Levels of Thyroxine

Bioequiv EMR200125-001 Page 801 of 1628 \*ulsion vs. old formulation

Merck Serono
EMR 200125-001

Figure 15.4.2.2 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for total T4 Values)
(Safety Population)

Subject ID/Random Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Test</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
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<td>68</td>
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<tr>
<td>70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>74</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

T4 (ng/mL)

- Subjects excluded from PK Population; Horizontal lines represent the baseline of the respective treatments.
- Test: 600 mg (3 x 200 mg tablets) Levothyroxine new formulation.
- Reference: 600 mg (3 x 200 mg tablets) Levothyroxine old formulation.

Source: Listing 16.2.2.2

/project24/ep/blinded/e210899_mero/stats/versioncontrol/primary/scripts/program/main/TFL program/Figures/Figure 15.4.2.2

Document No. 000000b0e0803bb46 v1.0
CONFIDENTIAL
INFORMATION
1:DEC2014 09:04
801/1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total TV Values) (Safety Population)

Subject ID/Random Number:

@: Subjects excluded from PK Population; Horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levthyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levthyroxine old formulation.
Source: Listing 15.4.5.2
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 803 of 1628 \textbf{\textit{U}} \textbf{\textit{L}ation vs. old formulation}

March Serono
EMR 200125-001

\textbf{Figure 15.4.2.9} \textbf{\textit{C}}oncentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values)
(Safety Population)

\begin{center}
\begin{tikzpicture}
\begin{axis}[
width=\textwidth,
height=0.8\textwidth,
axis x line=middle,
axis y line=middle,
axis line style=-,%
]
\addplot[mark=*,mark options={solid}] coordinates {
(2, 270)
(3, 260)
(4, 250)
(5, 240)
(6, 230)
(7, 220)
(8, 210)
(9, 200)
(10, 190)
(11, 180)
(12, 170)
(13, 160)
(14, 150)
(15, 140)
(16, 130)
(17, 120)
(18, 110)
(19, 100)
(20, 90)
(21, 80)
(22, 70)
(23, 60)
(24, 50)
(25, 40)
(26, 30)
(27, 20)
(28, 10)
(29, 0)
};
\end{axis}
\end{tikzpicture}
\end{center}

\begin{itemize}
\item Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
\item Test: 606 \text{\mu}g (3-200 \text{\mu}g tablets) levothyroxine new formulation.
\item Reference: 600 \text{\mu}g (3-200 \text{\mu}g tablets) levothyroxine old formulation.
\item Source: Listing 16.2.5.2
\end{itemize}

/project24/ep/blinded/0210899/marc/stats/versioncontrol/primary/scripts/program/mais/TL programs/Figures/Figure 15.4.2.9.ess

\begin{tabular}{l}
\textbf{Document No.990f06d3d835b46 v1.0} & \textbf{CONFIDENTIAL} & \textbf{INFORMATION} & \textbf{11/02/2014 00:01} & \textbf{803/1628}
\end{tabular}
**Levothyroxine**

EMR 200125-001

Biovall: EMR200125-001 Page 804 of 1628

**Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)**

(Safety Population)

Subject ID/Random Number: ****

![Graph of Levothyroxine Concentration-Time Profiles](image)

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

- Subjects excluded from PK Population; horizontal lines represent the baseline of the respective treatments.
- Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
- Source: Listing 16.2.3.2

/project/blinded/e216899_merc/atlas/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure

15.4.2.9.png

Document No. 0900b0ef8085bb66 v1.0

CONFIDENTIAL INFORMATION
Levothyroxine

EMR 200125-001

Bioequiv EMR200125-001 Page 805 of 1628 Relation vs. old formulation

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

Subject TB/Random Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>T4 (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
</tr>
<tr>
<td>3</td>
<td>90</td>
</tr>
<tr>
<td>4</td>
<td>120</td>
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<tr>
<td>5</td>
<td>150</td>
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<tr>
<td>6</td>
<td>180</td>
</tr>
<tr>
<td>7</td>
<td>210</td>
</tr>
<tr>
<td>8</td>
<td>240</td>
</tr>
</tbody>
</table>

Treatment: Test: ––– Reference: –––

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

/project24/ep/blinded/e010899_mero/stats/versioncontrol/primary/scripts/program/main/T4L programs/figures/Figure
15.4.2.9.sas

Document No.99003bde8085b46 v1.0
CONFIDENTIAL
INFORMATION
11ME0214 08:31
805/1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)

Subject ID/Random Number:

