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

Subject ID/Randon Number: [empty]

8: Subjects excluded from PK population;
Test: 600 mg (3 x 200 µg tablets) L-levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) L-levothyroxine old formulation.
Source: Table 15.4.1.5.1
Figure 15.4.2.11 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T3 Values) (Safety Population)

Subject ID/Random Number:

Treatment: - Test  - Reference

6: Subjects excluded from PK Population.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Table 16.1.5.3
LEVOthyroxine
EMR 200125-001

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

Subject ID/Random Number:

Time Point (h)

0 2 4 6 8 10 12 14 16 18

0.2 0.4 0.6 0.8 1.0 1.2 1.4 1.6 1.8

Total T3 (ng/mL)

Treatment: ● ● ● Test  ● ● ● Reference

3: 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 16.7.5.1

/project24/ep/blinmed/a210889_marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.11.sas

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

Subject ID/Random Number:

Treatment:  •••• Test  •••• Reference

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 16.4.5.1

/project24/sps/blinded/6210999_merc/stats/versioncontrol/primary/cripts/program/main/TFL/programs/Figures/Figure
15.4.2.11.png
Levothyroxine Bioequiv EMR200125-901 Page 1406 of 1628

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 mcg (3×200 mcg tablets) levothyroxine new formulation.
  - Reference: 600 mcg (3×200 mcg tablets) levothyroxine old formulation.
  - Source: Table 16.1.5.3

/project24/ep/biowad/a210899.marc/stats/versioncontrol/primary/scripts/program/main/TEP programs/Figures/Figure 15.4.2.12.mxe

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

(For Total 73 values) (Safety Population)

Subject ID/Randnum Number

Treatment: ●●● Test  ❅❅❅ Reference

0: Subjects excluded from PK populations.
Test: 600 µg (2 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3
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: 500 µg (2×200 µg tablets) levothyroxine old formulation.
  - Source: Table 16.2.5.3

/project24/qp/blinded/6216399_mero/stats/versioncontrol/primary/scripts/program/main/IEL_programs/figures/Figure 15.4.2.12.sas

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1408/1628
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 (3x200 µg tablets) levothyroxine new formulation,
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation,
Source: Table 16.2.5.1.
Levothyroxine Bioequiv EMR200125-901 Page 1410 of 1628ination vs. old formulation
EMR 200125-901
Merck Serono
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:

![Graph showing concentration-time profiles](image)

- 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 14.2.5.1

/project24/ep/blinded/w210999_merc/stats/versiconcontrol/primary/scripts/program/main/T3 programs/Figures/Figure 15.4.2.12.snh
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Healthy Population)

Subject ID/Random Number:

Treatment:
- - - - - Test
- - - - - Reference

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 16.7.3.3.
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:

![Graph showing concentration-time profiles for individual subjects.](image-url)

- Subjects excluded from PK Population:
- Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
- Source: Table 15.2.5.3

/project24/wp/blinded/e210099_macro/stats/versioncontrol/primary/scripts/progrom/main/TFL_programs/Figures/Figure 15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (for Total T3 values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population:
Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Table 16.2.5.)
Levothyroxine

EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/Random Number:

Treatment: ●●●● Test ●●●● Reference

Subjects excluded from PK Population:
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Table 15.4.2.4.3

/project24/ep/blinded/e210999_marx/stats/versioncontrol/primary/scripts/program/main/FPL programs/Figures/Figure
15.4.2.12.enm
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:

Treatment:

Test
Reference

0: Subjects excluded from PK Population.
Test: 500 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 500 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.5.5.3

/project24/ep/blinded/6210893_netc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.12.ass
Levothyroxine

EMR 200125-001

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:

![Graph showing concentration-time profiles](image)

- Treatment: ●●● Reference

0: Subjects excluded from PK Population:
Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation,
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Table 16.2.3.5.3

/project/24/dp/blinded/e210999_marco/stats/version/control/primary/scripts/program/azm/YL program/Figures/Figure
15.4.2.12.sas

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population;
Test: 400 µg (3×200 µg tablets) levothyroxine new formulation;
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.6.3.

