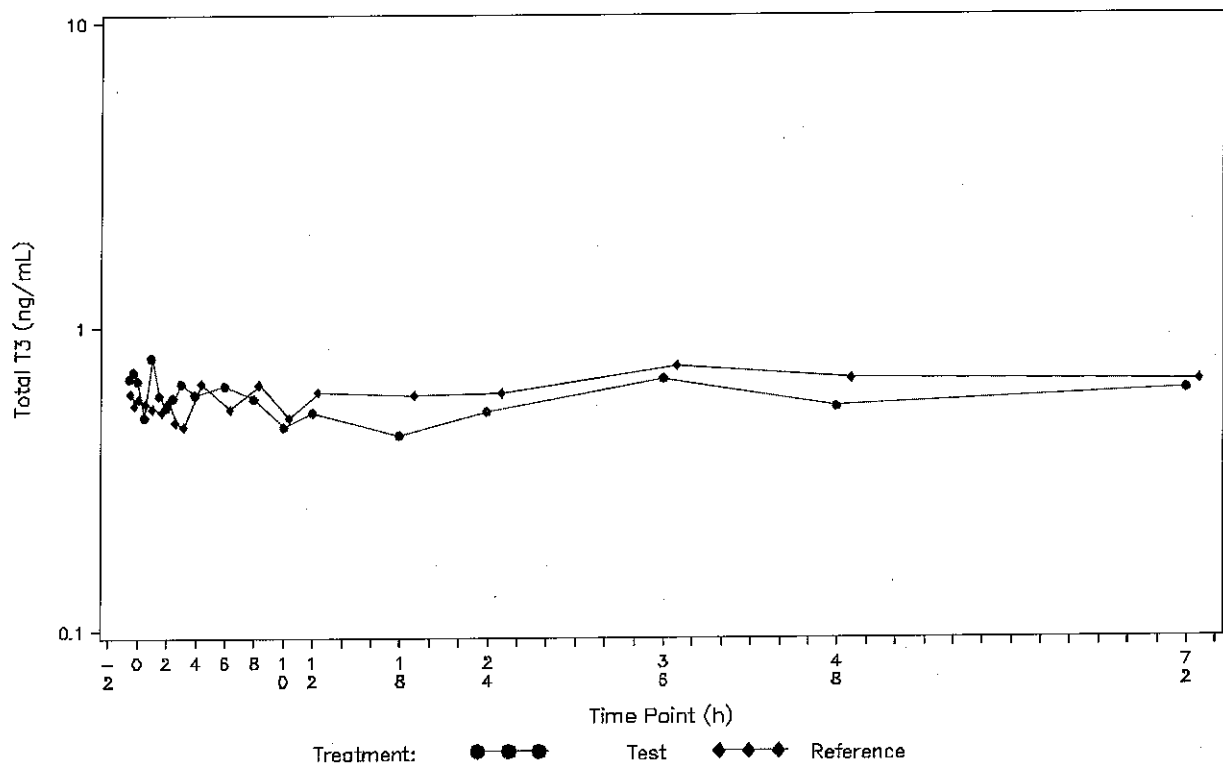
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Source: Table 16.2.5.3

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:

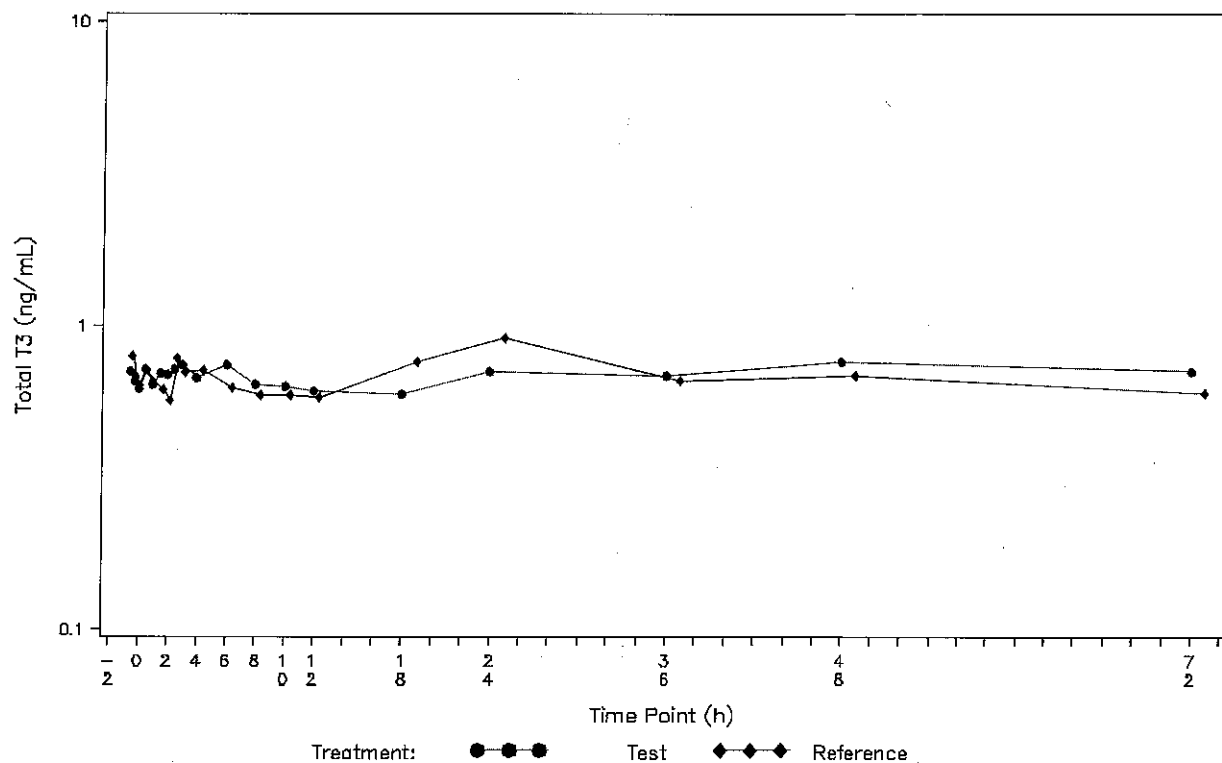


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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

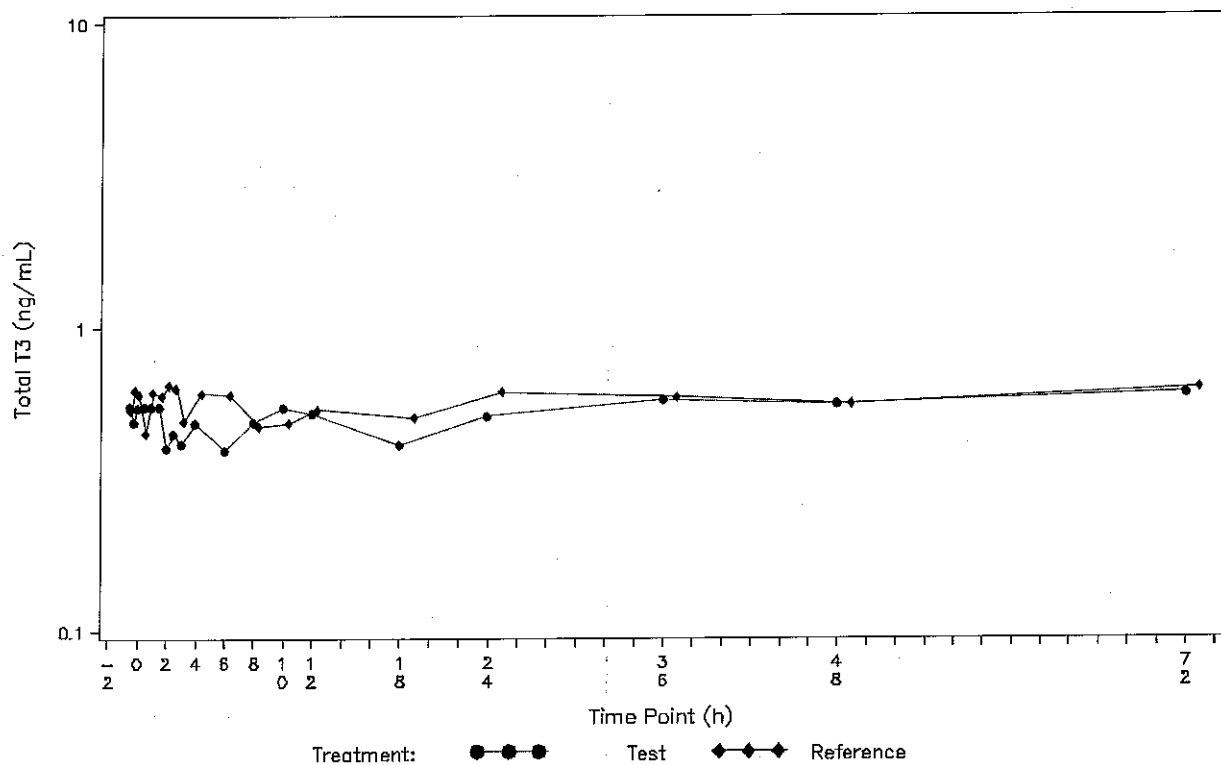
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



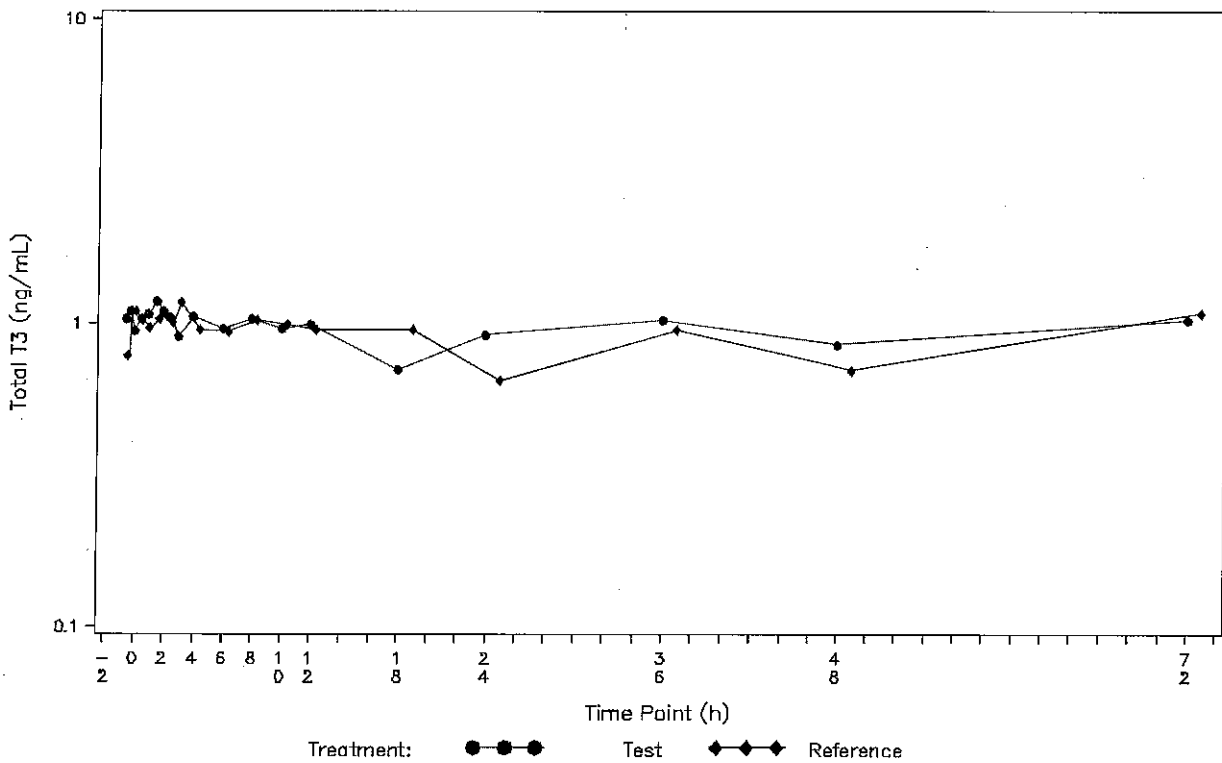
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15.4.2.12.sas

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



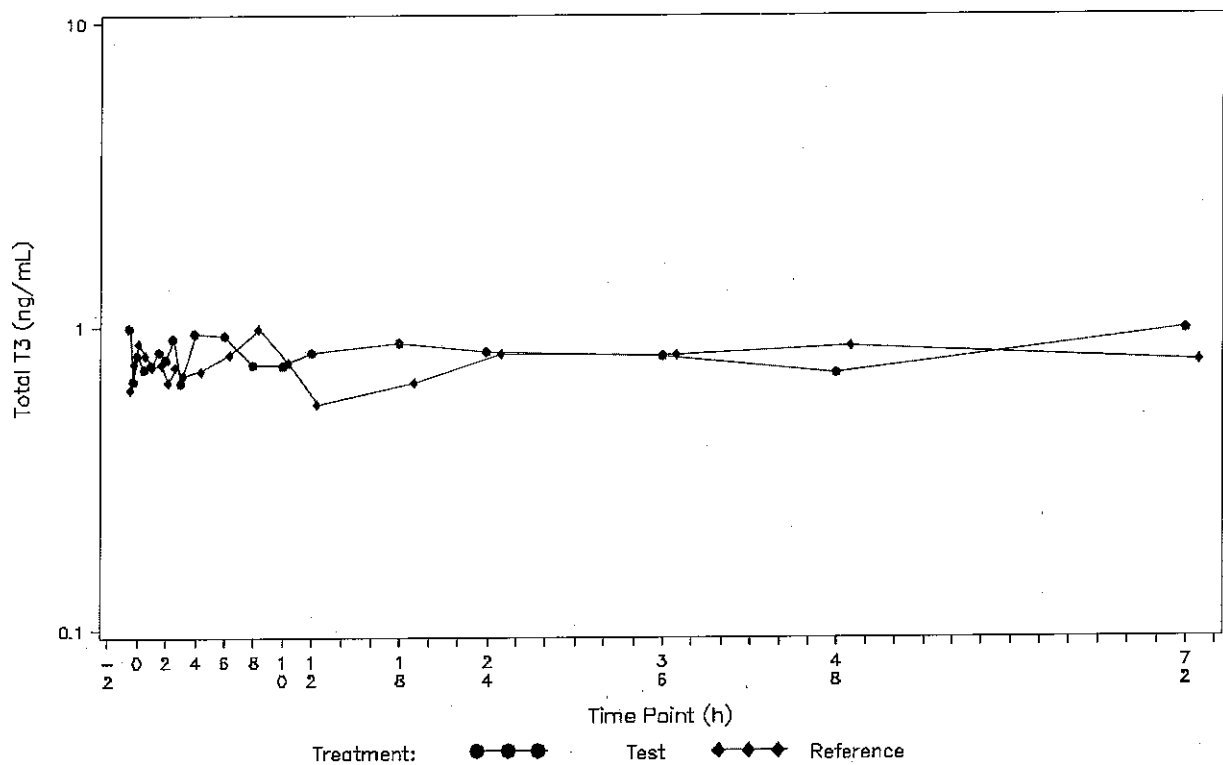
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



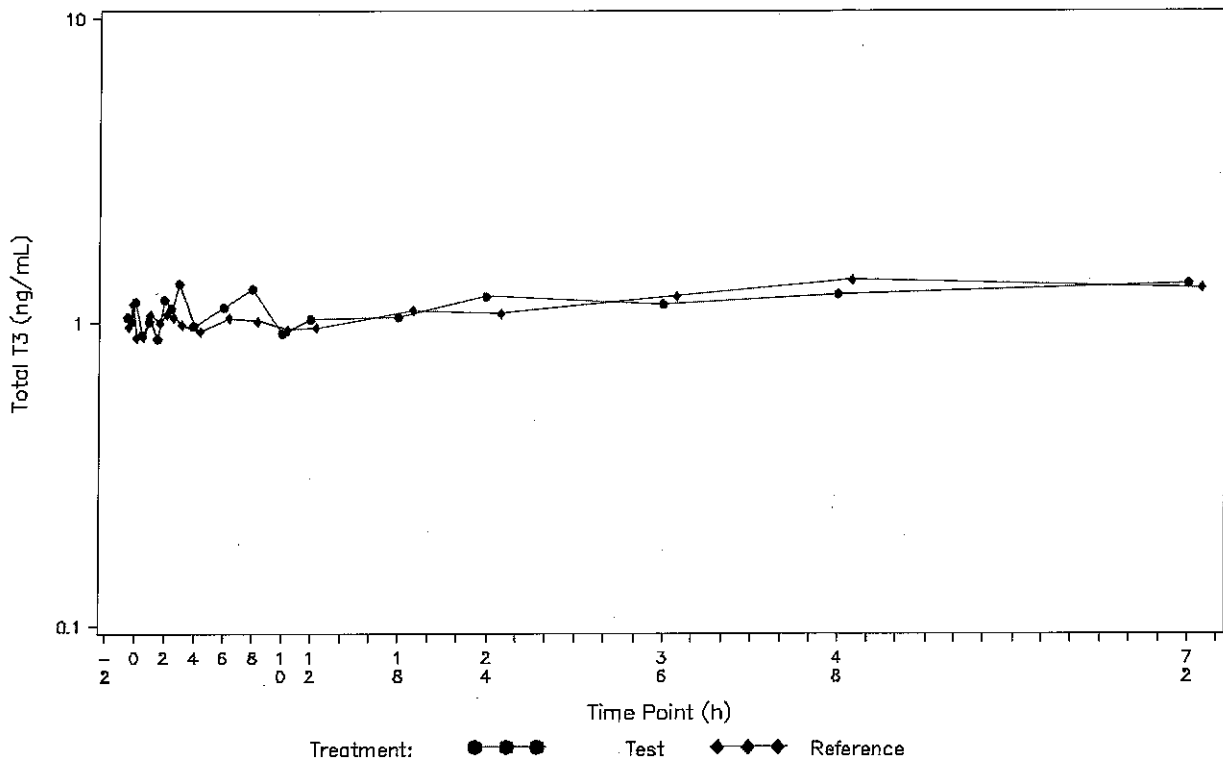
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Source: Table 16.2.5.3

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: .