Treatment: ●●●● Test  ●●●Reference

Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 300 µg (3*100 µg tablets) levothyroxine old formulation.
Source: listing 15.2.5.2

/project24/ep/blinded/6215999_merc/stats/versioncontrol/primary/scripts/program/main/TFL_programs/figures/Figure
15.4.2.9.sas
Subject ID/Random Number:

0  2  4  6  8  10  12  14  16  18  20  22  24

0  60  120  180  240  270

5:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 mg (3*200 mg tablets) levothyroxine new formulation.
Reference: 600 mg (3*200 mg tablets) levothyroxine old formulation.
Source: Listing 15.4.2.5.2

/project24/np/blinded/neo39_marc/stats/versioncontrol/primary/scripts/program/main/T4_programs/figures/Figure
15.4.2_4.sas
Subject ID/Random Number: '  

Treatment: • • • Reference

@: Subjects excluded from PK Population; Horizontal lines represent the baseline of the respective treatments.
Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Listing 15.2.9.2

/project/24/ep/blinded/e210b99_marv/stataversioncontrol/primary/scripts/program/main/T4K_programs/Figures/figure 15.4.2.9.sas
Bioequiv EMR200125-001 Page 810 of 1628

Levothyroxine
EMR 200125-001

Figure 13.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values)

(Safety Population)

Subject ID/Random Number:

\[
\begin{align*}
\text{Total T4 (ng/mL)} & \quad \text{Time Point (h)} \\
\hline
\text{2} & \quad \text{0} & \quad \text{2} & \quad \text{4} & \quad \text{8} & \quad \text{12} & \quad \text{18} & \quad \text{24} & \quad \text{30} & \quad \text{36} & \quad \text{48} & \quad \text{60} & \quad \text{72} \\
\end{align*}
\]

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

Source: Listing 16.2.5.2

\[\text{/project24/cp/blinded/e210890_mero/stats/versioncontrol/primary/scripts/program/main/PL programs/Figures/Figure 15.4.2.9.doc} \]

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\[\text{EMR200125} \]
**Levotyroxine**

**EMR 200125-001**

**Bioequiv: EMR200125-001 Page 811 of 1628**

**Santo Mauro Seroni**

**EMR 200125-001**

**Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 94 Values)**

(Safety Population)

**Subject ID/Random Number:** ?

---

**Total T4 (ng/mL):**

- **0:** Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- **Test:** 600 μg (3×200 μg tablets) levotyroxine new formulation.
- **Reference:** 600 μg (3×200 μg tablets) levotyroxine old formulation.
- **Source:** Listing 16.2.6.2

---

**Treatment:**

- **- - -** Test
- **- - - - -** Reference

---

**Time Point (h):**

- 0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36 38 40 42 44 46 48 50 52 54 56 58 60 62 64 66 68 70 72

---

**/project/seg/blinded/0210899_marc/stats/versioncontrol/primary/scripts/program/main/T1T programs/Figures/Figure 15.4.2.9.cass**

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INFORMATION
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 812 of 1628ulation vs. old formulation

Merck Serono
EMR 200125-001

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

Subject ID/Random Number: 1

![Graph showing concentration-time profiles for individual total T4 values in linear scale.](image)

- **Treatment:**
  - Test
  - Reference

- Subsets excluded from PK Population. Horizontal lines represent the Baselines of the respective treatments.
- Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
- Source: Listing 16.2.3.2

/project/24/ep/blinded/c10699_merk/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/figure

15.4.2.9.png

Document No.00008a88089e644 v1.0

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812/1628
Levothyroxine
EMR 200125-001

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

Subject ID/Random Number:

0: Subjects excluded from PK Population; horizontal lines represent the Baseline of the respective treatments. Test: 600 µg (5x200 µg tablets) Levothyroxine new formulation. Reference: 690 µg (3x200 µg tablets) Levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/621009_merc/stats/versionscontrol/primary/scripts/program/main/T4L program/Figures/Figure 15.4.2.9.sas

Document No: 690090a8eb085b66 v1.0

CONFIDENTIAL
INFORMATION
Figure 15.4.2.3 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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

/project24/ep/blindnc/s218099_mero/stats/versioncontrol/primary/scripts/program/main/TVL programs/Figures/Figure 15.4.2.3.sas
Levothyroxine

Bioequiv EMR200125-001 Page 815 of 162

Figure 15.6.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Rando 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>
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<tr>
<td>2</td>
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<tr>
<td>20</td>
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</tbody>
</table>

