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

Subject ID/Randome Number: 7

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 16.2.3.2

/project24/ap/blinded/a10899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure
15.4.2.10.ass

Document No. 0800b3ed083bb66 v1.9
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1099/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

For Total % Values (Safety Population)

Subject ID/Random Number:

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

Source: Listing 15.2.5.2

/project24/ep/blinded/e210699_neco/stata/versioncontrol/primary/scripts/program/main/TVA programs/figures/figure 15.4.2.10.sas
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 Values) (Safety Population)

Subject 18/Random Number:

@Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 500 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

/project54/ep/blinded/e210699_merc/stdr/versioncontrol/primary/scripts/program/main/7FL programs/figures/Figure
15.4.2.10.668

Document No: 004084185889b34v1.0
CONFIDENTIAL INFORMATION
1101/1628
Levothyroxine
EMR 200125-001
Figure 15.4.2.10 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: ●●●●

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

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CONFIDENTIAL
INFORMATION
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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: 660 μg (3×200 μg tablet) levothyroxine new formulation.
Reference: 600 μg (3×200 μg tablet) levothyroxine old formulation.
Source: Listing 15.2.3.2

/project24/ag/blinded/e31888_xerca/state/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.10.sas
Levothyroxine
EMR 200125-001

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 Values! Safety Population)

Subject ID/Random Number: 1

E: 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/24/wp/blinded/210099_merc/stats/versioncontrol/primary/scripts/program/main/PL programs/Figure 15.4.2.13.sas

11/30/2014 00:01
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 16.7.3.3

/project40011195920203205051/stats/versioncontrol/primary/scripts/program/main/TFL Programs/Figures/Figure 15.4.2.10.sas

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CONFIDENTIAL INFORMATION
1105/1628
Figure 15.4.2.16 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total TV Values) (Safety Population)

Subject ID/Random Number: 

-Subjects excluded from PW 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/e2108099_mecro/stats/versioncontrol/primary/scripts/program/main/TF programs/Figures/Figure 15.4.2.16.sas

11/02/2014 09:01
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Random Number: 1

- Subjects excluded from BE 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.

SAS Procedure: PROC TTEST

/package/ep/blinded/e210095_merc/stats/versioncontrol/primary/scripts/program/main/MFL programs/Figures/Figure 15.4.2.10.sas

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1107/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 Values) (Safety Population)

Subject ID/Random Number:

<table>
<thead>
<tr>
<th>Treatment:</th>
<th>Test</th>
<th>Reference</th>
</tr>
</thead>
</table>

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/a213849_marc/state/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure 15.4.2.10.sas

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1128/1628
Figure 15.4.2.10 CONCENTRATION-TIME PROFILES: INDIVIDUAL CONCENTRATION VERSUS ACTUAL TIME IN SEMI-LOGARITHMIC SCALE
(For Total 74 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 (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.75.2

/project24/ep/blinded/oa310899_mec/args/versioncontrol/primary/scripts/program/main/TPL programs/Figures/Figure 15.4.2.10.sas

11dec2014 02:41
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population) Subject ID/Rollin 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

/project24/ep/blinded/2102999_merc/stats/versioncontrol/primary/scripts/program/main/TFLprograms/Figures/Figure 15.4.2.10.see

11mar2014 08:01
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (3x200 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

/project2/ep/blinded/e210899/marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas

11/03/2014 06:01
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(Per Total T4 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 (3×200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3×200 μg tablets) levothyroxine old formulation.
- Source: Listing 16.i.5.2

/project24/wp/blinded/6110899_meco/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/figure
15.4.2.10.esd
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

/project4/ep/blindad/e210999_necp/stats/versioncontrol/primary/scripts/program/main/TLU programs/Figures/Figure 15.4.2.10.pdf

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[Graph showing concentration-time profiles with different markers for treatment and baseline lines.]