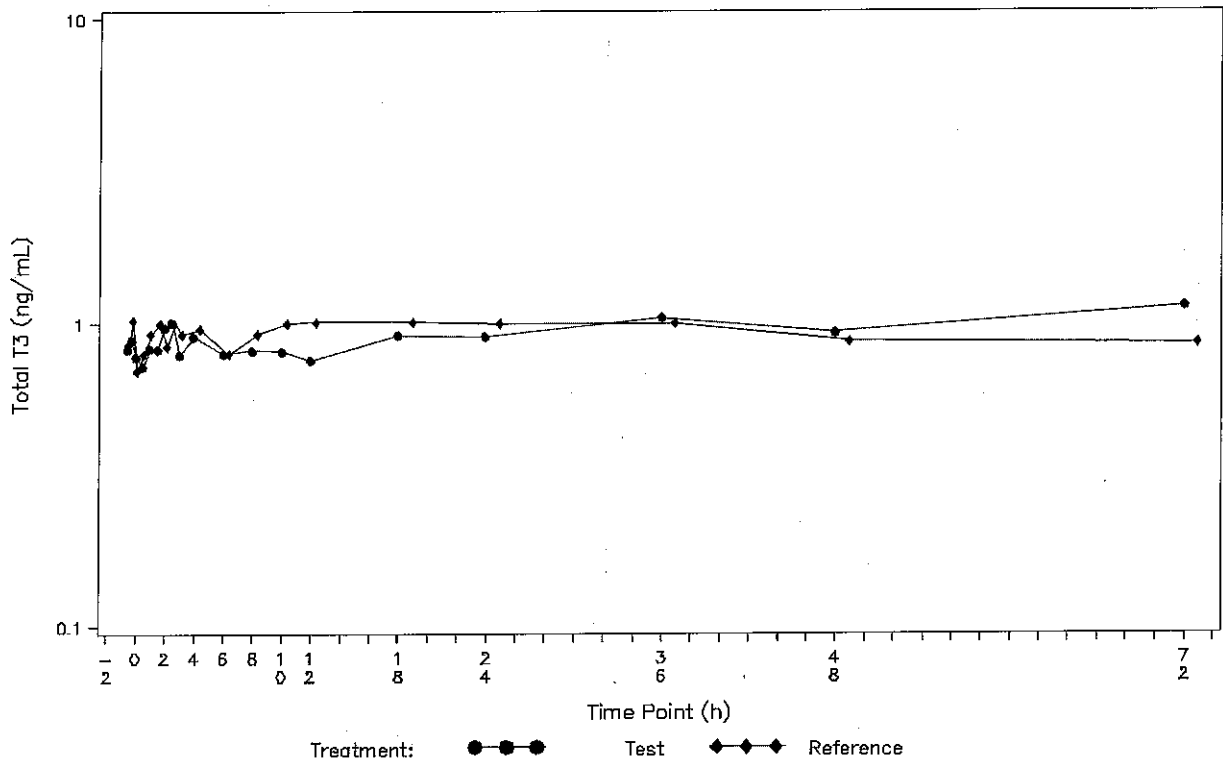


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Source: Table 16.2.5.3

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

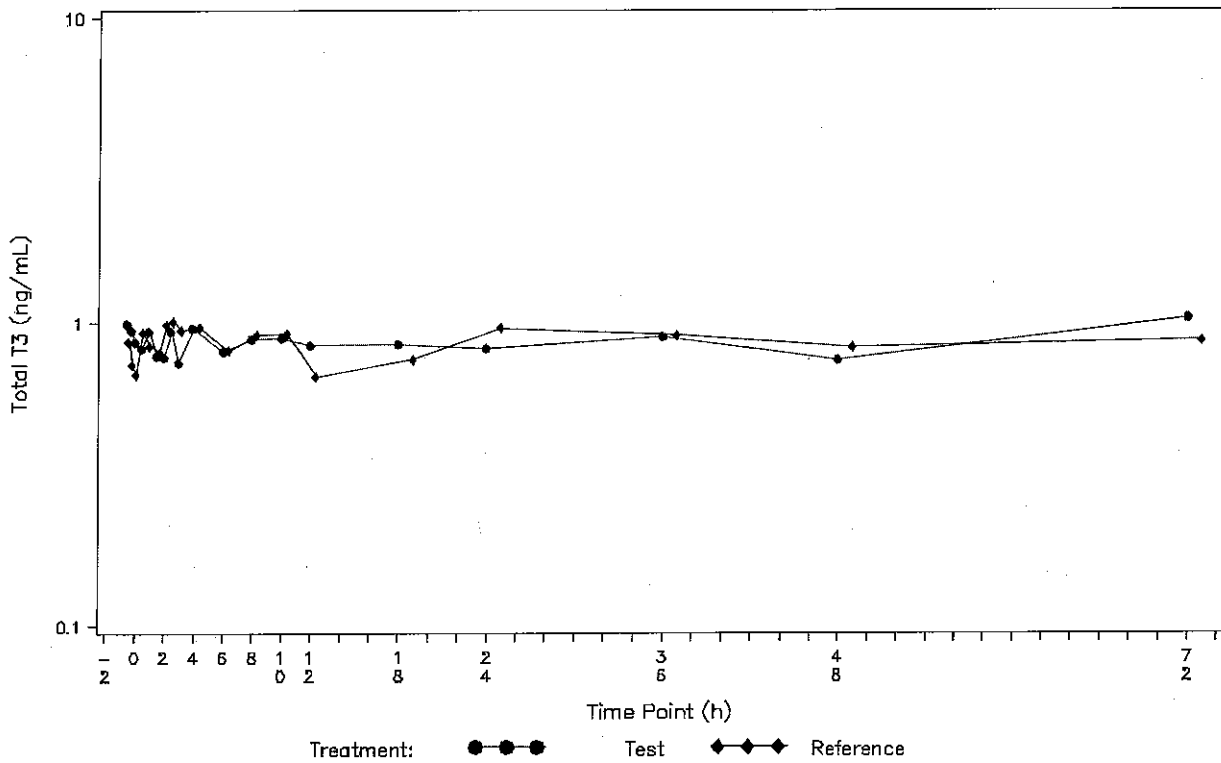
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



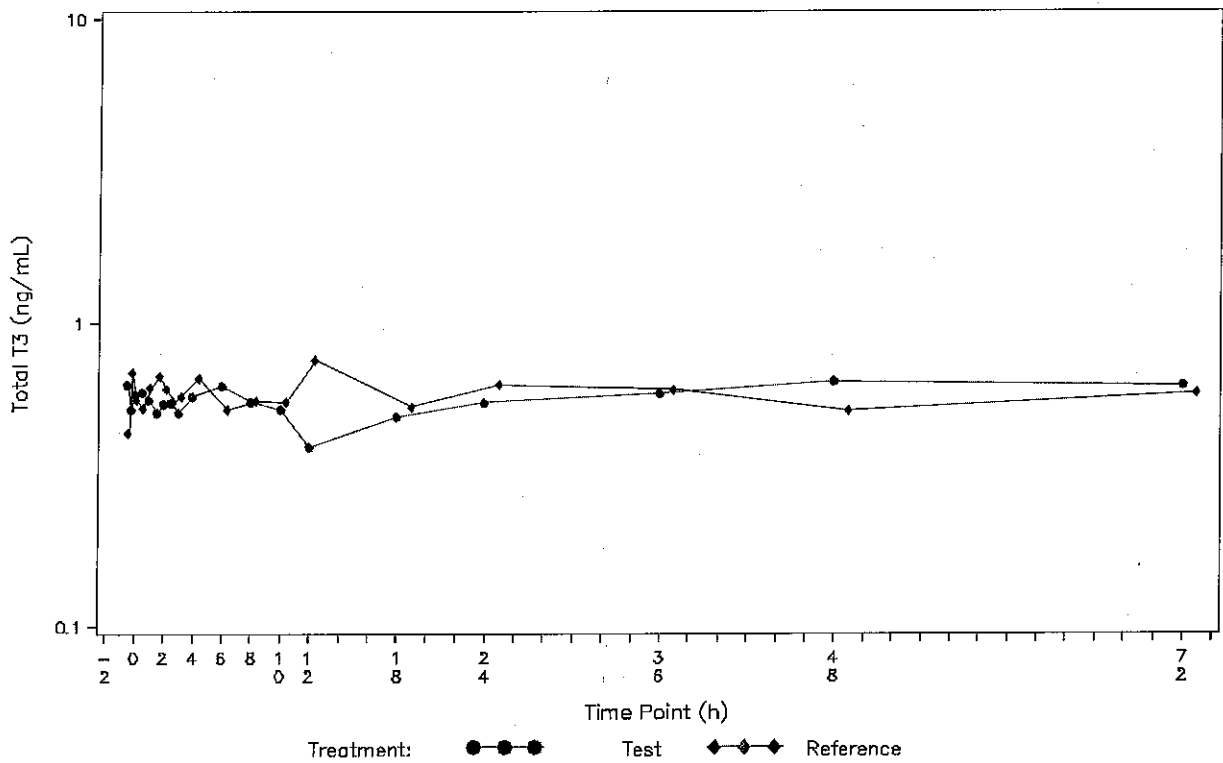
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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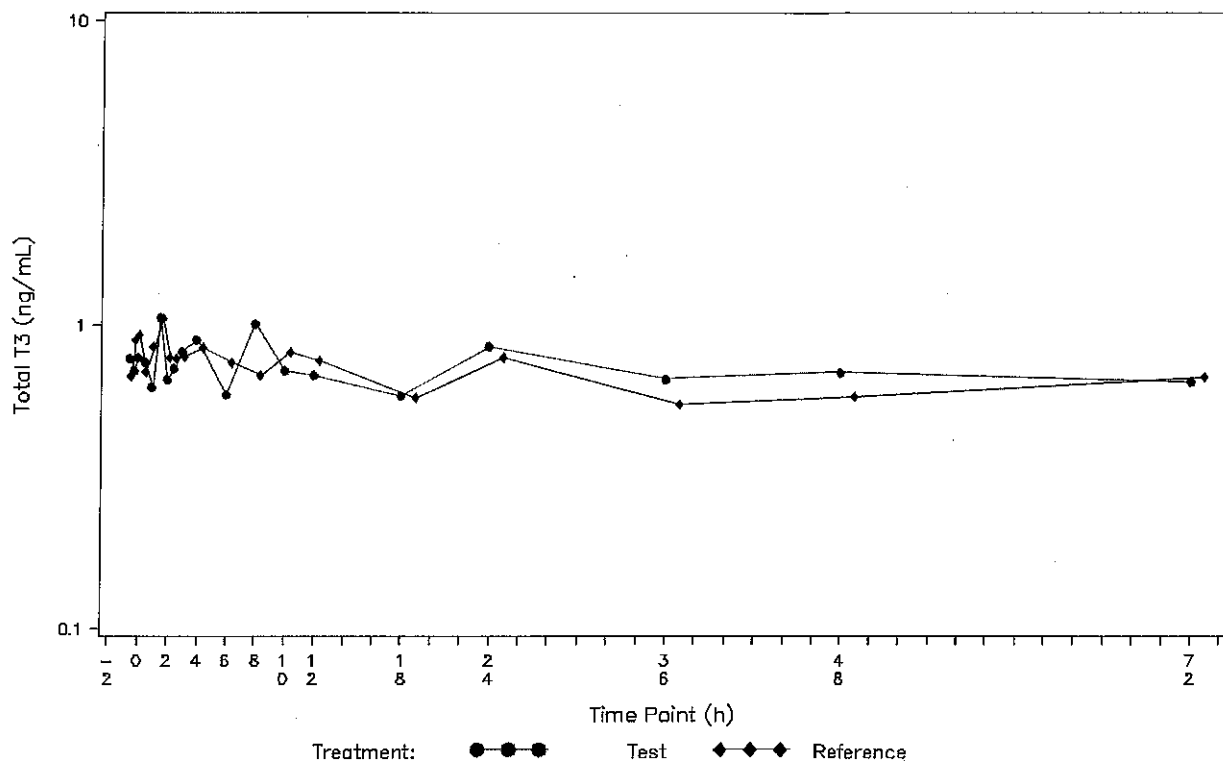
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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

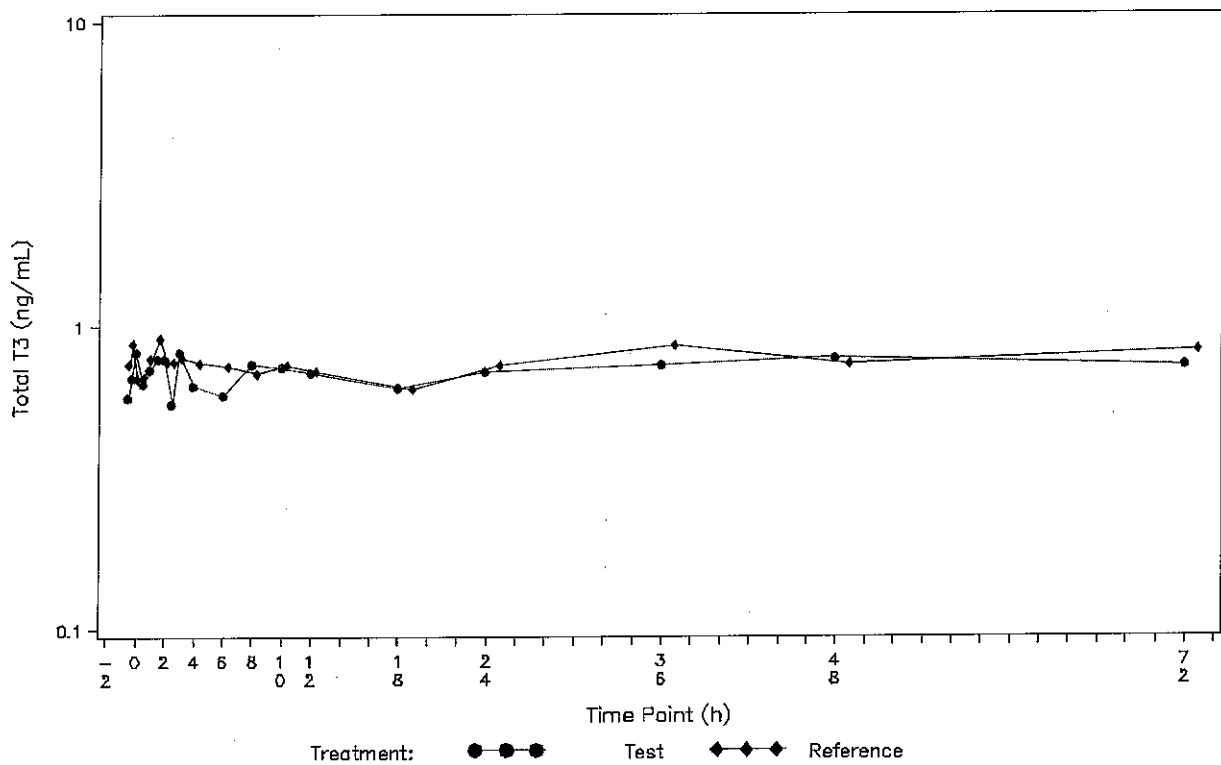
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



