

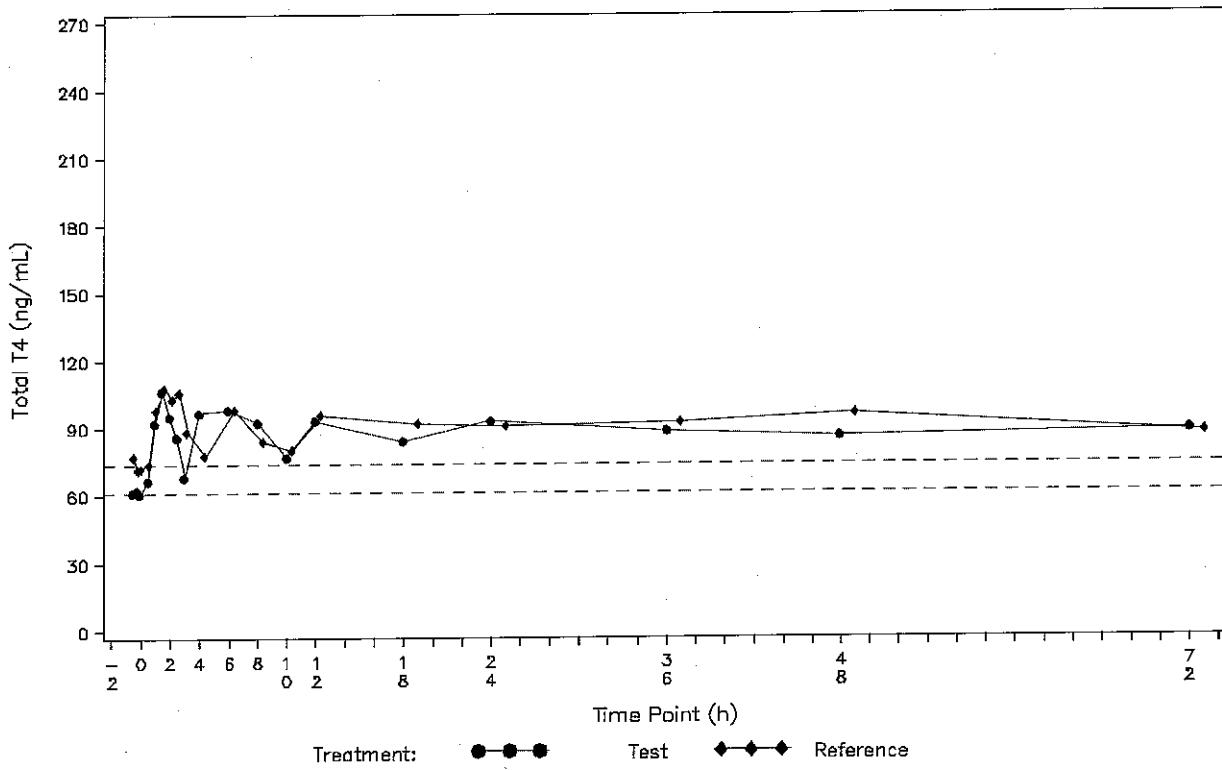
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 801 of 1628 ualuation vs. old formulation

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Confidential

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:



@: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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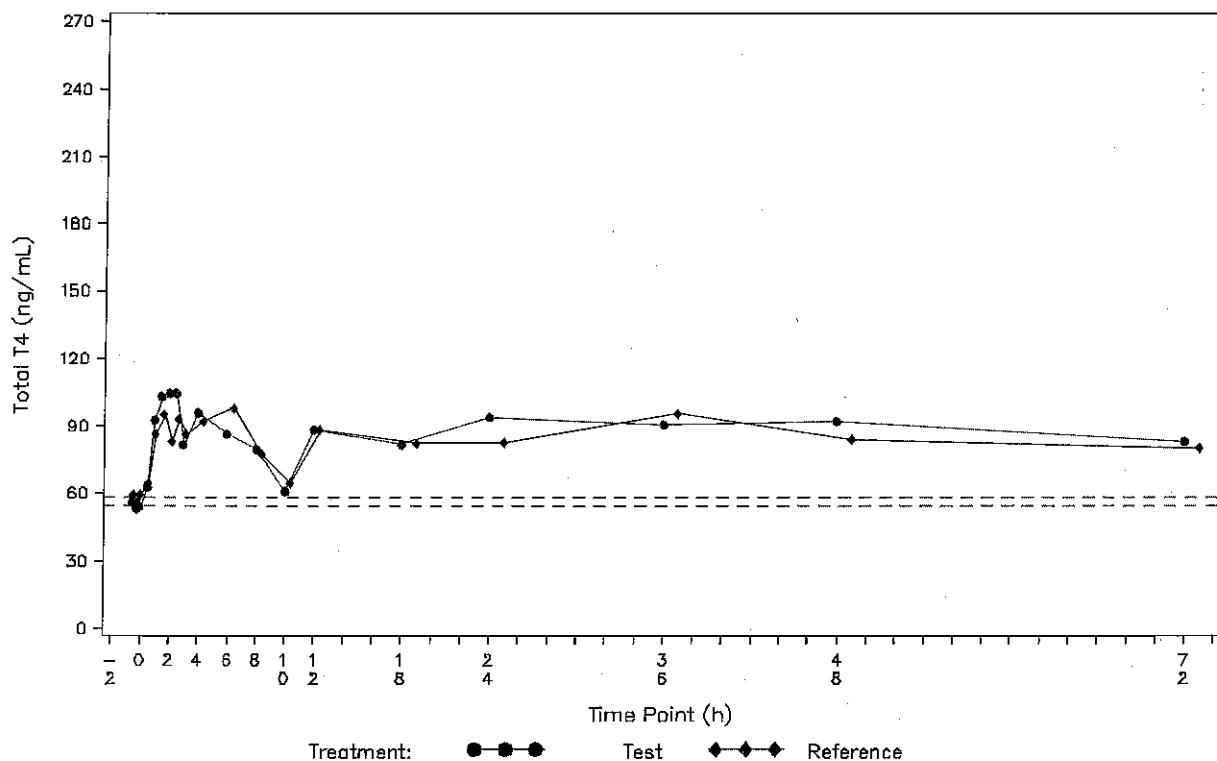
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



@: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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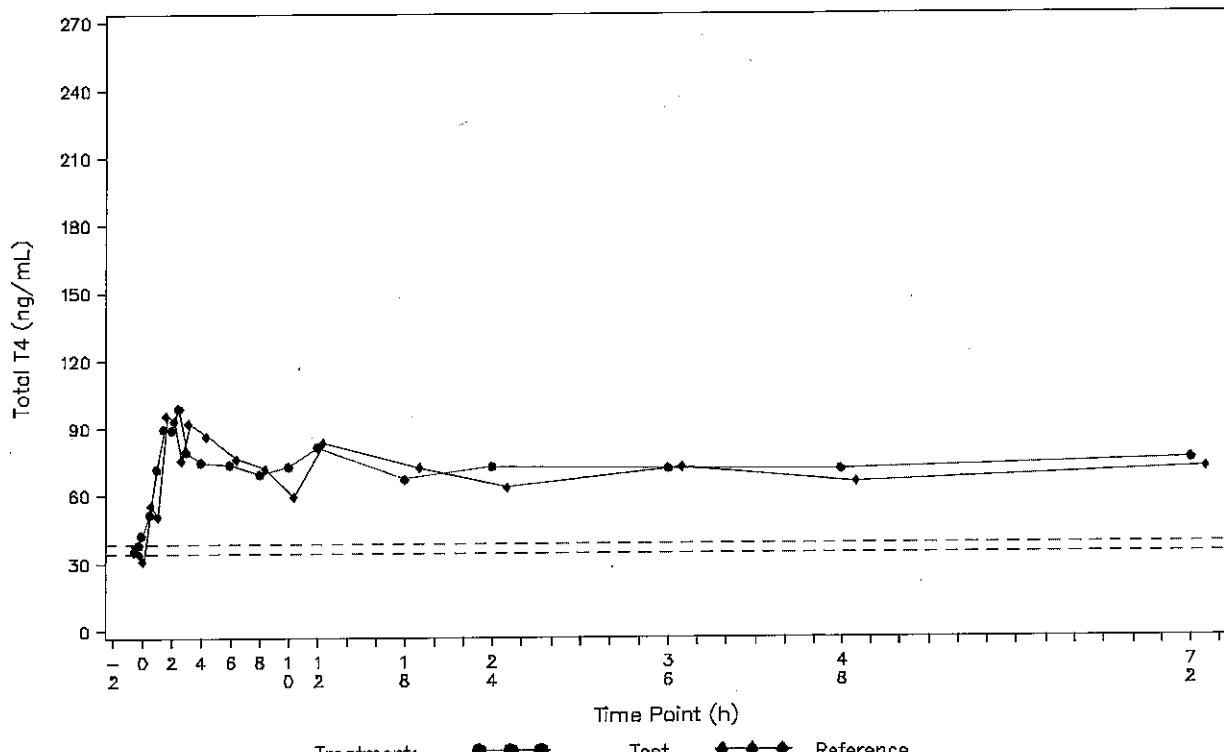
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 803 of 1628 ulation vs. old formulation

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Confidential

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: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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15.4.2.9.sas

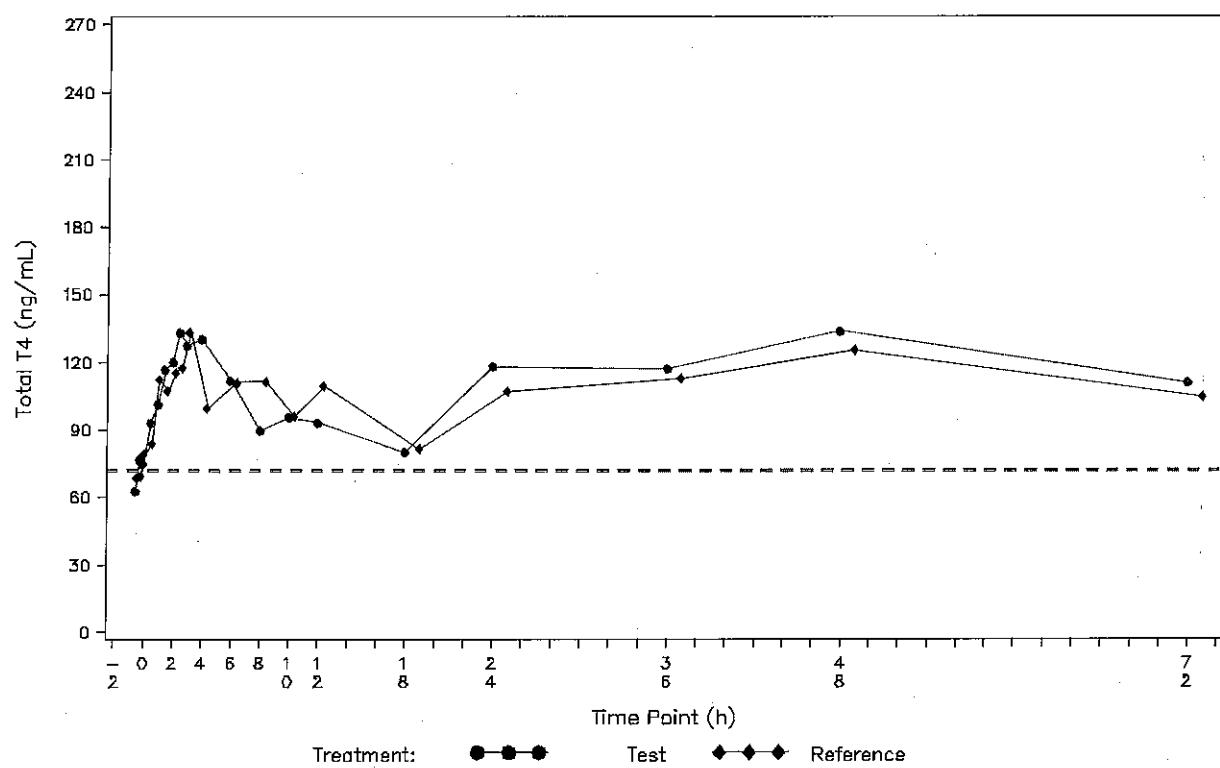
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number: 1155



@: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE
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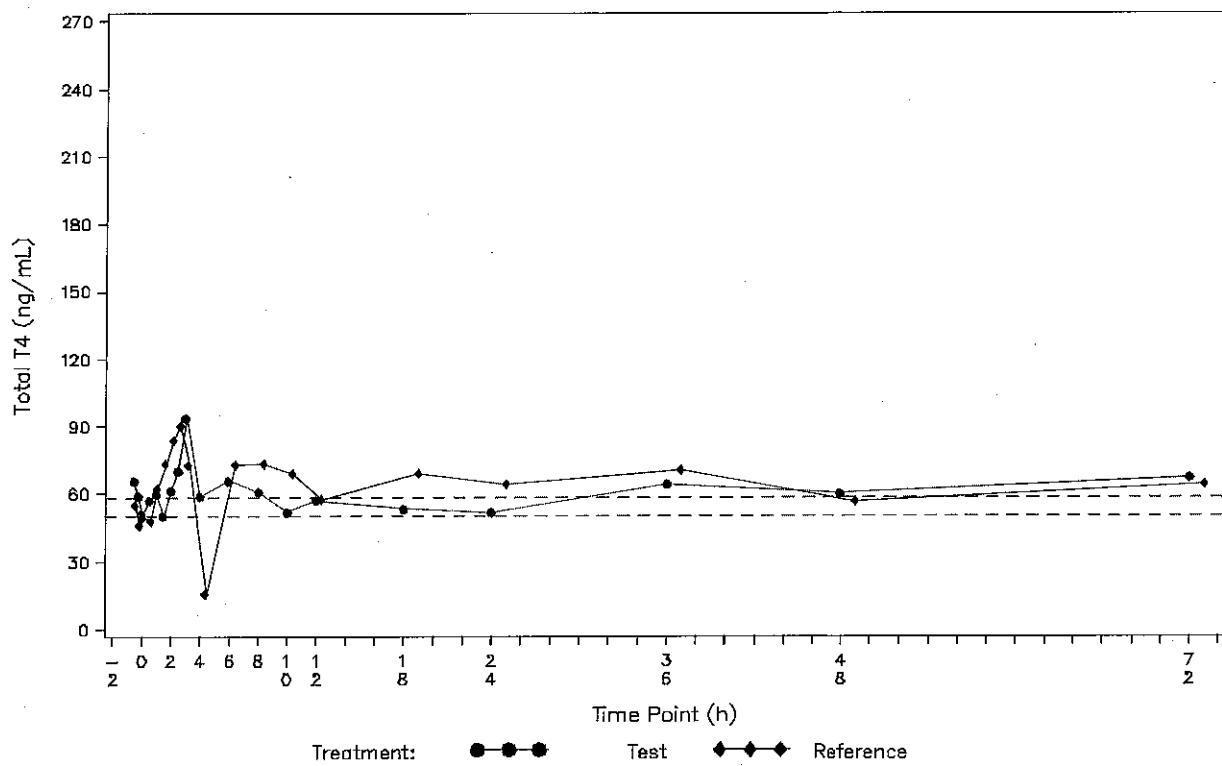
Levothyroxine
EMR 200125-001

Bioequiv^e EMR200125-001 Page 805 of 1628 ualuation vs. old formulation

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Confidential

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: Listing 16.2.5.2

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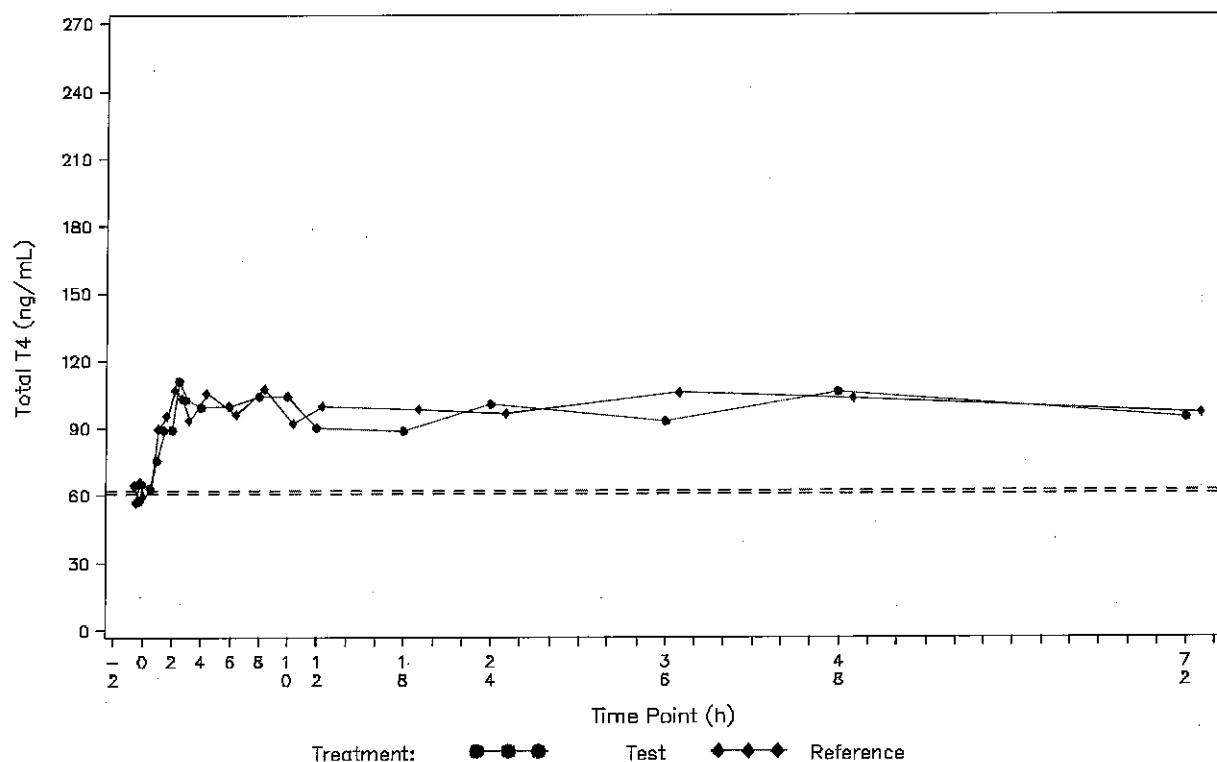
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 806 of 1628 ulation 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)

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Confidential

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 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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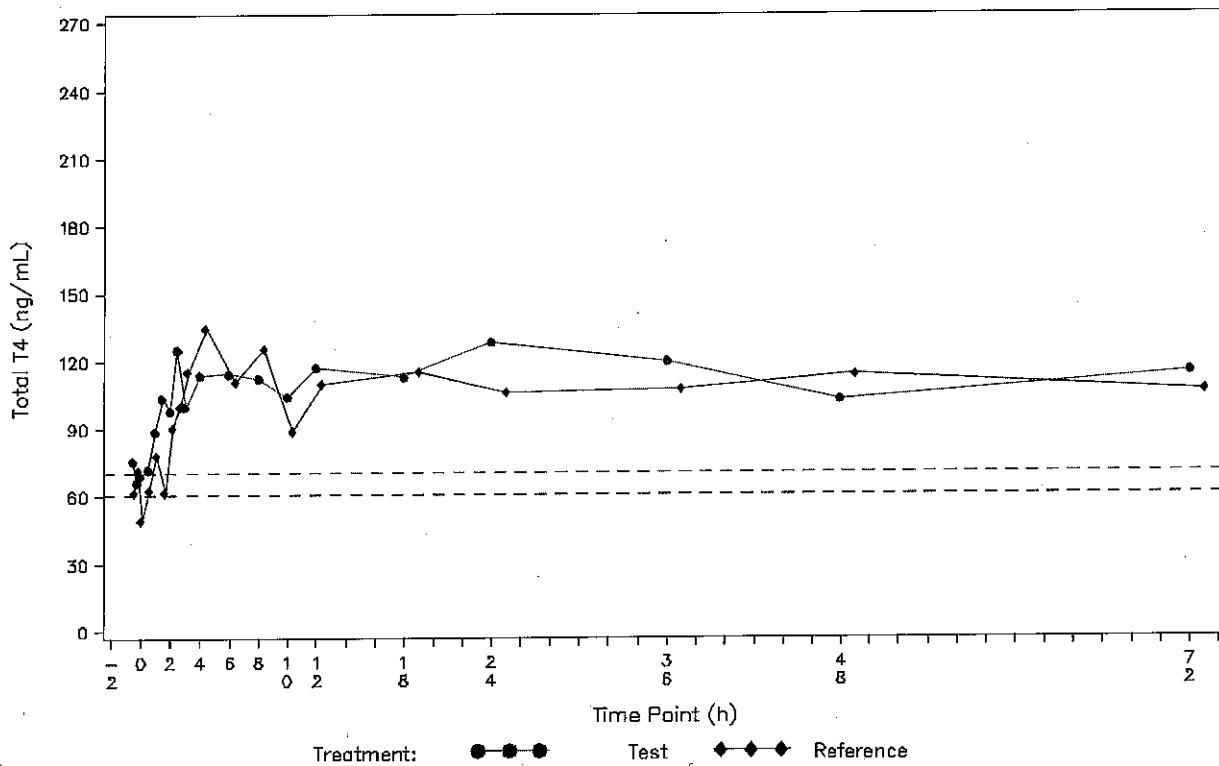
Levothyroxine
EMR 200125-001

Bioequiv^v EMR200125-001 Page 807 of 1628 ulation vs. old formulation

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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:



@: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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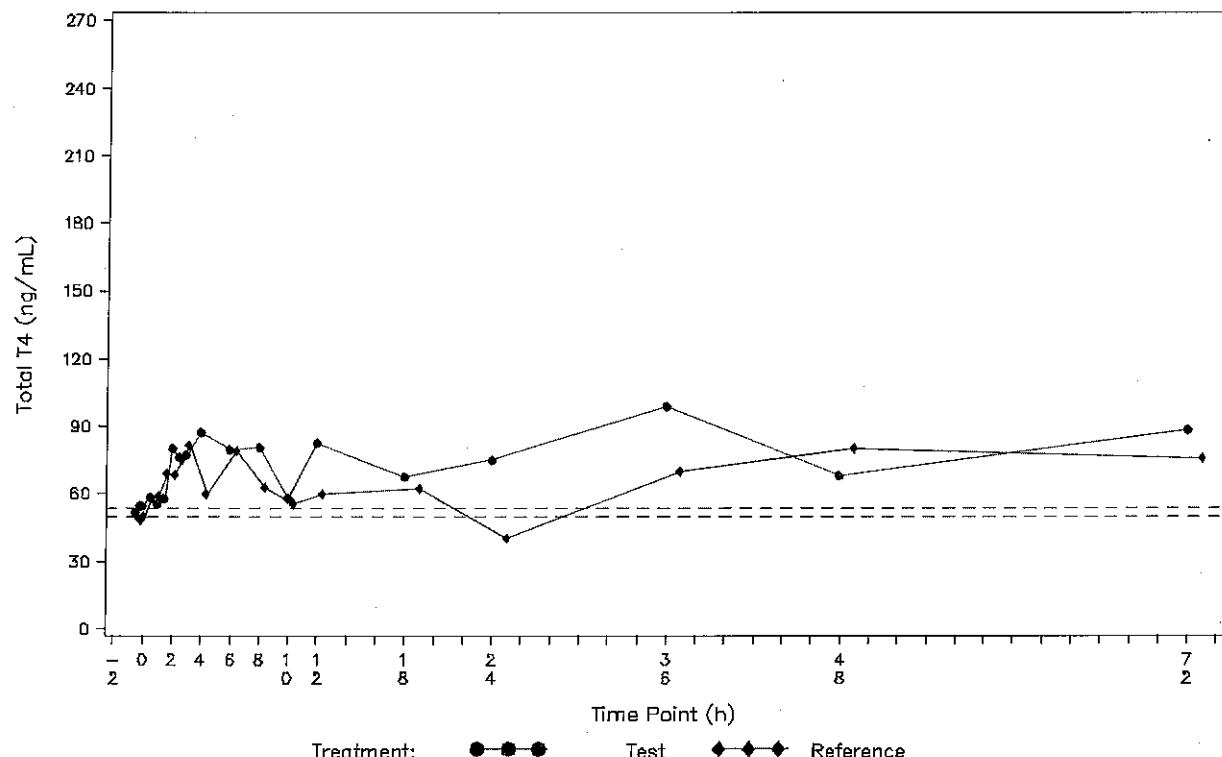
**Levothyroxine
EMR 200125-001**

Bioequiv EMR200125-001 Page 808 of 1628 ulation 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)

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Subject ID/Random Number:



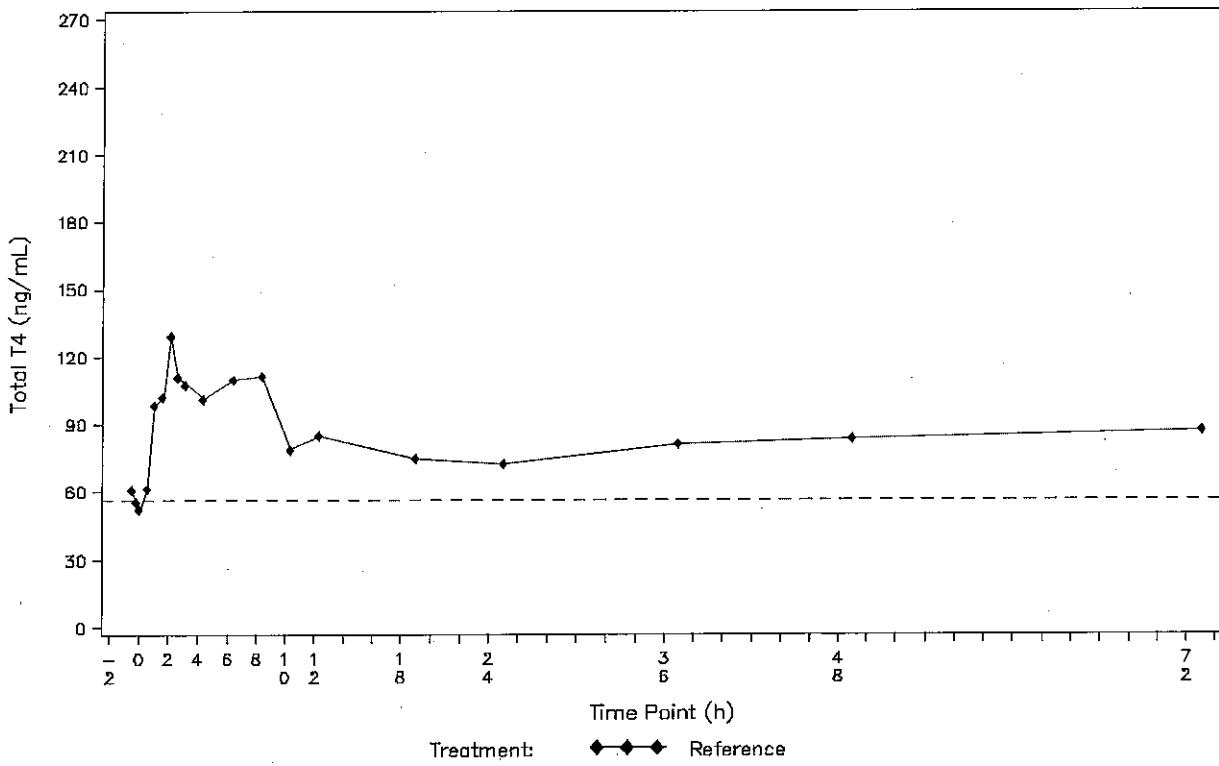
Levothyroxine
EMR 200125-001

Bioequiv^e EMR200125-001 Page 809 of 1628 ualuation vs. old formulation

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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:



@: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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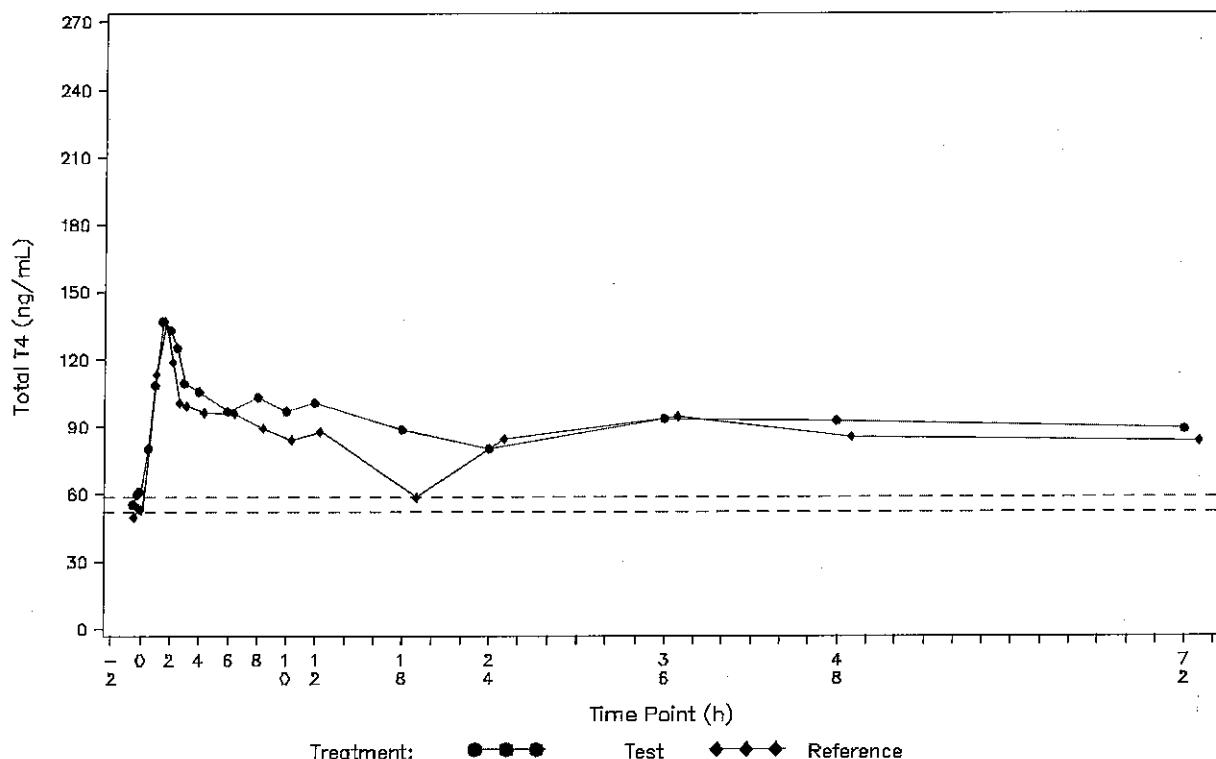
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



@: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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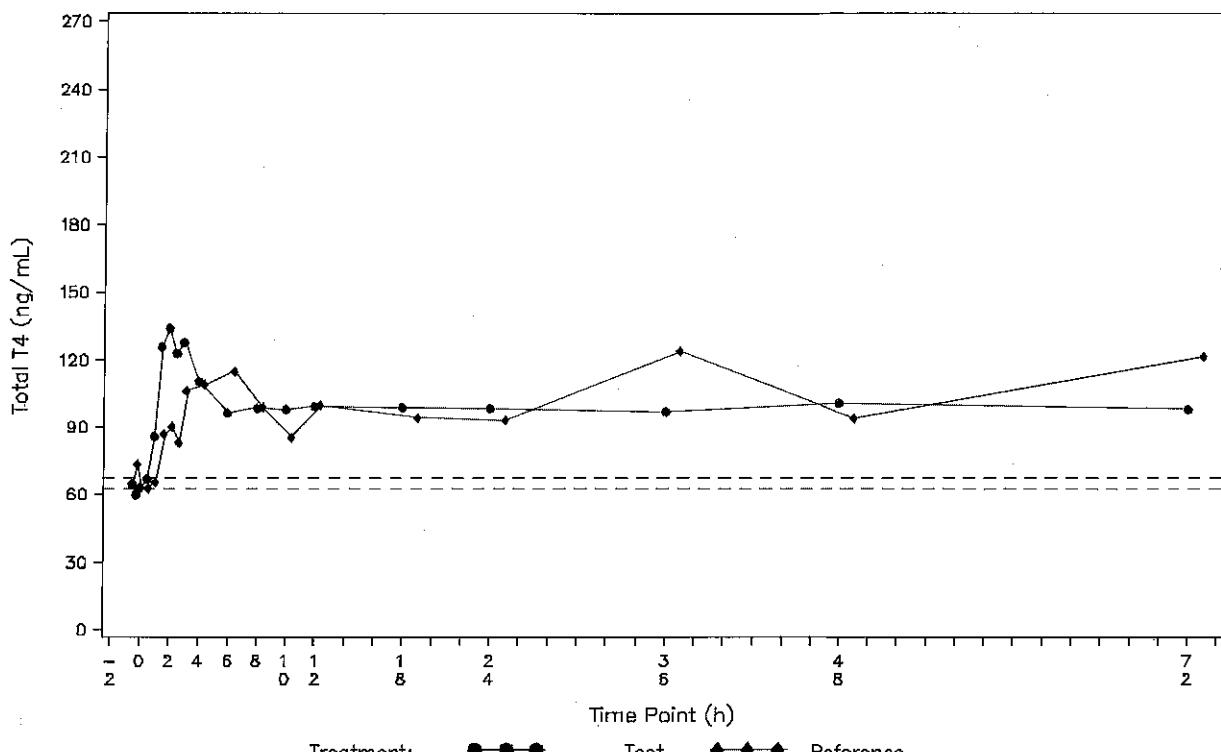
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 811 of 1628 ualation vs. old formulation

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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: 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

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15.4.2.9.sas

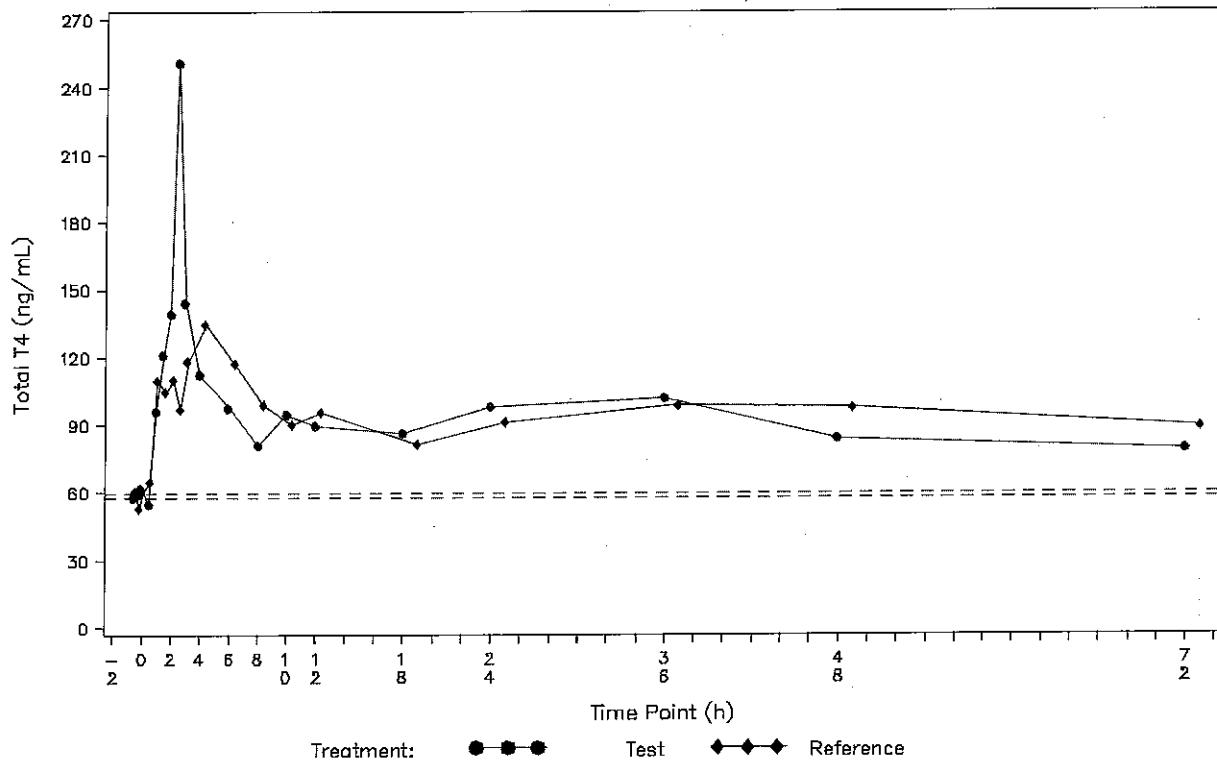
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles; Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number: 1