/project24/op/blindwd/a213899/marc/stats/versioncontrol/primary/scripts/program/main/TEL programs/Figures/Figure
15.4.2.12.jpg
Levothyroxine
Bioequiv EMR200125-001 Page 1418 of 1628

Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 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

/project24/cp/blinded/c210899_merz/state/versioncontrol/primary/scripts/program/main/7FL programs/figures/Figure
15.4.2.12.png
Figure 25.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 Values) (Safety Population)

Subject ID/Random Number:

Treatment:
- --- --- Reference

8: Subjects excluded from PK Population:
Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Table 16.2.3.5

/project24/ep/blinded/e210899_mepo/stats/versioncontrol/primary/scripts/program/main/FL_programs/Figures/Figure
15.4.2.12.sas
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1420 of 1628

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/Rando Number:

![Graph showing concentration-time profiles for levothyroxine]

- Treatment: Test
- Reference

Subjects excluded from PK Population:
Test: 600 mcg (3x200 mcg tablets) levothyroxine new formulation.
Reference: 600 mcg (3x200 mcg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/sp/himned/is100599_emrc/stats/versioncontrol/primary/scripts/program/main/TFL_progress/Figures/Figure 15.4.2.12.png

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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:

Treatment: ●●●● Test  ●●●● Reference

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 16.6.5.5
Levothyroxine
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: 650 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 15.2.5.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TPL program/figures/Figure
15.4.2.12.png
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:

8: Subjects excluded from PK Population;
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.1.1
Levothyroxine

EMR 200125-001

Bicarbo EMR200125-001 Page 1424 of 1628 sation 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:

![Graph showing concentration vs. time for different treatments]

8: Subjects excluded from PK Population:

Test: 600 µg (2 x 300 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210599_mero/stats/versioncontrol/primary/scripts/program/main/FPL programs/Figures/figure
15.4.2.12.png

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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:

![Graph](image-url)

- 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 15.4.2.12.3
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: ...

- Treatment:  ••••• Test:  ••••• Reference

Subjects excluded from NW Population:
Test: 600 μg (3*200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Table 15.2.4.3

/project24/ep/blinded/e2.10899_marcc/stats/versioncontrol/primary/scripts/program/main/TEL program/Figures/Figure 15.4.2.12.png

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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: 

Treatment: ●●●● Test ●●●●● Reference

1. Subjeets excluded from PK Population:
Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Table 16.1.5.3

/project26/ep/blinded/e310099_merc/stats/versioncontrol/primary/scripts/program/main/TPL programs/Figures/Figure 15.4.2.12.png
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:

![Graph showing concentration-time profiles for different treatments.]

Legend:
- Treatment
- Test
- Reference

Notes:
- Subjects excluded from PK Population:
- Test: 600 μg [1*200 μg tablets] levothyroxine new formulation.
- Source: Table 16.2.5.3

Source file:
/project24/op/blinded/e210999_merc/state/versioncontrol/primary/scripts/program/main/YFL_programs/Figures/Figure
15.4.2.12.png
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:

Treatment: ●●●● Test: ●●●● Reference

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 14.2.5.2
Levothyroxine Bioequiv EMR200125-001 Page 1430 of 1628 amination vs. old formulation
EMR 200125-001

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 12/Rand Number:

![Concentration-Time Profiles Graph](image_url)

- Subjects excluded from FK 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/cp/blinded/c210999.marc/data/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.12.sas

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1430/1522
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/Rando Number:

Treatment: ● ● ● ● Test ● ● ● Reference

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 16.1.3.3.1

/project24/myp/blinded/2108999_mero/stats/versioncontrol/primary/scripts/program/main/% programs/Figures/Figure15.4.2.12.00a

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1431/1628
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/Random Number:

#Subjects excluded from PK population:
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 15.2.1.5.3
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:

Treatment: Test ---- Reference

8: Subjects excluded from PK Population:
Test: 600 μg (2 x 200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Table 16.2.3.3
Levithroxyine

EMR 200125-001

Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/Random Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Total T3 (mg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>2</td>
<td>0.1</td>
</tr>
<tr>
<td>4</td>
<td>0.1</td>
</tr>
<tr>
<td>6</td>
<td>0.1</td>
</tr>
<tr>
<td>8</td>
<td>0.1</td>
</tr>
<tr>
<td>10</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Treatment:

- : Subjects excluded from PK Population.
- : Test: 600 μg (3×200 μg tablets) levithroxyine new formulation.
- : Reference: 600 μg (3×200 μg tablets) levithroxyine old formulation.