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11/05/2014 09:01
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

[Graph showing concentration-time profiles for different treatments]

- 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 (6.2.5.2)

/Project/Blinded/21099900/prj/primary/scripts/program/main/TFL Programs/Tables/Figure 15.4.2.10.txt

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1114/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Random Number: 1

- Subjects excluded from main population: horizontal lines represent the baseline of the respective treatments.
- Test: 500 µg (3 x 100 µg tablets) levothyroxine new formulation.
- Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
- Source: Listing 15.4.2.1

/project24/ep/blinded/c510999.merger/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.4.2.10.jpg
Subject ID/Random Number: 

Treatment: Test --- Reference

Subjects excluded from PK Populations; Horizontal lines represent the Baseline of the respective treatments. Test: 500 µg (3*160 µg tablets) levothyroxine new formulation. Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.3.5.2
**Figure 15.4.2.10** Concentration-Time Profiles: Individual Concentration versus Actual Time In Semi-Logarithmic Scale (For Total 74 Values) (Safety Population)

**Subject ID/Rand Number:**

![Graph](image)

- **Treatment:**
  - O---O: Test
  - X---X: 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 tablet) levothyroxine old formulation.

**Source:** Listing 16.2.5.2

`/project24/op/blinded/e2110899_marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas`

**Document No:** 0990b4bd6b4a644 v1.0

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Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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: 300 µg (2 x 150 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

/project24/wp/blinded/6216899_euro/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas

11DEC2014 09:01
Levothyroxine
EMR 200125-001
Bioequiv EMR200125-001 Page 1119 of 1628 saline vs. old formulation

Merek Serono
EMR 200125-001
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (3 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (2 x 300 µg tablets) levothyroxine old formulation.
Source: testing 16.1.9.7

/project/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/ITL_programs/figures/Figure 15.4.2.10.sas

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

Subject ID/Random Number: 1

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: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 15.4.2.10

/project24/ep/blinded/e210819_nece/stats/versioncontrol/primary/scripts/programs/main/TFL programs/Figures/Figure 15.4.2.10.maa

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Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1121 of 1628

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

[For Total T4 Values] [Safety Population]

Subject ID/Randone Number:

1000

150

10

-2 0 2 4 6 8 10 12 14 16 18 20

Time Point (h)

-2 0 2 4 6 8 10 12 14 16 18 20

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/blinded/a210899_zero/stats/versioncontrol/primary/scripts/program/main/FL programs/figures/Figure
15.4.2.10.mso

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Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (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

/project34/ep/blinded/a210899_xml/stats/versioncontrol/primary/scripts/program/main/TPL_programs/Figures/Figure
15.4.2.10.rst
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Random Number: 1

Legend:
- 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 (2 x 300 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.3.2

/project24/ap/blinded/e210699_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.msql
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T4 Values) (Safety Population)

Subject ID/Random Number: 1

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 16.2.5.2

/project24/wp/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TL program/Figures/Figure 1542.10_sex

11 Mar 2014 09:01

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Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 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 x 200 µg tablets) levothyroxine new formulation.
Reference: 500 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 15.4.3.2

/project24/ep/b1ndos/a210059_nerc/stats/versioncontrol/primary/scripts/program/meir/TFK programs/Figures/Figure
15.4.2.10.png

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CONFIDENTIAL
INFORMATION

1125/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Random Number:

Total T4 (ng/mL)

Time Point (h)

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

T 4: 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

/project224/cp/blinded/e210899_naro/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.4.2.10.png
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 16.3.5.2

/project24/ep/blandad/e210899_merc/stats/versionscontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas

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CONFIDENTIAL
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Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

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/arm2/arm2perl/scripts/program/main/ML_programs/figures/Figure 15.4.2.10.sas
Levethyroxine
EMR 200125-001
Merk Sero methodology
EMR 200125-001

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 Values) (Safety Population)

Subject ID/Random Number:

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

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

/project/24/mg/blinded/e970a99_rece/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figures 15.4.2.10.888

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

Subject ID/Random Number: 1

Treatment: 

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/a210899_merca/stats/versioncontrol/primary/scripts/program/main/TFL program/Figures/figure 15.4.2.10.88

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1130/1628
Levthyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1131 of 1628 solution vs. old formulation

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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: 660 µg (3*200 µg tablets) levthyroxine new formulation.
Reference: 500 µg (2*200 µg tablets) levthyroxine old formulation.
Source: Listing 15.4.2.6.4

/project24/spt/bil4/0210899_meepsilon/0210899_meepsiloncontrol/primary/scripts/program/main/TEF program/Figures/15.4.2.10.001
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T4 Values) [Safety Population]

Subject ID/Rando 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

/project24/qg/blanked/6216995_merc/stats/versioncontrol/primary/scripts/program/main/TEP program/Figures/figure
15.4.2.10.png