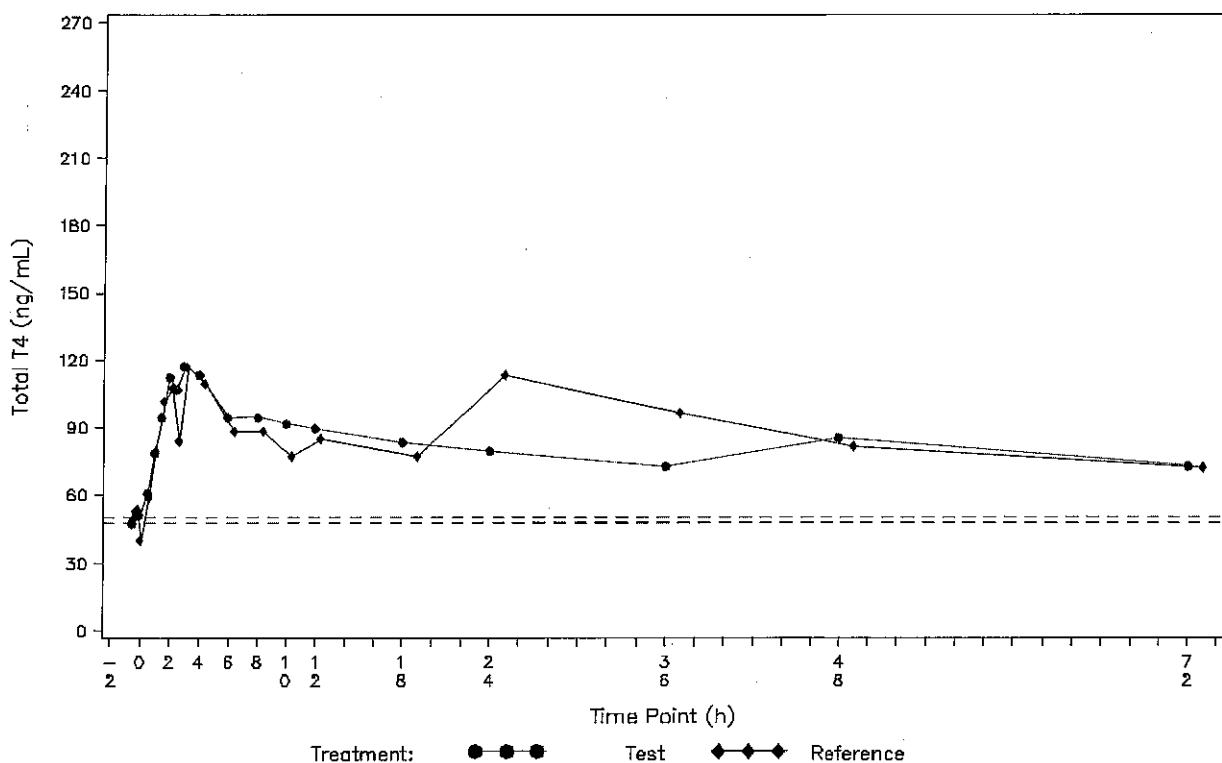


④ Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TEF 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:

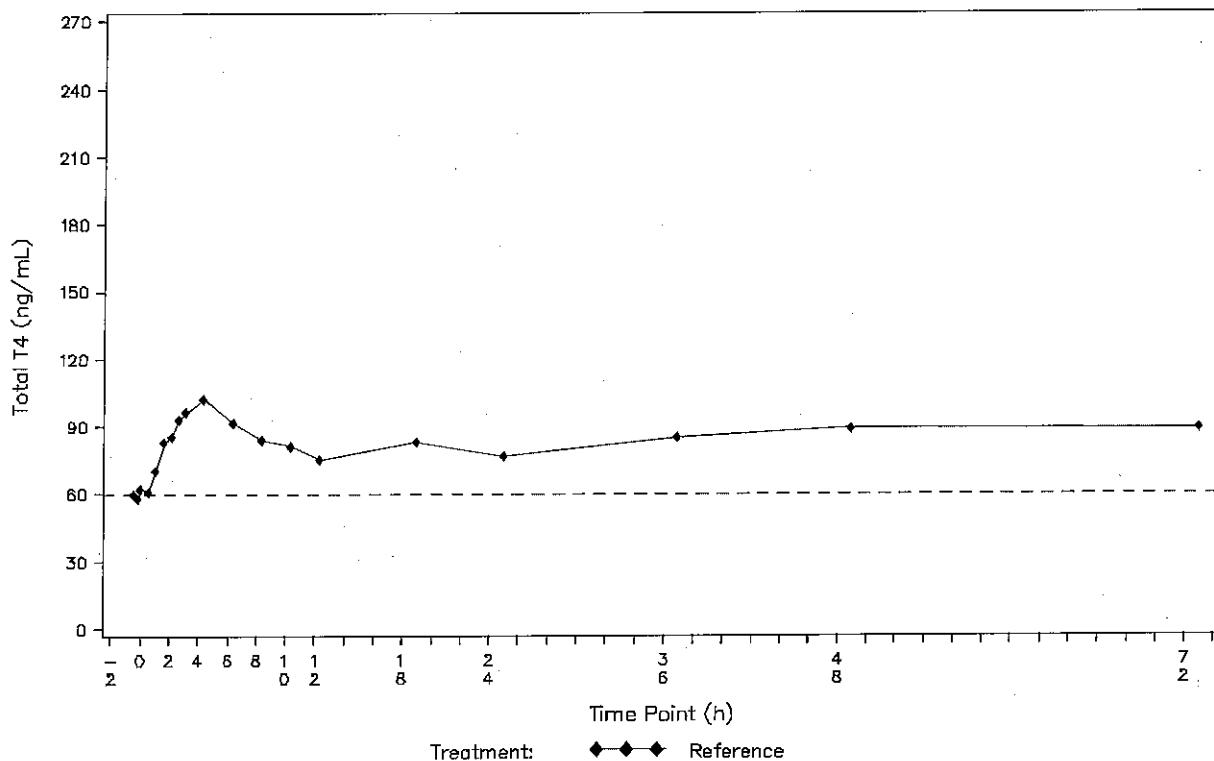


@:Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
Source: Listing 16.2.5.2

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15.4.2.9.sas

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:



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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15.4.2.9.sas

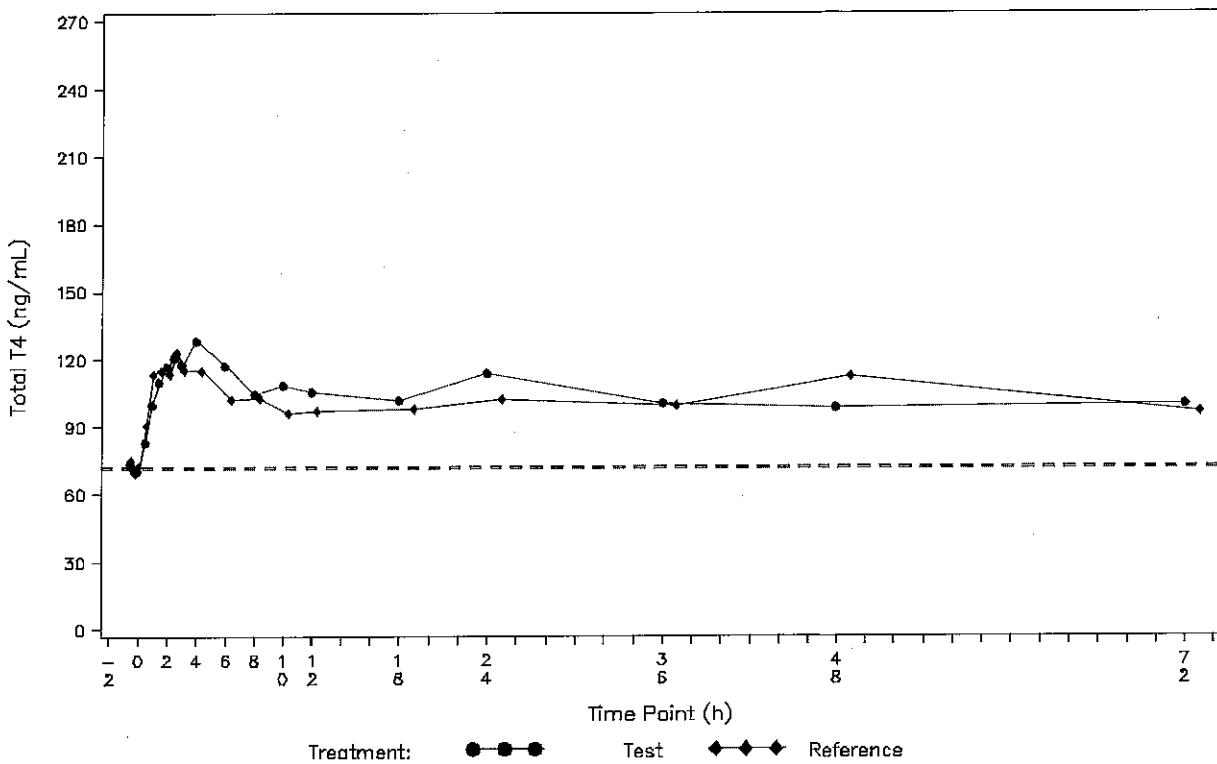
Levothyroxine
EMR 200125-001

Bioequiv^v EMR200125-001 Page 815 of 1628 ulation vs. old formulation

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Confidential

Merci 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:



④ 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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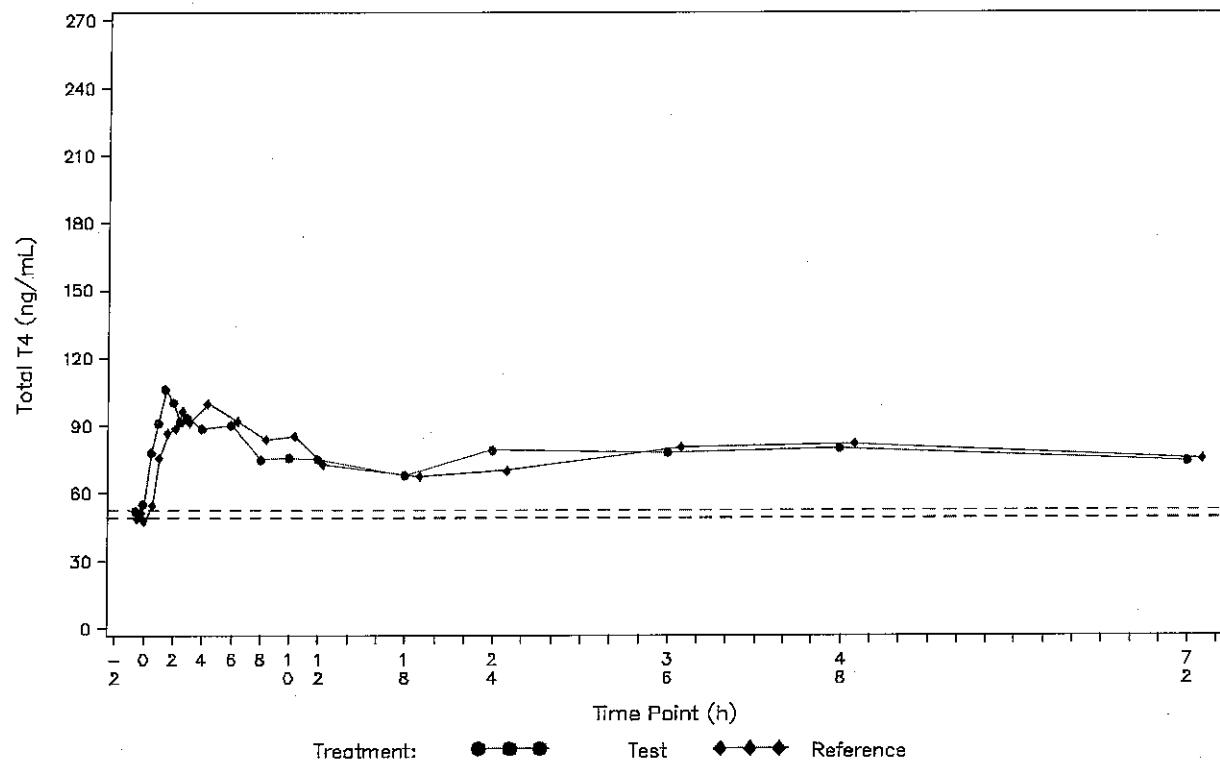
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:

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④: 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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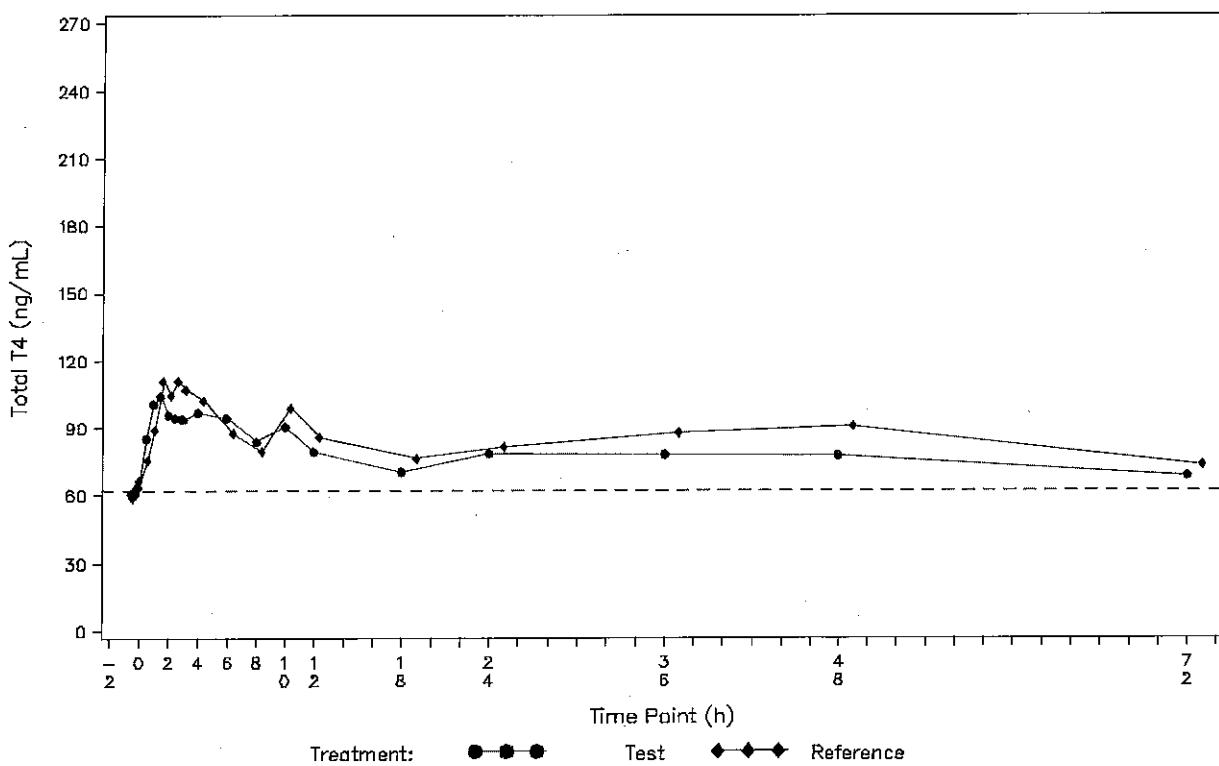
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 817 of 1628 ulation vs. old formulation

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Confidential

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:



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 16.2.5.2

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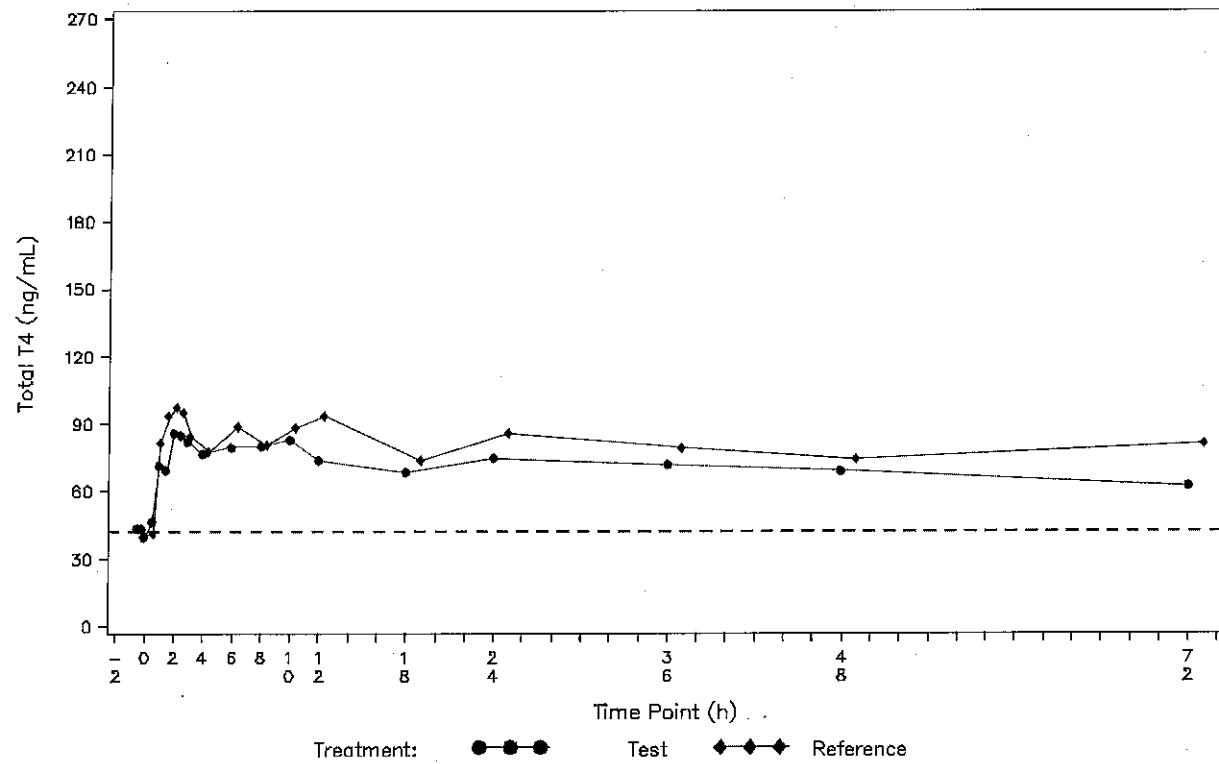
Levothyroxine
EMR 200125-001

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

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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:



©: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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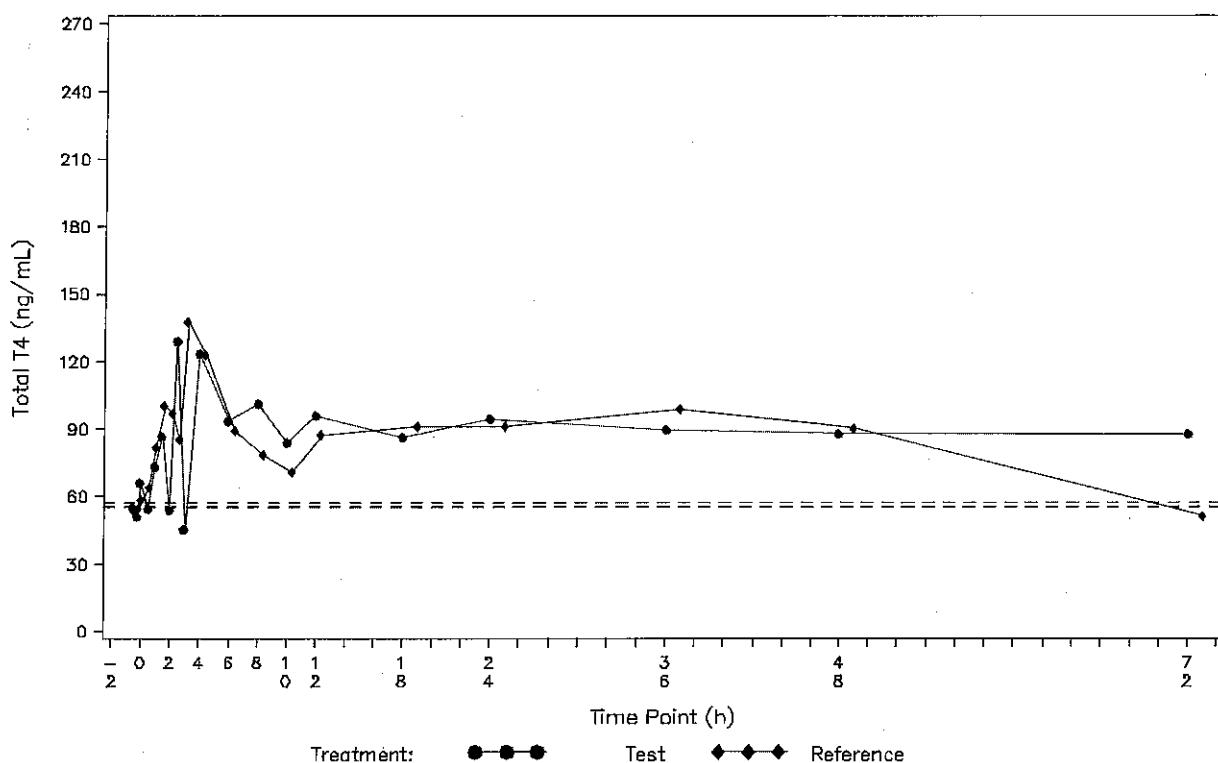
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



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

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

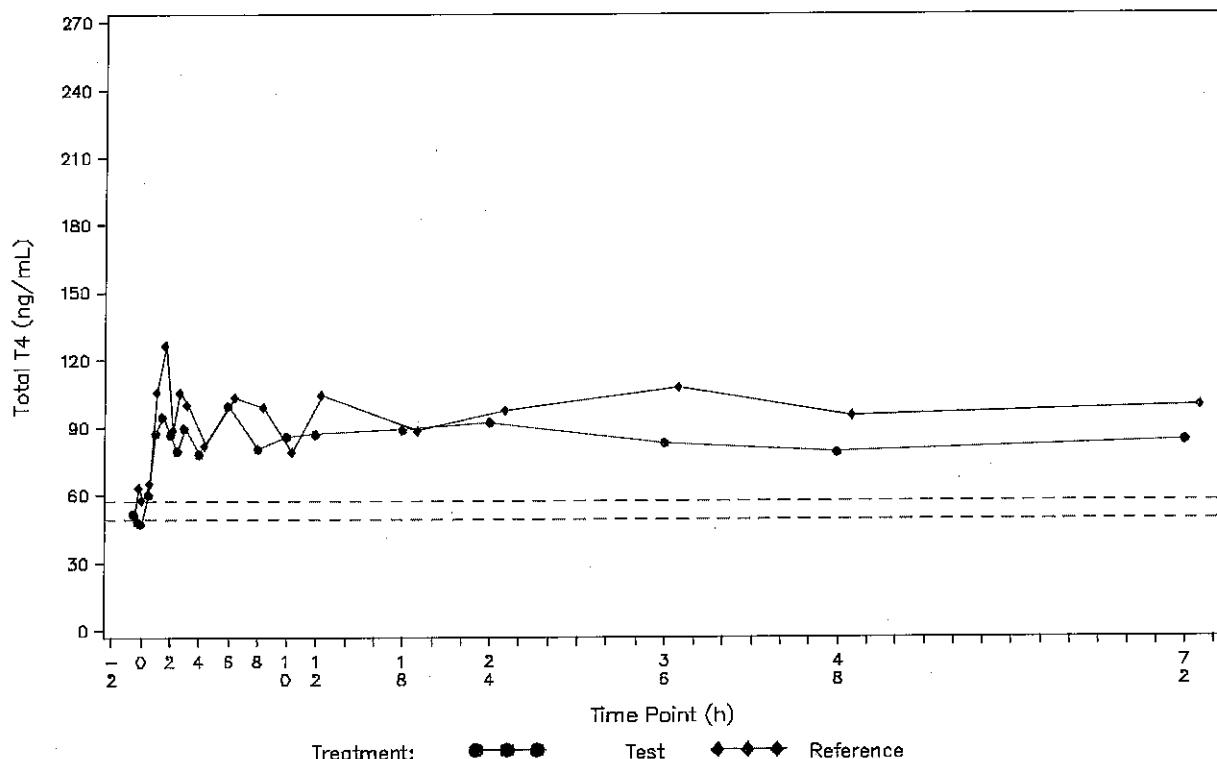
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

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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:



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.

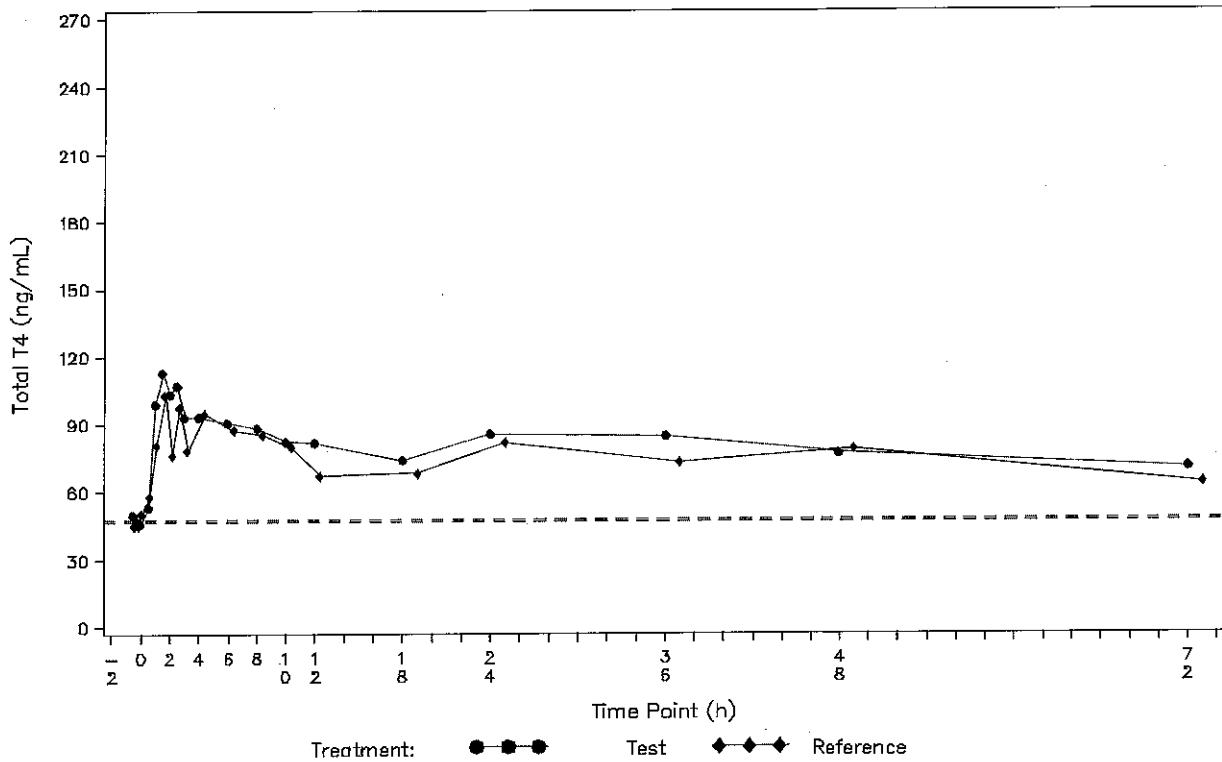
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

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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:



@: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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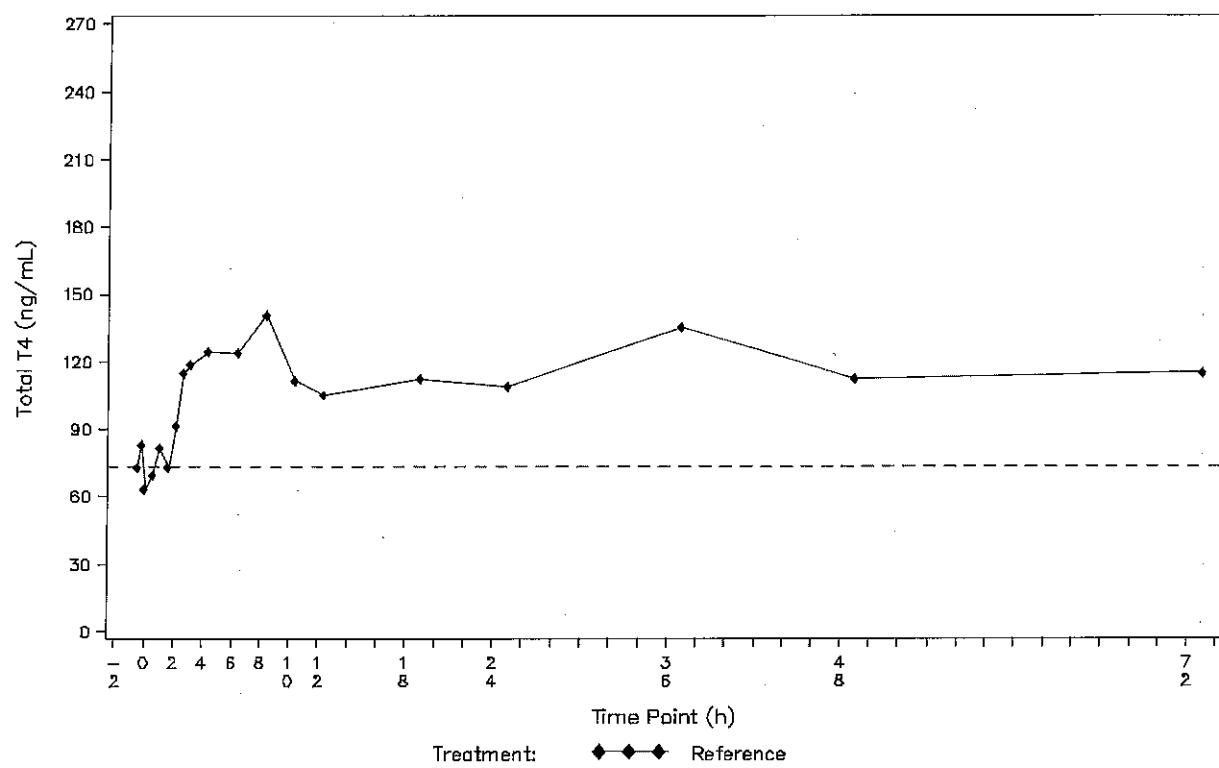
Levothyroxine
EMR 200125-001

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

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Confidential

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

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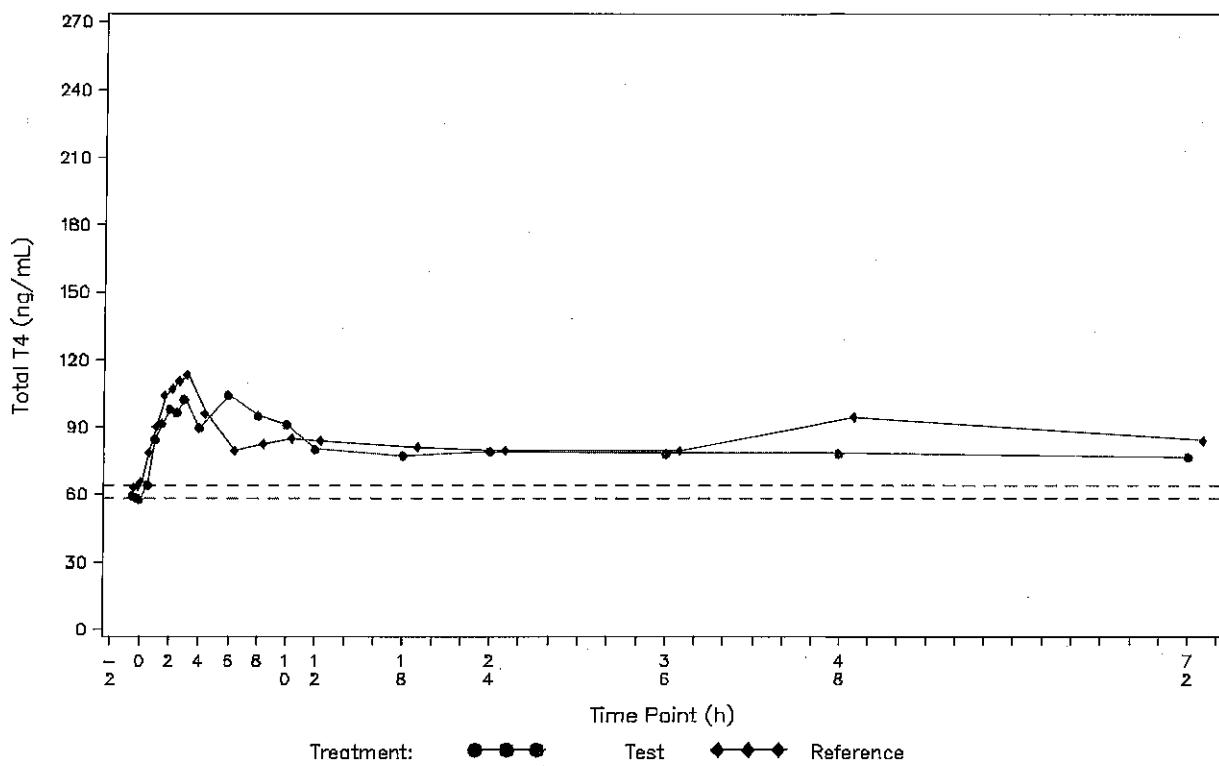
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number: 10000000



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

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

Source: Listing 16.2.5.2

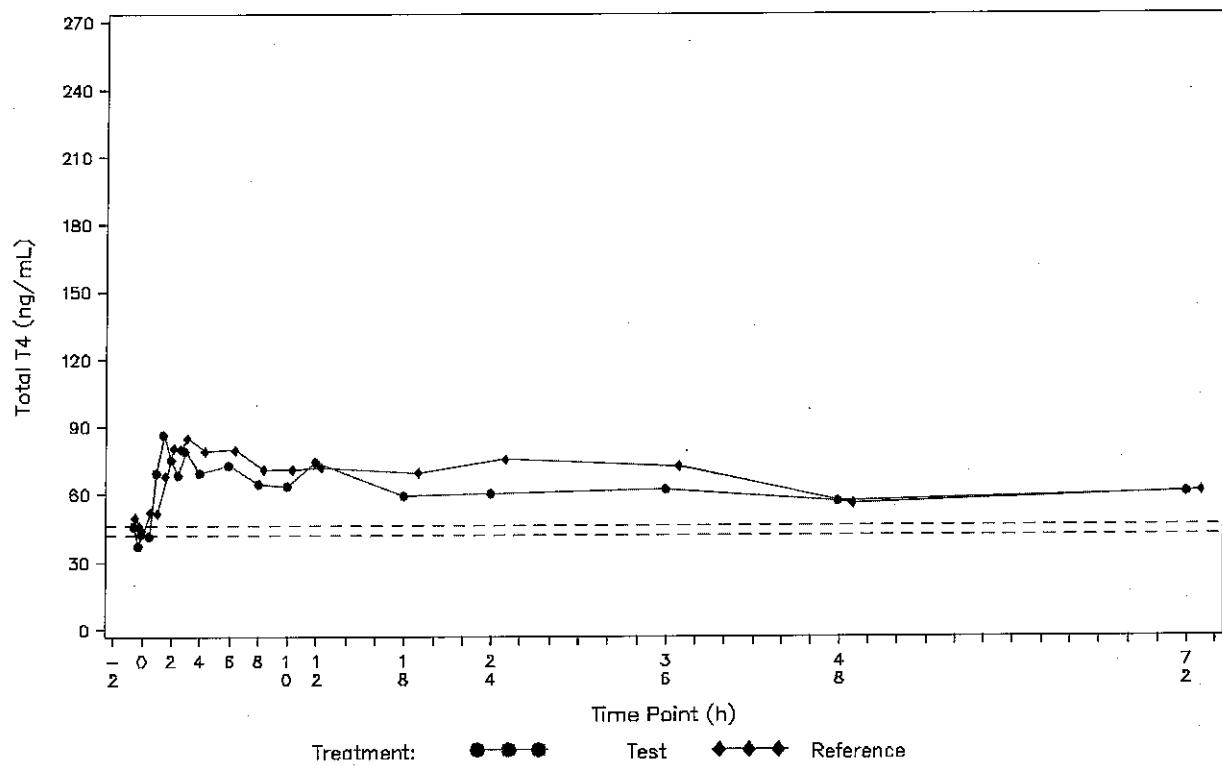
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Merck Serono
EMR 200125-001

