

**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1501 of 1628 nlation vs. old formulation

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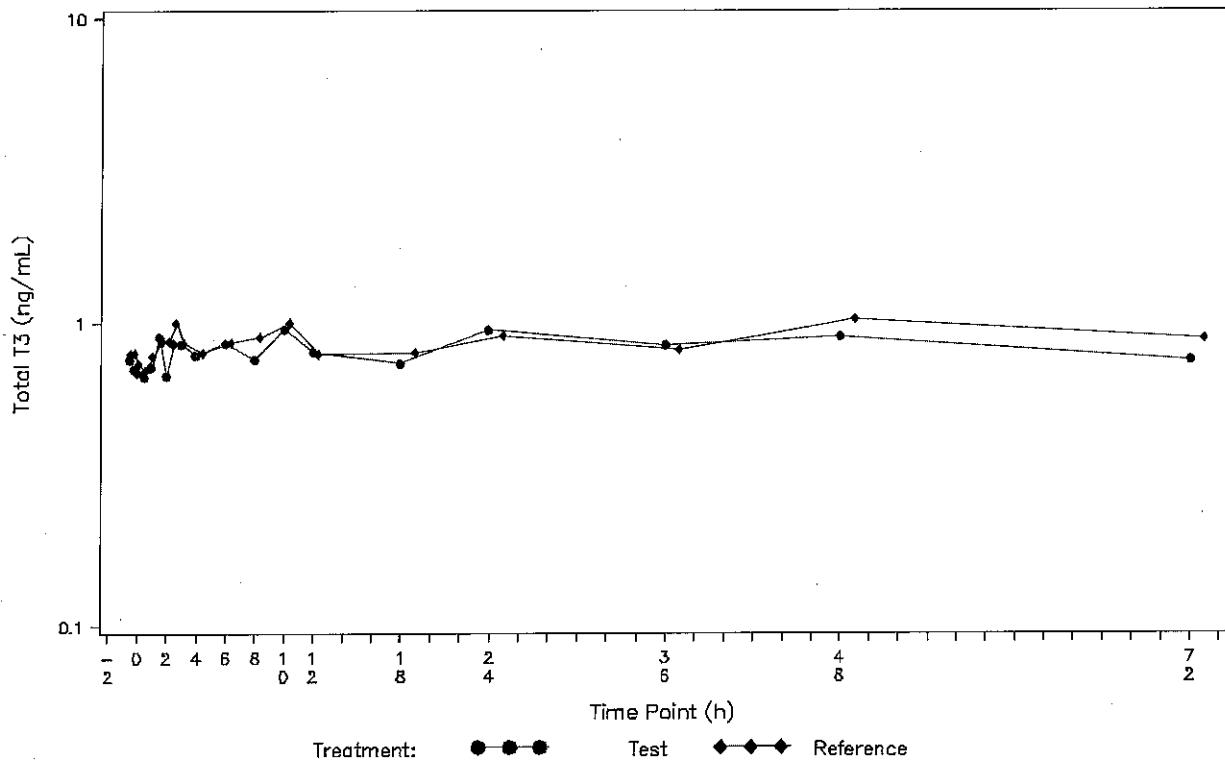
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EMR 200125-001

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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

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EMR 200125-001

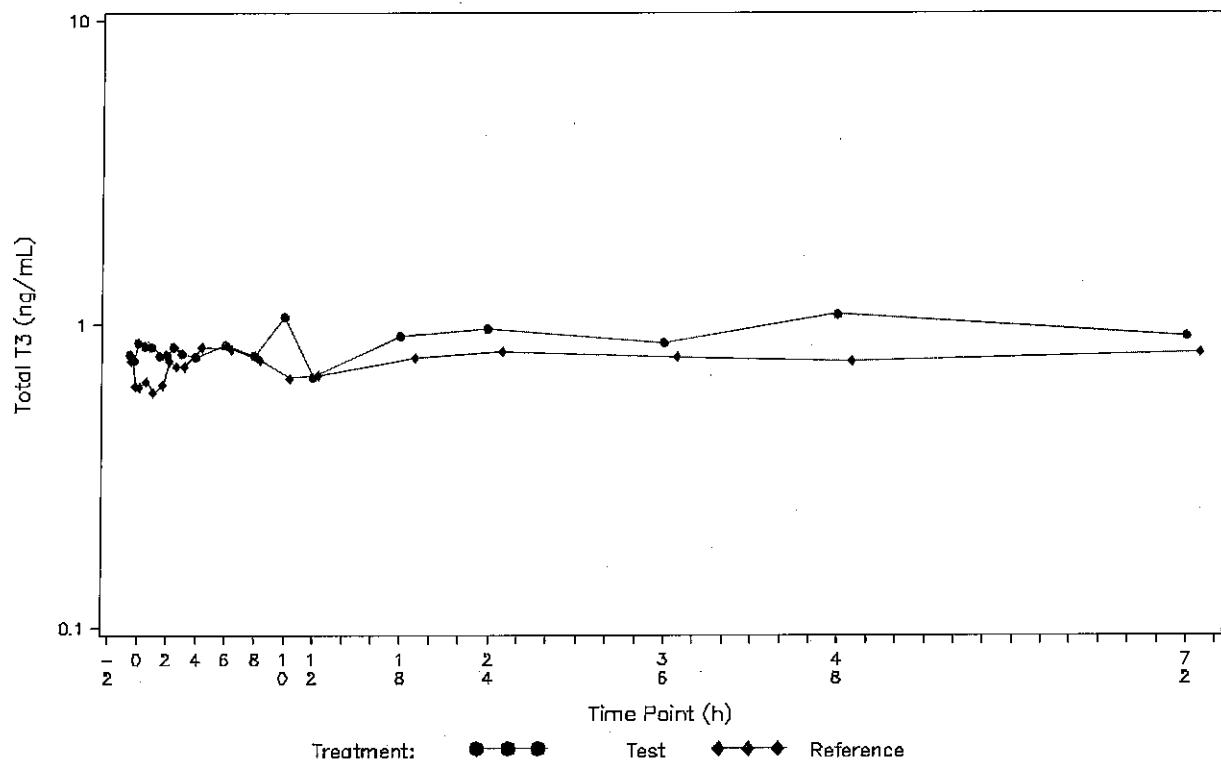
Bioequiv EMR200125-001 Page 1502 of 1628 elation vs. old formulation

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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:



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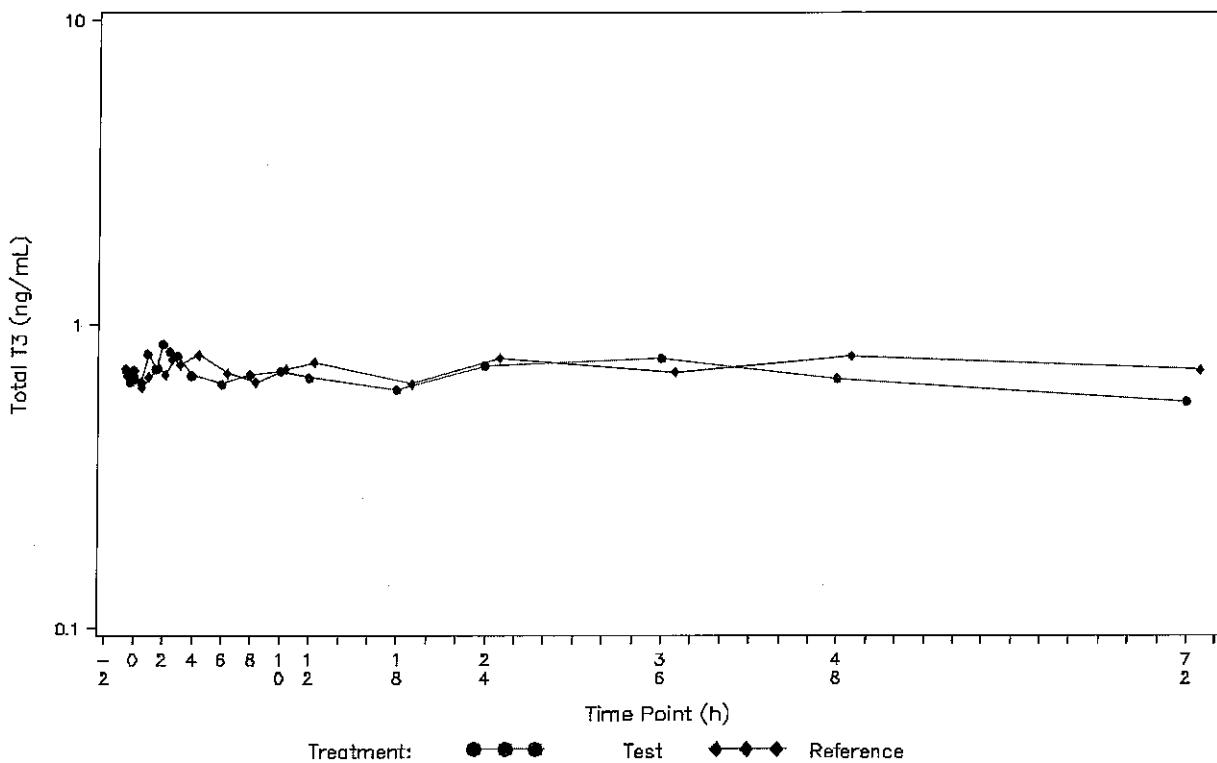
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1503 of 1628 alation vs. old formulation

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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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**Levothyroxine
EMR 200125-001**

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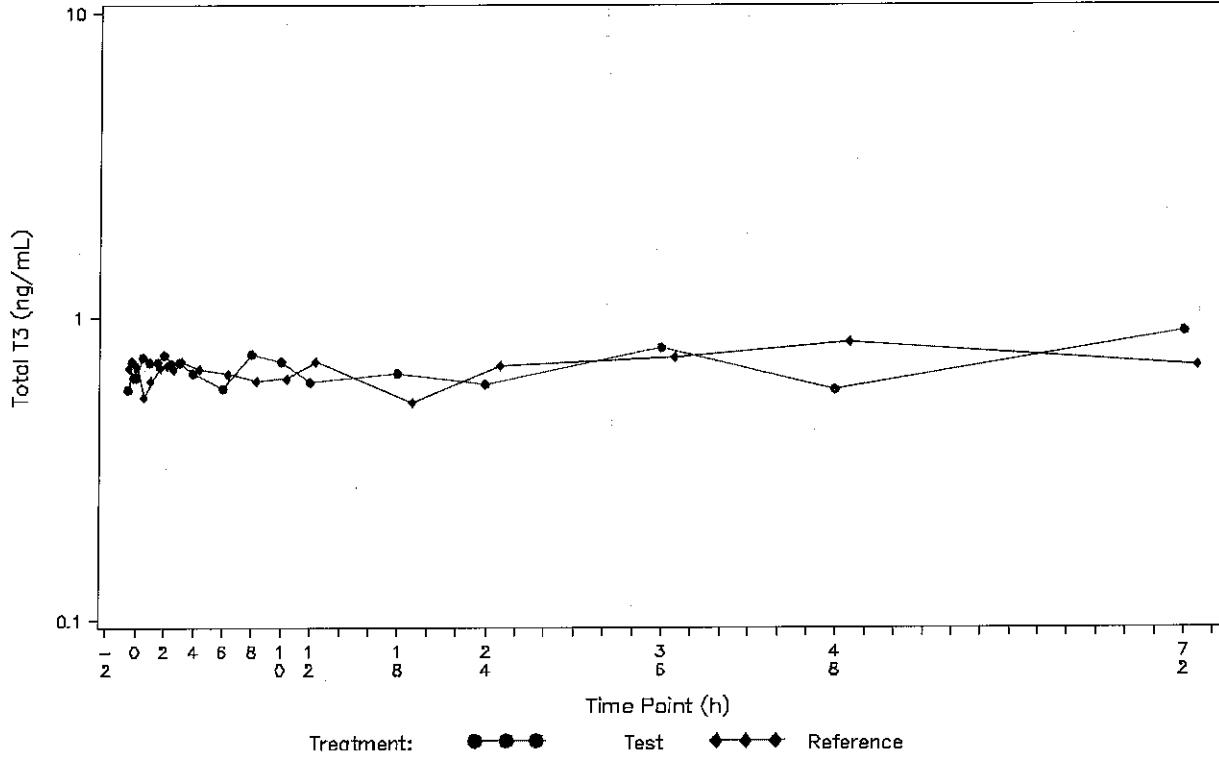
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EMR 200125-001

Figure 15.4.2.

(For Total T3 values) (Safety Population) Subject ID/Random Number:

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Subject ID/Random Number:



6:Subjects excluded from PK Population;
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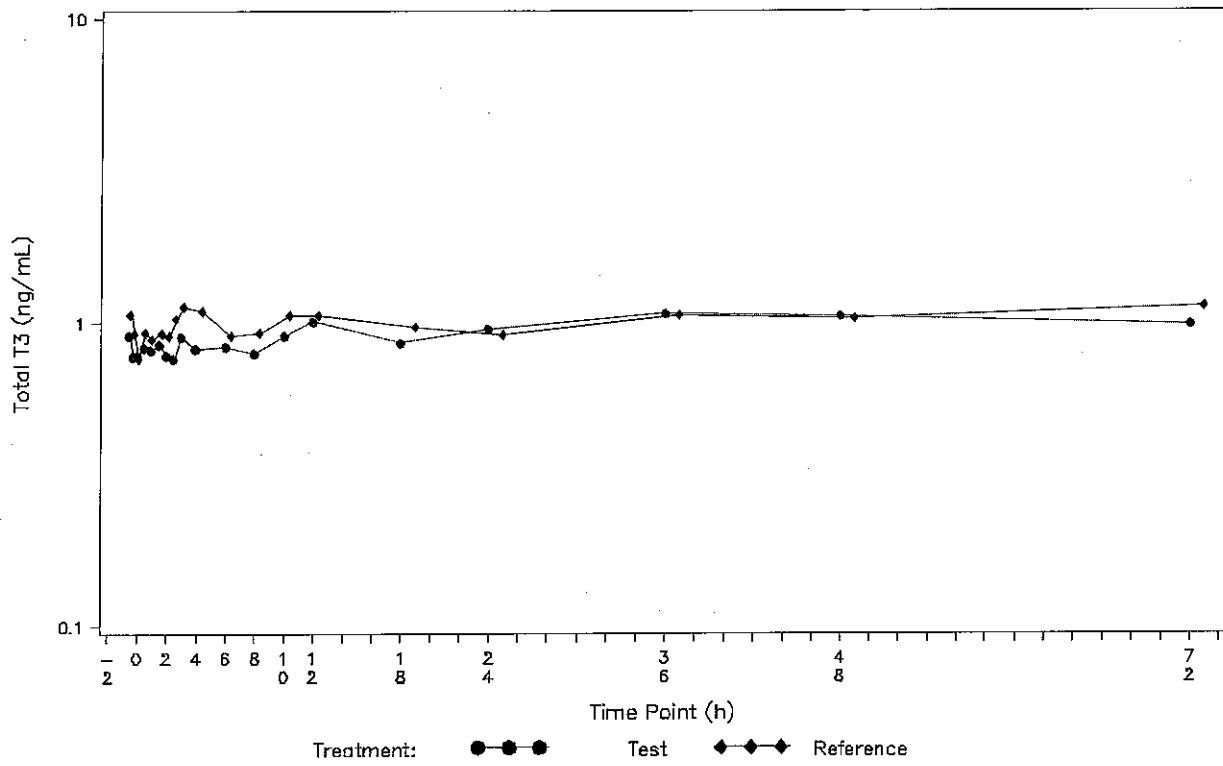
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1505 of 1628 alation 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:



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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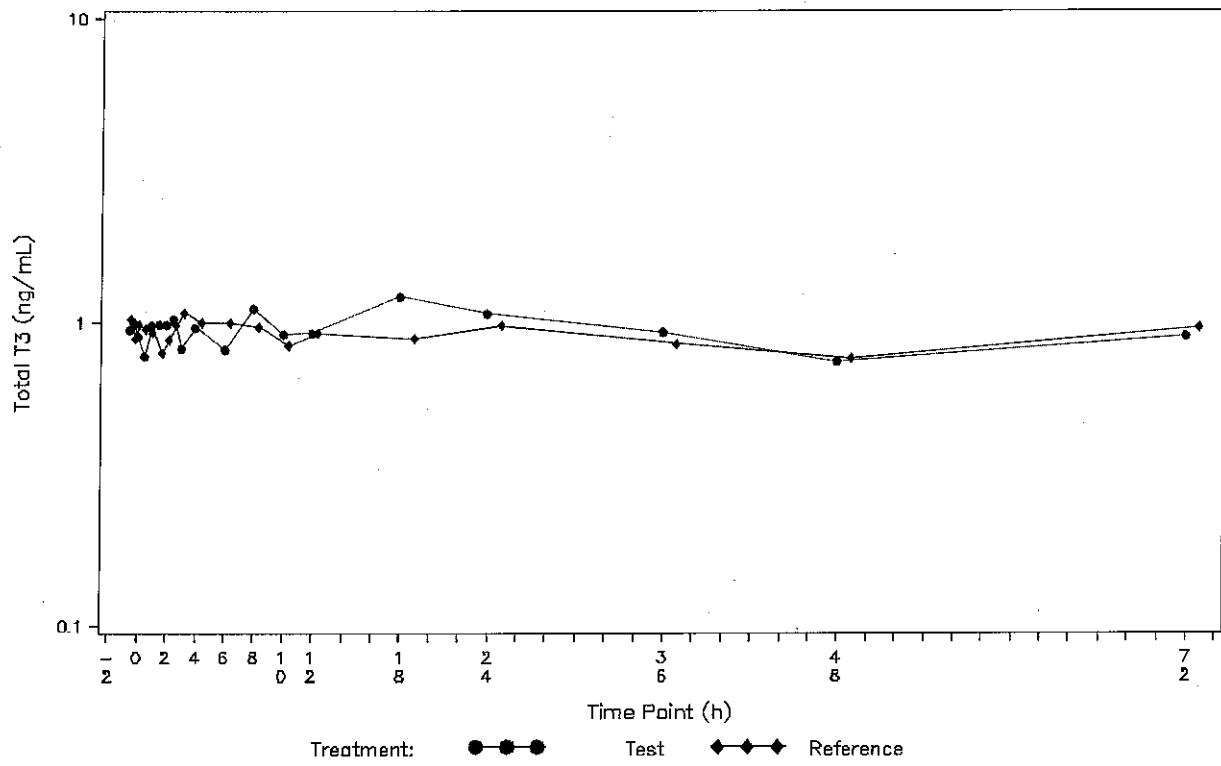
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1506 of 1628 nulation 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:



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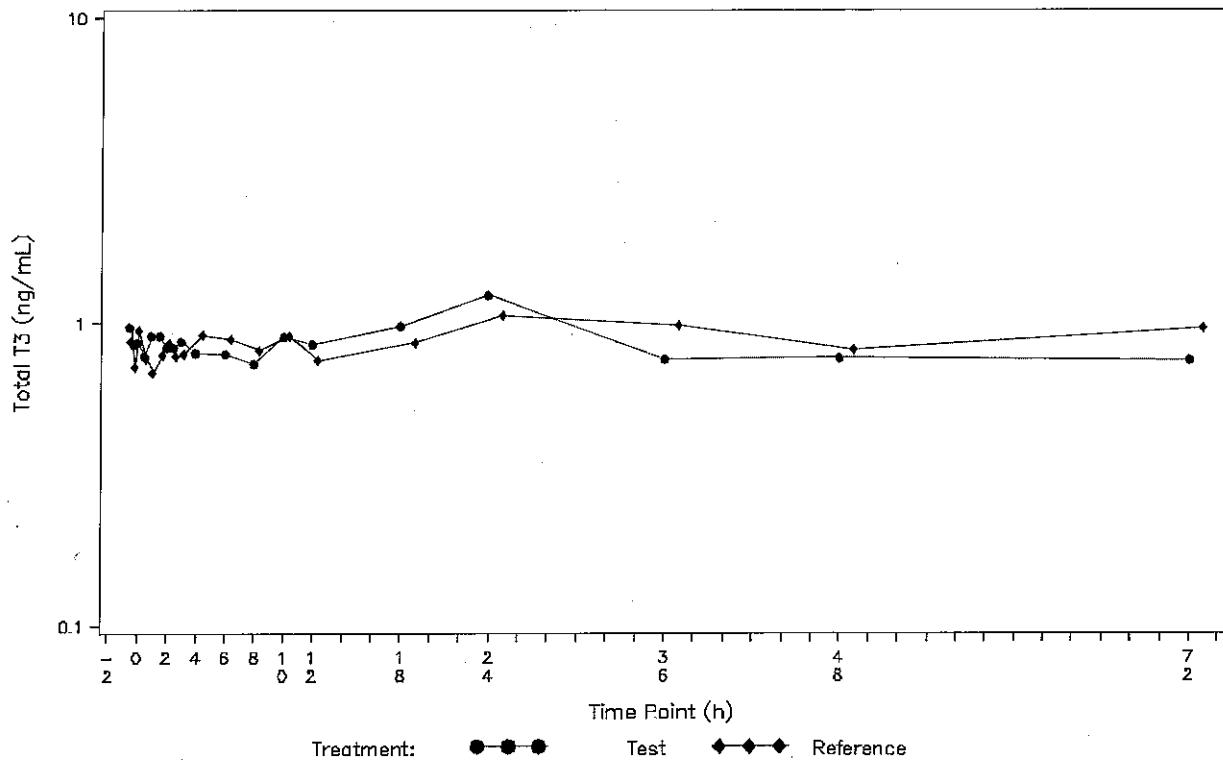
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1507 of 1628 alation vs. old formulation

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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:



**Levothyroxine
EMR 200125-001**

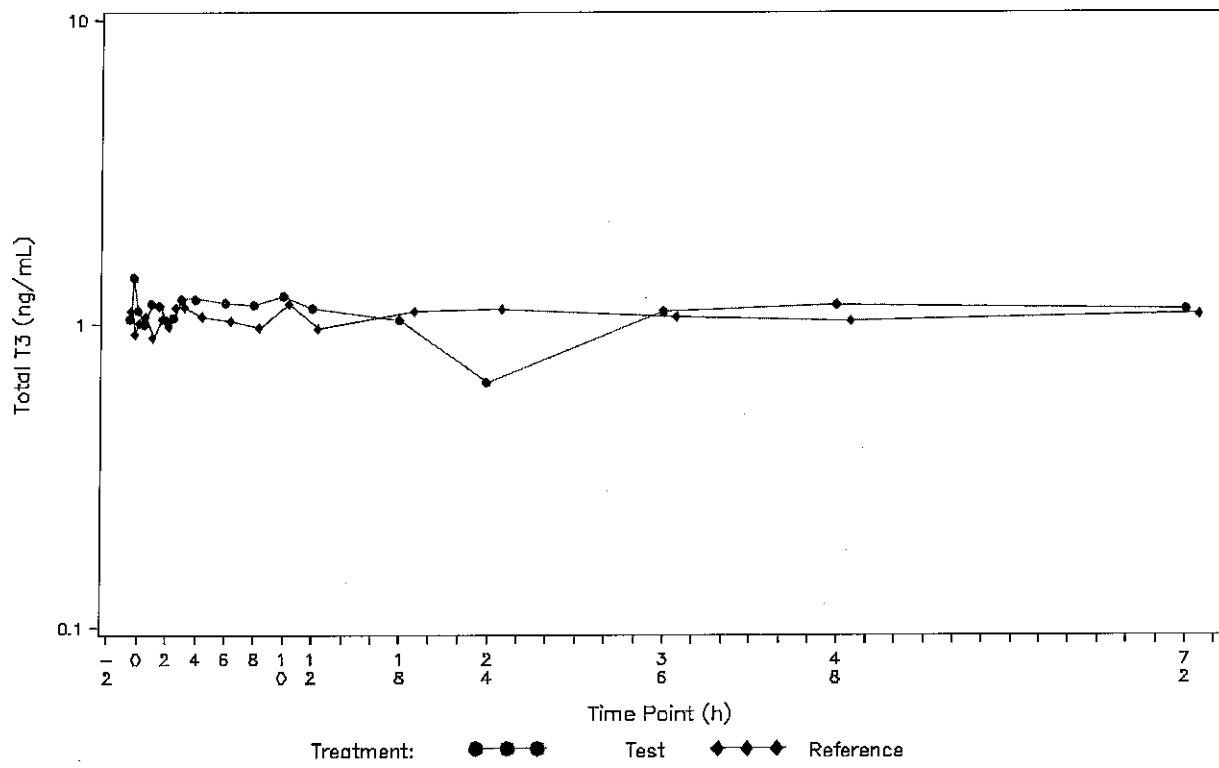
Bioequiv EMR200125-001 Page 1508 of 1628 nulation vs. old formulation

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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:



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Source: Table 16.2.5.3

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EMR 200125-001

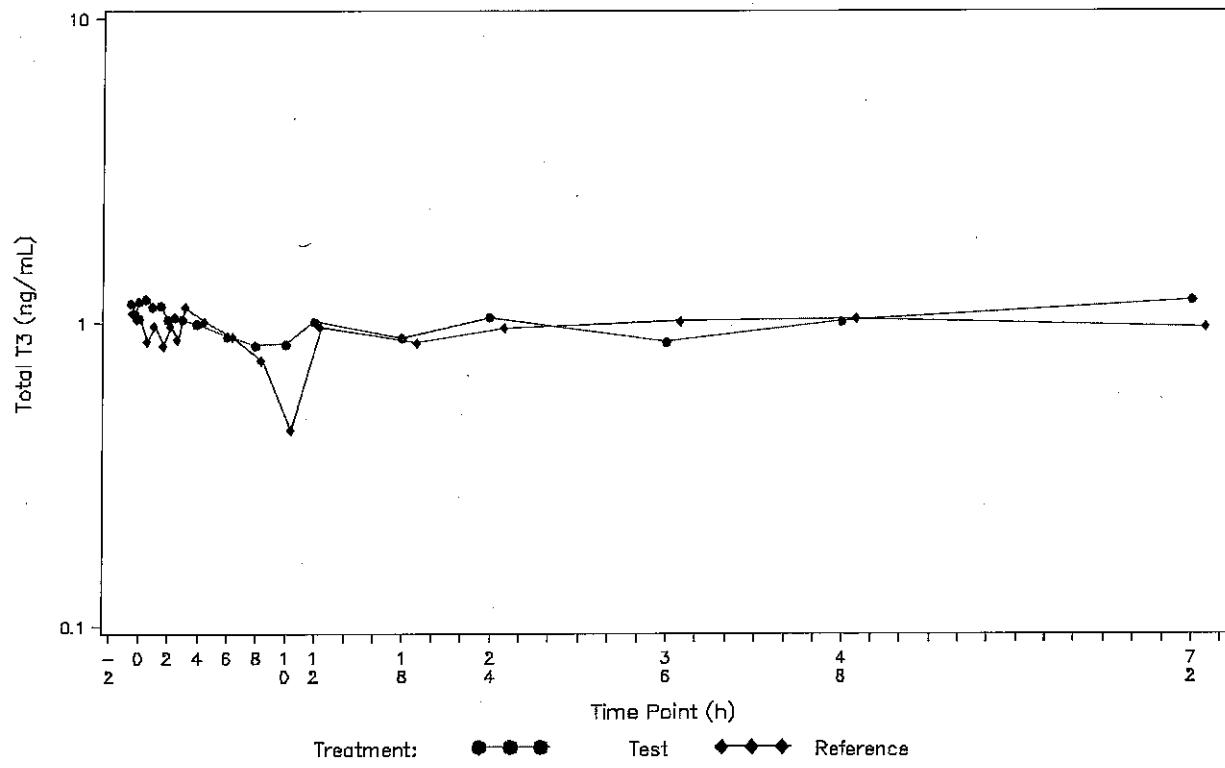
Bioequiv EMR200125-001 Page 1509 of 1628 nulation vs. old formulation

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

Source: Table 16.2.5.3

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**Levothyroxine
EMR 200125-001**

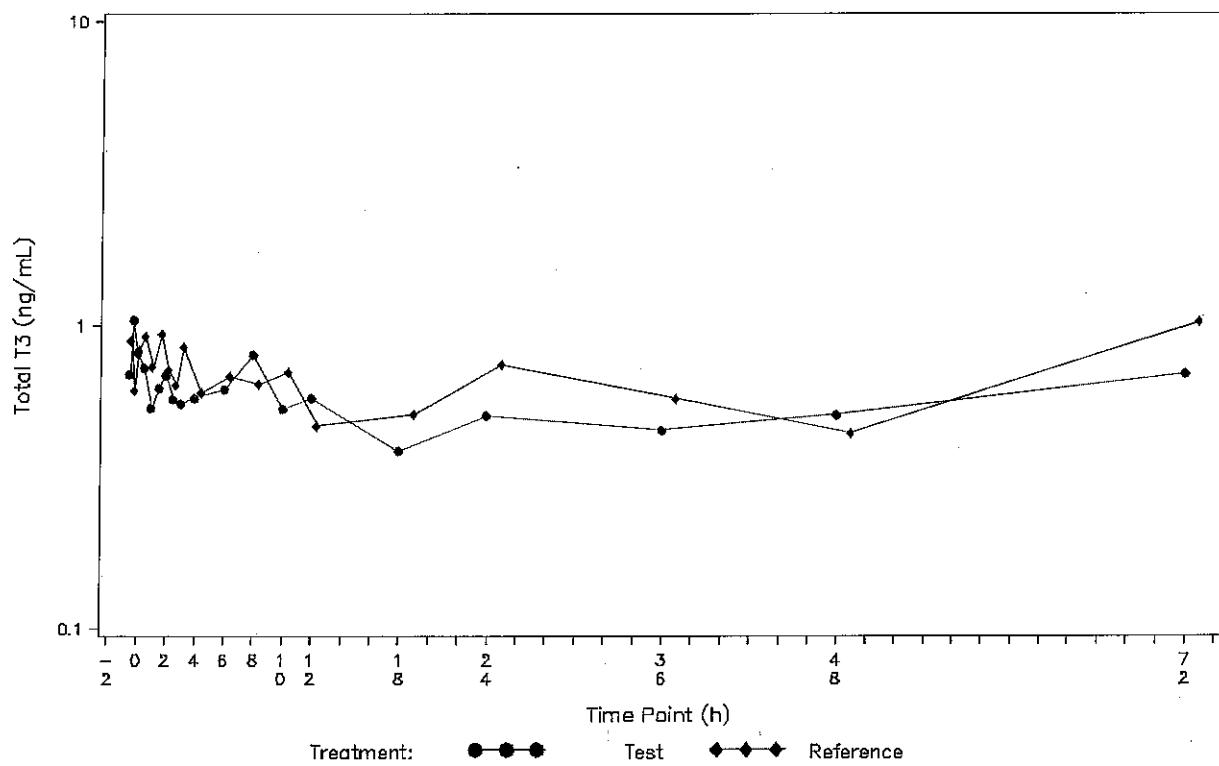
Bioequiv EMR200125-001 Page 1510 of 1628 alation vs. old formulation

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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: :



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

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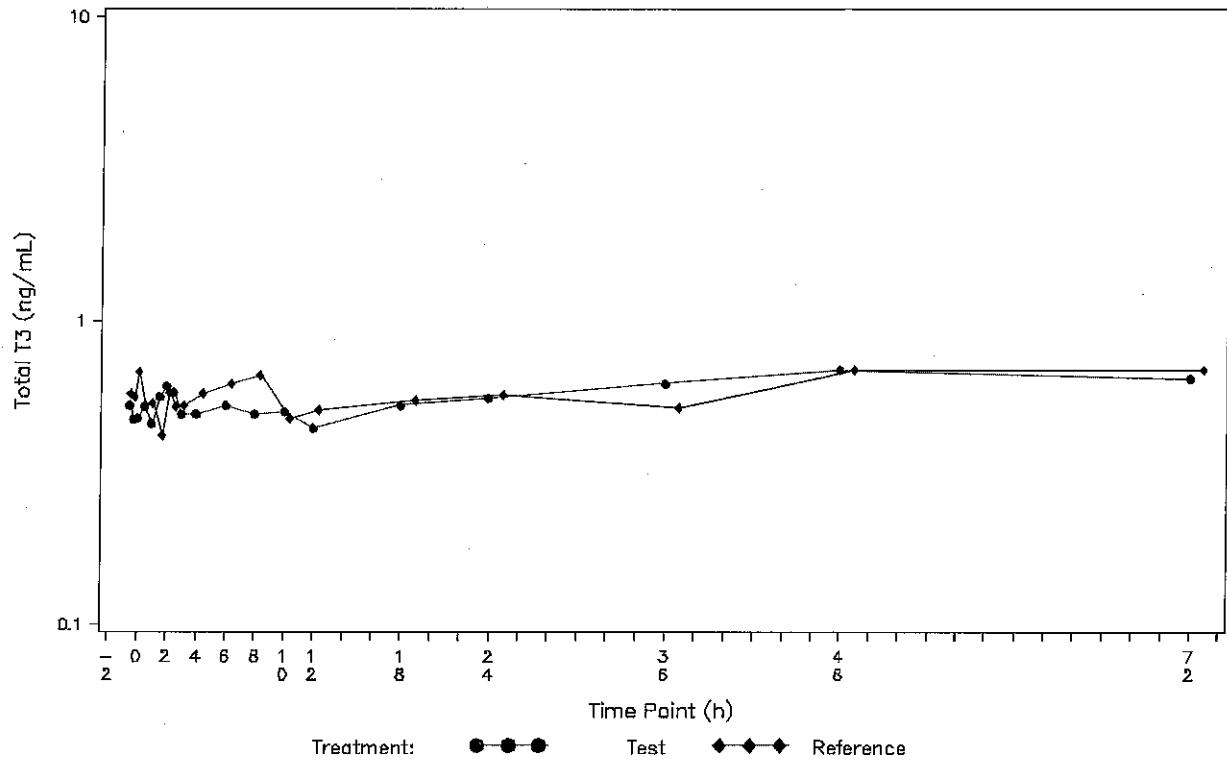
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 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

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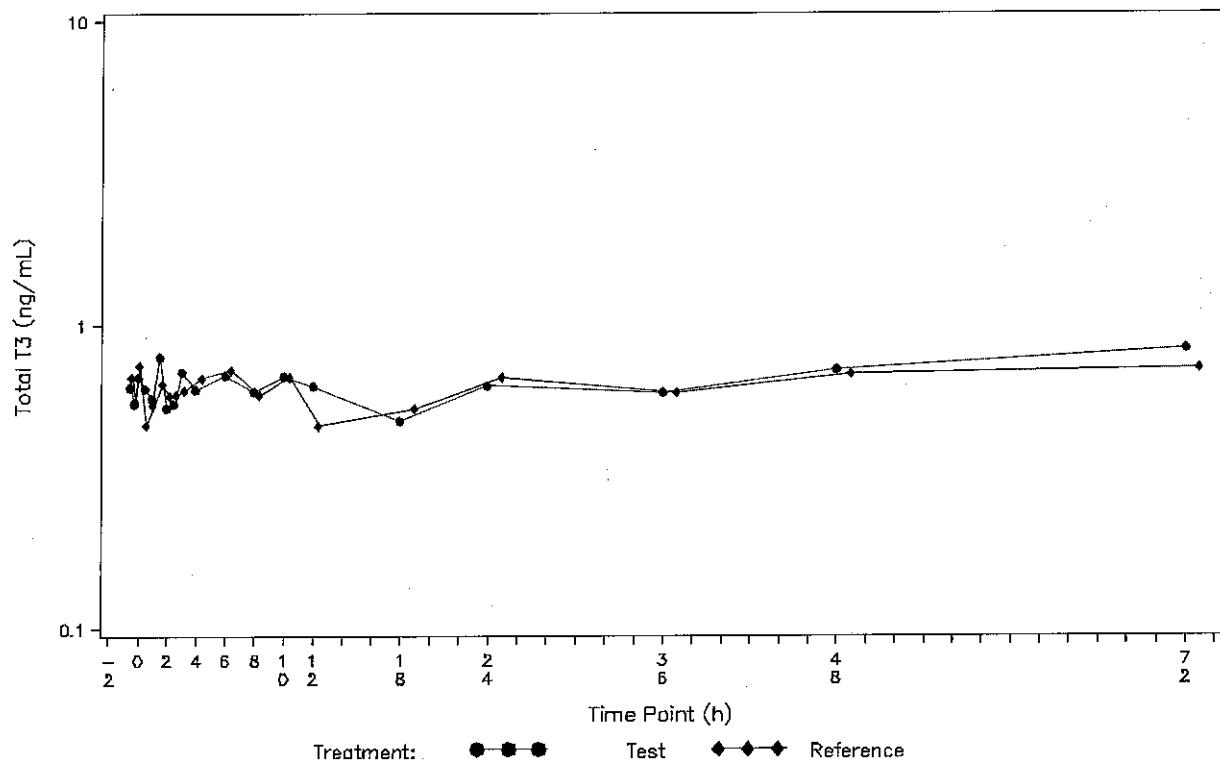
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1512 of 1628 ilation vs. old formulation

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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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EMR 200125-001

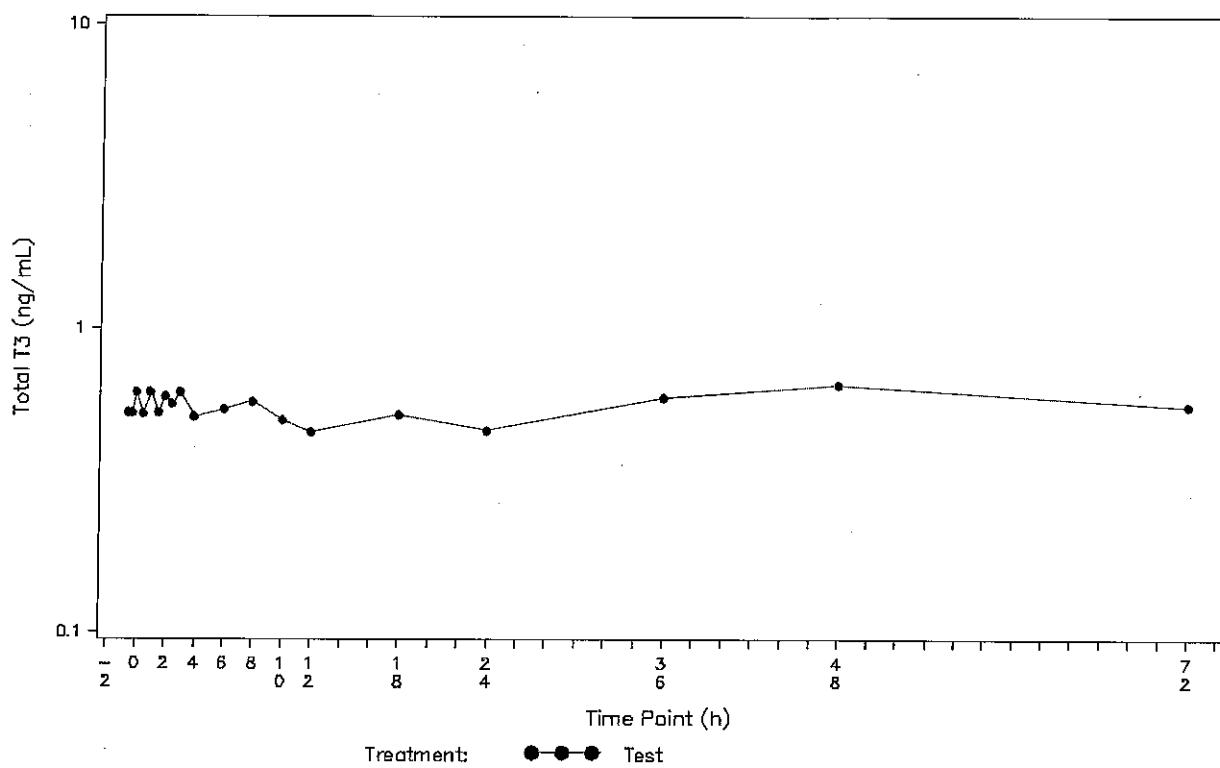
Bioequiv EMR200125-001 Page 1513 of 1628 uation vs. old formulation

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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:



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**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1514 of 1628 nulation vs. old formulation

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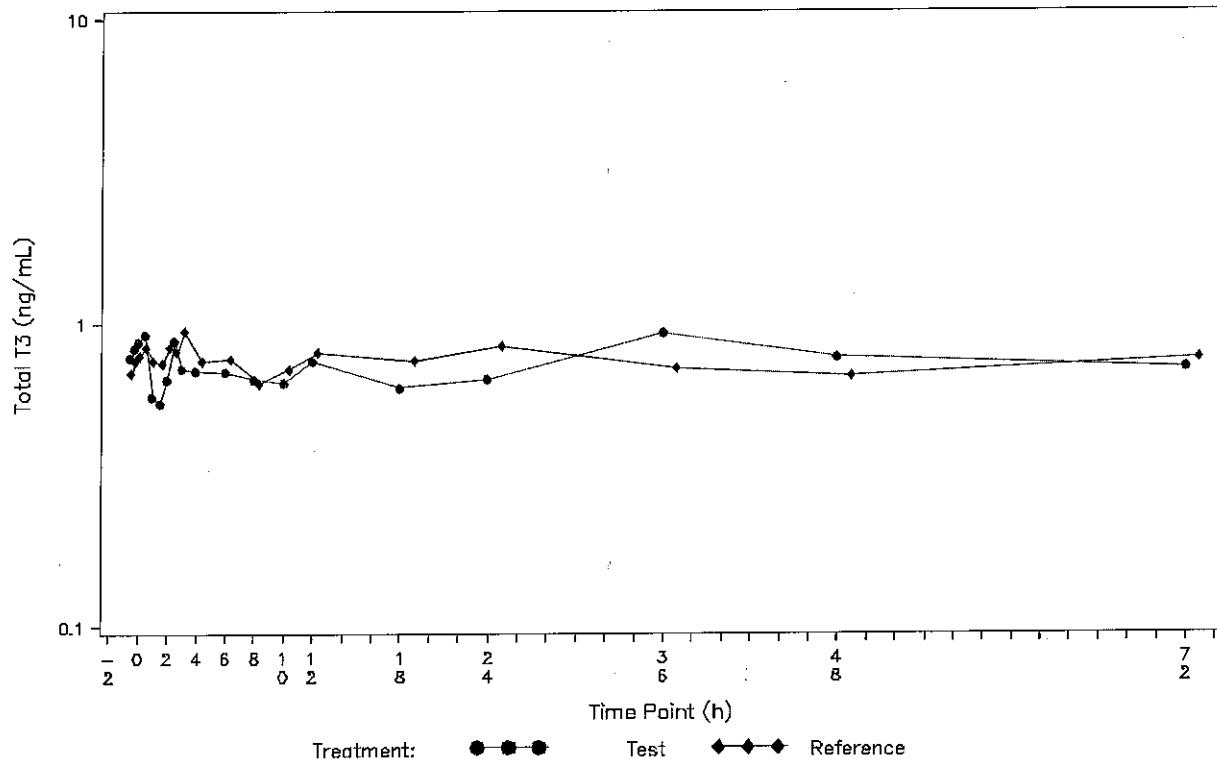
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EMR 200125-001

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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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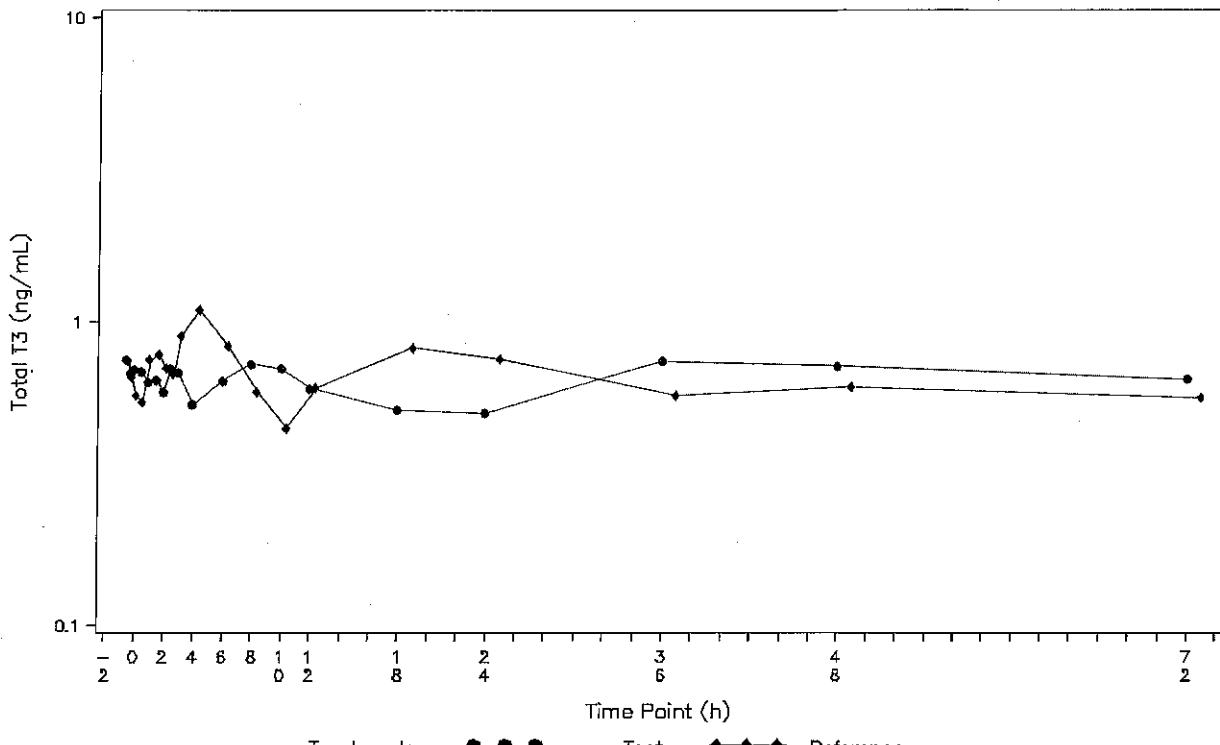
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1515 of 1628 alation vs. old formulation

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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)

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**Levothyroxine
EMR 200125-001**

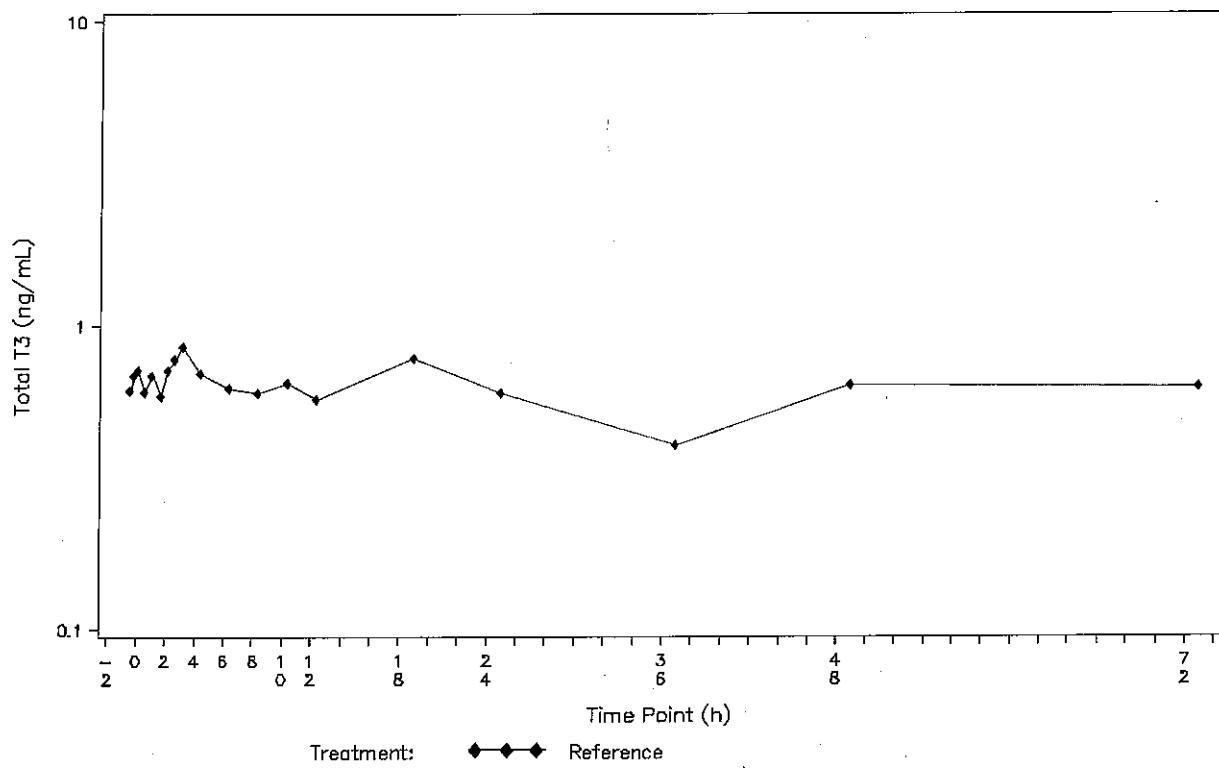
Bioequiv EMR200125-001 Page 1516 of 1628 nulation vs. old formulation