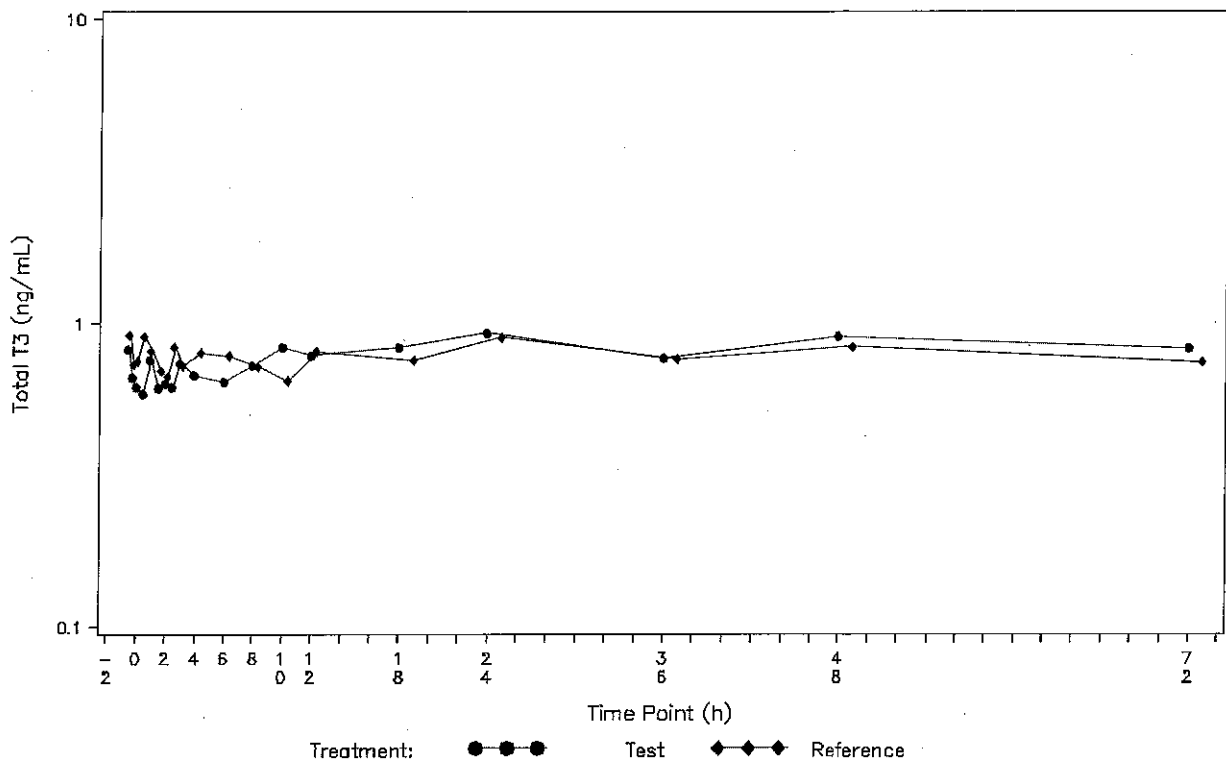
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



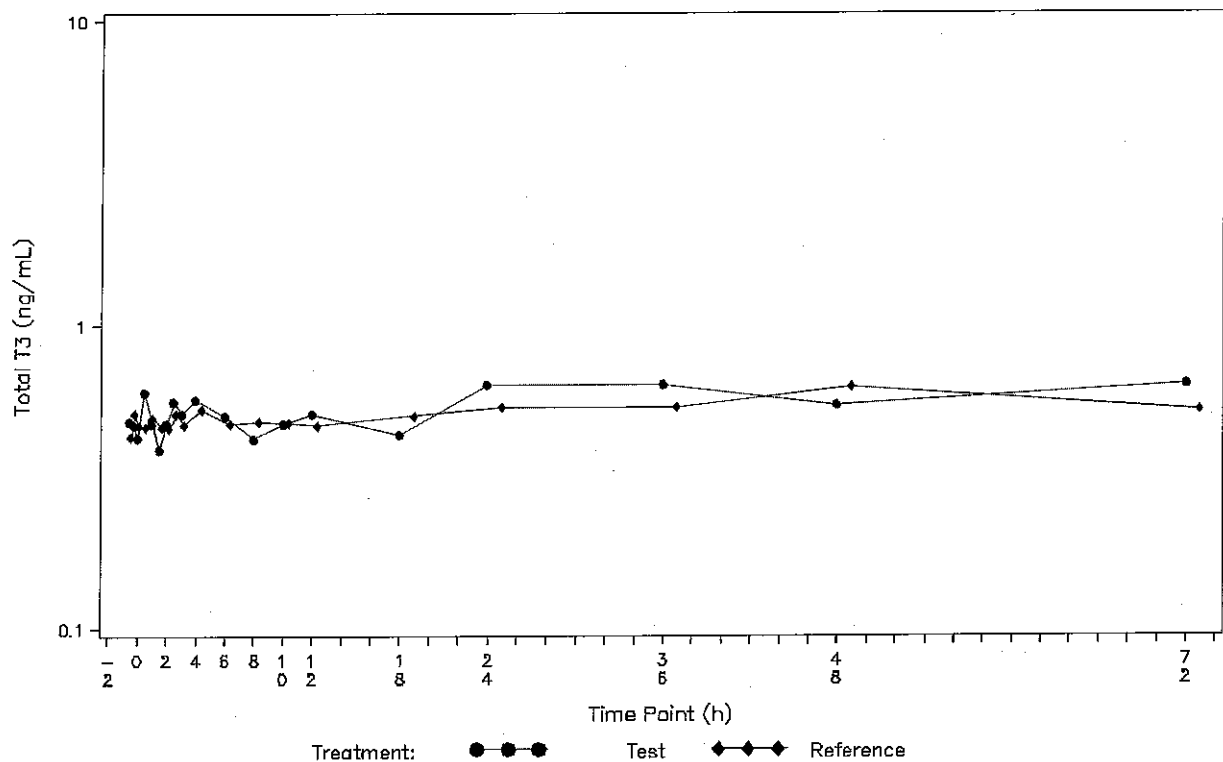
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

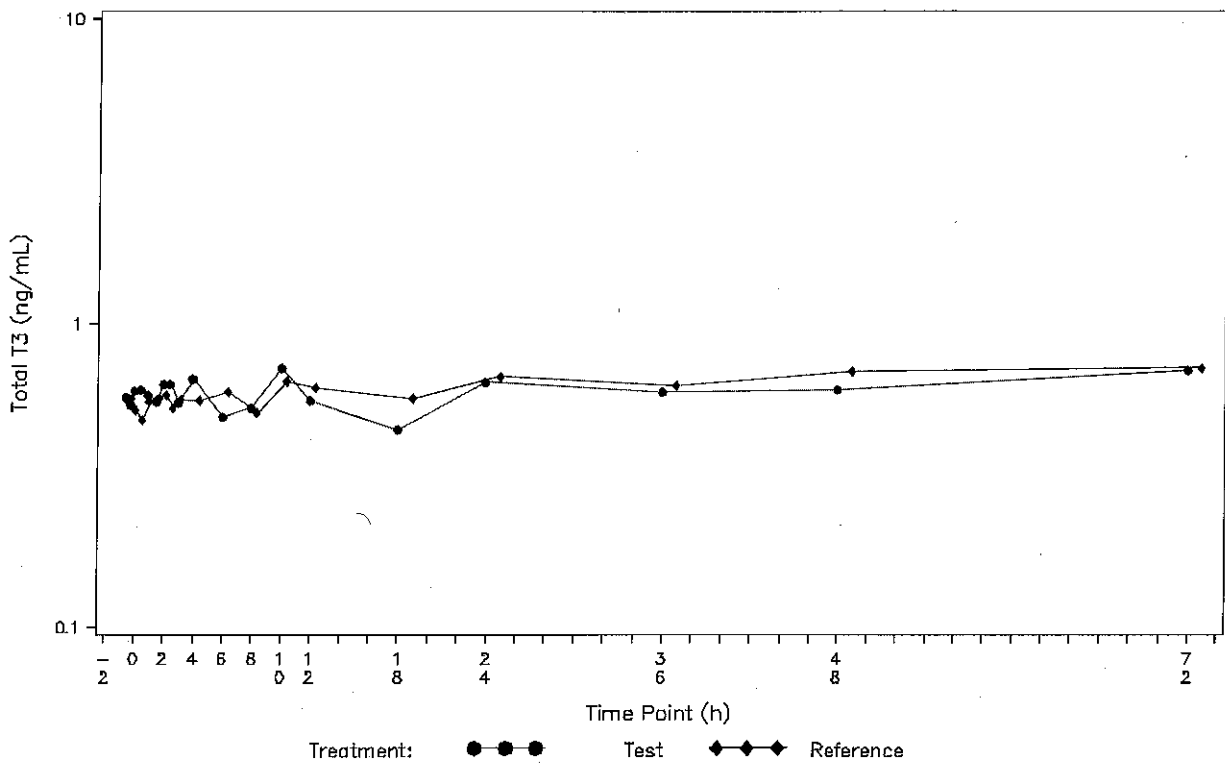
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15.4.2.12.sas



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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

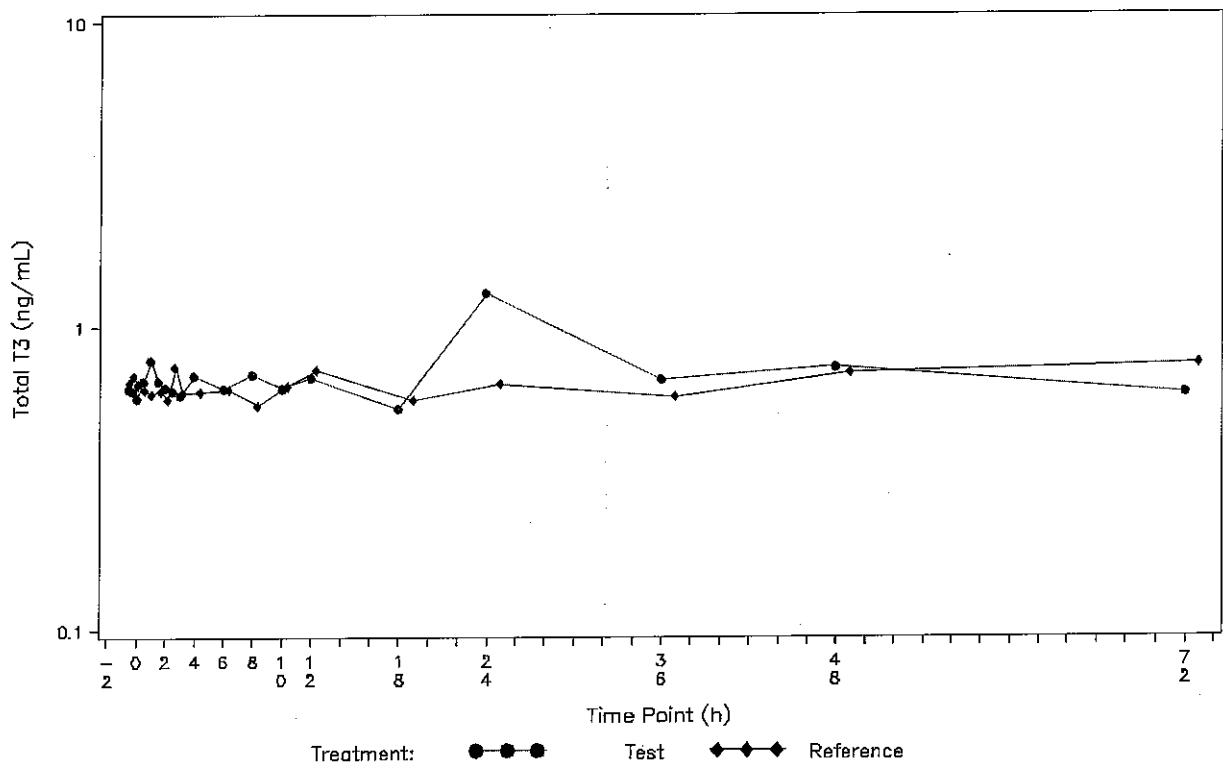


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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas

Levothyroxine
EMR 200125-001

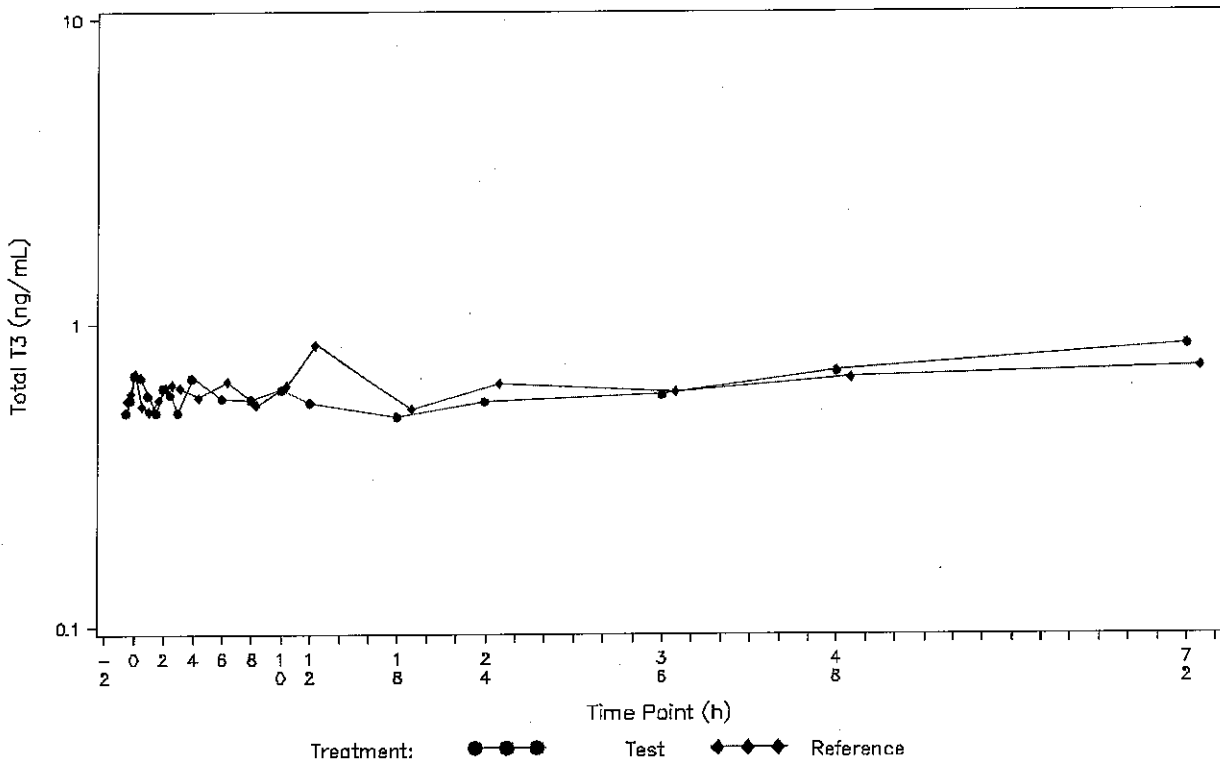
Bioequiv EMR200125-001 Page 1599 of 1628 ulation vs. old formulation

Merck Serono
EMR 200125-001

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



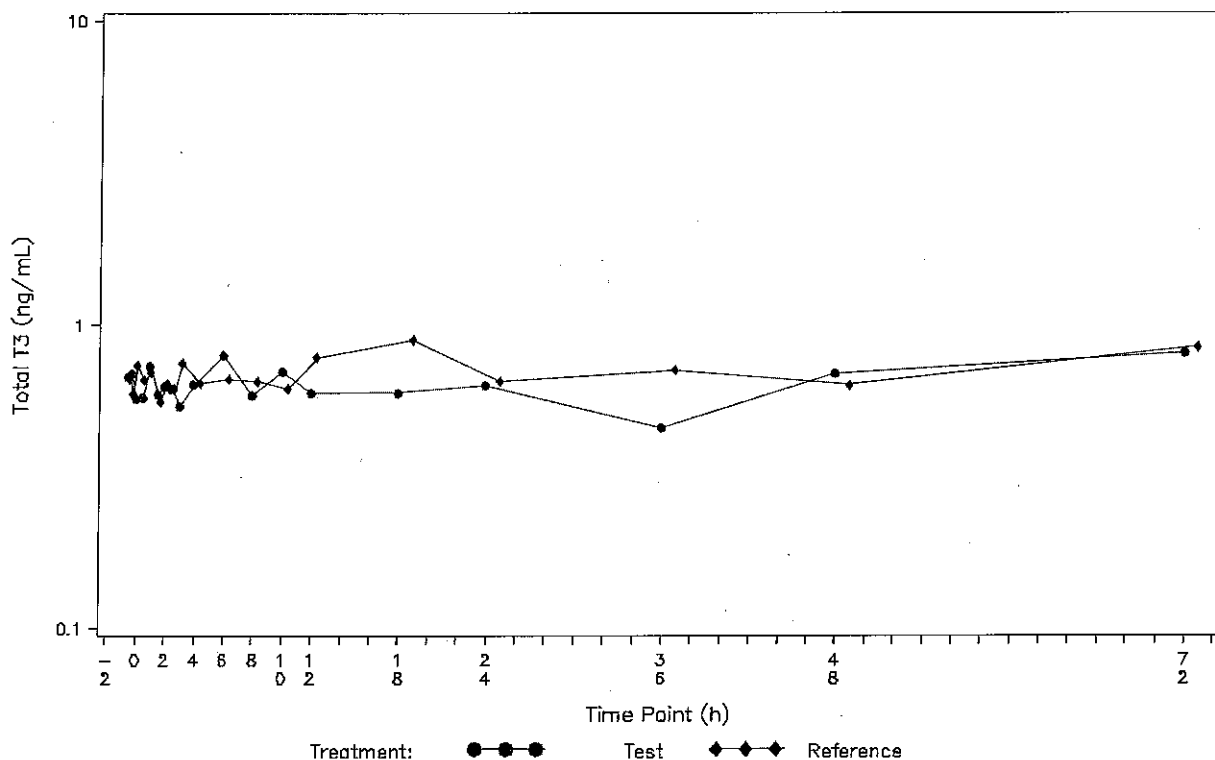
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