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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:



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

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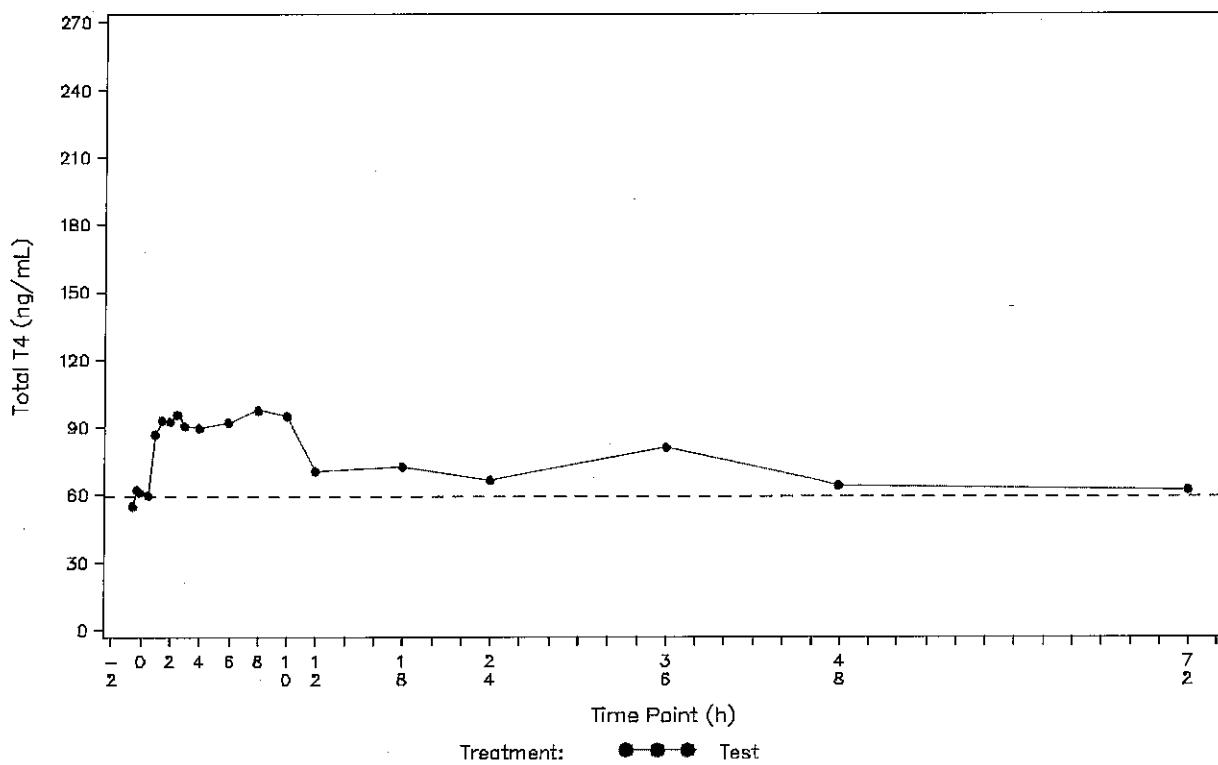
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



@: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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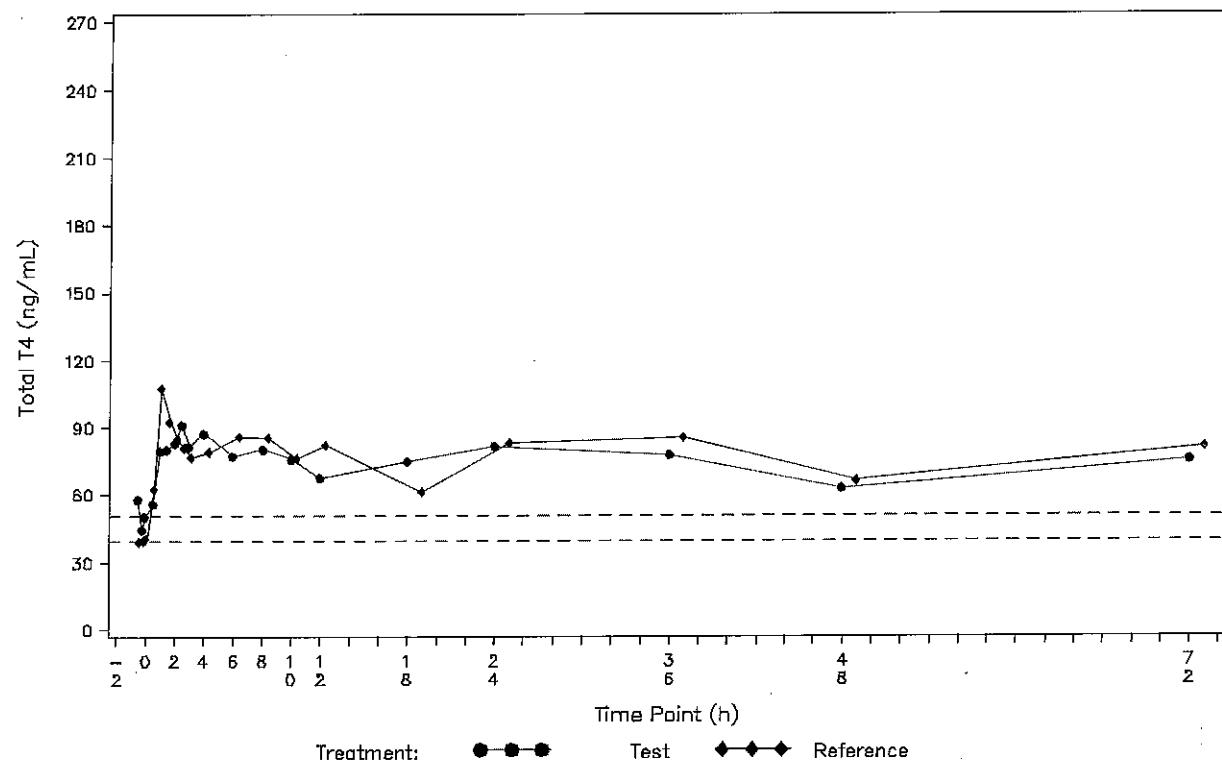
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EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



①: 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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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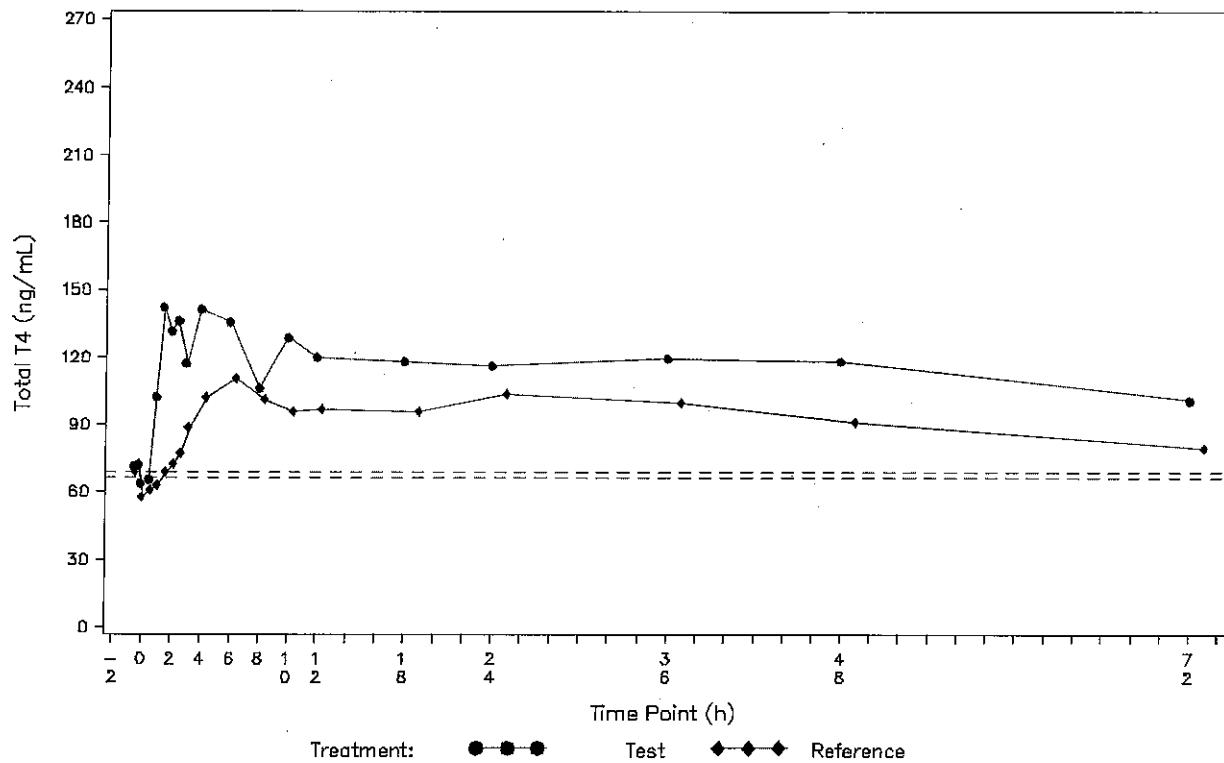
CONFIDENTIAL
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:



@: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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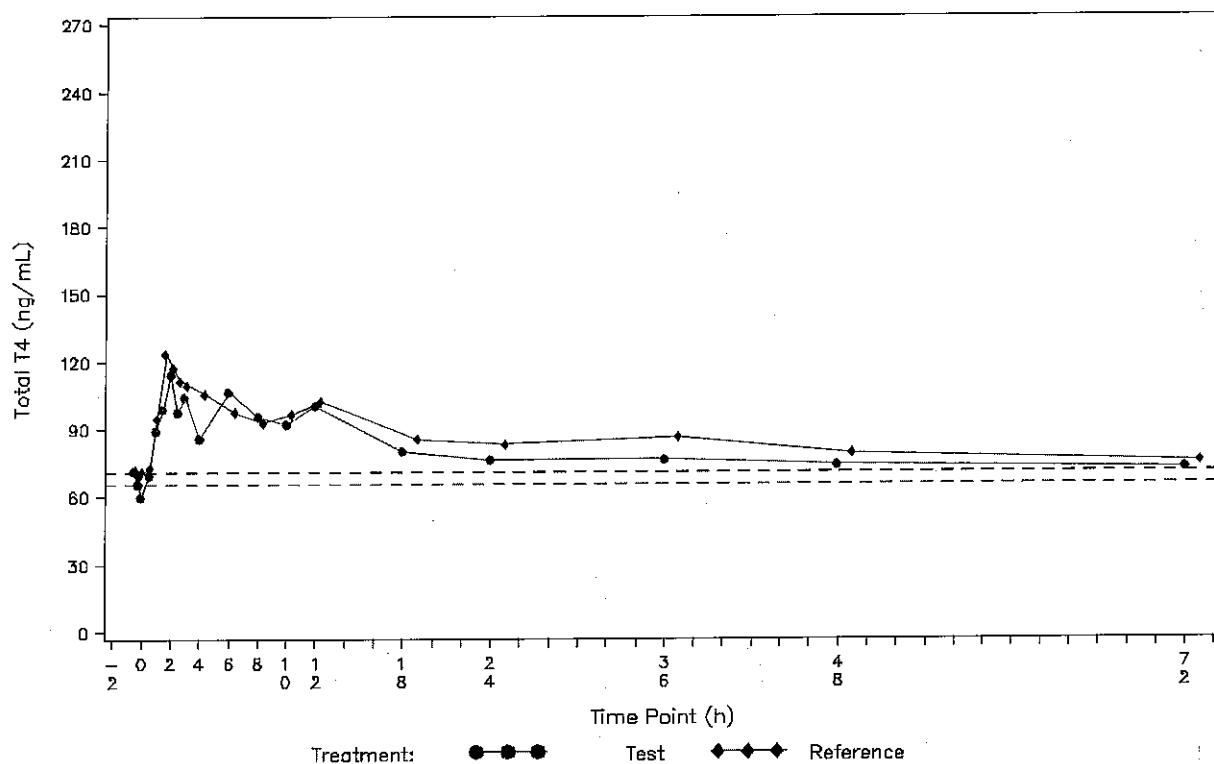
Levothyroxine
EMR 200125-001

Bioequivalence EMR200125-001 Page 828 of 1628 Evaluation vs. old formulation

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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:



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

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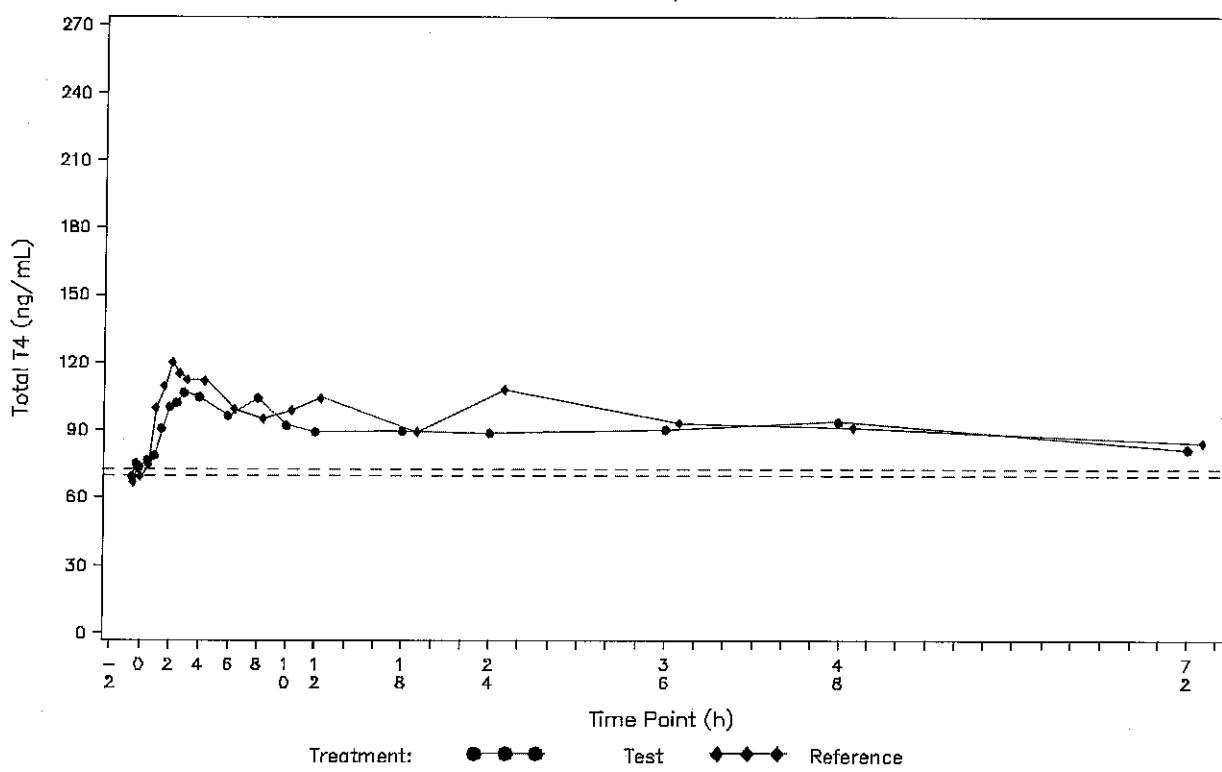
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



#: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE
15.4.2.9.sas

Levothyroxine
EMR 200125-001

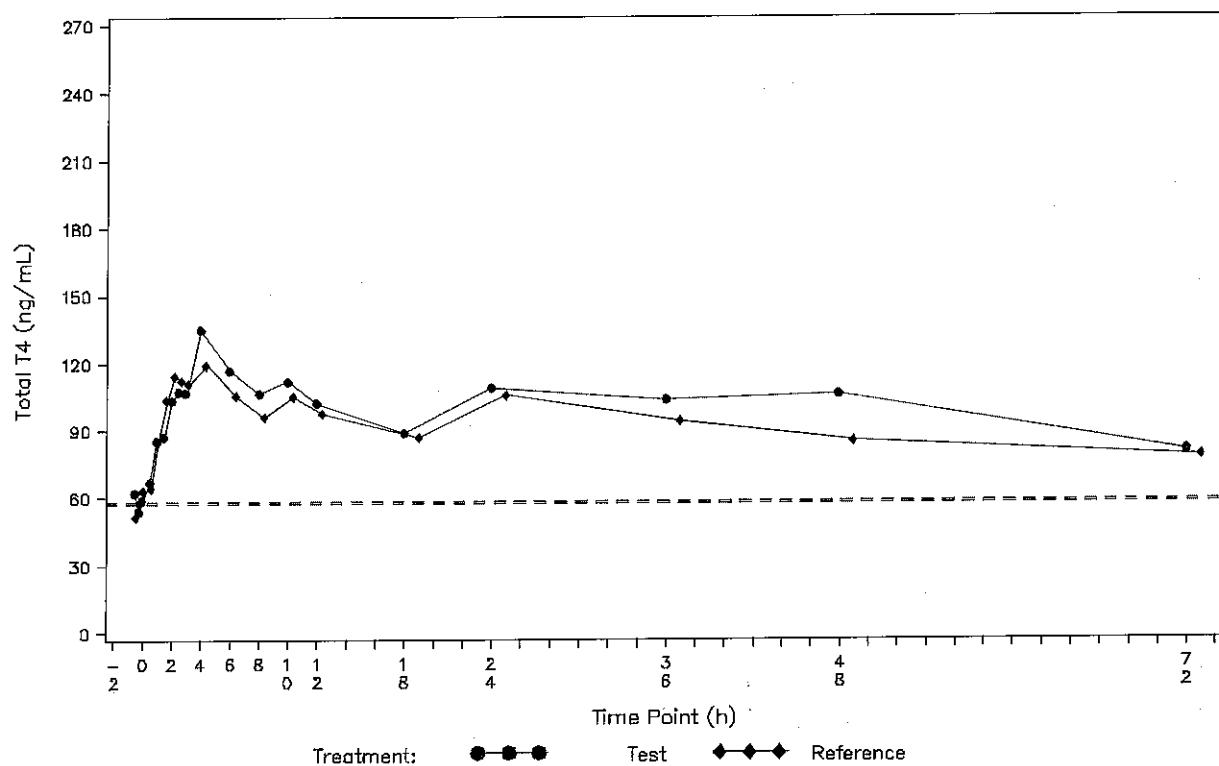
Bioequiv: EMR200125-001 Page 830 of 1628 ultation vs. old formulation

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:

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◎: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE
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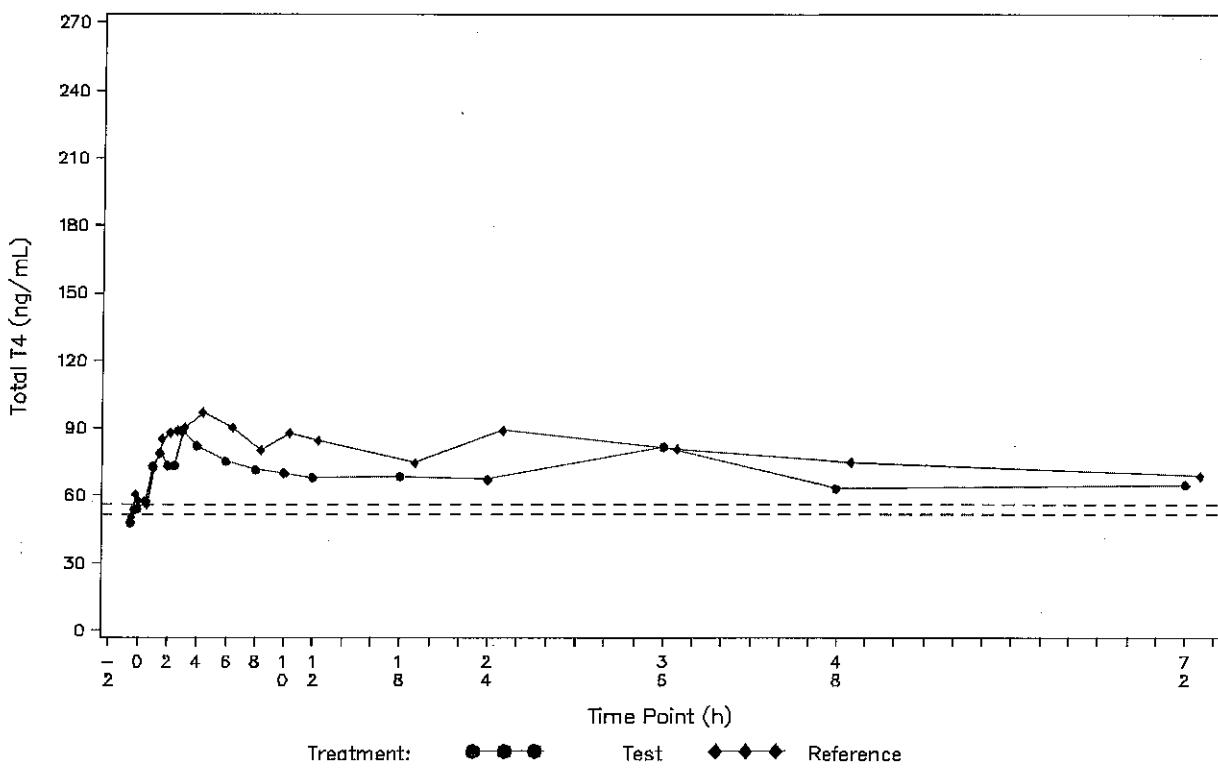
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T₄ Values)
(Safety Population)

Subject ID/Random Number:



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.

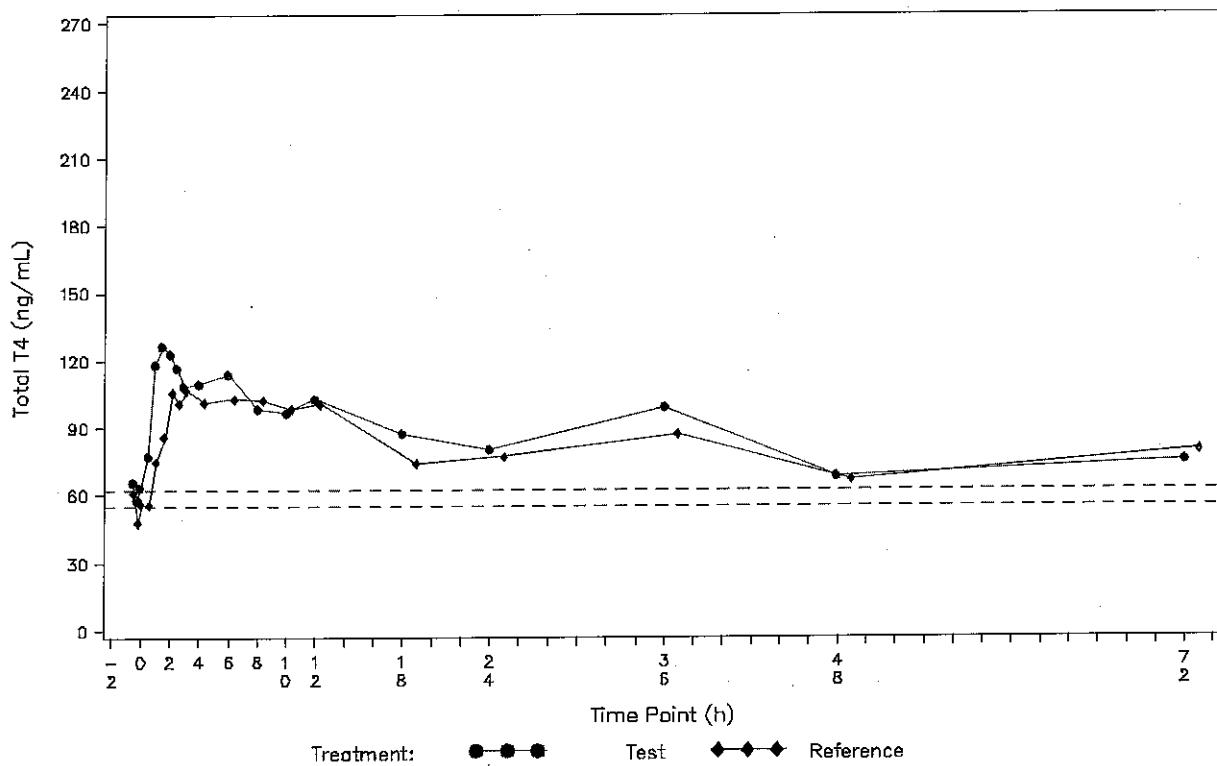
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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:



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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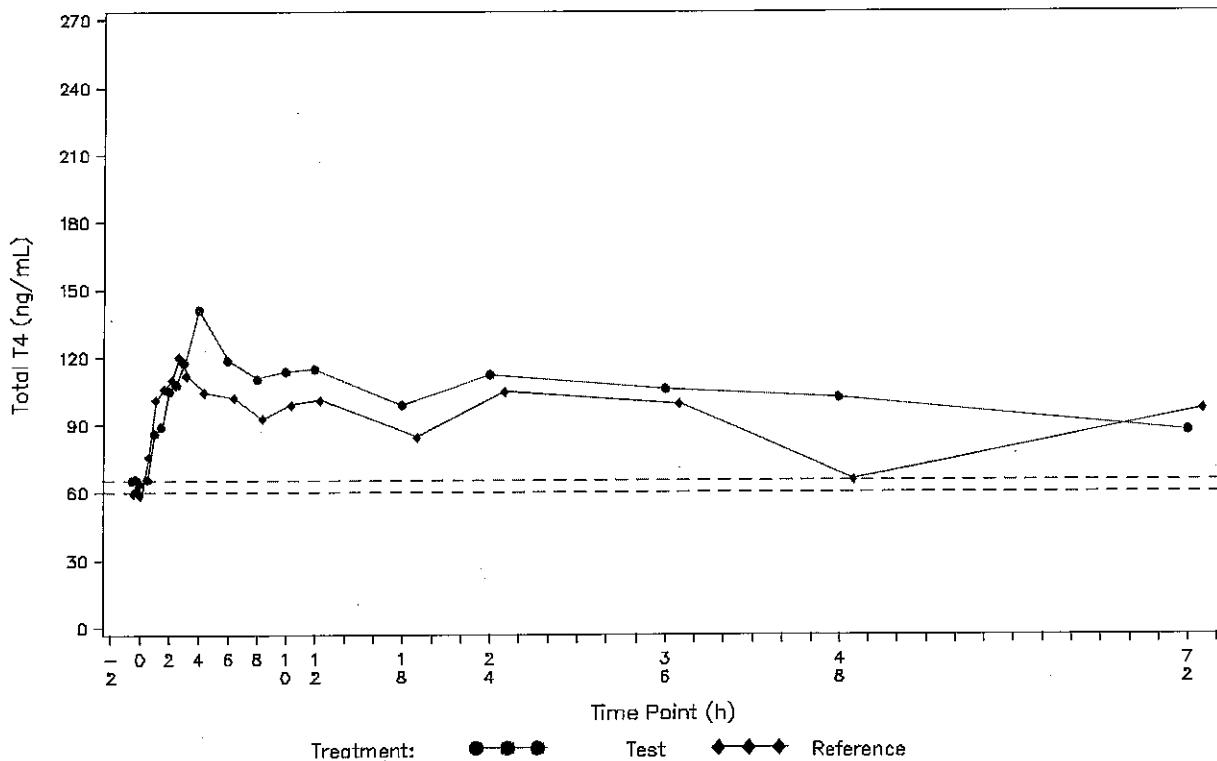
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 833 of 1628 nulation vs. old formulation

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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:



④ 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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15.4.2.9.sas

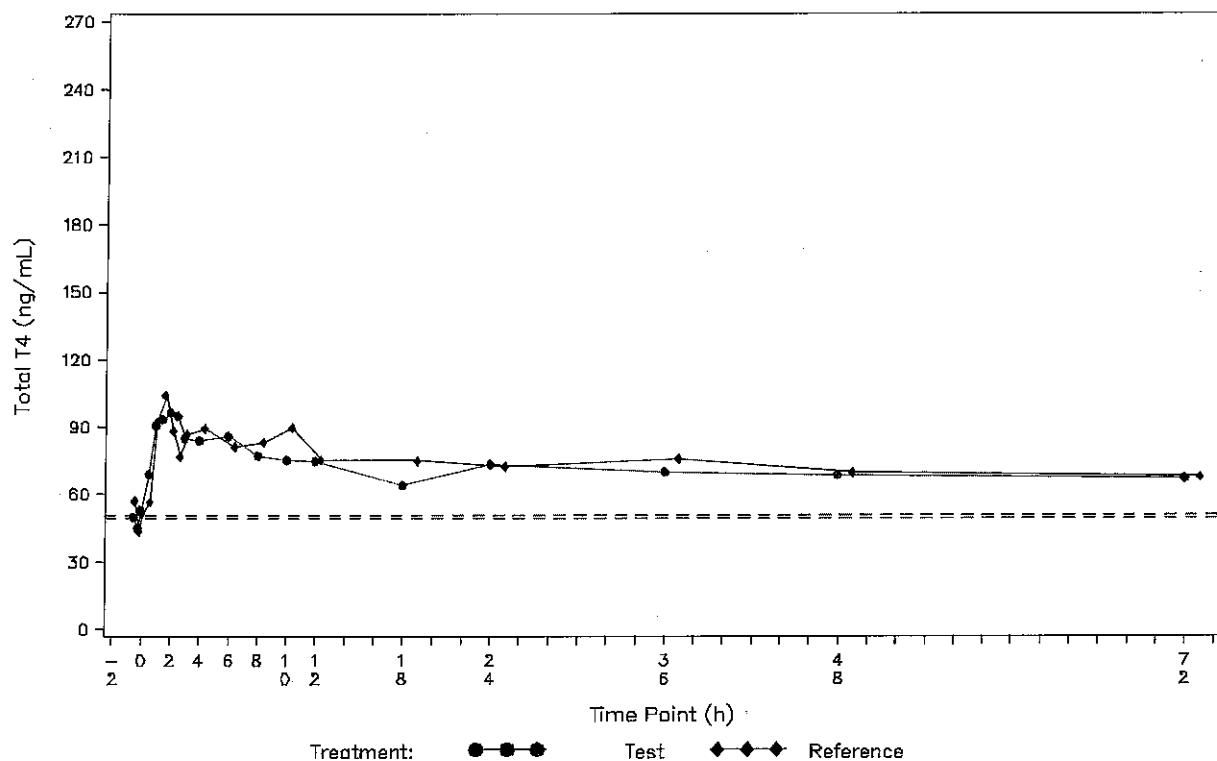
Document No.0900babe8085bb46 v1.0

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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: [REDACTED]



④: Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.

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

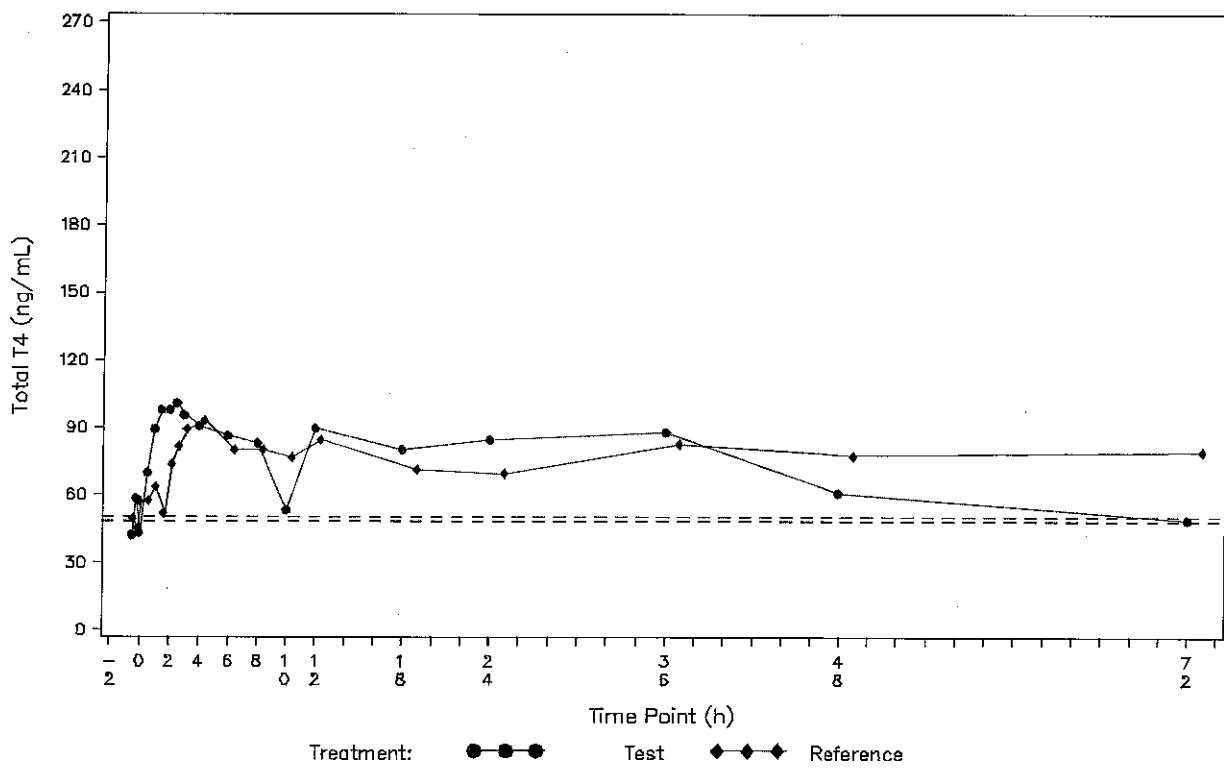
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

/project24/ep/blinded/e210899_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:



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.