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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)

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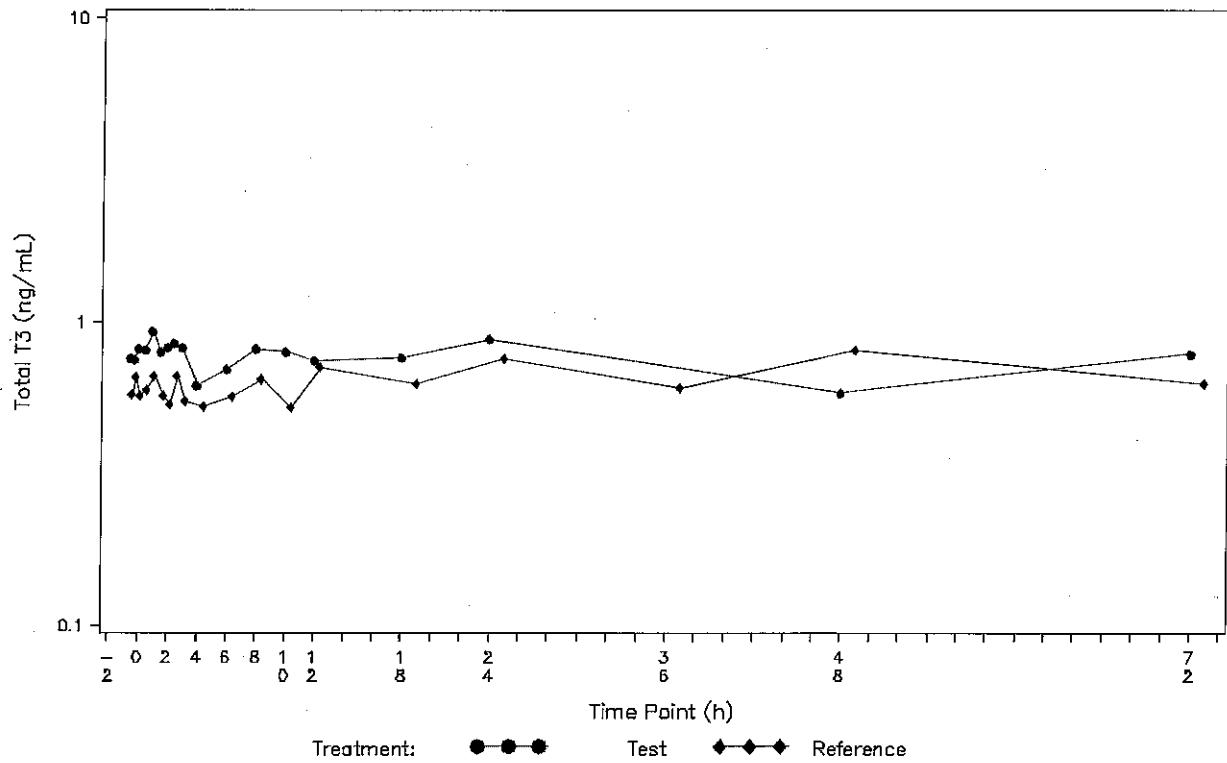
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1517 of 1628 nulation 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:



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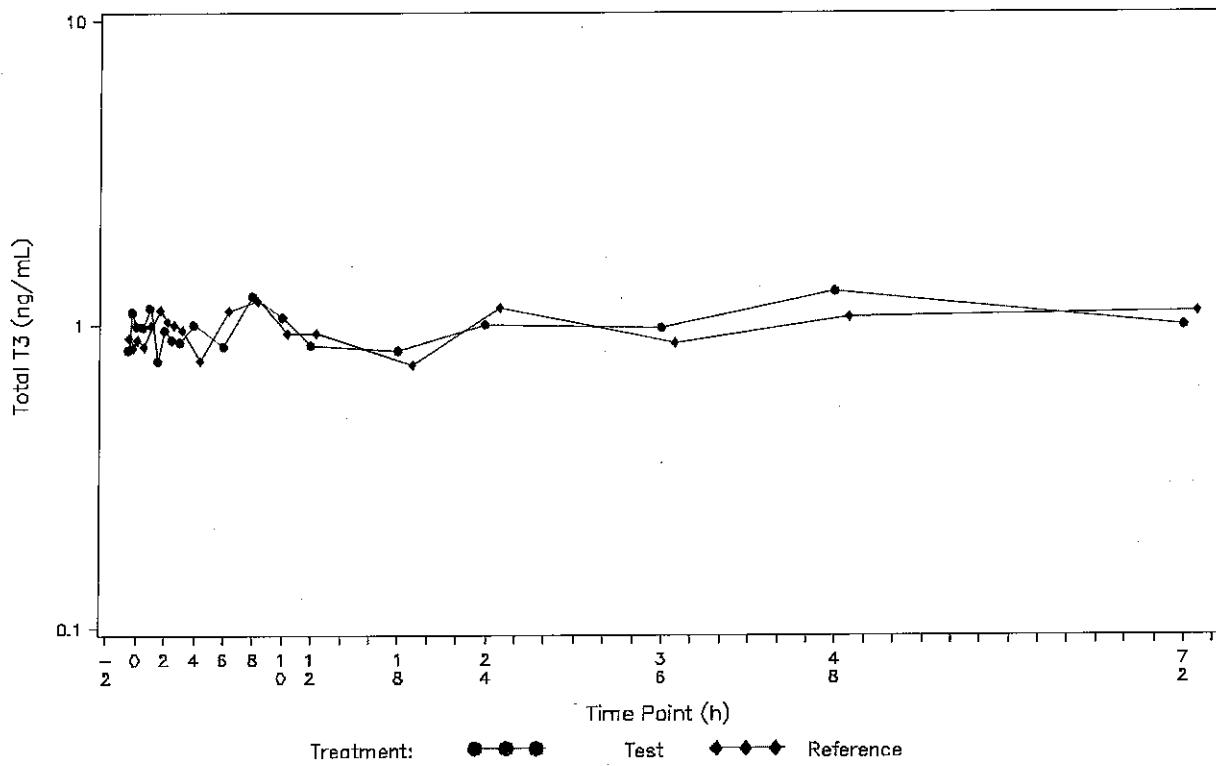
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1518 of 1628 uation vs. old formulation

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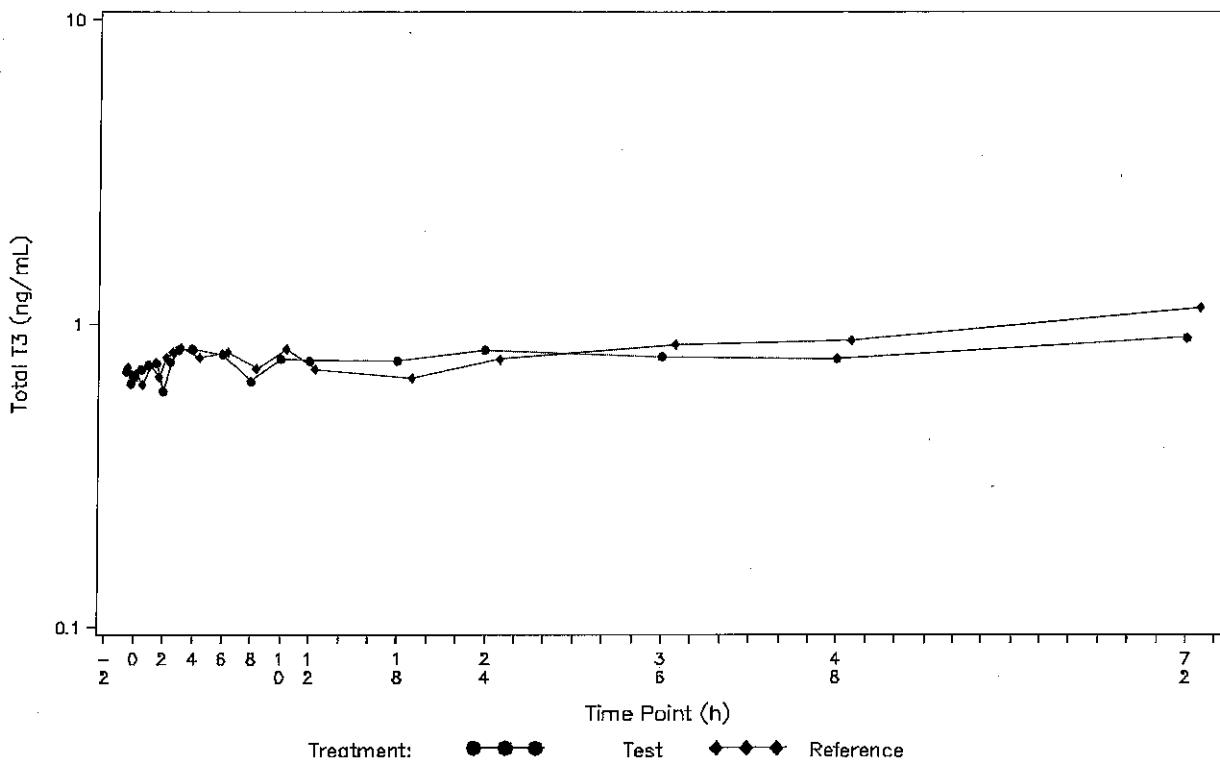
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EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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Levothyroxine
EMR 200125-001

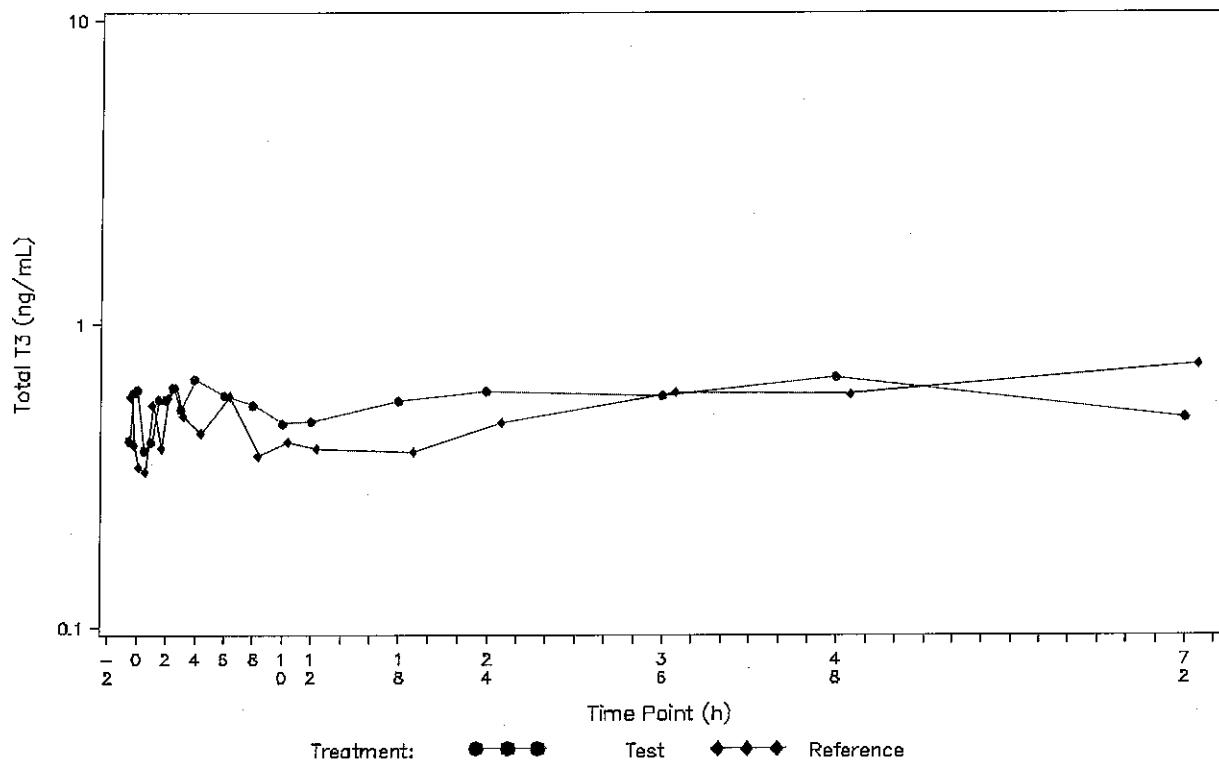
Bioequiv EMR200125-001 Page 1520 of 1628 alation vs. old formulation

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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:



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Levothyroxine
EMR 200125-001

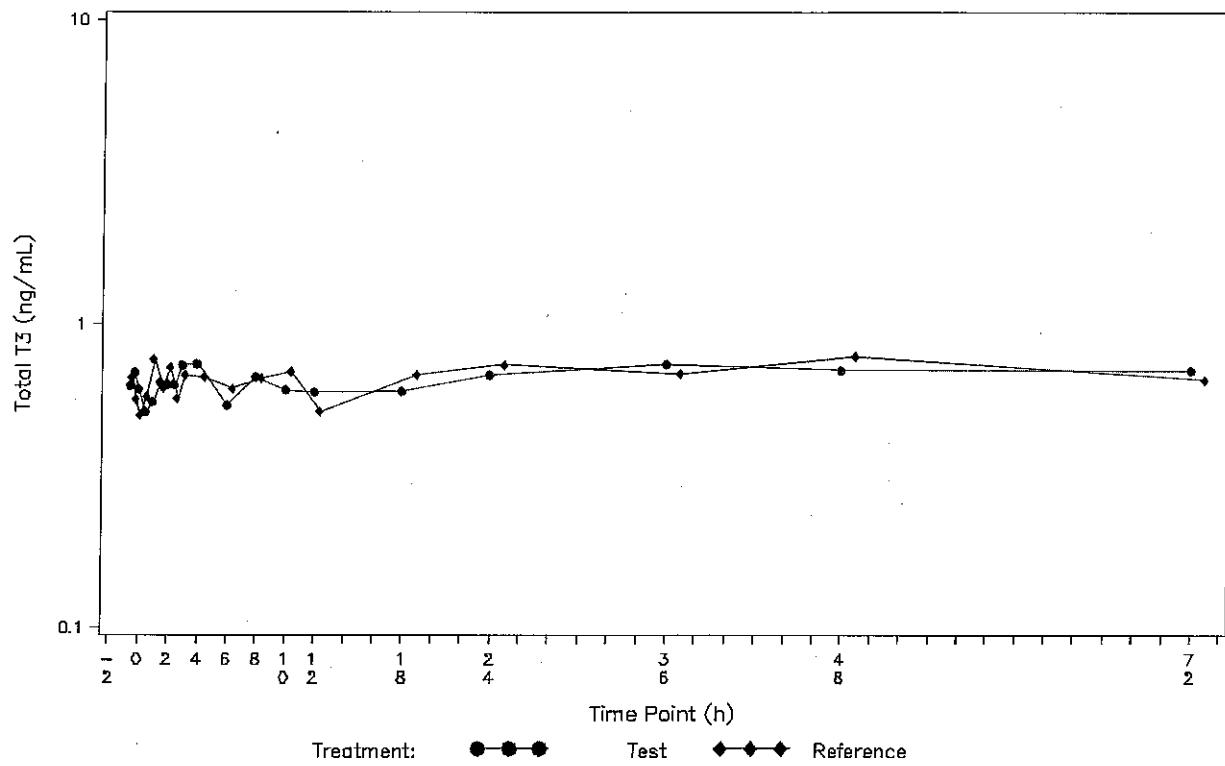
Bioequiv EMR200125-001 Page 1521 of 1628 nulation vs. old formulation

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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:



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**Levothyroxine
EMR 200125-001**

Bioequiv **EMR200125-001** Page 1522 of 1628 ulation vs. old formulation

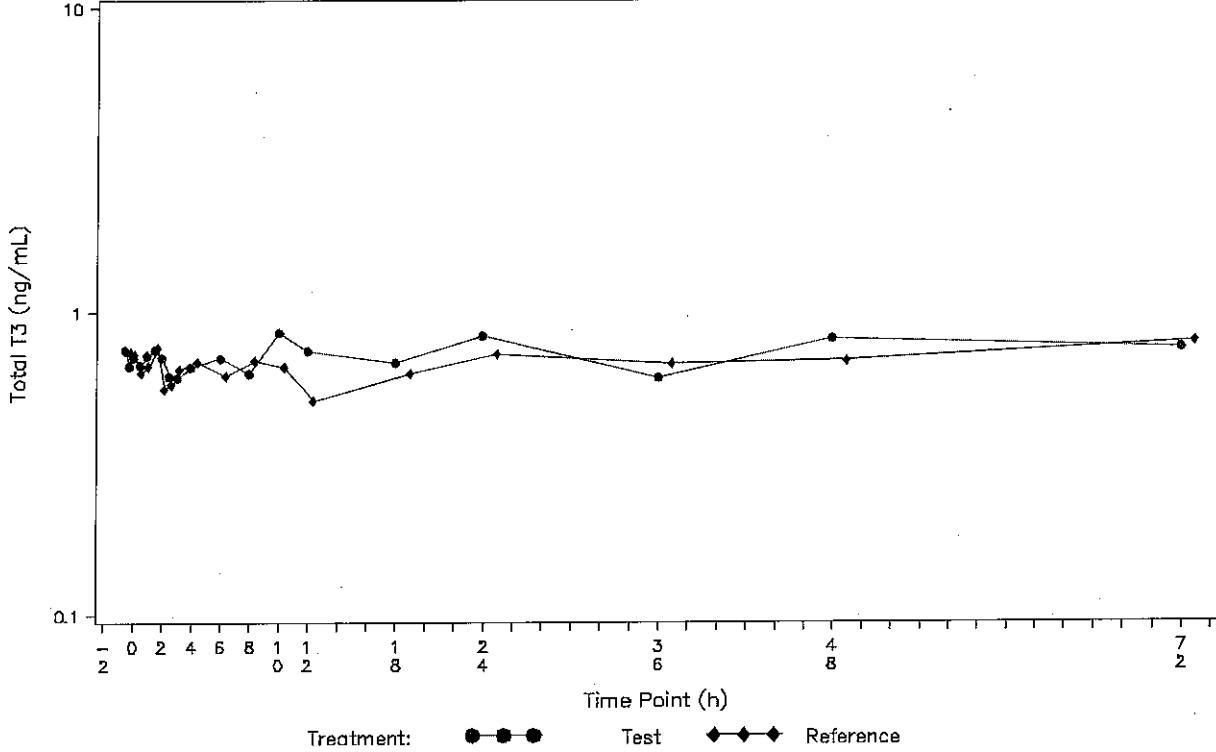
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EMR 200125-001

EMR 200129-001

Figure 15.4.2...
(For Total T3 =

(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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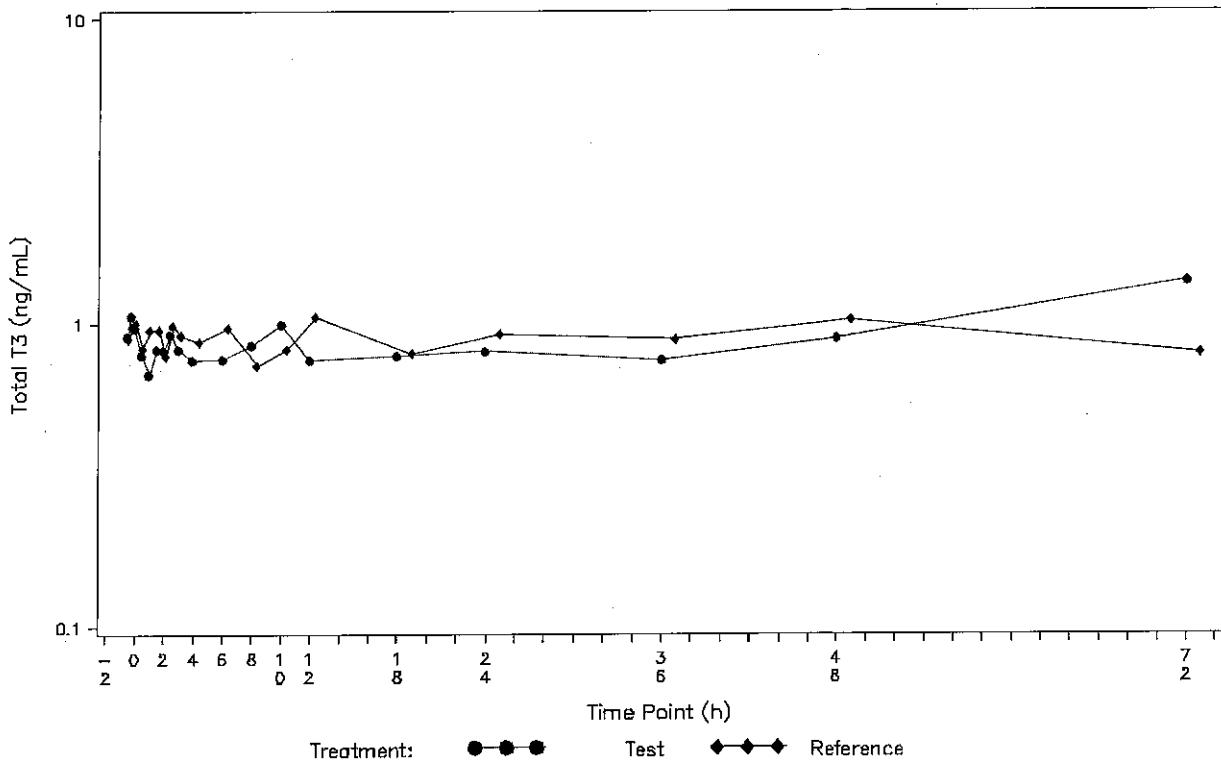
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1523 of 1628 nulation vs. old formulation

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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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Levothyroxine
EMR 200125-001

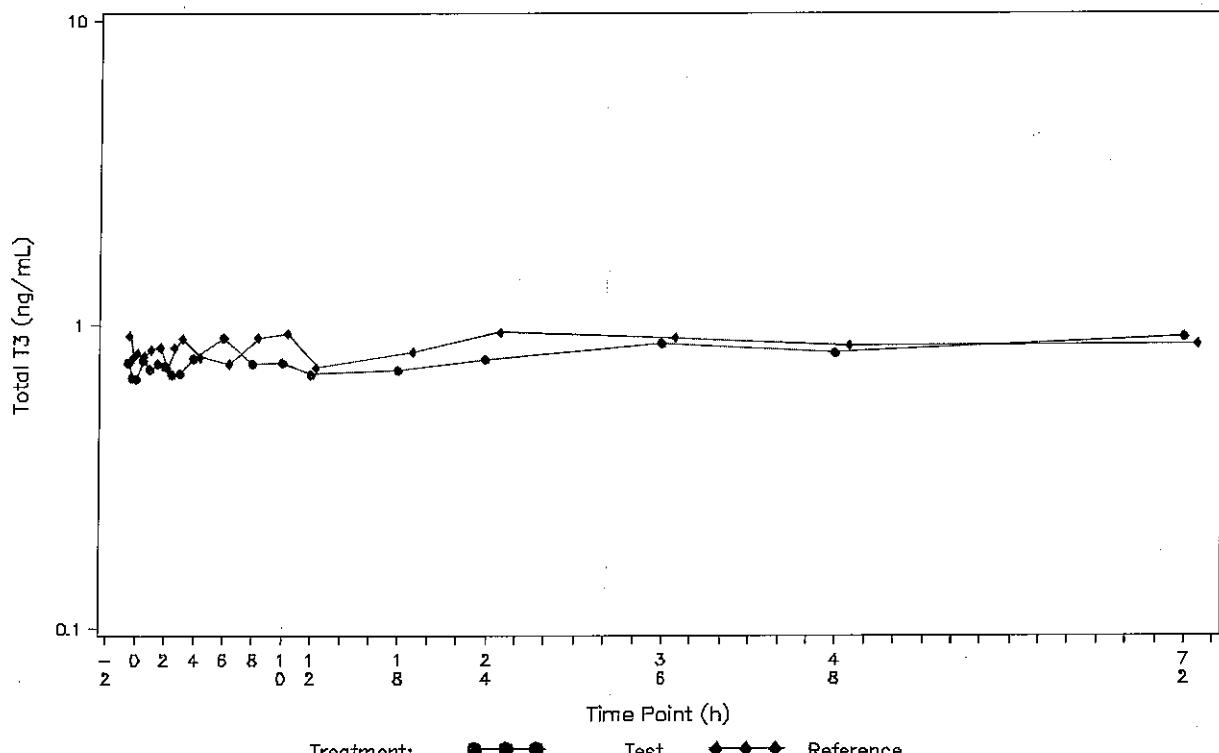
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EMR 200125-001

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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:



④: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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**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1525 of 1628 ulation vs. old formulation

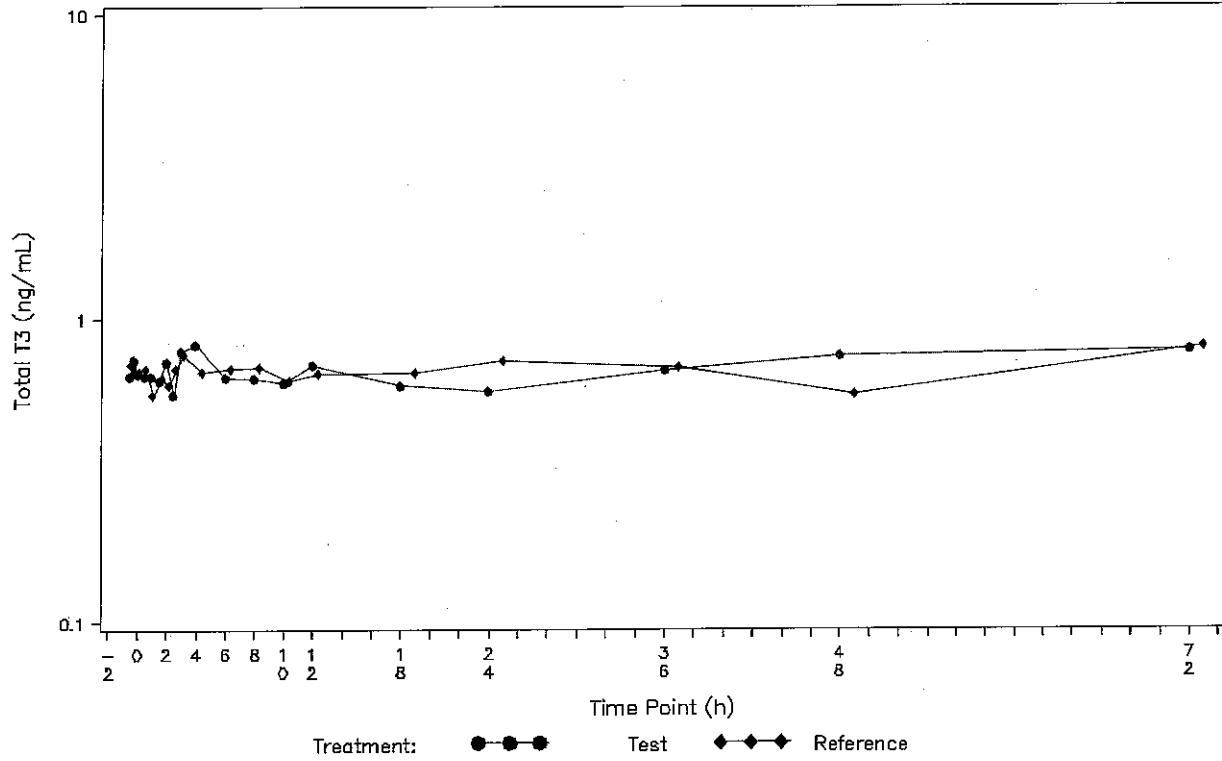
Page 120 of 216
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Merck Serono
EMR 200125-001

Figure 15.4.2

Subject ID/Random Number:

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

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**Levothyroxine
EMR 200125-001**

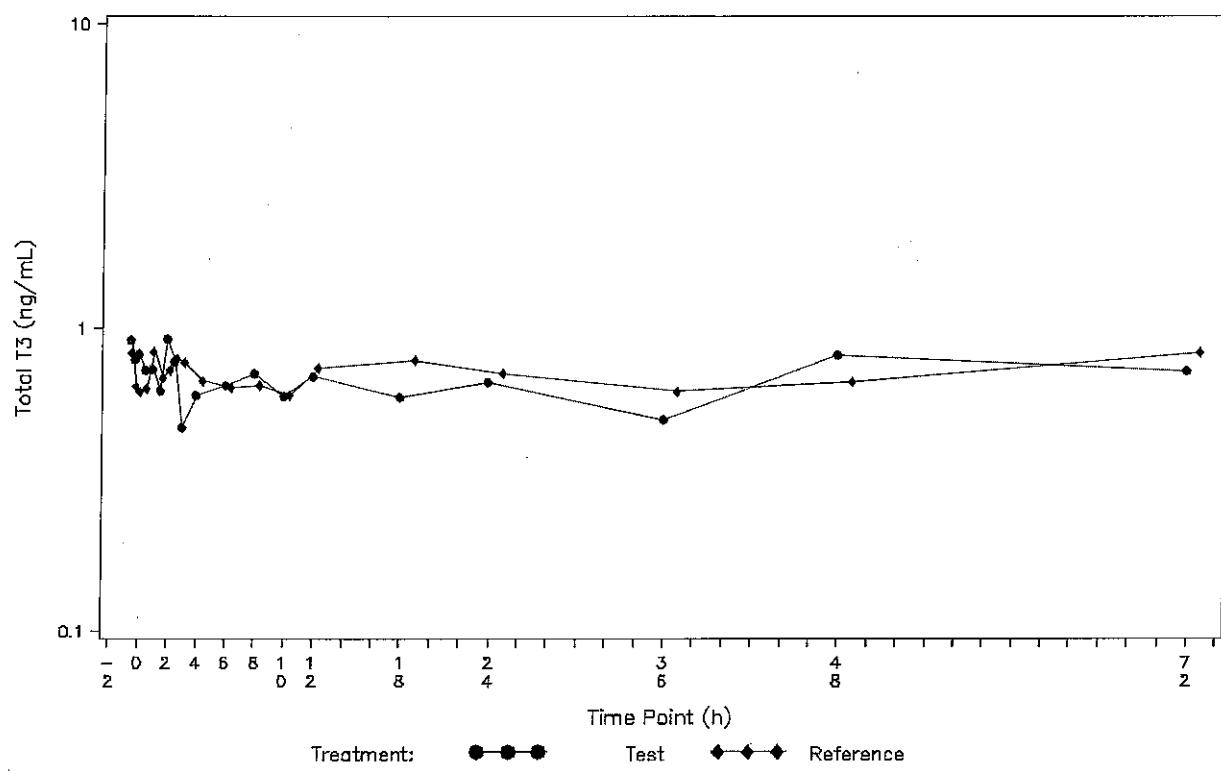
Bioequiv EMR200125-001 Page 1526 of 1628 nulation vs. old formulation

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:



④: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
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Levothyroxine
EMR 200125-001

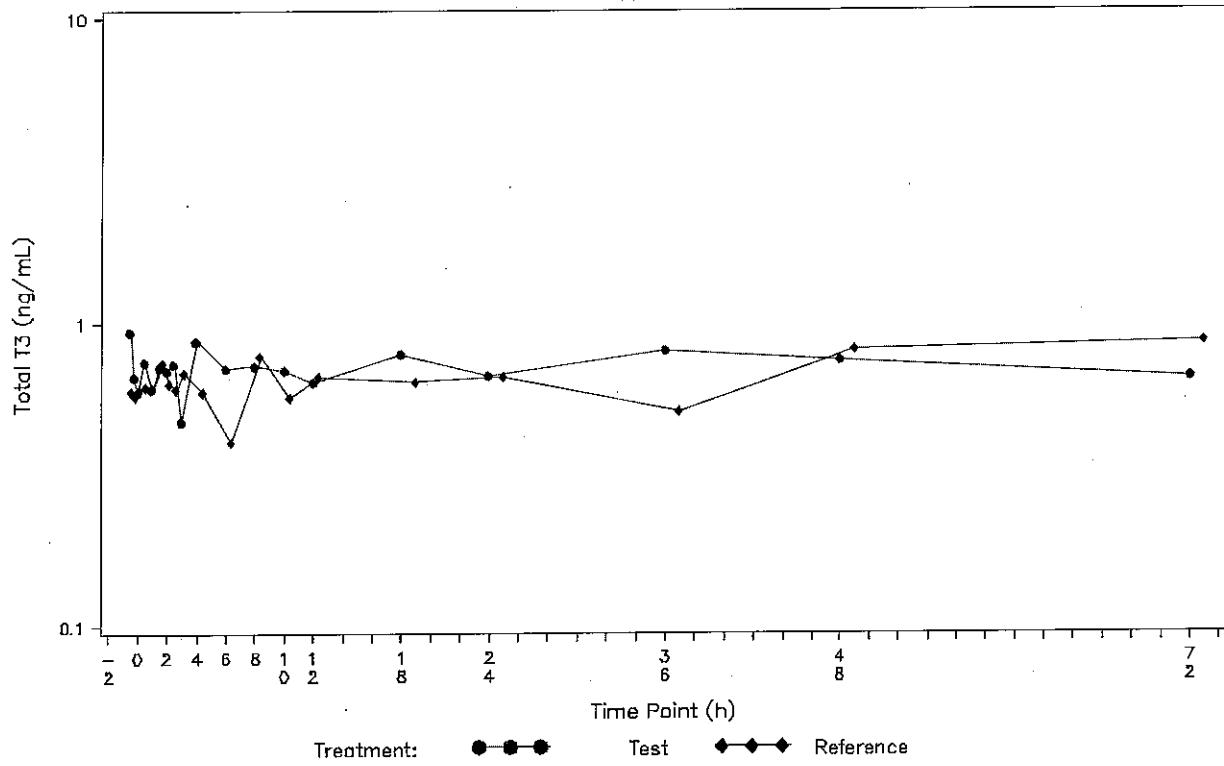
Bioequiv EMR200125-001 Page 1527 of 1628 nlation vs. old formulation

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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

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**Levothyroxine
EMR 200125-001**

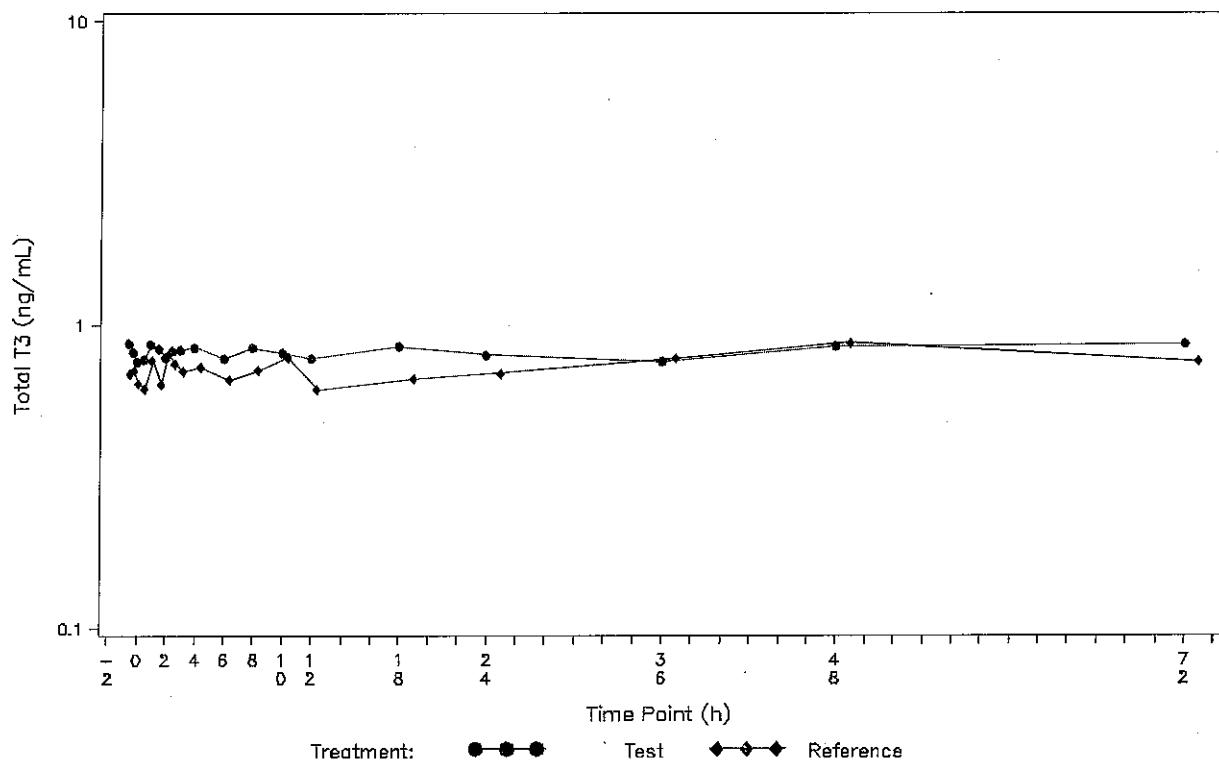
Bioequiv EMR200125-001 Page 1528 of 1628 ulation vs. old formulation

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

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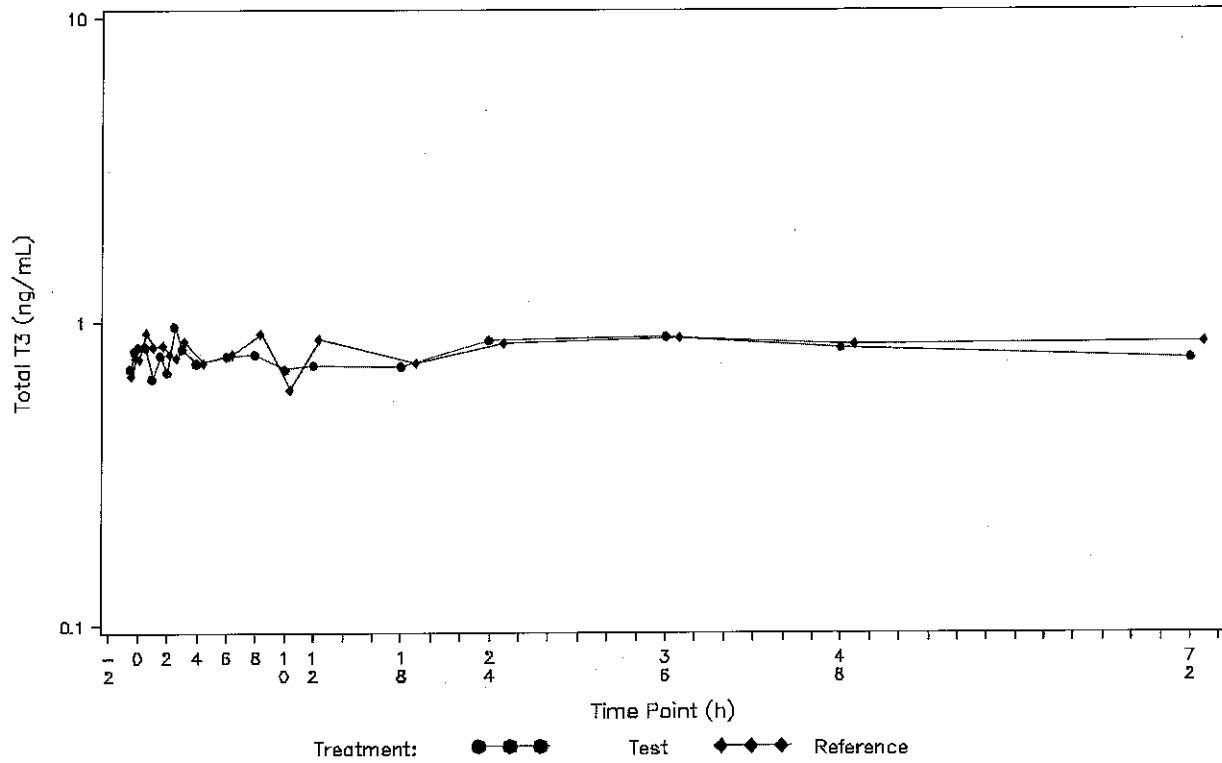
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1529 of 1628 uation 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

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Levothyroxine
EMR 200125-001

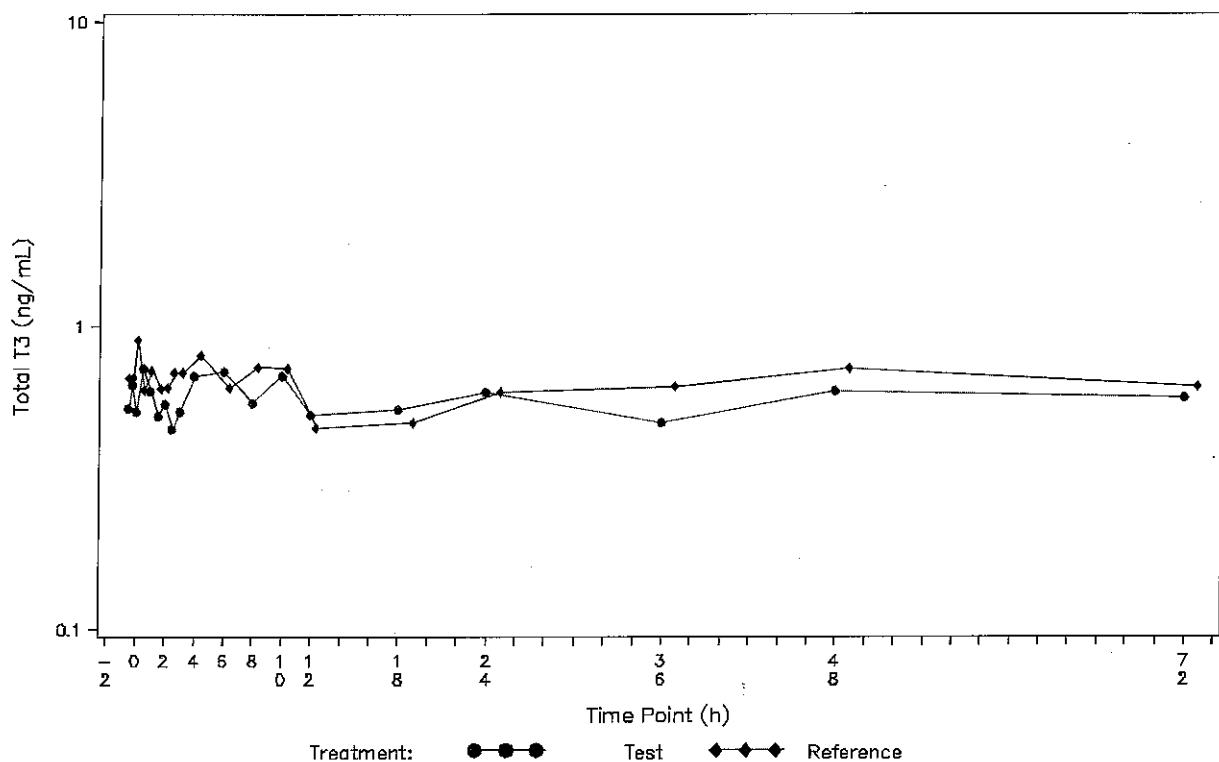
Bioequiv EMR200125-001 Page 1530 of 1628 ulation vs. old formulation

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: 1



④: 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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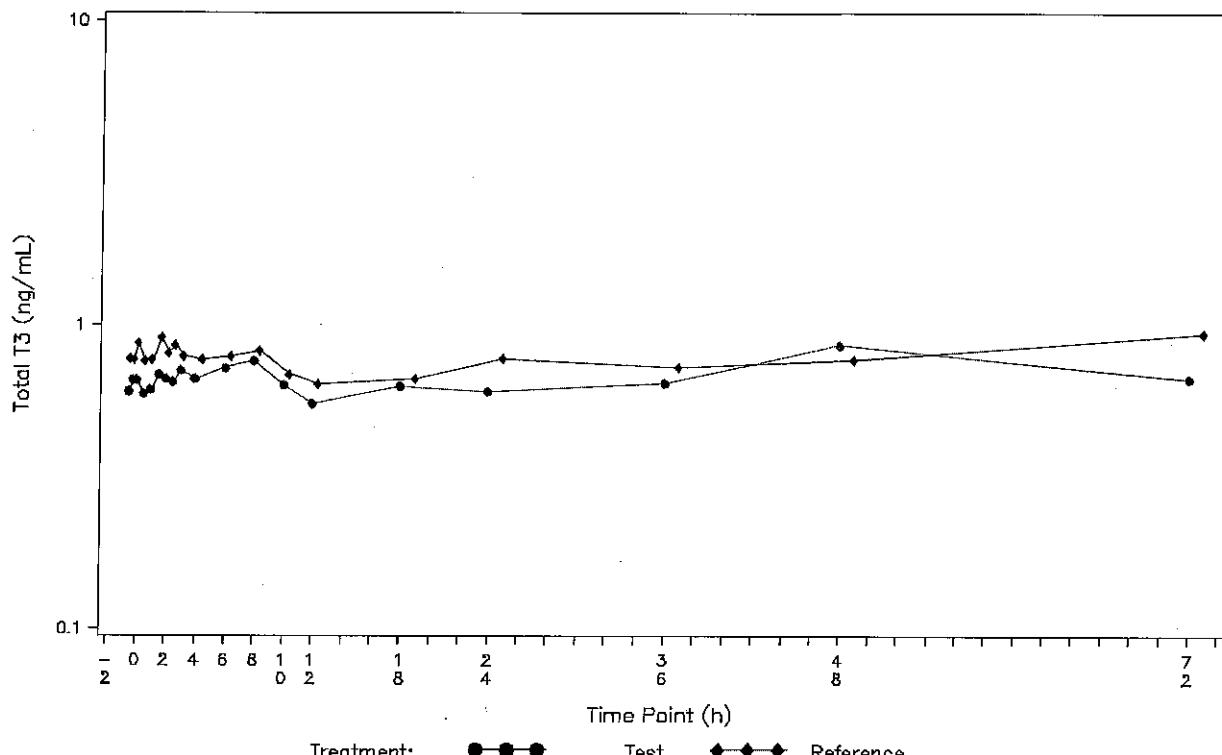
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1531 of 1628 alation 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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EMR 200125-001

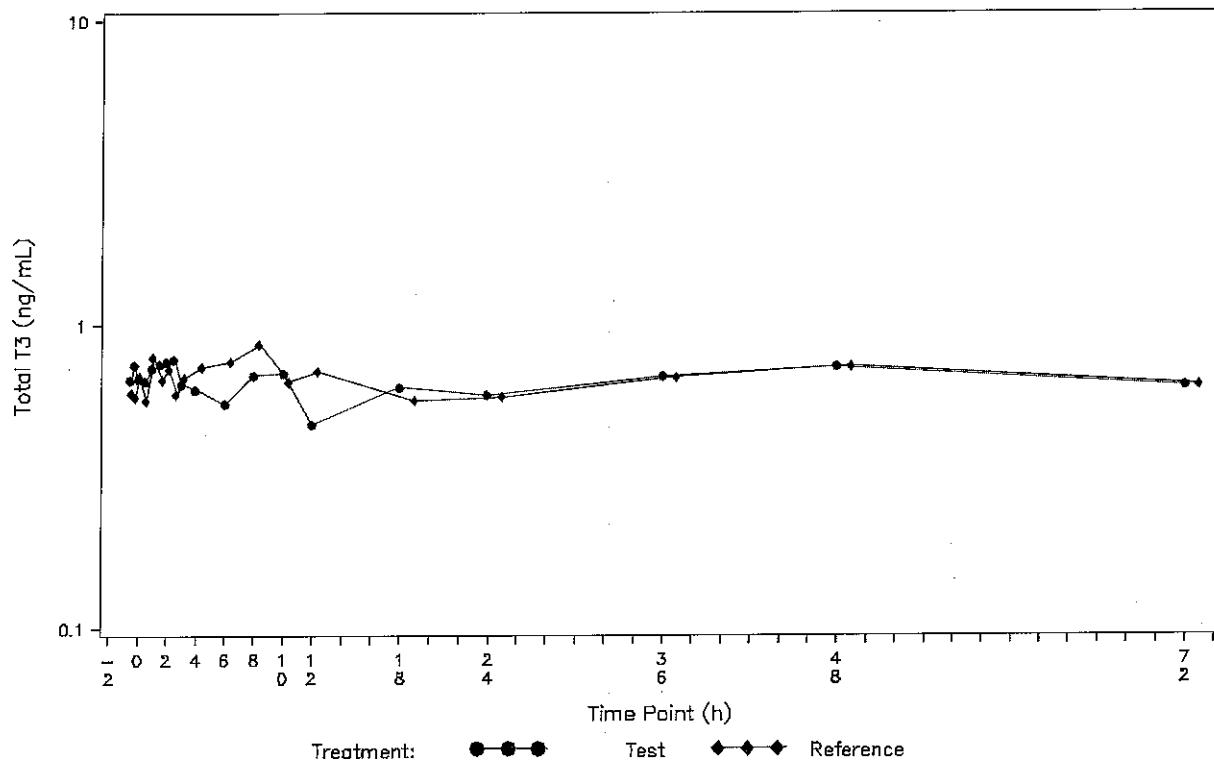
Bioequiv EMR200125-001 Page 1532 of 1628 nlation vs. old formulation