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11/06/2014 30:31
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 24 Values) (Safety Population)

Subject ID/Randoon Number:

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 16.1.5.2

/project24/glindas/0210899_merc/stats/versioncontrol/primary/scripts/program/ens/TP programs/Figures/Figure 15.4.2.10.888

11/08/2014 00:01
Figure 15.4.2.10 Concentration-time Profiles: Individual Concentration versus Actual Time in Semi-logarithmic Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

$\text{Total T4 (ng/mL)}$

$\text{Time Point (h)}$

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

Source: Listing 16.3.3.2

$\text{Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.}$

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1136/7628
Figure 15.4.2.19 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T4 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</td>
</tr>
<tr>
<td>Reference</td>
<td></td>
</tr>
</tbody>
</table>

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: 400 µg (3×133.3 µg tablets) levothyroxine old formulation.
Source: Listing 15.2.3.2

/project24/gp/blinded/e010899_marco/stats/versioncontrol/primary/scripts/program/main/TEL programs/figures/Figure 15.4.2.19.mam

11mar2014 06:01

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Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 74 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 16.7.5.2

/project2/ep/blinded/213899_mec/stats/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.4.2.16.988

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CONFIDENTIAL INFORMATION 1138/1628
Figure 15.4.2.10: Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 24 Values) (Safety Population)

Subject ID/Randm Number:

Treatment: Test Reference

#: subjects excluded from DK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 506 μg (2×200 μg tablets) levothyroxine new formulation.
Reference: 620 μg (3×200 μg tablets) levothyroxine old formulation.
Source: Listing 16.5.5.2

/project54/ep/blinded/c01089/node/resources/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas
Levothyroxine Bioequiv EMR200125-001 Page 1148 of 1628 Station vs. old formulation

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

Subject ID/Random Number:

- Subjects excluded from PK Population; Horizontal lines represent the baselines 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/wp/biindr/e215099_merc/stat/ versióncontrol/primary/scripts/program/main/TL program/Figures/Figure
15.4.2.10.sas

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Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 Values) [Safety Population]

Subject ID/Random Number:

- Subjects excluded from SA 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

Source: /project24/exported/4210093/macc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure 15.4.2.10.888

Date: 2014-06-30

Document No. 0900b6a6d085e46 v1.0

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1141/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-logarithmic Scale (for Total 74 Values) (Safety Population)

Subject ID/Rando Number:

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

- Subjects excluded from PK Population; horizontal lines represent the baselines of the respective treatments.
- Test: 600 µg (3 x 200 µg tablets) levothyroxine new formulation.
- Reference: 300 µg (3 x 100 µg tablets) levothyroxine old formulation.

Source: Listing 15.2.5.2

/project24/cp/blinded/e210499_wasc/stat/versioncontrol/primary/scripts/program/main/TPL/programs/figures/figure 15.4.2.10.sas
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1143 of 1628

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 Values) (Safety Population)

Subject ID/Random Number:

![Graph showing concentration vs. time profiles for levothyroxine treatments]

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 16.2.5.2

/project24/ap/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.man

11/05/2014 20:21
Levothyroxine
EMR 200125-001
Biecquiv EMR200125-001 Page 1144 of 162

Merck Serono
EMR 200125-001
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

/preproj2/cp/blinded/0210499_merc/stats/versioncontrol/primary/scripts/program/main/TTL programs/Figures/Figure 15.4.2.10.nsh

Document No.99058b4e80355866 v1.0
CONFIDENTIAL INFORMATION
1144/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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.
- Treatment: 600 μg (3x200 μg tablets) levothyroxine new formulation.
- Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
- Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.