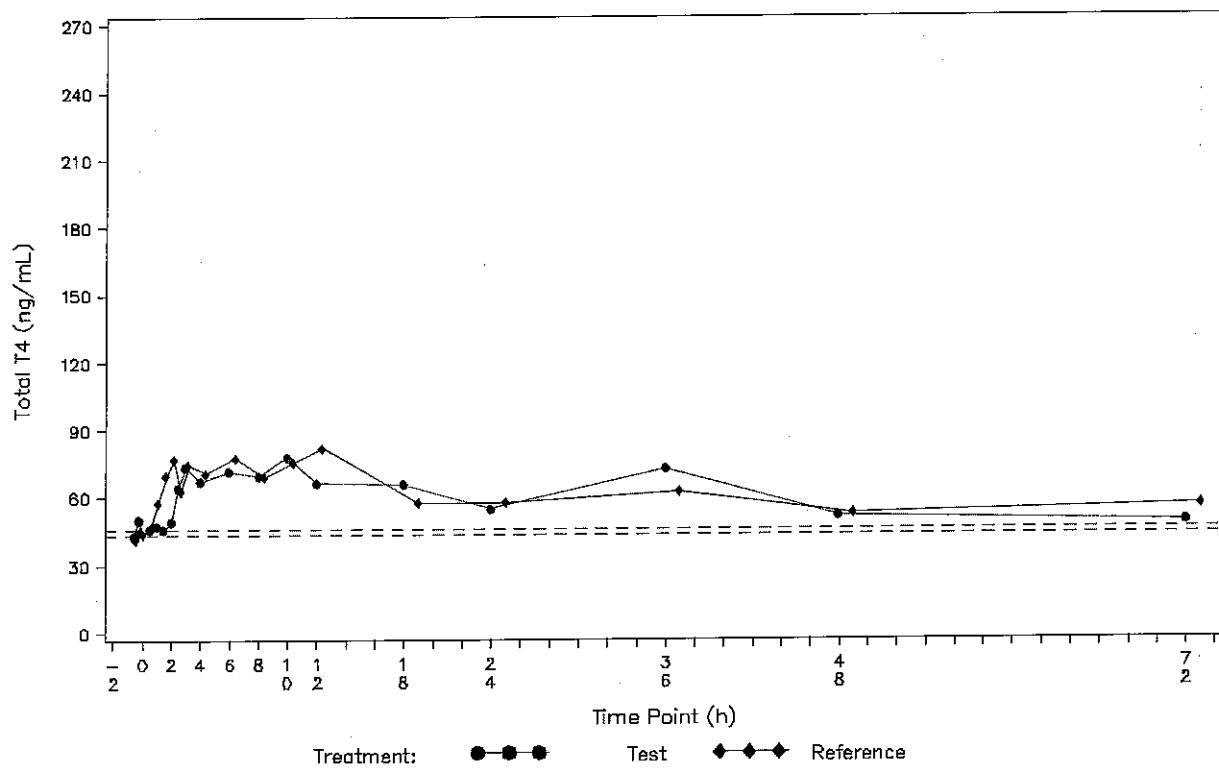
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

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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:



@: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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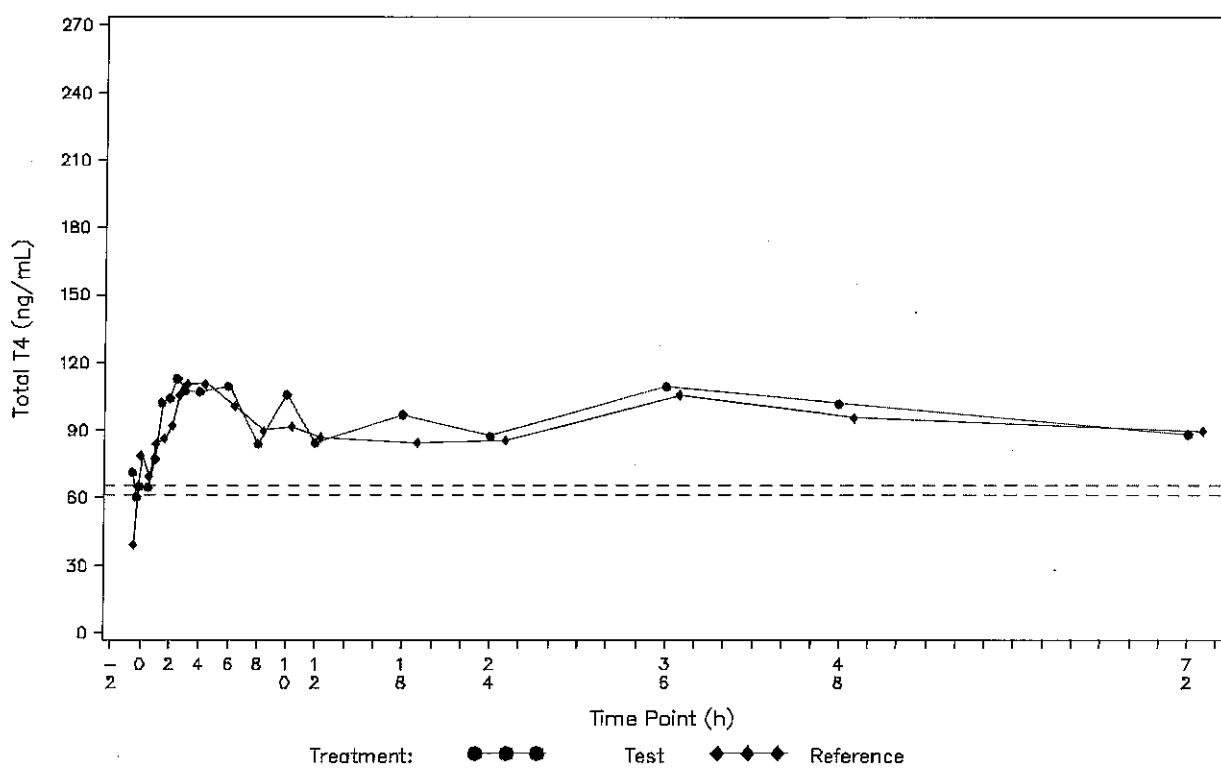
Levothyroxine
EMR 200125-001

Bioequiv^v EMR200125-001 Page 837 of 1628 ulation vs. old formulation

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Confidential

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

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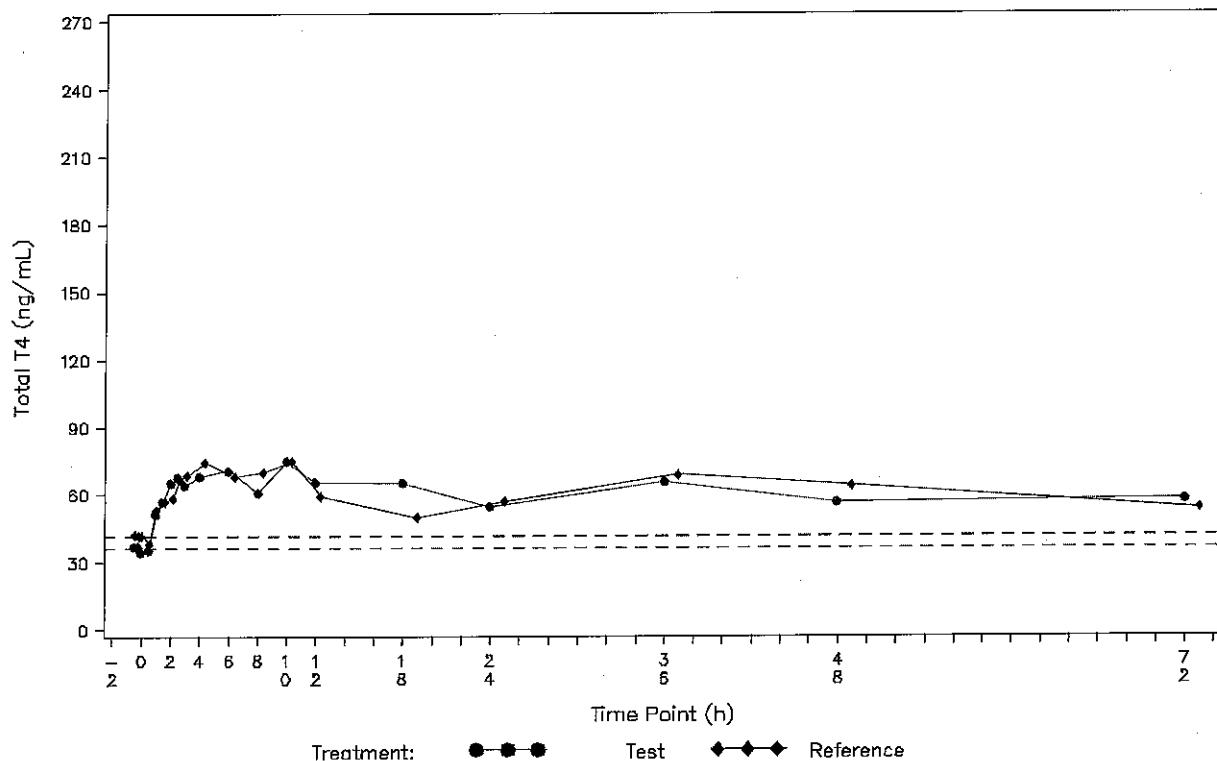
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T₄ Values)
(Safety Population)

Subject ID/Random Number: :



●: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 839 of 1628 ulation vs. old formulation

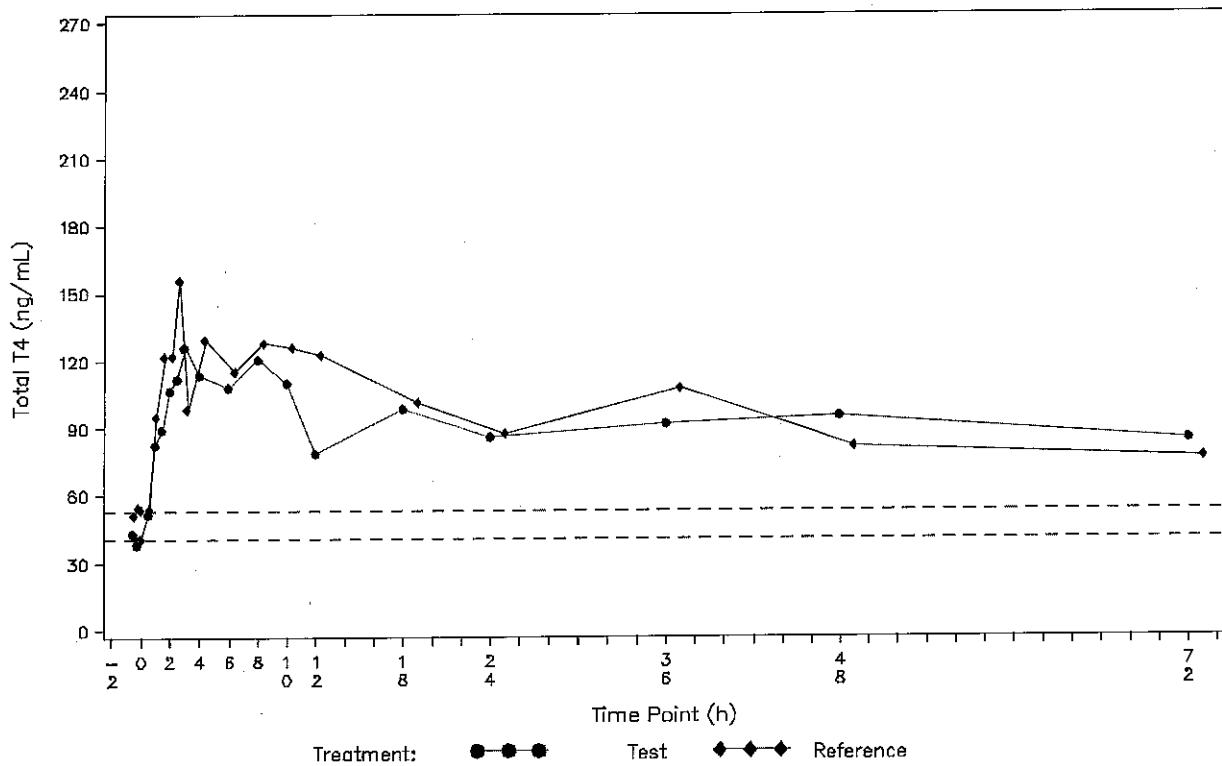
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Merck Serono
EMR 200125-001

EMR 200123-001
Figure 15.4.3.9

Subject ID/Random Number:

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 16-2, 5, 2

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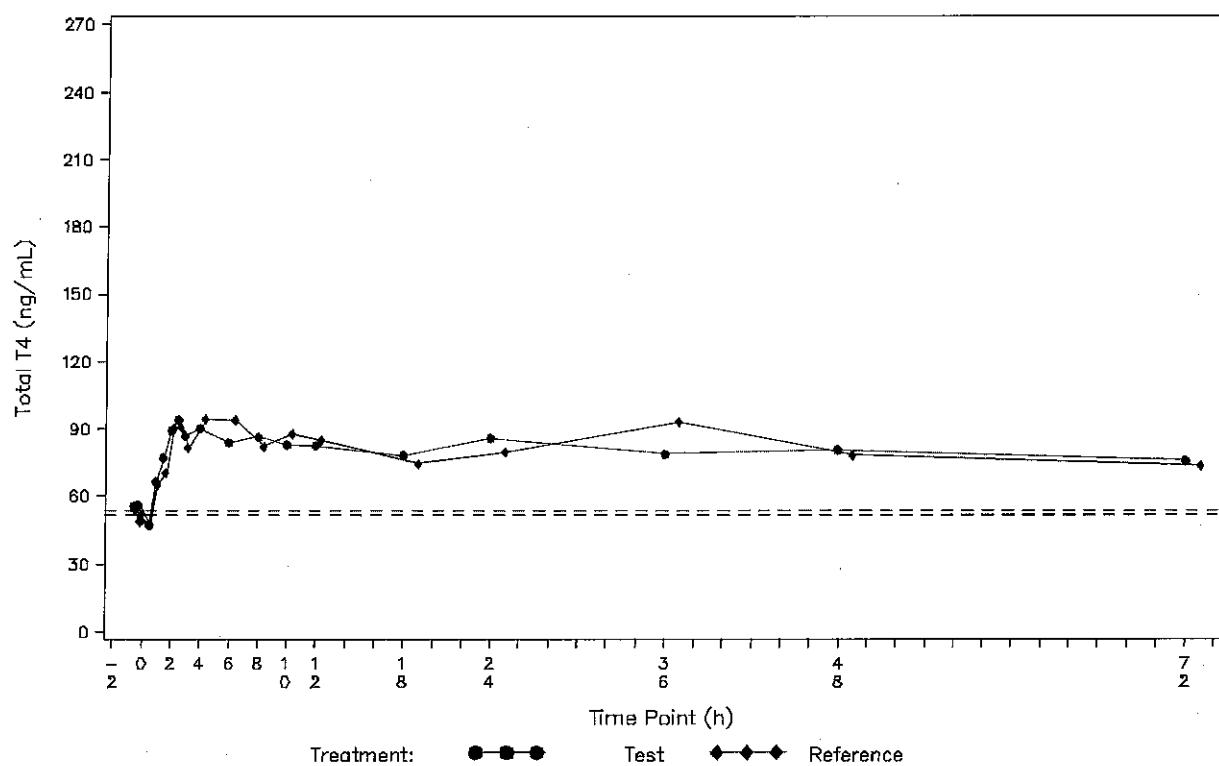
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 840 of 1628 ualation vs. old formulation

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Confidential

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:



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 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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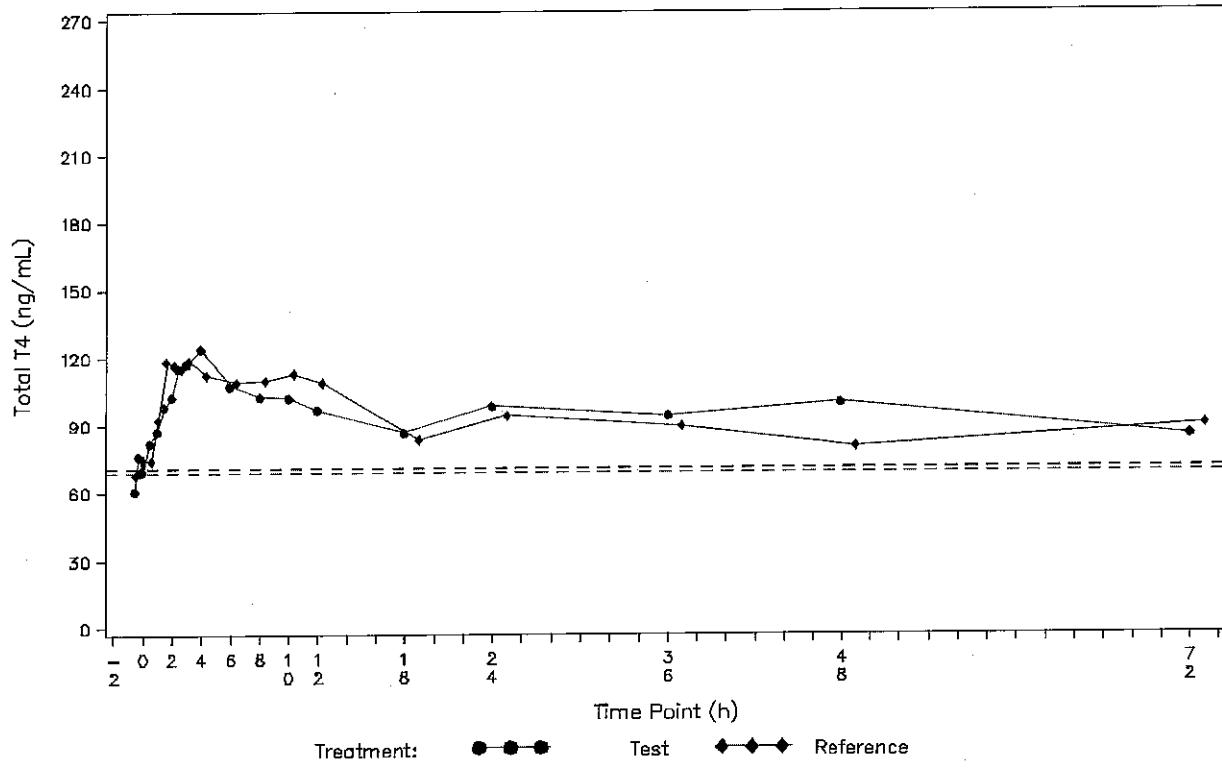
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 841 of 1628 ulation vs. old formulation

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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:



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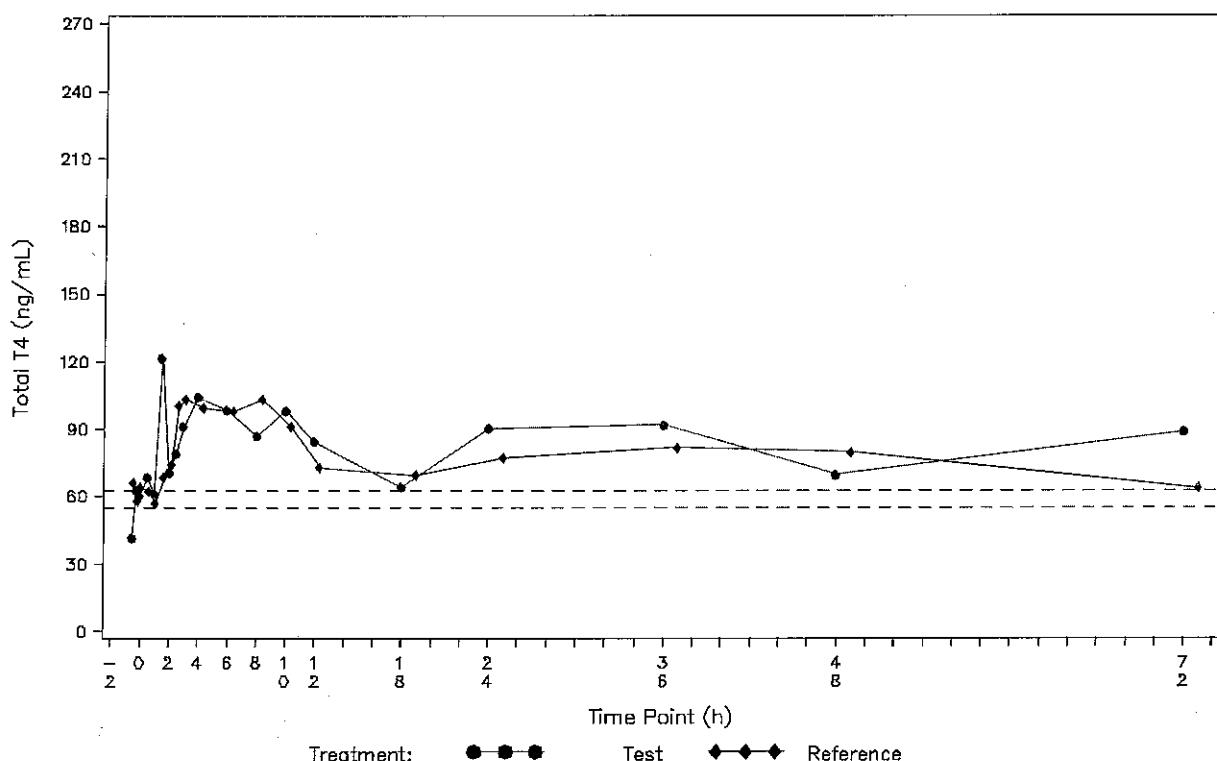
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:



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 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

Levothyroxine
EMR 200125-001

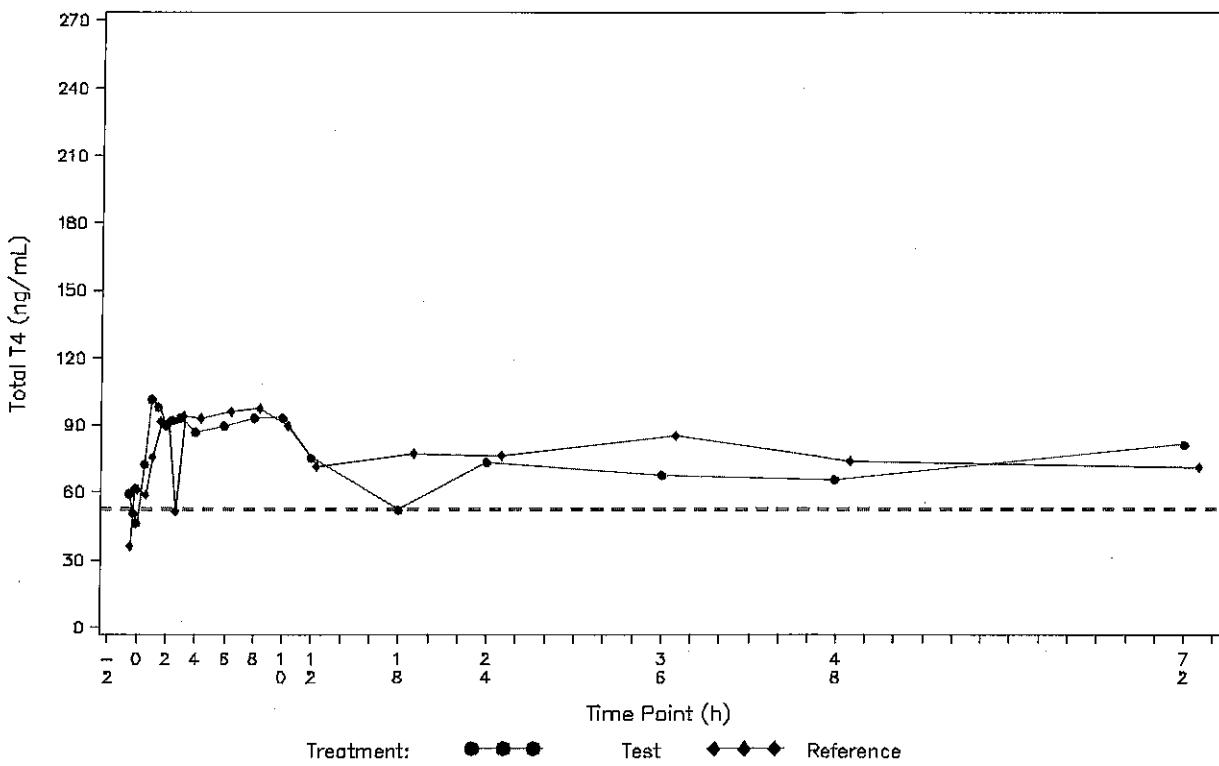
Bioequiv[†] EMR200125-001 Page 843 of 1628 ulation vs. old formulation

Merck Serono
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:



@: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE 15.4.2.9.sas

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Levothyroxine
EMR 200125-001

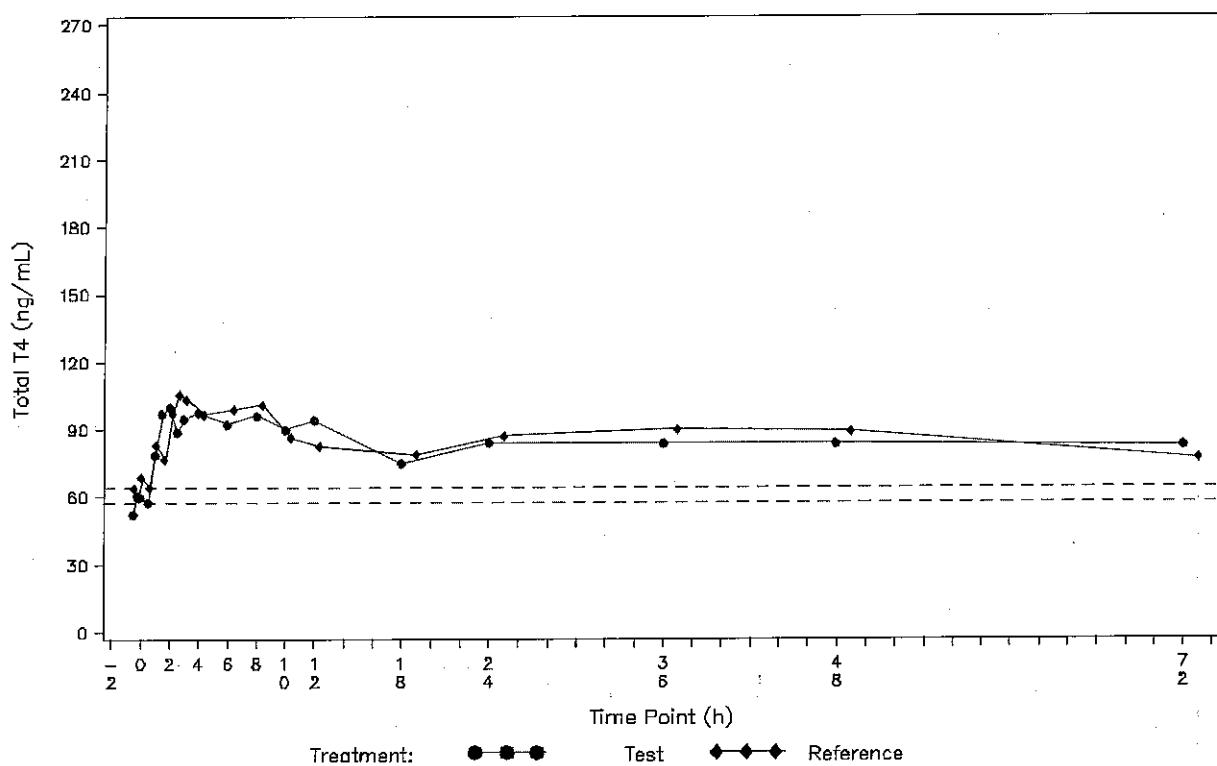
Bioequiv: EMR200125-001 Page 844 of 1628 ulation vs. old formulation

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:

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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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure
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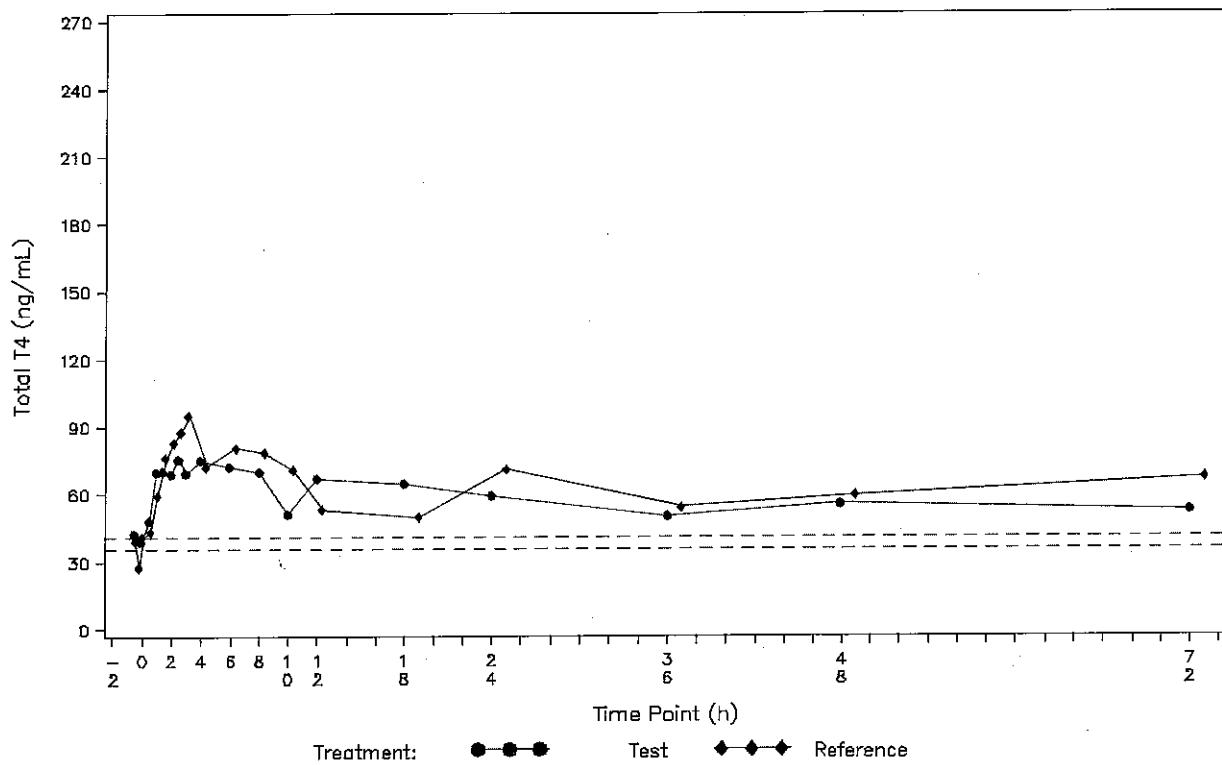
**Levothyroxine
EMR 200125-001**

Bioequivⁱ EMR200125-001 Page 845 of 1628 ulation vs. old formulation

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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:



@: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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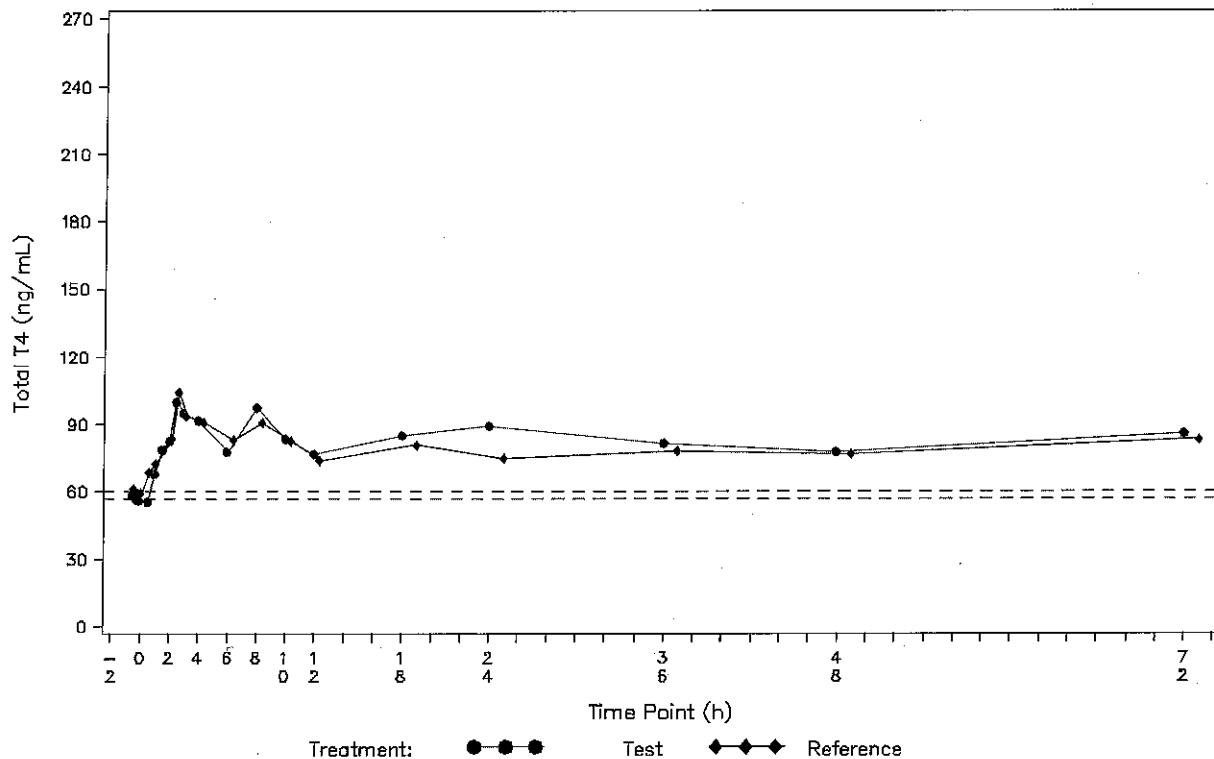
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 846 of 1628 nulation 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)

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Subject ID/Random Number:



①Subjects 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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE
15.4.2.9.sas

Document No.0900babe8085bb46 v1.0

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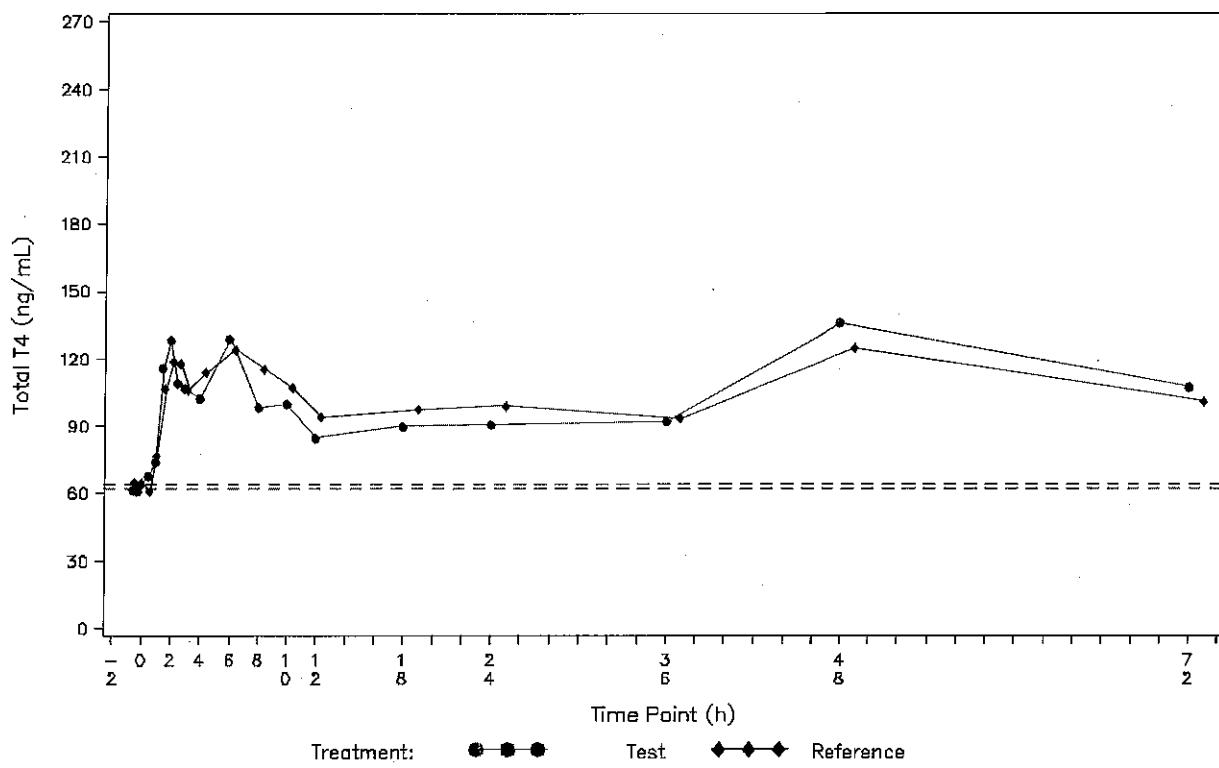
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



④ Subjects excluded from PK Population; Horizontal lines represent the Baseline of the respective treatments.