Source: Table 16.2.5.1
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:

Treatment:  ● ● ● Test  ▲▲▲ Reference

- Subjects excluded from PK Population:
  - Test: 850 μg (3 x 280 μg tablets) levothyroxine new formulation.
  - Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.

Source: Table 15.4.2.2

/project/240/200899 merc/stats/versionscontrol/primary/scripts/program/main/TFL program/Figures/Figure 15.4.2.12.mso
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:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Treatment:</th>
<th>Test</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>●●●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>●●●</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>●●●</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>●●●</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
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</tr>
<tr>
<td>16</td>
<td></td>
<td>●●●</td>
<td></td>
</tr>
</tbody>
</table>

0: Subjects excluded from SM Population;
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 14.2.5.3

/project24/eg/blinded/e210899_marco/stats/versioncontrol/primary/scripts/program/main/TEL programs/Figures/figure_15.4.2.12.png

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1436/1622
Levothyroxine

Figure 15.6.2.12 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 34.2.5.1

/project24/m/p/blinded/e2/08399_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.6.2.12.png
Levothyroxine

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:

![Graph showing concentration-time profiles for Levothyroxine, comparing test and reference formulations.]

- Test: 600 μg (3 x 200 μg tablets) Levothyroxine new formulation.
- Reference: 600 μg (3 x 200 μg tablets) Levothyroxine old formulation.

0: Subjects excluded from PK population:

Source: Table 16.7.5.3

/project2463/encore/mero/stats/versioncontrol/primary/scripts/program/main/LEF program/figures/figure 15.4.2.12.sas
Levothyroxine
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:

Treatment: 
- Test
- Reference

0: Subjects excluded from OK Population;
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.1.1

/project24/ep/blinded/e210899_narc/stats/versioncontrol/primary/scripts/program/main/TFL_programs/figures/figure
15.4.2.12.msp
Levothyroxine

Bioequiv EMR200125-001 Page 1440 of 1628

Figure 25.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (for Total T3 values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration-time profiles for T3 with different formulations.](image)

- Subjects excluded from PK Population:
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
- Source: Table 18.2.5.3

/project24/gp/b1inded/e010999_nerc/stats/versioncontrol/primary/scripts/program/min/TIL program/Figures/Figure 15.4.2.12.xls

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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 15.2.5.3

/project/ep/blinded/s210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Randorn Number:

Total T3 (ng/mL)

- 0 1 2 3 4 5 6 7
- 0.1 1 10

Time Point (h)

Treatment: ●●●● Test  ▼▼▼▼ Reference

Subjects excluded from PK Populations:
Test: 600 μg (3*200 μg tablets) Levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) Levothyroxine old formulation.
Source: Table 16.2.1.1

/project24/gp/blinded/e210899_marx/stats/versioncontrol/primary/scripts/program/main/YFL programs/figures/Figure 15.4.2.12.msn
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:

Treatment: •••• Test •••••• Reference

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.

/project24/ep/blinded/e210899_merck/stats/versioncontrol/primary/scripts/program/main/TFL/program/figures/Figure15.4.2.12.png
Levothyroxine
EMR 200125-001

Biergaj EMR200125-001 Page 1445 of 1628 Station vs. old formulation

March Barcoo
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population) Subject ID/Random Number:

\[\text{Total T3 (ng/mL)}\]

\[\begin{array}{c}
0.1 \\
1 \\
10 \\
\end{array}\]

\[\begin{array}{c}
2 \\
4 \\
6 \\
8 \\
10 \\
\end{array}\]

\[\begin{array}{c}
0 \\
1 \\
2 \\
3 \\
4 \\
5 \\
6 \\
7 \\
\end{array}\]