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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:



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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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Levothyroxine
EMR 200125-001

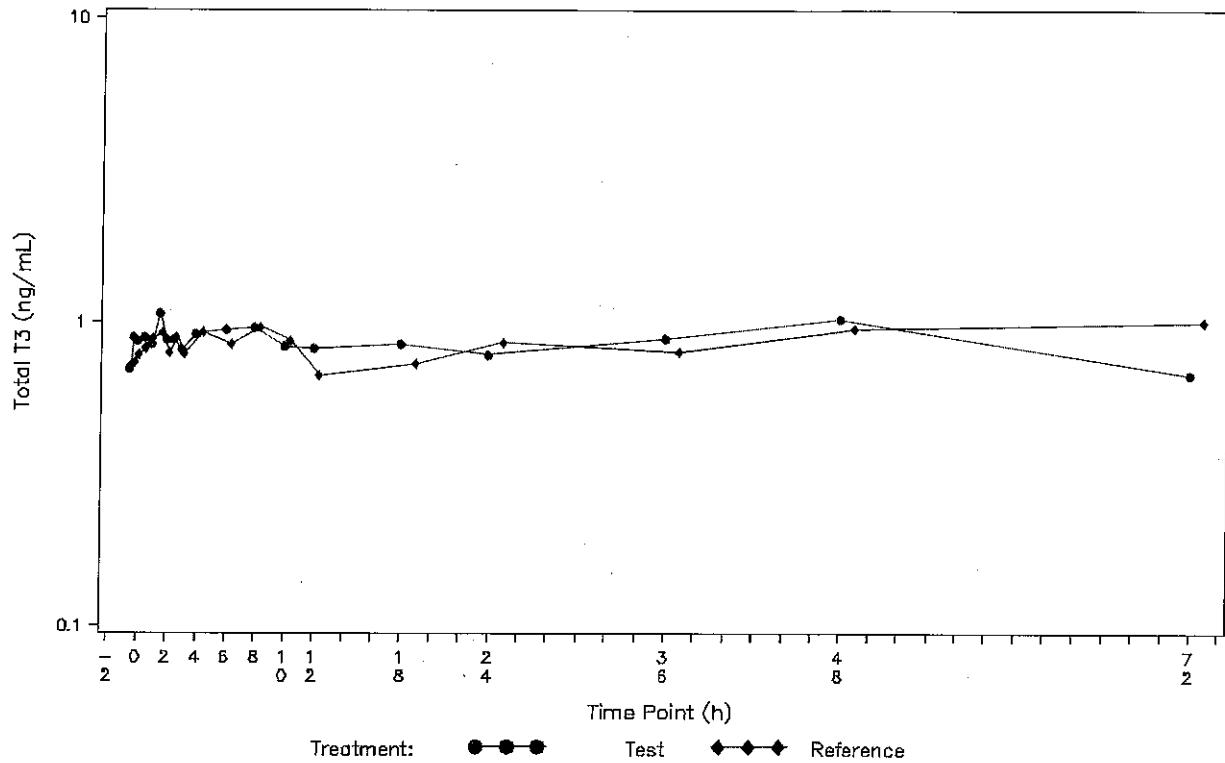
Bioequiv EMR200125-001 Page 1533 of 1628 alation vs. old formulation

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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

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Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1534 of 1628 nlation vs. old formulation

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EMB 300135-001

EMR 200125-001

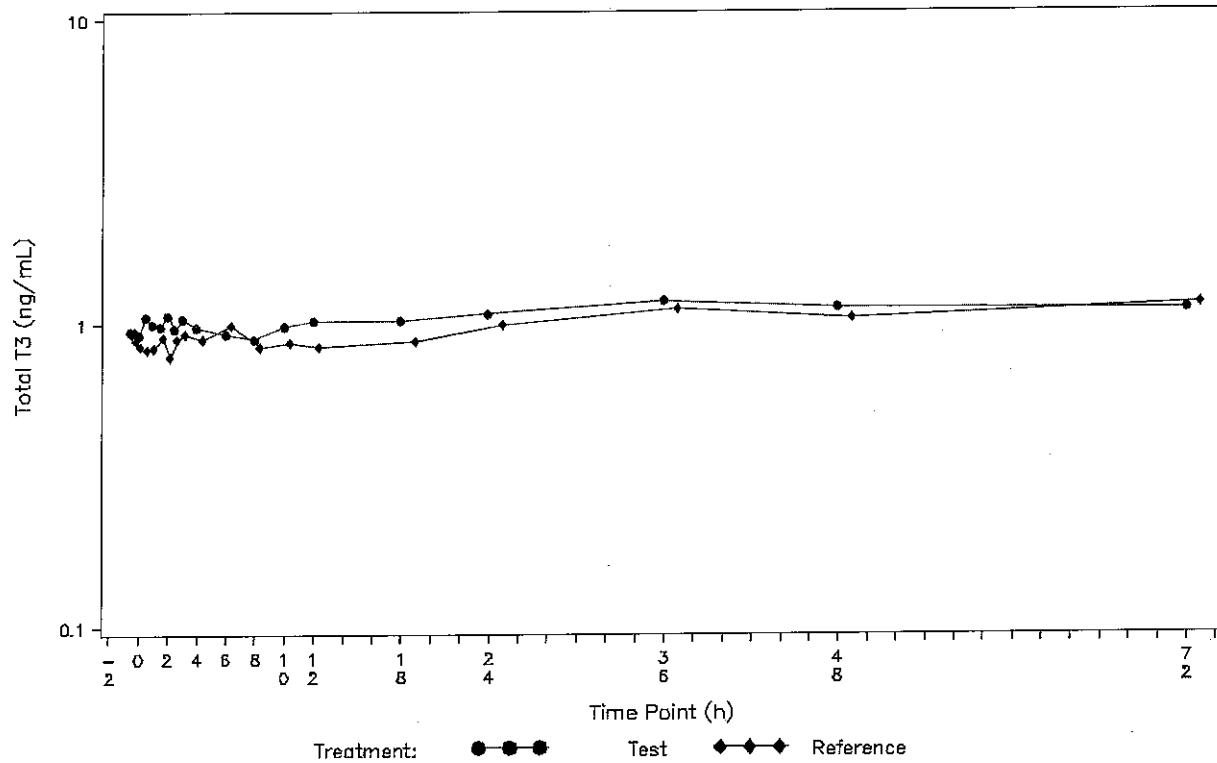
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
 (For Total T3 values) (Safety Population)

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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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Levothyroxine
EMR 200125-001

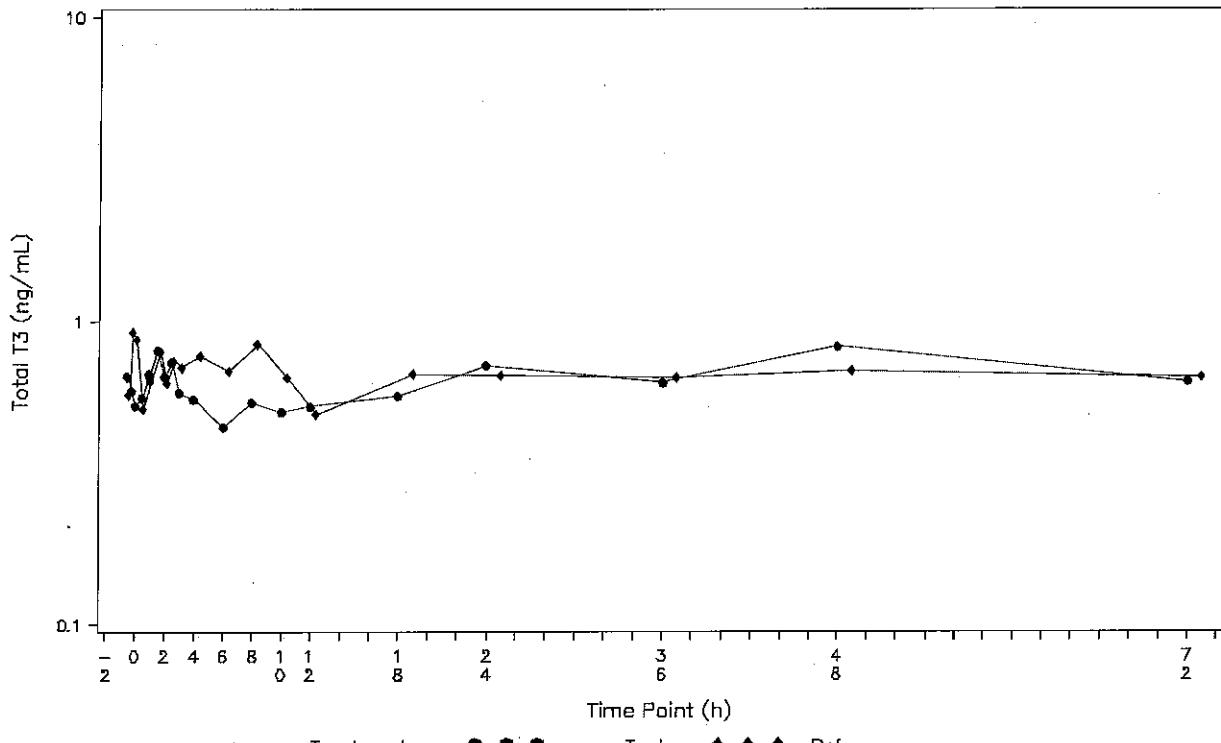
Bioequiv EMR200125-001 Page 1535 of 1628 alation vs. old formulation

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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

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Levothyroxine
EMR 200125-001

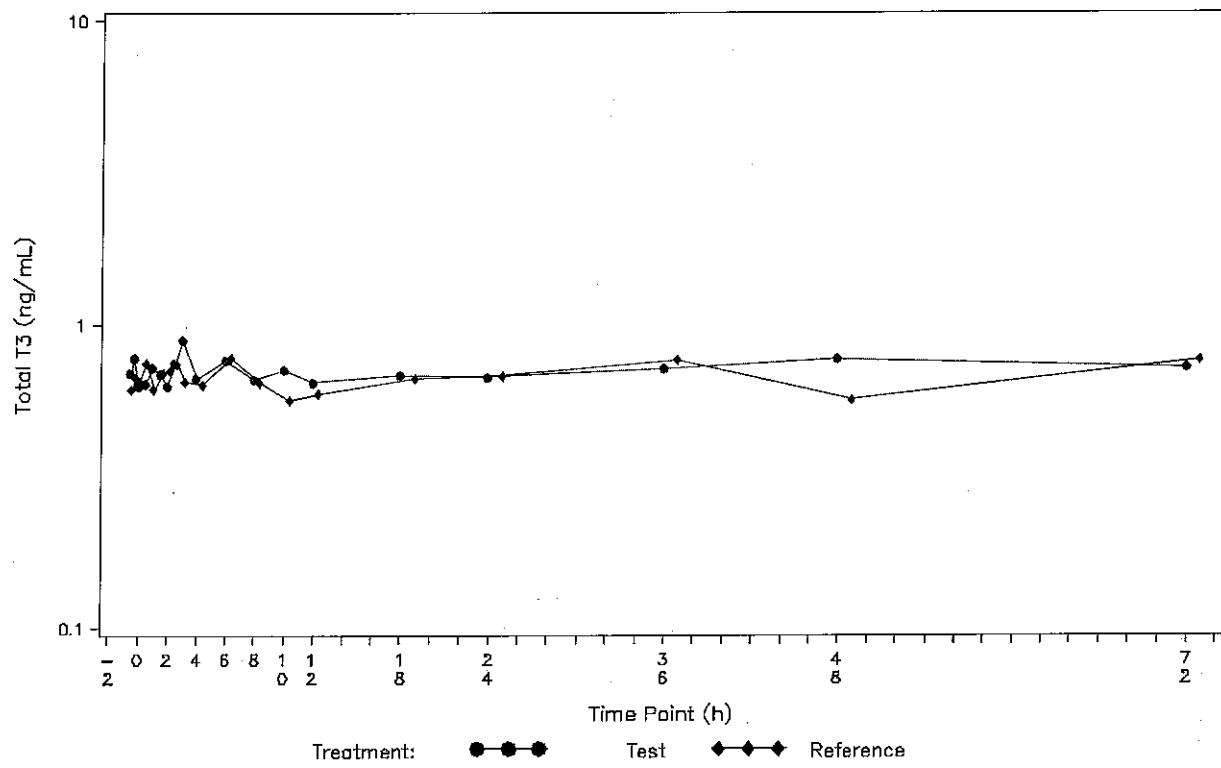
Bioequiv EMR200125-001 Page 1536 of 1628 ulation vs. old formulation

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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: 1



Levothyroxine
EMR 200125-001

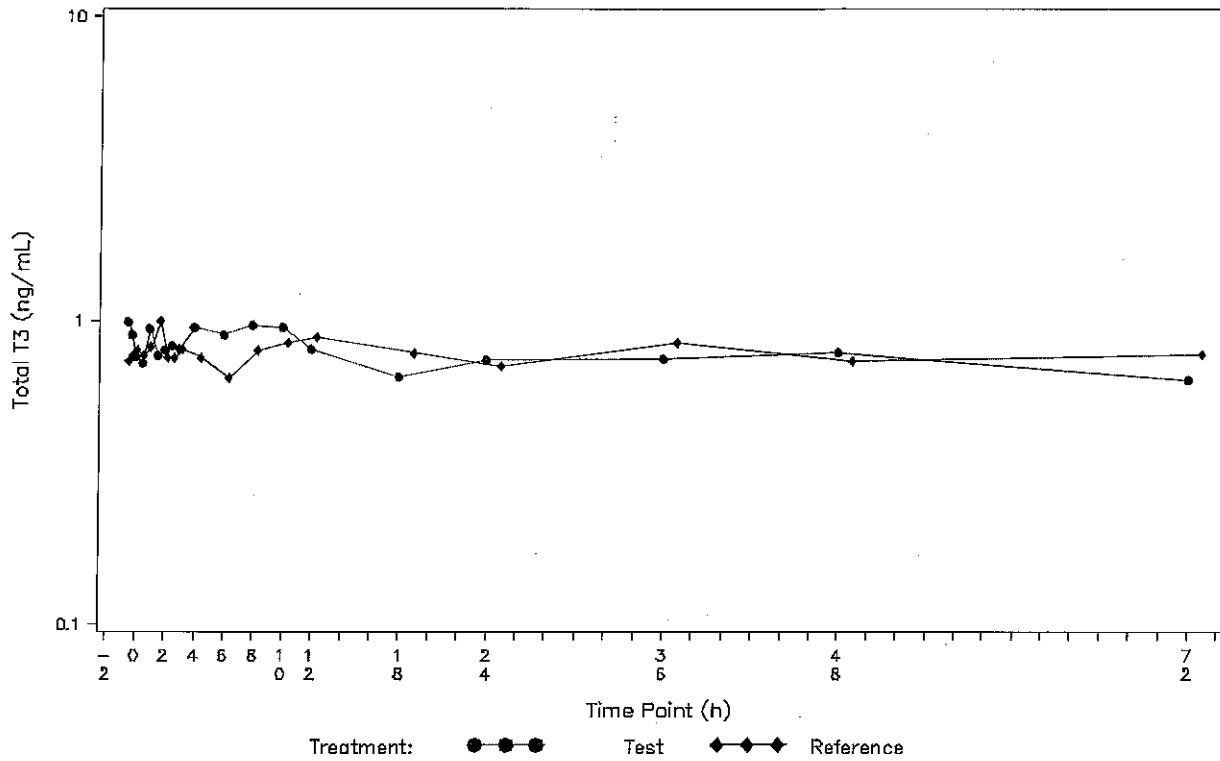
Bioequiv EMR200125-001 Page 1537 of 1628 ulation vs. old formulation

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

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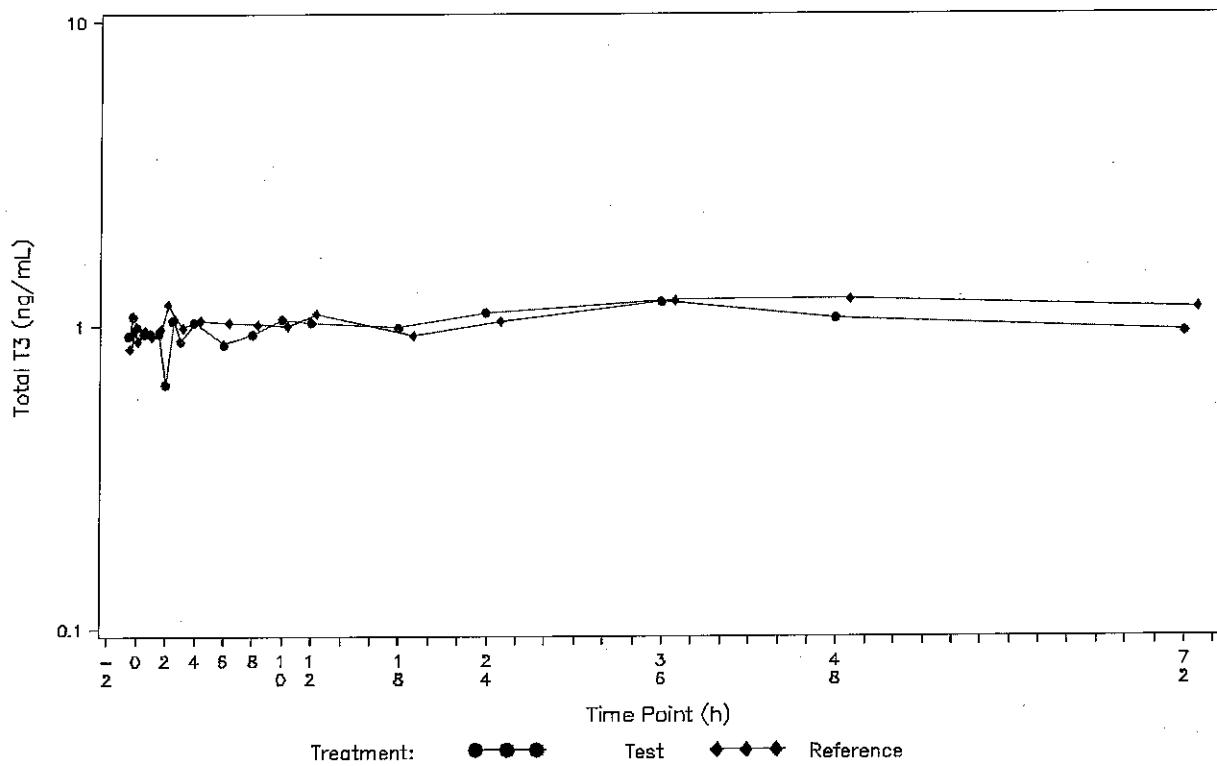
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1538 of 1628 ultation 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:



⑥Subjects 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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EMR 200125-001

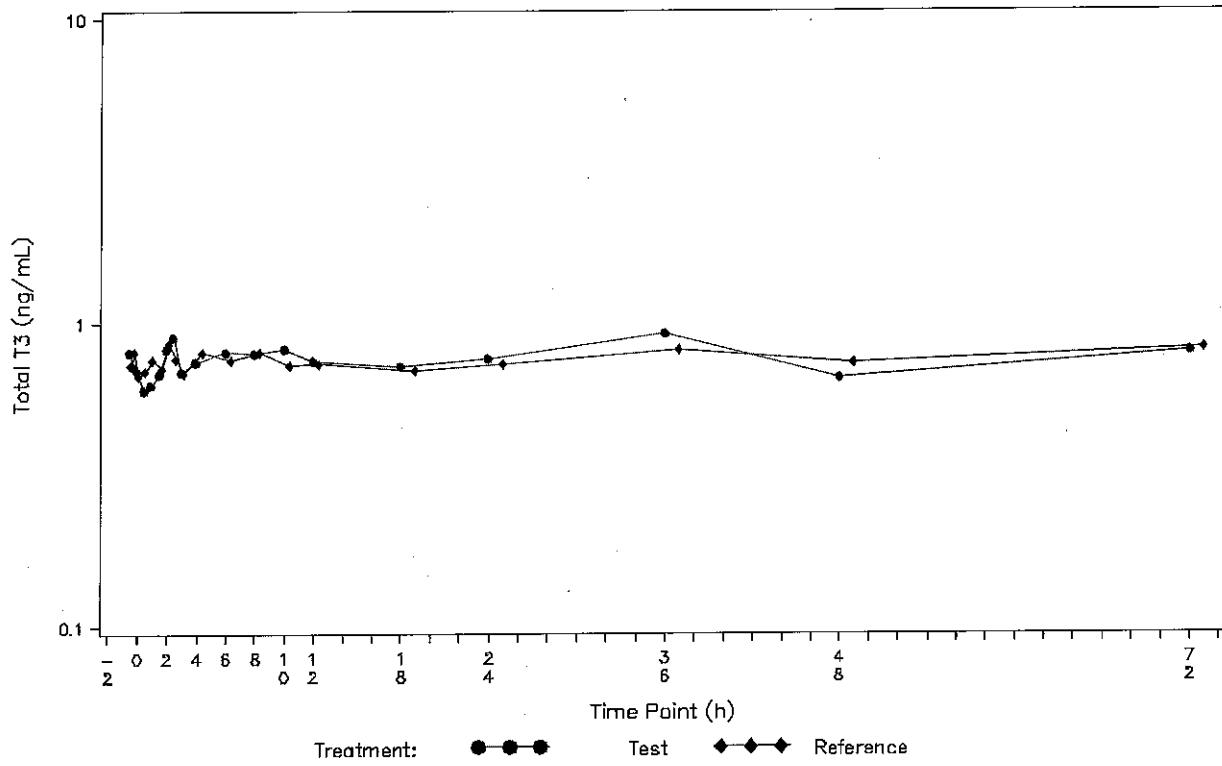
Bioequiv EMR200125-001 Page 1539 of 1628 alation vs. old formulation

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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:



⑥: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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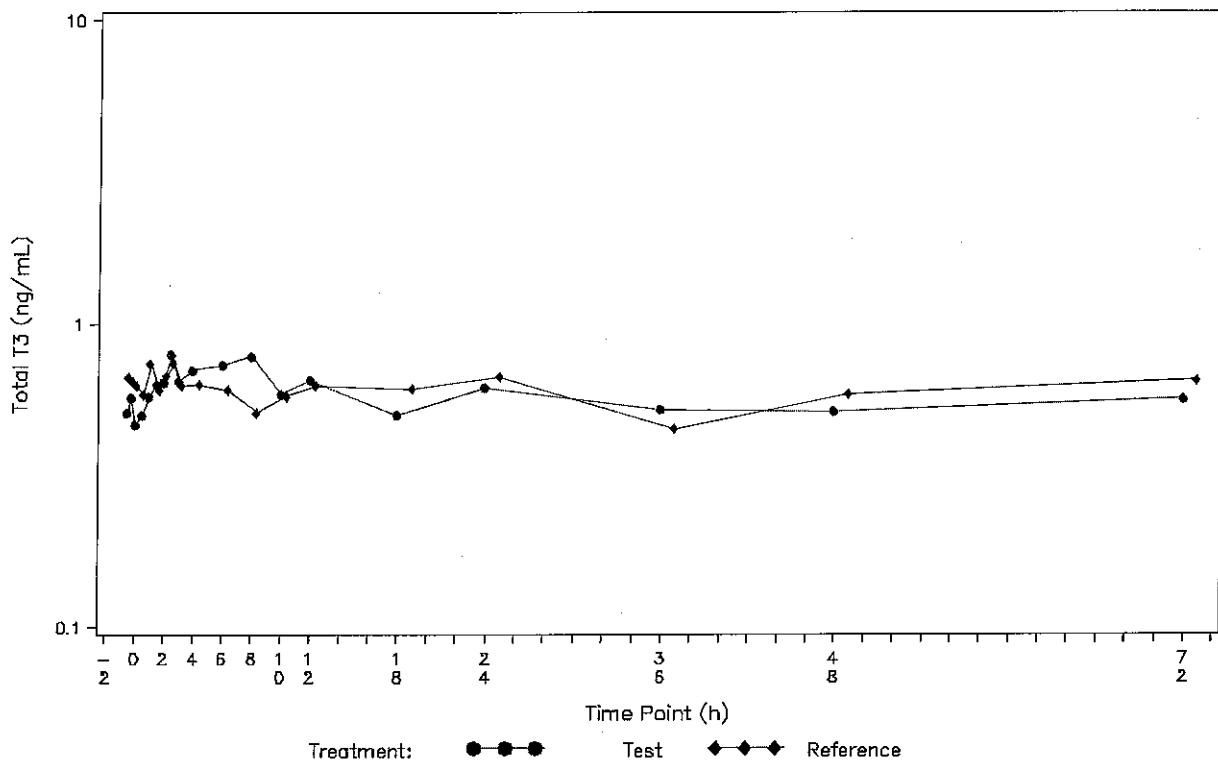
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1540 of 1628 alation 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:



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.
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Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1541 of 1628 alation vs. old formulation

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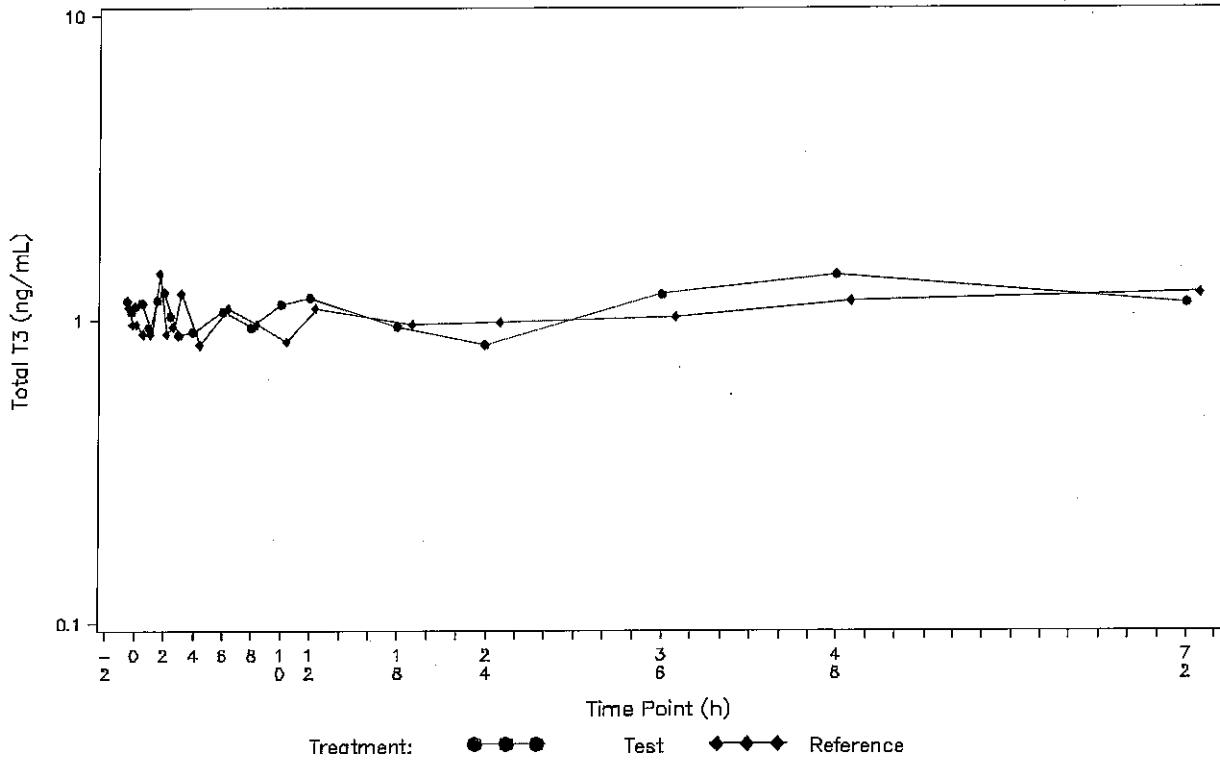
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EMR 200125-001

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: 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

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Levothyroxine
EMR 200125-001

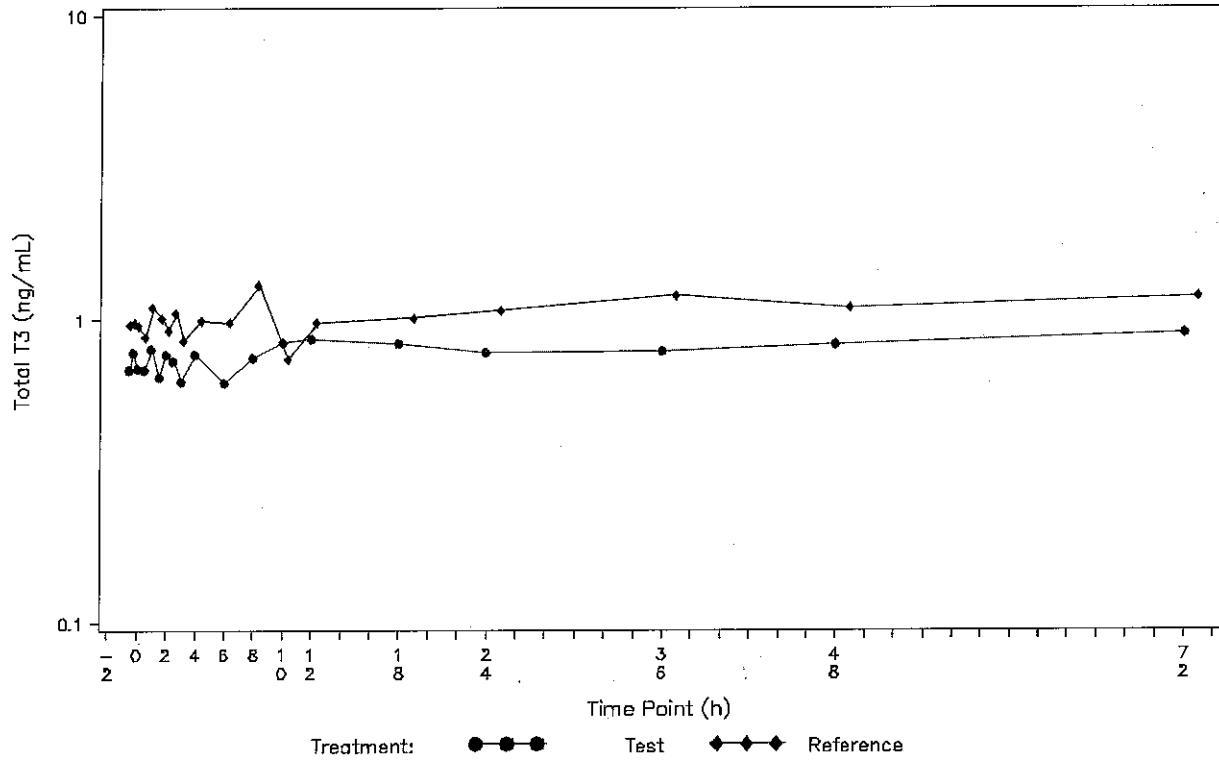
Bioequiv EMR200125-001 Page 1542 of 1628 alation vs. old formulation

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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:



⑥: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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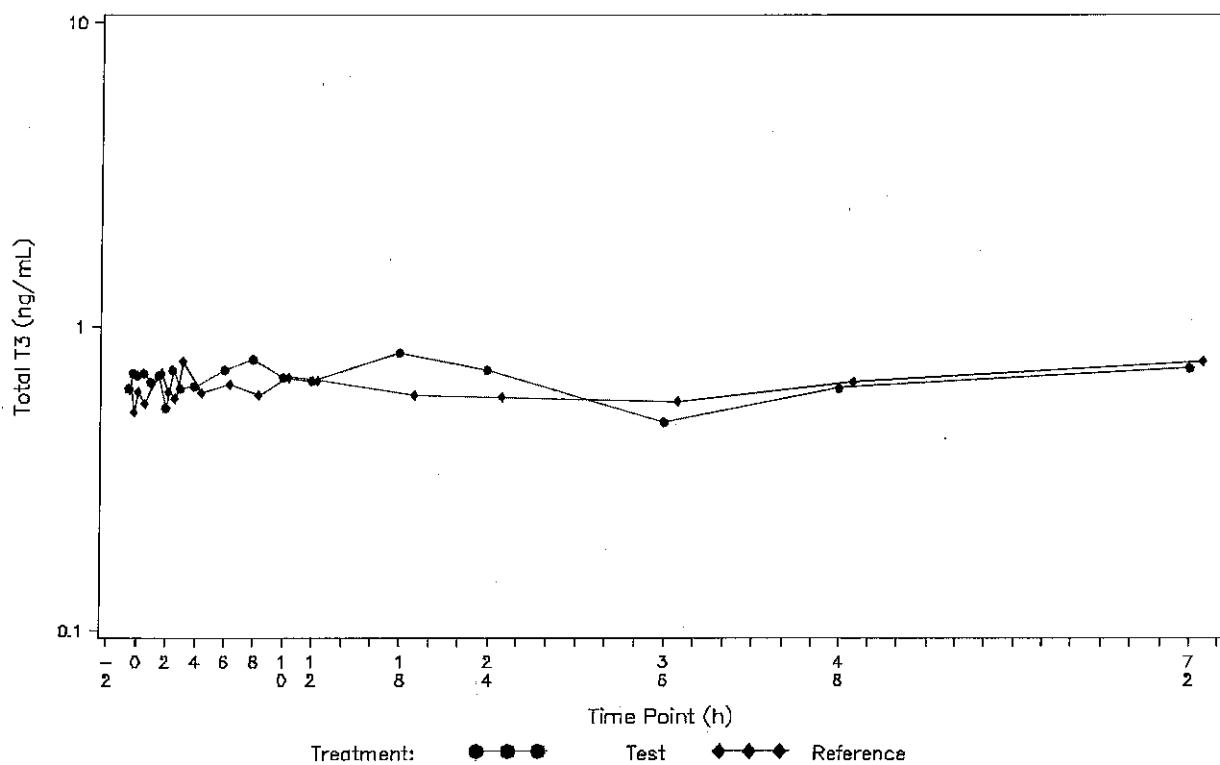
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T₃ values) (Safety Population)

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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**Levothyroxine
EMR 200125-001**

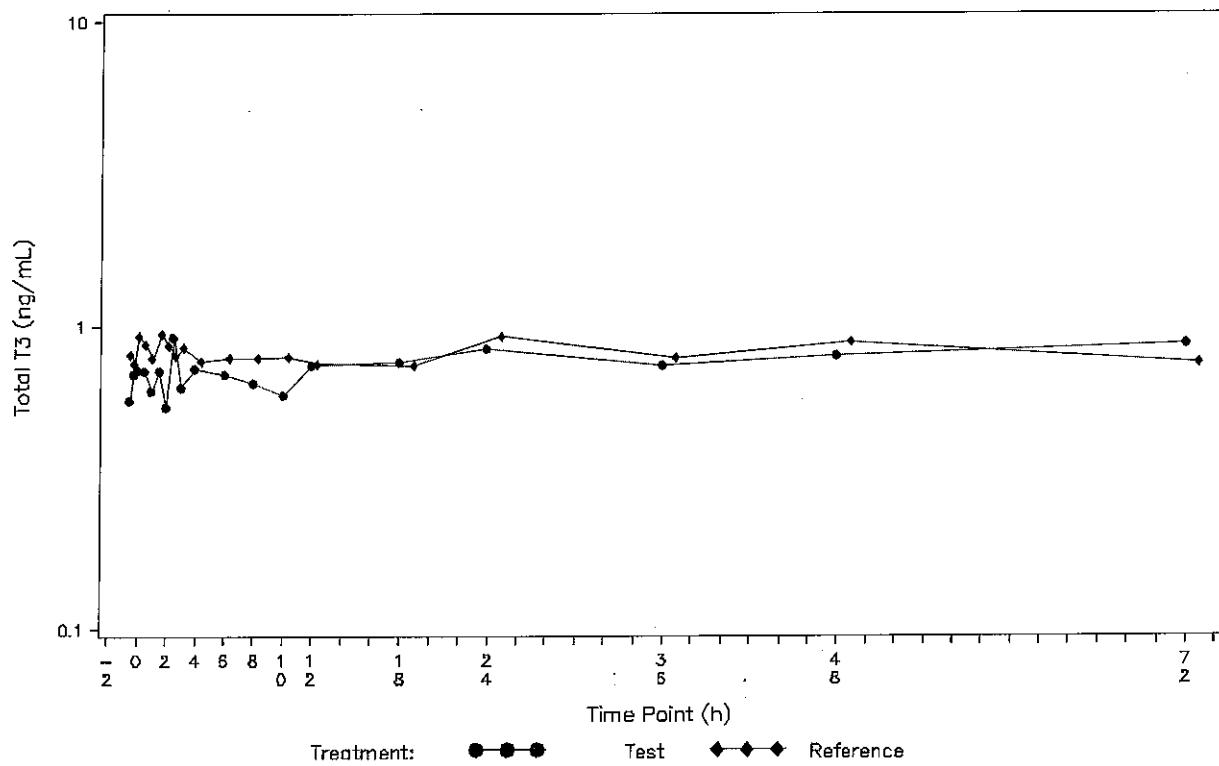
Bioequiv EMR200125-001 Page 1544 of 1628 uation vs. old formulation

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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:



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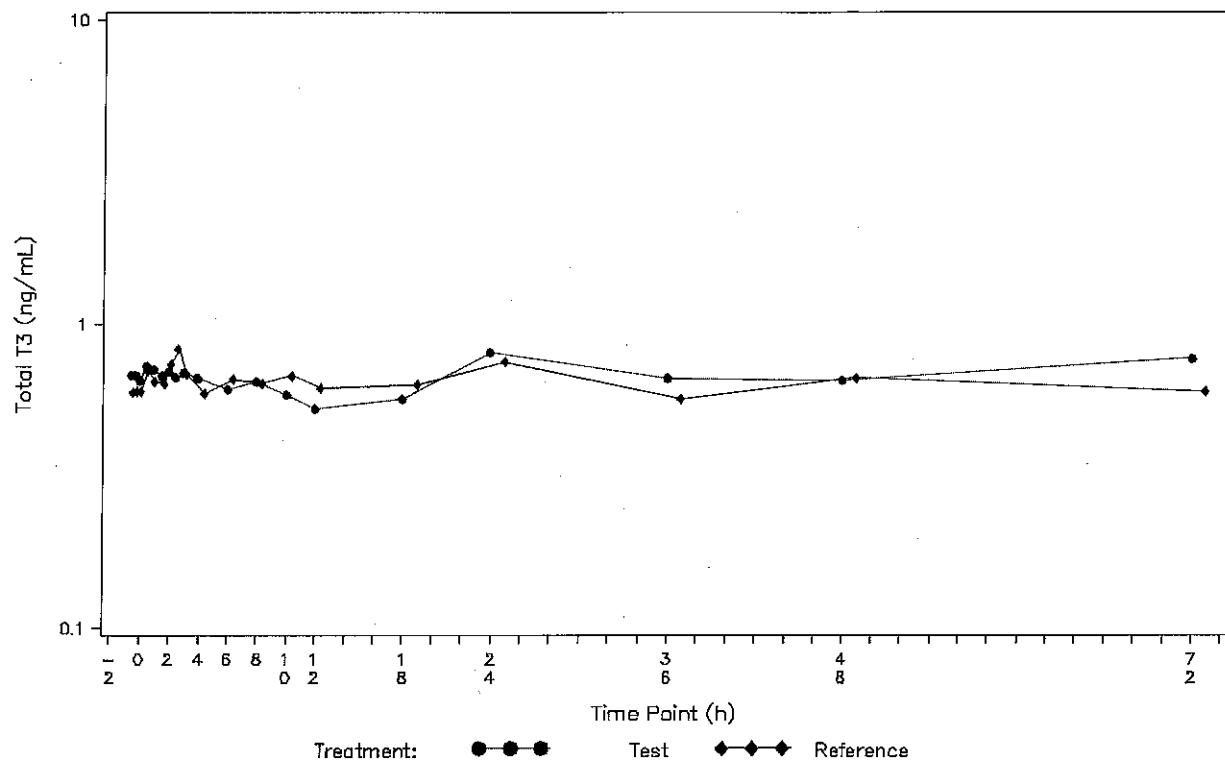
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EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T₃ values) (Safety Population)

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

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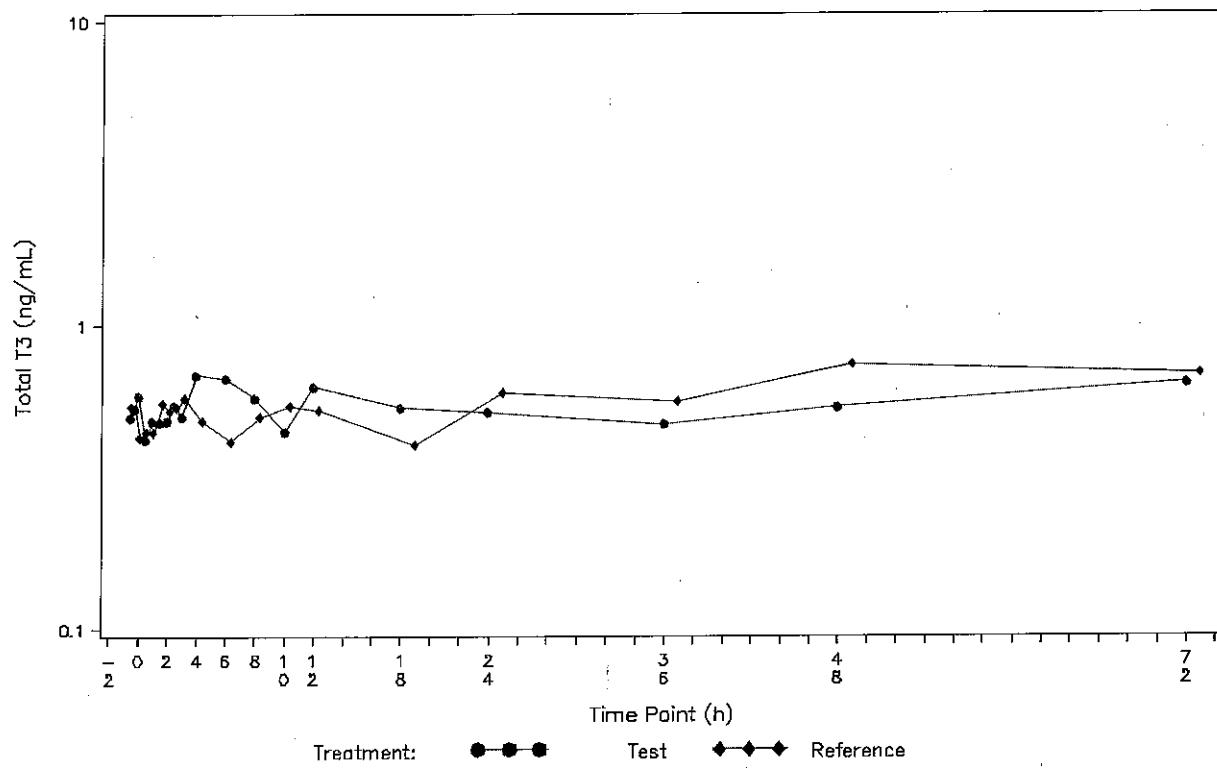
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1546 of 1628 lation 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.
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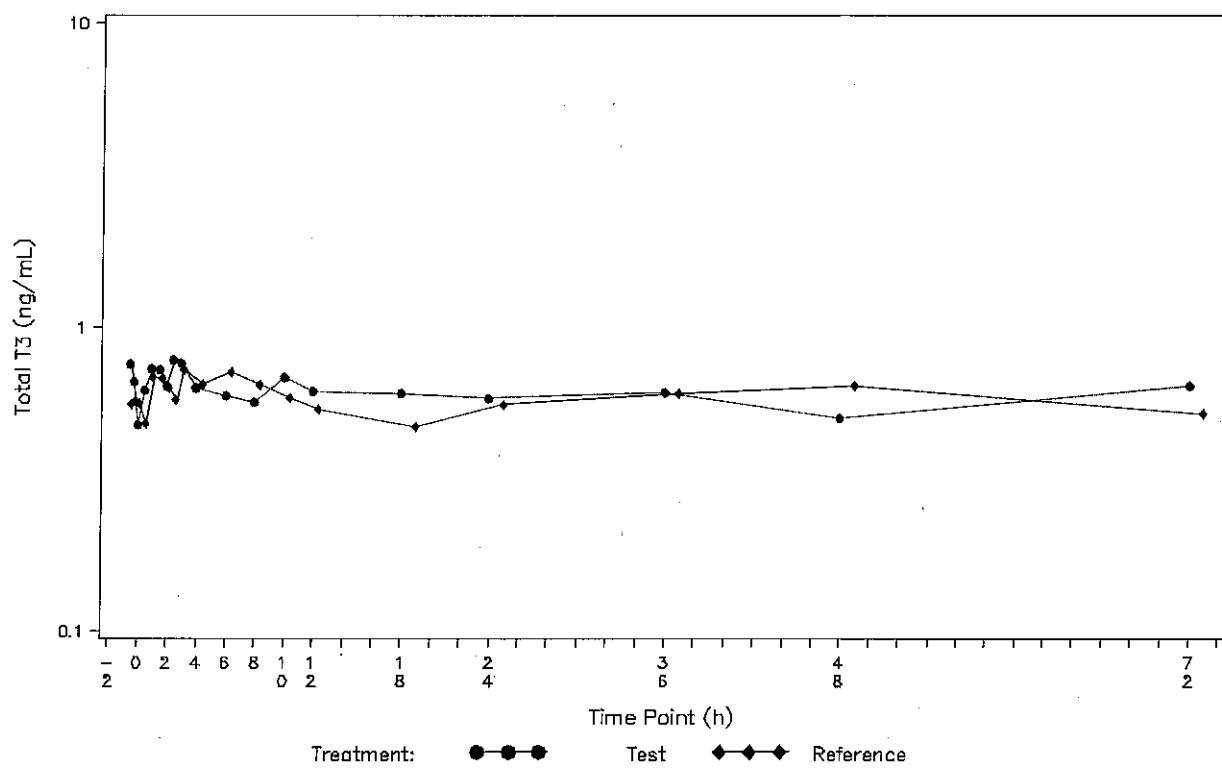
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1547 of 1628 nulation 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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Levothyroxine
EMR 200125-001