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

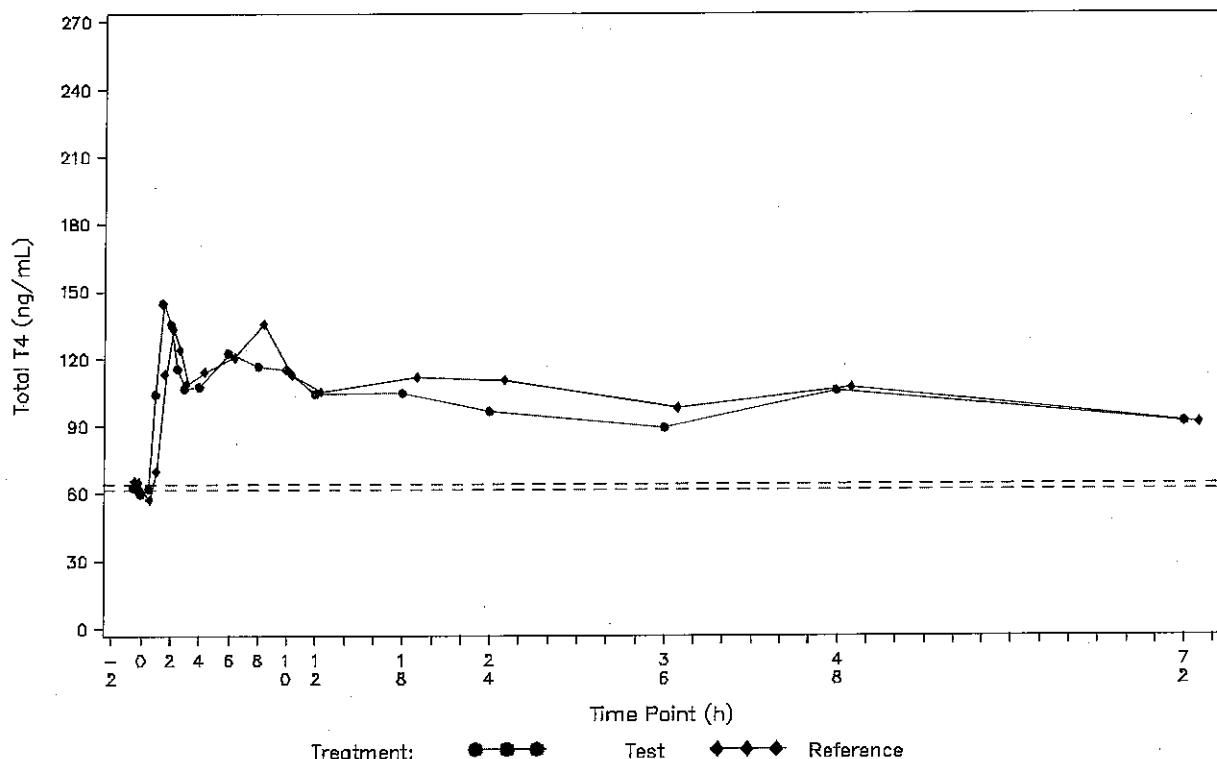
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

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

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:



@: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 849 of 1628 ulation vs. old formulation

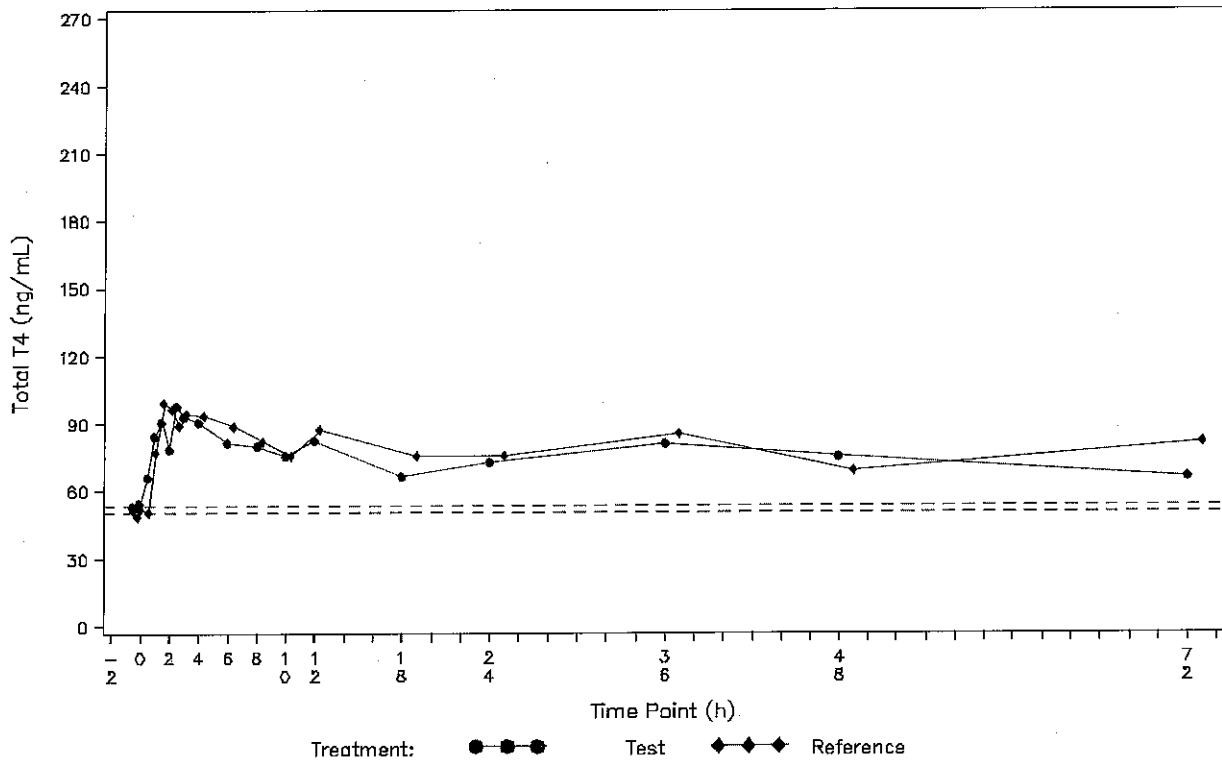
Page 92 of 216
Confidential

Merck Serono
EMR 200125-001

Figure 15.4.2.9

Subject ID/Random Number:

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 16,2,5,2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE 15.4.2.9.sas

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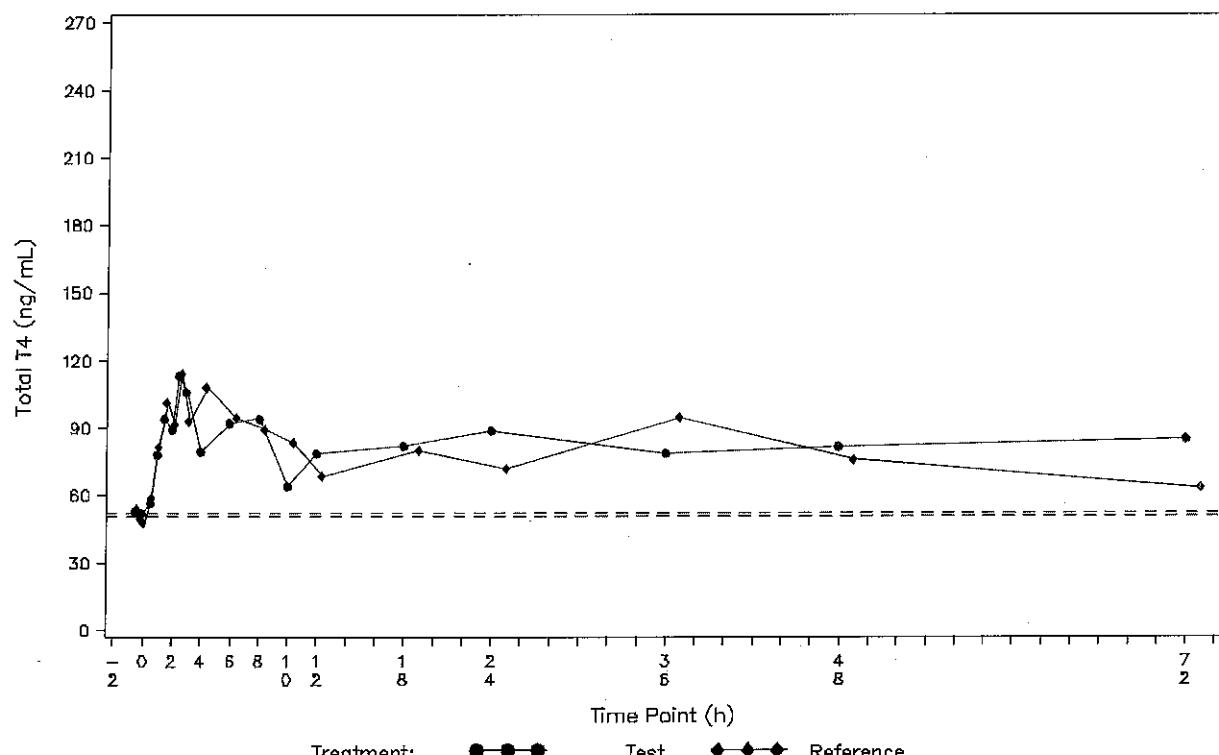
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 850 of 1628 uation vs. old formulation

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Confidential

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: Listing 16.2.5.2

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Levothyroxine
EMR 200125-001

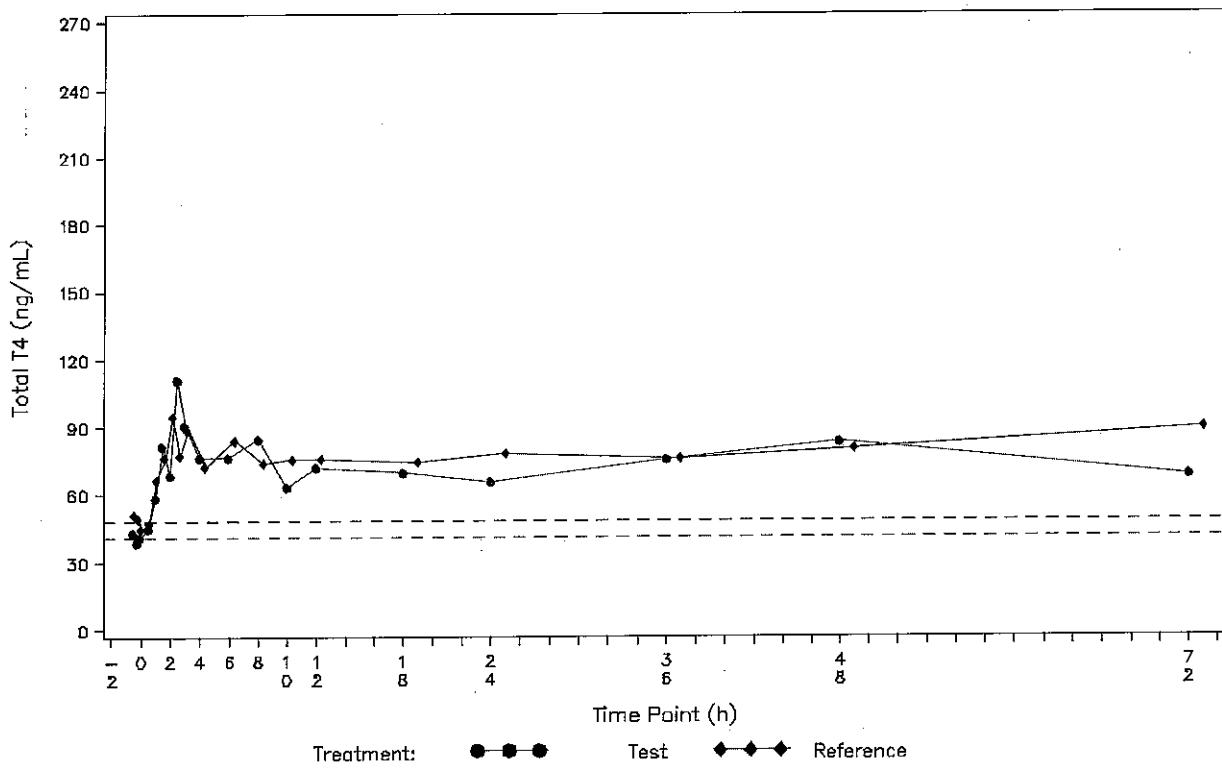
Bioequiv^e EMR200125-001 Page 851 of 1628 ualuation vs. old formulation

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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:



@: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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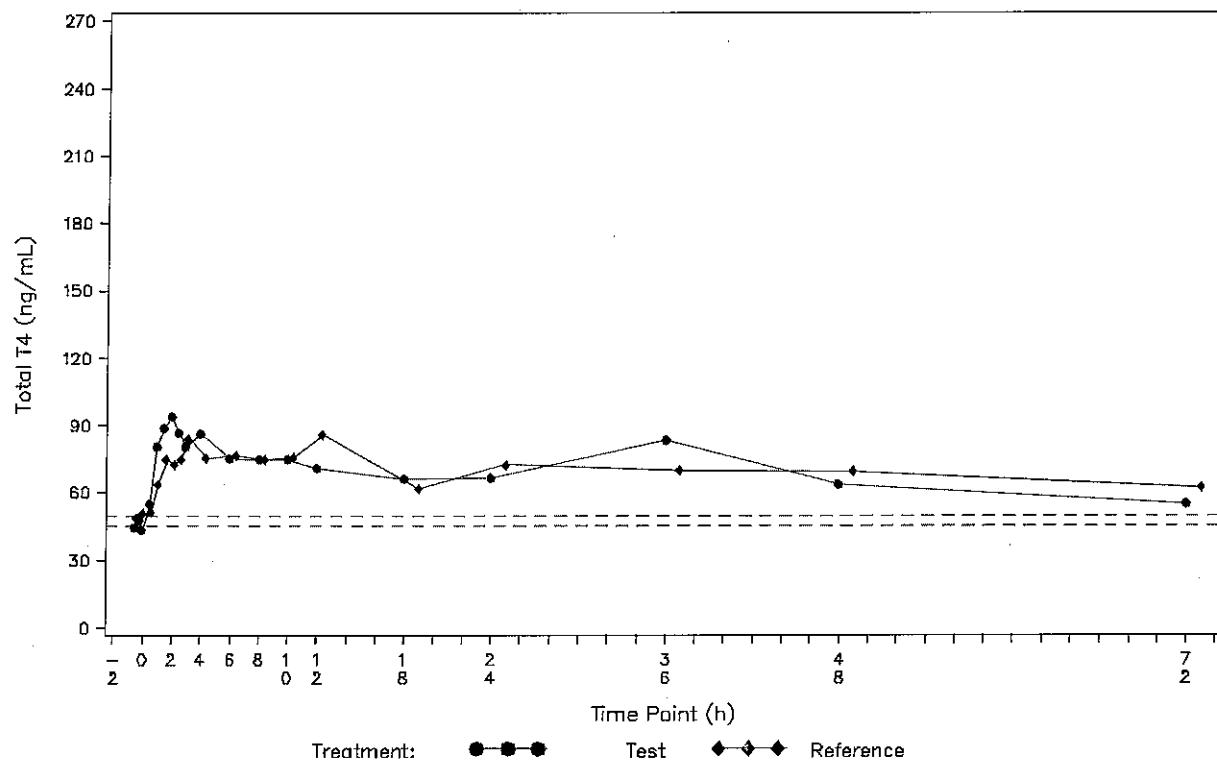
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 852 of 1628 ualuation vs. old formulation

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Confidential

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: Listing 16.2.5.2

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MM

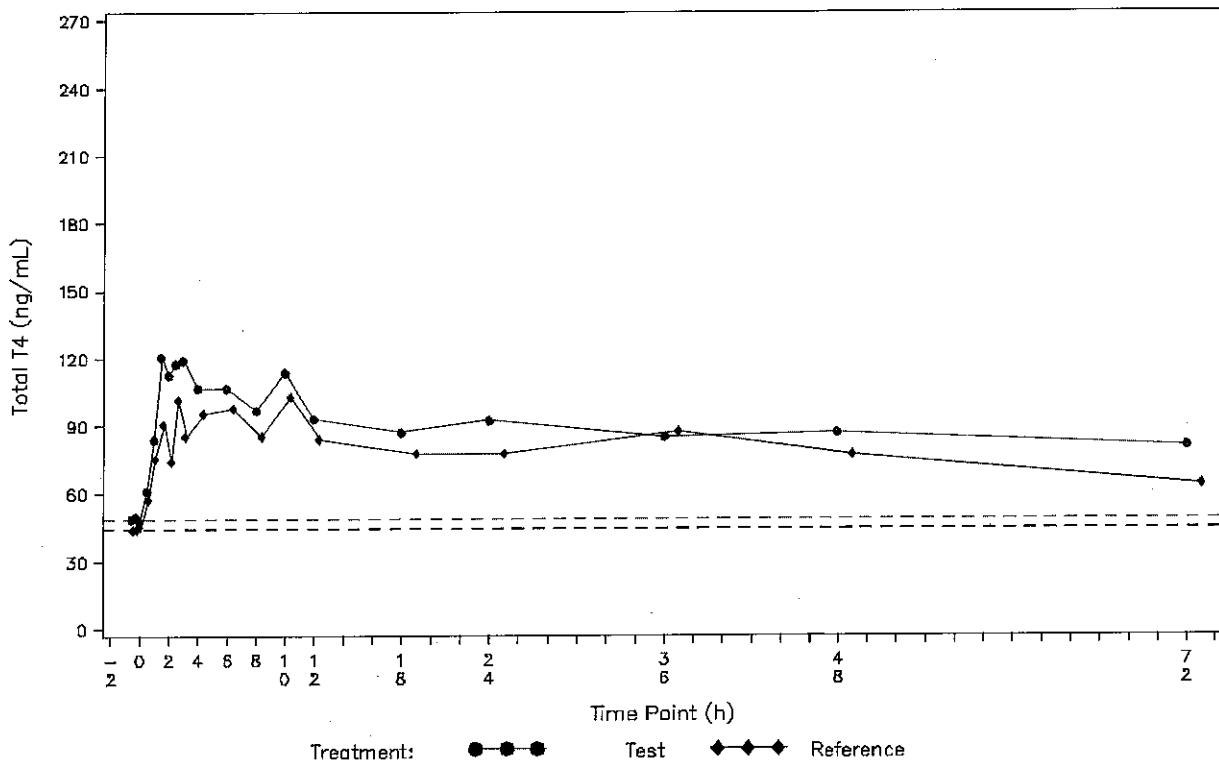
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 853 of 1628 ulation vs. old formulation

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Confidential

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:



④ 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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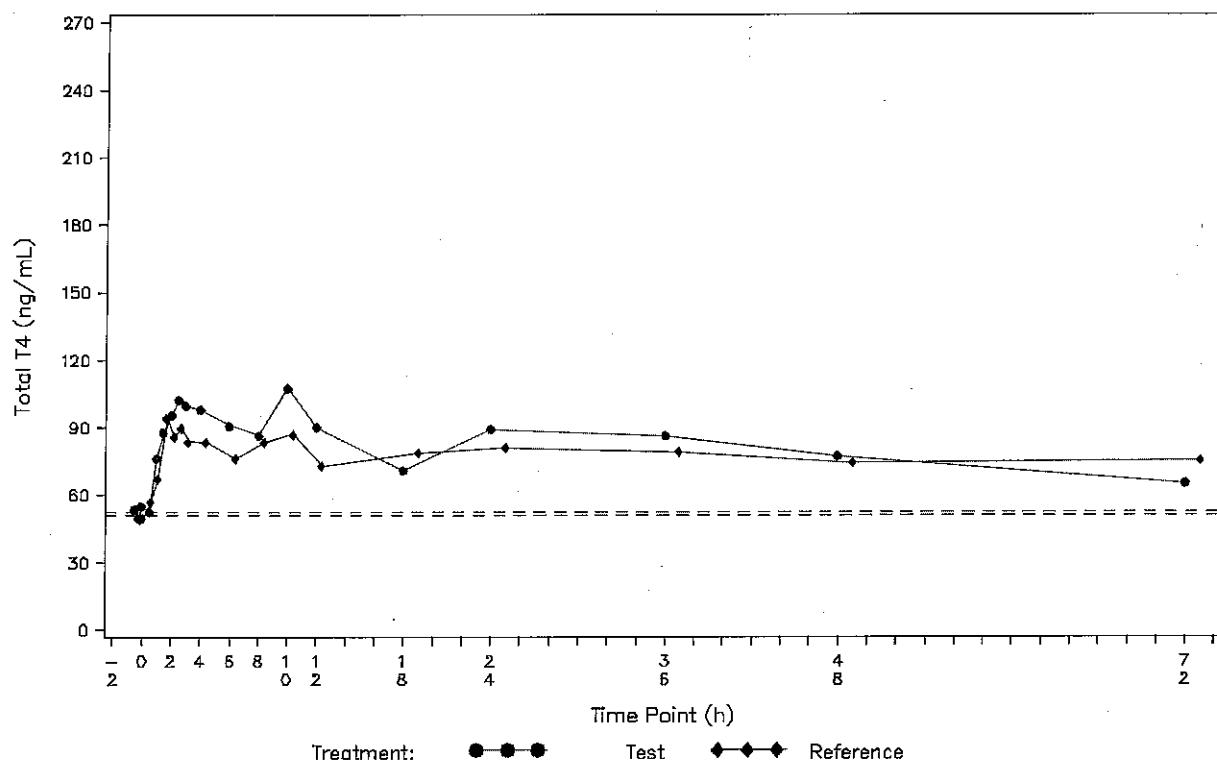
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:



Q: 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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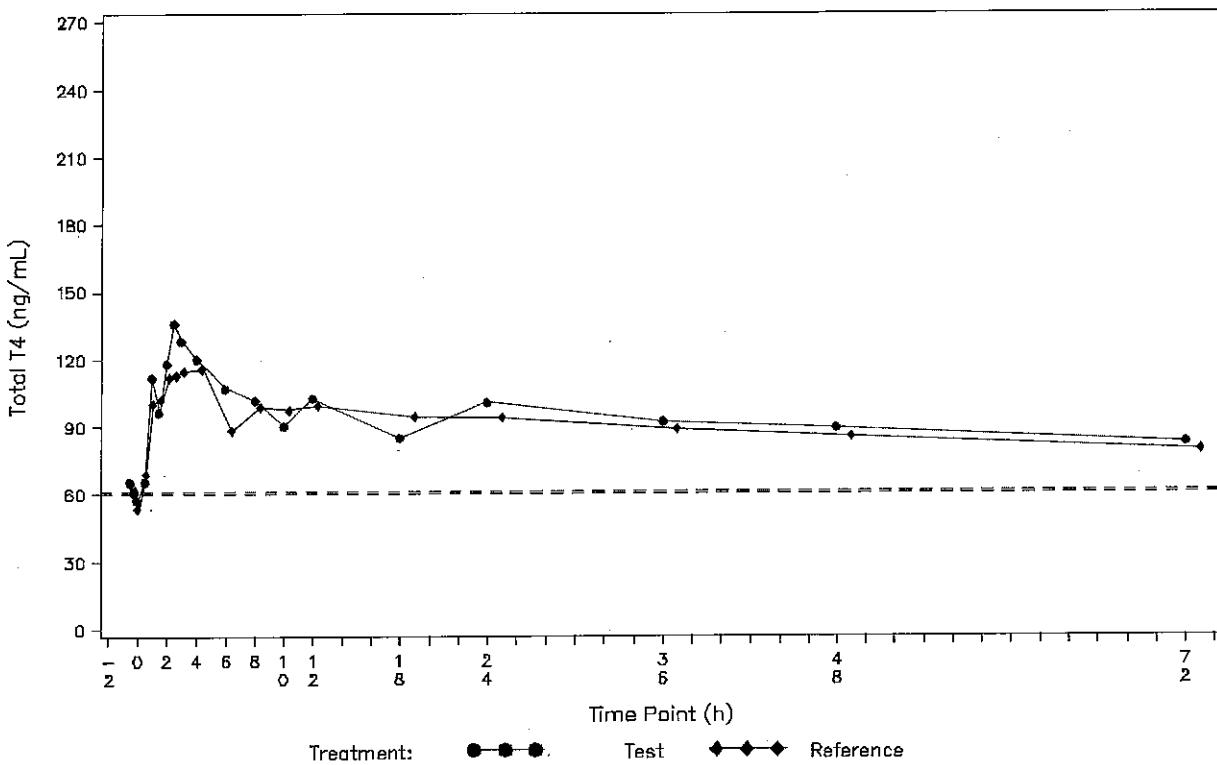
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 855 of 1628 ulation vs. old formulation

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Confidential

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:



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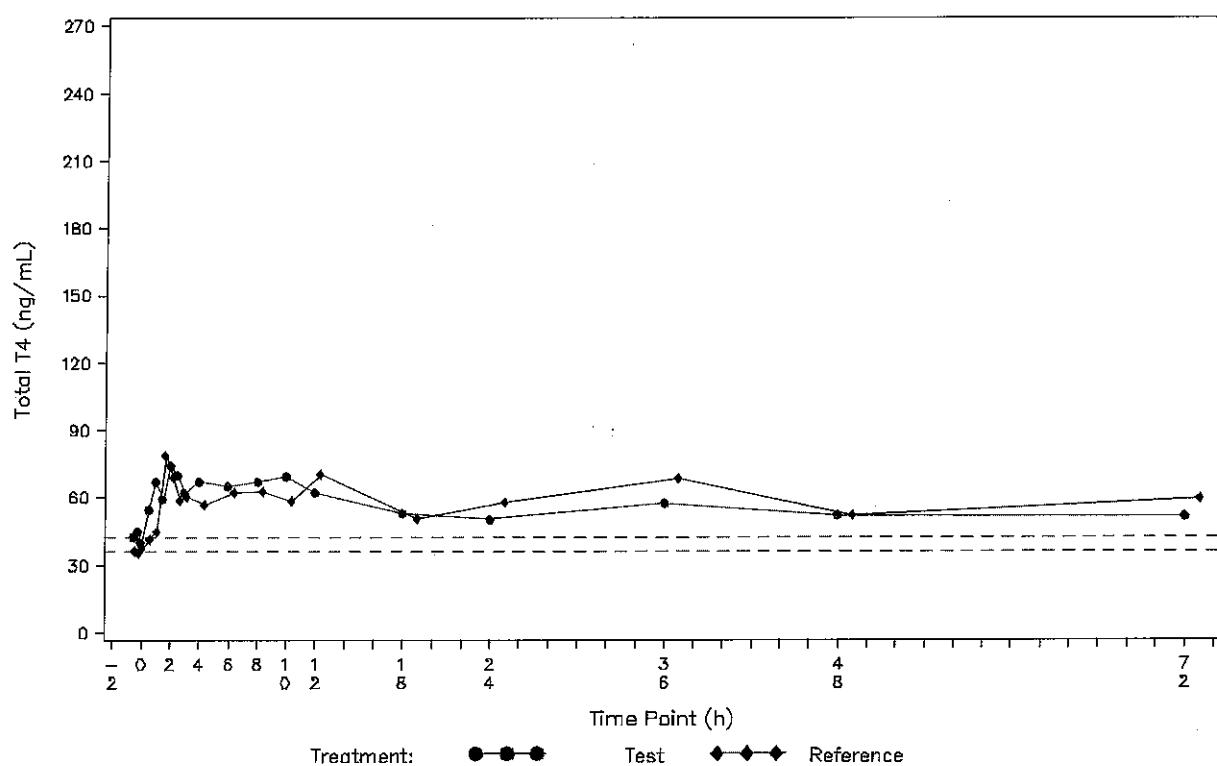
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T₄ Values)
(Safety Population)

Subject ID/Random Number:



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

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

**Levothyroxine
EMR 200125-001**

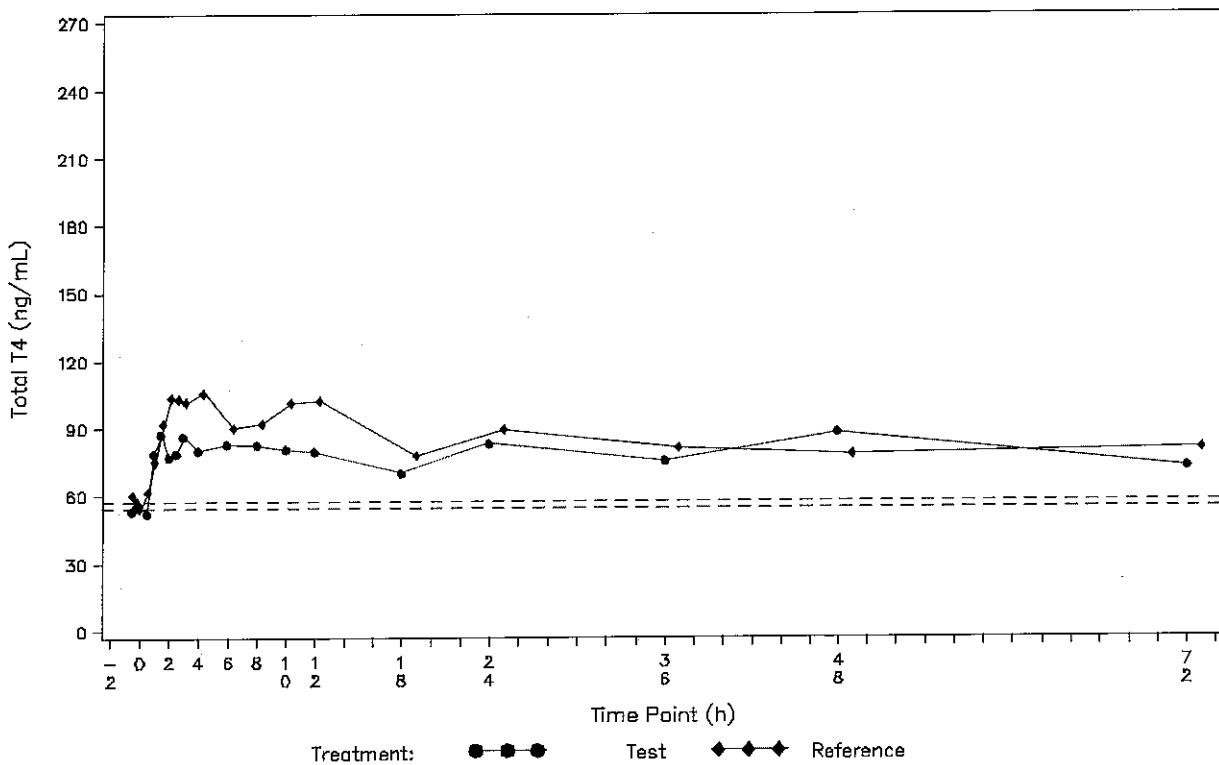
Bioequiv: EMR200125-001 Page 857 of 1628 nulation vs. old formulation

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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:



④ 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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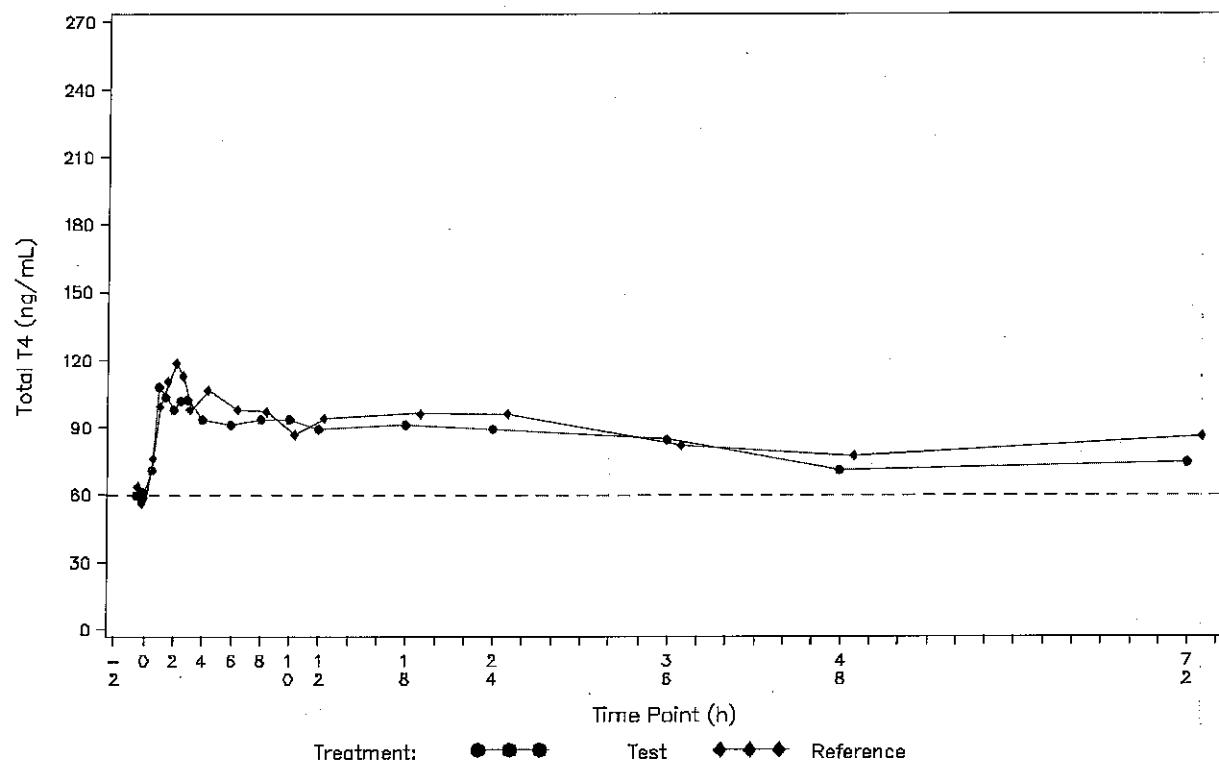
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T₄ Values)
(Safety Population)

Subject ID/Random Number:



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.

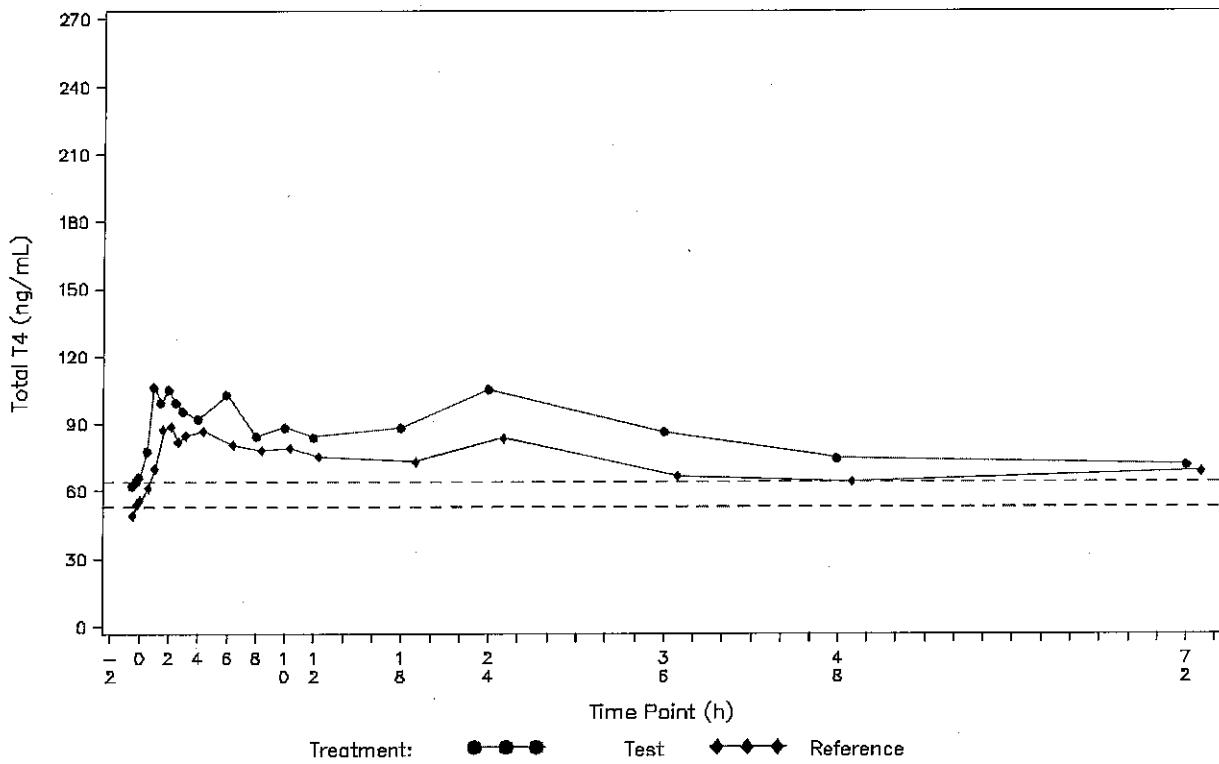
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

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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:



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.