Source: Listing 16.5.5.2

/project14/ep/blinded/6210899_marc/stats/versioncontrol/primary/scripts/program/main/TPX program/Figures/Figure 15.4.2.10.sas

11/8/2014 09:01

Document No: 9889876876569906 v1.0

CONFIDENTIAL
INFORMATION
Figure 15.4.2.16 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Random Number:

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

Source: Listing 14.2.3.2

/project/24/ep/blinded/210899_marc/state/versioncontrol/primary/scripts/programs/main/ITL programs/Figures/Figure 15.4.2.16.exe

Document No.909bbed88f3bb66 vol.1.0
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total TV Values) (Safety Population)

Subject ID/Rand Number:

8: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 699 µg (3x200 µg tablets) Levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) Levothyroxine old formulation.
Source: Listing 15.2.2.2
/project24/eq/blinded/e210899_warcs/stats/versioncontrol/primary/scripts/program/main/TPL programs/Figures/Figure
15.4.2.10_ran

Document No: 09016jbc80655h46 r1.0
CONFIDENTIAL
INFORMATION

1147/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 15.2.5.2

/project24/ep/blinded/e210959_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure 15.4.2.10.sas
Levethyroxine
EMR 200125-001

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total 74 Values) (Safety Population)

Subject ID/Random Number: **

Treatment: ○○○ Test

@ Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (2 x 200 µg tablets) levethyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levethyroxine old formulation.
Source: Listing 16.3.5.2

/project24/ep/blinded/821099_marx/stats/versioncontrol/primary/scripts/program/main/tif programs/figures/figure
15.4.2.10.png

Document No.9900babe80851b46 v1.0

CONFIDENTIAL
INFORMATION

1149/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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>0</td>
<td>Test</td>
</tr>
<tr>
<td>2</td>
<td>Test</td>
</tr>
<tr>
<td>4</td>
<td>Test</td>
</tr>
<tr>
<td>6</td>
<td>Test</td>
</tr>
<tr>
<td>8</td>
<td>Test</td>
</tr>
<tr>
<td>10</td>
<td>Test</td>
</tr>
</tbody>
</table>

- 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 16.2.2.2

/project24/ep/blinded/e210899_merc/state/versioncontrol/primary/scripts/program/main/YYl programs/figures/figure
15.4.2.10.exe
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total N 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: 400 µg (2 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 16.3.5.2

/project24/cp/blinded/a0108981/merge/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.10.sas

16DEC2014 50:21

Document No: 09060b10e085bb46 v1.0

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151/152
Levothyroxine
EMR 200125-001

Biorheology EMR 200125-001 Page 1152 of 1628 Site vs. old formulation

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 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>
<td>●●●●</td>
<td>●●●●</td>
</tr>
<tr>
<td>10</td>
<td>●●●●</td>
<td>●●●●</td>
<td>●●●●</td>
</tr>
</tbody>
</table>

Subjects excluded from PK Population; horizontal lines represent the Baseline of the respective treatments.
Test: 690 µg (3×230 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.

Source: Listing 16.5.3.2

/project24/ep/blind/4218899_merc/stats/versioncontrol/primary/scripts/program/merl/program/Figures/Figures/15.4.2.10.asc

Document No. 1150125-001
CONFIDENTIAL INFORMATION
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Levothyroxine

EMR 200125-001 Page 1153 of 1628

Subject ID/Random Number:

![Graph showing Concentration-Time Profiles]

- 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: 630 µg (3 x 200 µg tablets) levothyroxine old formulation.

Source: Listing 16.5.5.2

/project24,ep/blinded/6210899_marc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.10.xlsx

1153/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale

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 (2 x 200 μg tablets) levothyroxine old formulation.
Source: Listing 16.3.3.2

/project24/ep/blanked/e210899_marc/stats/versioncontrol/primary/scripts/program/main/TL programs/figures/figure 15.4.2.10.sas

Confidential

Document No: 09000abce8055bb6 v1.0

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Levothyroxine
EMR 200125-001

Figure 15.4.7.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (for Total T4 Values) (Safety Population)

Subject ID/Randon 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: 500 µg (3*166.6 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/p110889_encaps/saas/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.9.10.sas

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INFORMATION

1155/1528
Levothyroxine
EMR 200125-001

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-logarithmic 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 tablet) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Listing 15.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas

Document No:9908abed485b846 v1.0
CONFIDENTIAL
INFORMATION
1156/1628
Levothyroxine

Bioequiv EMR200125-001 Page 1157 of 1629 isolation vs. old formulation

Figure 15.4.2.19 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale 
(For Total T4 Values) (Safety Population)

Subject ID/Random Number:

86: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600μg (3x200μg tablets) levothyroxine new formulation.
Reference: 600μg (3x200μg tablets) levothyroxine old formulation.
Source: listing 10.3.5.7

/project24/ep/blinded/s210699_meco/stats/versioncontrol/primary/scripts/program/main/TFL.programs/Figures/Figure 15.4.2.19.mss

11DEC2014 00:01
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) [Safety Population]

Subject ID/Random Number:

- Subjects excluded from FE 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 16.4.5.2

/project24/ep/bin/download/010899_mero/state/versioncontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.4.2.10.exe

Document No.0908ebe4385bb46 v1.0

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

Subject ID/Random Number:

![Graph showing concentration-time profiles with labeled treatments and time points.]