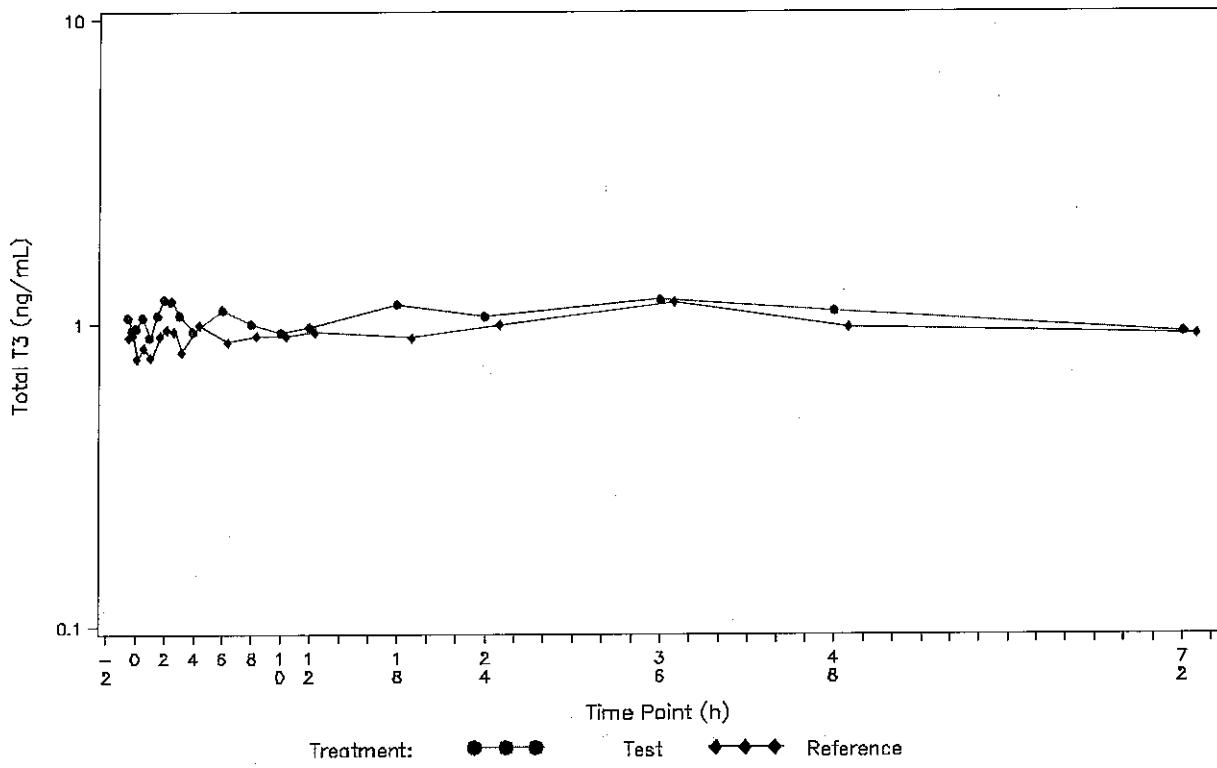
Bioequiv EMR200125-001 Page 1548 of 1628 uation vs. old formulation

Merck Serono
EMR 200125-001

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Cocentration 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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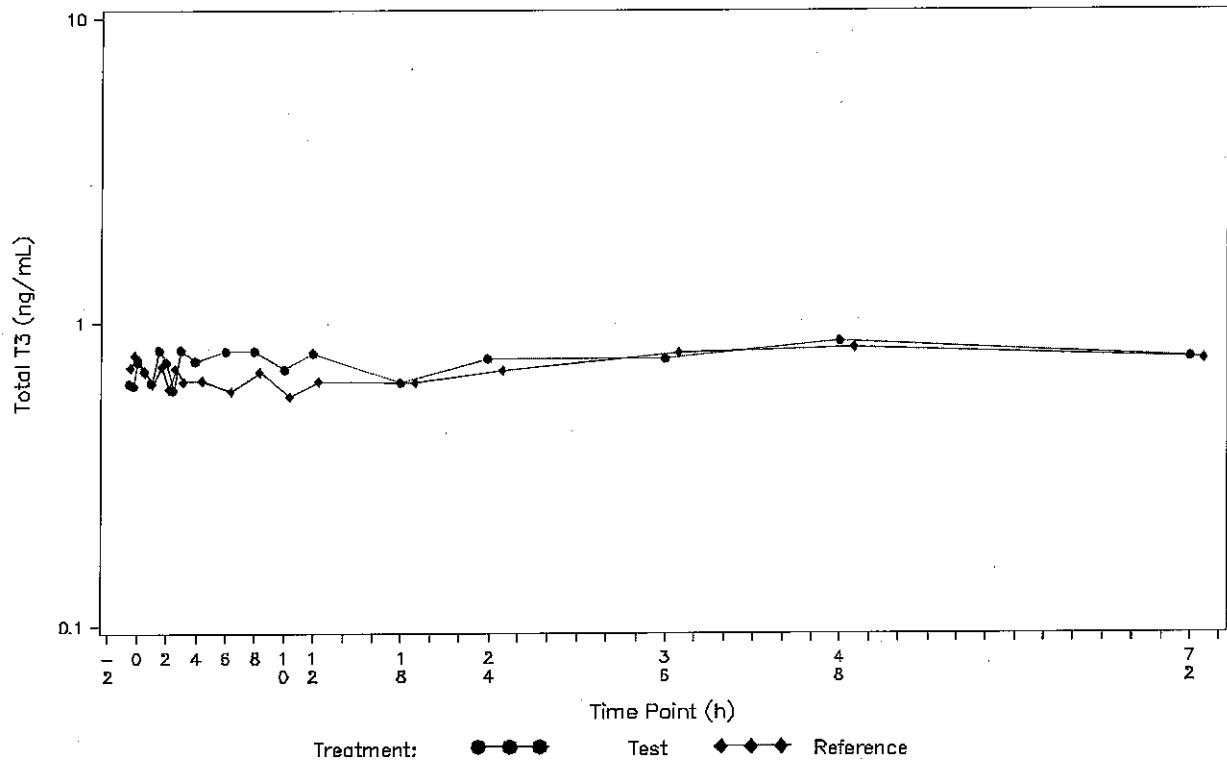
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1549 of 1628 alation 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

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**Levothyroxine
EMR 200125-001**

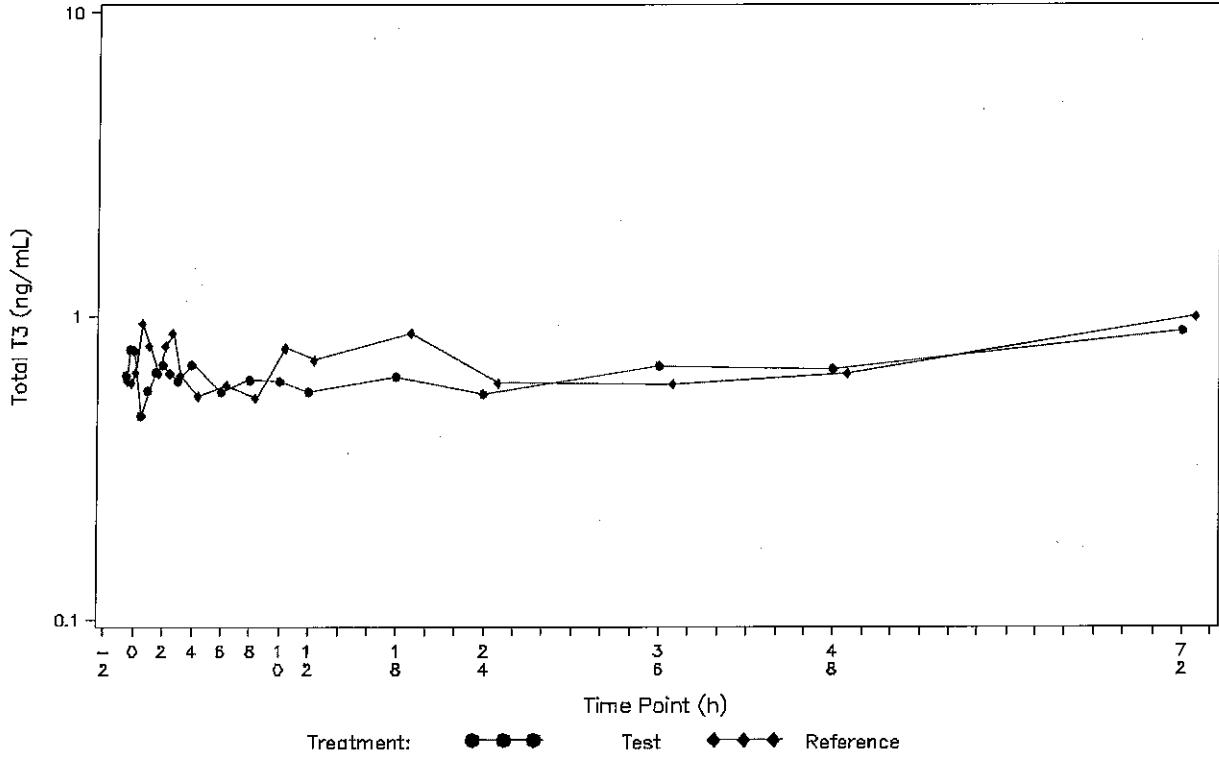
Bioequiv EMR200125-001 Page 1550 of 1628 ulation vs. old formulation

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)

(For Total T3 values) (Safety Population) Subject ID/Random Number:

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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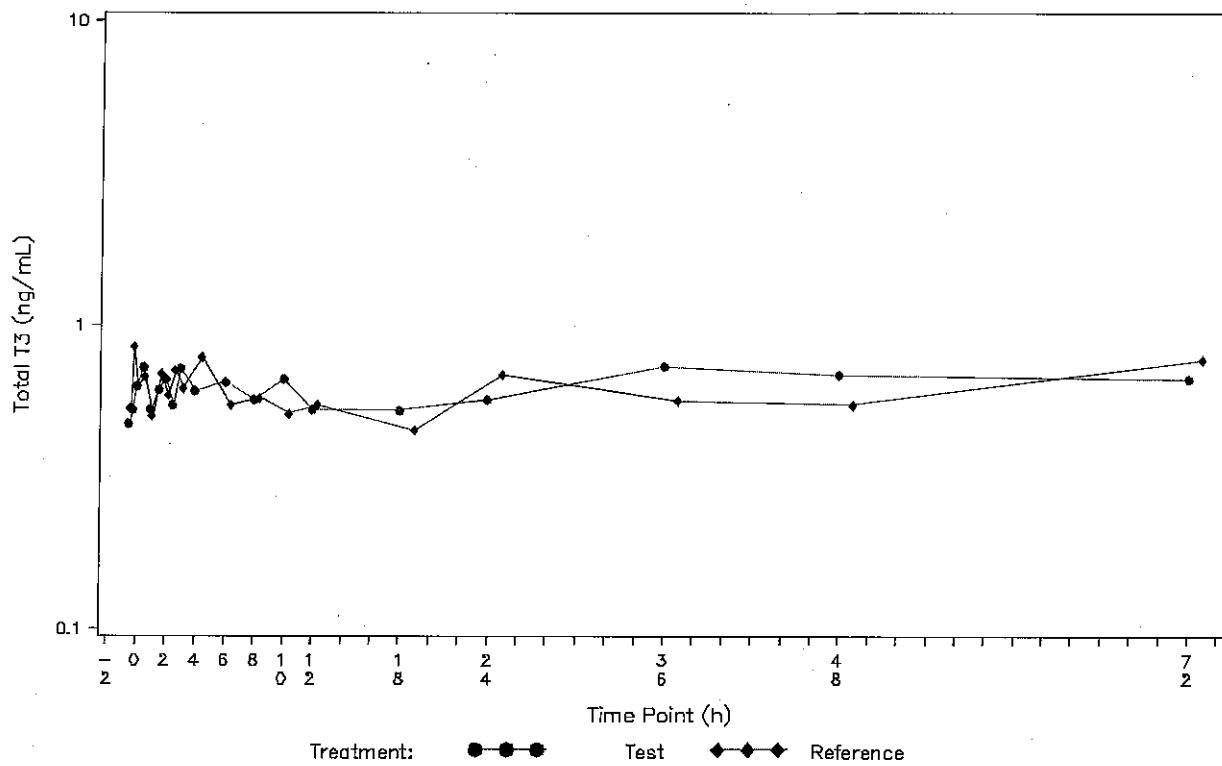
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1551 of 1628 nulation 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

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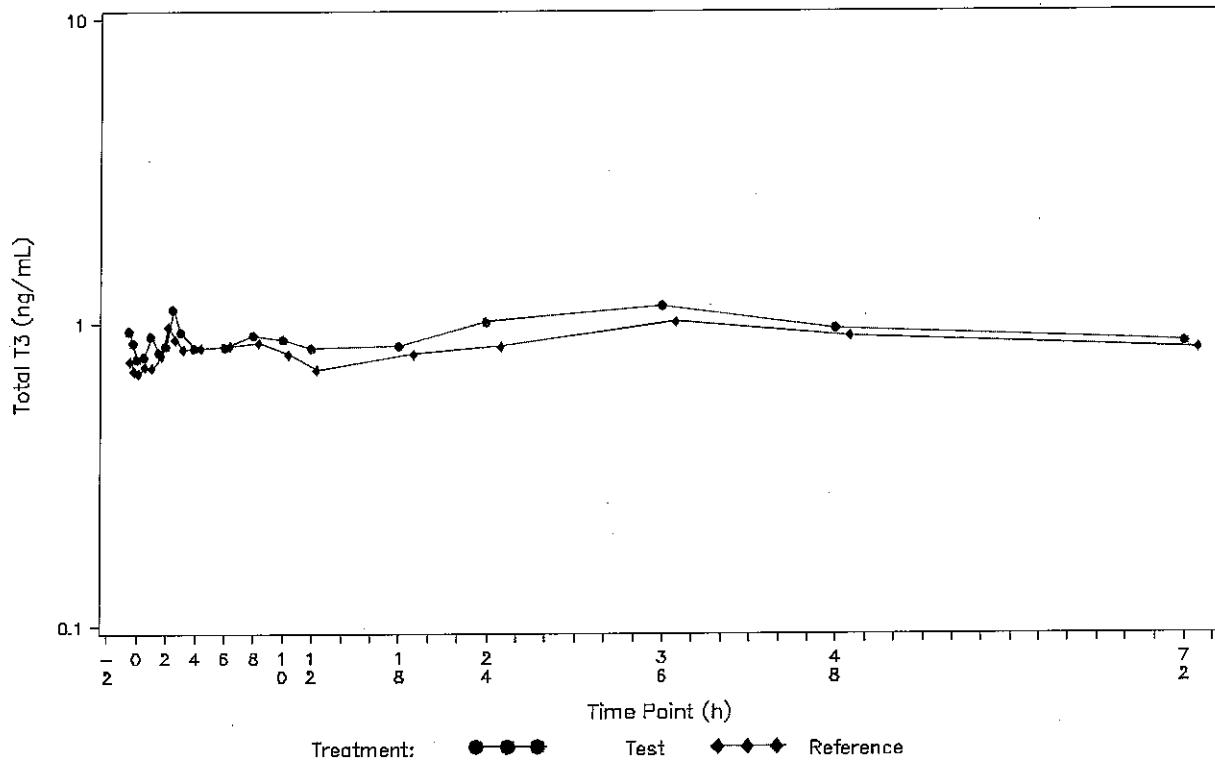
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1552 of 1628 nlation 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

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Levothyroxine
EMR 200125-001

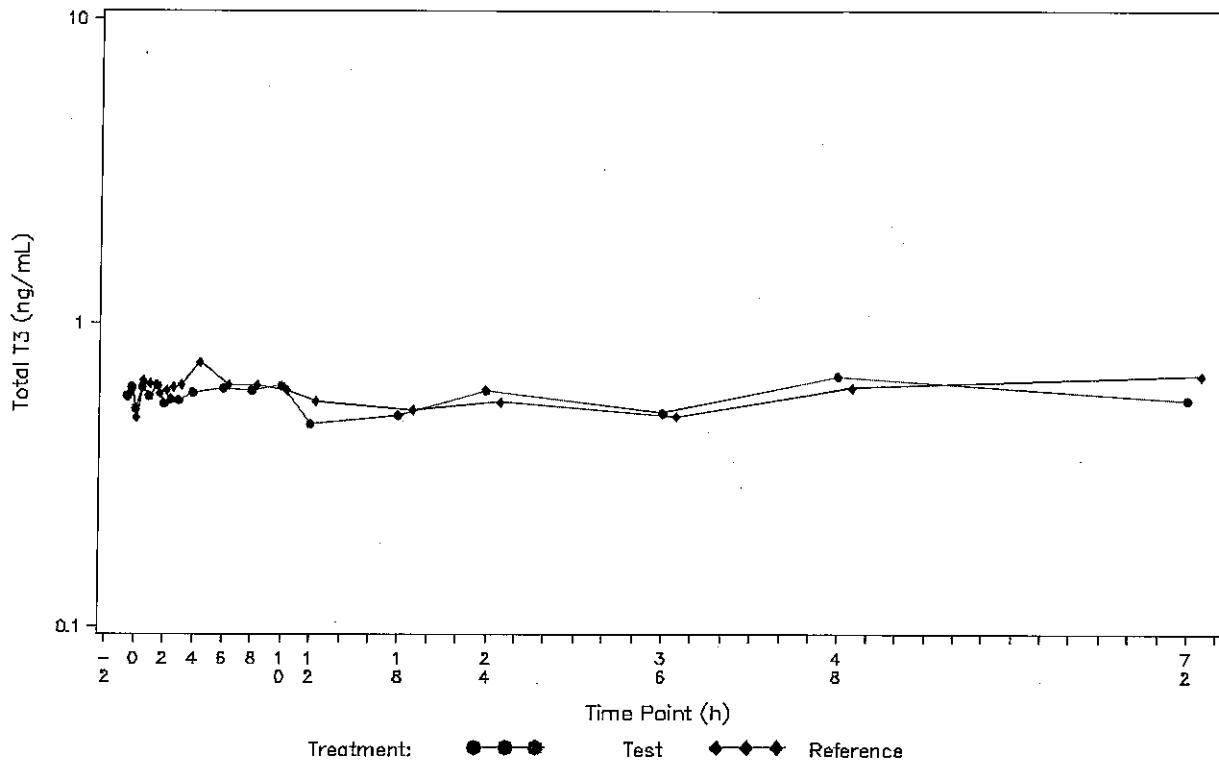
Bioequiv EMR200125-001 Page 1553 of 1628 alation vs. old formulation

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

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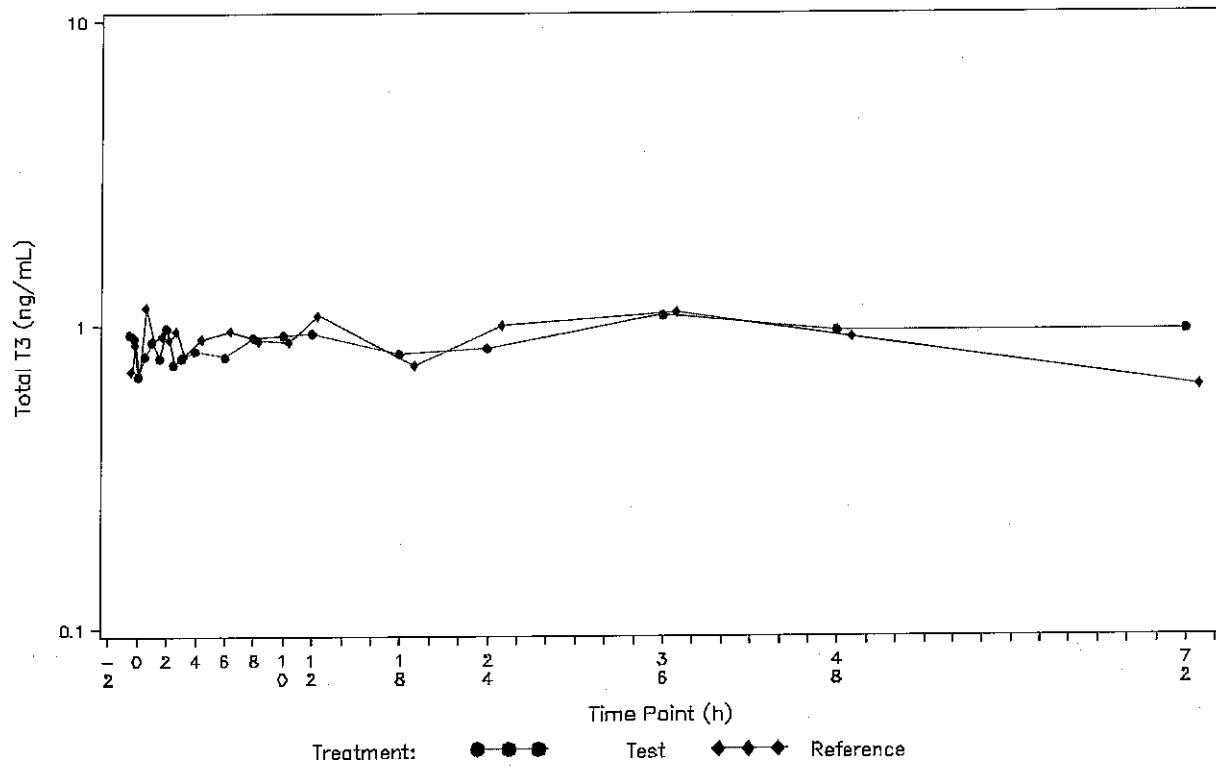
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Merck Serono
EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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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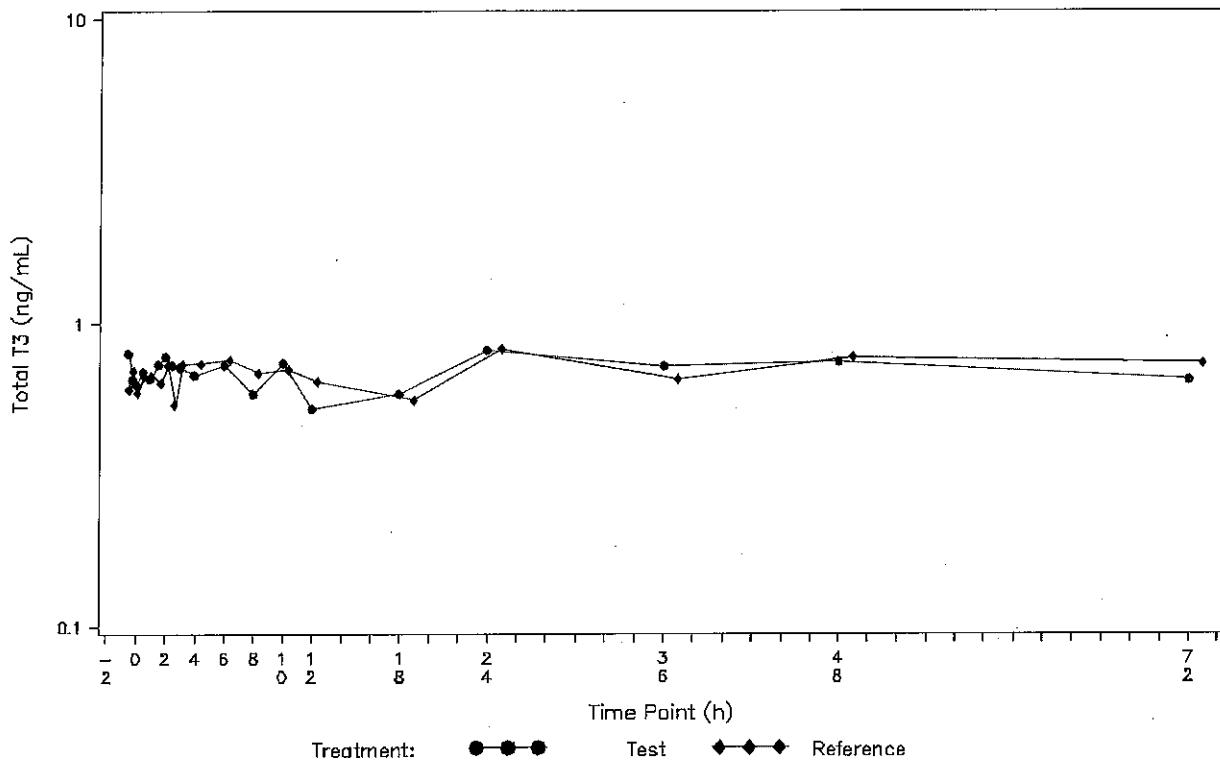
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1555 of 1628 alation 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: _____



①Subjects excluded from PK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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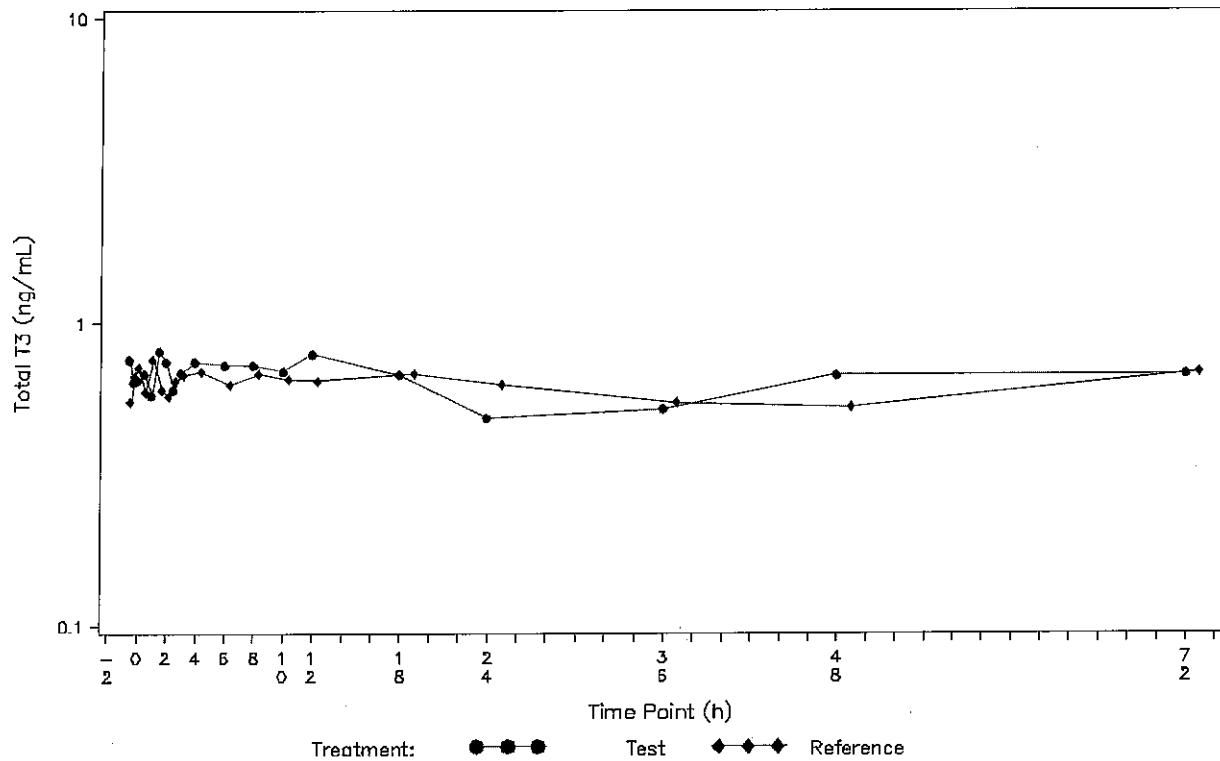
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1556 of 1628 ilation 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: 101



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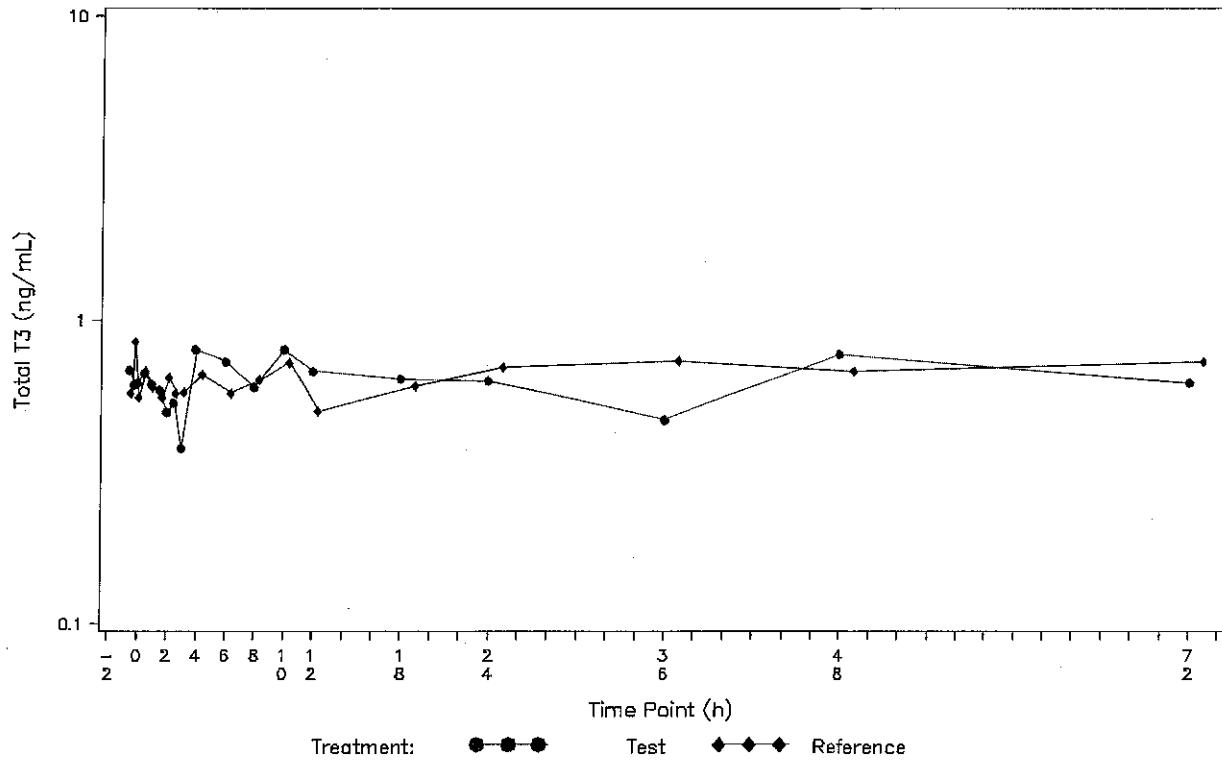
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T₃ values) (Safety Population)

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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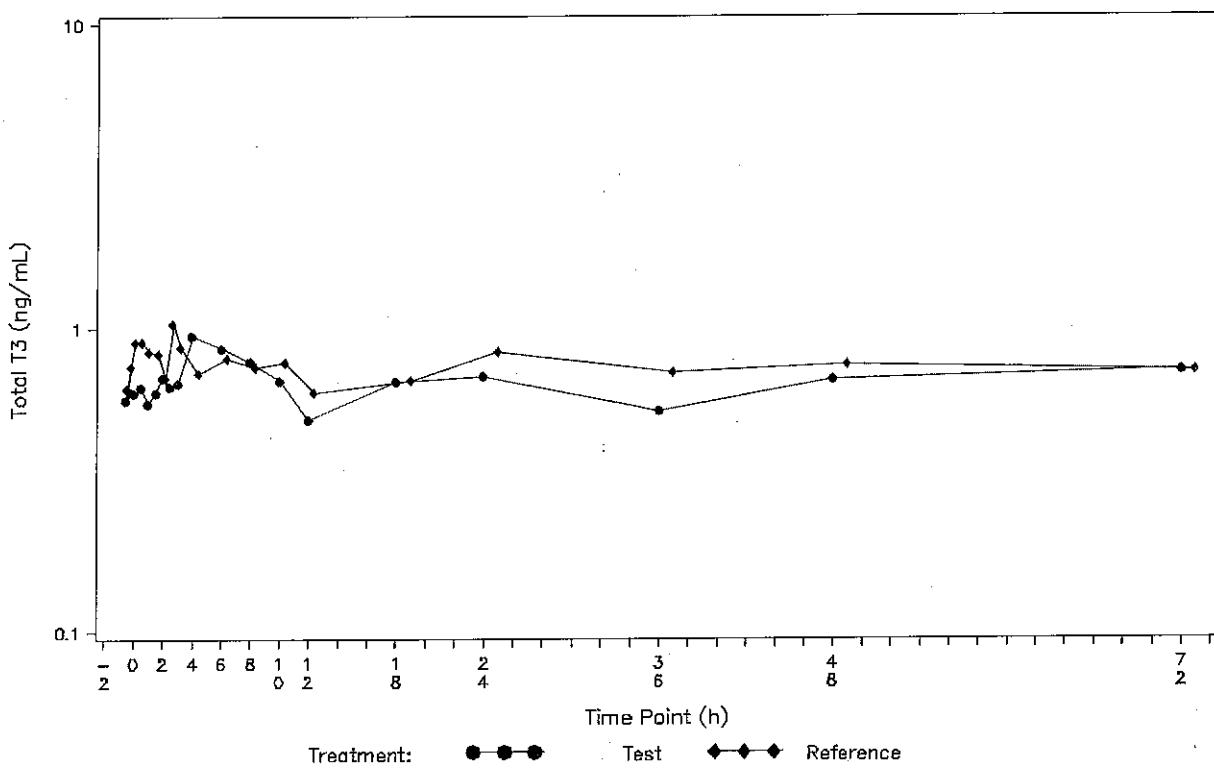
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**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1558 of 1628 nulation 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.
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Levothyroxine
EMR 200125-001

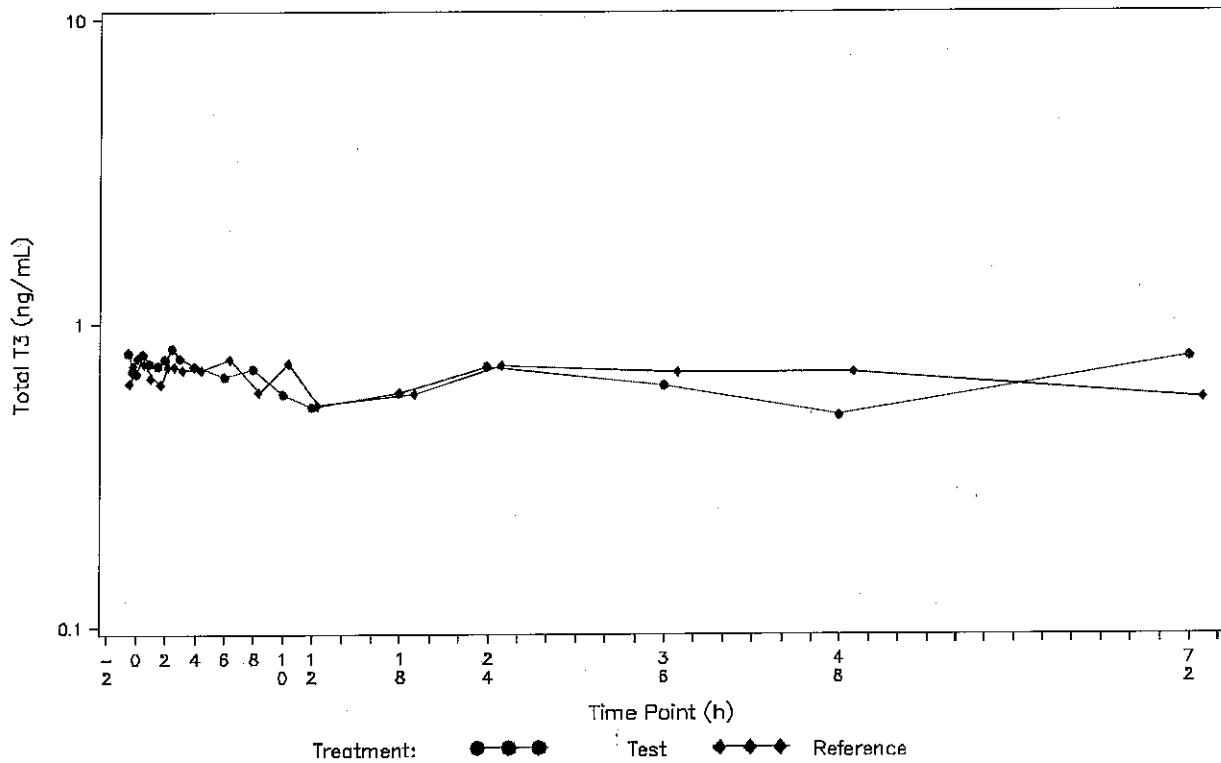
Bioequiv EMR200125-001 Page 1559 of 1628 alation vs. old formulation

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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:



Levothyroxine
EMR 200125-001

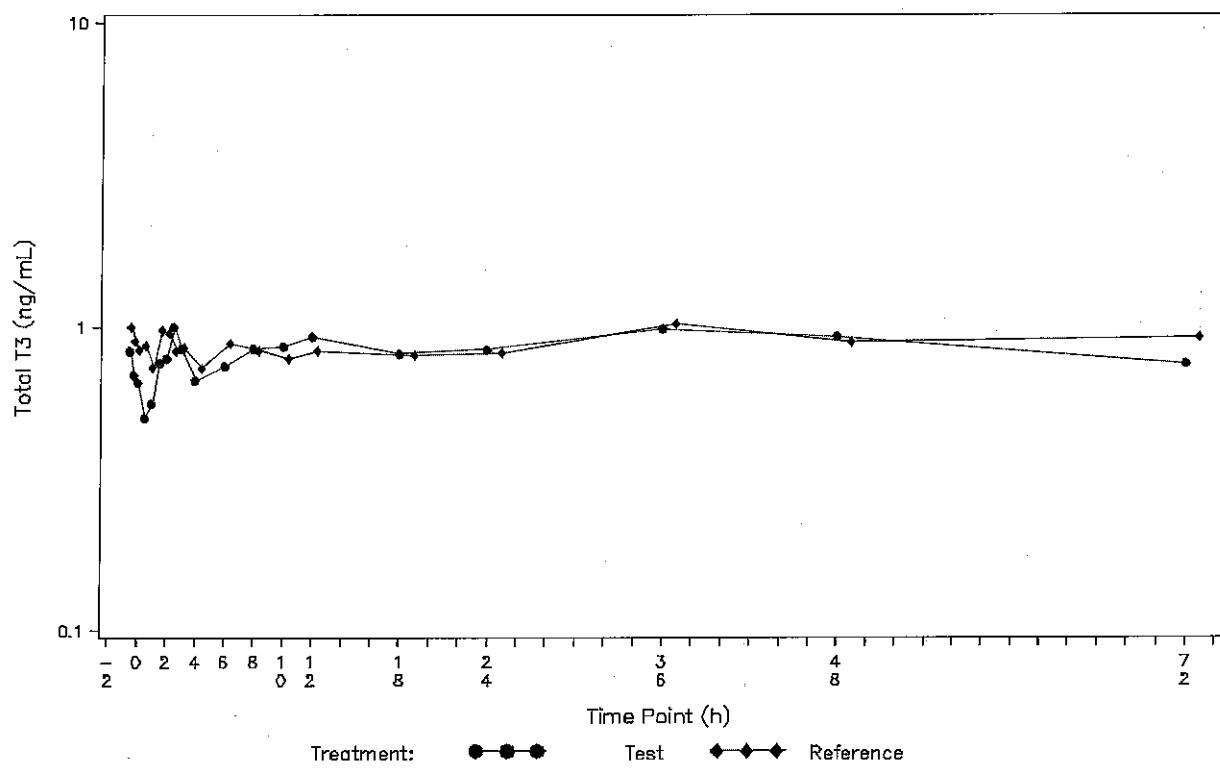
Bioequiv EMR200125-001 Page 1560 of 1628 nulation vs. old formulation

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.
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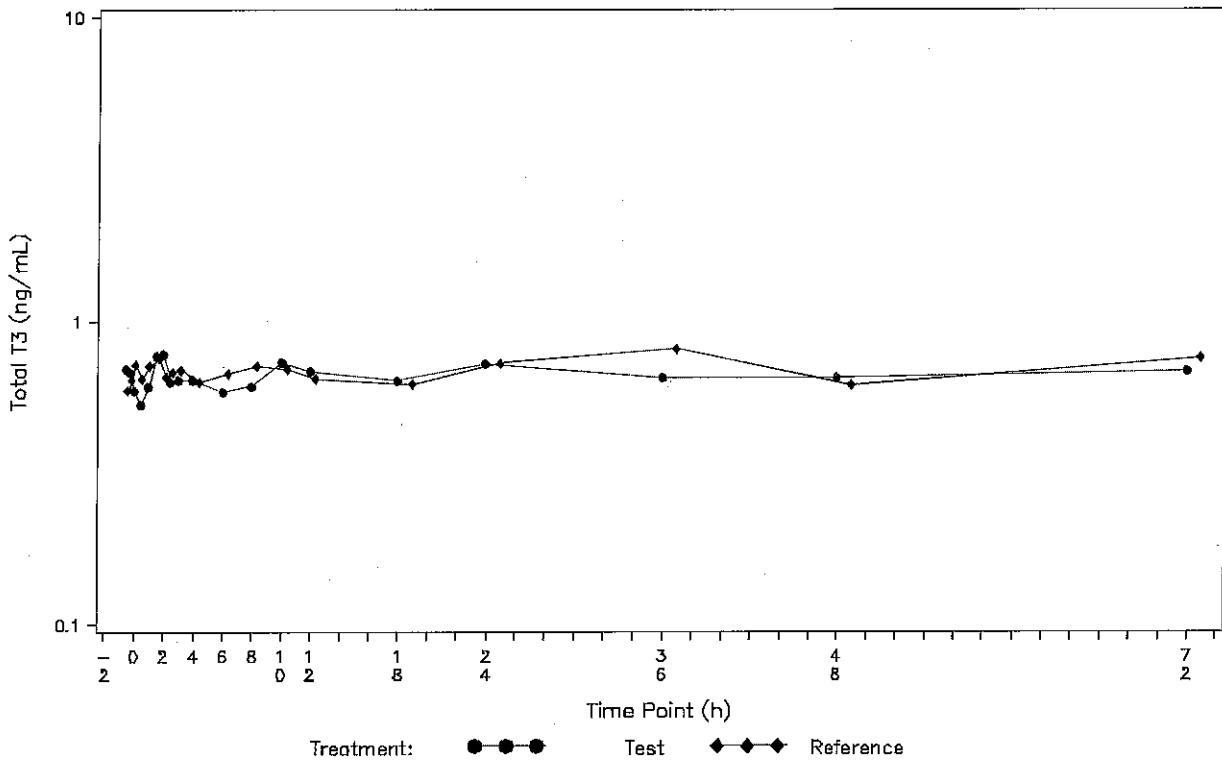
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1561 of 1628 uation 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.
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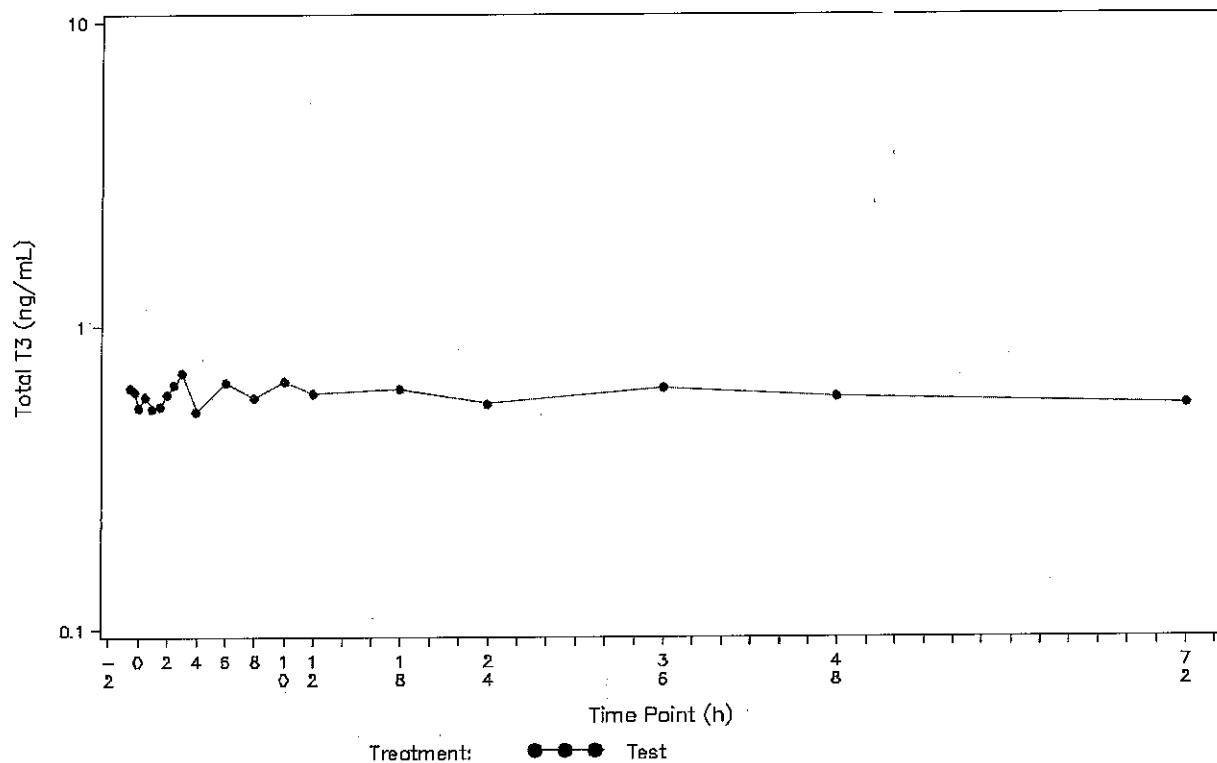
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1562 of 1628 nulation 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:



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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EMR 200125-001

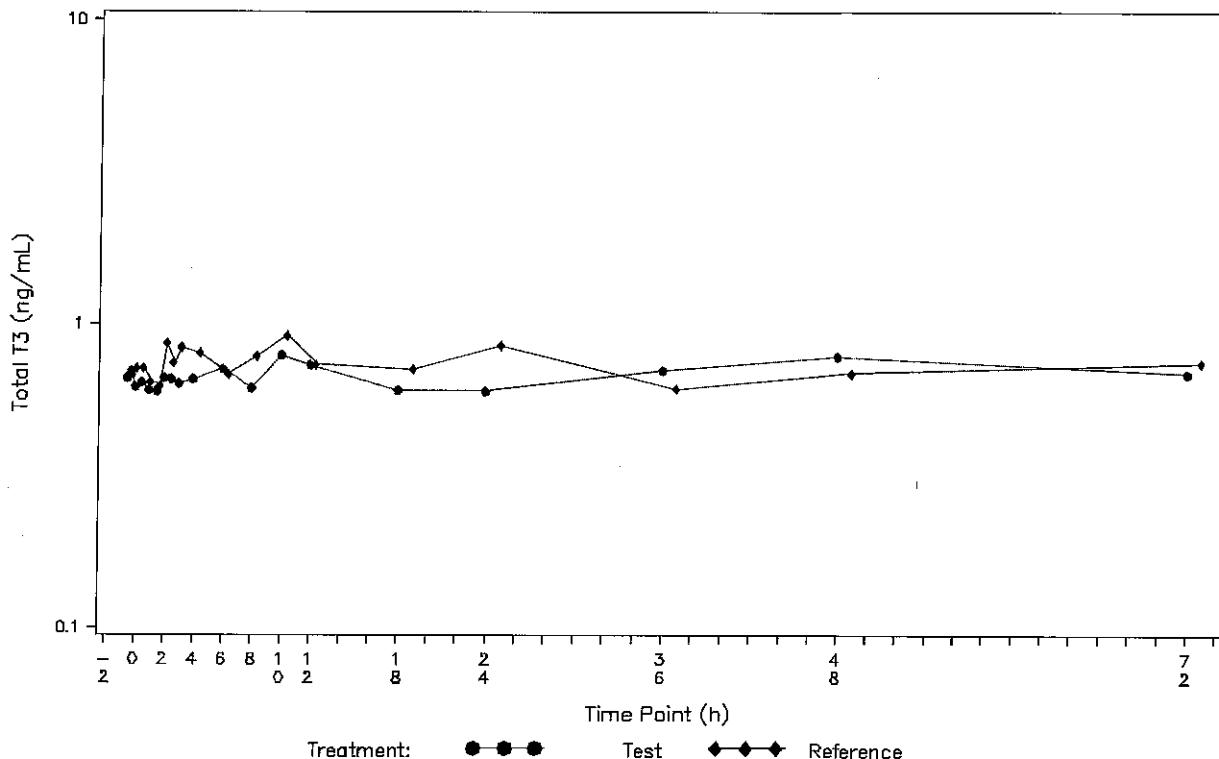
Bioequiv EMR200125-001 Page 1563 of 1628 alation vs. old formulation

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;