Subjects excluded from PK Population; Horizontal lines represent the baseline of the respective treatments.
Test: 620 μg (3×200 μg tablets) levothyroxine new formulation.
Reference: 620 μg (3×200 μg tablets) levothyroxine old formulation.
Source: Listing 16.5.5.2

/projects/ep/blinded/e016696_novo/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure
15.6.2.9.sas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Treatment:  Test  Reference

6: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments. Test: 600 µg (3x200 µg tablets) levothyroxine new formulation. Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

/project24/sp/blind/grid1/0099_marcs/primary/scripts/program/main/FITL program/figures/Figure15.4.2.9.gsp
Figure 15.4.2.9 Concentration-time Profiles: Individual concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

![Graph](image)

Treatment: ● ● ● Test ▲ ▲ ▲ Reference

Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.0.2

[Link to source]
Levothyroxine

EMR 200125-001

Bioequiv EMR200125-001 Page 818 of 1628 ulation vs. old formulation

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

(Safety Population)

Subject 15/Random Number:

270
240
210
180
150
120
90
60
30
0

Total T4 (ng/mL)

-2 -1 0 1 2 4 6 8 11 14 16 20 22

Time Point (h)

Treatment: ●●●● Test ●●●● Reference

8.Subjects excluded from PK Population; horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
Reference: 300 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/0110899_marco/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9

Document No.0506babe8058b846 v1.0

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TCG 2014 10:31
Levotiroxine

EMR 200125-001

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

Subject ID/Random Number:

8 Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.

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

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

Source: Listing 16.2.5.2

/project24/ep/blinded/e210999_nero/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas
Levothyroxine

EMR 200125-001

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

Subject ID/Random Number:

0: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 500 μg (3x100 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

Document No.0900156218834846 v1.0
CONFIDENTIAL
INFORMATION
11082014 05:10
Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values)

Subject ID/Random Number:

- Subjects excluded from PW Population; horizontal lines represent the baseline of the respective treatments.
- Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
- Source: Listing 16.1.5.2
Levothyroxine

Bioequiv EMR200125-001 Page 822 of 1628 evaluation vs. old formulation

Merck Sermo
EMR 200125-001

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

Subject ID/Random Number:

![Graph showing concentration-time profiles for levothyroxine.

Symbols separated by dotted lines:

T4 (ng/mL)

Time Point (h)

Treatment: ● ● ● Reference

0: Subjects excluded from PK Population. Horizontal lines represent the Baseline of the respective treatments.

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

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

Source: Listing 16.5.5.2

/project24/ep/blinded/e210899_merco/stats/versioncontrol/primary/scripts/program/main/T3L programs/Chinese/Figure/Figure 15.4.2.9.sas

Document No.9006b68085b46 v1.0
CONFIDENTIAL
INFORMATION 11/06/2014 20:51

EMR 200125-001 Page 823 of 1628
Figure 15.1.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number: 12345678

Treatment:  
- Test  
- Reference

Graph showing concentration-time profiles with different markers for test and reference treatments. The graph includes a baseline and indicates concentrations in mg/mL.

Subjects excluded from PK Population: Horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

![Graph with Total T4 levels over time for different treatments.]

Treatment: ●●● Test  ○○○ Reference

6: Subjects excluded from PK Population; Horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (2×200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/o218699_merc/stats/versioncontrol/primary/scripts/program/main/TEL programs/Figures/Figure 15.4.2.9.msc
Figure 13.6.7.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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

/project24/ep/blinded/010099_merc/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.6.7.9.cgs
Levothyroxine EMR 200125-001

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject ID/Random Number:

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

/project24/rep/blinded/e210099_mccc/state/versioncontrol/primary/scripts/program/main/7FL programs/Figures/Figure 15.4.2.9.tas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

- Total T4 (ng/mL)

- Treatment: ● ● ● Test ● ● ● Reference

8: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.

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

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

Source: Listing 15.2.5.2

/project24/gp/modified/010099_merc/stats/versioncontrol/primary/scripts/program/main/TL programs/Figures/Figure 15.4.2.9.s20

Document No. 899/899868S5b46 v1.0
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11 DECO 2014 00:01
Levothyroxine
EMR 200125-001

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

Subject ID/Random Number:

---

8: Subjects excluded from DK Population; horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 15.2.5.2

/project24/op/blinded/0210899_mare/stats/versioncontrol/primary/scripts/program/main/TLI programs/Figures/Figure 15.4.2.9.png

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11062014 16:31
828/1628
Levothyroxine
EMR 200125-001

Figure 15.4.3.8 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 24 Values) (Safety Population)

Subject ID/Randoh Number:

Treatment: ●●● Test ——— Reference

8 Subjects excluded from PK Population; Horizontal lines represent the Baseline of respective treatments.

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

Source: Listing 16.2.5.2
/project/ep/blended/ed210899_merc/stats/versioncontrol/primary/scripts/program/main/TEG program/Figures/Chapter 15.4.2.8.gas
Figure 15.6.1.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject ID/Random Number:

2-Subjects excluded from 9% Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

/project24_gp/blinded/0210399 marec/stats/versioncontrol/primary/scripts/program/main/TSL Programs/Figures/figure
15.4.2.9.mne

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CONFIDENTIAL INFORMATION
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30/1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population; horizontal lines represent the baseline of the respective treatments.
Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Listing 16.3.2.2.
Levothyroxine
EMR 200125-001

Merck Serono
EMR 200125-001

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

Subject ID/Random Number:

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<tr>
<th>Time Point (h)</th>
<th>Treatment: Test</th>
<th>Reference</th>
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<tr>
<td>12</td>
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</tr>
</tbody>
</table>

0: Subjects excluded from PK population. Horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 630 µg (2×200 µg tablets) levothyroxine old formulation.
Source: Listing 16.1.3.2

/project24/ep/blinded/0210899_merck/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.4.2.9.pdf
Figure 15.4.2.6 Concentration-time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject: JU/Random Number:

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

/working/wp/blinded/ea210899_merc/stats/versioncontrol/primary/scripts/program/main/TFI programs/Figures/figure
15.4.2.6.sas

Document No.9008adsb5854b46 v.1.0

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1/18/2015 00:00

EMR200125-001 Page 833 of 1628
Figure 15.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Treatment: Test  Reference

8: Subjects excluded from PK population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3*200 μg tablet) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Listing 16.3.5.9
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values)
(Safety Population)

Subject ID/Random Number:

Treatment: Test, Reference

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

/project24/cp/blinded/4110699_maro/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.png
Levothyroxine
EMR 200125-001

Figure 13.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration over time for levothyroxine in a linear scale. The graph includes data points for different treatments and time points.]

- Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
- Test: 660 µg (3 x 220 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.

Source: Listing 16.5.5.2

\(/project24/ep/blinded/e210899_marc/stats/versioncontrol/primary/scripts/program/main/TEL programs/figures/Figure 15.4.2.9.txt\)
Levothyroxine
EMR 200125-001

Bionequiva
EMR200125-001 Page 837 of 1628 Couso vs. old formulation

Figure 15.4.2.19 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale for Total T4 Values
(Safety Population)

Subject ID/Random Number:

![Graph of Total T4 (ng/mL) vs. Time Point (h)](image)

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

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

/project24/ap/biased/e210999_r removeObject/primary/scripts/program/sin/TEL programs/Figures/Figure 15.4.2.19.sas
Levothyroxine
EMR 200125-001

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

Subject ID/Random Number:

8: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

/project24/ep/blinded/0210899_marx/state/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas
Levothyroxine
EMR 200125-001

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

Subject ID/Random Number:

Treatment:
- Test
- Reference

Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2
Levothyroxine
EMR 200125-001

Figure 15.4.2.3 Concentration-Time Profiles: Individual Concentration versus Actual Time in linear scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Treatment: Test

Reference

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

Source: Listing 15.2.6.2.

/project24/ap/blinded/e210859_mrec/stats/versioncontrol PRIMARY/scripts/program/main/T4 program/figures/Figure 15.4.2.3.xxx

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Figure 15.4.2.1.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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

- Subjects excluded from PK population; horizontal lines represent the baseline of the respective treatments.
- Treatments: 600 µg (3x200 µg tablet(s) levothyroxine new formulation.
- Reference: 600 µg (3x200 µg tablet(s) levothyroxine old formulation.
- Source: Listing 16.2.5.2

/project24/op/blinded/c110899_merc/stats/versiocontrol/primary/scripts/program/main/TFL programs/Figures/Figure15.4.2.1.9.png

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841/1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

- Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- Test: 500 μg (3x200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
- Source: Listing 16.3.5.2

/project24/ep/blinded/e210899_marcs/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.txt
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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<th>Test</th>
<th>Reference</th>
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<tr>
<td>14</td>
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<td></td>
</tr>
</tbody>
</table>

Legend:
- : Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 μg (3×200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3×200 μg tablets) levothyroxine old formulation.