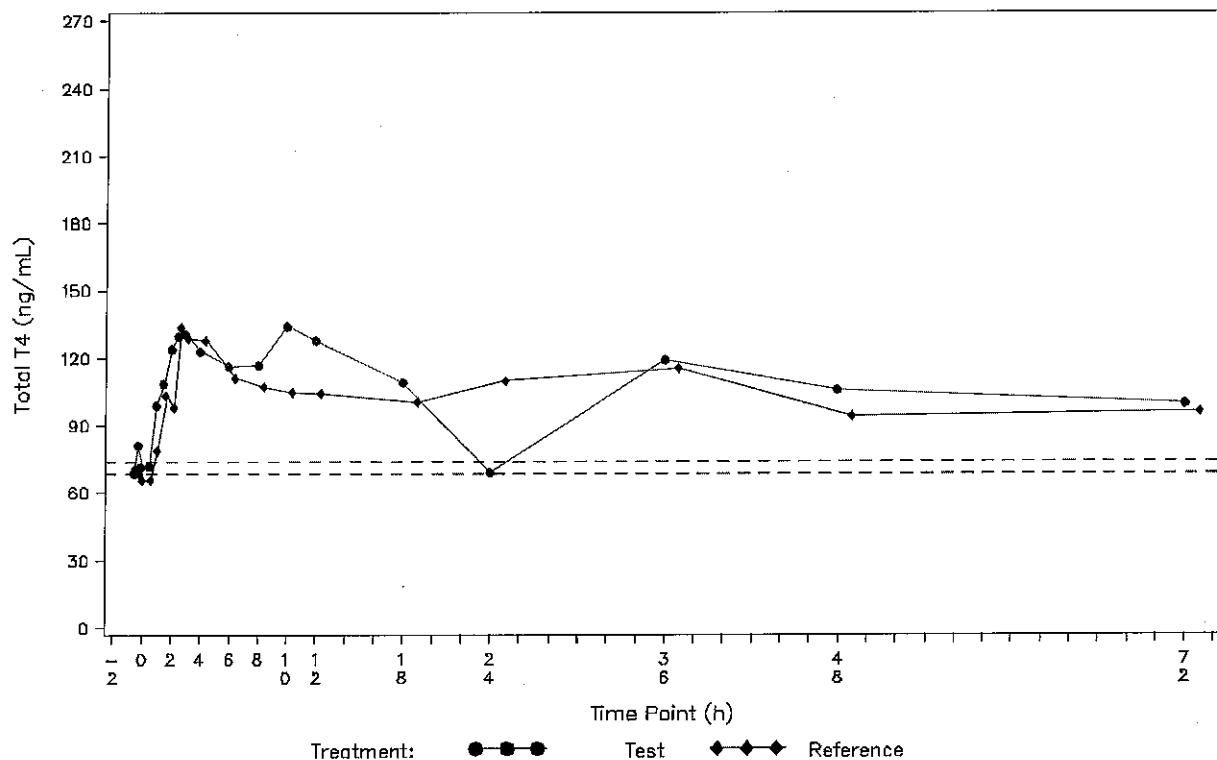
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

Source: Listing 16.2.5.2

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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:



@: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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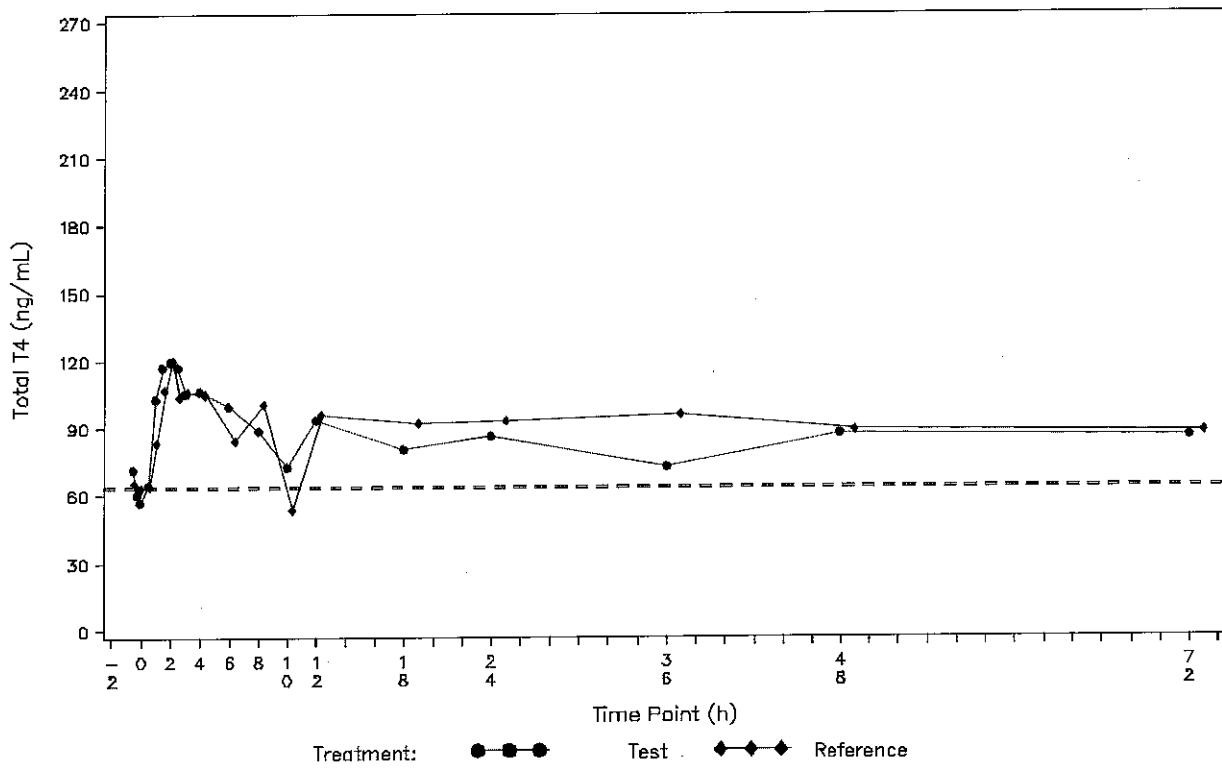
**Levothyroxine
EMR 200125-001**

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

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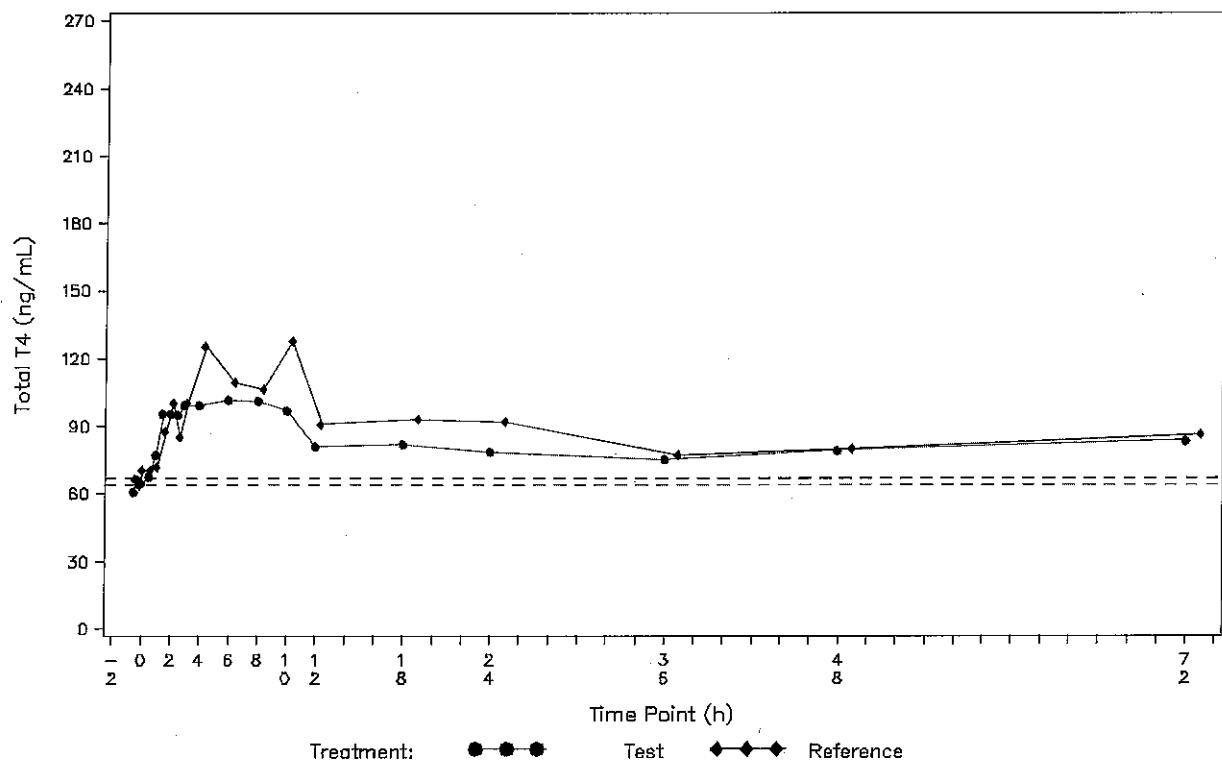
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:



⑥Subjects 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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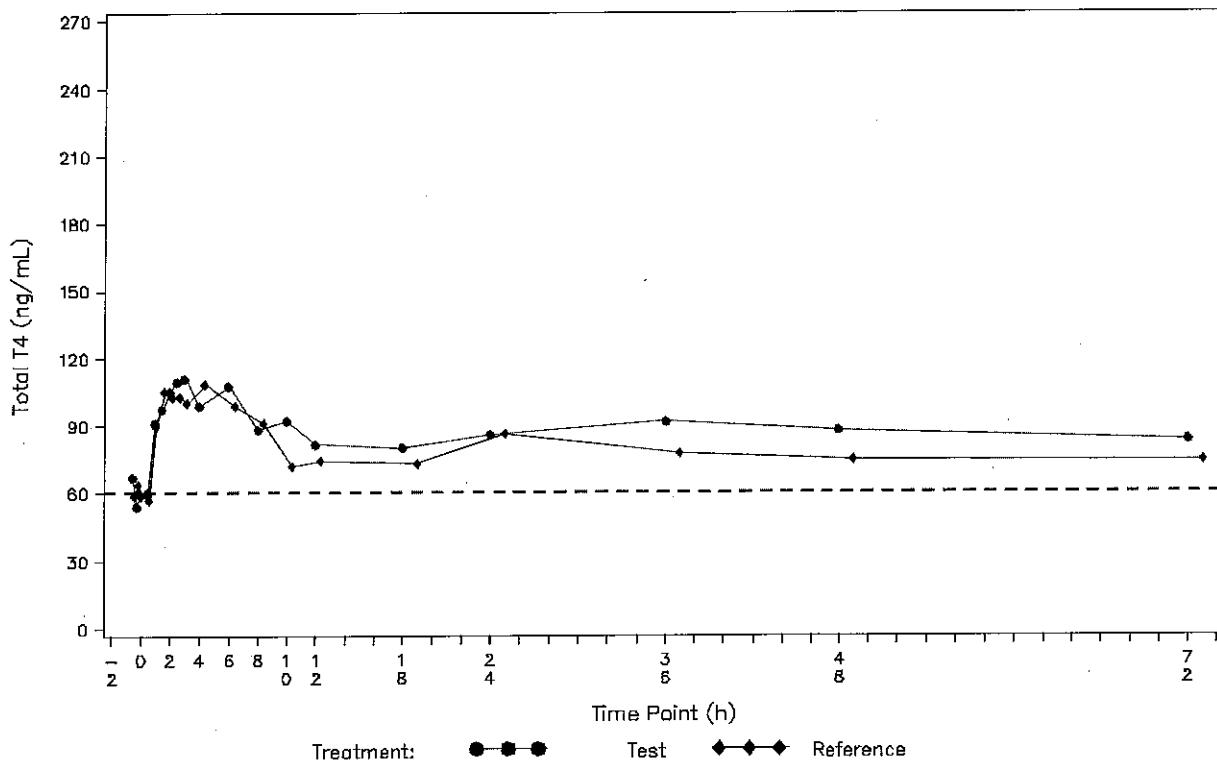
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 863 of 1628 ualuation vs. old formulation

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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:



@: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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**Levothyroxine
EMR 200125-001**

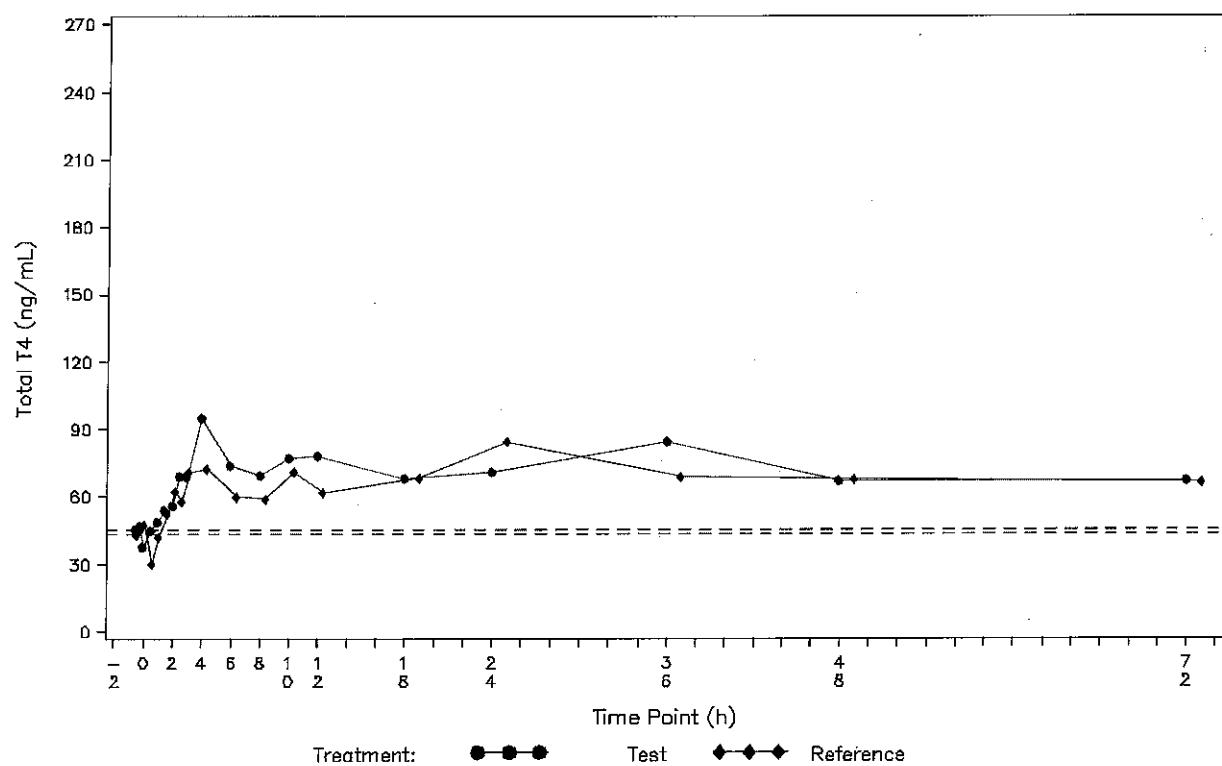
Bioequiv: EMR200125-001 Page 864 of 1628 ulation vs. old formulation

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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:



④: 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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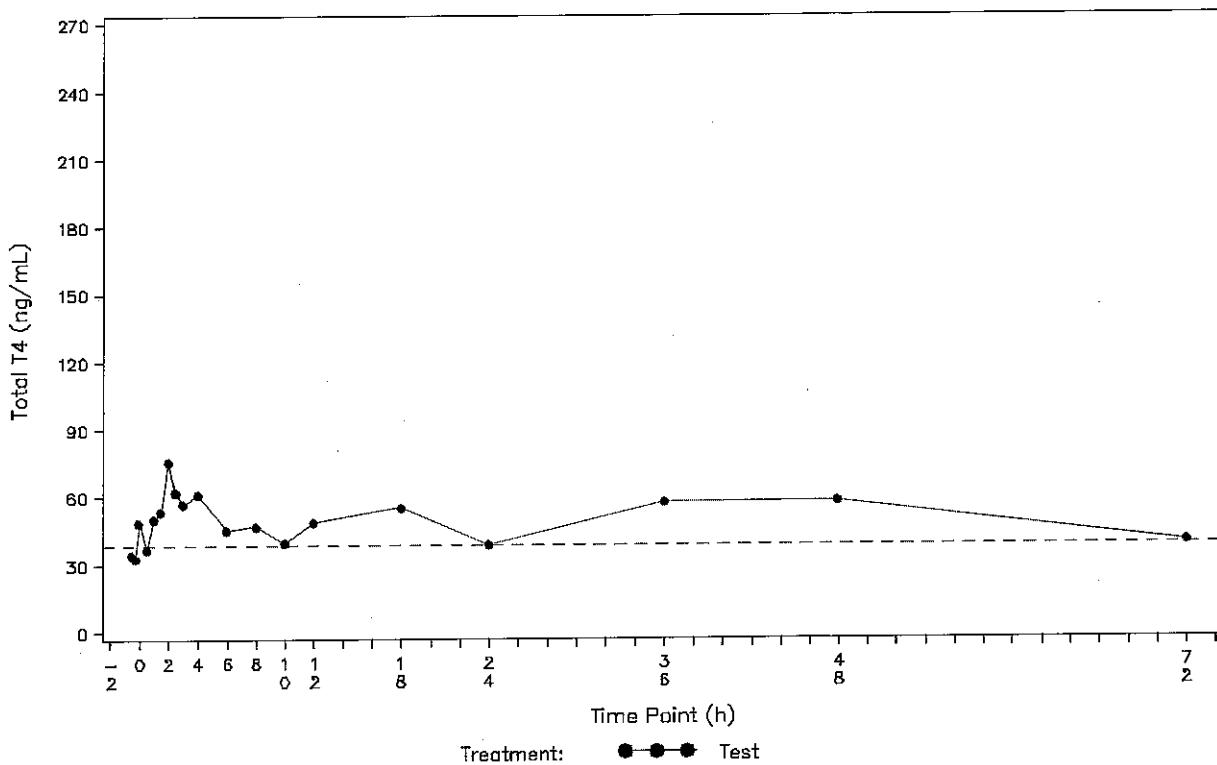
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number: 1



@: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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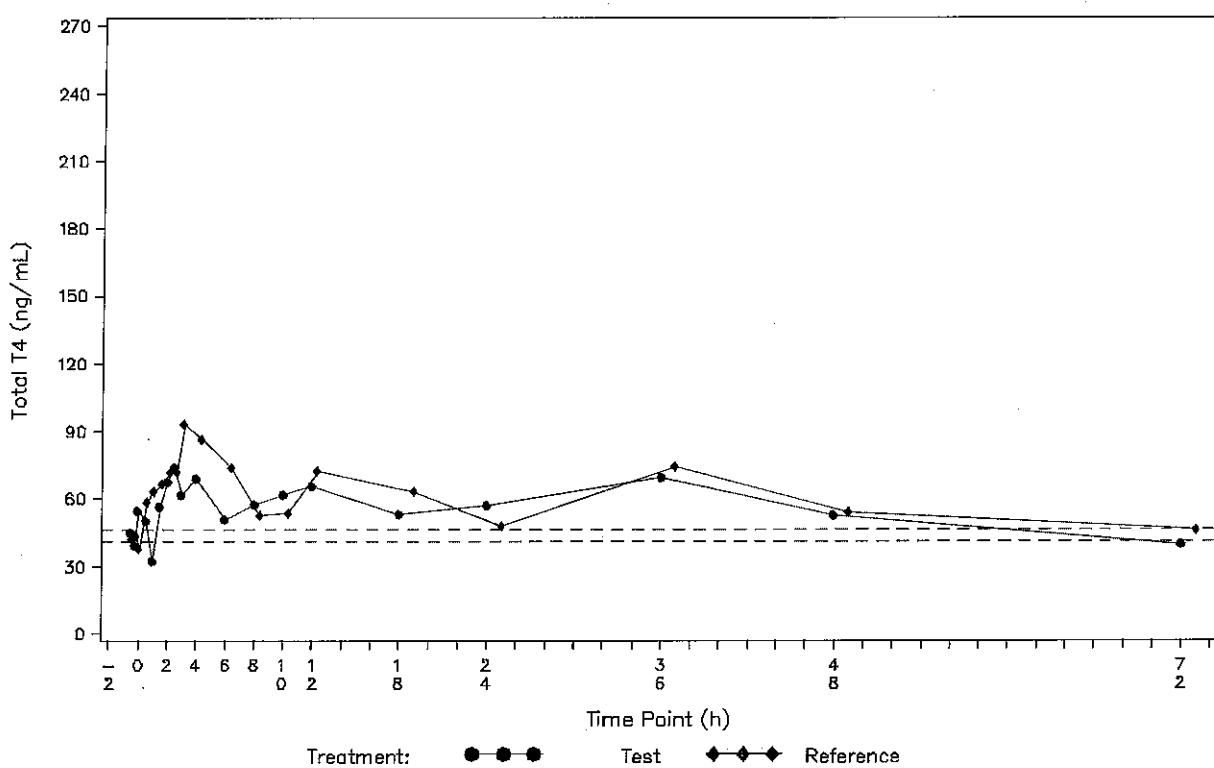
Levothyroxine
EMR 200125-001

Bioequiv^a EMR200125-001 Page 866 of 1628 ualuation 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)

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Subject ID/Random Number:



^a: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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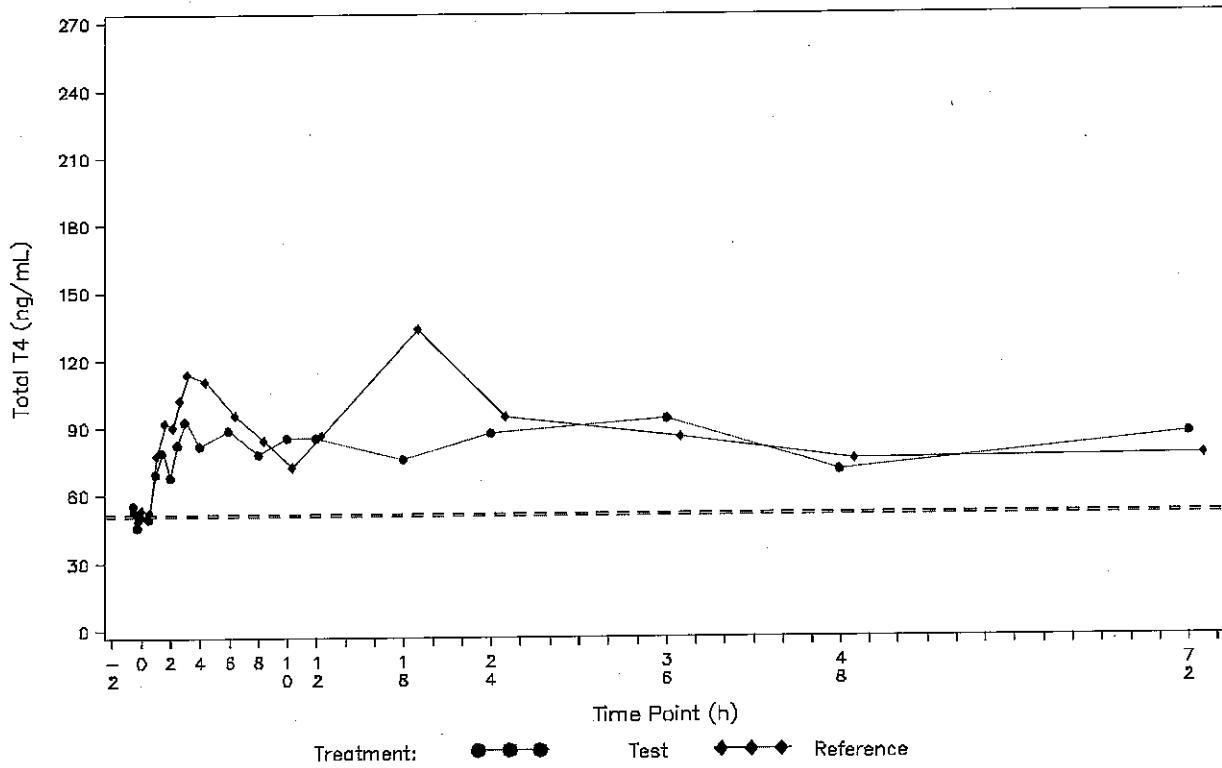
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



Levothyroxine
EMR 200125-001

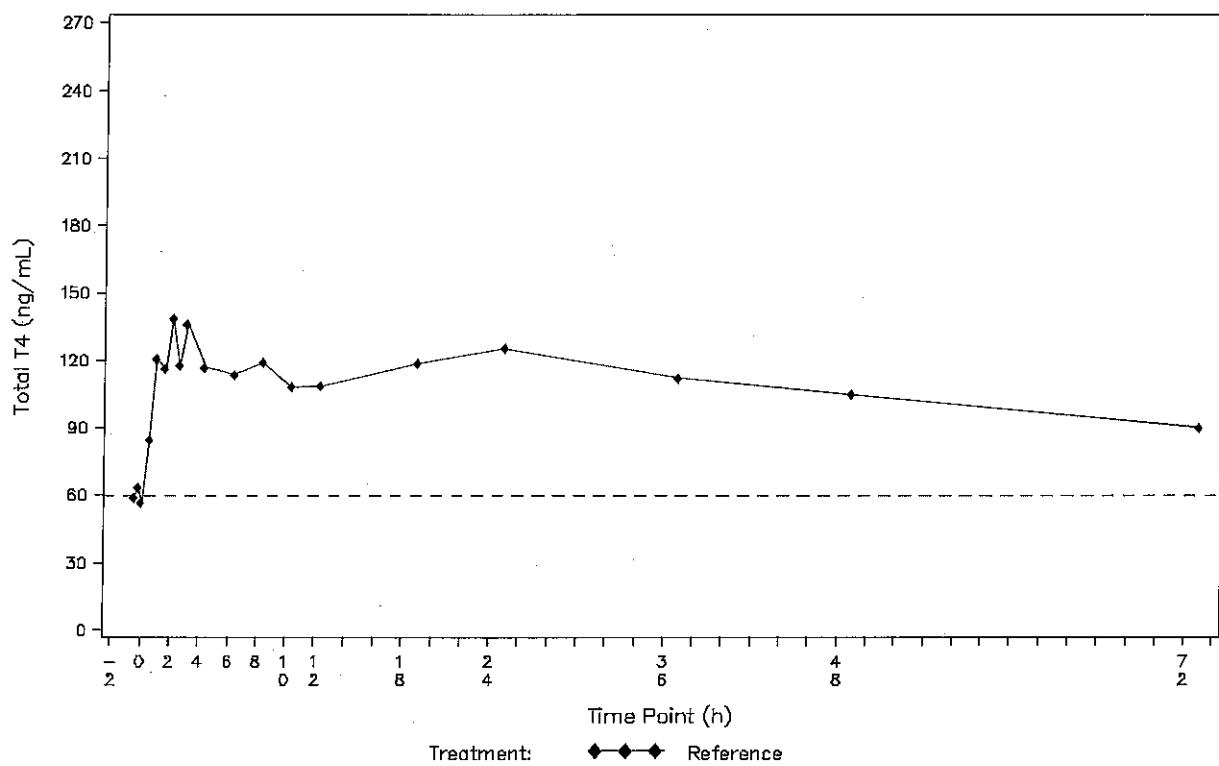
Bioequivalence EMR200125-001 Page 868 of 1628 Evaluation vs. old formulation

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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:



@: 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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**Levothyroxine
EMR 200125-001**

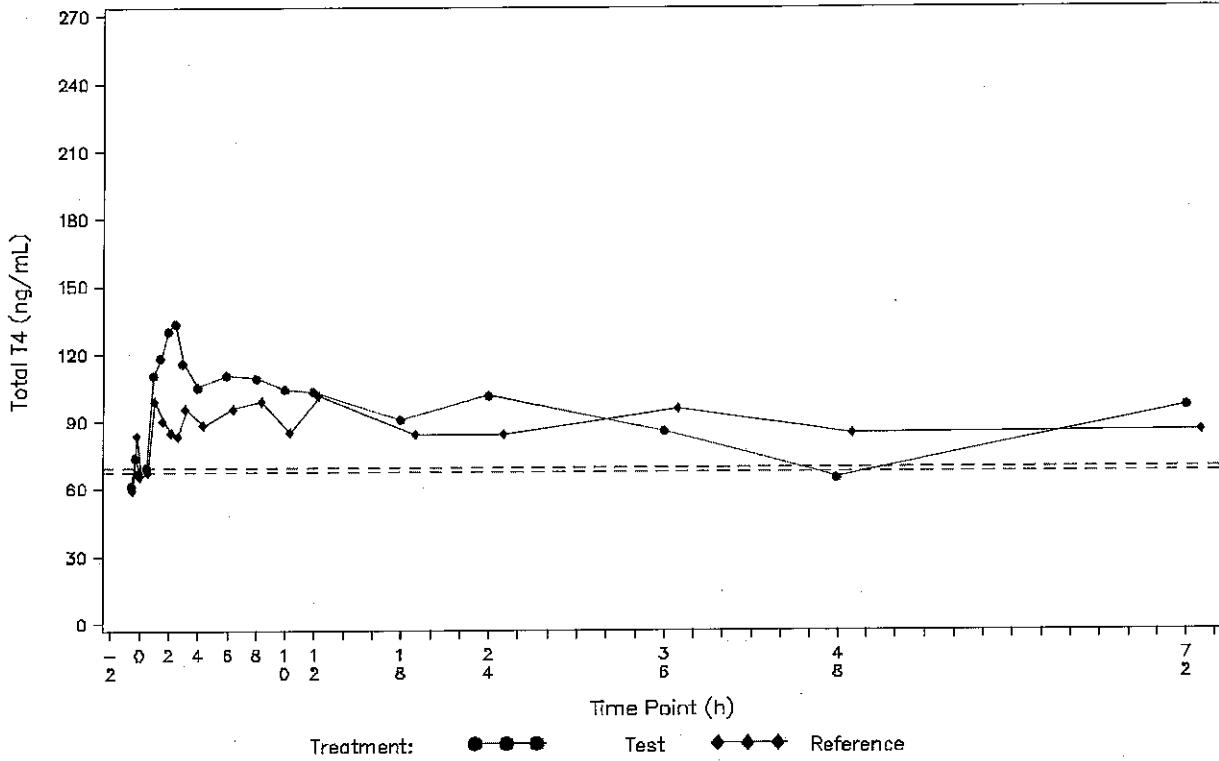
Bioequiv: EMR200125-001 Page 869 of 1628 ulation vs. old formulation

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)

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:

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 16.2.5.2

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**Levothyroxine
EMR 200125-001**

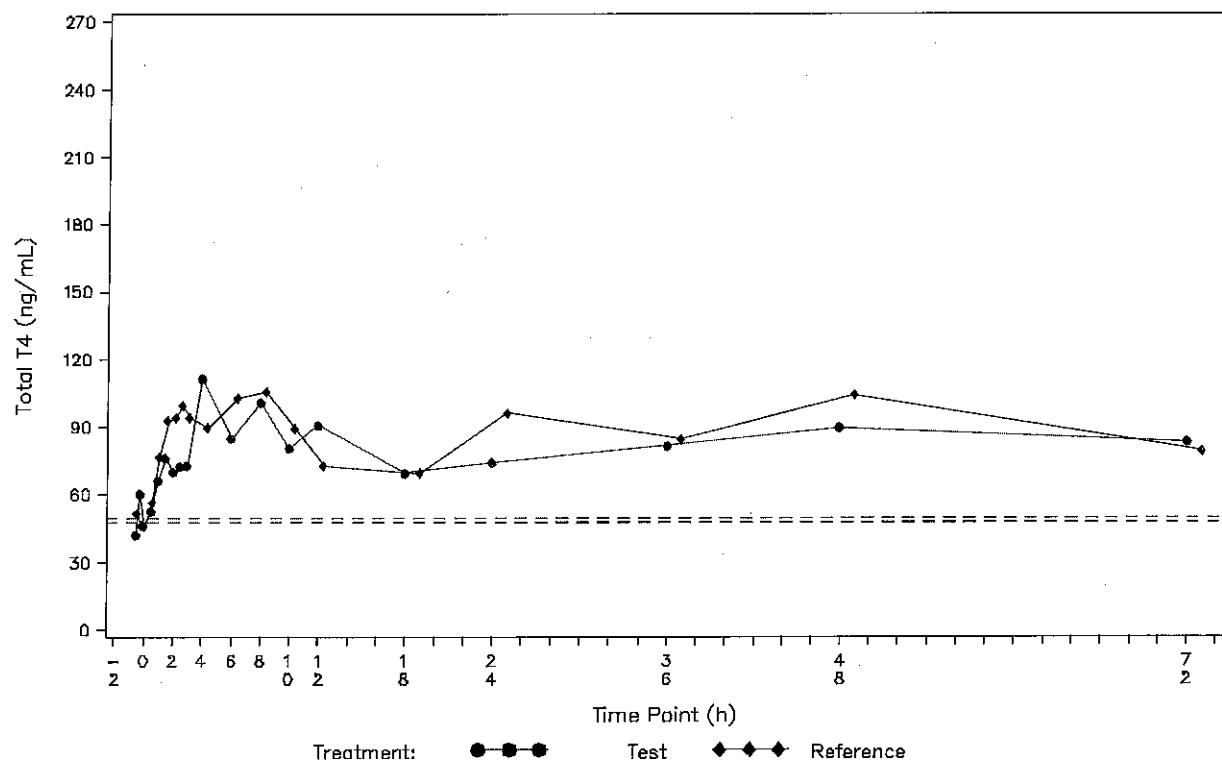
Bioequiv: EMR200125-001 Page 870 of 1628 ultation vs. old formulation

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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:



@: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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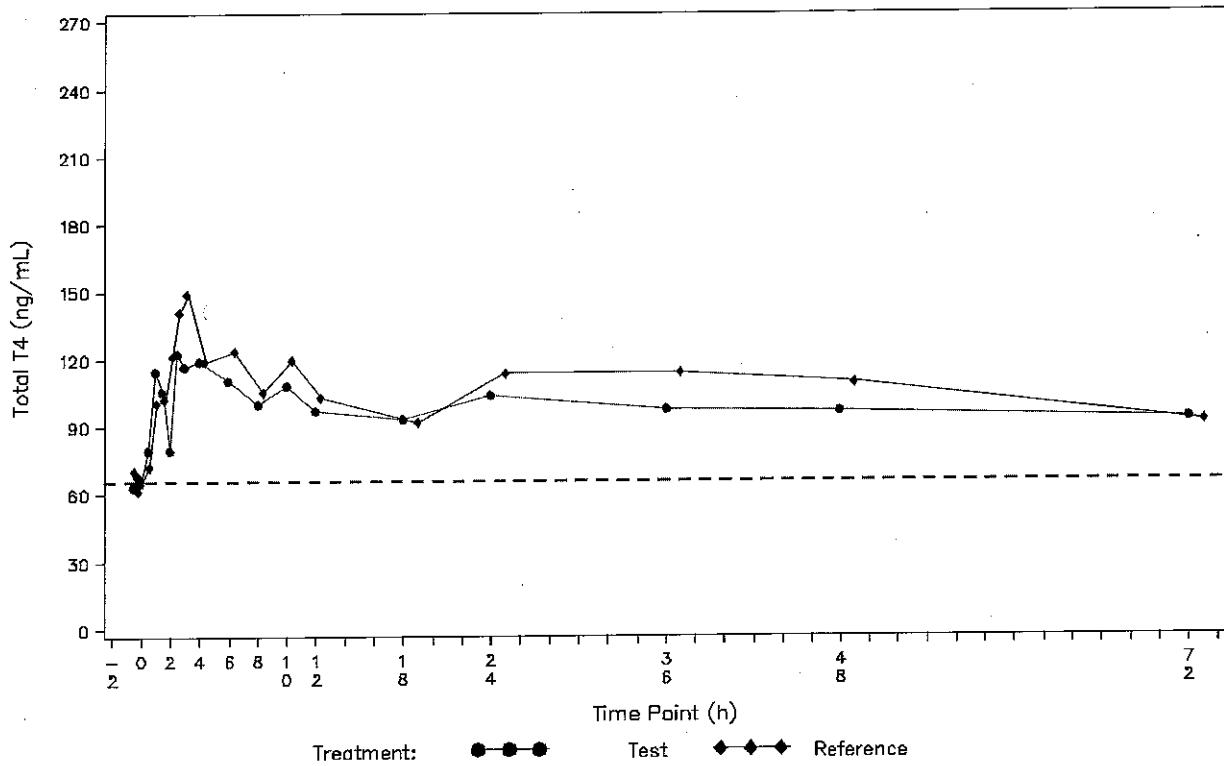
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