Treatment: 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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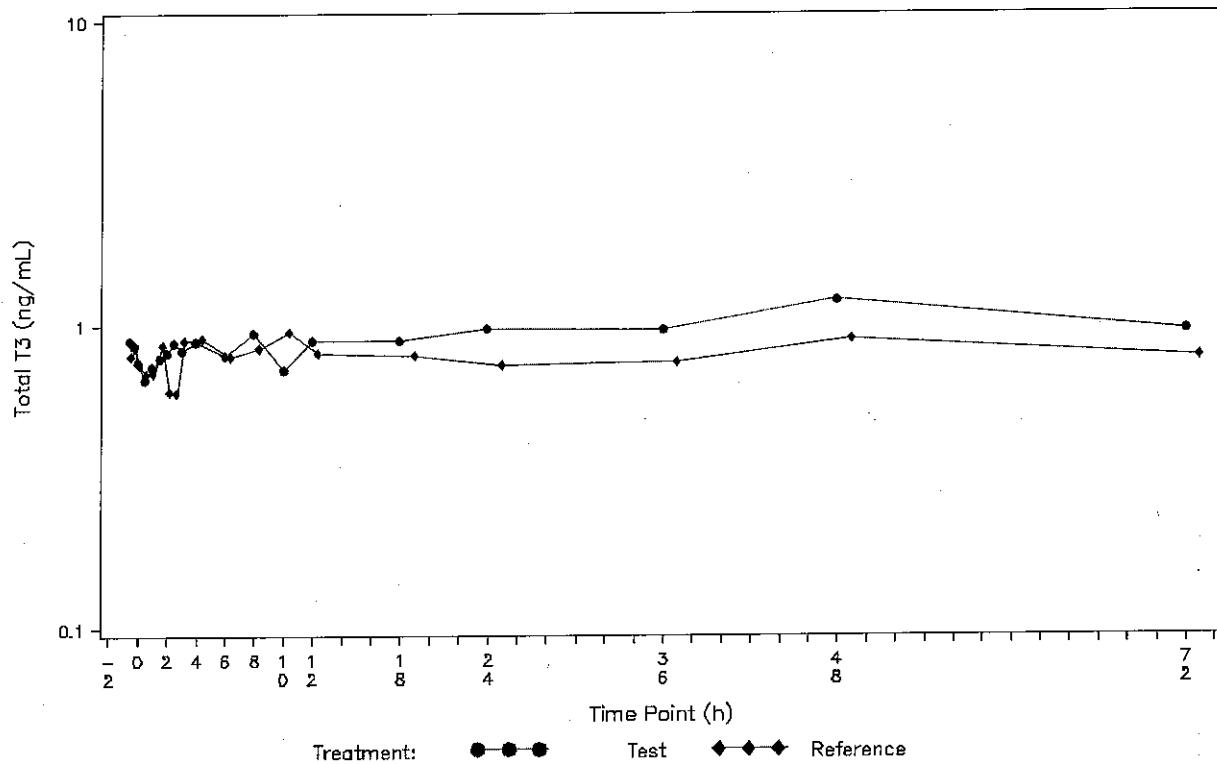
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1564 of 1628 nulation 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

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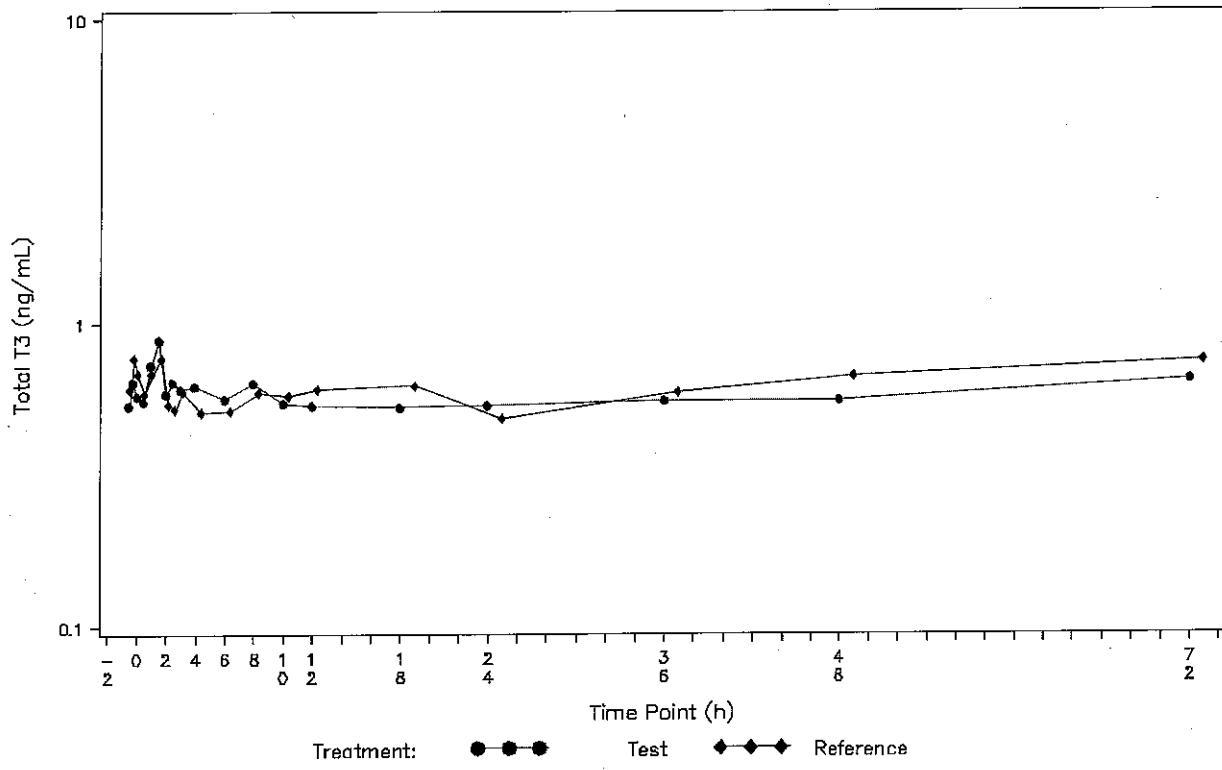
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Merck Serono
EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



⑥: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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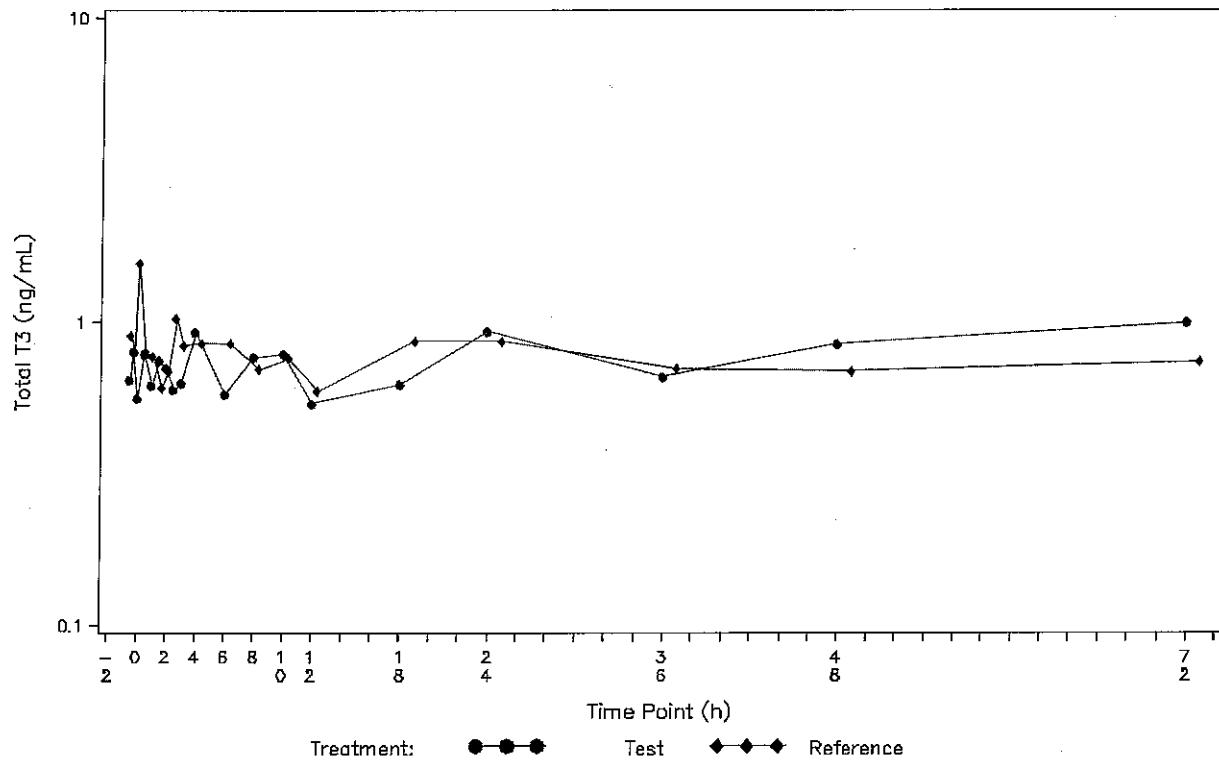
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1566 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

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Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1567 of 1628 ulation vs. old formulation

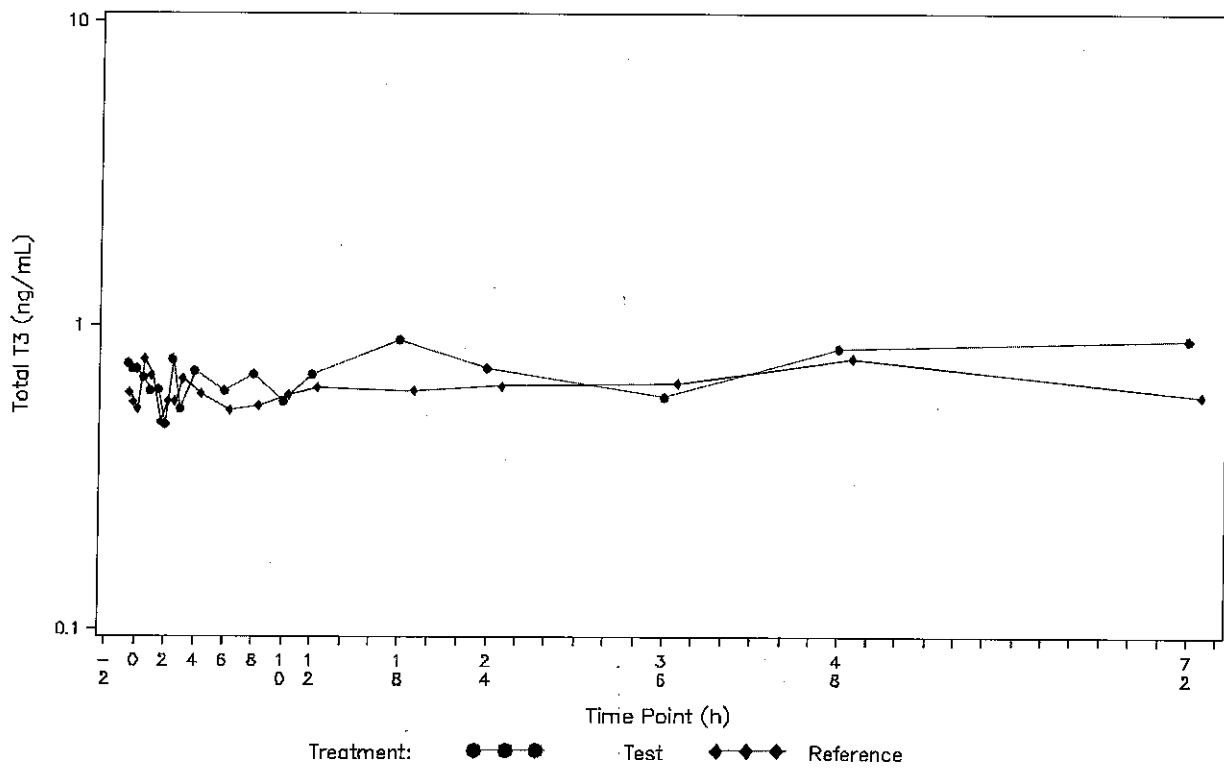
Merck Serono
EMR 200125-001

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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

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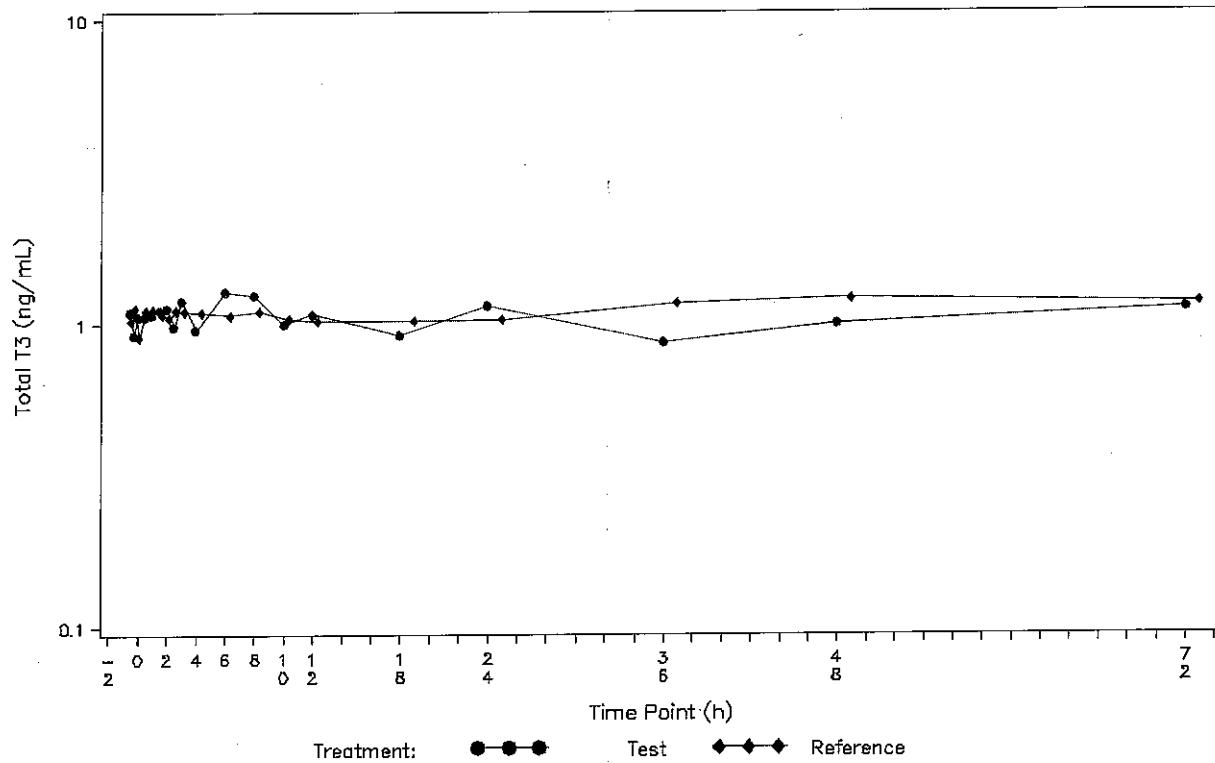
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1568 of 1628 ilation 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:



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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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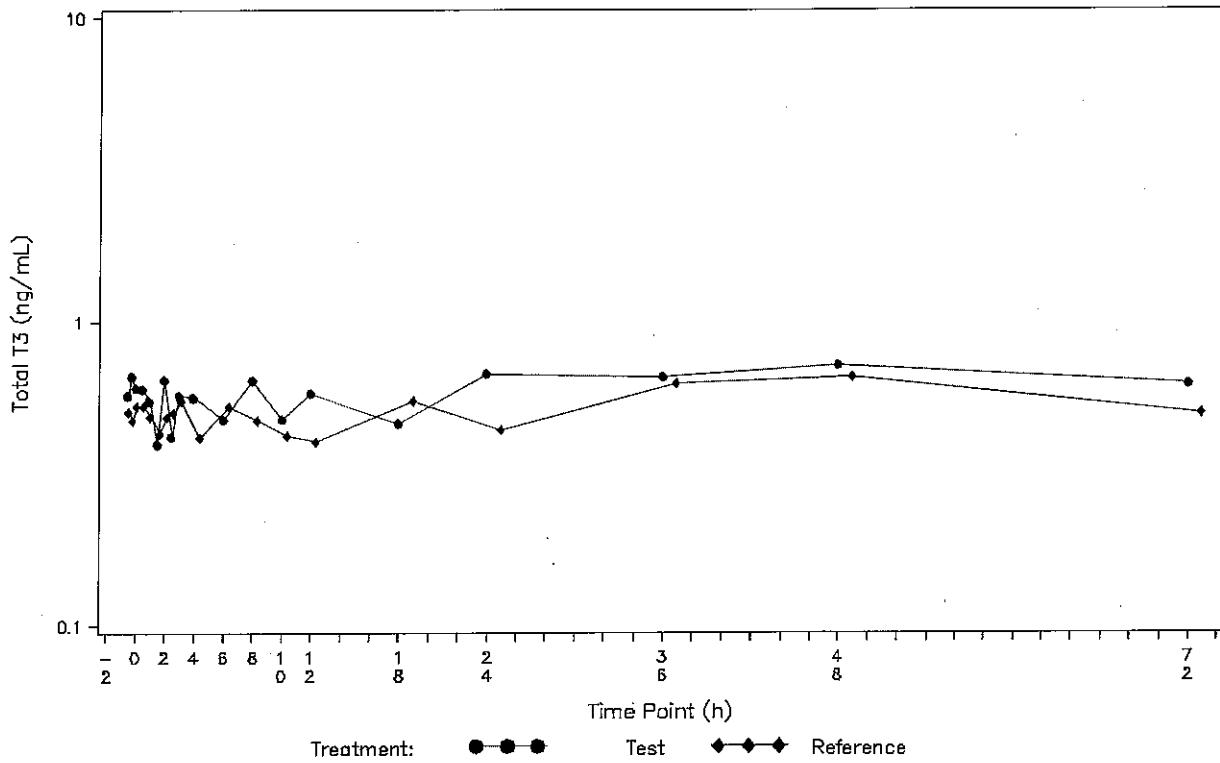
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1569 of 1628 alation vs. old formulation

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Confidential

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: 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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Levothyroxine
EMR 200125-001

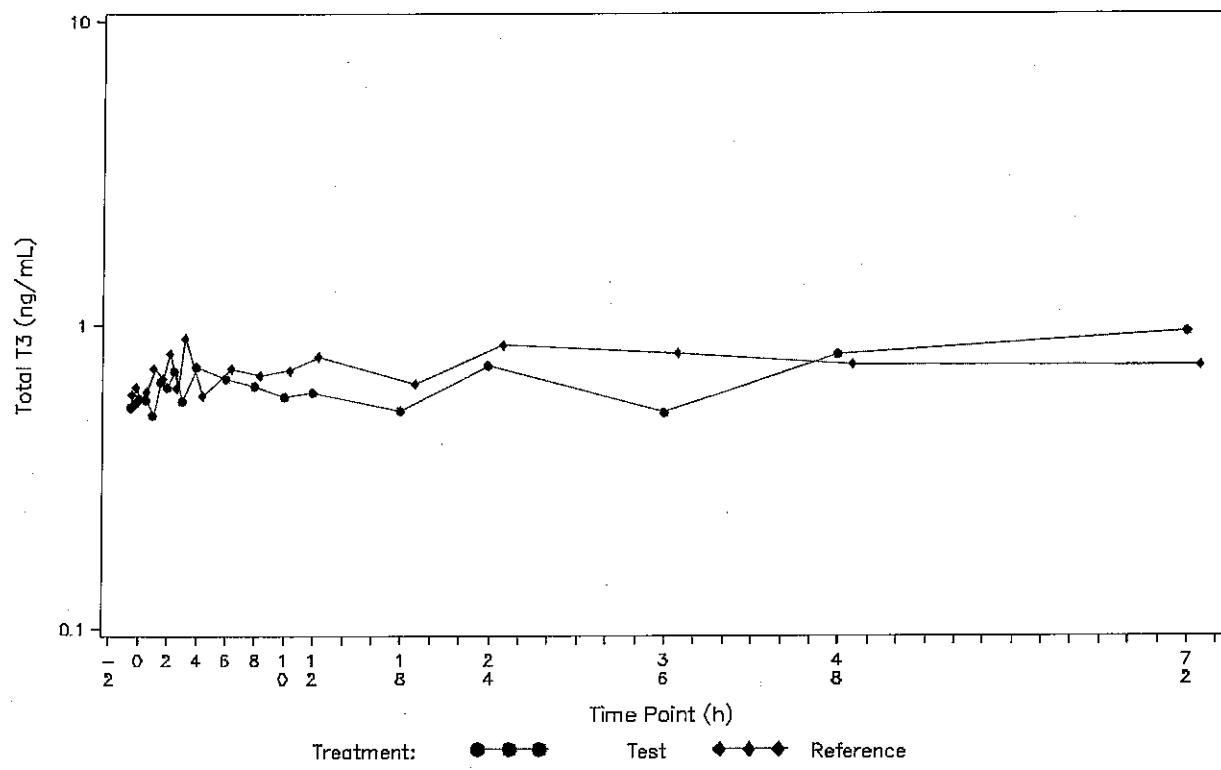
Bioequiv EMR200125-001 Page 1570 of 1628 alation vs. old formulation

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:



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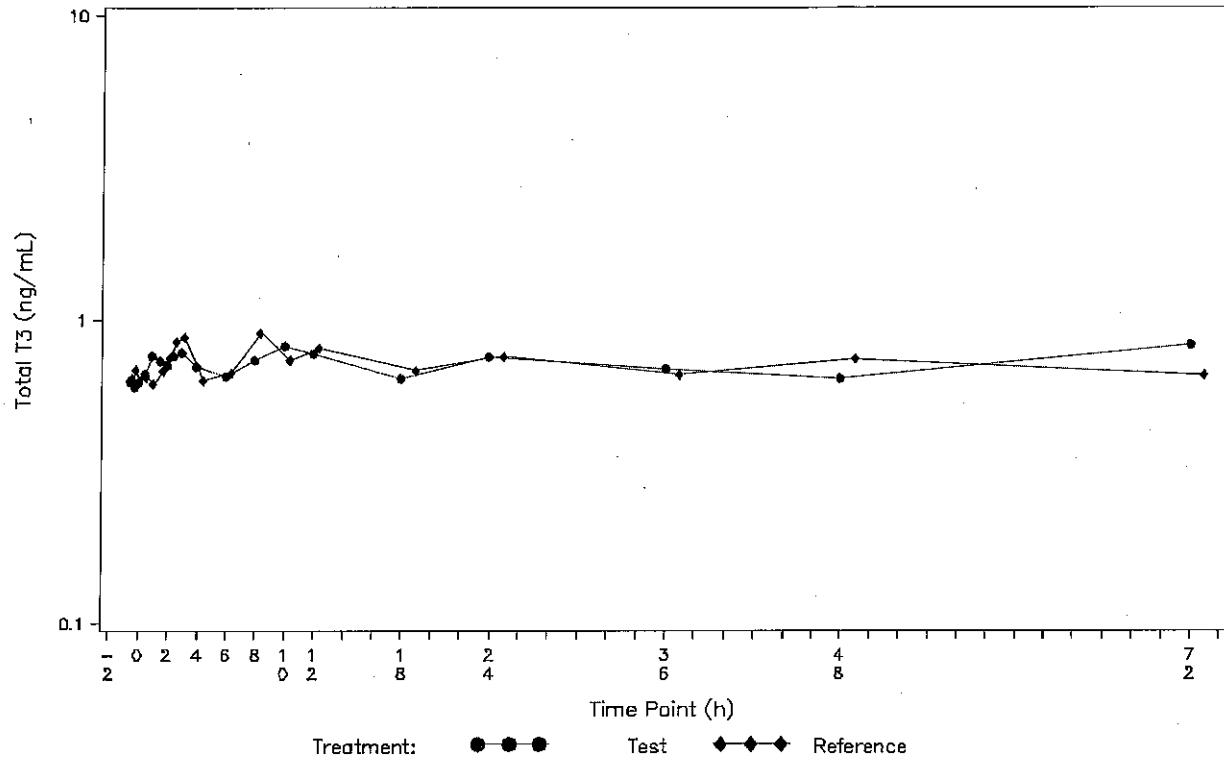
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



⑥: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 16.3.5.3

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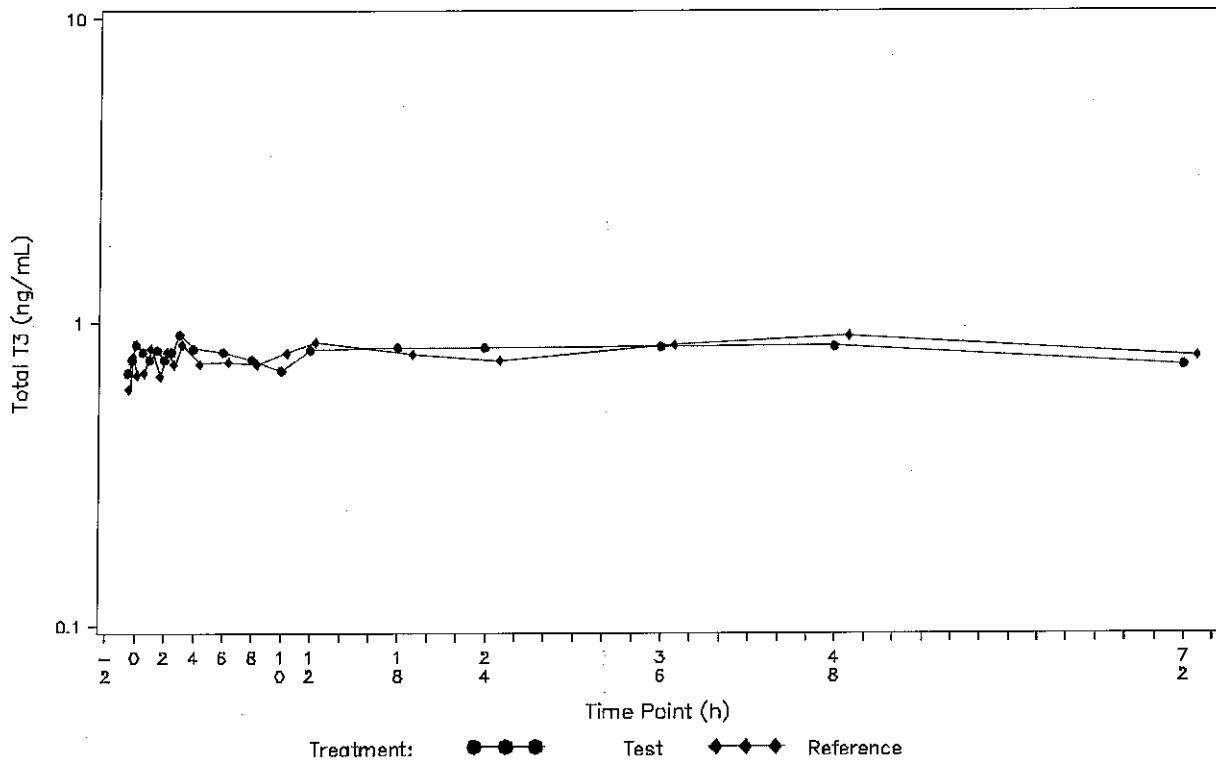
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1572 of 1628 alation 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:



⑥: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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Levothyroxine
EMR 200125-001

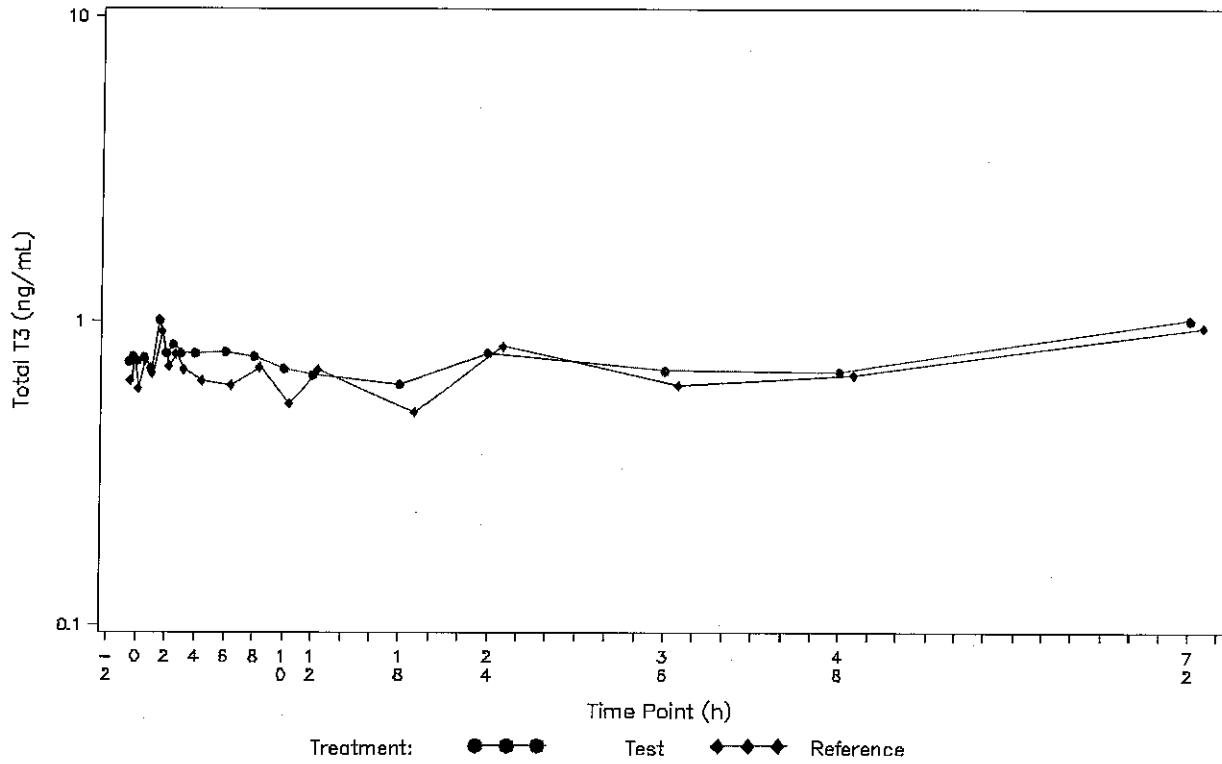
Bioequiv EMR200125-001 Page 1573 of 1628 alation vs. old formulation

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

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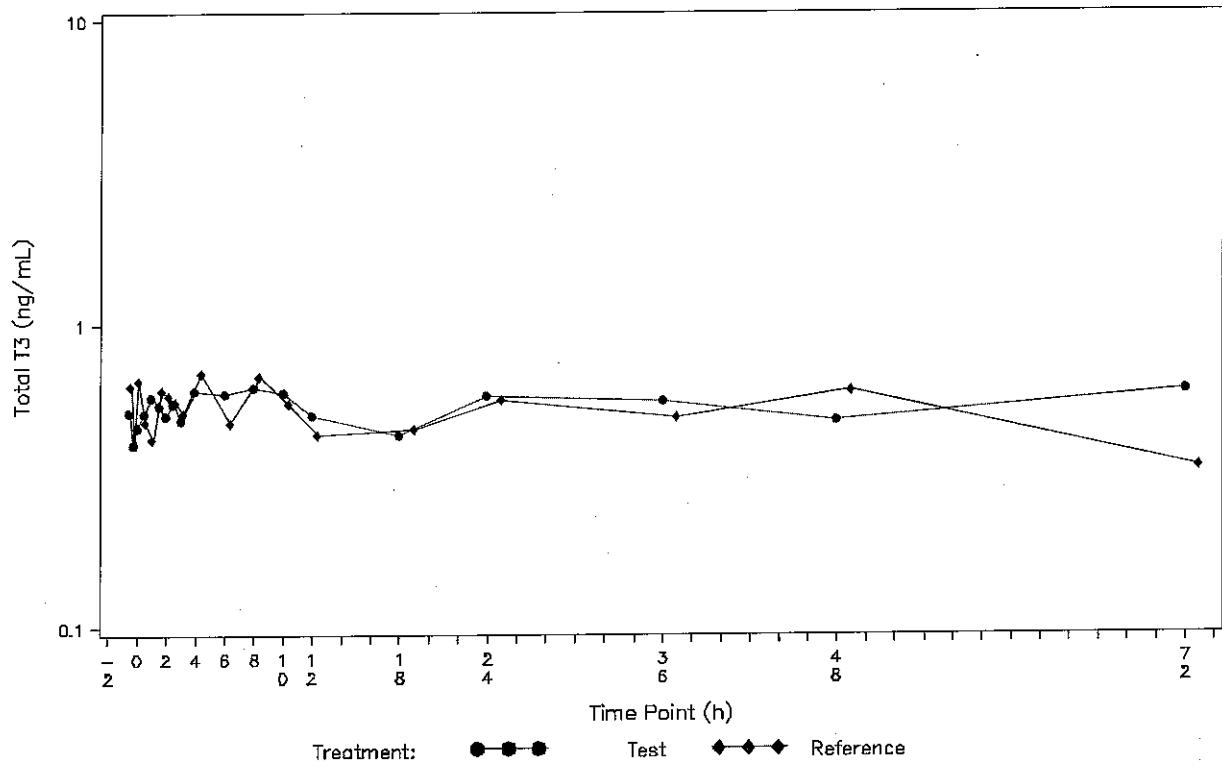
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1574 of 1628 uation 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:



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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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EMR 200125-001

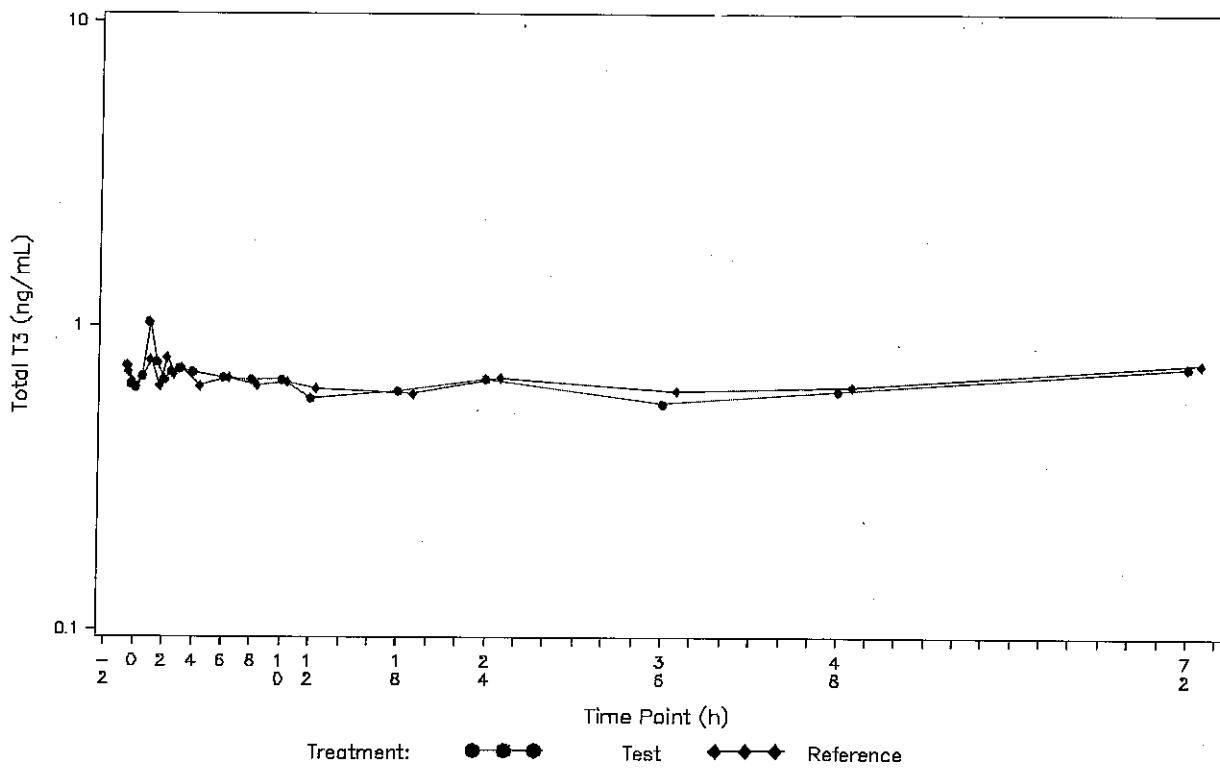
Bioequiv EMR200125-001 Page 1575 of 1628 alation vs. old formulation

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

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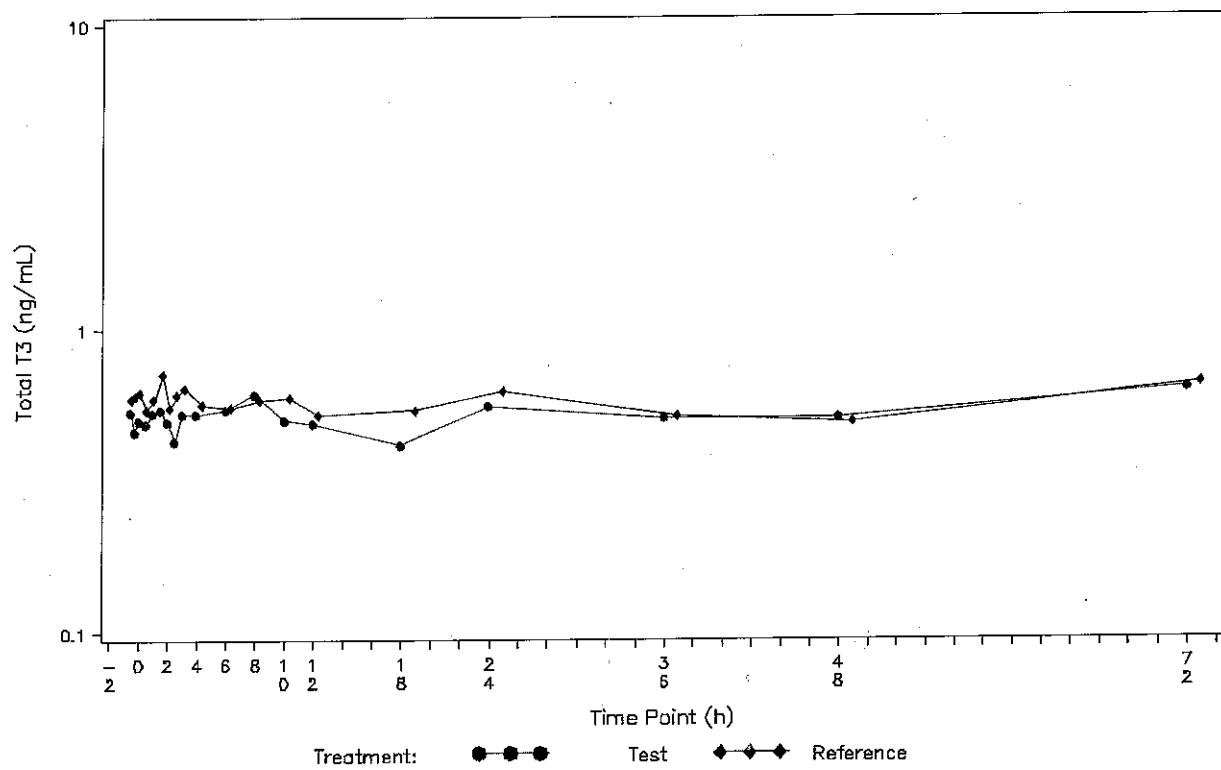
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Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1576 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: 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

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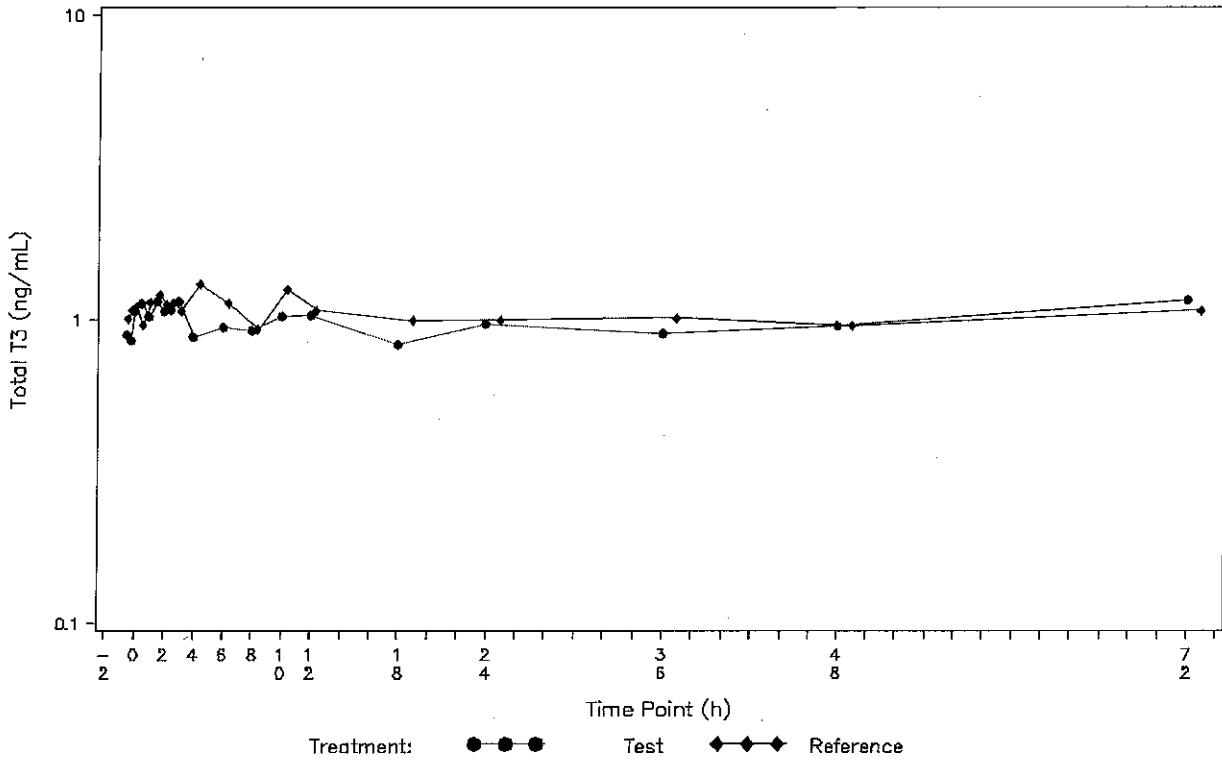
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EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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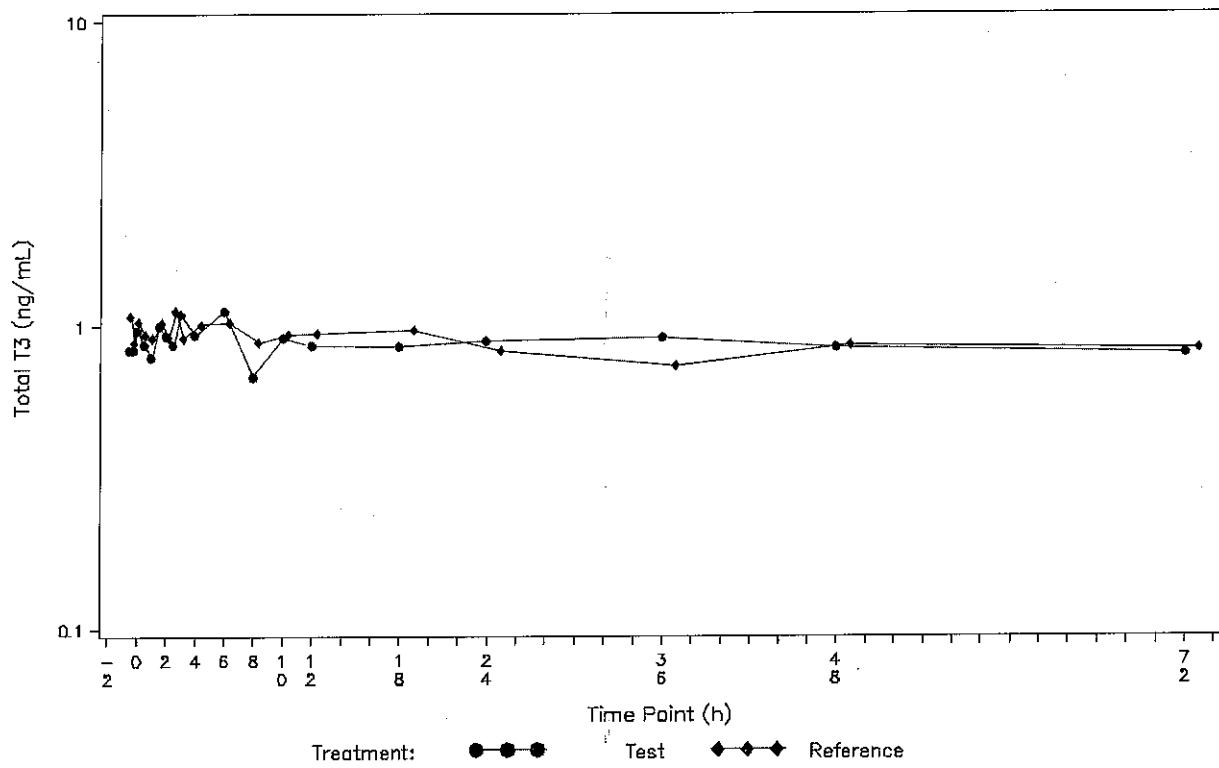
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1578 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:



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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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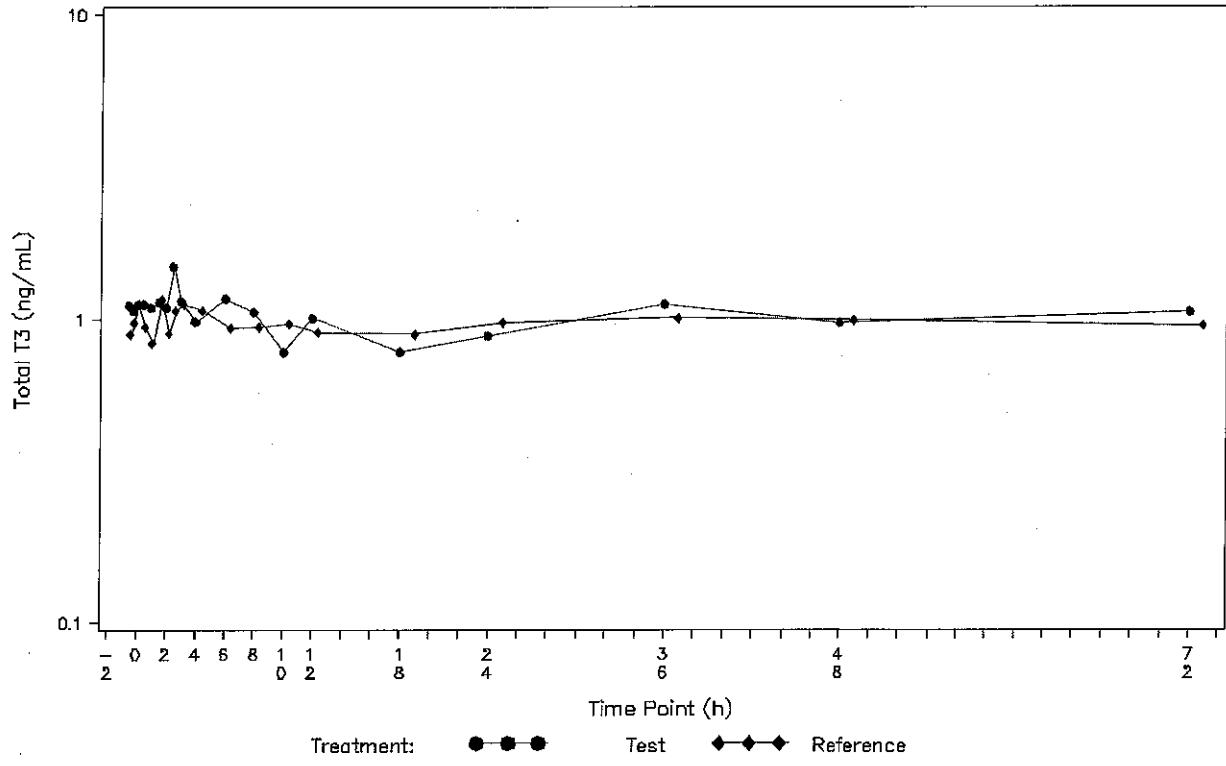
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1579 of 1628 alation 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:



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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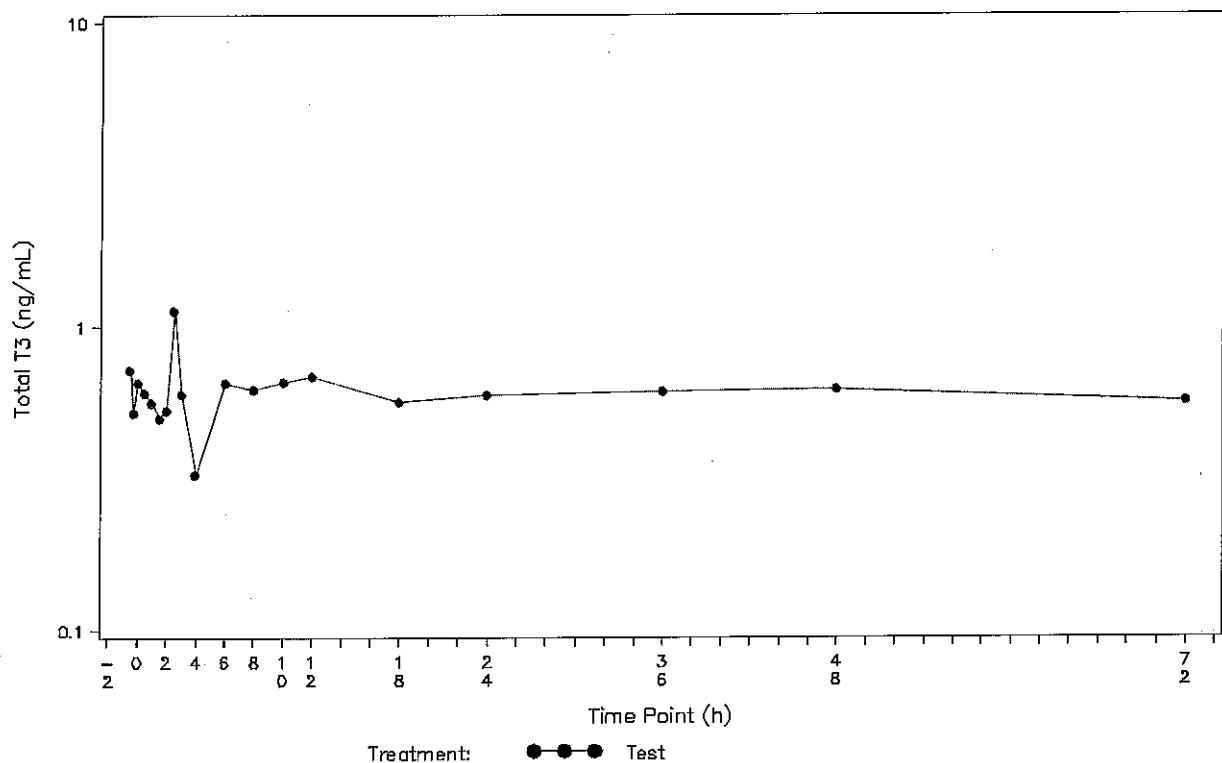
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1580 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: :



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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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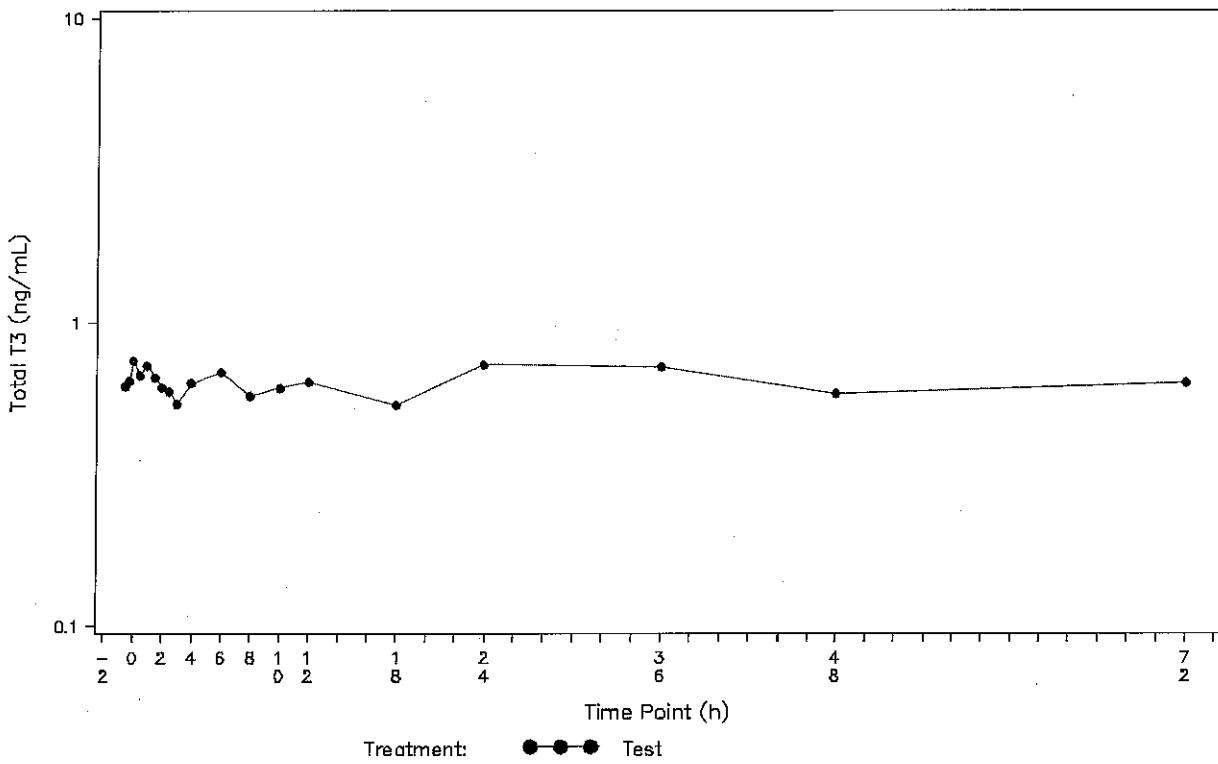
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1581 of 1628 nlation 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:



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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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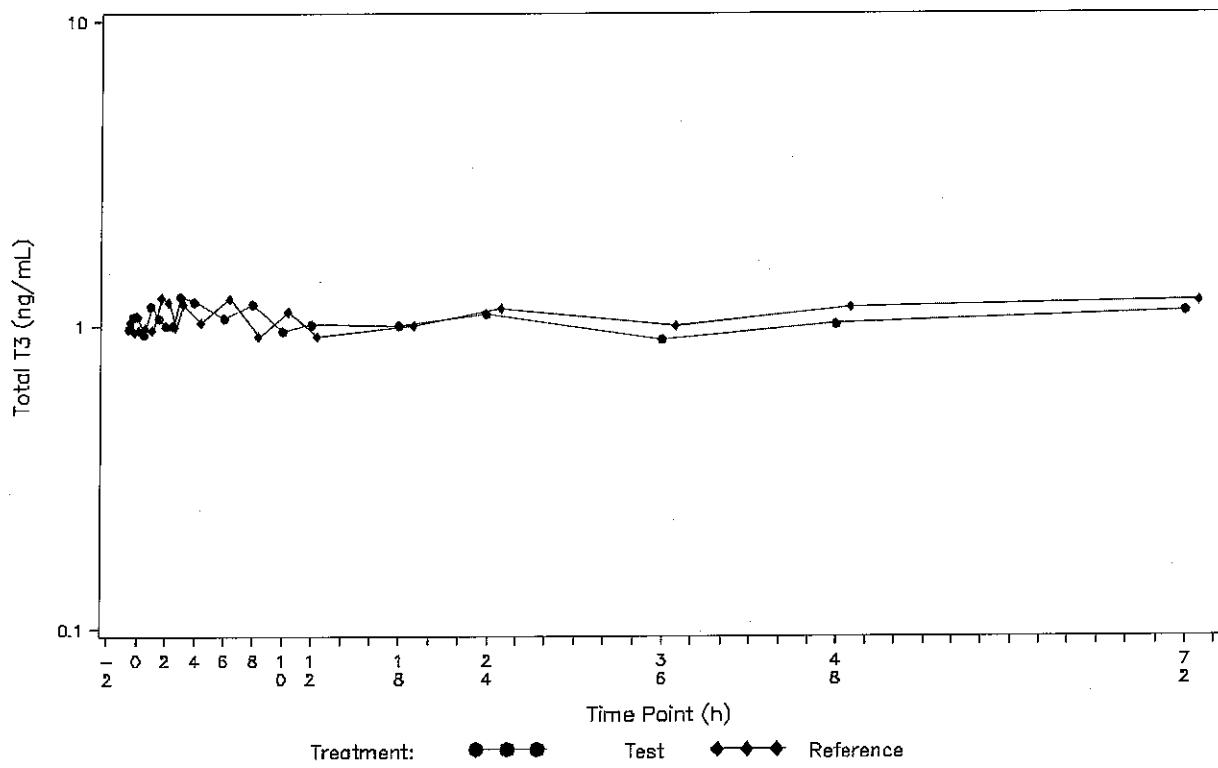
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1582 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:



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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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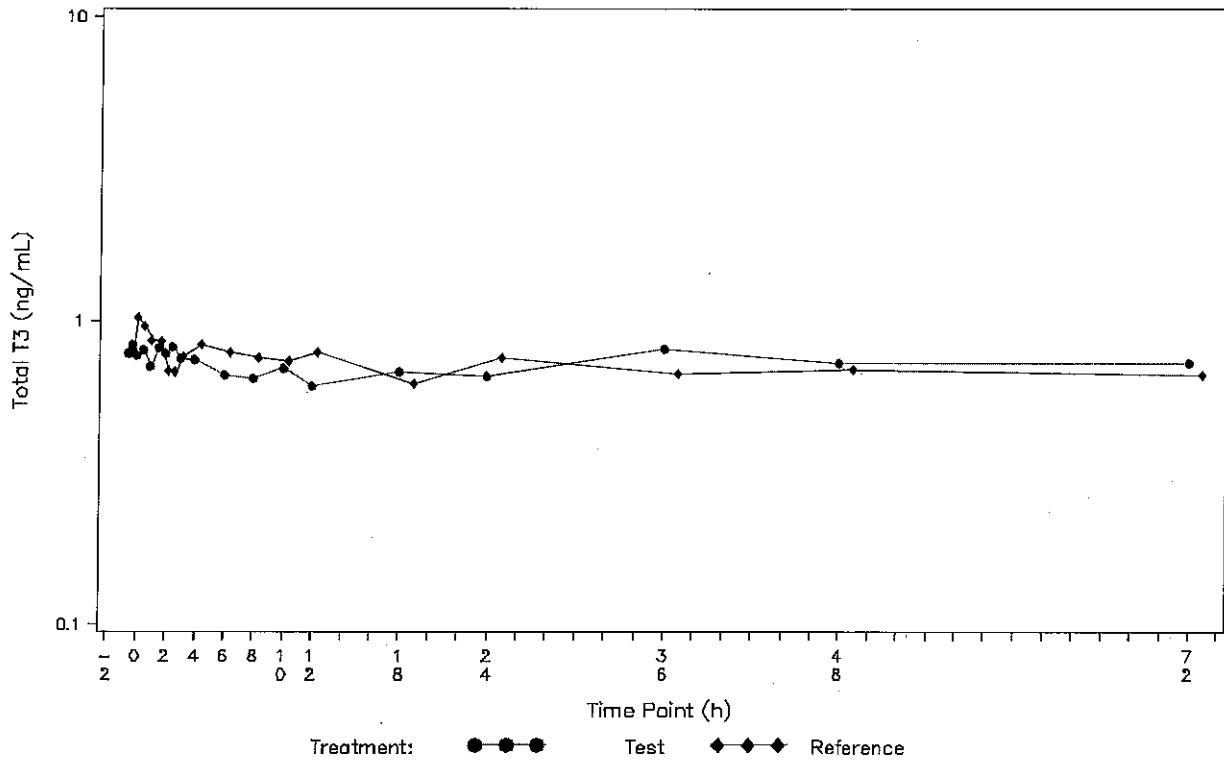
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EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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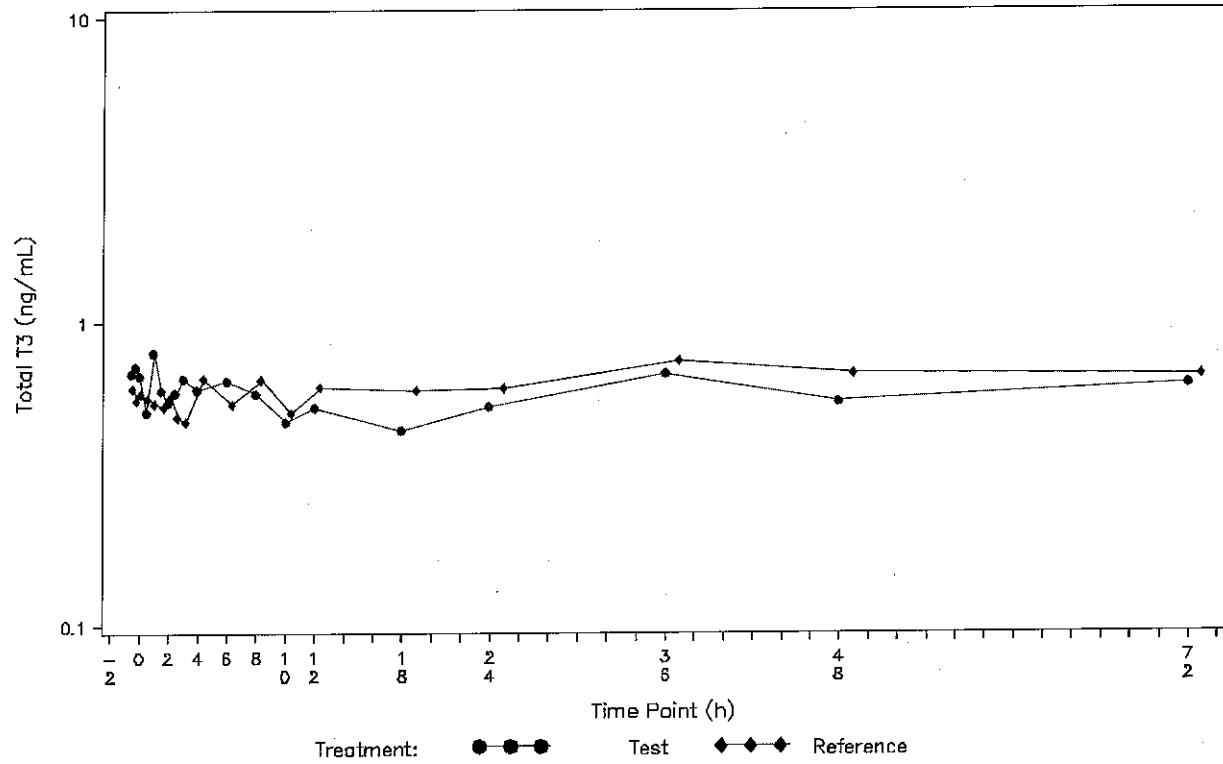
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1584 of 1628 uation 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:



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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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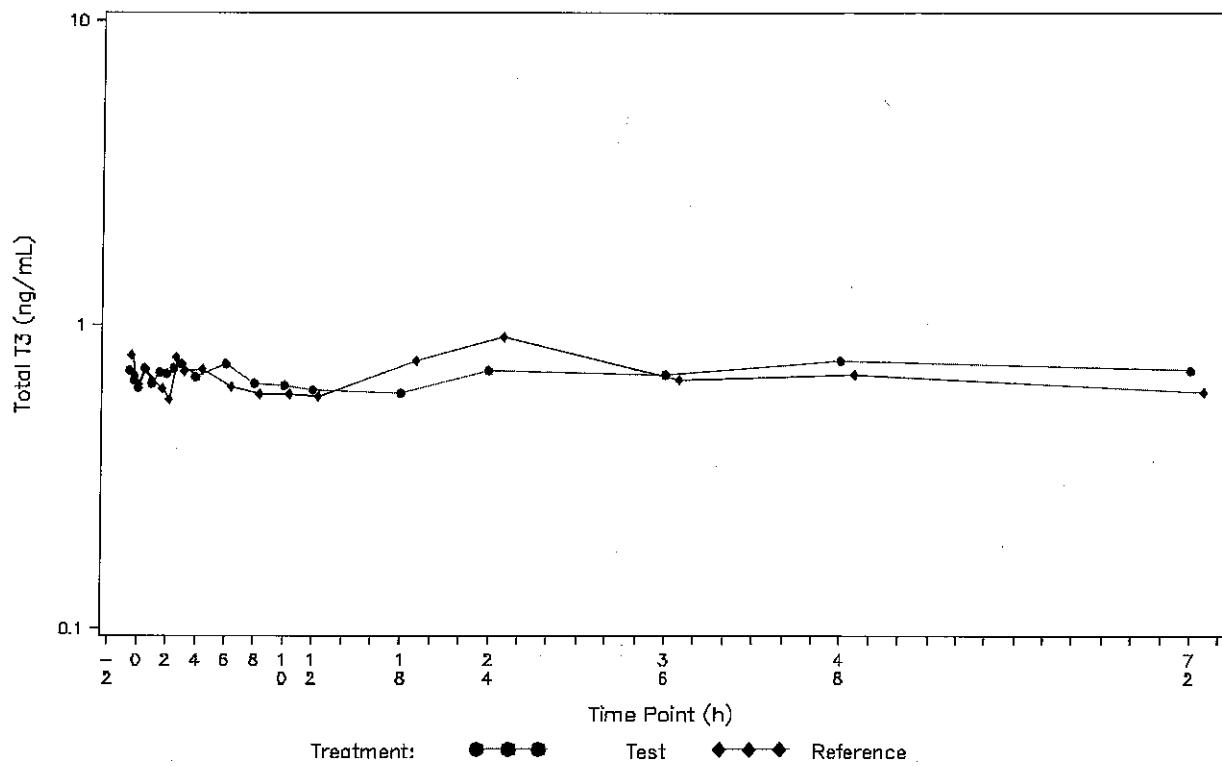
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1585 of 1628 uation 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: :



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

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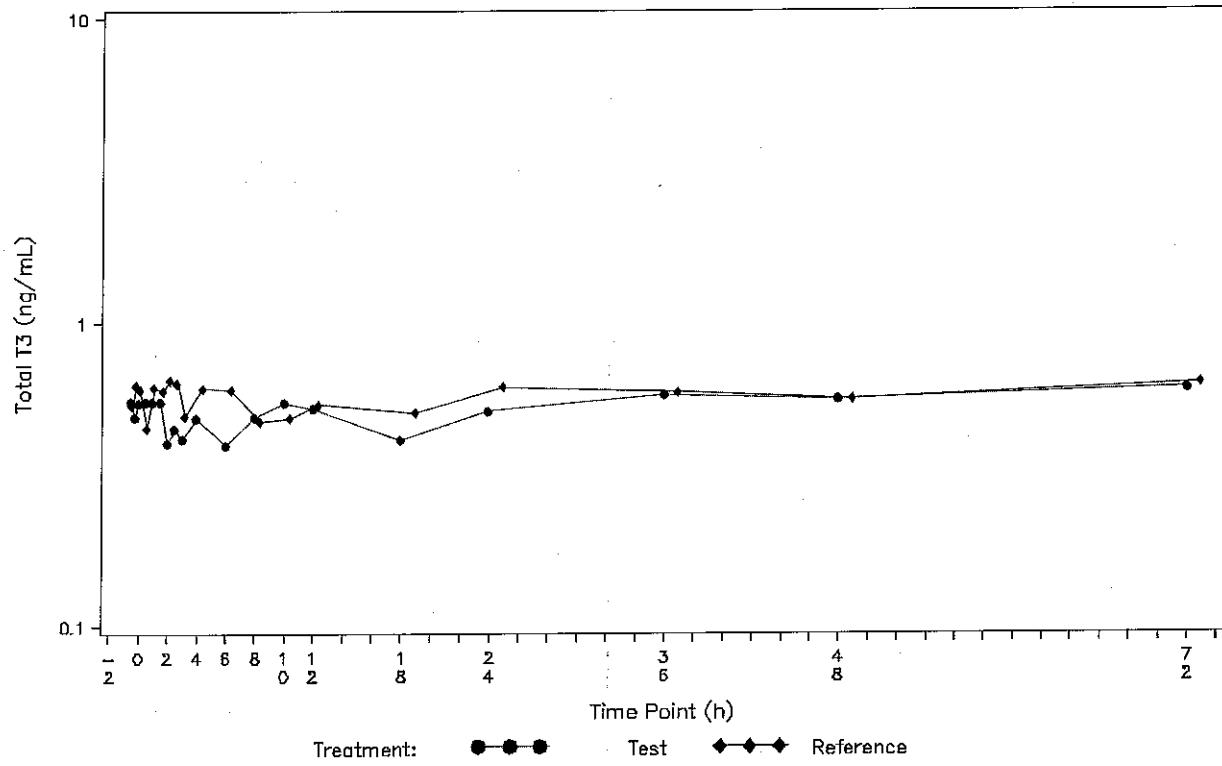
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1586 of 1628 ilation 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:



⑥: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.
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EMR 200125-001

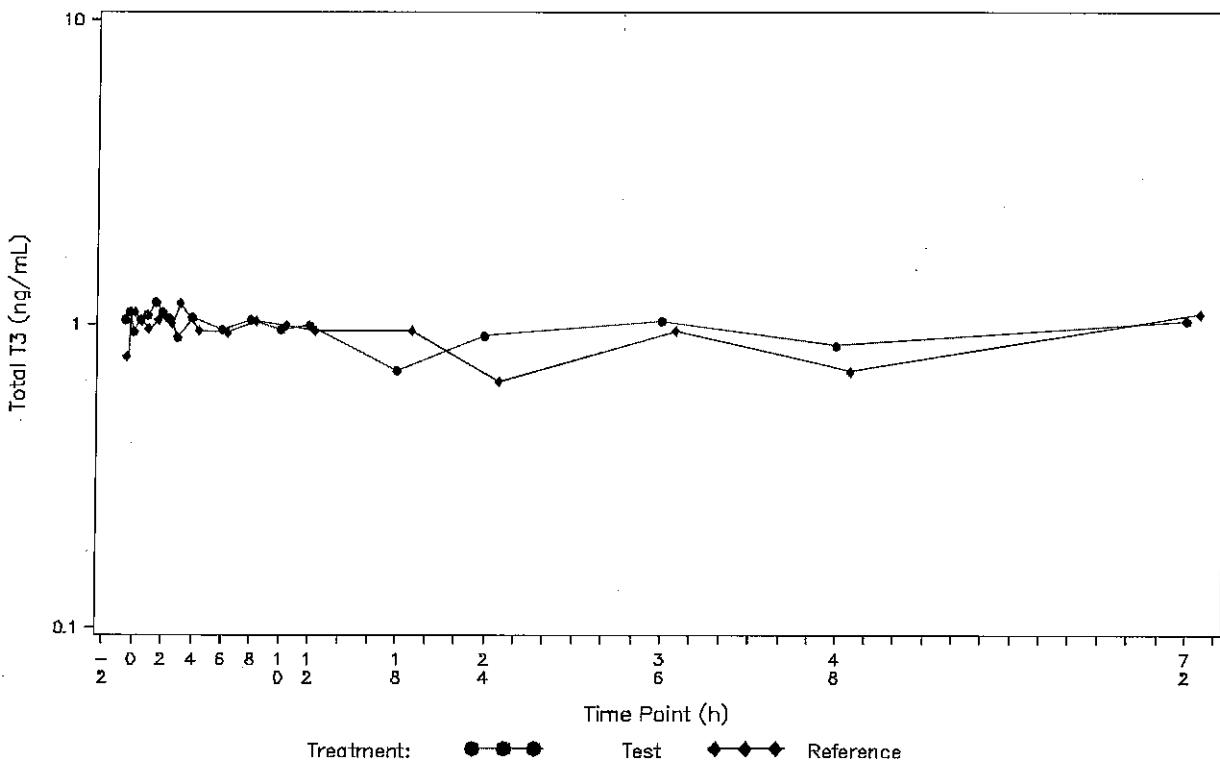
Bioequiv EMR200125-001 Page 1587 of 1628 nulation vs. old formulation

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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:



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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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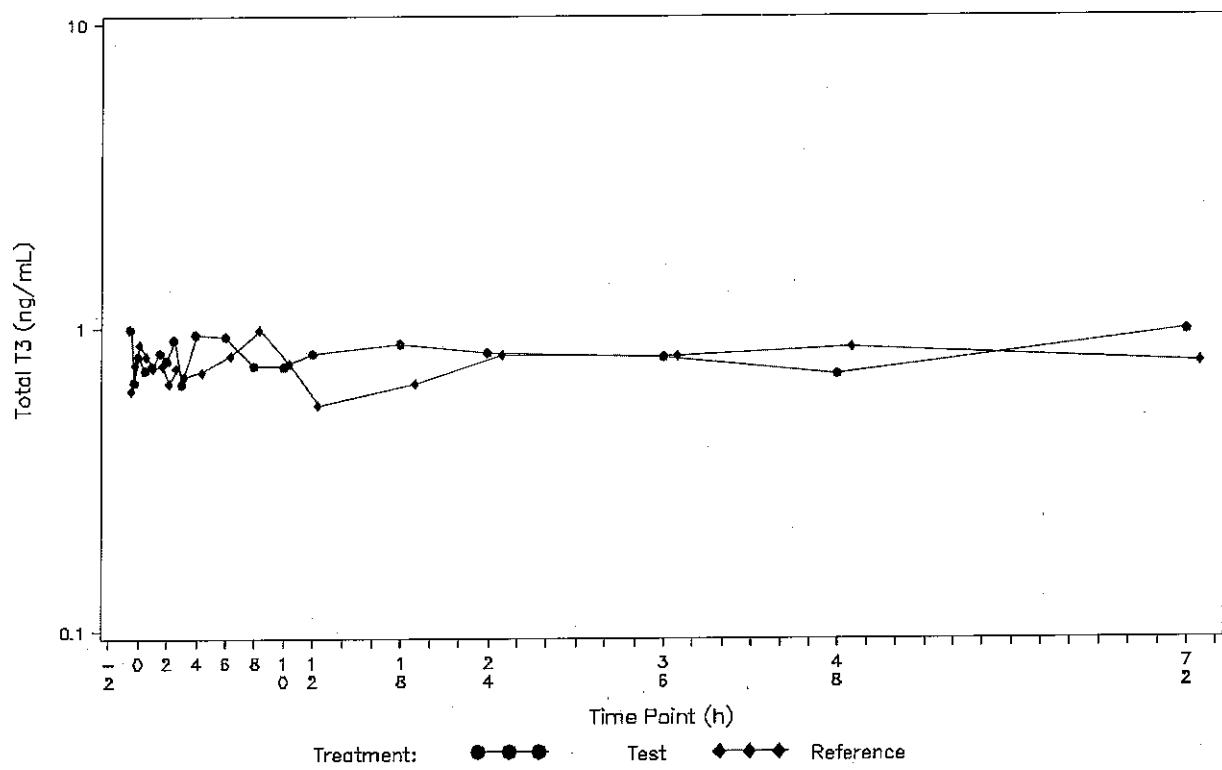
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1588 of 1628 nulation 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:



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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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**Levothyroxine
EMR 200125-001**

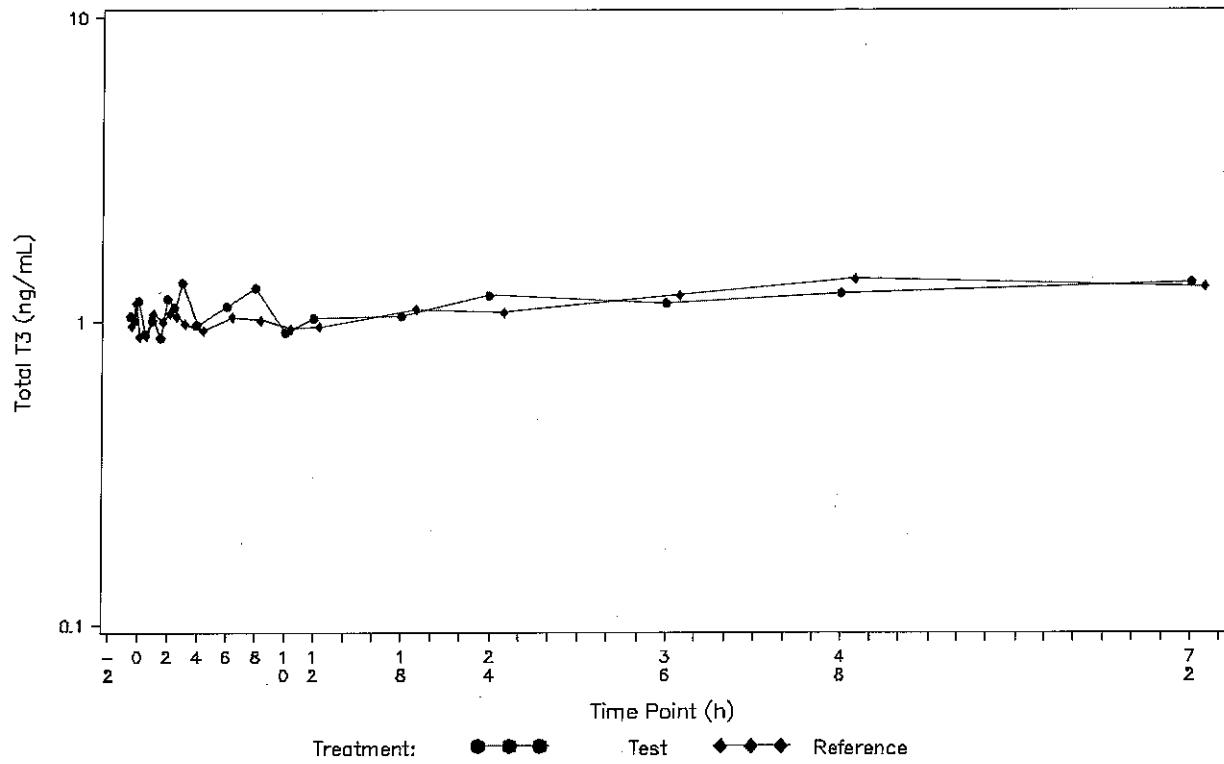
Bioequiv EMR200125-001 Page 1589 of 1628 alation vs. old formulation

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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:



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Levothyroxine
EMR 200125-001

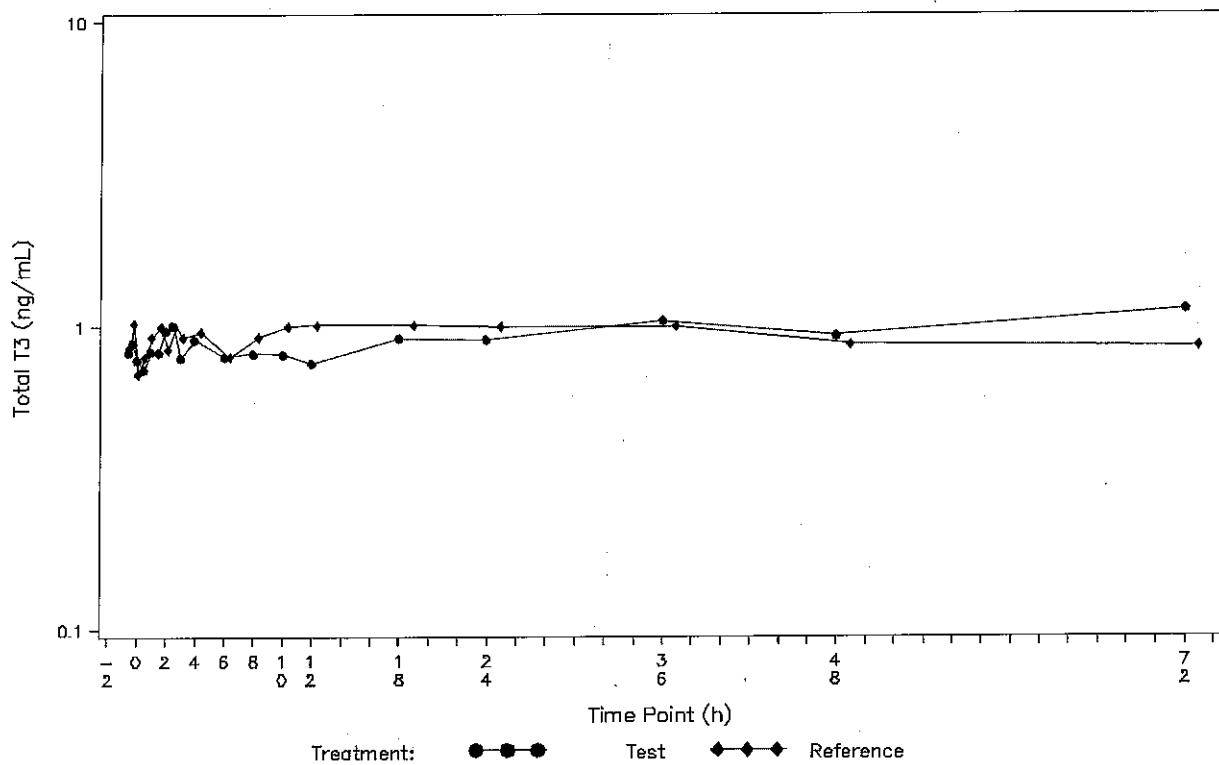
Bioequiv EMR200125-001 Page 1590 of 1628 alation vs. old formulation

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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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Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
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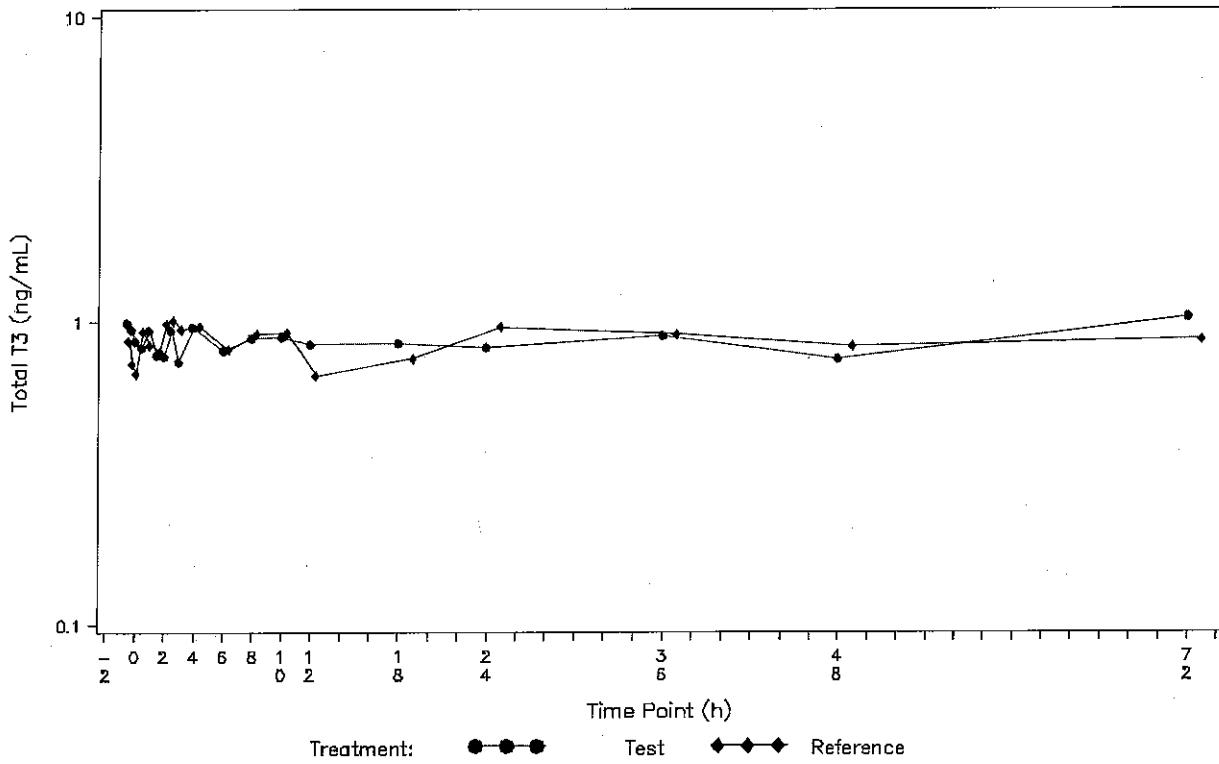
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EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: :



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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EMR 200125-001

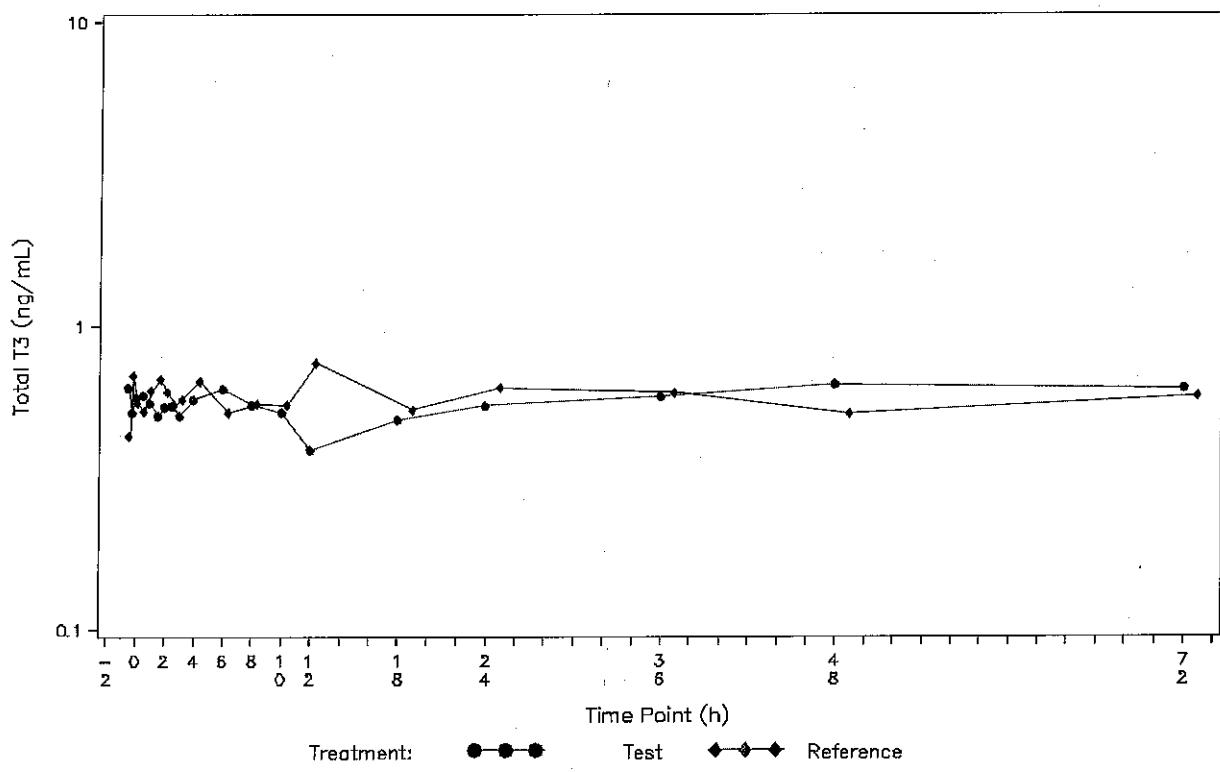
Bioequiv EMR200125-001 Page 1592 of 1628 ualation vs. old formulation

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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:



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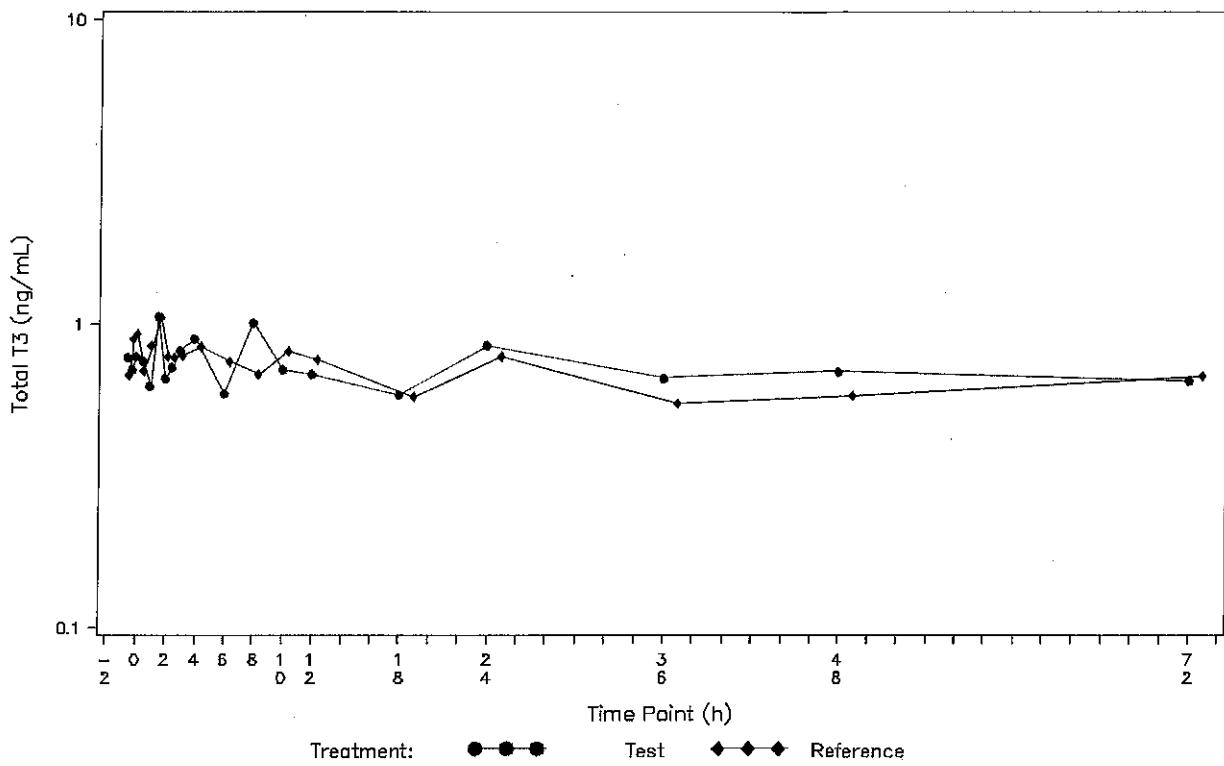
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T₃ values) (Safety Population)

Subject ID/Random Number: 1



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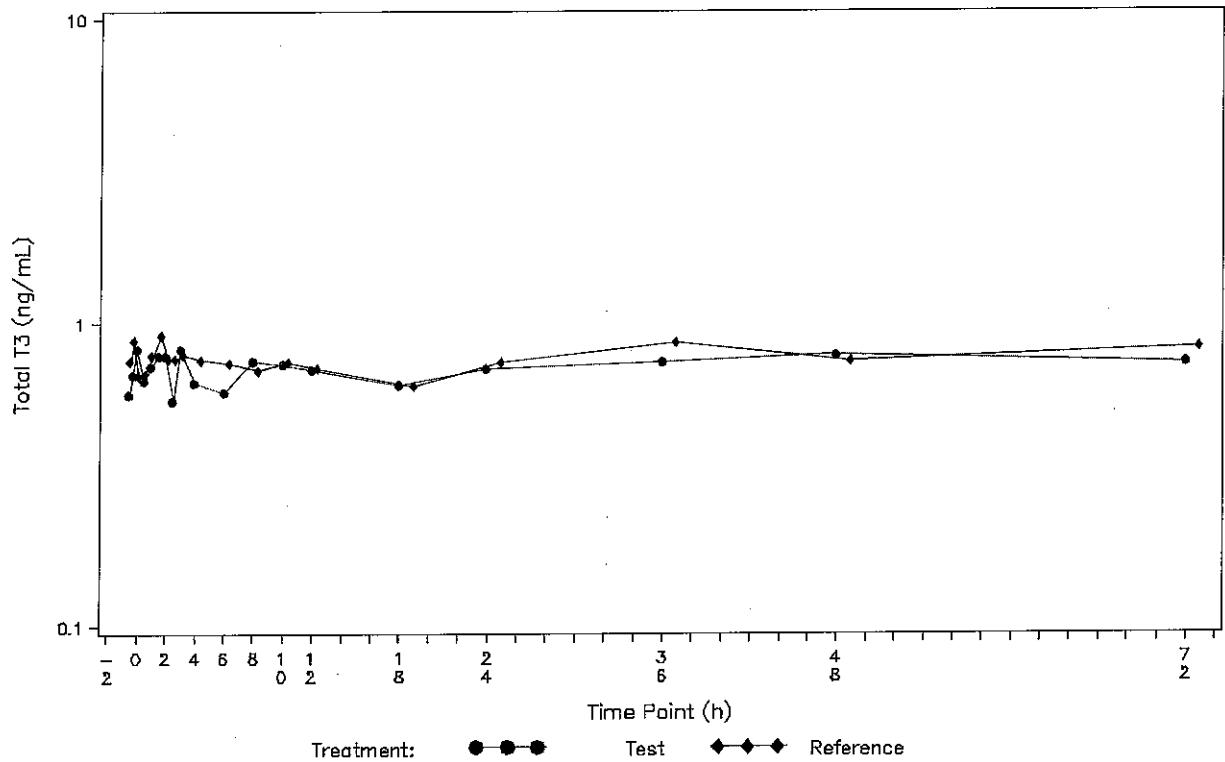
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1594 of 1628 uation 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: :



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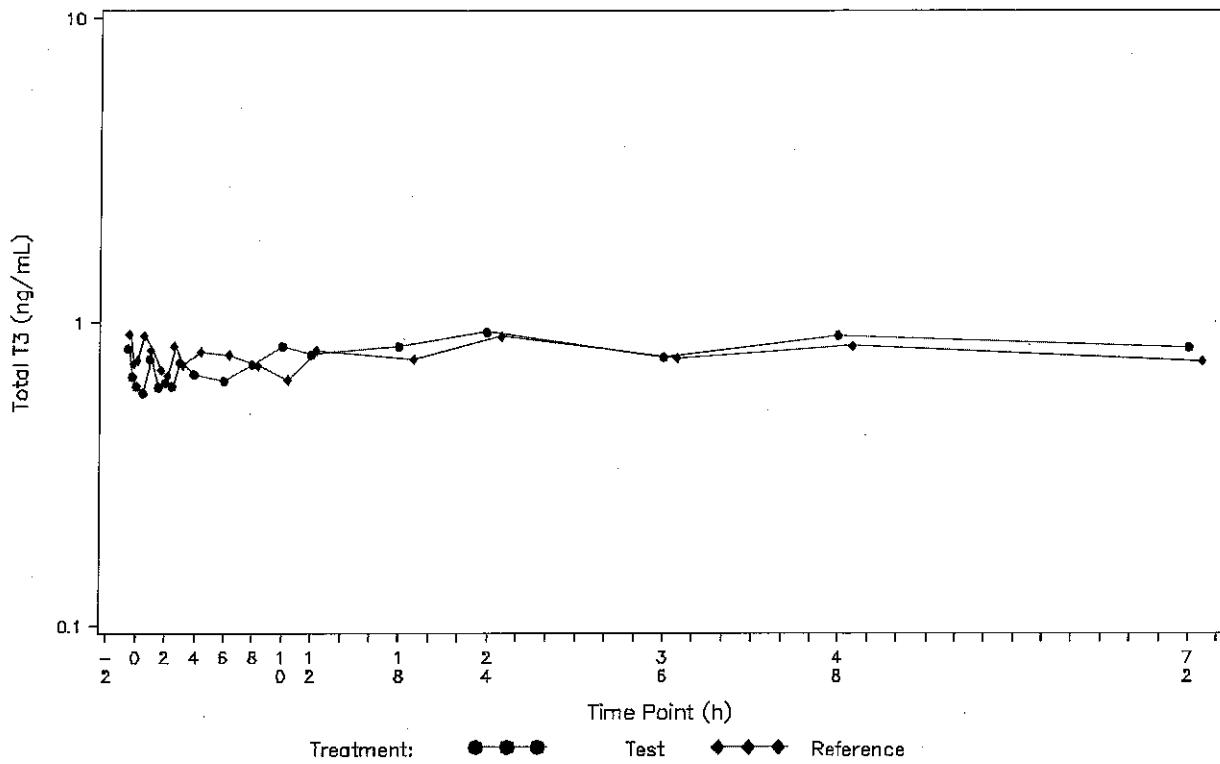
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1595 of 1628 nulation vs. old formulation