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

Test: 600 μg (3x200 μg tablets) levothyroxine new formulation.
Reference: 400 μg (3x200 μg tablets) levothyroxine old formulation.

Source: Listing 16.3.3.2

/project/04/sp/blinded/a10/09/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas

Document No.09083b4e80858846 v1.0

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Levothyroxine Bioequiv EMR200125-001 Page 1160 of 1628

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) [Safety Population] Subject ID/Random Number:

1000

100

10

Total T4 (mg/L)

0

2 4 6 8 10 12 2 4 6 8 10 12

Time Point (h)

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 15.7.5.7

/project24/ep/blinded/4219899_merck/stats/versionscontrol/primary/scripts/program/main/TFL_programs/Figures/Figure 15.4.2.10.sae

11DEC2014 00:01
Figure 15.4.2.30 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 15.4.2.2
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Rando Number:

- 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/e210699_mcrs/stats/versioncontrol/primary/scripts/program/main/TEI/programs/Figures/Figure 15.4.2.10.sas

Document No. 09000b948d93bb46 v.1.0
CONFIDENTIAL INFORMATION

1162/1623
Figure 15.4.2.10 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: 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 15.4.2.2

/project24/dr/021999/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure 15.4.2.10.sas
Levothyroxine

Merck Serono
EMR 200125-001

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total 74 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: 500 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.1.5.2
Levothyroxine
EMR 200125-001

Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic scale
(For Total 74 Values)(Safety Population)

Subject ID/Random Number:

Total T4 (ng/mL)

Time Point (h)

Treatments
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 16.4.2.2

/project24/op/blinded/8210899_mrec/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.10.mad
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population) Subject ID/Random Number: 1

- Subjects excluded from % 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 16.5.5.2

/project24/op/blindse/a210899_merc/stats/versioncontrol/primary/scripts/progmn/main/TEG programs/Figures/Figure 15.4.2.10.sae
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (3 x 200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3 x 200 μg tablets) levothyroxine old formulation.
Source: Listing 16.3.2

/project/ep/blinded/a210899_mncx/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
15.4.2.10.png

11DEC2018 00:01
Figure 15.4.2.10 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; 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 16.1.b.2.

/project24/ep/hbbind/m210949_merc/stats/versioncontrol/primary/scripts/program/main/XPL program/figures/Figure 15.4.2.10.398

Document No. 0000babe40839b48 v1.0
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Levothyroxine Bioequiv EMR200125-001 Page 1169 of 1628

Subject ID/Random Number:

@Subjects excluded from 9% Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 800 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 608 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Listing 10.3.5.2

/project24/ep/blinded/e210899_parac/stats/versioncontrolPRIMARY/scripts/program/main/spl programs/Figures/Figure
15.4.2.10.sas

11/04/2014 00:00
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (3x200 μg tablets) levthyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levthyroxine old formulation.
Source: Listing 15.2.5.2

/project24/wp/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.jpg

Document No:0900babc8486666666 v1.0

CONFIDENTIAL INFORMATION

11701628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Randome Number:

[Graph showing concentration-time profiles with legend: 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 14.5.5.2

/project24/ep/blinded/e210093_merc/stats/versioncontrol/primary/scripts/program/main/TFL_programs/figures/figure
15.4.2.10.css

Document No.0906bea80850b46 v.1.0

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INFORMATION

1171/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 15.4.2.5.2

/Project24/ep/blinded/e210899_marcc/stata/versioncontrol/primary/scripts/program/main/TEF программы/figures/Figure
15.4.2.10.sas

Document No: 0080bc8b80895b49 v1.0
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Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1173 of 1628

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

Subject ID/Randome Number:

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: 400 μg (3*133 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/wp/blinded/a210699_mars/stats/versioncontrol/primary/scripts/program/main/IFL programs/Figures/Figure
15.4.2.10.msm