./project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

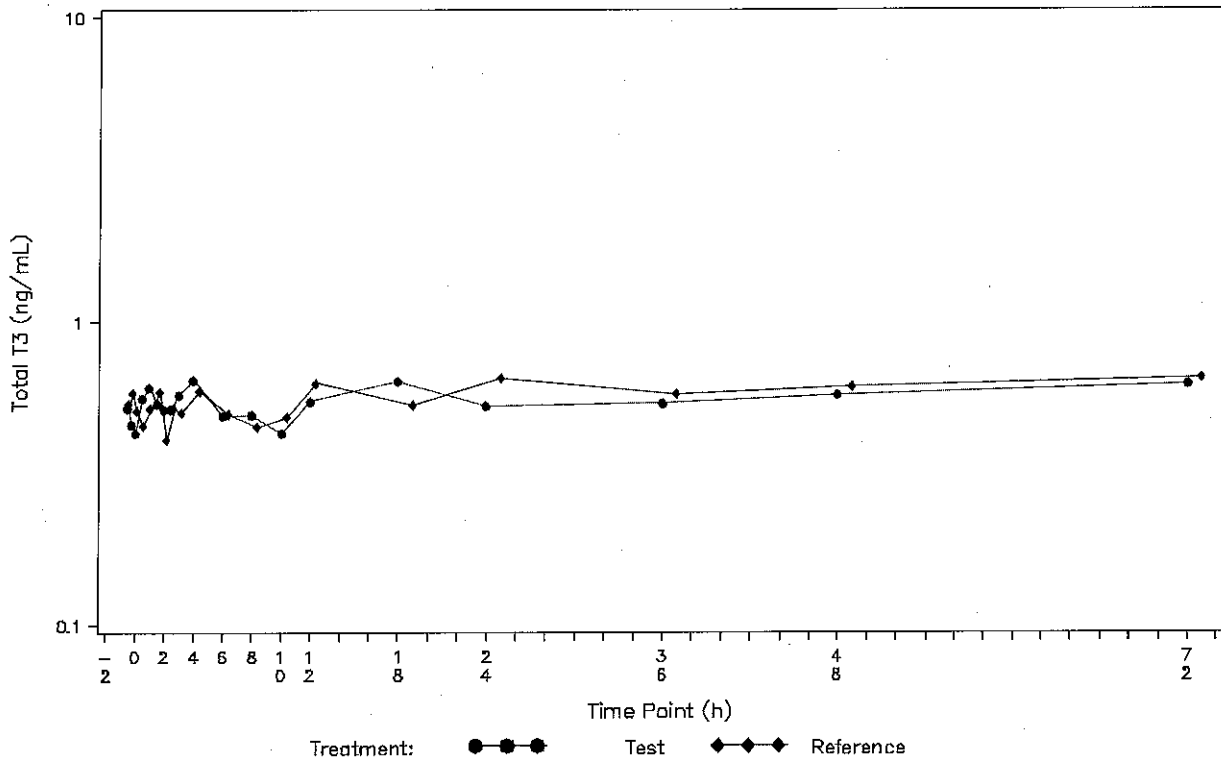
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15.4.2.12.sas



Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



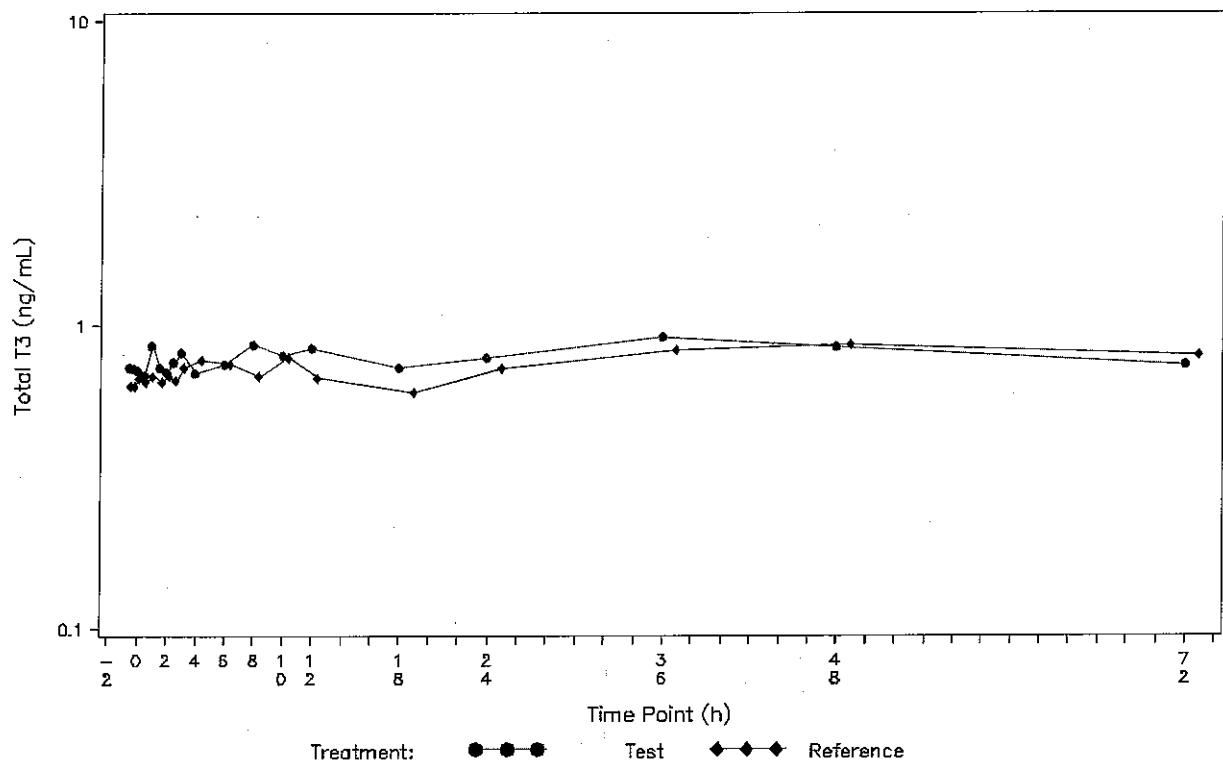
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



0: Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

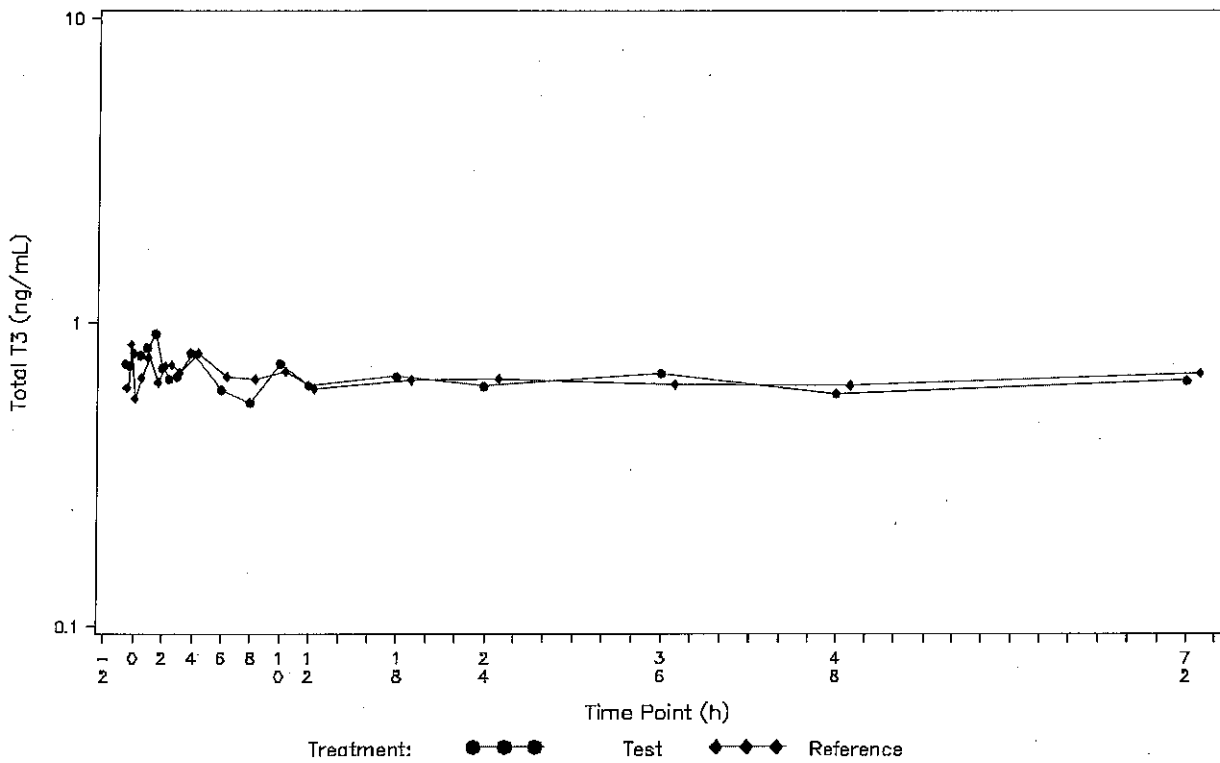
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15.4.2.12.sas



Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

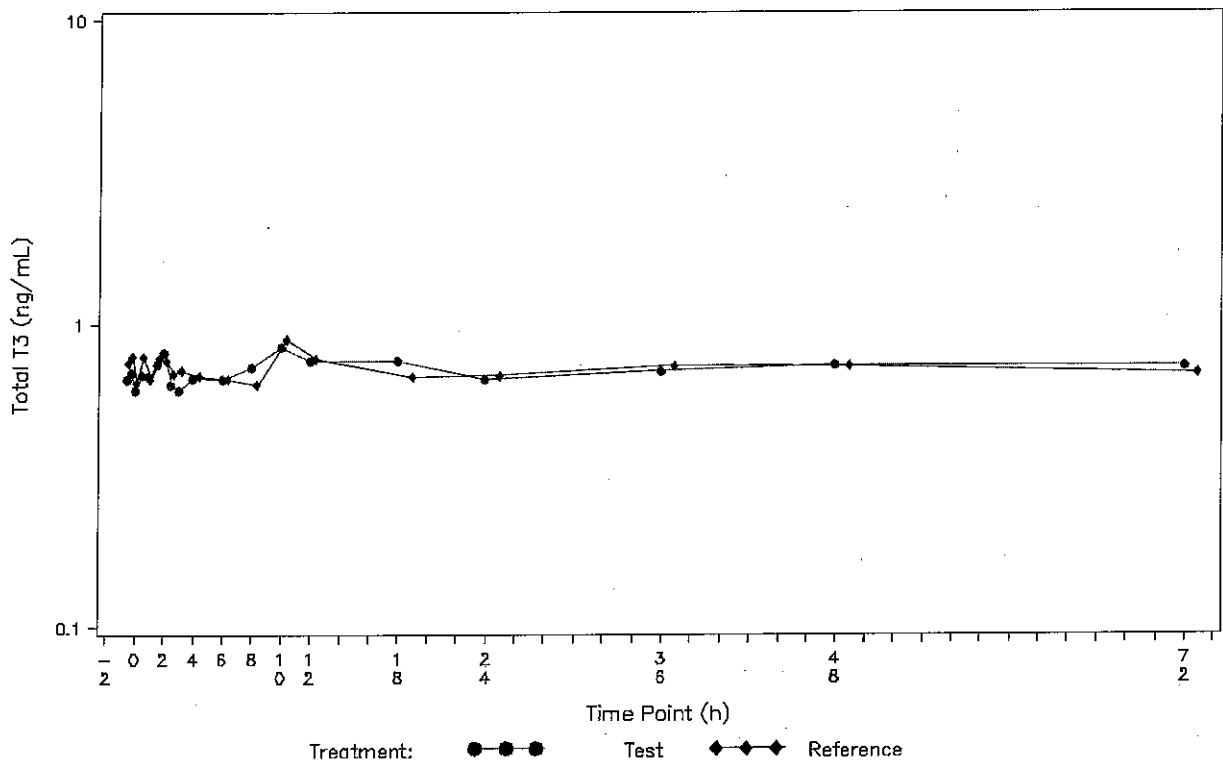


@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

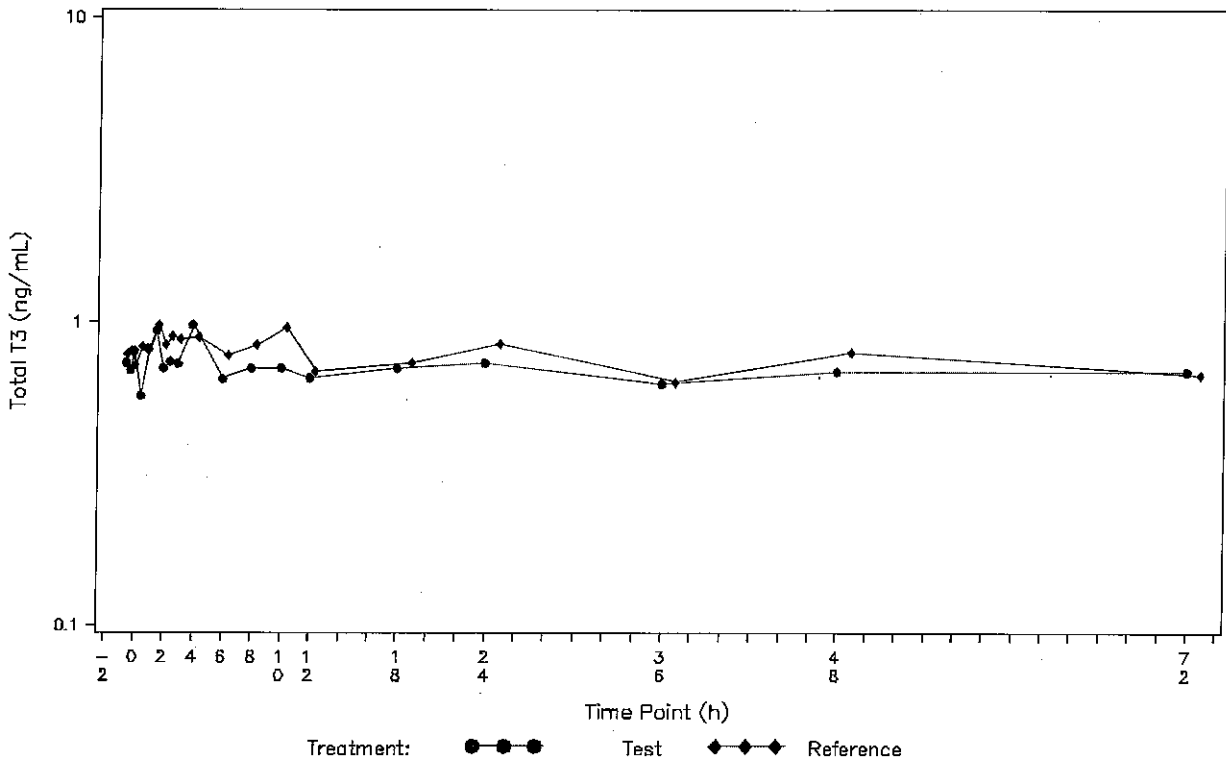


@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



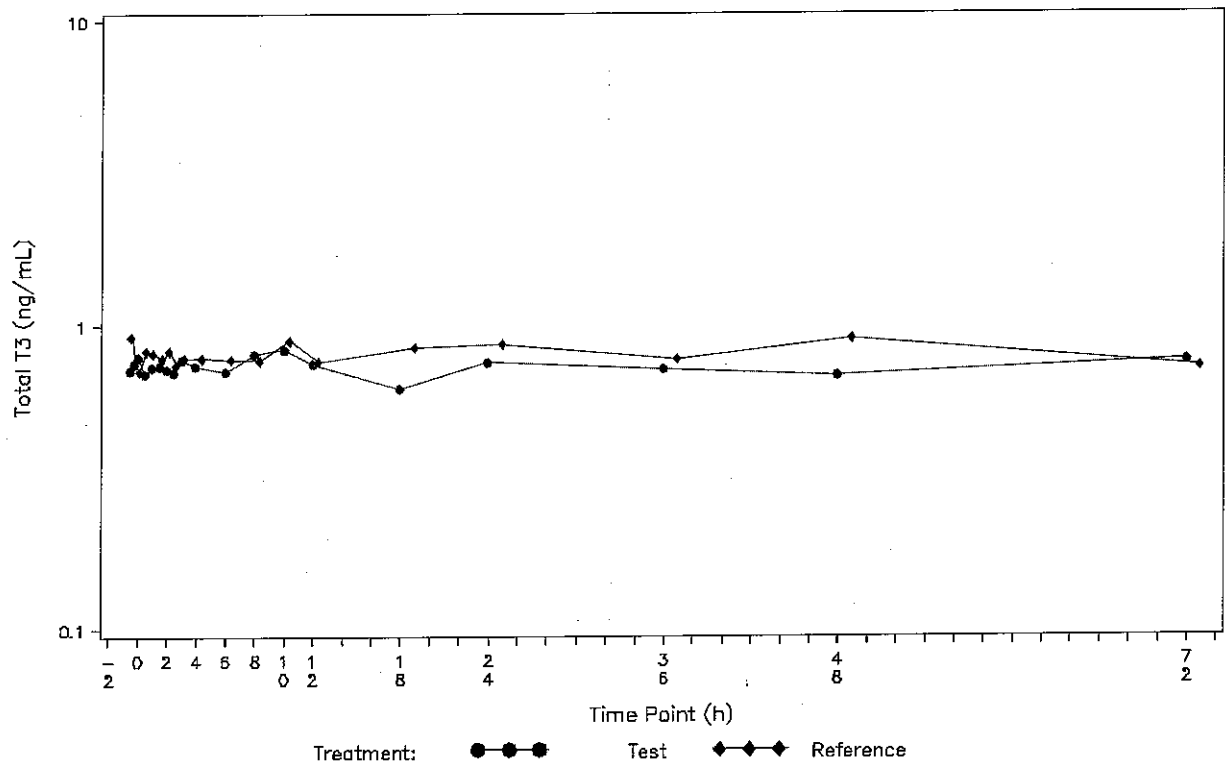
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

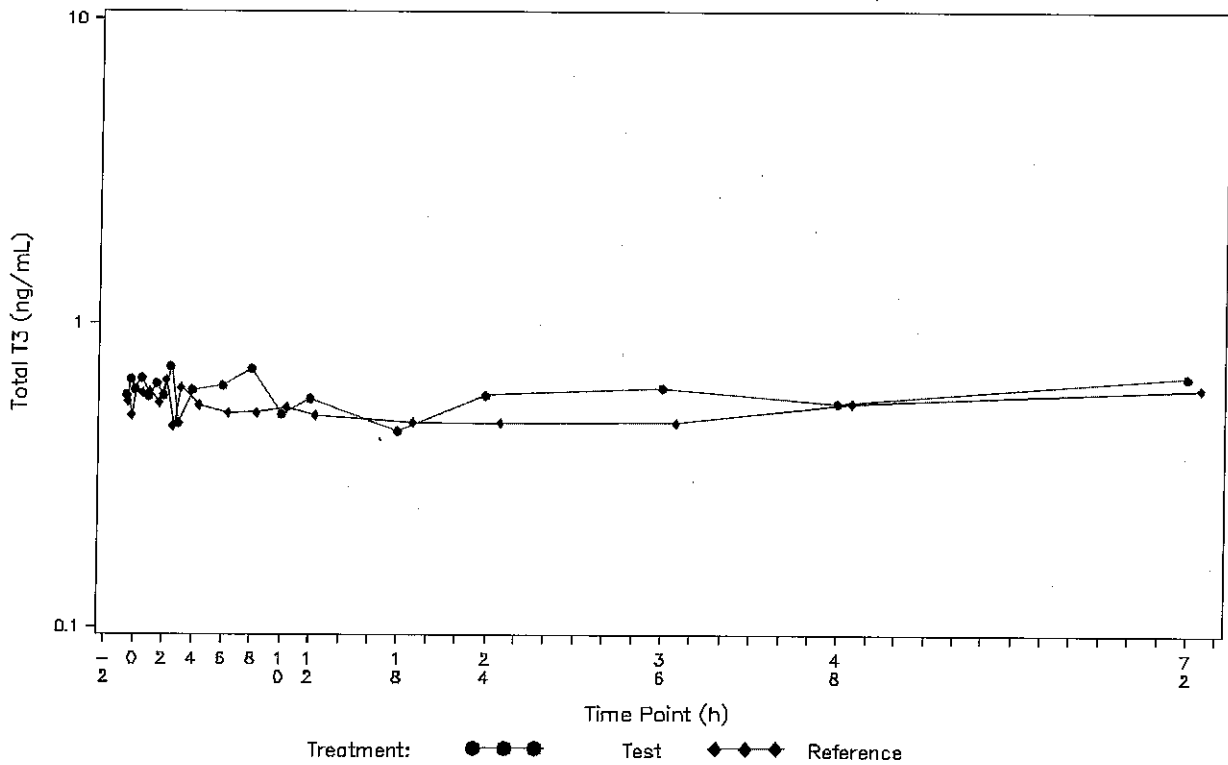


@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: .



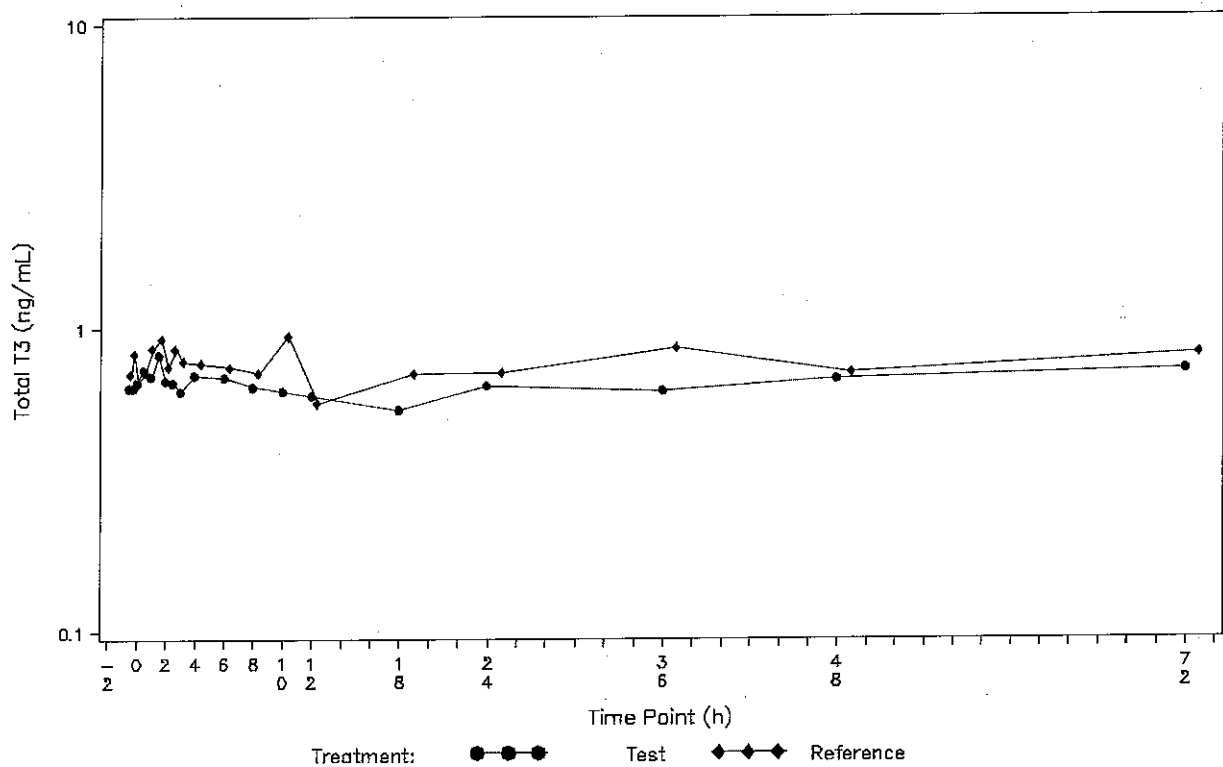
0: Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



①: Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas

Levothyroxine
EMR 200125-001

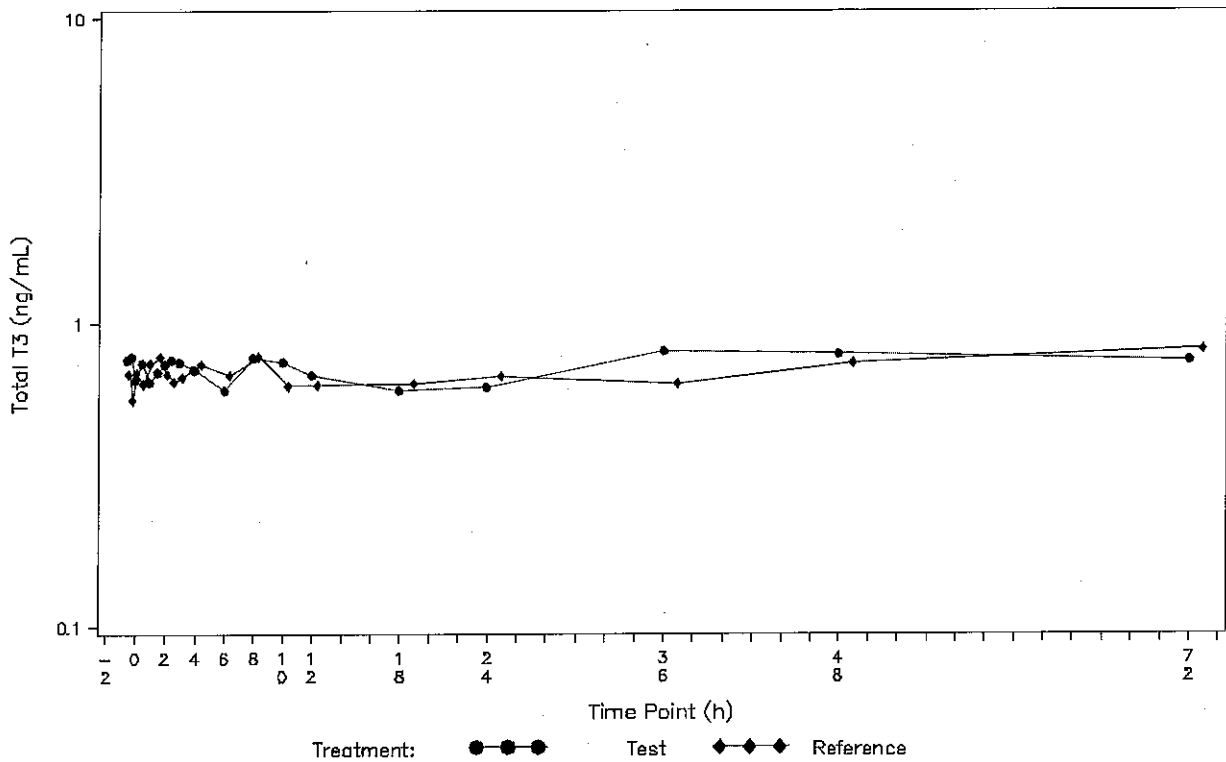
Bioequiv EMR200125-001 Page 1609 of 1628 ulation vs. old formulation

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Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



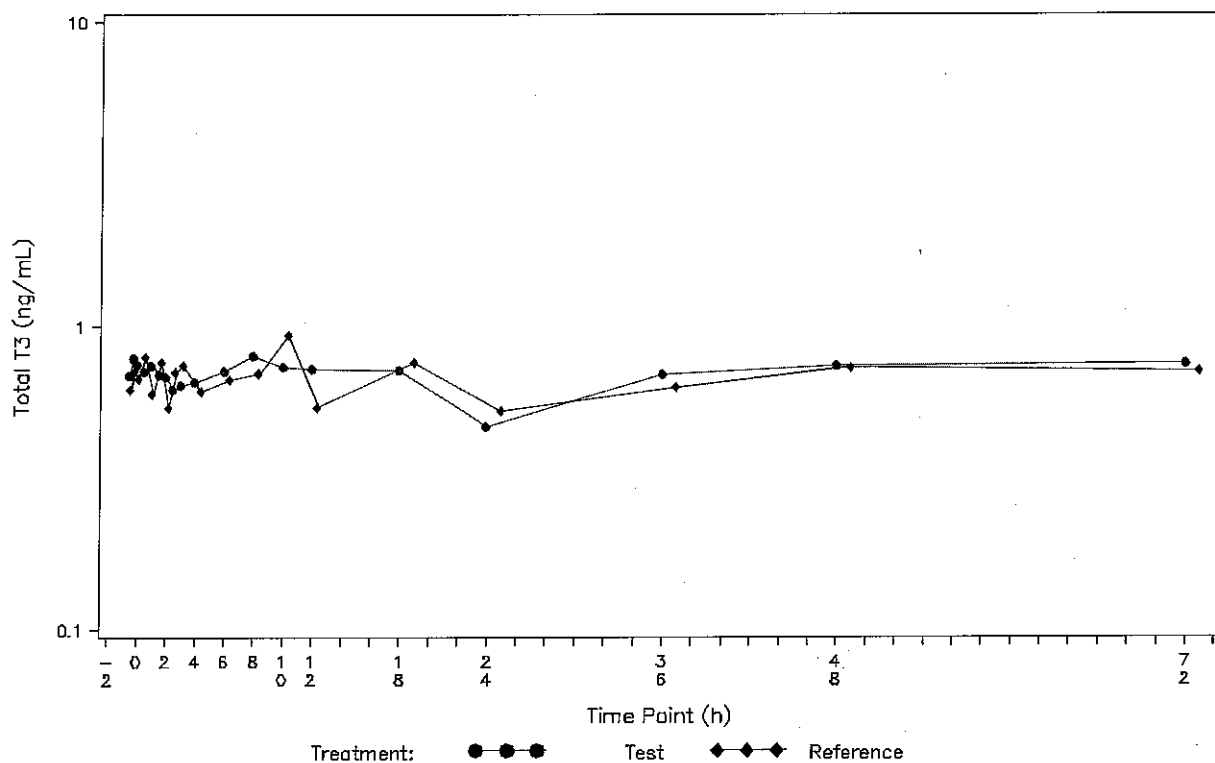
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



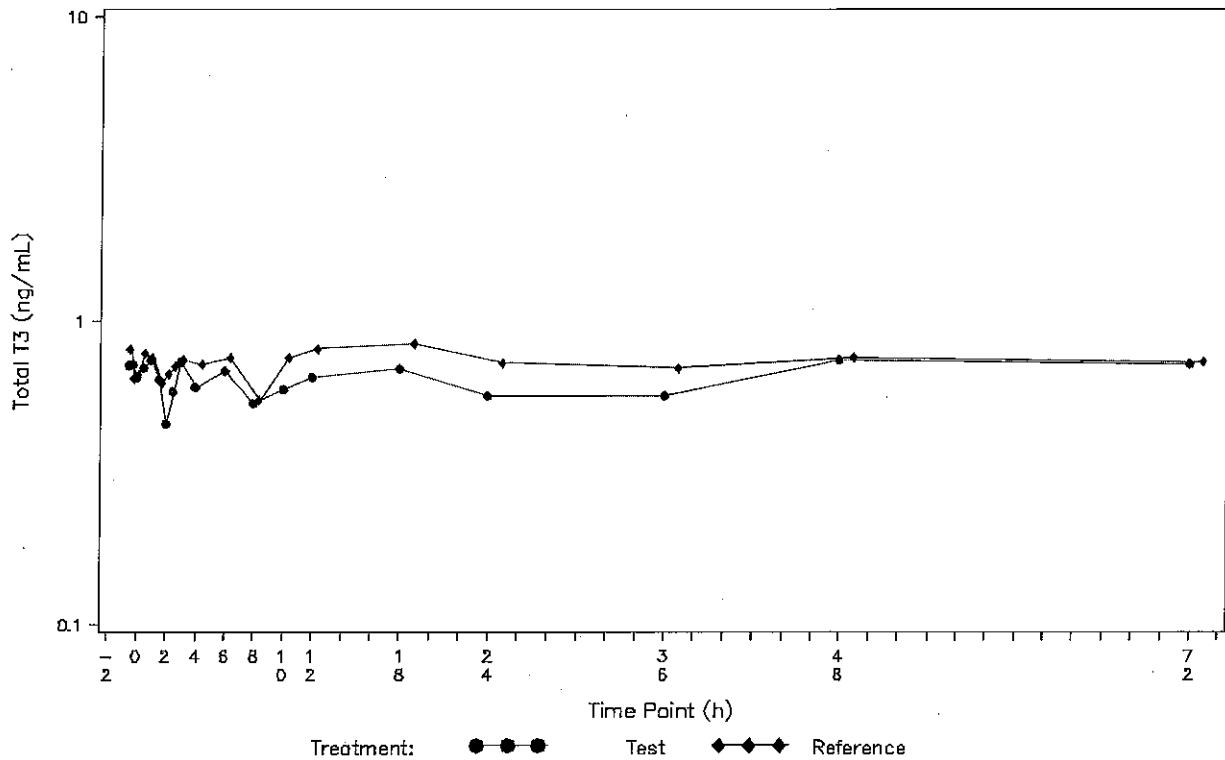
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