Source: Listing 15.4.2.5.2

/project34/wb/blinded/4218999_nexa/stata/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.png
Levothyroxine

EMR 200125-001

Subject ID/Random Number:

9: Subjects excluded from PK Population; horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Listing 10.2.3.2

/project/24/op/blindon/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TPL programs/Figures/Figure
15.4.2.5.sas

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Levothyroxine

Bioequivalency Study: LEV 200125-001 Page 845 of 1628

Figure 15.4.2.7 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total % Changes)

(Safety Population)

Subject ID/Randome Number:

 Treatment: 

Time Point (h)

0 2 4 6 8 10 12 14

Total T4 (ng/mL)

150 200 250 300 350 400

©: Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.

Test: 600 µg (3 x 200 µg tablets) levotyroxine new formulation.

Reference: 600 µg (3 x 200 µg tablets) levotyroxine old formulation.

Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_nero/stats/versionscontrol/primary/scripts/program/min/CIL programs/Figures/Figure 15.4.2.7.sas

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INFORMATION

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845/1628
Levothyroxine

EMR 200125-001

Figure 15.1.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject ID/Random Number:

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<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>Test</td>
<td>2 3 4 5 6 7</td>
</tr>
<tr>
<td>Reference</td>
<td>9 10 11 12</td>
</tr>
</tbody>
</table>

Testing: 500 mcg (3*200 mcg tablets) levothyroxine new formulation.
Reference: 500 mcg (3*200 mcg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

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8461628
Levothyroxine bioequivalent EMR200125-001 Page 847 of 1628 evaluation vs. old formulation

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

Subject ID/Random Number:

![Graph showing concentration-time profiles for levothyroxine bioequivalence study.]

- Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
- Source: Listing 15.2.8.2

/project24/ep/blinded/e210899_marc/stats/versioncontrol/primary/scripts/program/main/TPF_programs/figures/figure_15.4.2.9.png
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Rand Number:

Treatment: ●●● Test ●●●● Reference

0: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (1×500 µg tablets) levothyroxine new formulation.
Reference: 600 µg (2×300 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_marco/stats/vercioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure
15.4.2.9.888
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject ID/Random Number:

- Subjects excluded from PK population; horizontal lines represent the baseline of the respective treatments.
- Test: 300 μg (3*100 μg tablets) levotiroxine new formulation.
- Reference: 600 μg (3*200 μg tablets) levotiroxine old formulation.

Source: Listing 15.2.9.2

/project24/ep/blinded/a210999_marc/stats/versioncontrol/primary/scripts/progms/main/Figures/Figures/15.4.2.9.sas

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CONFIDENTIAL INFORMATION
Levothyroxine

Bioequiv EMR200125-001 Page 850 of 1628

Figure 15.4.2.8 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration-time profiles for levothyroxine treatment.]

- Subjects excluded from PK Population. Horizontal lines represent the baseline of the respective treatments.
- Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
- Source: Listing 16.3.5.5.

/project/24/ep/blindac/a210b999_marc/stats/versioncontrol/primary/scripts/program/main/21l_programs/figures/Figure 15.4.2.8.gph

Document No: 09008189888bb46 v1.0

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850/1628
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 851 of 1628 Relation vs. old formulation

Emerson Serono
EMR 200125-001

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 24 Values)
(Safety Population)

Subject ID/Random Number:

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

---

Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.

Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24//ep/blinded/a210994_marc/stats/versioncontrol/primary/scripts/program/main/TEI programs/Figures/Figure
15.4.2.9.png

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INFORMATION

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851/1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number: ☐

Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Liming 16.5.3.2
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Treatment:  
Test  
Reference

6 Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3*200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablets) levothyroxine old formulation.
Source: Listing 16.3.5.2
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

- Treatments:
  - Test
  - Reference

8: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3×200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (2×300 μg tablets) levothyroxine old formulation.

Source: Listing 16.3.5.2

/project24/ep/blinded/e210899_marc/stats/variancontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.xlsx
Levothyroxine
EMR 200125-001

Biosimilarity EMR200125-001 Page 855 of 1628 Evaluation vs. old formulation

Merck Serono
EMR 200125-001

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

Subject ID/Random Number:

![Graph showing concentration-time profiles for individual concentration versus actual time in linear scale for total T4 values.]