11/01/2014 06:21

Document No.9900abbe#0831b46 v1.0

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1173/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 x 200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levothyroxine old formulation.
Source: Listing 16.7.3.2

/project/24/ep/blinded/s210699_mero/stats/versioncontrol/primary/scripts/program/main/TFL_programs/figures/figure 15.4.2.10.png
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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

/project24/ep/blinded/e210894_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/figures/Figure 15.4.2.10.sas

11may2014 09:01
Subject ID/Random Number:

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

- **Treatment:** 600 mg (3×200 mg tablets) levotyroxine new formulation.
- **Test:** 600 mg (3×200 mg tablets) levotyroxine old formulation.

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

Reference: 600 mg (3×200 mg tablets) levotyroxine old formulation.

Source: Listing 16.4.2.10

Confidential

Document No. 890018ab40859b46 v1.0

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INFORMATION

1176/1628
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentrations versus Actual Time in Semi-logarithmic Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:

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 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Listing 16.3.5.2

/project24/ep/blinded/e21089x_mec/stats/versioncontrol/primary/scripts/program/main/7FL programs/Figures/Figure 15.4.2.10.sas

1/12/2014 62:51
Figure 15.4.2.10 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; horizontal lines represent the baseline of the respective treatments.
Test: 600 µg [5×120 µg tablets] levothyroxine new formulation.
Source: Listing 16.7.5.2

/project24/op/blindtca0210899_medc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas

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1176/1628
Figure 15.4.2.30 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (For Total T4 Values) (Safety Population)

Subject ID/Random Number:

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

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: Lasting et al.
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale (for Total T4 Volume) (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>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
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<td>12</td>
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<td>14</td>
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<tr>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8: Subjects excluded from PK Population: Horizontal lines represent the Baseline of the respective treatments.
Test: 400 µg (3×100 µg tablets) levotyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levotyroxine old formulation.

Source: Listing 16.2.5.2

/project26/ep/blinded/e21089_merc/stats/versioncontrol/primary/scripts/program/main/T5B programs/figures/Figure 15.4.2.10.sas
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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: 690 µg (3×230 µg tablets) levothyroxine new formulation. Reference: 690 µg (3×230 µg tablets) levothyroxine old formulation.

Source: Listing 15.2.5.2

/project24/wp/blinded/6310969_nerc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 (3x200 μg tablets) levothyroxine new formulation.
Reference: 600 μg (3x200 μg tablets) levothyroxine old formulation.
Source: Listing 16.2.4.2

/project24/ep/blindroc/210999_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.10.sas

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1182/1623
Levotyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1183 of 1628

Subject ID/Random Number:

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

Treatment: [Graph showing concentration-time profile]

0: Subject 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 16.2.8.2

/project24/ap/blinded/m210899_merc/stats/versioncontrol/primary/scripts/program/main/YFL/programs/figures/figure
15.4.2.10.mes

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CONFIDENTIAL
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1183/1628
8: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Treat: 600 µg (3x200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3x200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.3.2

/project24/ap/blinded/e110890_maxc/stats/versioncontrol/primary/scripts/program/main/TLT_program/figures/figure
15.4.2.10.sas
Figure 15.4.2.13 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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 mcg (3×200 mcg tablets) levothyroxine new formulation.
Reference: 600 mcg (3×200 mcg tablets) levothyroxine old formulation.

Source: Listing 15.2.5.2

/project24/ge/blinded/e210899_marc/statarevisedcontrol/primary/scripts/program/main/ITL programs/Figures/Figure 15.4.2.13.eas

Document No 09087be0885a46 v1.0
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1185/1628
Levethyroxine
EMR 200125-001

Figure 16.4.2.10 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; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3 x 200 µg tablets) levethyroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levethyroxine old formulation.
Source: Listing 16.2.5.2

/project2439p/blinded/411899_merc/stats/versioncontrol/primary/scripts/program/main/TEL program/Figures/Figure 16.4.2.10.mss

Document No.090888b60685b666 v1.0 CONFIDENTIAL INFORMATION 11B9/1625
Levothyroxine
EMR 200125-001

Bioserv EMR200125-001 Page 1187 of 162

Figure 15.4.2.30 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic Scale
(For Total T4 Values) (Safety Population)