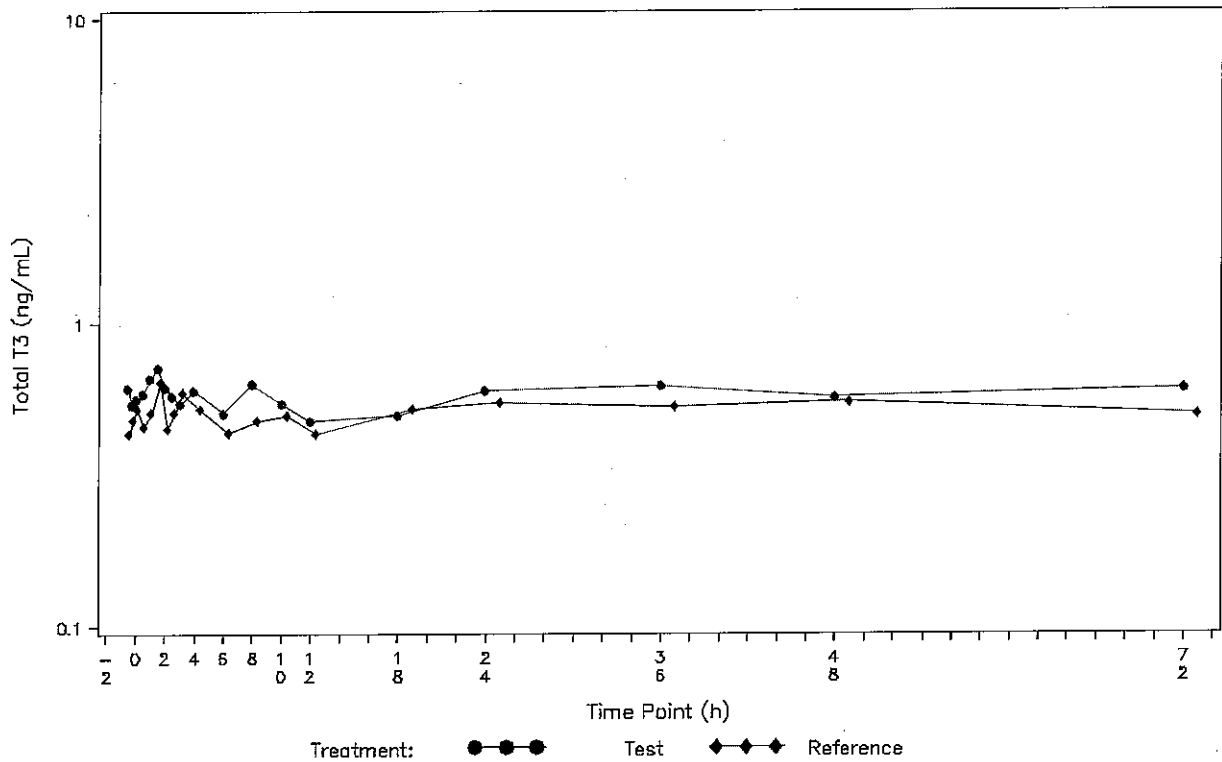
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

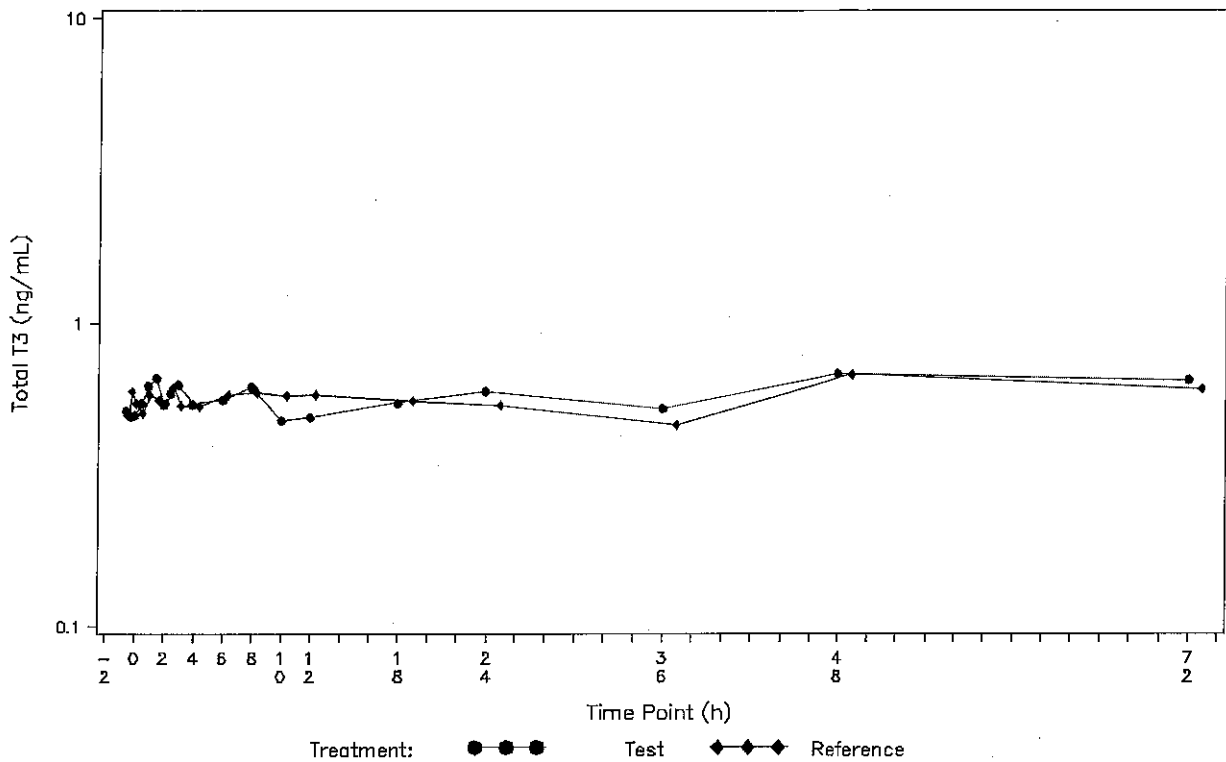
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15.4.2.12.sas



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EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:



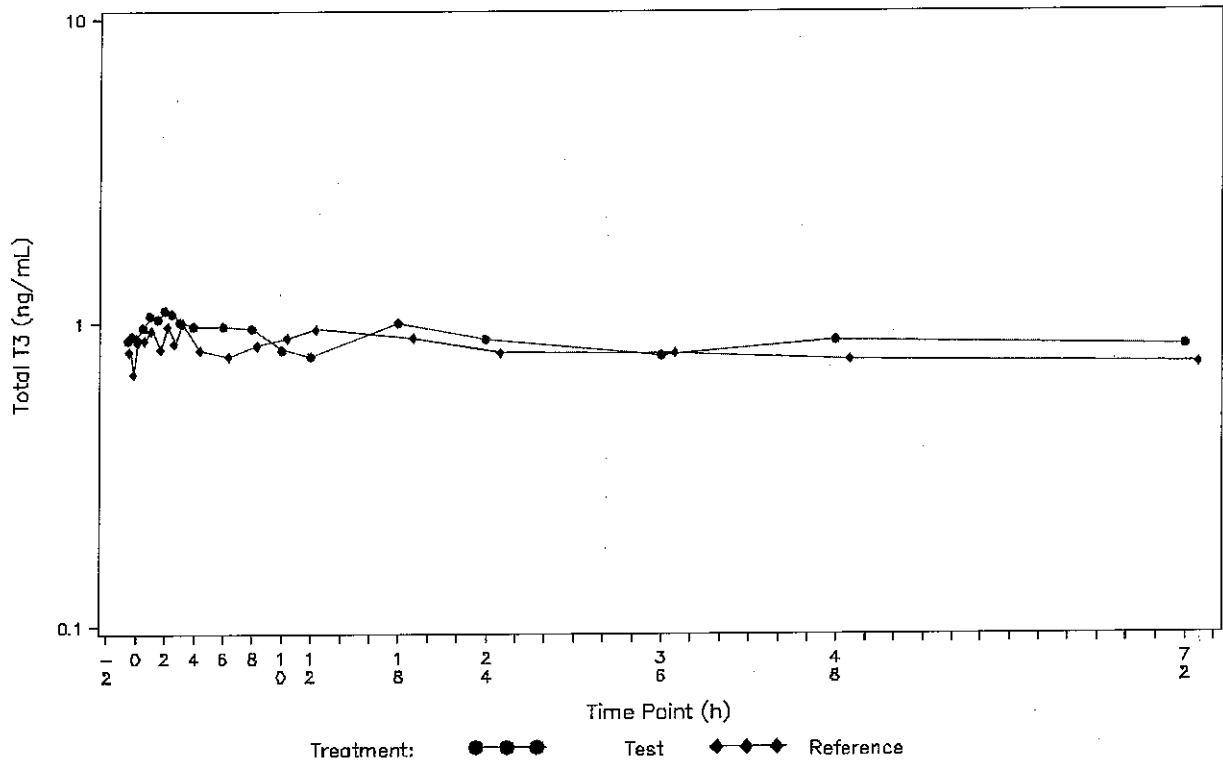
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1728



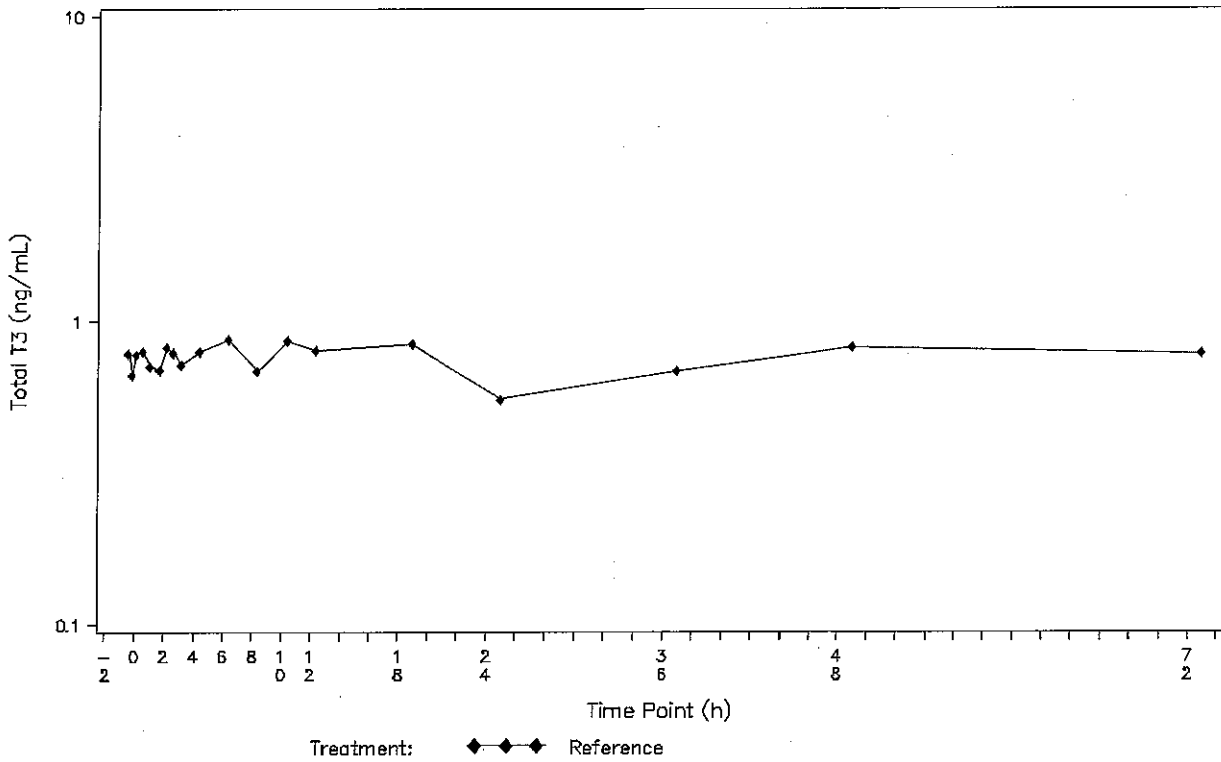
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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

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



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1



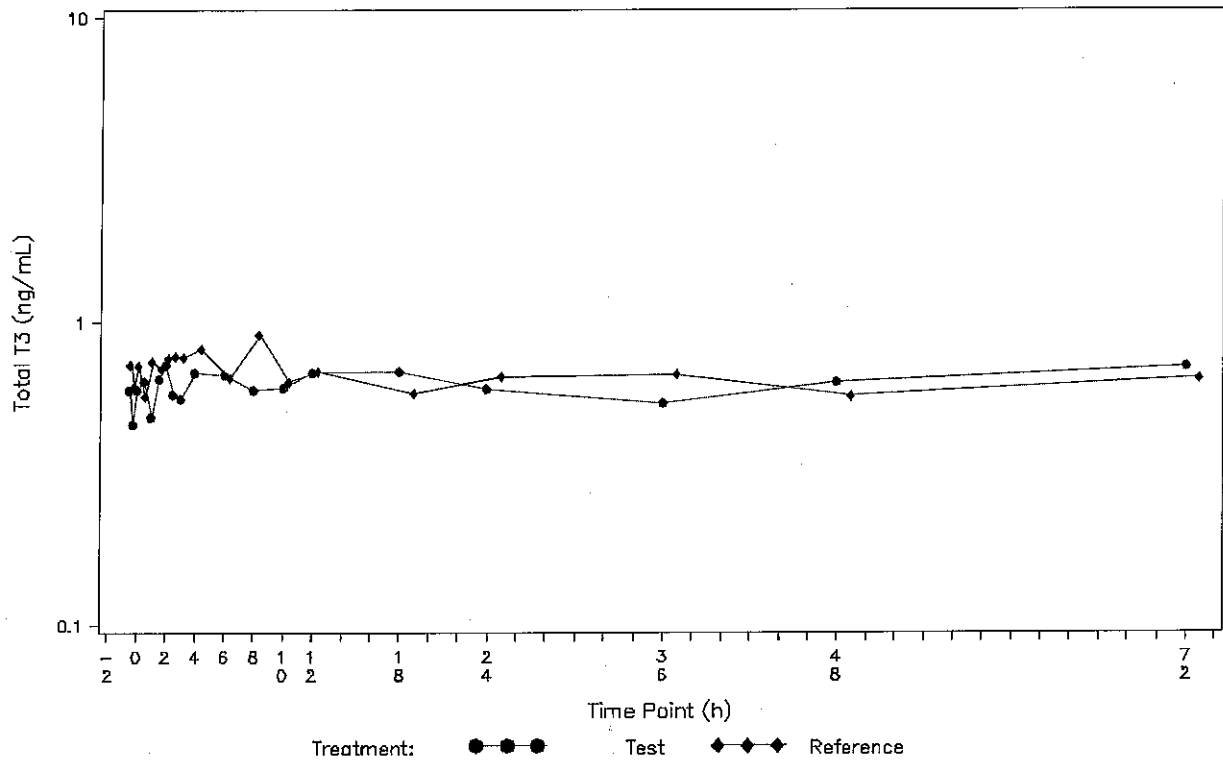
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