Treatment: ♦♦♦♦ Test ♦♦♦♦ Reference

8 Subjects excluded from PK Population;
Test: 600 ug (3*200 ug tablets) levothyroxine new formulation.
Reference: 600 ug (3*200 ug tablets) levothyroxine old formulation.
Source: Table 15.4.2.12.1

/project24/ap/blinded/a219899_nero/stats/versioncontrol/primary/scripta/program/main/TFL programs/Figures/Figure
15.4.2.12.ssg

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CONFIDENTIAL INFORMATION

Page 10 of 215
Confidential
Levothyroxine

Bioequiv EMR200125-001 Page 1446 of 1628lation vs. old formulation

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) levthyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levthyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
13.4.2.12.png

CONFIDENTIAL
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual time in Semi-Logarithmic Scale
(For total 73 values) (Safety Population)

Subject ID/Random Number:

Treatment: Test
Reference

Subjects excluded from PK Population:
Test: 600 μg (3*200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (2*300 μg tablets) levothyroxine old formulation.

Source: Table 14.2.1.1

/project24/sp/blinded/6310899_marx/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.4.2.12.png
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Random Number:

- Treatment: ●●●● Test ●●●● Reference

Subjects excluded from PK Population:
- Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (2×300 µg tablets) levothyroxine old formulation.

Source: Table 16.2.3.3

/project24/sp/leed/sp10/bio/095/pharm/primary/scripts/program/main/T4 programs/forinks/Figure 15.4.2.12.png
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

(For Total T3 values) (Total Population)

Subject ID/Random Number:

- Treatment: •••• Test
- Reference: ••••

Subjects excluded from PK Population:
Test: 600 µg (2×200 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_necz/states/versioncontrol/primary/scripts/program/main/TFB programs/Figures/FIGURE 15.4.2.12.mso
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 13 values) (Safety Population)

Subject ID/Random Number: .

Subjects excluded from PK Population:
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 400 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.1.3.

/project24/ep/blinded/o210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure 15.4.2.12.xlsx
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:

![Graph showing concentration-time profiles.](image)

2: Subjects excluded from PK Population:
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.1.1
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: ........

Total T3 (ng/mL)

Time Point (h)

Treatment: ●●●● Test ●●●● Reference

6: Subjects excluded from PK Population:
Test: 600 mg (3x200 mg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project34/ep/blinded/e210499.msrc/stats/versioncontrol/primary/scripts/program/main/TXL_programs/figures/figure15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: 1

Test: 600 µg [300 µg tablets] levothyroxine new formulation.
Reference: 600 µg [300 µg tablets] levothyroxine old formulation.
Source: Table 15.4.2.1.3

T3 (µg/mL) vs. Time (h)

Treatment: ●●●● Test ◆◆◆◆◆ Reference
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/Random Number:

Treatment:  
Test  
Reference

E: Subjects excluded from PK Population;
Test: 600 μg (3*200 μg tablets) levothyroxine new formulation.
Reference: 400 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Table 16.2.3.3
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:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Time Point (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>0.5 1.5 2.5</td>
</tr>
<tr>
<td>Reference</td>
<td>0.5 1.5 2.5</td>
</tr>
</tbody>
</table>

0: Subjects excluded from PK Population
Test: 600 mcg (3*200 mcg tablets) levothyroxine new formulation.
Reference: 600 mcg (3*200 mcg tablets) levothyroxine old formulation.
Source: Table 16.2.1.8
Levothyroxine

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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 (3x200 µg tablets) levothyroxine new formulation.
  - Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.

Source: Table 14.3.5.3

/project24/ep/blinded/e216099_merc/stats/versioncontrol/primary/scripts/program/main/2FL program/Figures/Figure
15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 73 values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration-time profiles](image)

Treatment: + + + + Reference

8 Subjects excluded from PK Population:
Test: 600 mg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 mg (4*200 µg tablets) levothyroxine old formulation.
Source: Table 14.7.5.3
Levothyroxine

EMR 200125-001

Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration-time profiles for different treatments.

Total T4 (ng/mL)

Time Point (h)

Treatment: ●●●● Test ●●●● Reference

- Subjects excluded from PK Population:
- Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.