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Confidential

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

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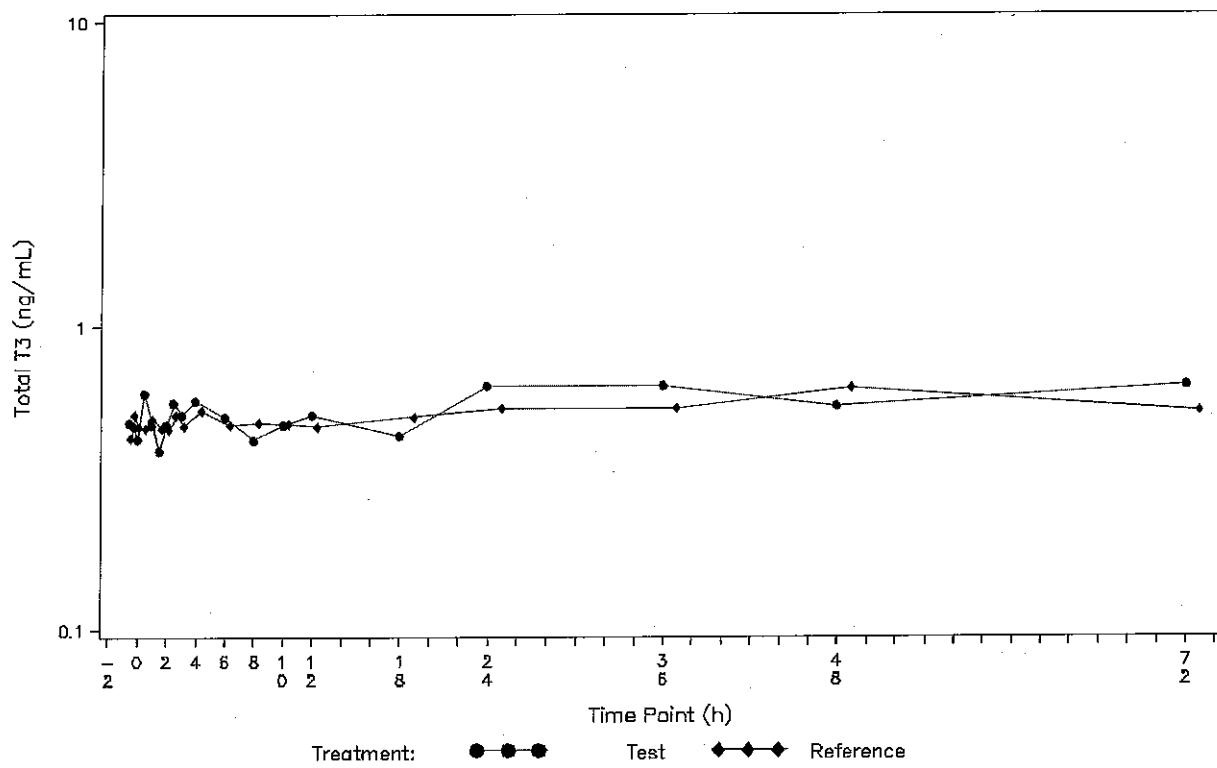
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1596 of 1628 nlation vs. old formulation

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Confidential

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: 1



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

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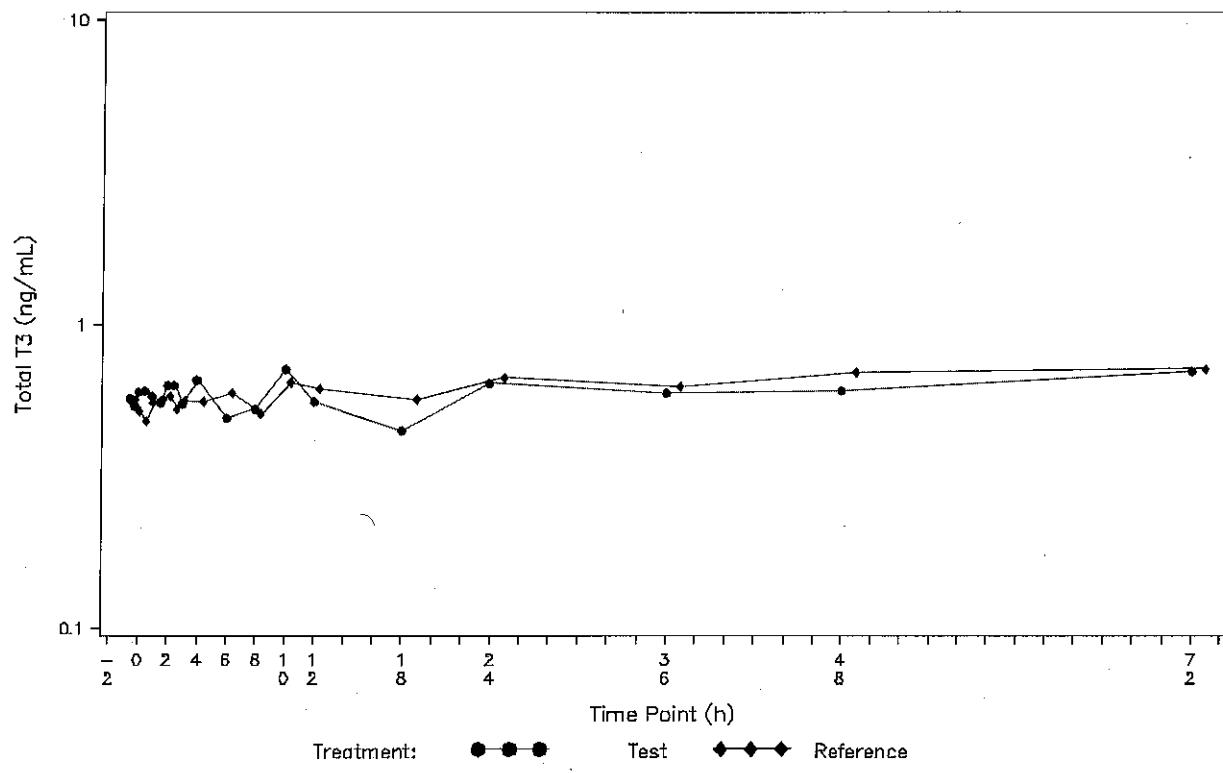
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1597 of 1628 alation vs. old formulation

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Confidential

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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**Levothyroxine
EMR 200125-001**

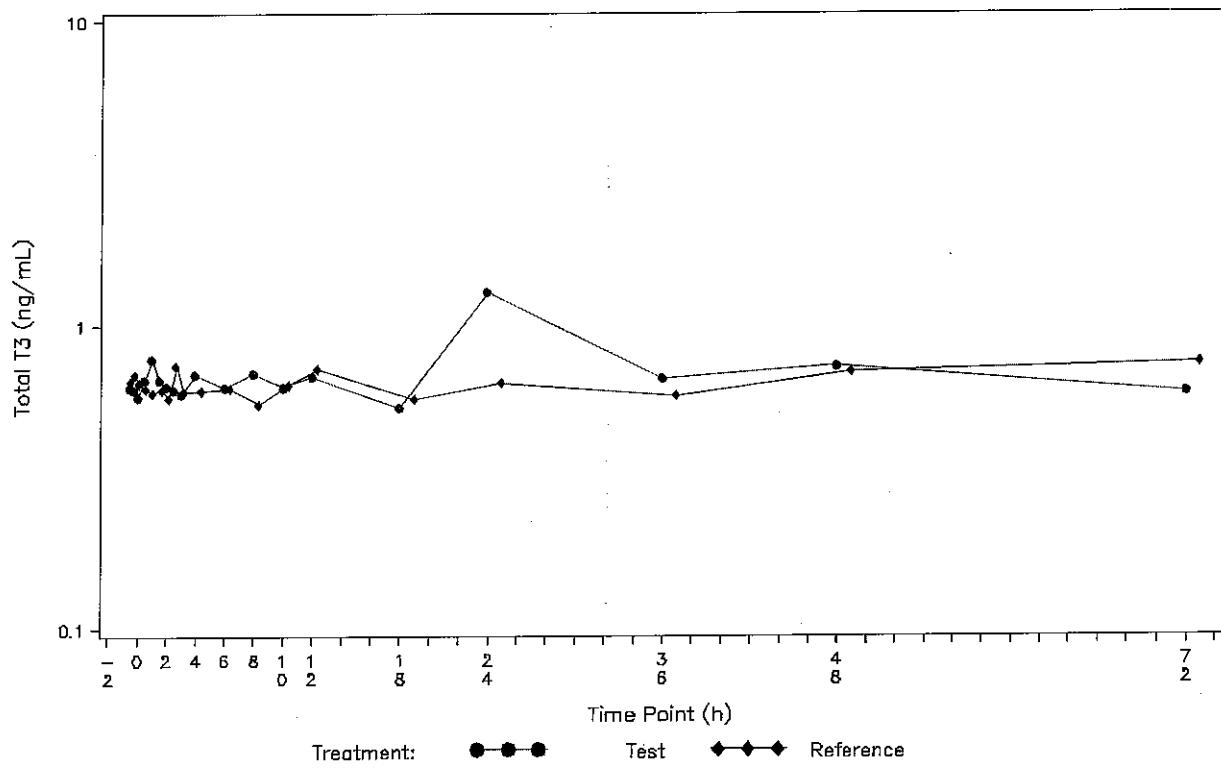
Bioequiv EMR200125-001 Page 1598 of 1628 nulation vs. old formulation

Merck Serono
EMR 200125-001

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Confidential

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

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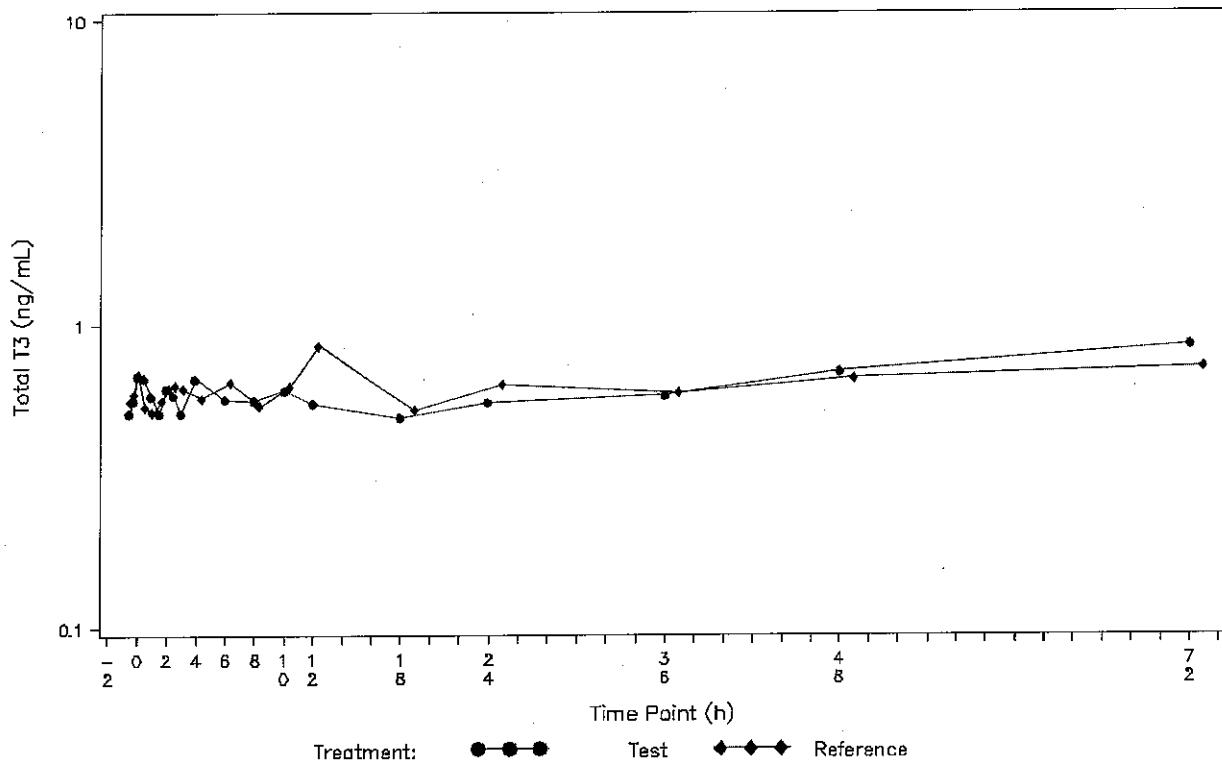
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Merck Serono
EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T₃ values) (Safety Population)

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

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EMR 200125-001

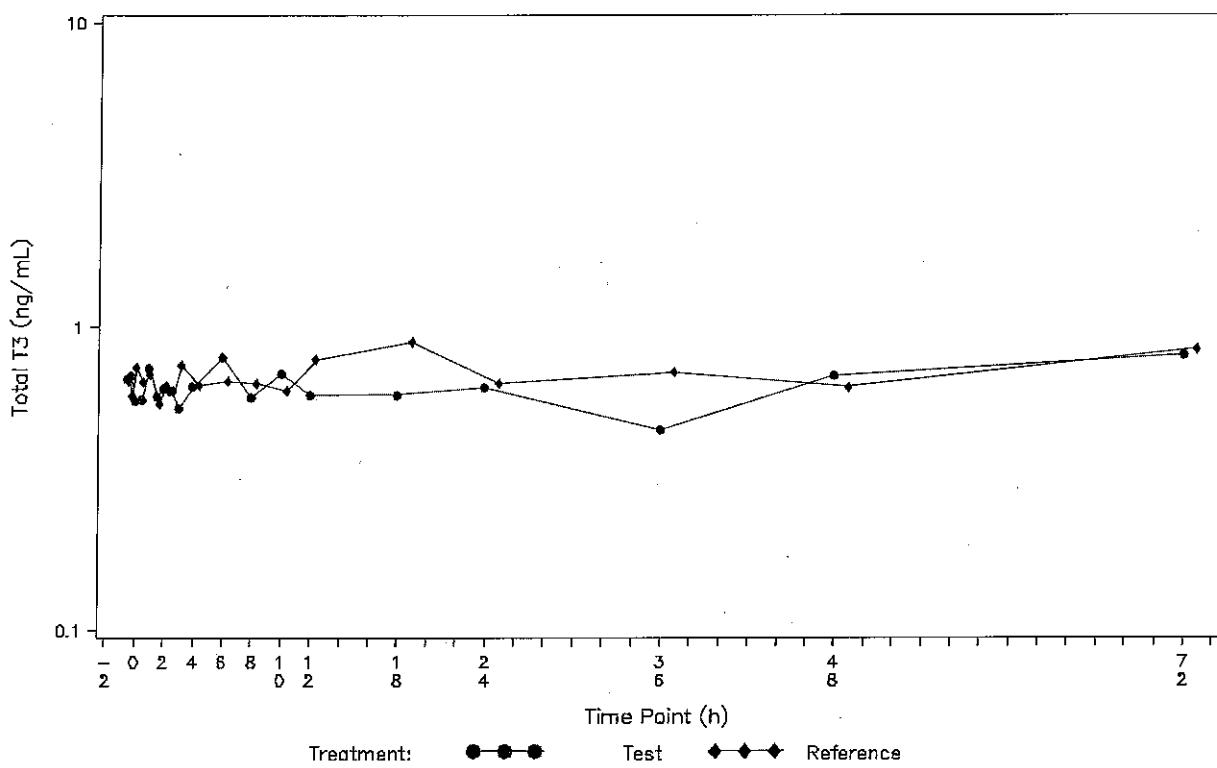
Bioequiv EMR200125-001 Page 1600 of 1628 alation vs. old formulation

Merck Serono
EMR 200125-001

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Confidential

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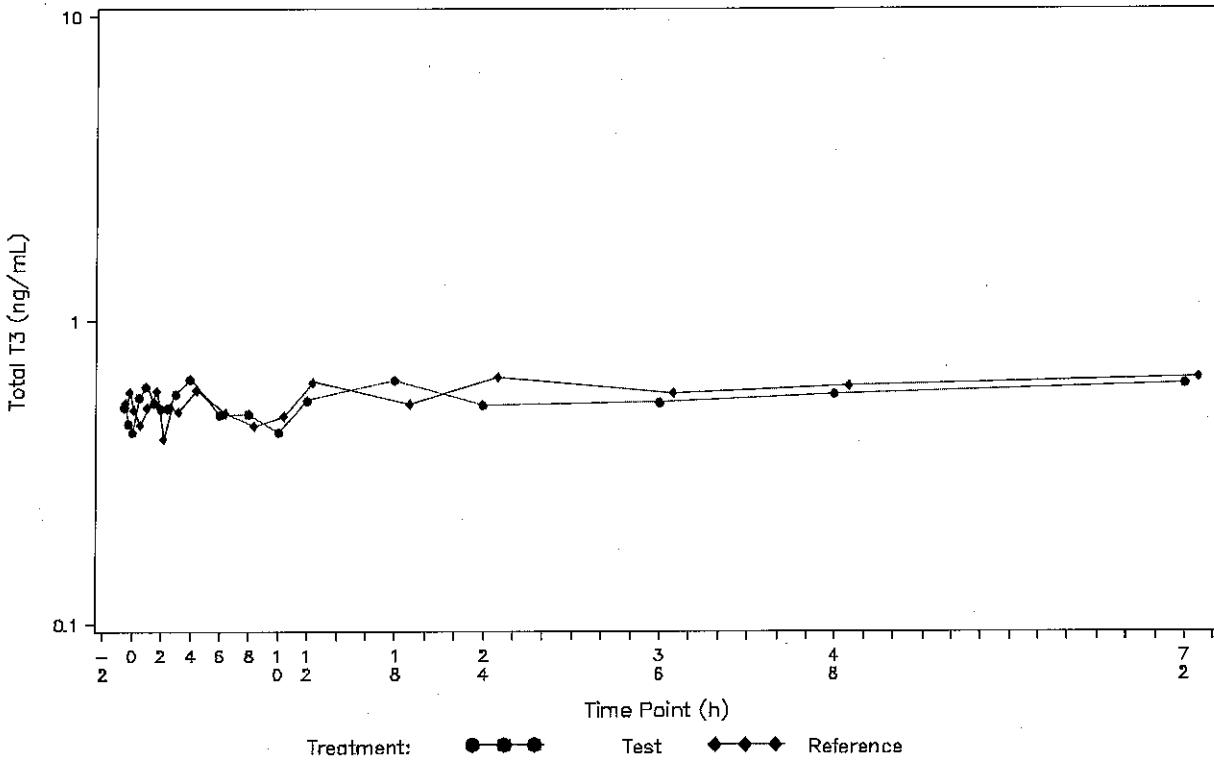
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Merck Serono
EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:



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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
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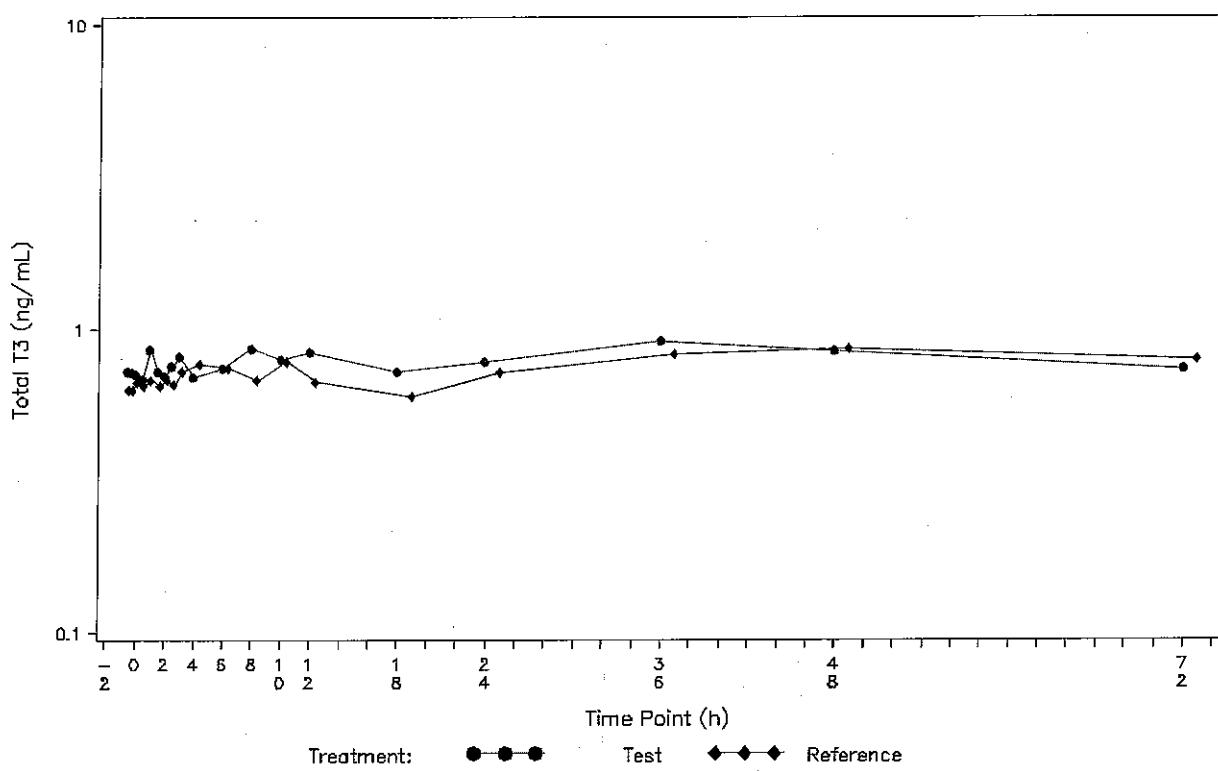
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1602 of 1628 elation vs. old formulation

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Confidential

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: 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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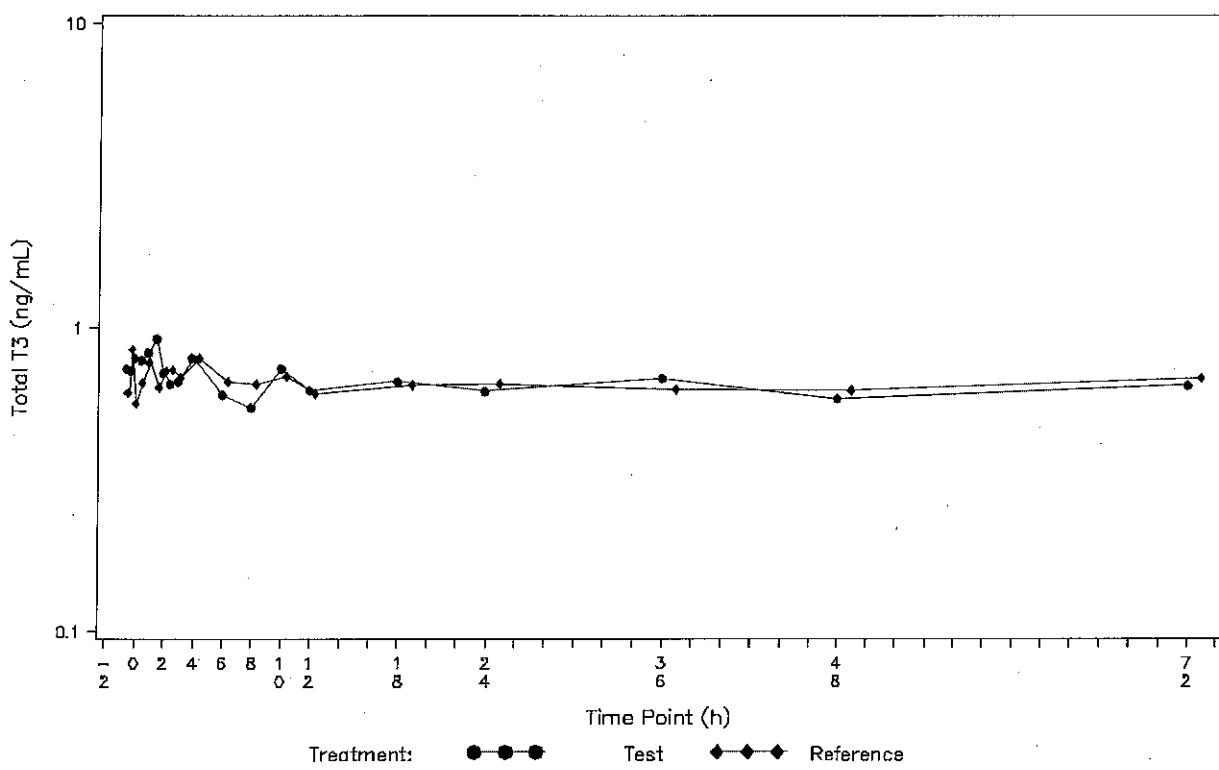
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1603 of 1628 alation vs. old formulation

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Confidential

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

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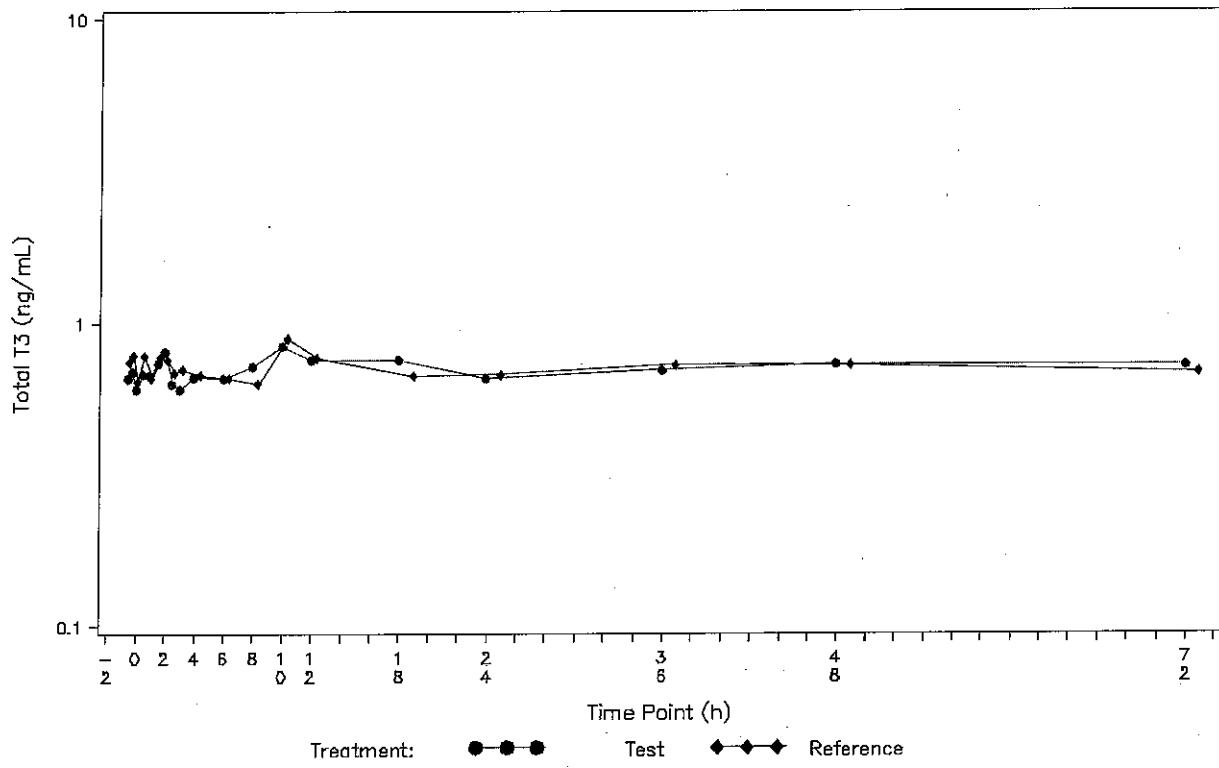
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1604 of 1628 alation vs. old formulation

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Confidential

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:



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

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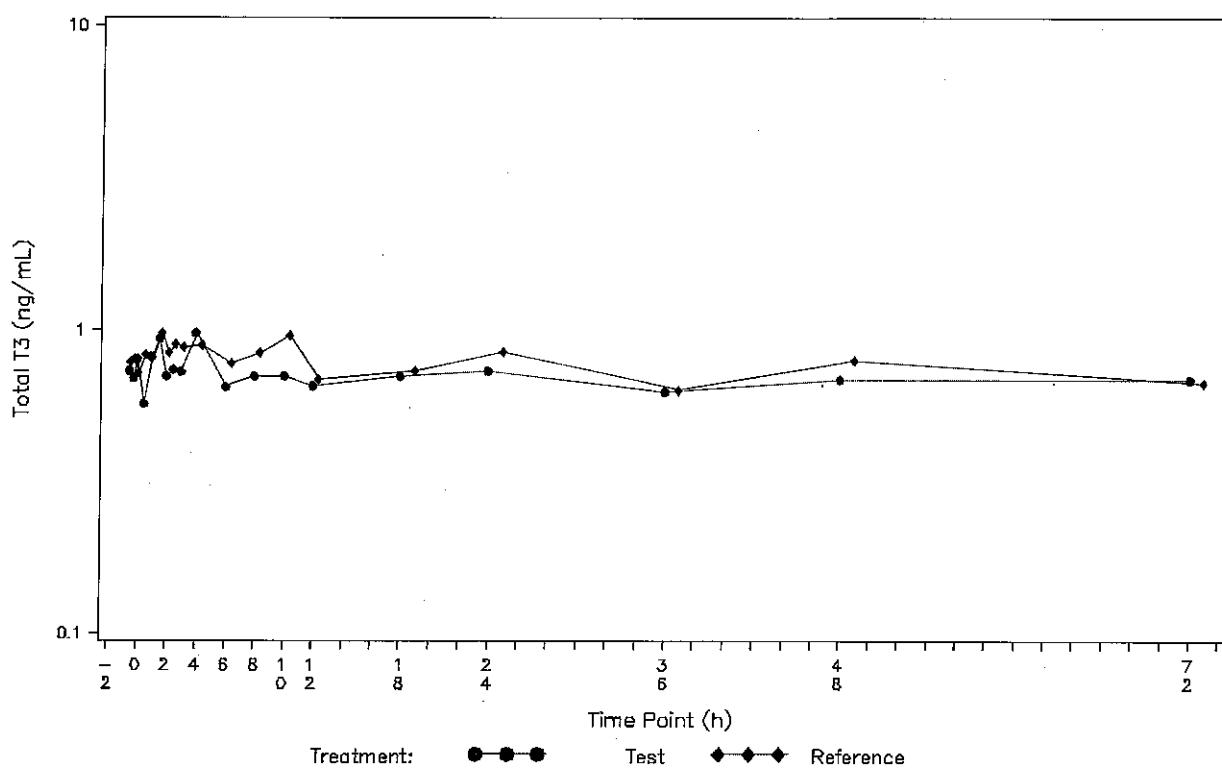
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1605 of 1628 alation vs. old formulation

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Confidential

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

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Levothyroxine
EMR 200125-001

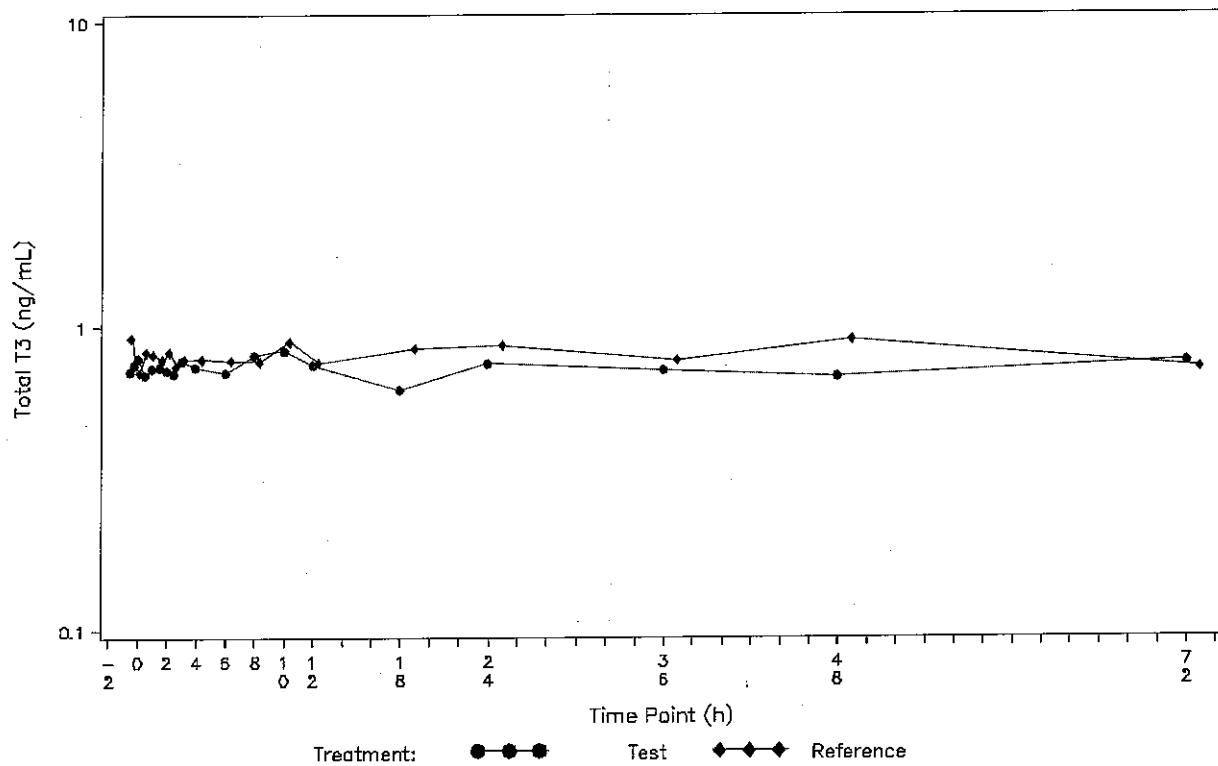
Bioequiv EMR200125-001 Page 1606 of 1628 nulation vs. old formulation

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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:



⑥: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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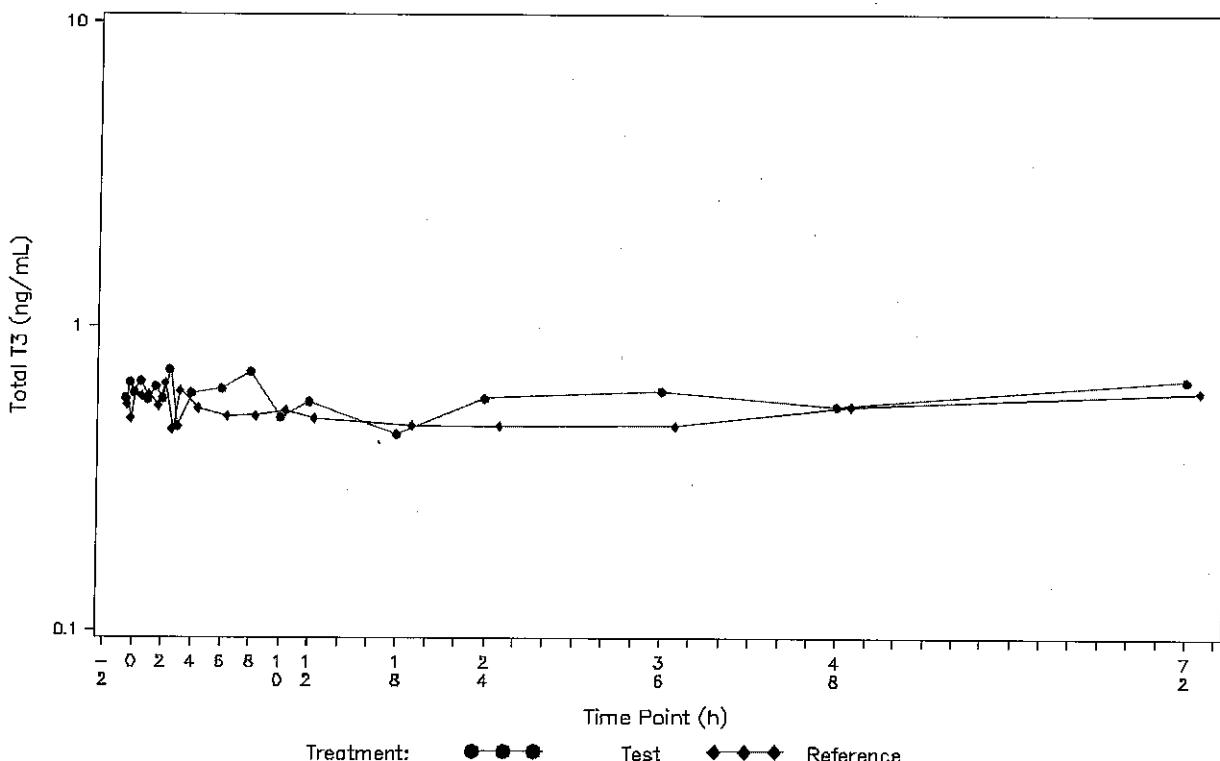
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1607 of 1628 alation vs. old formulation

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Confidential

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:



⑧Subjects excluded from PK Population;
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**

Bioequiv EMR200125-001 Page 1608 of 1628 ulation vs. old formulation

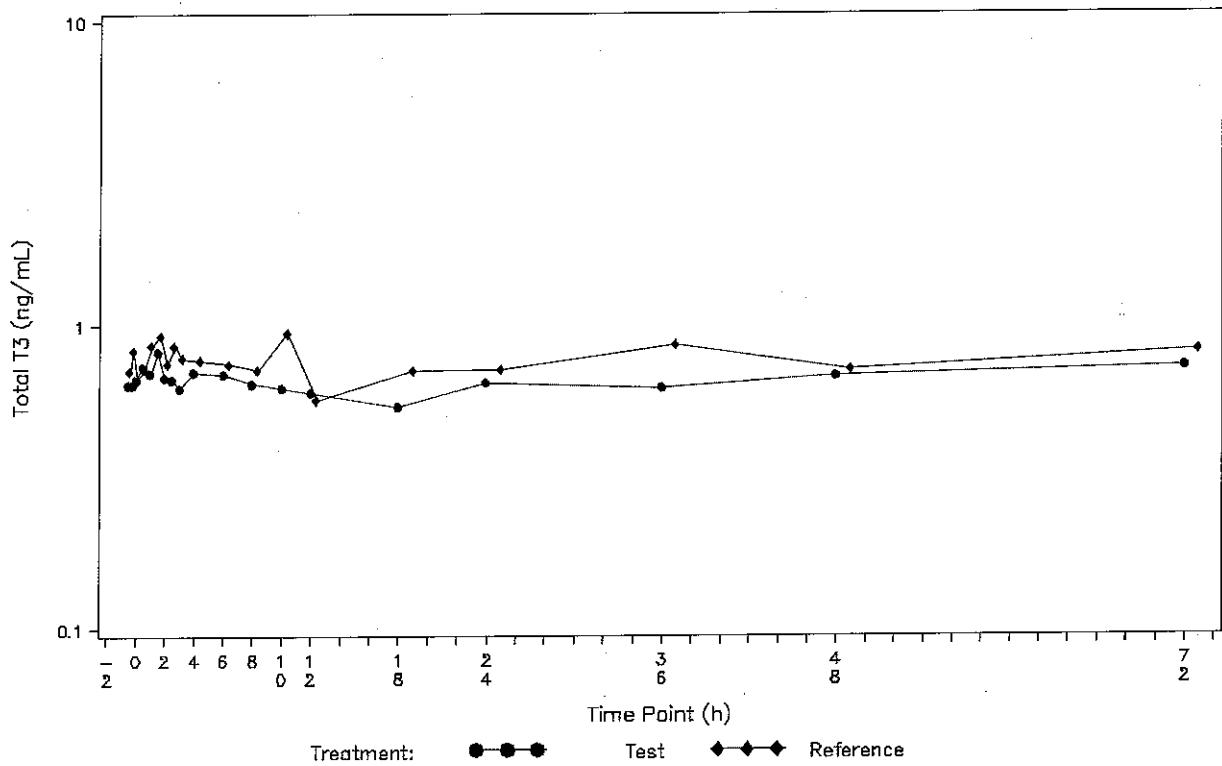
Merck Serono
EMR 200125-001

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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)

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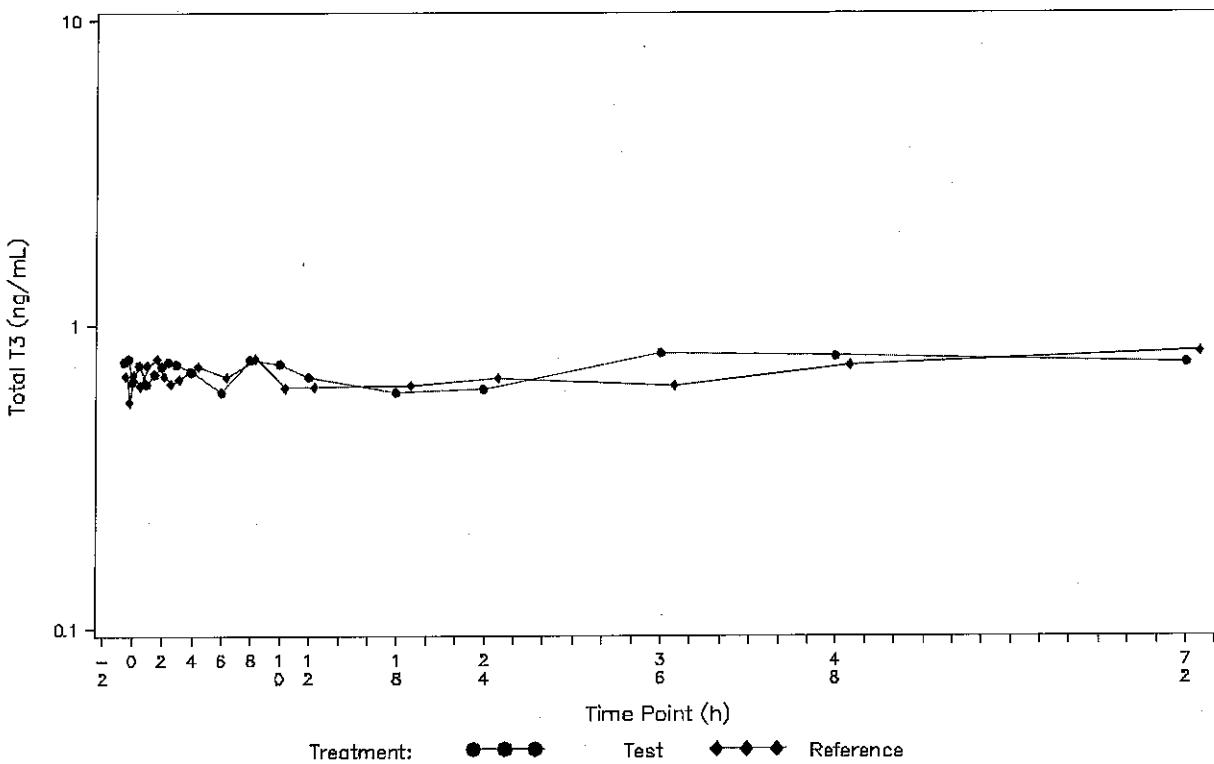
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EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

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.
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Levothyroxine
EMR 200125-001

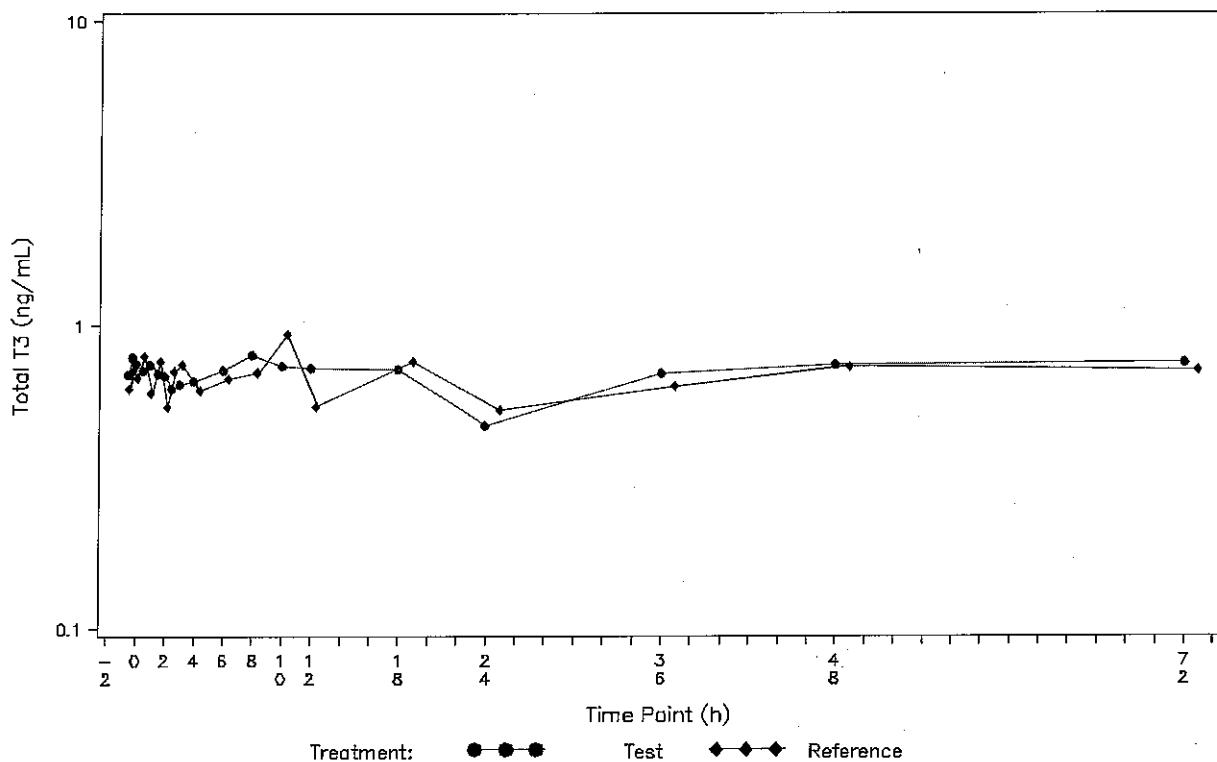
Bioequiv EMR200125-001 Page 1610 of 1628 nulation vs. old formulation

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

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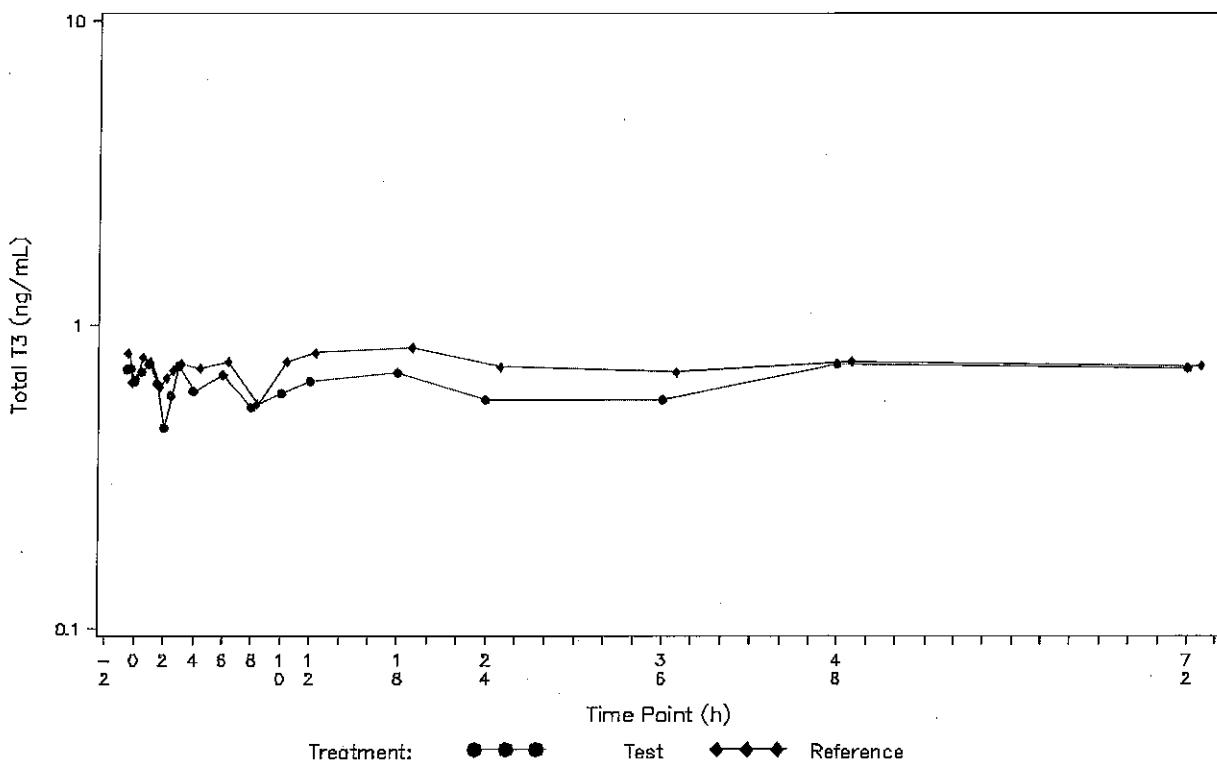
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EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T₃ values) (Safety Population)