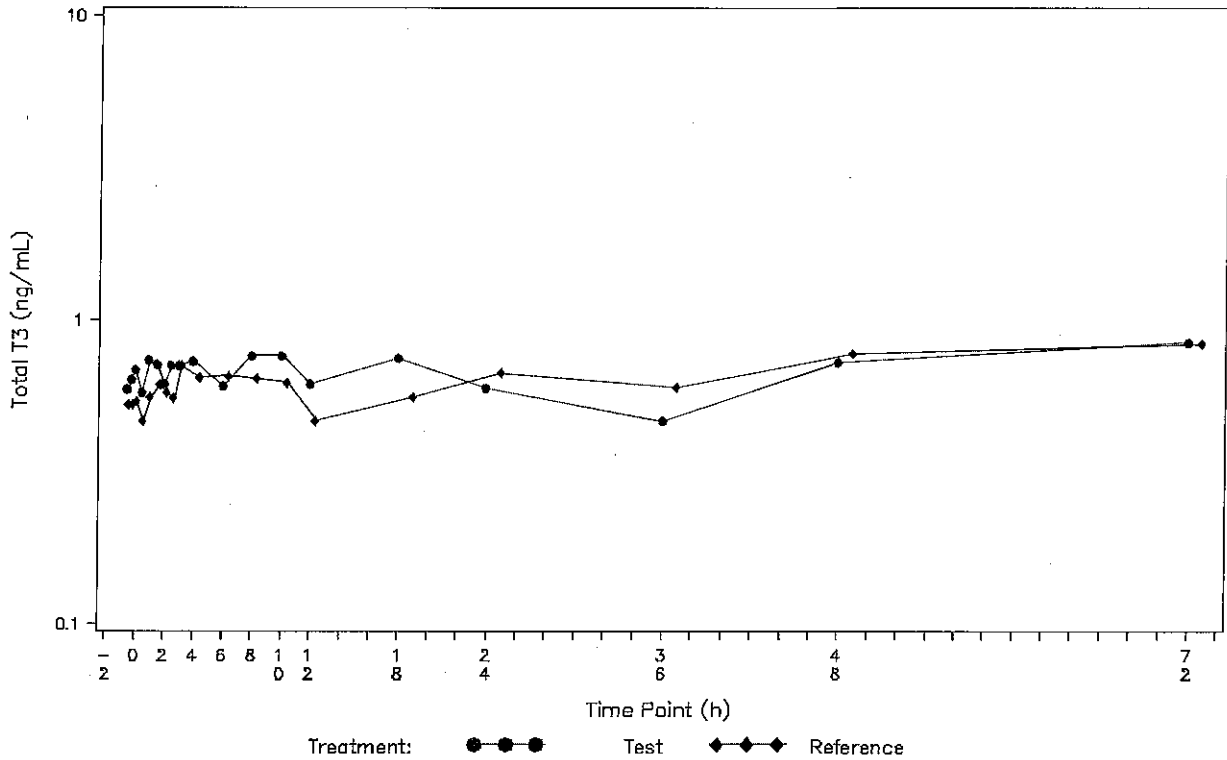
/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: .



@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Levothyroxine
EMR 200125-001

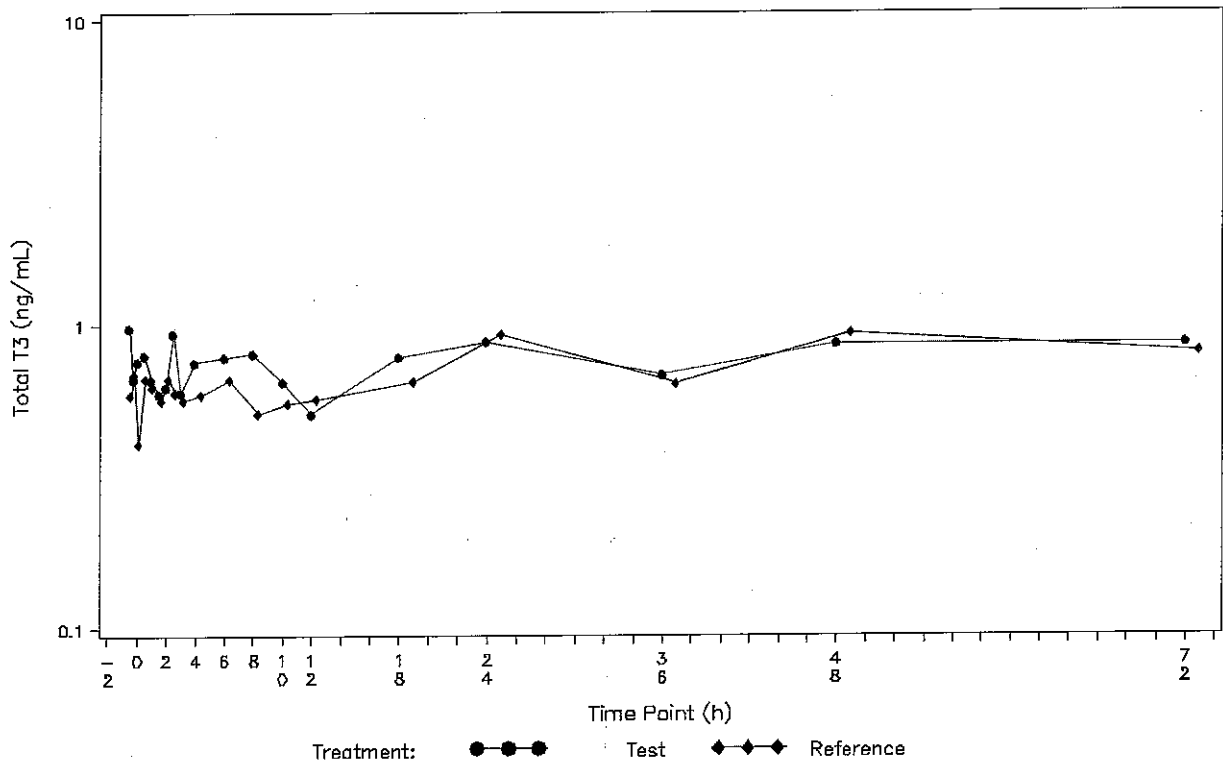
Bioequiv EMR200125-001 Page 1618 of 1628 alation vs. old formulation

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EMR 200125-001

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



⊘: Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

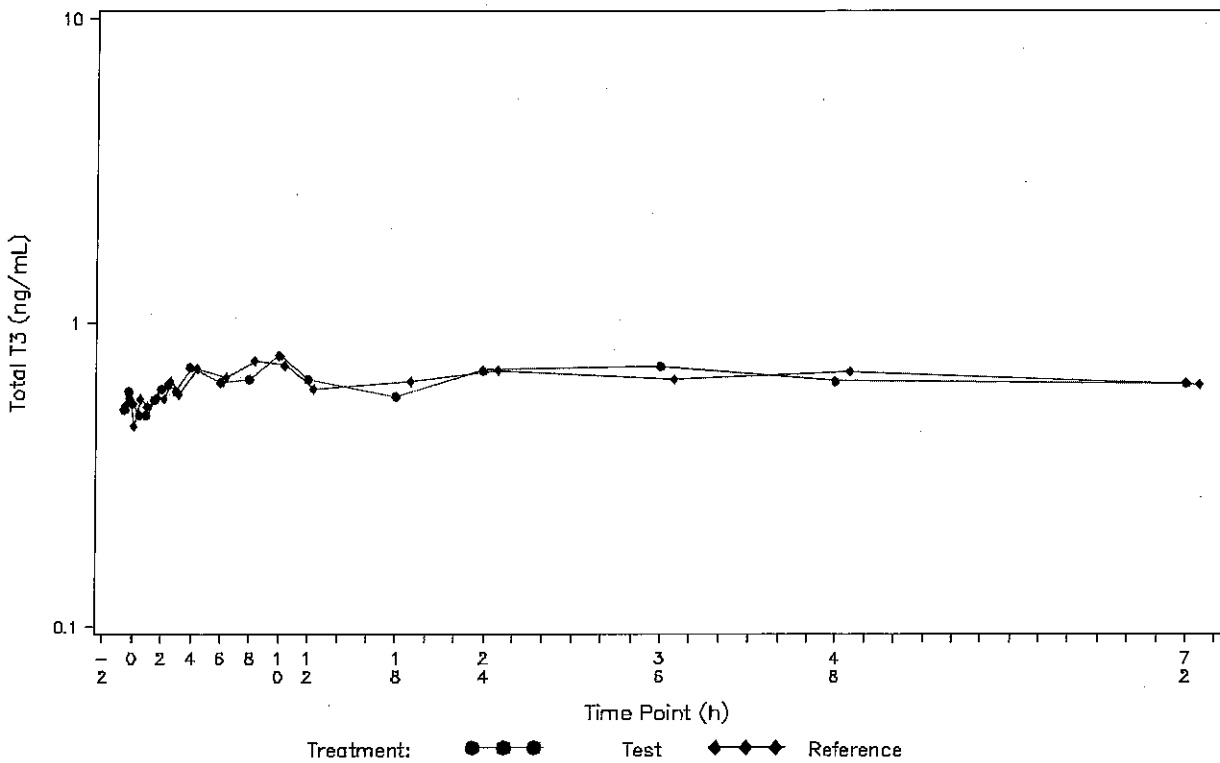
/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population).

Subject ID/Random Number:



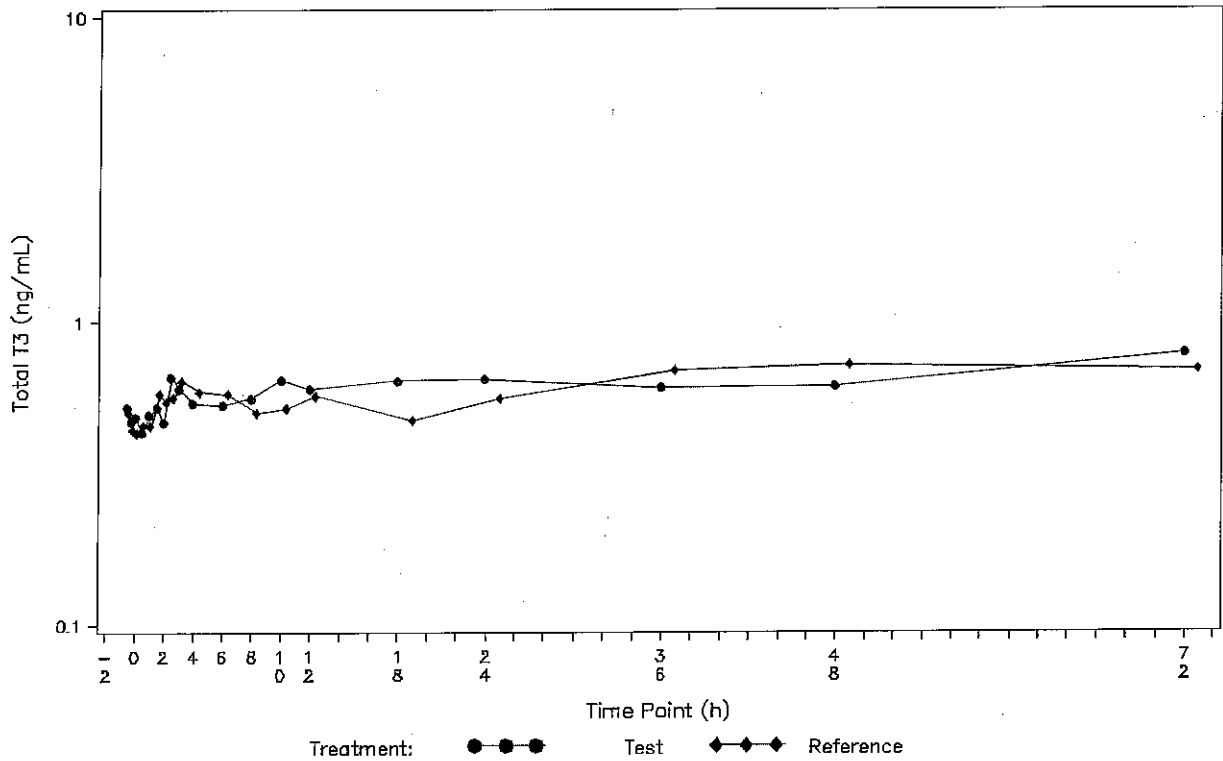
@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number



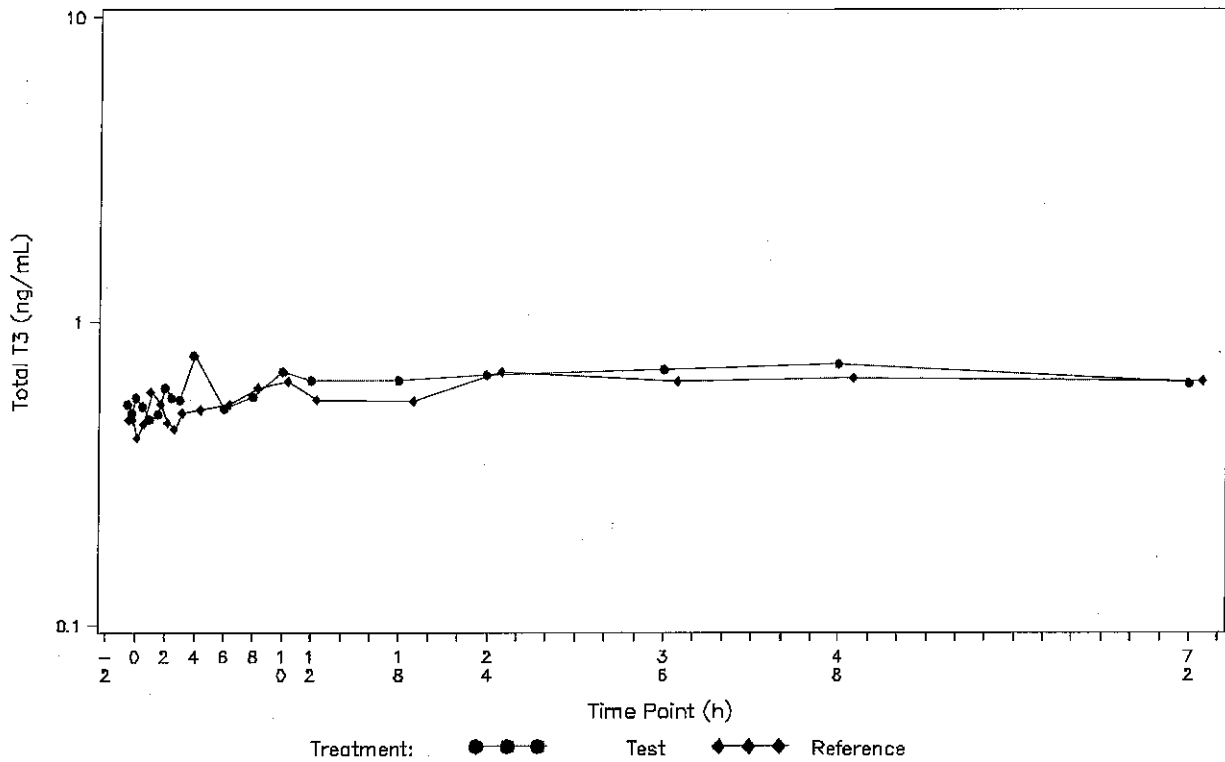
0: Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Merck Serono
EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

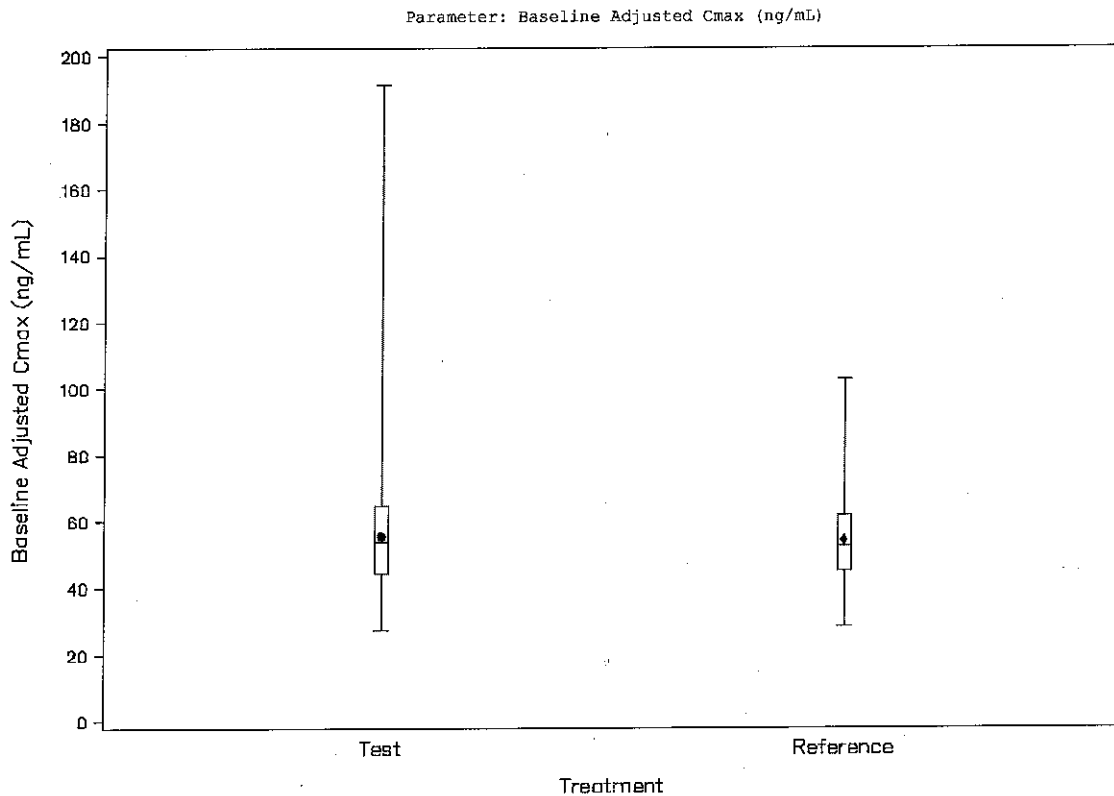


@:Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.12.sas



Figure 15.4.3.1.1 Boxplot: Baseline Adjusted Cmax and Baseline Adjusted AUC0-72 for Total T4 (Pharmacokinetic Population)



Subjects ere excluded from the PK Population.