- Subjects excluded from PK Population: Horizontal lines represent the baseline of the respective treatments.
- Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
- Source: Listing 16.2.3.2

/project/.../merc/stats/versioncontrol/primary/scripts/program/main/TTL programs/figures/figure 15.4.2.9.css

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855/1628
Levotyroxine
EMR 200125-001

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

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<td>18</td>
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</table>

Treatment:  
- Reference
- Test

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

/project24/ep/blinded/e210899_mrc/stats/verisoncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.5.msr
Levothyroxine
EMR 200125-001

Figure 25.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population; Horizontal lines represent the baseline of the respective treatments.
Test: 620 µg (3 x 206 µg tablets) levothyroxine new formulation.
Reference: 660 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/mp/blinded/421899_marx/stats/versioncontrol/primary/scripts/program/main/TPL programs/Figures/Figure 25.4.2.9.sas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Treatment: ●●●● Test ★★★★ Reference

@Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (2*300 µg tablets) levothyroxine old formulation.
Source: Listing 16.5.3.2

/project74/exp/blinded/e210899_mscr/stats/versioncontrol/primary/scripts/program/main/YF1_programs/Figures/Figure 15.4.2.9.xls
Figure 15.4.3.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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8: Subjects excluded from PK Population. Horizontal lines represent the baseline of the respective treatments.

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

Source: Listing 16.3.5.2

/project24/ap/blinded/e210899_marc/stats/versioncontrol/primary/scripts/program/main/FL programs/Figures/Figure
15.4.3.9.jpg
Figure 15.4.3.8 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values)
(Safety Population)

Subject ID/Random Number:

- Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 60 µg (2 x 300 µg tablets) levothyroxine old formulation.
- Source: Listing 15.4.3.6
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 861 of 1628 Vision vs. old formulation

Subject ID/Random Number:

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<td>7</td>
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<td>90</td>
</tr>
</tbody>
</table>

Subjects excluded from PK Population. Horizontal lines represent the baseline of the respective treatments.

Test: 800 µg (3×266.67 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

https://project24.ep/blinded/e210899_marc/stats/versioncontrol/primary/scripts/program/main/TXL programs/Figures/Figure 15.4.2.9.pdf

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11DEC2014 09:01
861/1628
Levotyroxine
EMR 200125-001

Biosimilars EMR200125-001 Page 862 of 1628

Figure 15.4.2.2 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Treatment:</th>
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<tbody>
<tr>
<td>2</td>
<td>●●●Test</td>
</tr>
<tr>
<td>3</td>
<td>Reference</td>
</tr>
</tbody>
</table>

Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levotyroxine new formulation.
Reference: 400 µg (3x100 µg tablets) levotyroxine old formulation.
Source: Listing 16.3.5.2

/project24/ep/blinded/e210099_merc/state/versioncontrol/primary/scripts/program/main/TPR programs/Figures/Figure

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11DEC2014 00:00
862/1628
Subject ID/Randoom Number:

Treatment:  
Test  
Reference

Subjests excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3*200 μg tablet) levothyroxine new formulation.
Reference: 600 μg (3*200 μg tablet) levothyroxine old formulation.
Source: Listing 16.2.6.2

(project24/ep/blinded/de2108499_mecr/stats/versioncontrol/primary/scripts/program/min/TFL programs/figures/Figure 13.4.2.0.sas)
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Graph:
- Total T4 (ng/mL)
- Time Point (h)
- Treatment: •••• Test  •••• Reference

- Subjects excluded from PK Population: Horizontal lines represent the baseline of the respective treatments.
- Test: 600 pg (3*200 pg tablets) levothyroxine new formulation.
- Reference: 600 pg (3*200 pg tablets) levothyroxine old formulation.
- Source: Listing 15.2.5.7

/project24/mp/blinded/e210099/marc/stats/versivolcontrol/primary/sculpta/program/main/TVL programs/Figures/figure15.4.2.9.tfl
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 865 of 1628 Validation vs. old formulation

Merck Serono
EMR 200125-001

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

Subject ID/Random Number:

270
240
210
180
150
120
90
60
30
0

Total T4 (ng/mL)

0 2 4 6 8 10 12 14 16 18 20 22 24

Time Point (h)

Treatment: 

Test

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

/project24/ep/blinded/s210899_marcc/stats/versioncontrol/primary/scripts/program/main/TTL program/Figures/Figure
15.4.2.9.sas

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Figure 15.4.2.1 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

- Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
- Source: Listing 16.3.5.2
Levothyroxine
EMR 200125-001

Bioequivalency Test
EMR 200125-001 Page 867 of 1628

Marck Storze
EMR 200125-001

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

Subject ID/Rand Number:

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

- Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
- Source: Listing 16.2.3.2

/project24/ep/blinded/a210899_mecu/states/versioncontrol/primary/scripts/program/main/TL program/Figures/Figure 15.4.2.9.png

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8671628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

Treatment:  