Subject ID/Random Number:



⑥: 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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**Levothyroxine
EMR 200125-001**

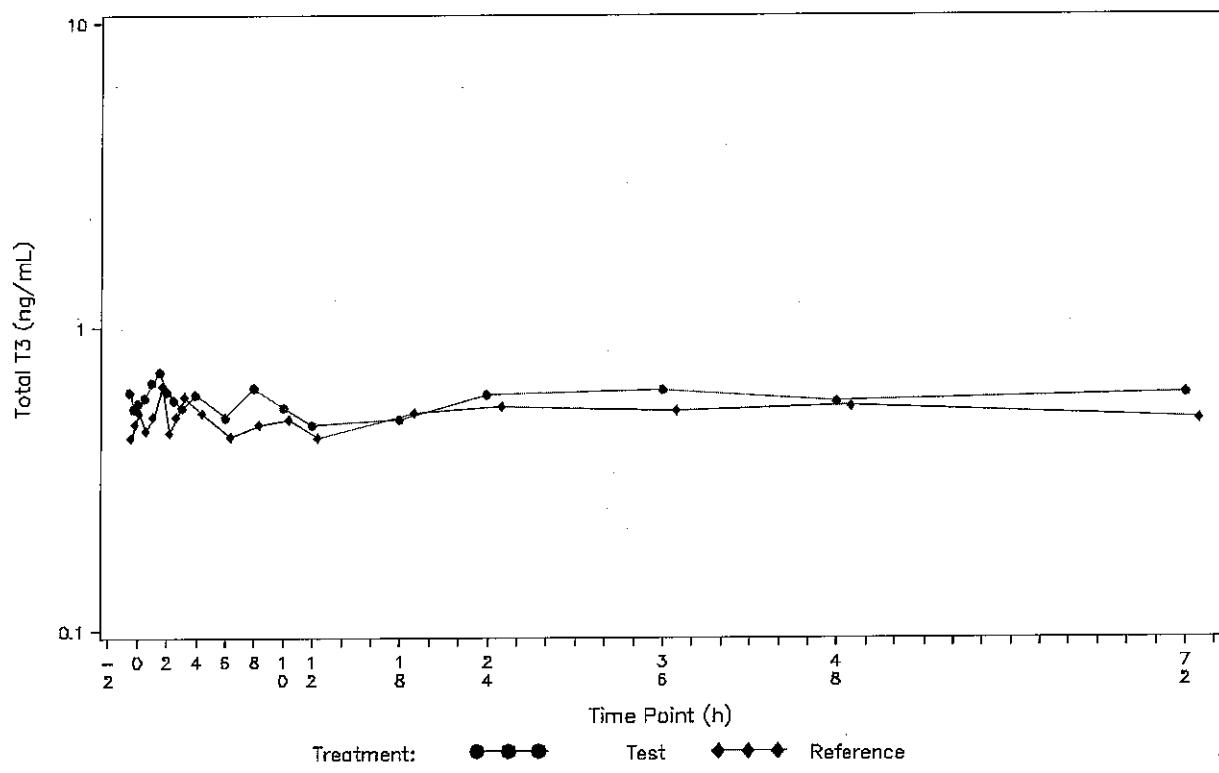
Bioequiv EMR200125-001 Page 1612 of 1628 nulation vs. old formulation

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:



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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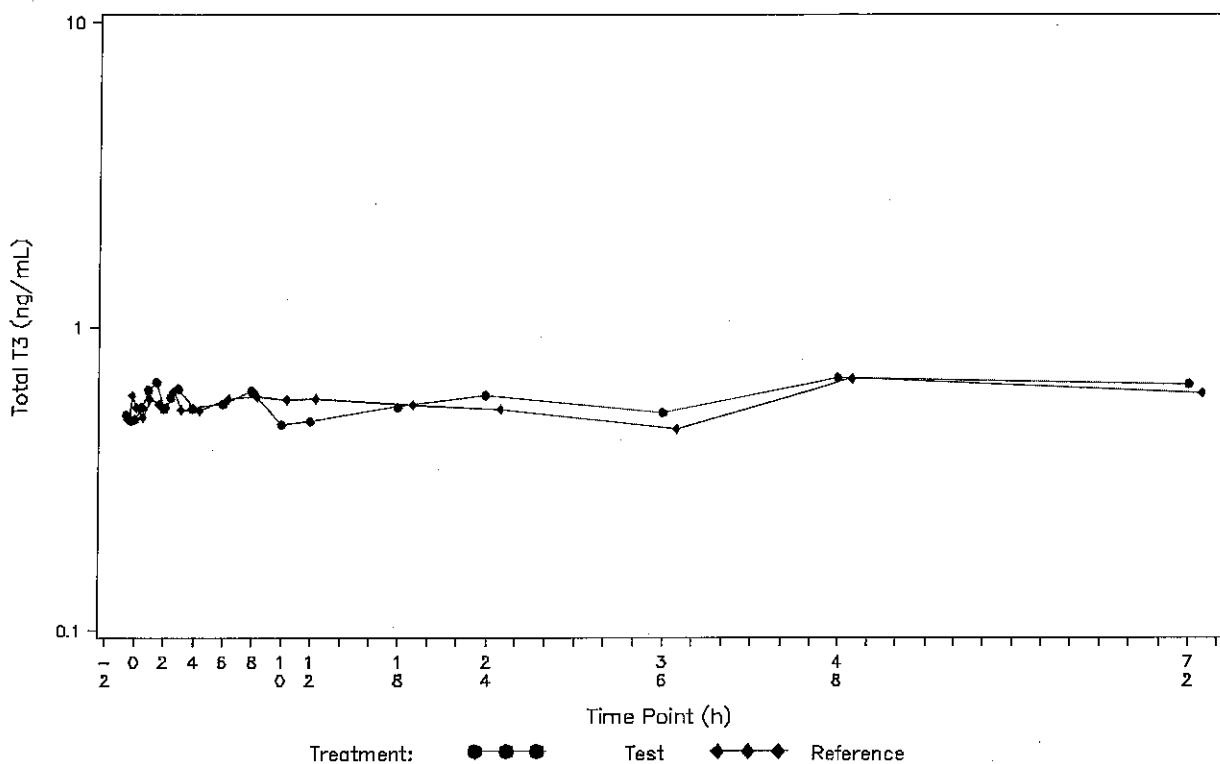
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1613 of 1628 nulation 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

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**Levothyroxine
EMR 200125-001**

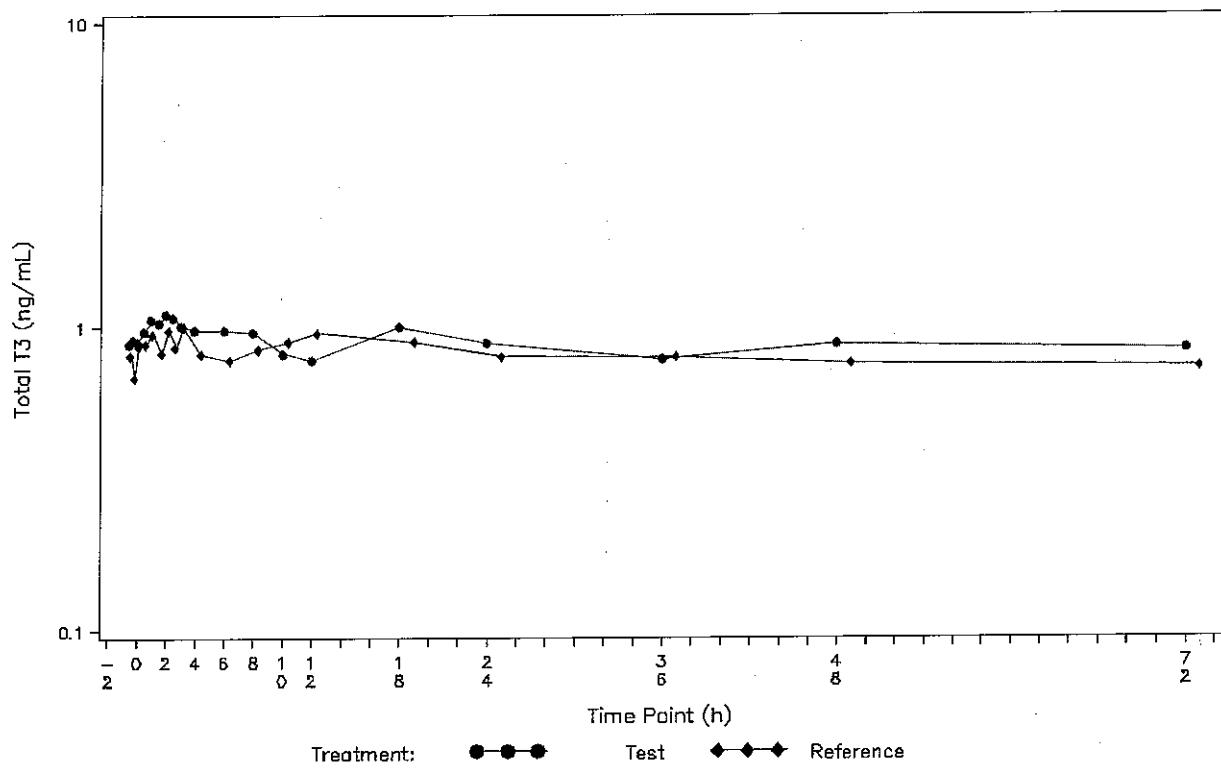
Bioequiv EMR200125-001 Page 1614 of 1628 ulation vs. old formulation

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: 1128



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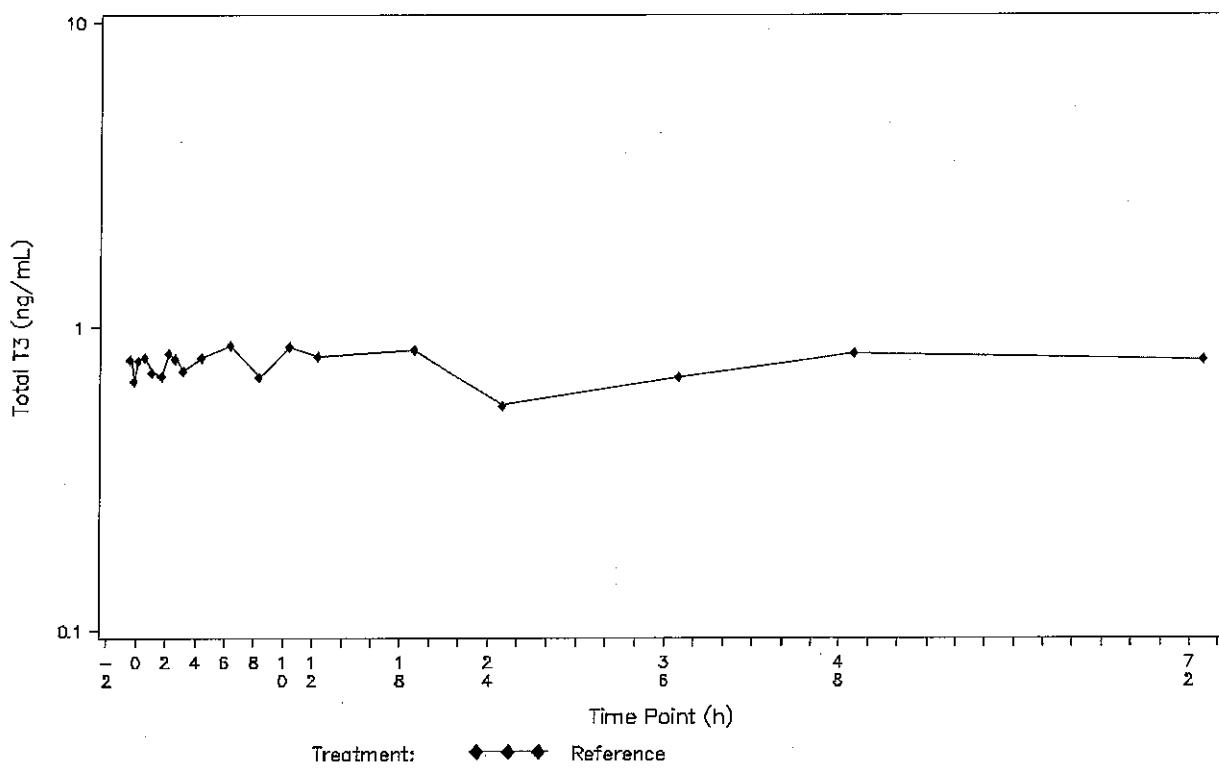
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Merck Serono
EMR 200125-001
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 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

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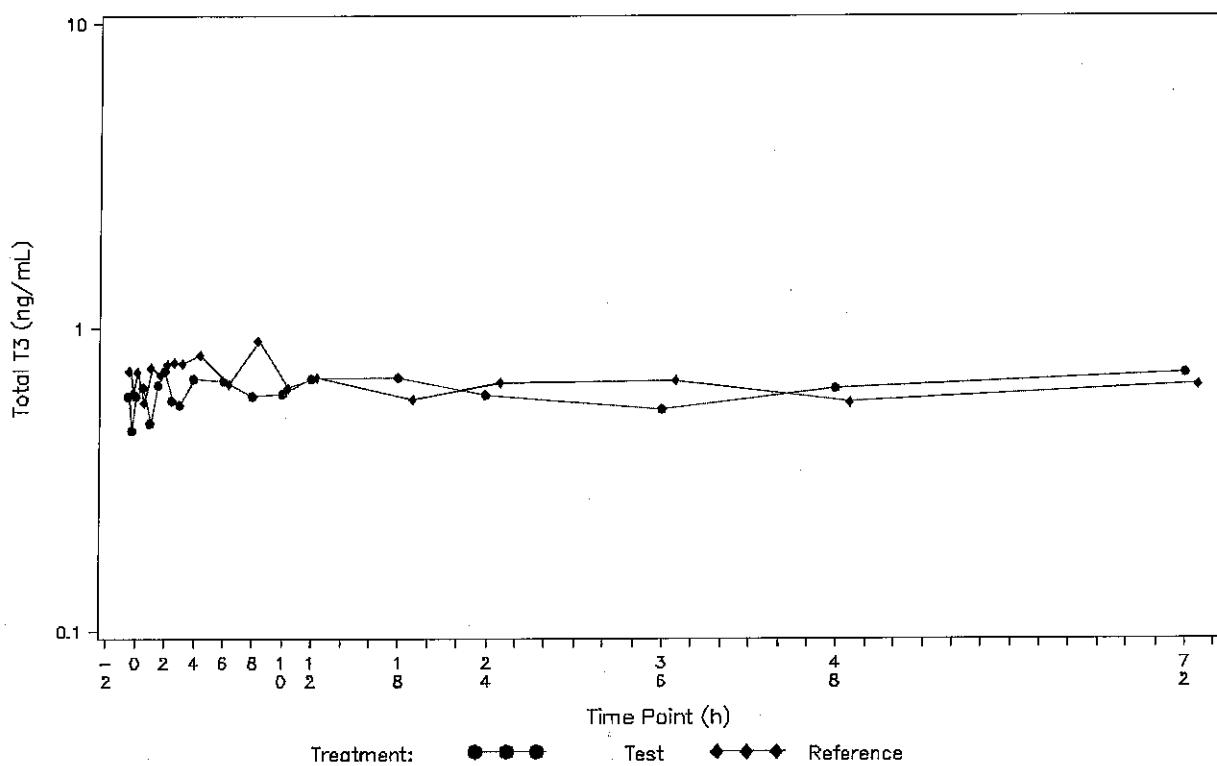
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1616 of 1628 nulation vs. old formulation

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)

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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.
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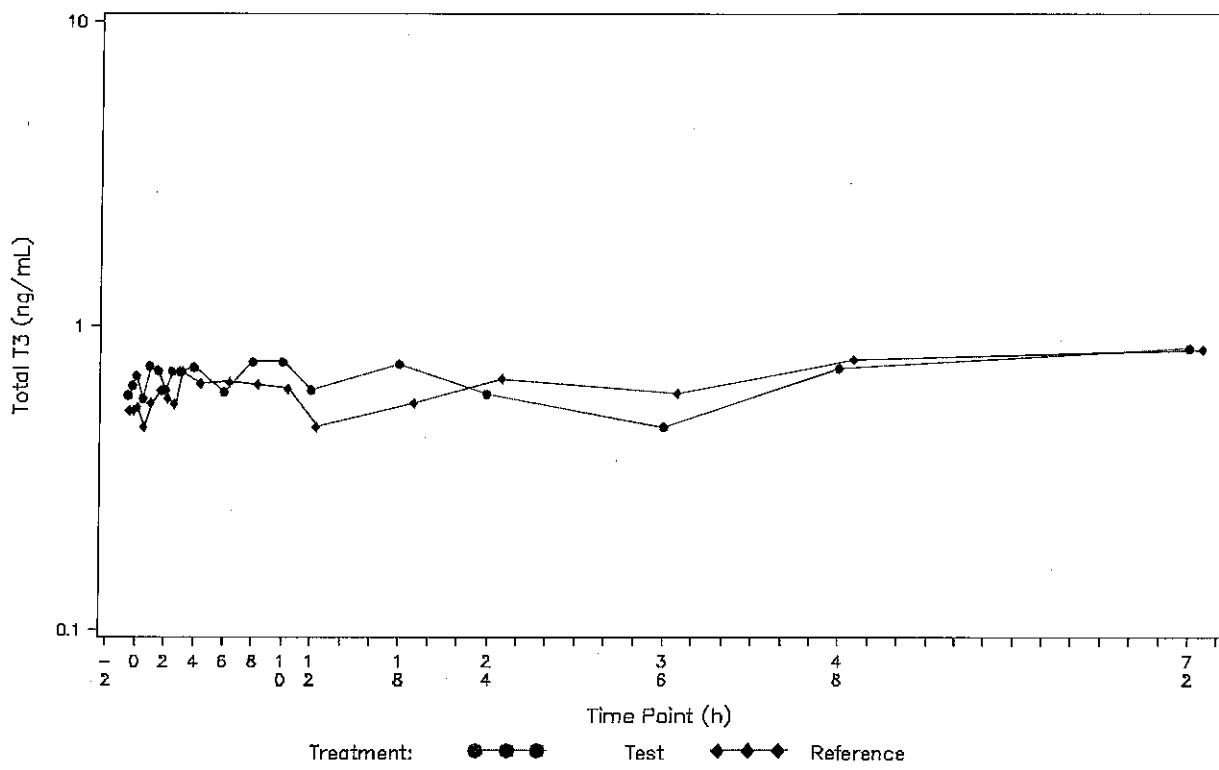
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 1617 of 1628 uation vs. old formulation

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Confidential

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:



④: 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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**Levothyroxine
EMR 200125-001**

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

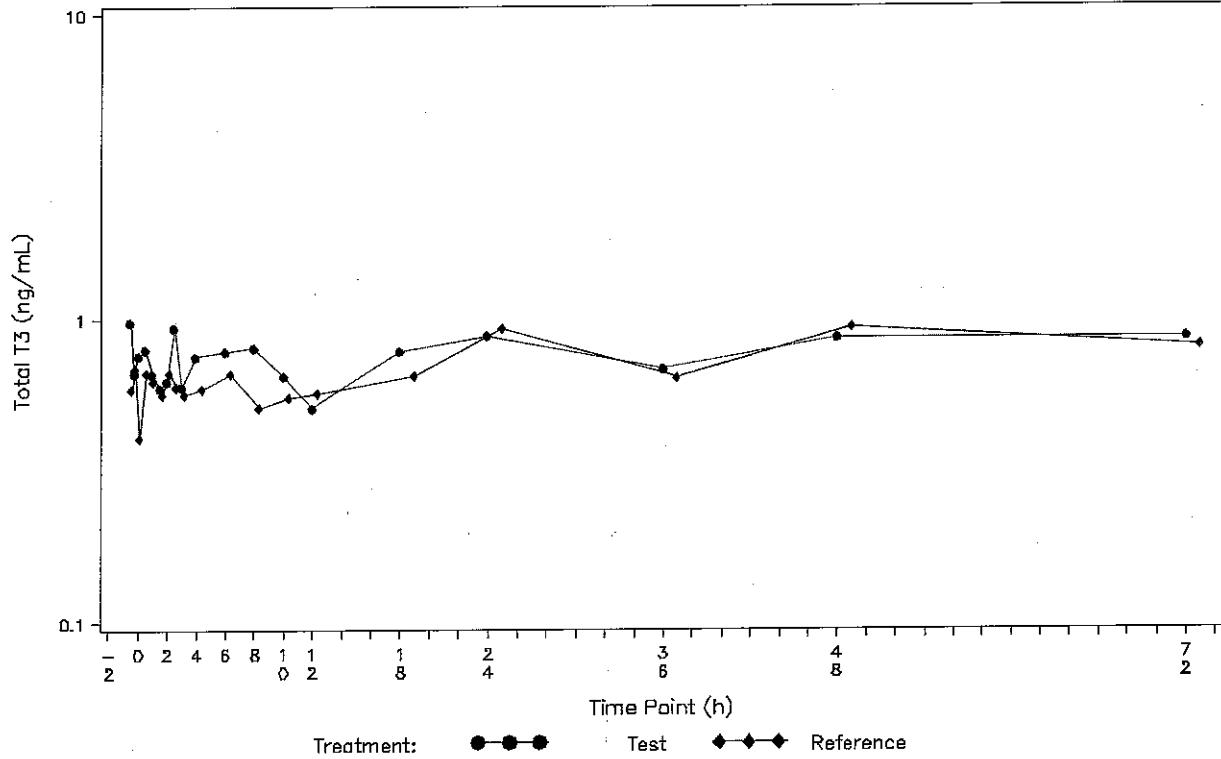
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

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 16-25-3

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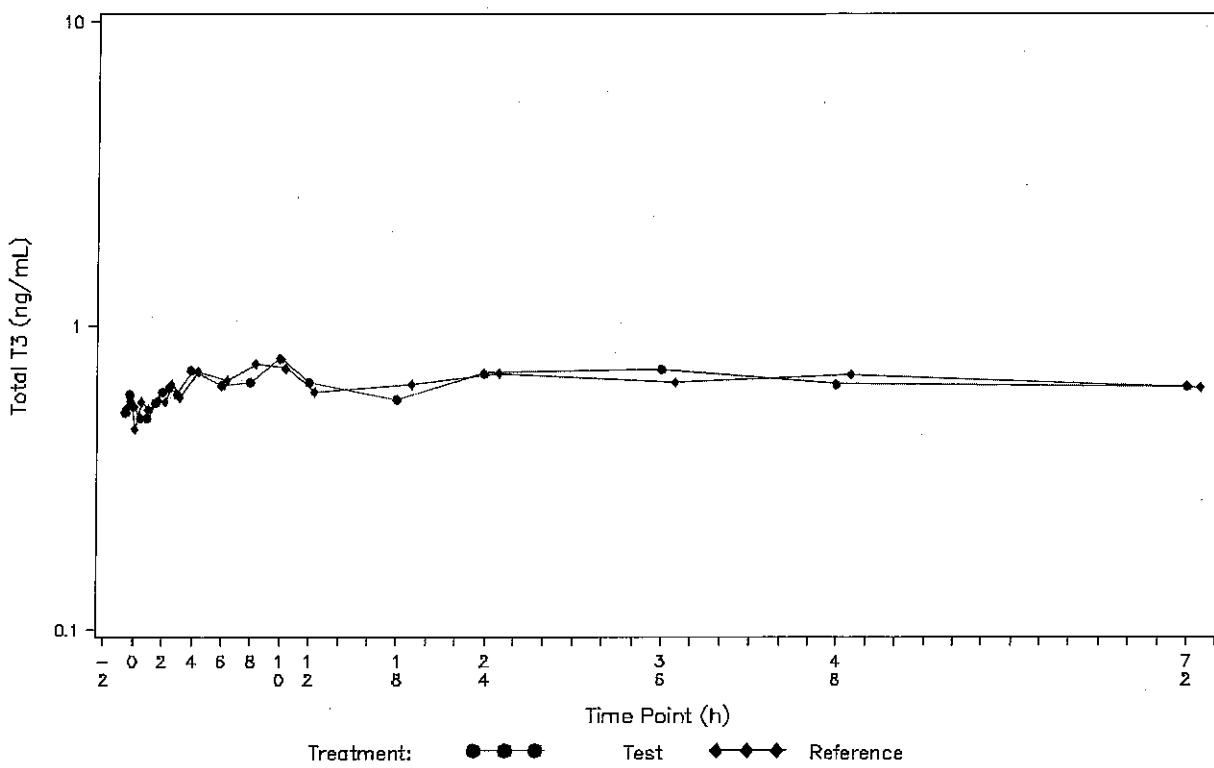
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1619 of 1628 alation 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

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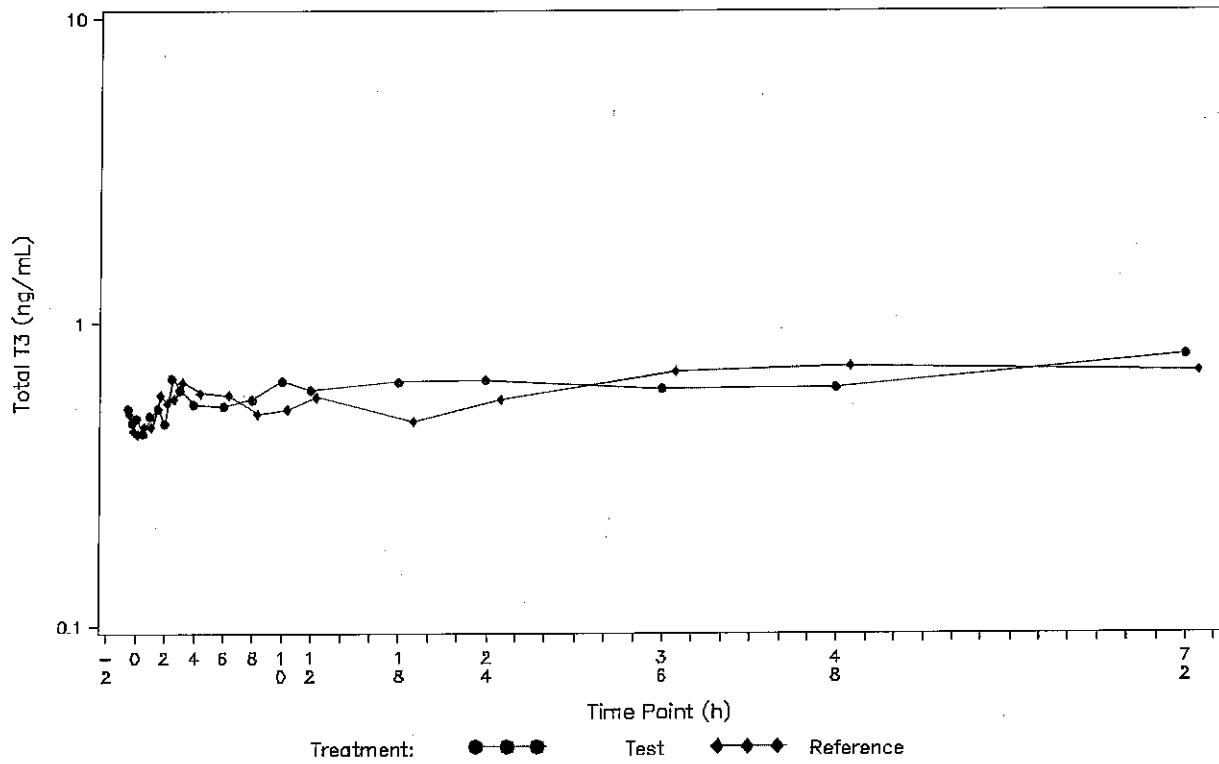
Bioequiv EMR200125-001 Page 1620 of 1628 alation vs. old formulation

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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 Number⁸



8: 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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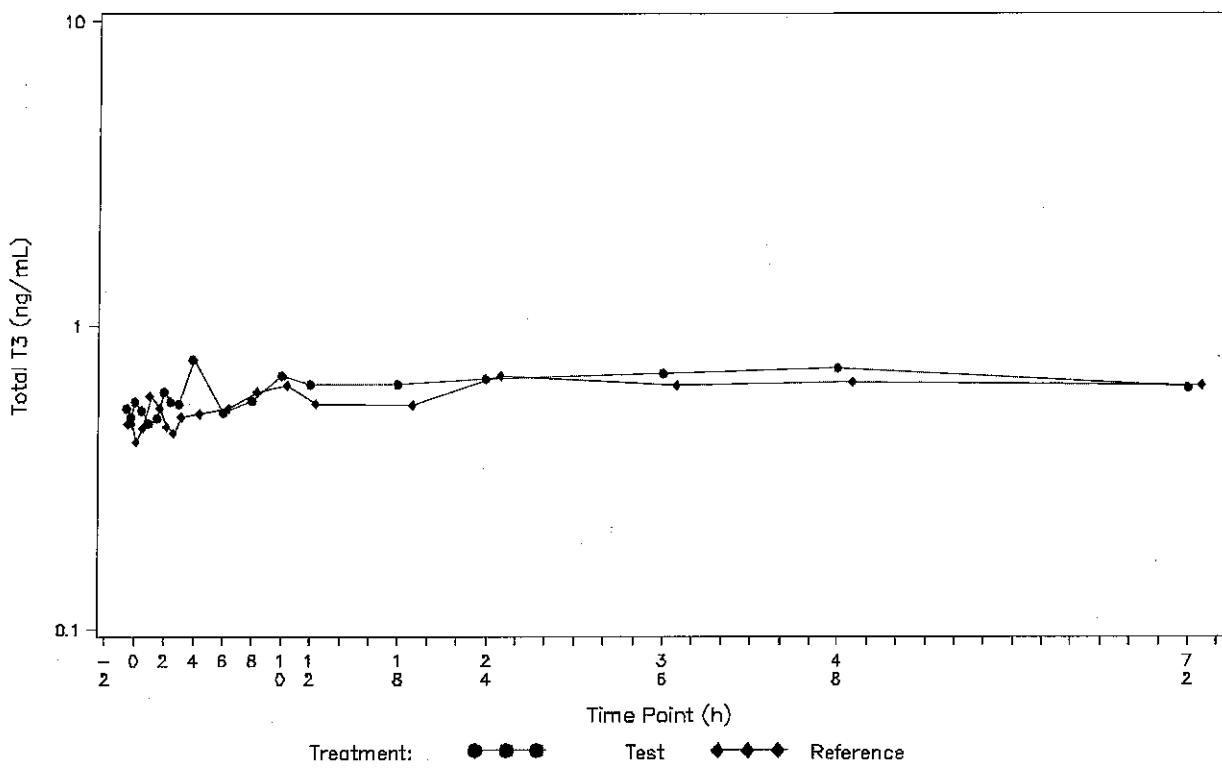
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T₃ values) (Safety Population)

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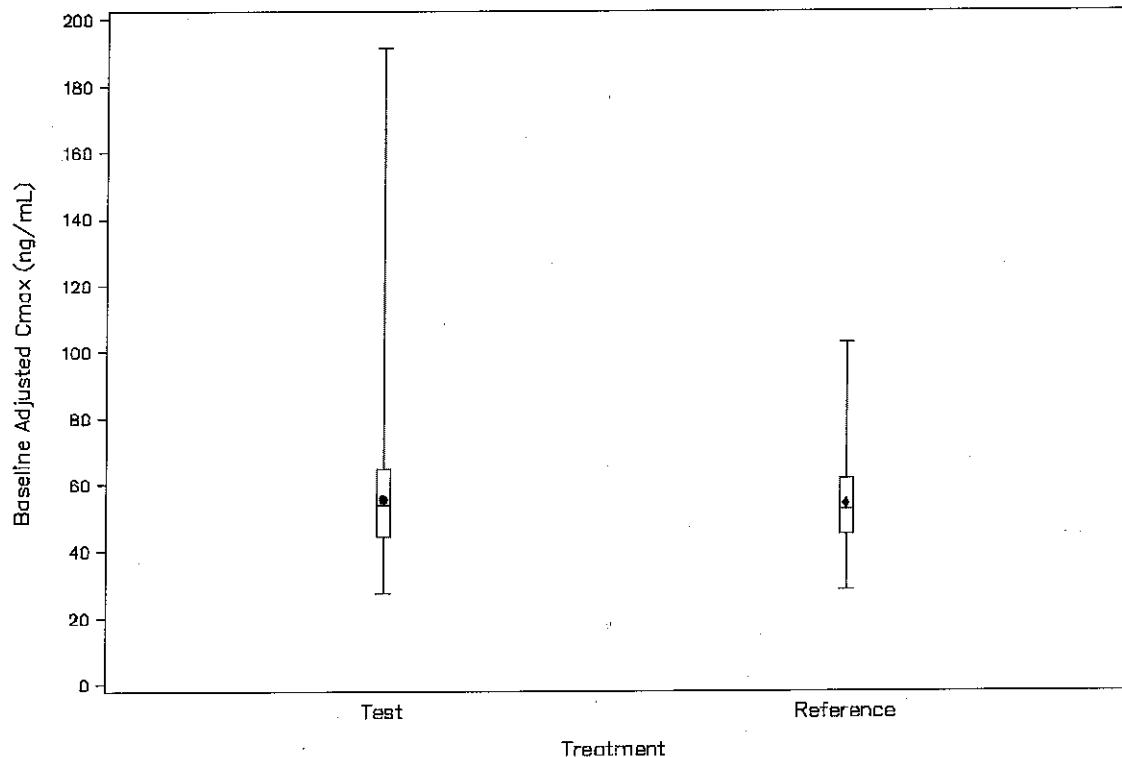
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Figure 15.4.3.1.1 Boxplot: Baseline Adjusted Cmax and Baseline Adjusted AUC0-72 for Total T4 (Pharmacokinetic Population)

Parameter: Baseline Adjusted Cmax (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.

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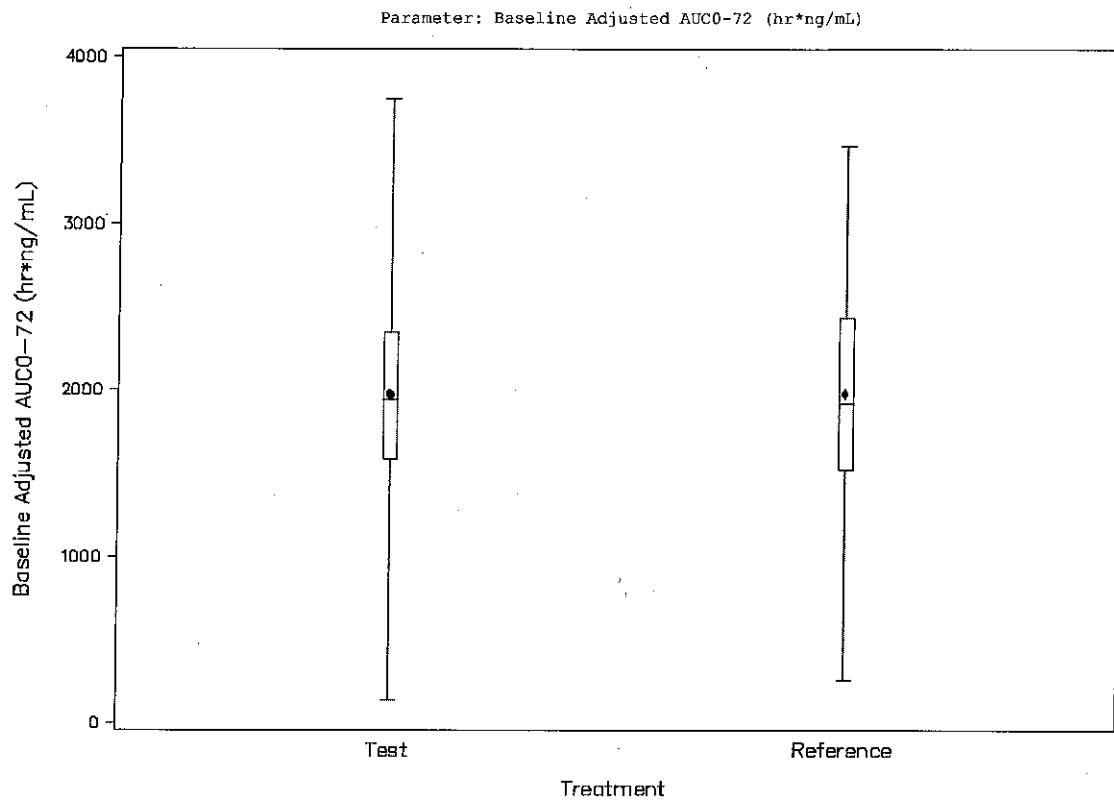
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Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1623 of 1628 nlation vs. old formulation

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EMR 200125-001
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.

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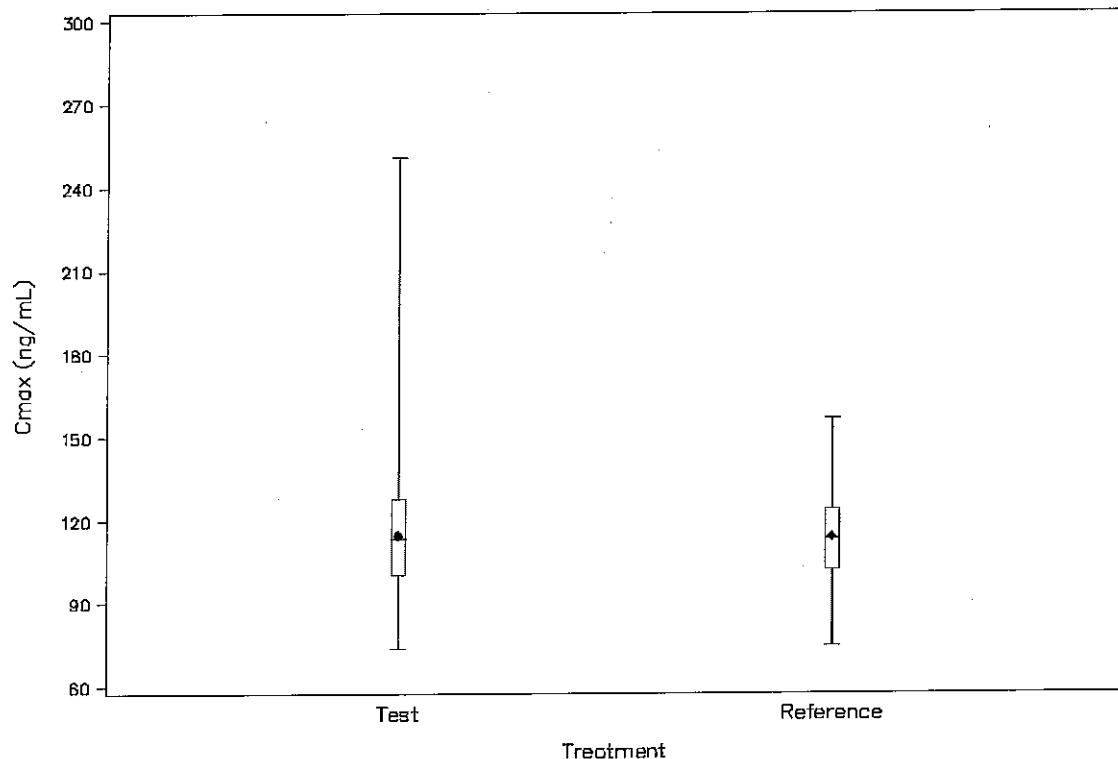
Bioequiv EMR200125-001 Page 1624 of 1628 uation vs. old formulation

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Merck Serono
EMR 200125-001

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

Parameter: Cmax (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.

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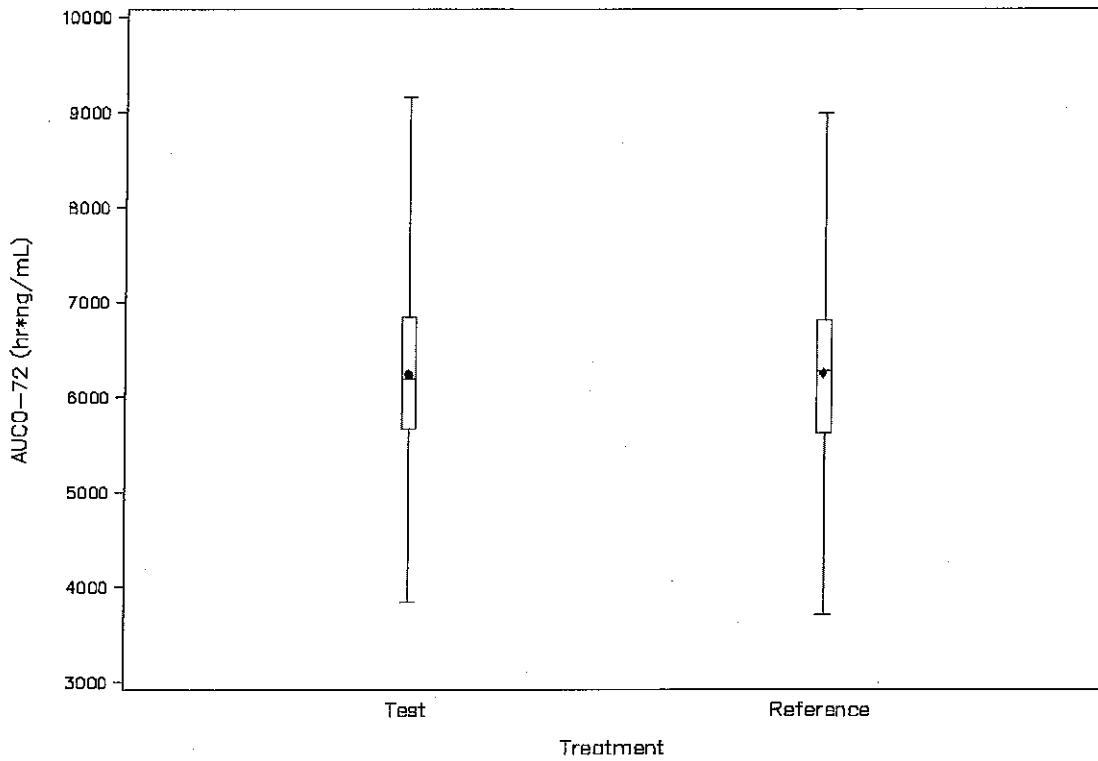
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1625 of 1628 nulation vs. old formulation

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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.

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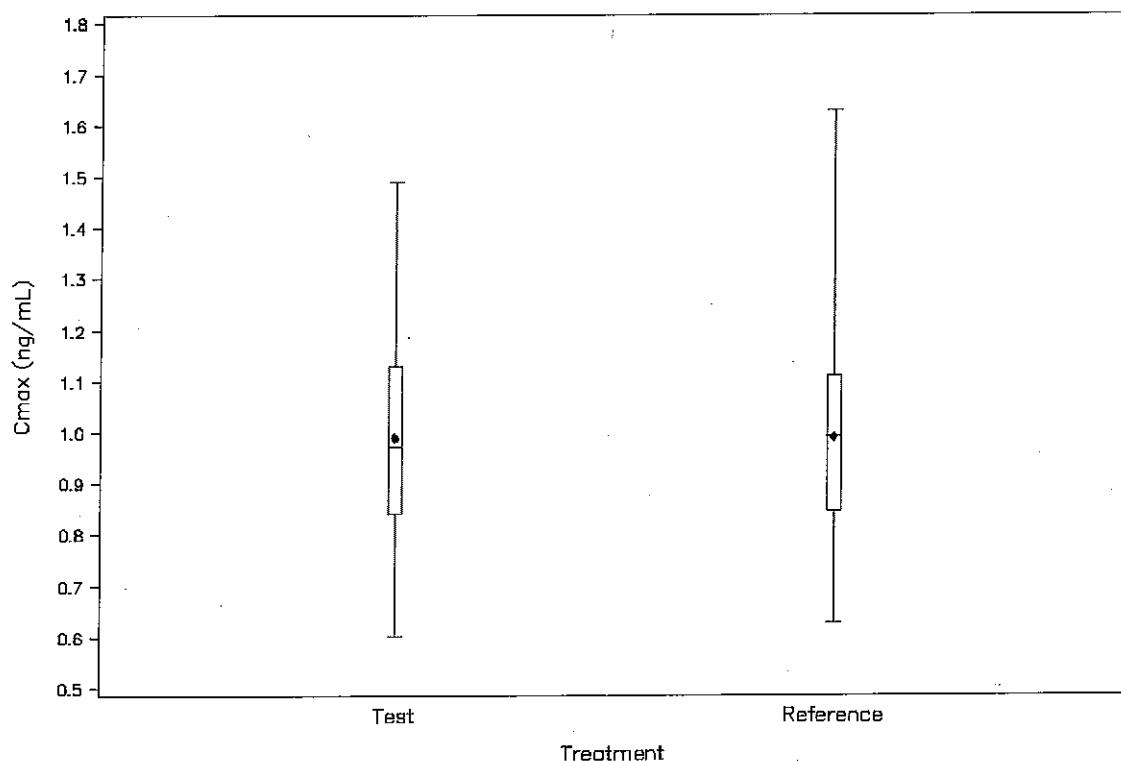
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1626 of 1628 nulation vs. old formulation

Merck Serono
EMR 200125-001
Figure 15.4.3.1.3 Boxplot: Cmax and AUC0-72 for Total T3 (Pharmacokinetic Population)

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Parameter: Cmax (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.

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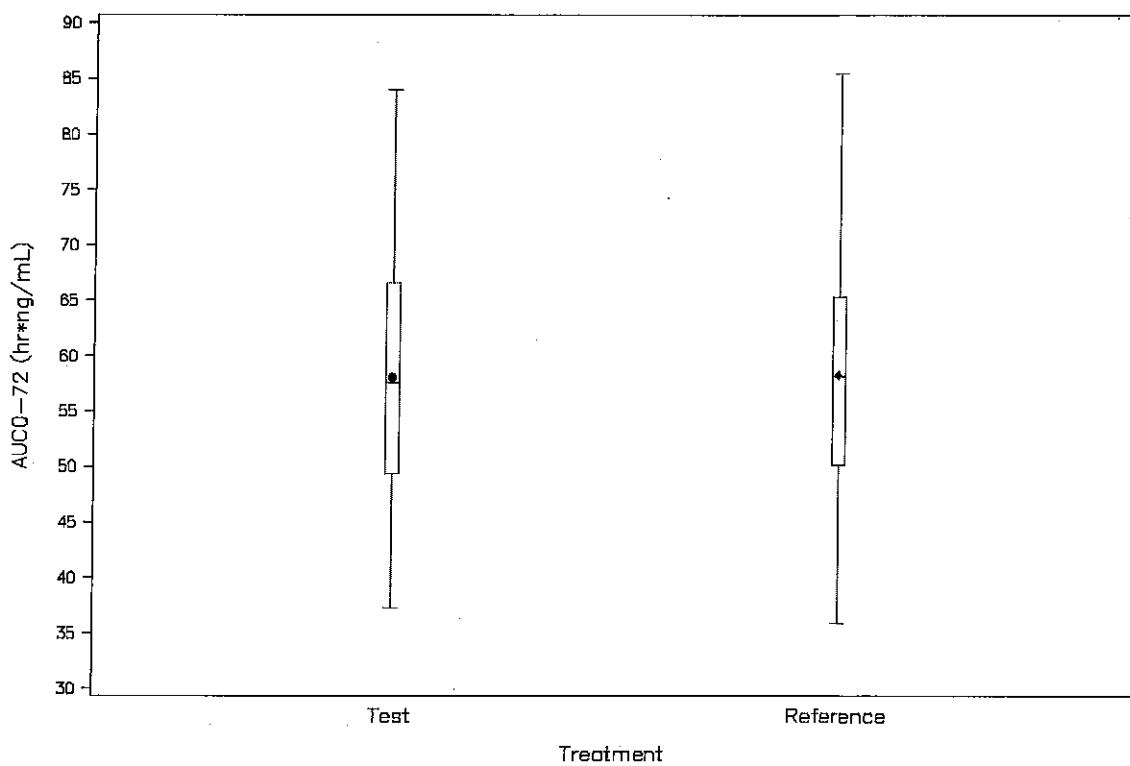
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Figure 15.4.3.1.3 Boxplot: Cmax and AUC0-72 for Total T3 (Pharmacokinetic Population)

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.

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Levothyroxine

Bioequivalence trial of new levothyroxine formulation versus old formulation

EMR 200125-001

15.5

Pharmacodynamic Data

There were no pharmacodynamic assessments performed during this trial.