④ 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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Levothyroxine
EMR 200125-001

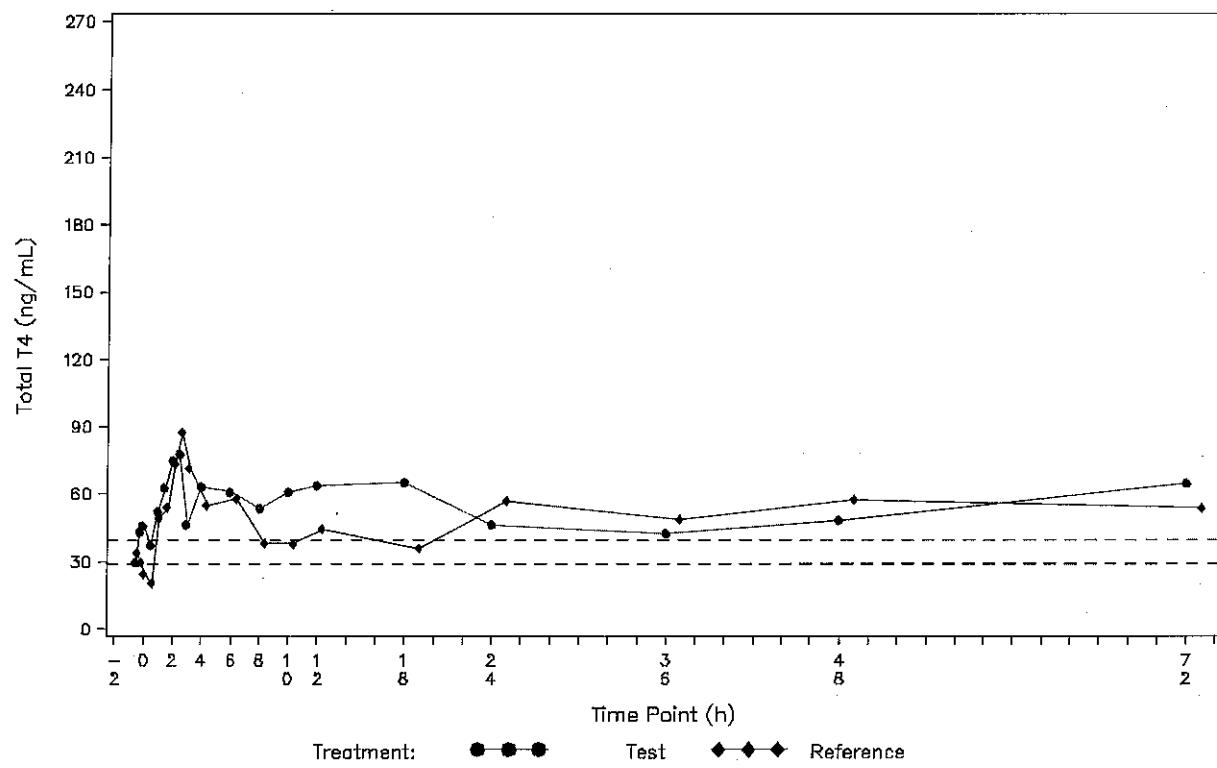
Bioequiv^t EMR200125-001 Page 872 of 1628 ultation vs. old formulation

Merck Serono
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:



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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Levothyroxine
EMR 200125-001

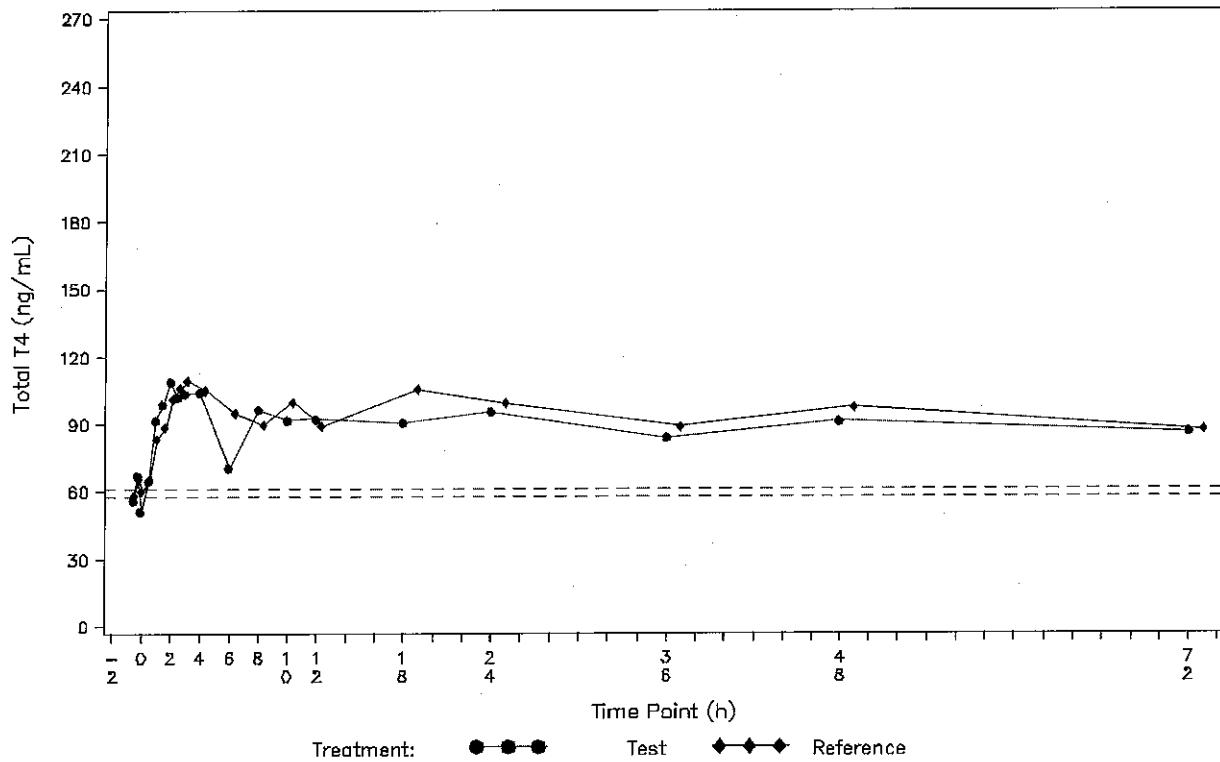
Bioequiv: EMR200125-001 Page 873 of 1628 nulation vs. old formulation

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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:



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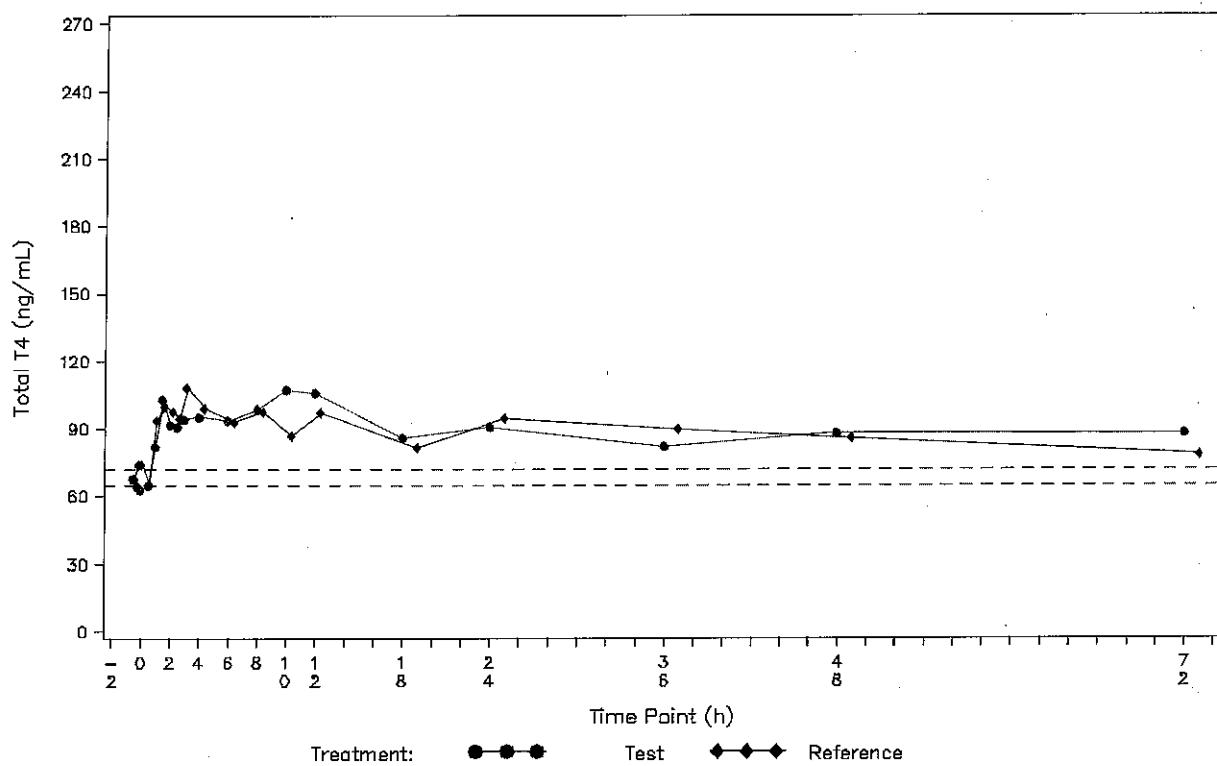
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values) (Safety Population)

Subject ID/Random Number:



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

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

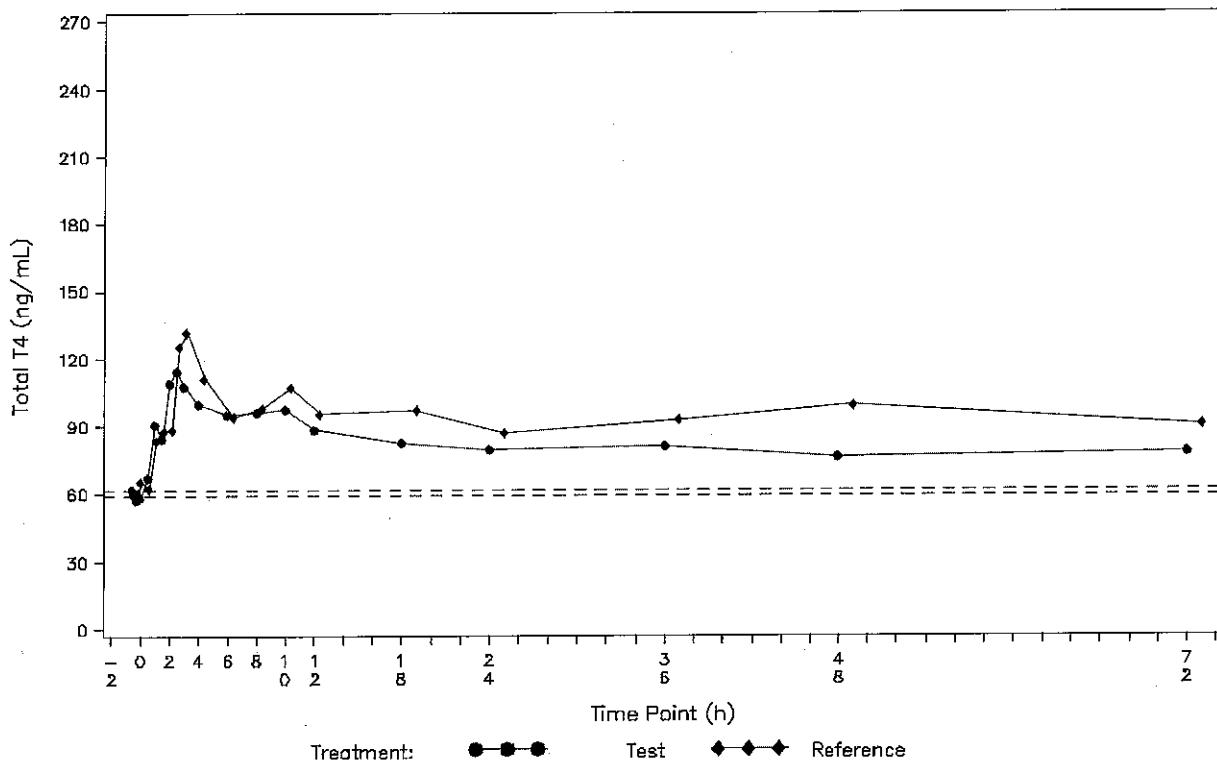
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



⑧Subjects 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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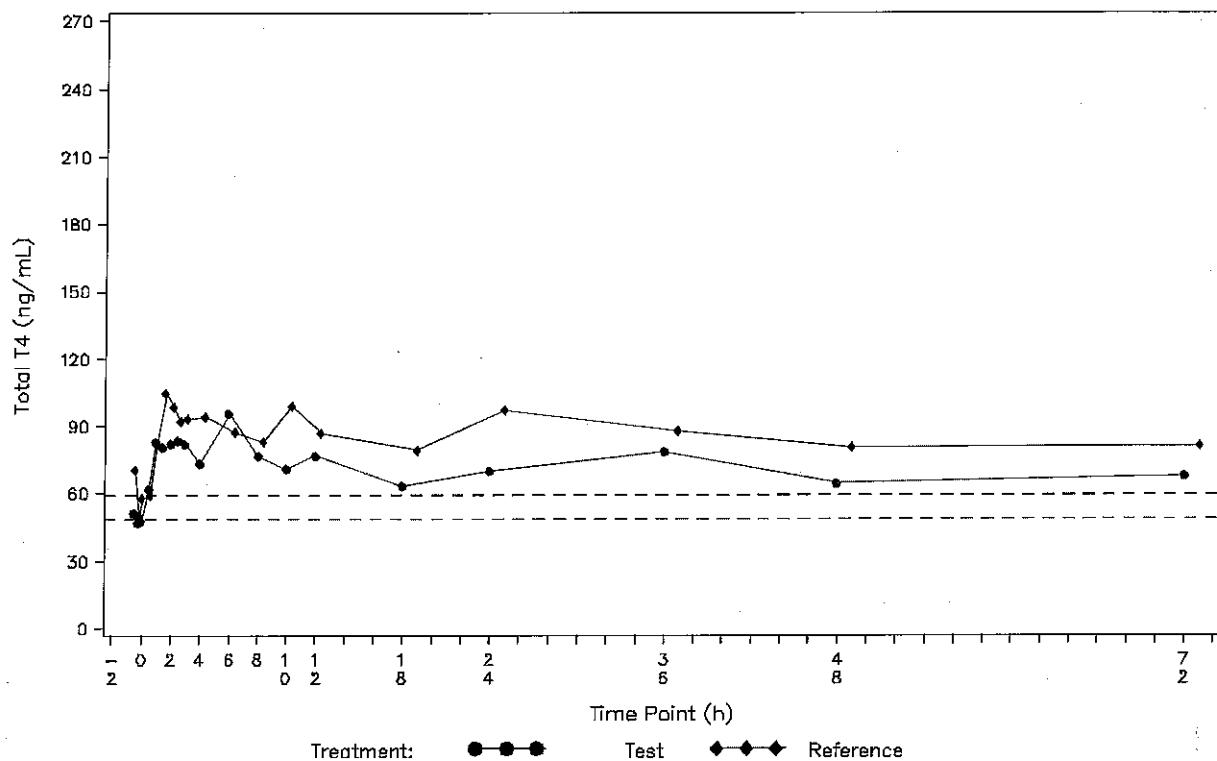
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 876 of 1628 ualuation vs. old formulation

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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:



@: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE 15.4.2.9.sas

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**Levothyroxine
EMR 200125-001**

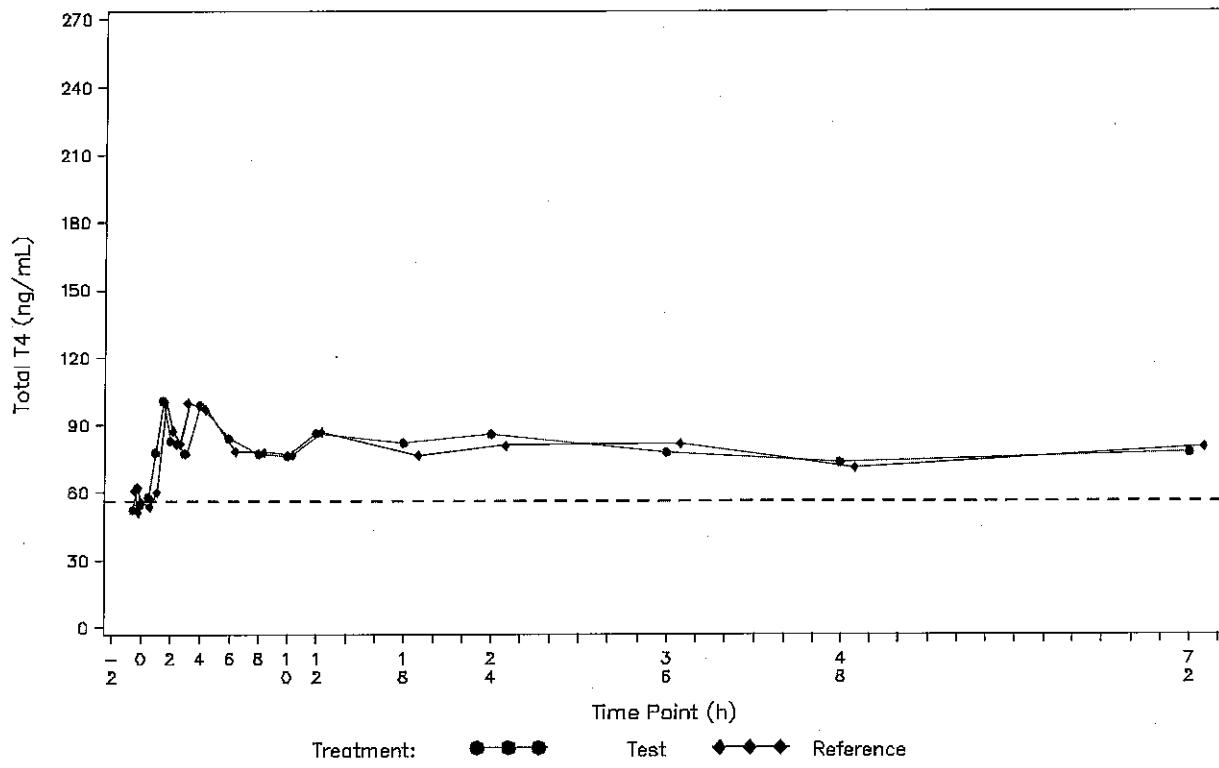
Bioequiv: EMR200125-001 Page 877 of 1628 ulation vs. old formulation

Merck Serono
EMR 200125-001

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Confidential

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: Listing 16.2.5.2

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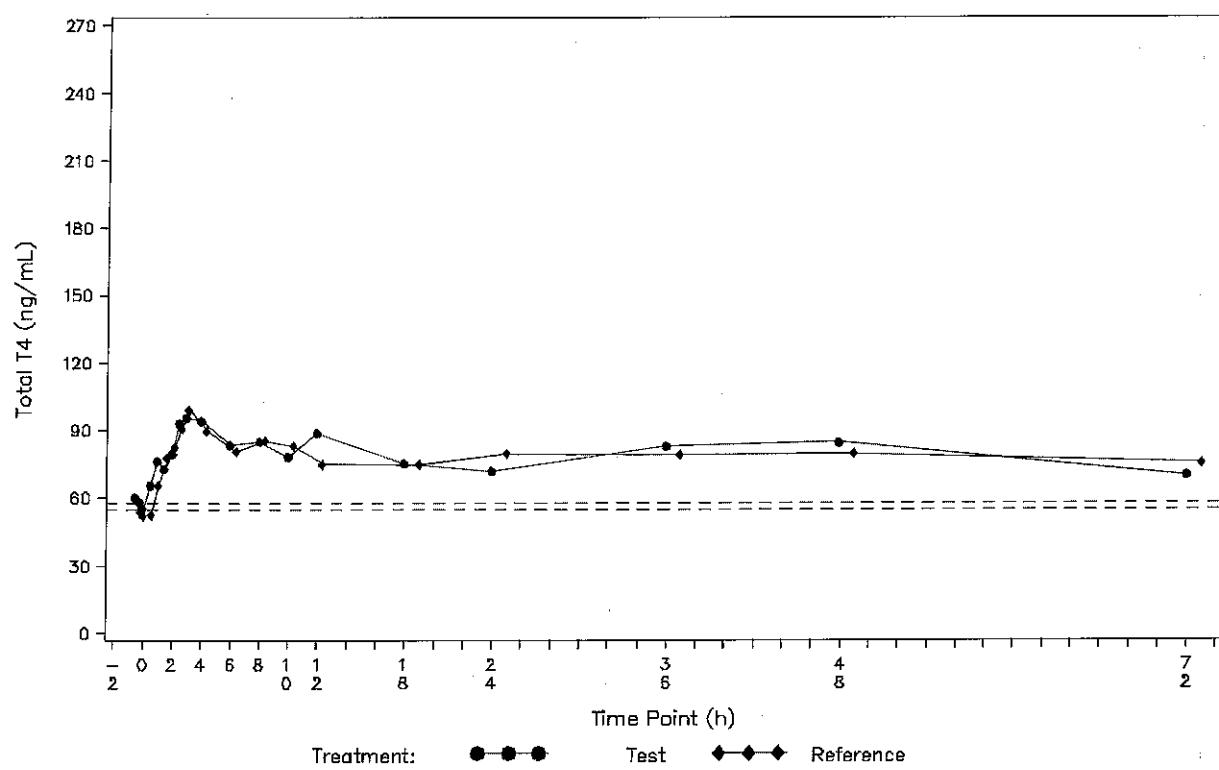
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 878 of 1628 ualuation vs. old formulation

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Confidential

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: Listing 16.2.5.2

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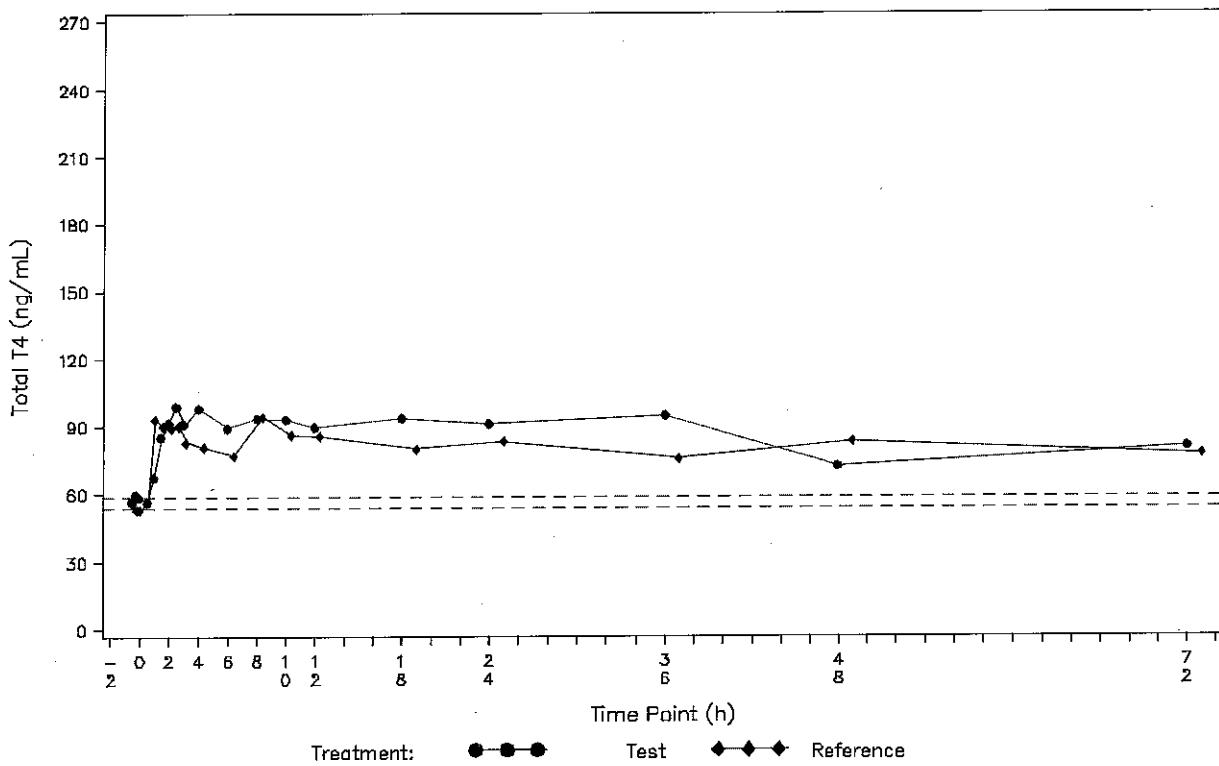
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



@: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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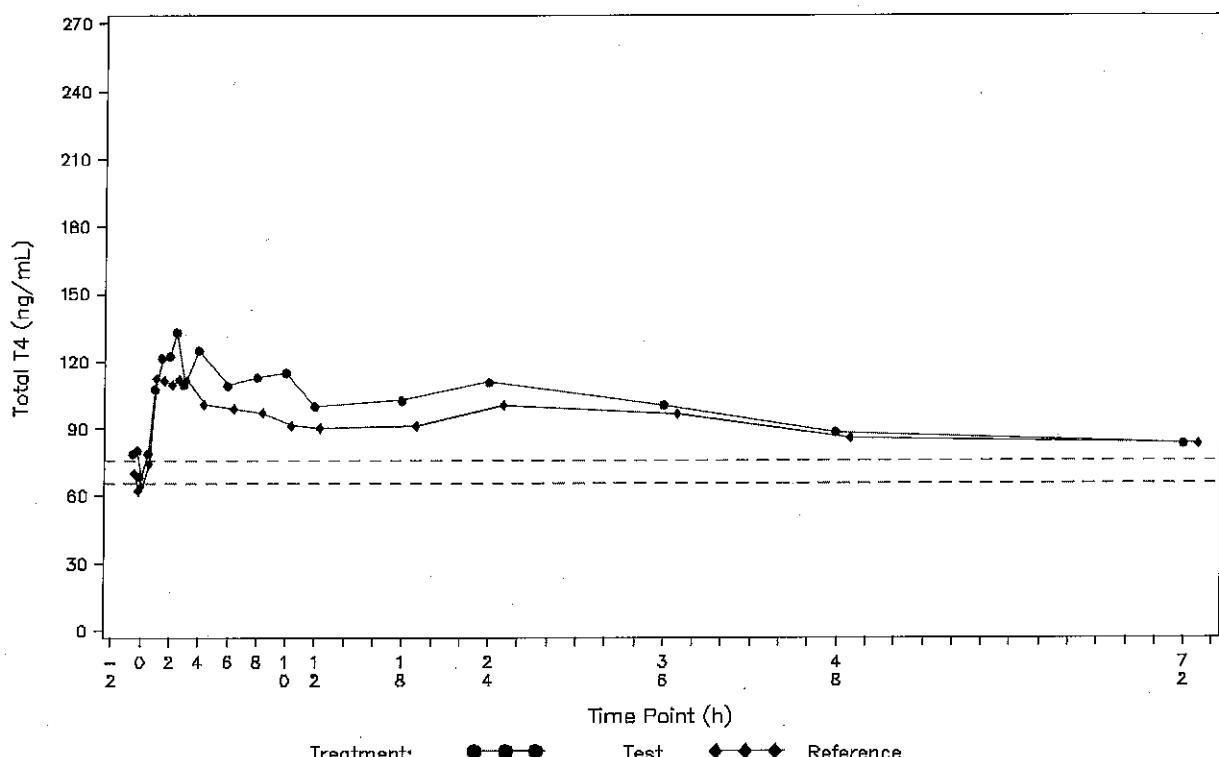
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 880 of 1628 nulation vs. old formulation

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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:



④ 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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Levothyroxine
EMR 200125-001

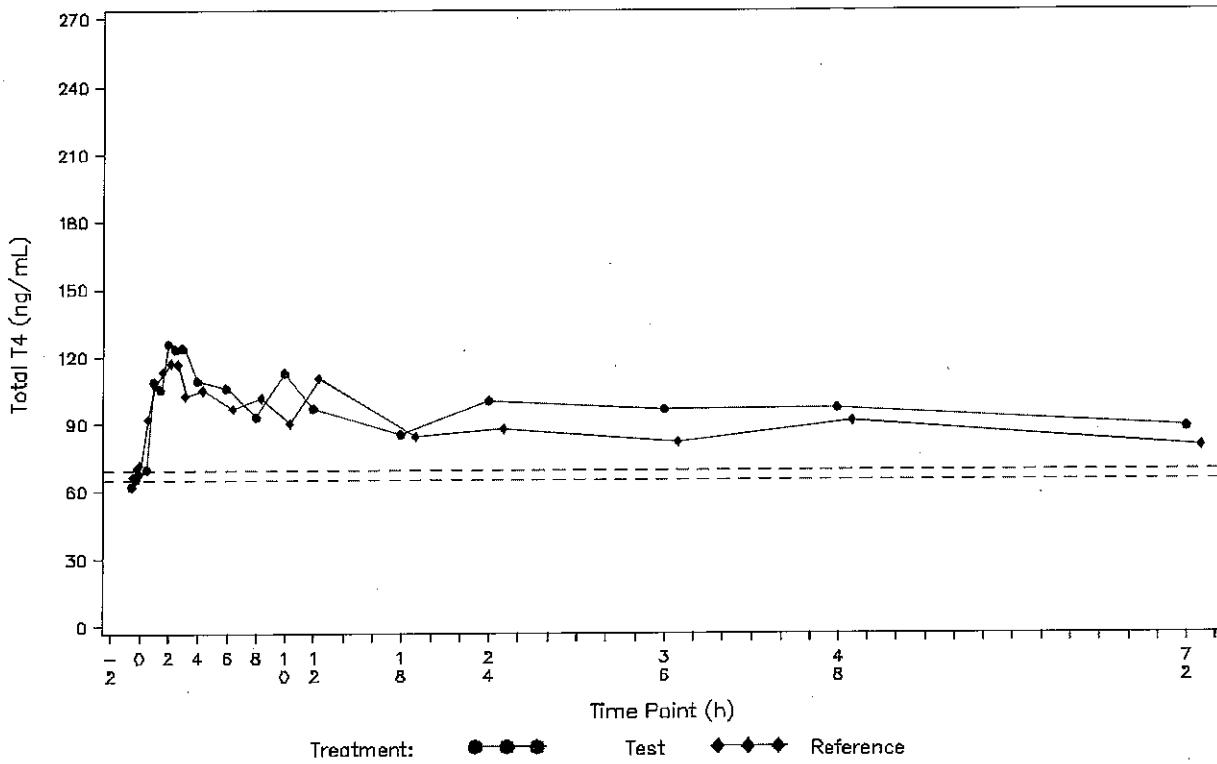
Bioequiv: EMR200125-001 Page 881 of 1628 nulation vs. old formulation

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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: J



@: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/FIGURES/FIGURE
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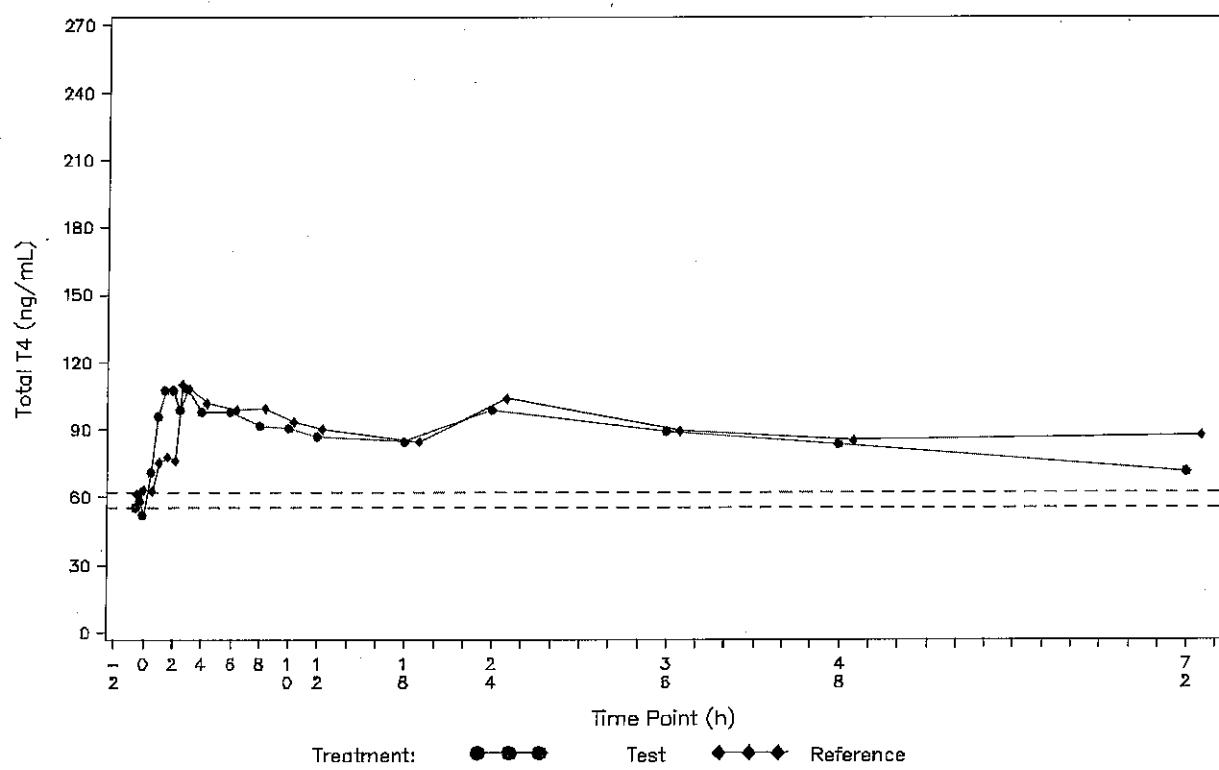
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 882 of 1628 nulation vs. old formulation