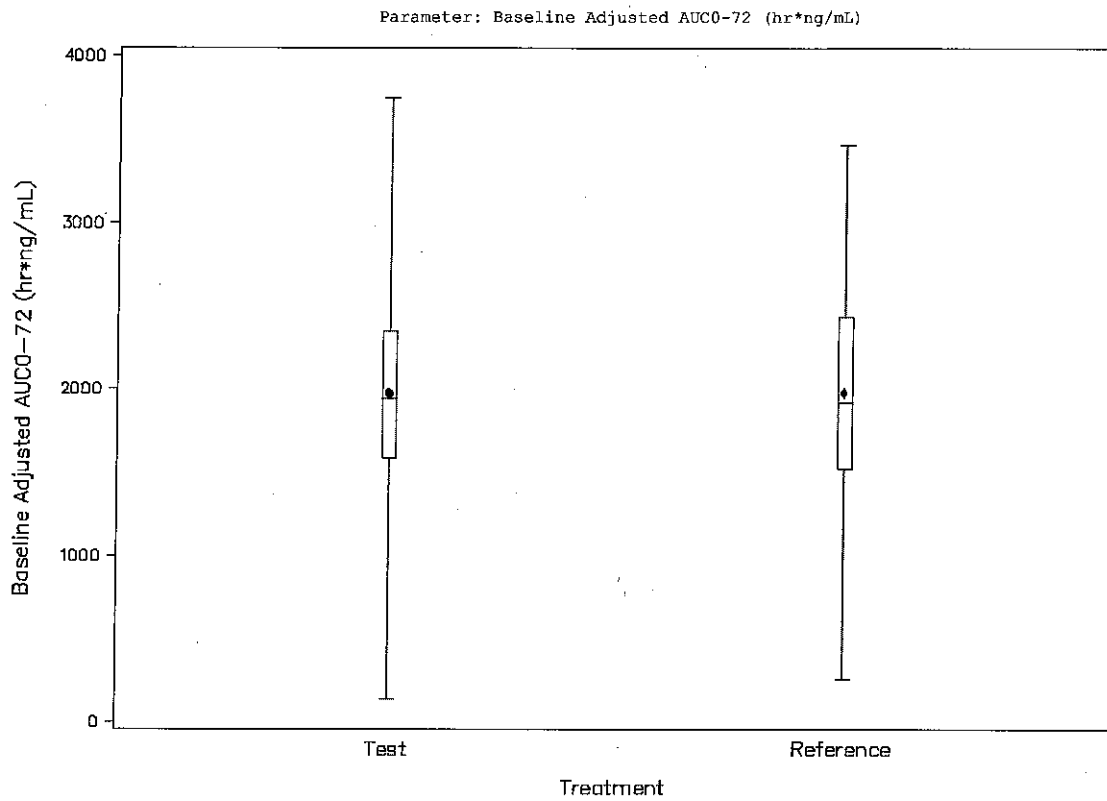
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.3.1.1.sas

11DEC2014 00:01



Figure 15.4.3.1.1 Boxplot: Baseline Adjusted Cmax and Baseline Adjusted AUC0-72 for Total T4 (Pharmacokinetic Population)

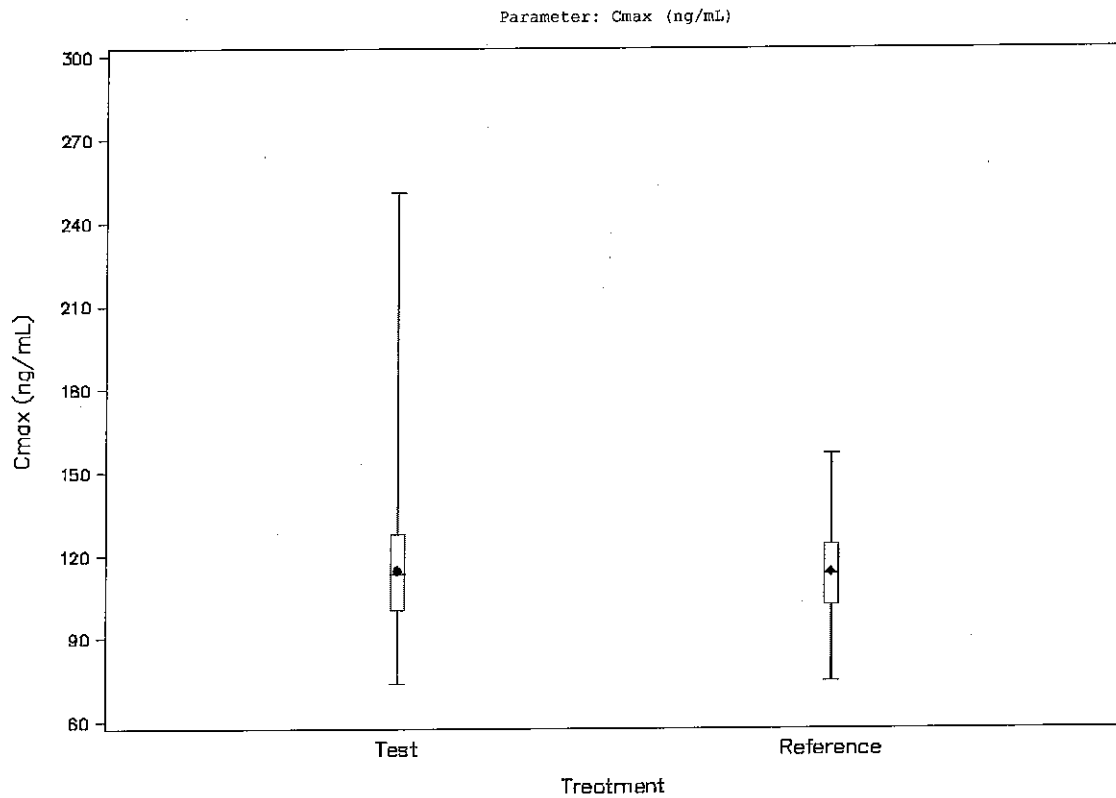


Subjects were excluded from the PK Population.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.3.1.1.sas

11DEC2014 00:01

Figure 15.4.3.1.2 Boxplot: Cmax and AUC0-72 for Total T4 (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.

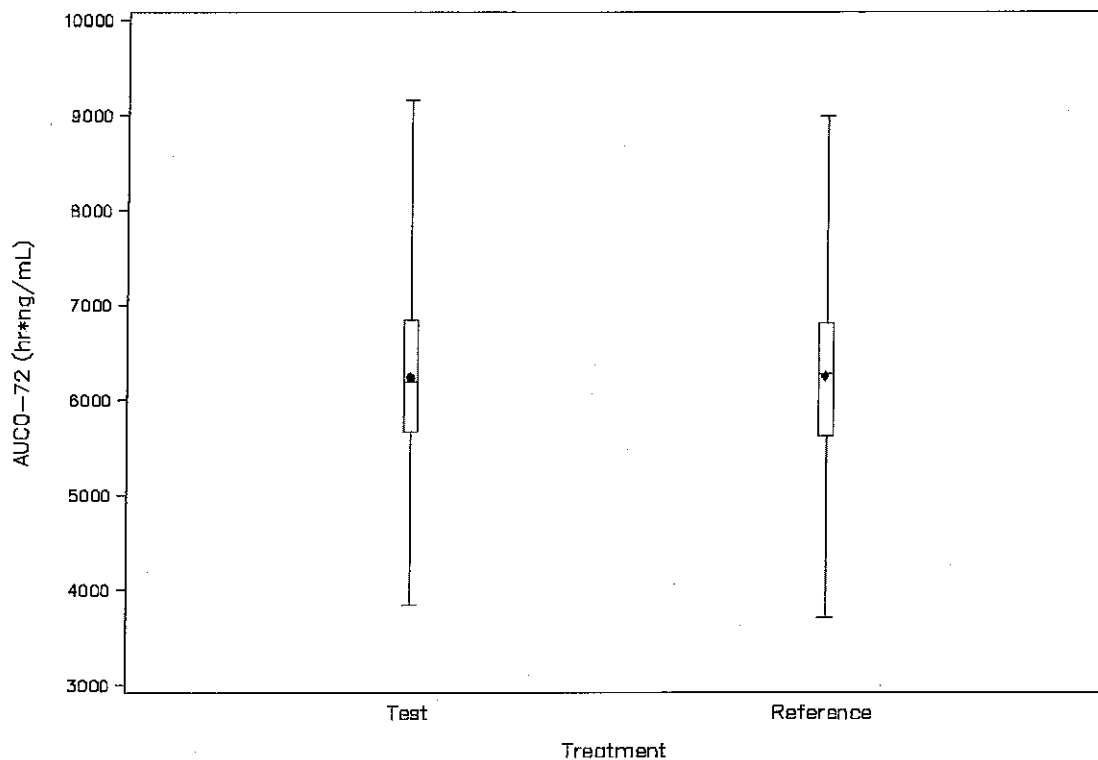
/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.3.1.2.sas

11DEC2014 00:01



Figure 15.4.3.1.2 Boxplot: Cmax and AUC0-72 for Total T4 (Pharmacokinetic Population)

Parameter: AUC0-72 (hr*ng/mL)



Subjects : _____ were excluded from the PK Population.

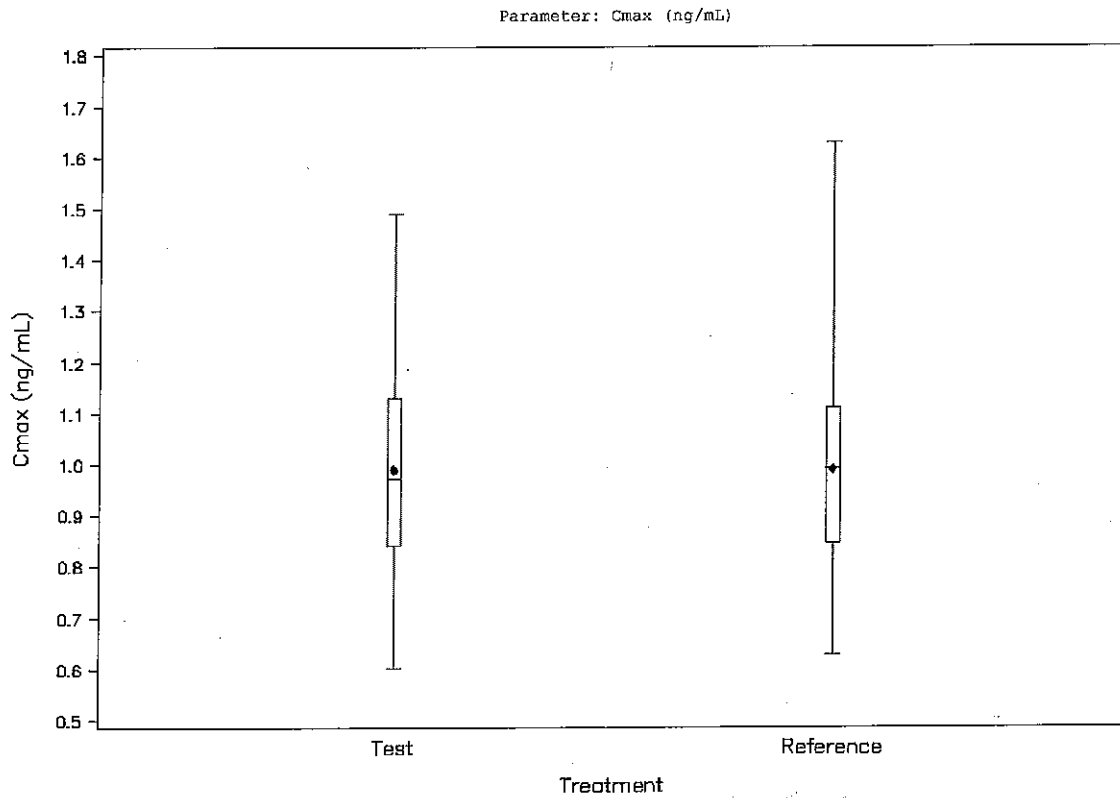
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation

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

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TEL programs/figures/figure
15.4.3.1.2.sas

11DEC2014 00:01

Figure 15.4.3.1.3 Boxplot: Cmax and AUC0-72 for Total T3 (Pharmacokinetic Population)

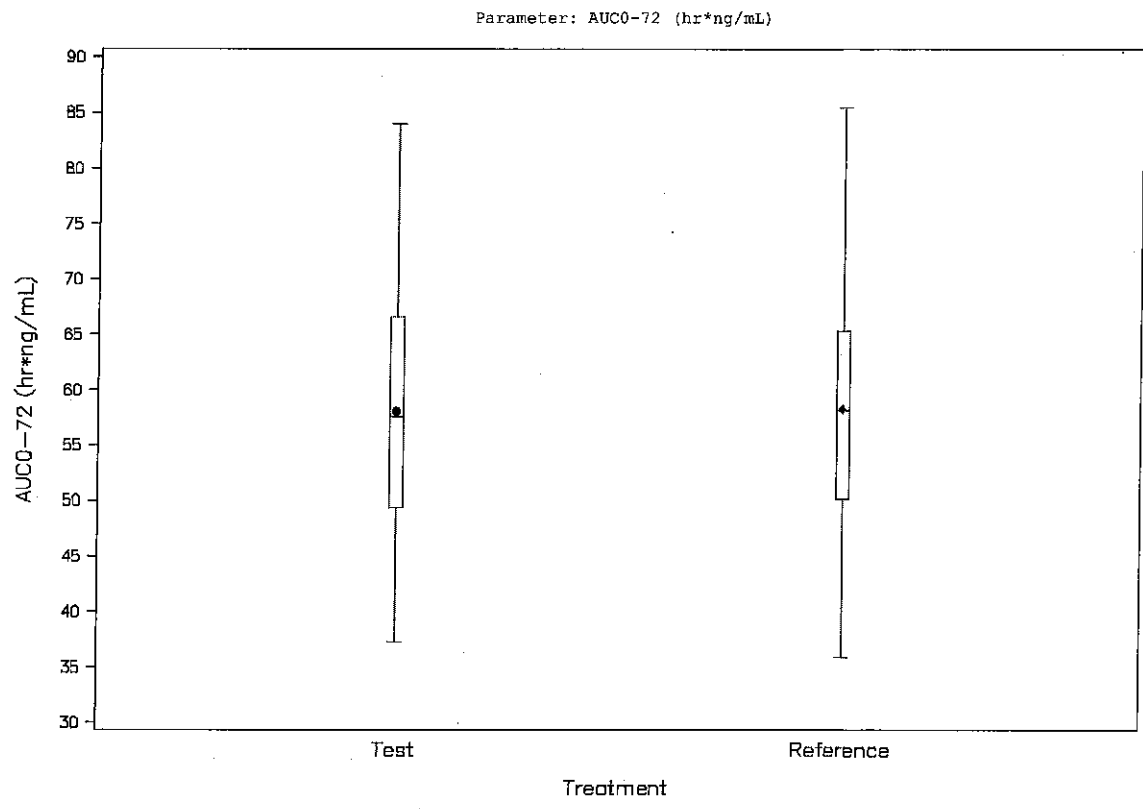


Subjects: ~~4~~ were excluded from the PK Population.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.3.1.3.sas

11DEC2014 00:01

Figure 15.4.3.1.3 Boxplot: Cmax and AUC0-72 for Total T3 (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.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.3.1.3.sas

11DEC2014 00:01