Source: Table 15.4.2.1.3

/project24/ep/blinded/c210899_merc/stats/ver1004001/primary/scripts/program/main/FL programs/images/Figure

15.4.2.12.sae
Figure 15.4.7.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

Treatment: •••• Test •••• Reference

Subjects excluded from PK Population;
Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Table 16.2.1.1
Levothyroxine

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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:

![Concentration-Time Profiles Graph](image-url)

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 16.2.5.1

/project24/ep/blinded/e210882_merck/stats/versioncontrol/primary/scripts/program/main/TTL_programs/Figures/figure
15.4.2.12.png

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EMR 200125-001
Levothyroxine

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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:

![Graph showing concentration over time](image)

- 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/sp/blinded/2110999_merc/state/versioncontrol/primary/scripts/program/main/TFS programs/Figures/Figure
15.4.2.12.mps
Levothyroxine  
Bioequiv EMR200125-001 Page 1462 of 1628  

dation vs. old formulation  
EMR 200125-001  

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:

![Graph showing concentration-time profiles for T3 values. The graph includes a line representing treatment with data points for each time point. The y-axis represents T3 concentration in ng/mL, and the x-axis represents time in hours.](image)

- Subjects excluded from PK Population;
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.

Source: Table 16.2.5.3

/project2/sub/blinded/e210399_merco/stats/versioncontrol/primary/scripts/program/main/TPL_program/Figures/Figure 15.4.2.12.png

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1462/1628
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:

8: Subjects excluded from PK Population:
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 400 µg (3x100 µg tablets) levothyroxine old formulation.
Source: Table 16.2.3.1

/project24/ep/blinded/6210999_marc/scripts/verstioncontrol/primary/scripts/program/sain/TFL programs/Figures/Figure
15.4.2.12.xxx

Document No. 0000babc805b1d46 v1.0
CONFIDENTIAL INFORMATION
ID: 1463/1628
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 73 values) [Safety Population] Subject ID/Random Number:

Treatment: ● Test ○ Reference

Test: 690 μg [3x200 μg tablets] levothyroxine new formulation.
Reference: 680 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Table 16.1.0.3

/project24/og/blinded/a210899_merc/stats/versiconcontrol/primary/scripts/program/main/7PL programs/Figures/Figure 15.4.2.12.msp
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:

---

Treatment: ●●●● Test  ●●●● Reference

---

2 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 16.7.5.3

project24/ep/blinded/a210999_merc/stats/versioncontrol/primary/scripts/program/main/TEL programs/Figures/Figure 15.4.2.12.txt
Levothyroxine

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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:

![Graph showing concentration-time profiles for levothyroxine.](image-url)

- Subjects excluded from PK Population:
- Test: 600 μg [3*200 μg tablets] levothyroxine new formulation.

Source: Table 16.2.5.3

/project24/ep/blinded/e279059_merc/stats/versioncontrol/primary/scripts/program/main/YFL programs/Figures/Figures
23.4.2.12.sas

Document No.6900be68b83b846 v1.0 CONFIDENTIAL INFORMATION 11DEC2014 26:01 1466/1628
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:

8: Subjects excluded from PK Population:
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 400 µg (3 x 200 µg tablets) levothyroxine old formulation.

Source: Table 16.2.5.1

/project24/gp/blinded/q210099_merck/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figures
15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number: ::

Treatment: ○ ○ ○ ○ Test  ■ ■ ■ ■ Reference

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 14.2.5.3

/project24/ep/blinded/s210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL program/Figures/Figure 15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration-time profiles for T3 values with treatment groups indicated]

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

Source: Table 16.6.8.1

/project24/mpl/01209399_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.12.css

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11DEC2014 09:01
1469/1628
Levothyroxine

Bioequiv EMR200125-001 Page 1470 of 1628 salation vs. old formulation

Emr 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (for Total 73 Values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration-time profiles for levothyroxine]

Treatment:
- Reference

Subjects excluded from PK Population:
Test: 600 μg (5*120 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) levothyroxine old formulation.