Subject ID/Random Number:

Total T4 (ng/mL)

0 1 2 3 4 5 6 7 8 9
Time Point (h)

0 100 200 300 400 500

Treatment: ● Test: ●Reference: ●

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 15.4.2.3.2
/project/ep/blinded/210899_merc/state/versioncontrol/primary/scripts/program/main/TFL programs/figures/figure
15.4.2.30.exe

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CONFIDENTIAL INFORMATION
Document No.9008abed083bbe6v1.0
Figure 15.4.2.10 Concentration-Time Profiles: Individual Concentration versus Actual Time in Semi-Logarithmic 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.
- Treatment: 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/libdren/e210899werp/stats/versioncontrol/primary/scripts/program/main/IT2programs/figures/figure 15.4.2.10.es8
Levothyroxine Bioequiv EMR200125-001 Page 1189 of 1628

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:

Graph showing the concentration-time profiles for levothyroxine with treatment categories indicated.

- 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

/content/ep/absn/40108595/absn/stats/merk/content/primary/abstract/program/main/4T3 programs/Figures/Figure 154.2.12.png

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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)

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 16.0.3.3.
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:

![Graph](image)

6: Subjects excluded from PK Populations:
Test: 800 µg (3×260 µg tablets) Levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) Levothyroxine old formulation.
Source: Table 16.2.5.1
Figure 15.4.2.11 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T3 Values) (Safety Population)

Subject ID/Random Number:

- Treatment: ● ● ● Test  ● ● ● Reference

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 16.2.5.3

/project24/ep/blinded/e210899_merco/stats getVersioncontrol/primary/scripts/program/main/TBL programs/Figures/Figure 15.4.2.11.rss
Figure 15.4.2.11 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total 73 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>2  4  6  8  1  3  5  7</td>
</tr>
<tr>
<td>Reference</td>
<td></td>
</tr>
</tbody>
</table>

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 16.4.5.3

/project24/ep/blinded/0211894_merc/stats/veveyloncontrol/primary/scripts/program/main/TPL programs/Figures/Figure 15.4.2.11.msp
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 (2×300 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.
Source: Table 16.2.3.3

/project24/ep/blind/22109596_aero/stats/versioncontrol/primary/scripts/program/assm/TFL programs/Figures/Figure 15.4.2.11.ras
Levotiroxine Bioequiv EMR200125-001 Page 1195 of 1628

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

8: Subjects excluded from PK Population;
Test: 600 µg (3 x 200 µg tablets) levotiroxine new formulation.
Reference: 600 µg (3 x 200 µg tablets) levotiroxine old formulation.
Source: Table 15.2.8.3

/project24/wp/blinded/wd10899_marc/stats/versioncontrol/primary/scripts/program/main/7FL_programs/Figures/Figure 15.4.2.11.msp
Subject ID/Random Number:

Treatment:

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

Subjects excluded from DX Population:

0

Reference:

Time Point (h)

0 2 4 6 8 1 2 4 6 8 10 12 14 16 18 20

0.2 0.4 0.6 0.8 1 1.2 1.4 1.6 1.8

Total T3 (ng/mL)
Levothyroxine

EMR 200125-001

Figure 15.4.2.13 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T3 Values) (Safety Population)

Subject ID/Random Number:

- Total T3 (ng/mL)
- Time Point (h)
- Treatment: Test, Reference

Subjects excluded from PK Population:
Test: 660 µg (3×200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3×200 µg tablets) levothyroxine old formulation.

Source: Table 15.4.5.3

/project24/ep/blinded/0310899/marc/stats/versioncontrol/primary/scripts/program/main/TLM programs/figures/figure
15.4.2.13.png
Figure 25.4.3.11 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear 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 16.2.5.3

[Graph showing concentration-time profiles with time points on the x-axis and T3 (µg/mL) on the y-axis.]
Figure 15.4.2.11 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T3 Values) (Safety Population)

Subject ID/Rand 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 16.2.5.3

/project24/write/blinded/s210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL/programs/Figures/Figure 15.4.2.11.png
Levothyroxine
EMR 200125-001

Bioequiv EMR200125-001 Page 1200 of 1628 elution vs. old formulation

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:  
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 16.2.9.3

/Project24/ep/blinded/q210999_necc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.11.a20

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