0: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3×200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3×200 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2
Levothyroxine Bioequiv EMR200125-001
EMR 200125-001

Marck Serono
EMR 200125-001

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

Subject ID/Random Number:

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

- Subjects excluded from PK Population; horizontal lines represent the Baseline of the respective treatments.
- Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
- Source: Listing 16.3.5.2

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8/19/1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Time Point (h)

Treatment: ●●●● Test  ●●●● Reference

@: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3×200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3×200 μg tablets) levothyroxine old formulation.
Source: Listing 16.1.5.2

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

Subject ID/Randon Number:

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<th>Time Point (h)</th>
<th>Test</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>20</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Listing 15.3.1.2

/project24/ap/blinded/z210890_merc/stats/versioncontrol/primary/scripts/program/misas/74l_programs/figures/figure15.4.2.9.sas
Figure 15.4.2.3 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 250 µg (2 x 125 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/cp/blinded/0210896_mero/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.3.sas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

8: Subjects excluded from DX Population: Horizontal lines represent the Baseline of the respective treatments.
8: Test: 600 pg (3*200 pg tablets) levothyroxine new formulation.
8: Reference: 600 pg (3*200 pg tablets) levothyroxine old formulation.

Source: Listing 10.2.1.2

/project24/sp/blinded/4210899_march/stats/versioncontrol/primary/scripts/program/main/TCL_programs/figures/figure 15.4.2.9.sas
**Levothyroxine**

**EMR 200125-001**

**Bioequiv EMR200125-001 Page 874 of 1629 Comparison vs. old formulation**

**Merck Serono**

**EMR 200125-001**

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

**Subject ID/Random Number:**

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

**Treatment:**

- **Reference:**
- **Test:**

**Explanation:**

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

**Source:** Listing 16.3.5.2

[Project Path: /project1/ep/blinded/e210889_maze/stats/versioncontrol/primary/scripts/program/main/T4_programs/Figures/Figure 15.4.2.9.png]
Figure 15.4.2.5 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

9: Subjects excluded from PK Population. Horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (2 x 300 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project/24/ep/blinded/a210999_merc/stats/versioncontrol/primary/scripts/progress/main/TPL programs/Figures/figure
15.4.2.9.eas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

T4 (ng/mL)

Time Point (h)

- - - - Test
- - - - Reference

S: Subjects excluded from PK Population. Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject ID/Random Number:

Treatment: Test, Reference

0: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/a210899/mail/stats/versioncontrol/primary/scripts/program/mac/ITL programs/Figures/Figure 15.4.2.9.cas
Levothyroxine
EMR 200125-001

Subject ID/Random Number:

Treatment: Test Reference

8: Subjects excluded from PK Population. Horizontal lines represent the Baseline of the respective treatments.

Test: 500 μg (3*300 μg tablets) levothyroxine new formulation.
Reference: 600 μg (2*300 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

//home/silvio/twinkle/docs/figures/15.4.2.9.pdf
Subject ID/Random Number:

8: Subjects excluded from PK Population; Horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Listing 15.2.5.2

/project/ep/blinded/m210899/merc/stats/versioncontrol/primary/scripts/protocol/main/ITL programs/figures/figure
15.4.2.5.xxx

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

Subject ID/Random Number:

Treatment: Test, Reference

Subjects excluded from PK population; horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation,
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/log/bldlog/a213899_merck/stats/versioncontrol/primary/scripts/program/main/RPL/programs/figures/Figure 15.4.2.9.png
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number: 1

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

/project24/ep/blinded/52312499_grcc/stats/versioncontrol/primary/scripts/program/main/T4_programs/Figures/Figure
15.4.2.9.888

Document No.0908068dc885bb46 v1.0

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INFORMATION

EMR200125-001 Page 98 of 1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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<thead>
<tr>
<th>Treatment:</th>
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<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Treatment: 

-- Test

--- Reference

*: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.

Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.

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

Source: Listing 16.2.3.2
Figure 15.4.2.9 Concentration-time profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

8: Subjects included from PK Population. Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3×200 µg tablets) Levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) Levothyroxine old formulation.
Source: Listing 16.2.5.2

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11/04/2014 00:31
884/1638
Levothyroxine
EMR 200125-001

March Serono
EMR 200125-001

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

Subject ID/Random Number: ...