Source: Table 16.1.5.3

/project24/smp/blinded/e210899.march/stats/versioncontrol/primary/scripts/program/main/PL program/Figures/figure
15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T3 Values) (Safety Population)

Subject ID/Randome Number:

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

Source: Table 16.5.3

/project24/wp/blinded/6216890_raro/stats/versioncontrol/primary/scripts/program/main/TFLprograms/Figures/figure15.4.2.12.png
Levotiriodine

EMR 200125-001

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:

Total T3 (ng/mL)

2 4 6 8 10

0 1 2 3 4 5 6 7

Time Point (h)

Treatment: Test Reference

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

/project24/gp/blinded/e210899_mero/stats/versioncontrol/primary/scripts/program/main/PFL programs/Figures/Figure
15.4.2.12.mso
Levotiroxine
EMR 200125-001

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Figure 13.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

---

Subjects included in PK Population:

Test: 600 μg (3x200 μg tablets) levotiroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levotiroxine old formulation.

Source: Table 16.2.3.3
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:

8 Subjects excluded from PK Population:
Test: 660 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 6.2.5.3

/project24/qe/blindmed/c210899.mec/scr/primary/scripts/program/main/TPL programs/Figures/Figure
15.4.2.12.sas
Levothyroxine

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:

Treatment: • Test ••• Reference

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 16.2.3.5.3
Levothyroxine

EMR 200125-001

Merck Serono
EMR 200125-001

Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale.

Subject ID/Randon Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Total T3 (mg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.1</td>
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<tr>
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<td>9.0</td>
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<tr>
<td>19</td>
<td>10.0</td>
</tr>
</tbody>
</table>

Treatment:
- - - - - Test
- - - - - Reference

Subjects excluded from PK Population:
- Test: 800 µg (1*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/a216999_merc/stats/versioncontrol/primary/scripts/program/main/YPL programs/figures/figure 15.4.2.12.png

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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:

Total T3 (ng/mL)

- - - - Test
- - - - Reference

-Subjects excluded from PK Population:
Test: 600 µg (2×300 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.6.3

/project24/ep/blinded/e210999_necc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.12.eay

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INFORMATION
Levothyroxine

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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 x 200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.

Source: Table 15.3.1.6.3

/project24/ep/blinded/e210899_necc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure
15.4.2.12.mne
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:

8: Subjects excluded from OK Population;
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Table 36.2.5.3

/project24/ip/blinded/c210999_merc/state/versioncontrol/primary/scripts/program/maim/TFL programs/Figures/Figure 15.4.2.12.mns
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: ...

Treatment: 
- - - - Test  
- - - - Reference

0: Subjects excluded from PK Population:
- Test: 600 µg (3x200 µg tablets) Levothyroxine new formulation.
- Reference: 600 µg (3x200 µg tablets) Levothyroxine old formulation.

Source: Table 16.5.5.3

/project24/ep/blinded/e210699_merc/stats/versioncontrol/primary/scripts/program/main/TEL Programs/Figures/Figure 15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

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

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 16.2.1.3

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/analysis/main/T3 programs/Figures/Figure
15.4.2.12.sas
Levothyroxine

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:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Treatment:</th>
<th>Test</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>●●●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>●●●</td>
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<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>6</td>
<td>●●●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>●●●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>●●●</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subjects excluded from PK Population:
Test: 600 μg (3*200 μg tablets) levothyroxine new formulation.
Reference: 400 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/project21/ep/blinded/e210659_mecx/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.12.msn
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/Randon Number: 

Treatment: ●●● Test  ●●● Reference

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 16.2.1.1
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:

Treatment:
- - - - Test
- - - - - Reference

Subjects excluded from 2% Population:
Test: 600 μg (3*200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Table 15.5.5.3
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:

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

/project24/ep/blinded/6210999/marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/figure15.4.2.12.png
Levothyroxine

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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:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Test</td>
</tr>
<tr>
<td>4</td>
<td>Reference</td>
</tr>
</tbody>
</table>

# Subjects excluded from PK Population:
- Test: 500 µg (3*200 µg tablets) levothyroxine new formulation
- Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation

Source: Table 16.2.5.1

/project14/gp/blinded/210599_merc/ets/ets/verionscontrol/primary/scripts/program/main/TLL program/Figures/Figure

15.4.2.12.sep

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Figure 15.4.2.12: Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

Subject ID/Random Number: 

8: Subjects excluded from PK Population; Test: 600 μg (3x200 μg tablets) levothyroxine new formulation. Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.