8: Subjects excluded from PK Population. Horizontal lines represent the baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 15.2.3.2

/project24/ap/blinded/021089_merc/stats/versiocontrol/primary/scripts/program/main/TFL Programs/Figures/Figure 15.4.2.9.sas
Levothyroxine
EMR 200125-001

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

Subject ID/Random Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td>4</td>
<td>Reference</td>
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<td>8</td>
<td>Reference</td>
</tr>
<tr>
<td>10</td>
<td>Reference</td>
</tr>
</tbody>
</table>

- Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 µg [3*200 µg tablets] levothyroxine new formulation.

Source: Listing 18.2.2.2

/project/34/b/blanked/e210999_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

Treatment: ●●●● Test ▲▲▲▲ Reference

- Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 μg (3×200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3×200 μg tablets) levothyroxine old formulation.
- Source: Listing 16.2.3.2
Levothyroxine
EMR 200025-001

Bioequiv EMR200125-001 Page 888 of 1628 ination vs. old formulation

Merck Serono
EMR 200125-001

Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values)
(Safety Population)

Subject ID/Randome Number:

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Test</th>
<th>Reference</th>
</tr>
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<tbody>
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</tr>
<tr>
<td>8</td>
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<td></td>
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</tbody>
</table>

# Subjects excluded from FE Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 mg (3*200 mg tablets) levothyroxine new formulation.
Reference: 600 mg (3*200 mg tablets) levothyroxine old formulation.
Source: Listing 16.7.8.2

/project24/ep/blinded/d210899_nero/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.9.sas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Total T4 (ng/mL)

-200
-150
-100
-50
0
50
100
150
200
250
300
350
400
450
500
550
600
650
700
750
800
850
900
950
1000
1050
1100
1150
1200
1250
1300
1350
1400
1450
1500
1550
1600
1650
1700
1750
1800
1850
1900
1950
2000
2050
2100
2150
2200
2250
2300
2350
2400
2450
2500
2550
2600
2650
2700

Treatment: Test
Reference

Time Point (h)

2 0 2 4 6 8 10 2 4 6 8 10

0: Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (5*120 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.1.5.2

/project24/wp/blindcoded21389999/proc/stat/versioncontrol/primary/scripts/program/min/TL programs/figures/figure15.4.2.9.sas
Levthyroxine
EMR 260125-001

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

Subject ID/Random Number:

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</tbody>
</table>

Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3×200 µg tablets) levthyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levthyroxine old formulation.
Source: Listing 16.2.5.2
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number: 1

- Subjects excluded from PK population: Horizontal lines represent the baseline of the respective treatments.
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

/project/ep/blinded/e210899_marcc/stats/versioncontrol/primary/scripts/program/mix/TFL programs/Figures/15.4.2.9.sas
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

Treatment: ●●● Test  ■■■ Reference

Subjects excluded from DE Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 400 µg (2x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2
Subject ID/Random Number:

Treatment: ● Test — Reference

8 Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: listing 16.2.1.5.2
Levothyroxine
EMR 200125-001

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

Subject ID/Random Number:

8: Subjects excluded from PK population; horizontal lines represent the Baseline of the respective treatments. Test: 600 μg (3 x 200 μg tablets) levothyroxine new formulation.
Reference: 650 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Listing 16.5.5.2

/project24/ep/blinded/9210899.mare/stats/versioncontrol/primary/scripts/program/main/71_figures/Figure 15.4.2.9.png

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894/1628
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/RAND narrowly:

6: Subjects excluded from PK Population. Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

/project24/np/ob/ncic/er/erc/narc/stats/versioncontrol/primary/scripts/program/main/TXL_programs/Figures/Figure 15.4.2.9.txt
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 74 Values) (Safety Population)

Subject ID/Sample Number:

Treatment: ●●● Test  ●●— Reference

@: Subjects excluded from PK Population. Horizontal lines represent the Baseline of the respective treatments.

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

/project24/op/blended/0210895_merco/stats/versioncontrol/primary/scripts/program/main/IFL_programs/figures/figure
15.4.2.9.mxs
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

- Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 µg (3x200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
- Source: Listing 16.2.3.2

/project24/mp/blinded/e210999_mercвать/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure 15.4.2.9.txt
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 14 Values) (Safety Population)

Subject ID/Random Number:

Treatment: ■■■ Test    ★★★ Reference

- Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- Test: 600 μg (2×300 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3×200 μg tablets) levothyroxine old formulation.
- Source: Listing 16.2.5.2
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number: 

Data: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 15.4.5.2

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Figure 15.4.5.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Rando Number: 7

- Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
- Test: 800 pg (3 x 200 pg tablets) levothyroxine new formulation.
- Reference: 600 pg (3 x 200 pg tablets) levothyroxine old formulation.
- Source: Listing 15.3.5.2

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