Source: Table 16.2.5.3

/project24/cp/blinded/ds10B99/mec/stats/versioncontrol/primary/scripts/program/main/TFL программы/Figures/Figure 15.4.2.12.mss
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/RandoX 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 16.2.5.1
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For 70% of T3 values) (Safety Population)

Subject ID/Random Number: 

Total T3 (ng/mL)

Time Point (h)

Treatment: ●●● Test  ●●● Reference

0: Subjects excluded from PK Population;
Test: 650 µg (3 x 200 µg tablets) levothyroxine new formulation,
Reference: 650 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.5.3

/production/Equiblinded/v210899_merca/state/versionscontrol/primary/scripts/program/main/TEI programs/Figures/Figure
15.4.2.12.e3
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (Per Total T3 values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population:
Test: 600 μg (3×200 μg tablets) levethyroxine new formulation.
Reference: 600 μg (3×200 μg tablets) levethyroxine old formulation.
Source: Table 16.2.5.3

/project24/ep/blinded/e210899_merco/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure 15.4.2.12.sas
Figure 13.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 13 Values) (Safety Population)

Subject ID: Random Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Treatment:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>●●●● Test</td>
</tr>
<tr>
<td></td>
<td>●●●● Reference</td>
</tr>
</tbody>
</table>

- Subjects excluded from PK Population:
  - Test: 650 μg (3×200 μg tablets) levothyroxine new formulation.
  - Reference: 600 μg (3×200 μg tablets) levothyroxine old formulation.
- Source: Table 16.7.5.3
Subject ID/Randon 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/gp/blindad/a218999_merc/stats/versioncontrol/primary/scripts/program/main/TL programs/Figures/Figure
15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profile: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 Values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration-time profile for T3 levels with time points from 0 to 7 hours and T3 levels from 0.1 to 10.0 mg/mL. The graph has two lines: one for the test and one for the reference treatment.]

9: Subjects excluded from PK population:
Test: 600 mg (3*200 mg tablets) levothyroxine new formulation,
Reference: 600 mg (3*200 mg tablets) levothyroxine old formulation.
Source: Table 16.2.3.1

/project24/ep/blinded/210899_marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure
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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 73 values) (Safety Population)

Subject ID/Random Number:

Treatment:
- - - - - Test  - - - Reference

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/a216895_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T3 values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population:
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Table 16.1.5.3.

/project24/ep/blinded/e218899_marc/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure
15.4.2.12.xxx

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 73 values) (Safety Population)

Subject ID/Random Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Total T3 (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
</tr>
</tbody>
</table>

Treatment:
- ••••• ••• Test
- ••••• ••• Reference

# Subjects excluded from PK Population:
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.

Source: Table 15.7.5.1

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure15.4.2.12.sas

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Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 13 Values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population:
Test: 600 µg (5×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Table 16.7.3.1
Levothyroxine
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

/project24/ag/blinded/e210939_marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.12.sas
Figure 15.4.2.12 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

For Total T3 values (Safety Population)

Subject ID/Random Number:

Treatment: Test
Reference

Subjects excluded from PK Population:
Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Table IC.2.1.3

/doc/blinded/3210898/marc/stats/versioncontrol/primary/scripts/program/main/TPL/program/Figures/Figure15.4.2.12.sas
Levothyroxine
Bioequiv EMR200125-001 Page 1500 of 1628 alation vs. old formulation

Subject ID/Randm Number:

Time Point (h)

Treatment:  ● ● ●  Test  ● ● ●  Reference

-Subjects excluded from PK Population:
- Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
- Reference: 800 µg (3x200 µg tablets) levothyroxine old formulation.
- Source: Table 14.1.5.3

/project24/pblindk/ex10899_reac/stats/secondary/scripts/primary/main/FTI programs/Figures/Figure 15.4.2.12.sas

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