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Confidential

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

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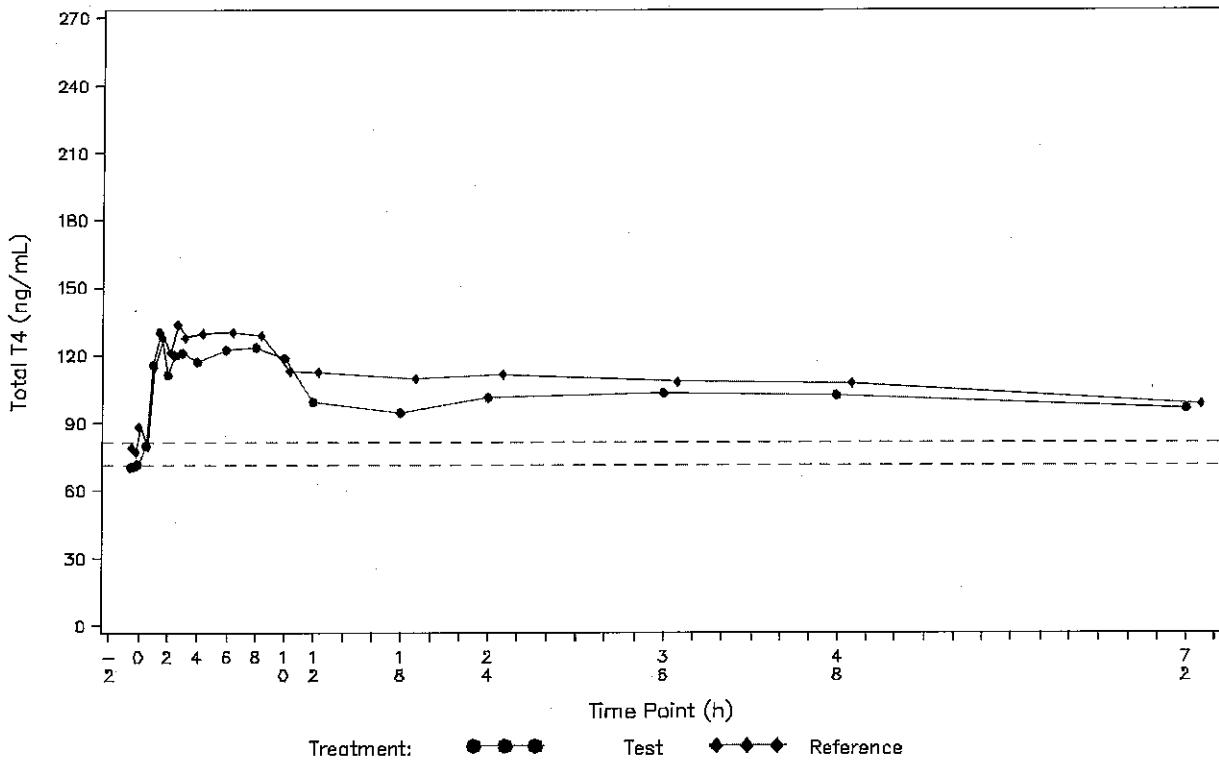
Levothyroxine
EMR 200125-001

Bioequiv: EMR200125-001 Page 883 of 1628 ulation vs. old formulation

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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:



@: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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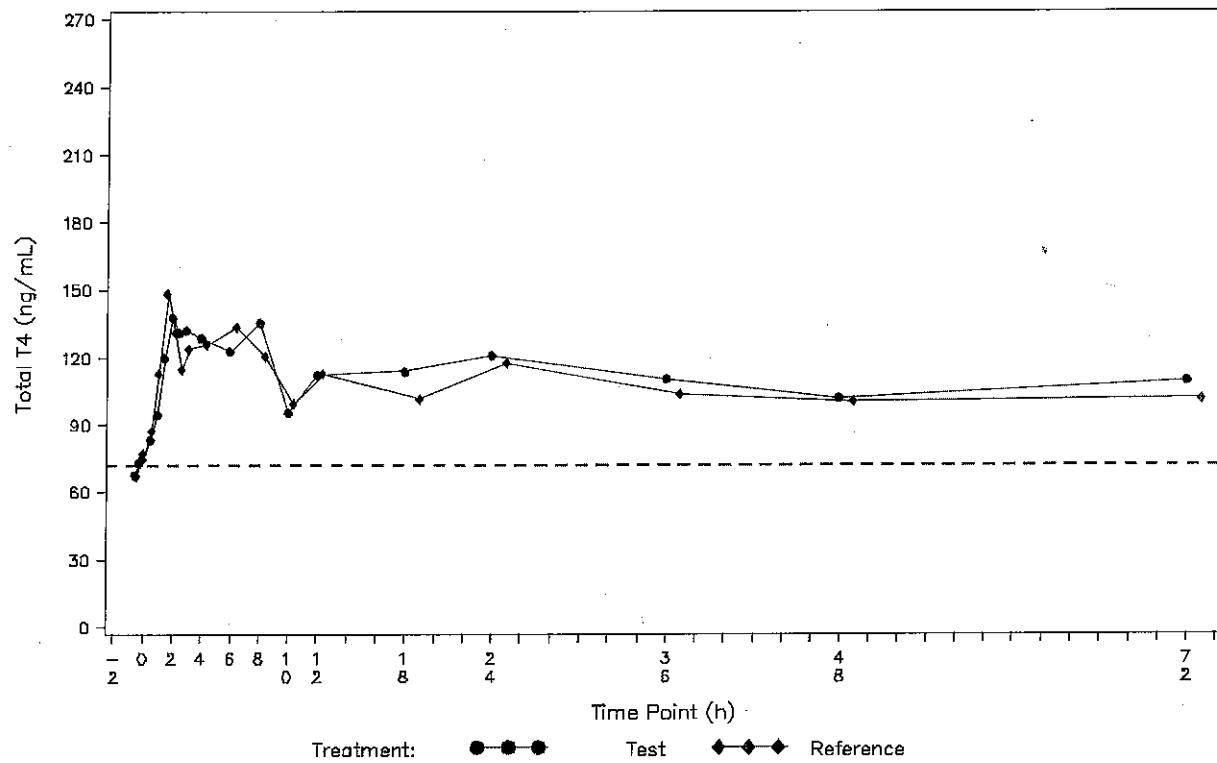
Levothyroxine
EMR 200125-001

Bioequiv^a EMR200125-001 Page 884 of 1628 ualuation vs. old formulation

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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:



^a: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/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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Levothyroxine
EMR 200125-001

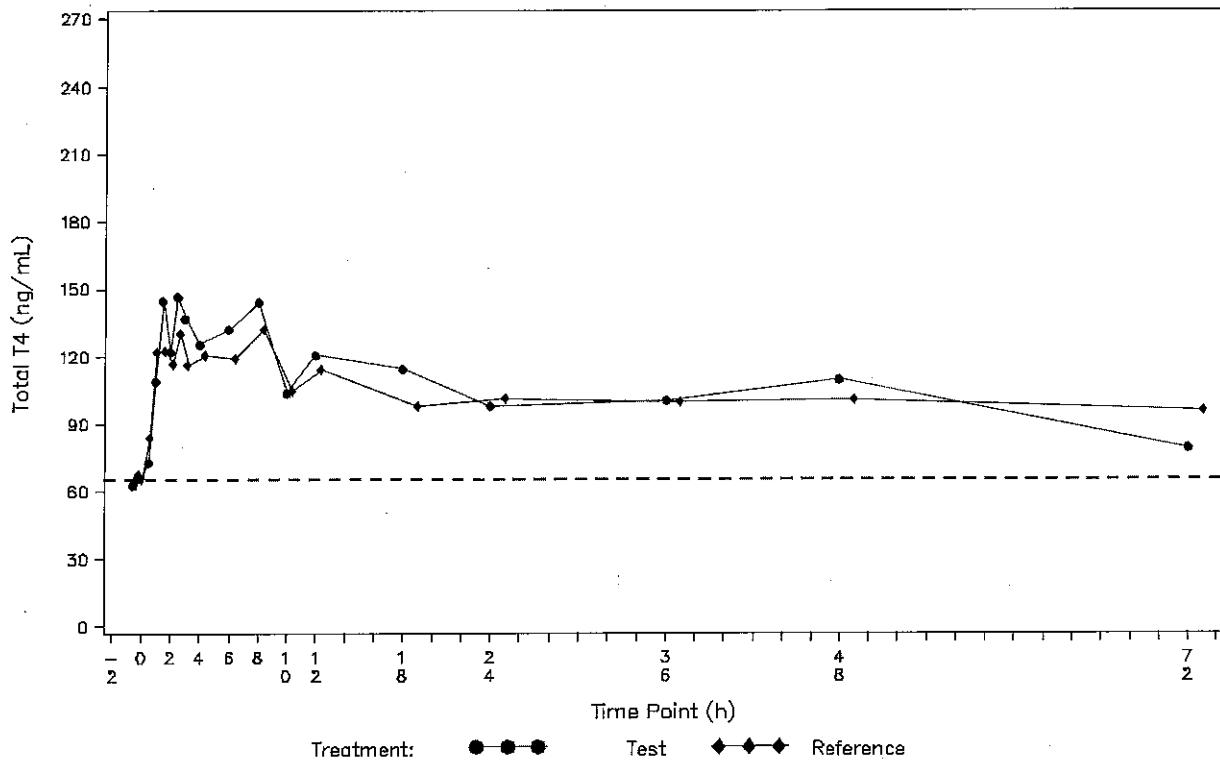
Bioequivⁱ EMR200125-001 Page 885 of 1628 ulation vs. old formulation

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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: ...



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

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

Source: Listing 16.2.5.2

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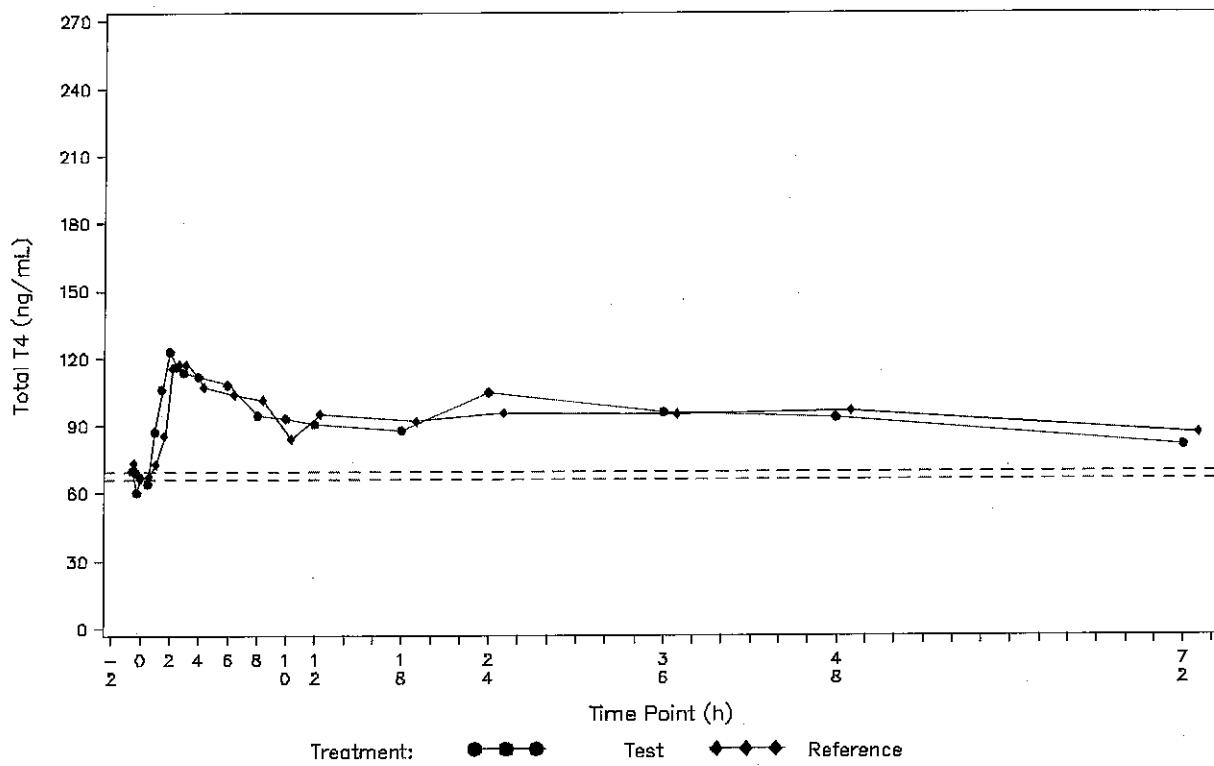
Levothyroxine
EMR 200125-001

Bioequiv~~s~~ EMR200125-001 Page 886 of 1628 ualuation 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)

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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 16.2.5.2

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Figures/Figure 15.4.2.9.sas

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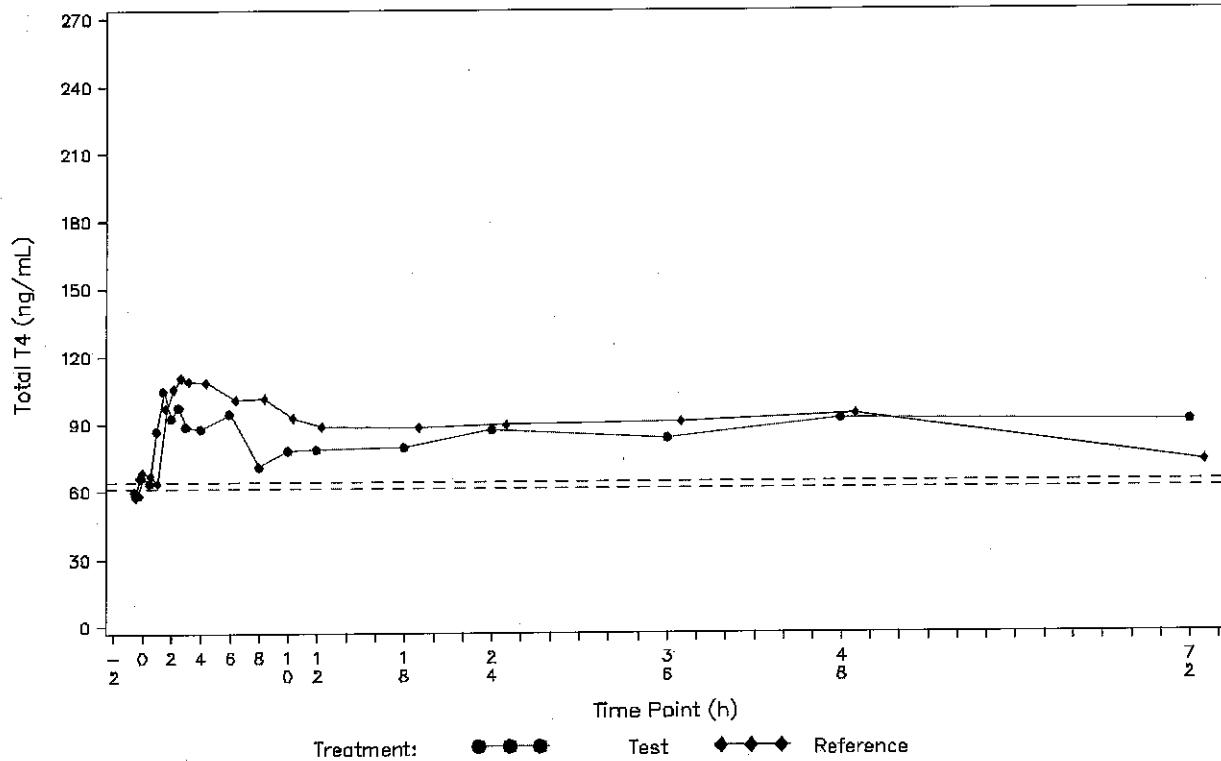
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



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 16.2.5.2

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**Levothyroxine
EMR 200125-001**

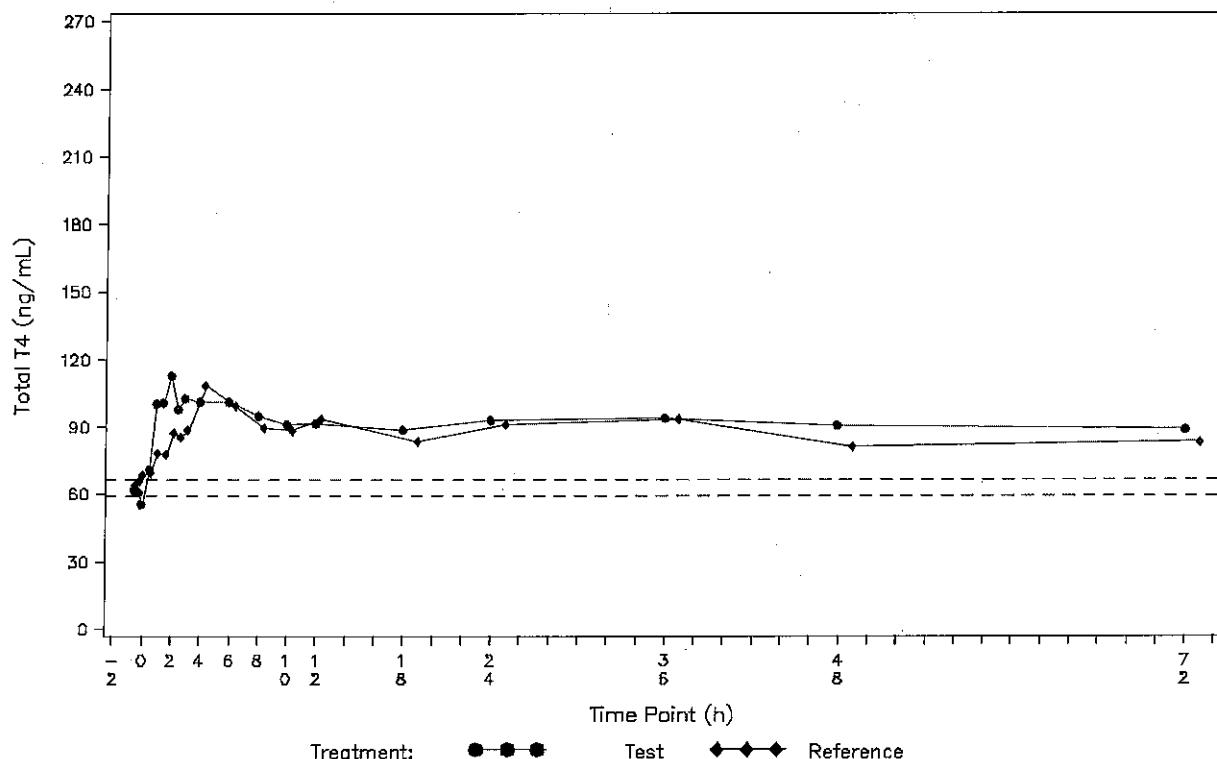
Bioequiv: EMR200125-001 Page 888 of 1628 ulation vs. old formulation

Merck Serono
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:



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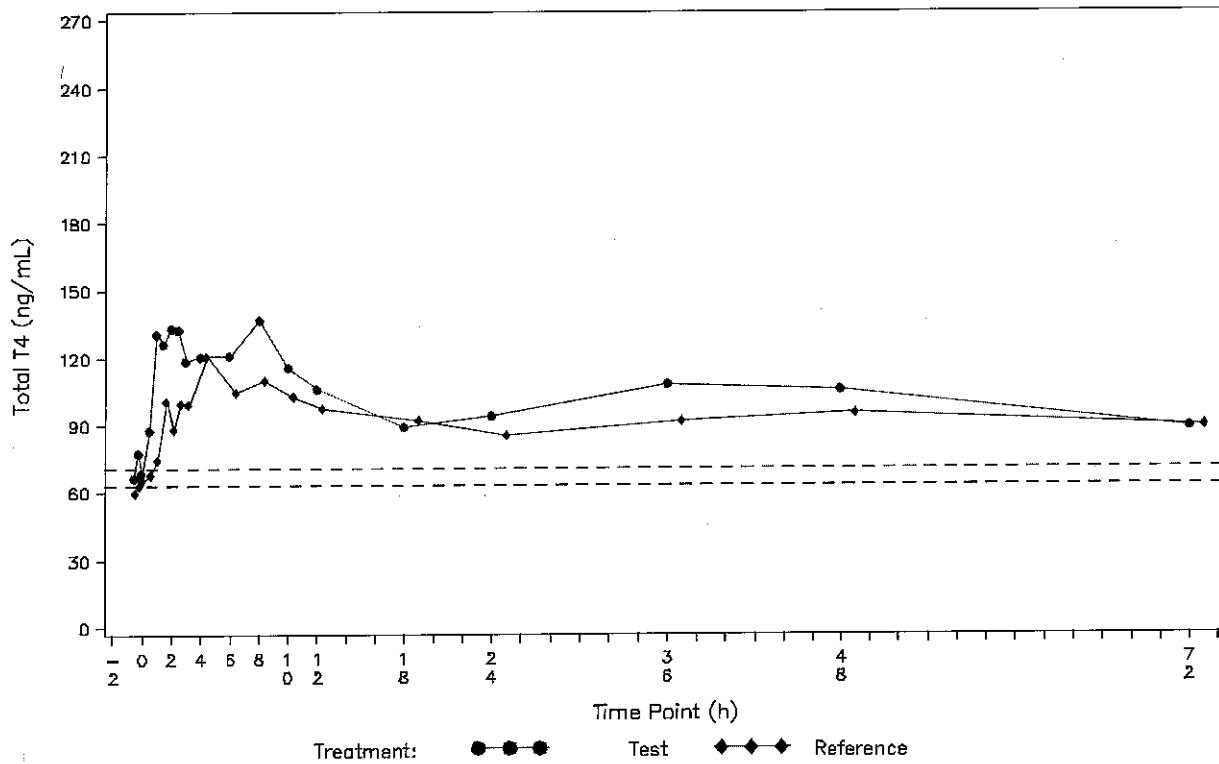
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



@: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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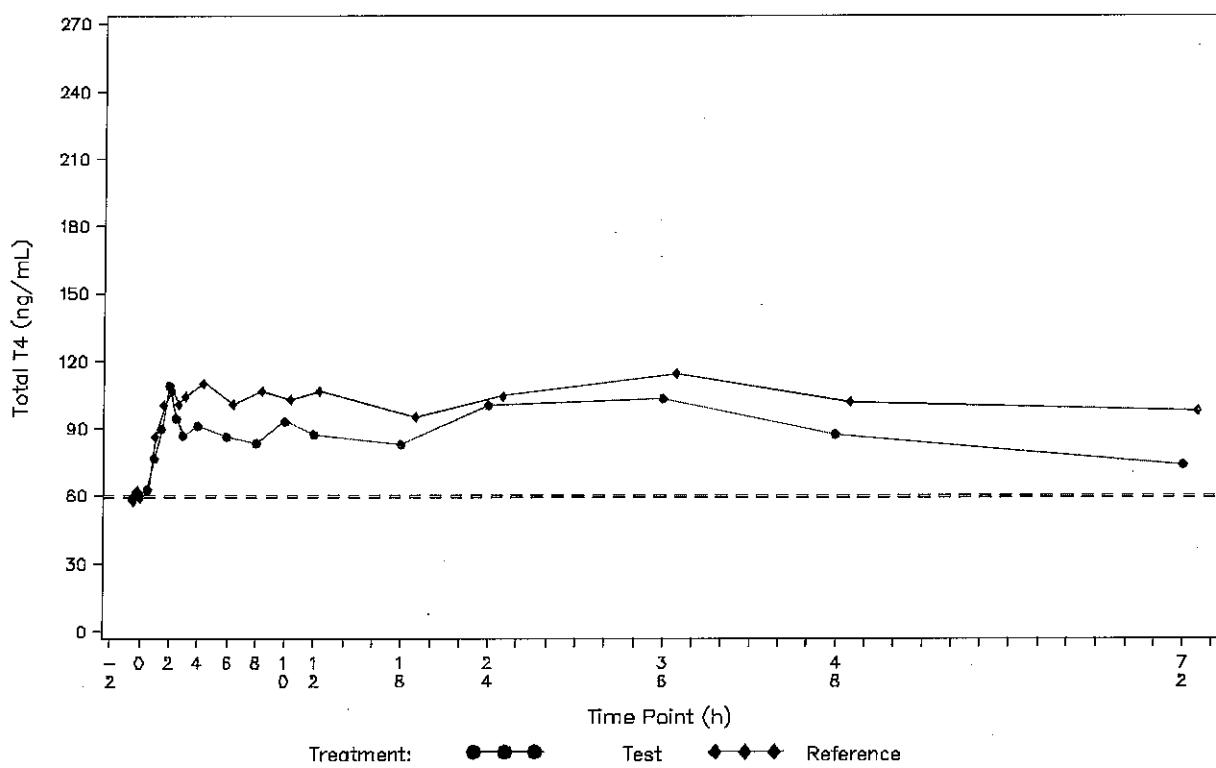
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 890 of 1628 nulation vs. old formulation

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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:



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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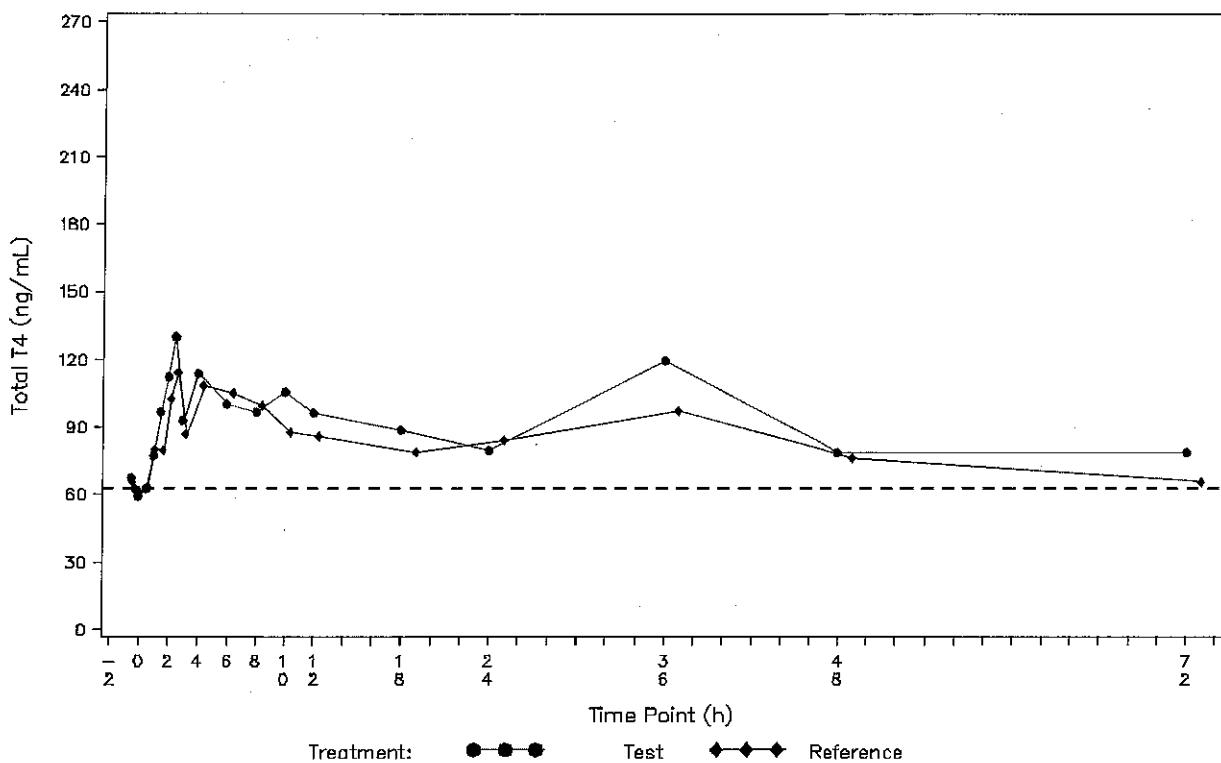
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Subject ID/Random Number: ?



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Levothyroxine
EMR 200125-001

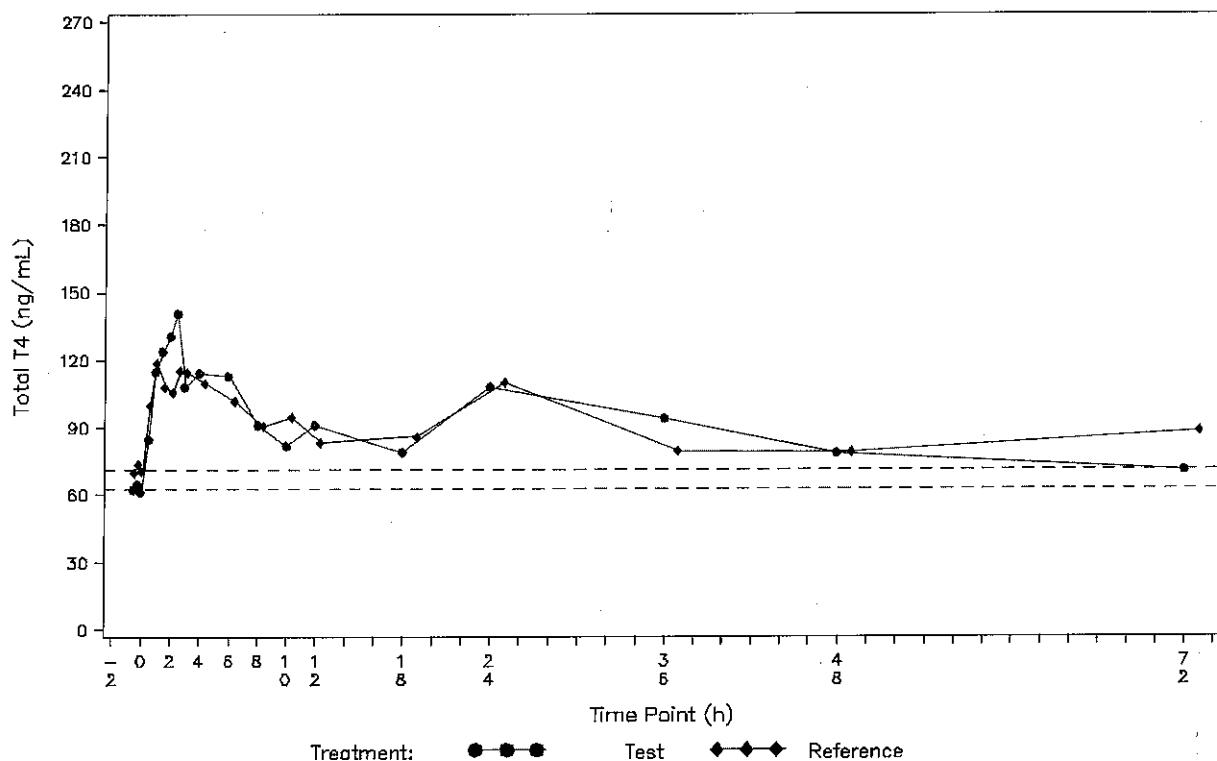
Bioequiv^e EMR200125-001 Page 892 of 1628 nulation vs. old formulation

Merck Serono
EMR 200125-001

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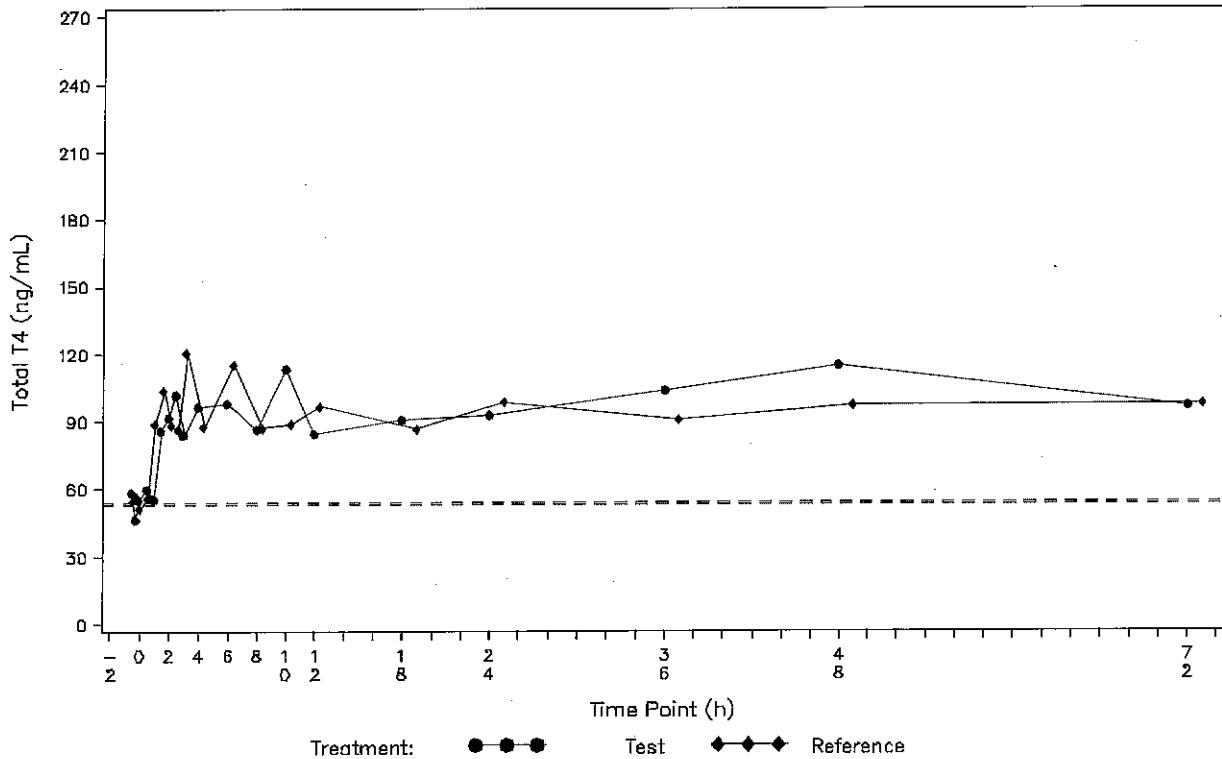
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



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:



@: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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**Levothyroxine
EMR 200125-001**

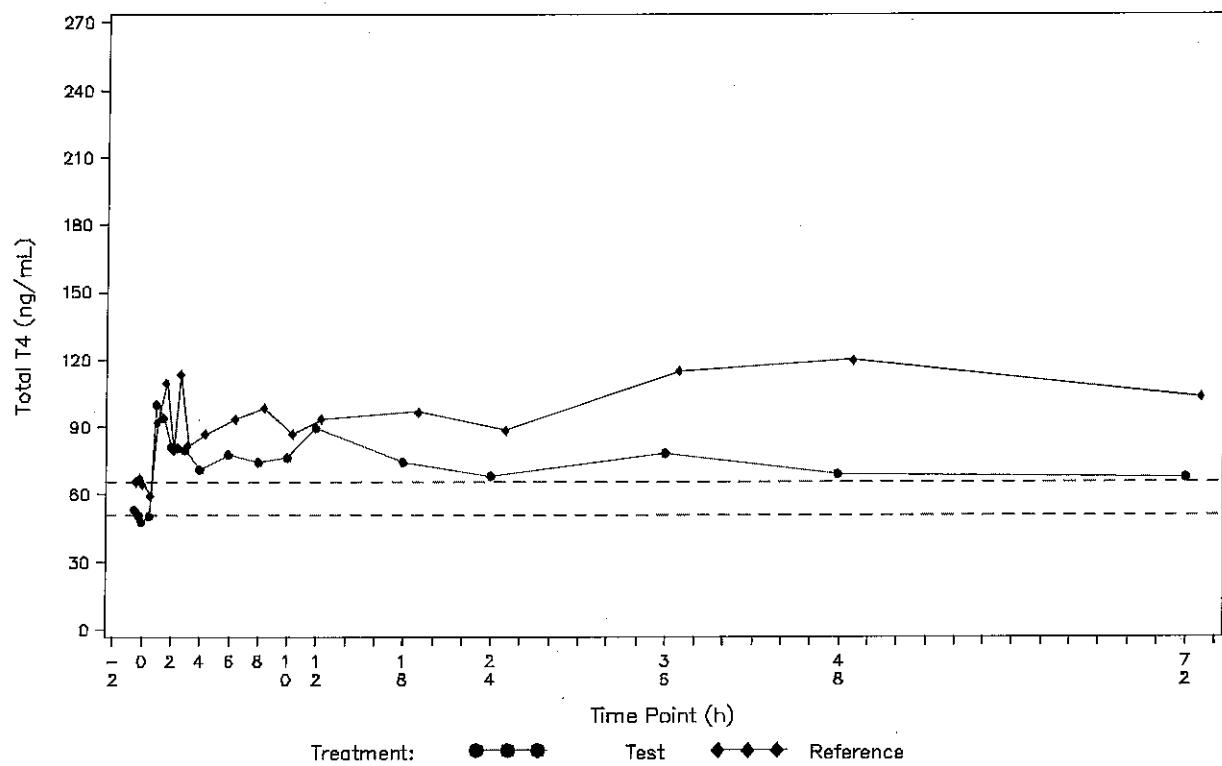
Bioequivivalence vs old formulation

Merci Serono
EMR 200125-001

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Confidential

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: Listing 16.2.5.2

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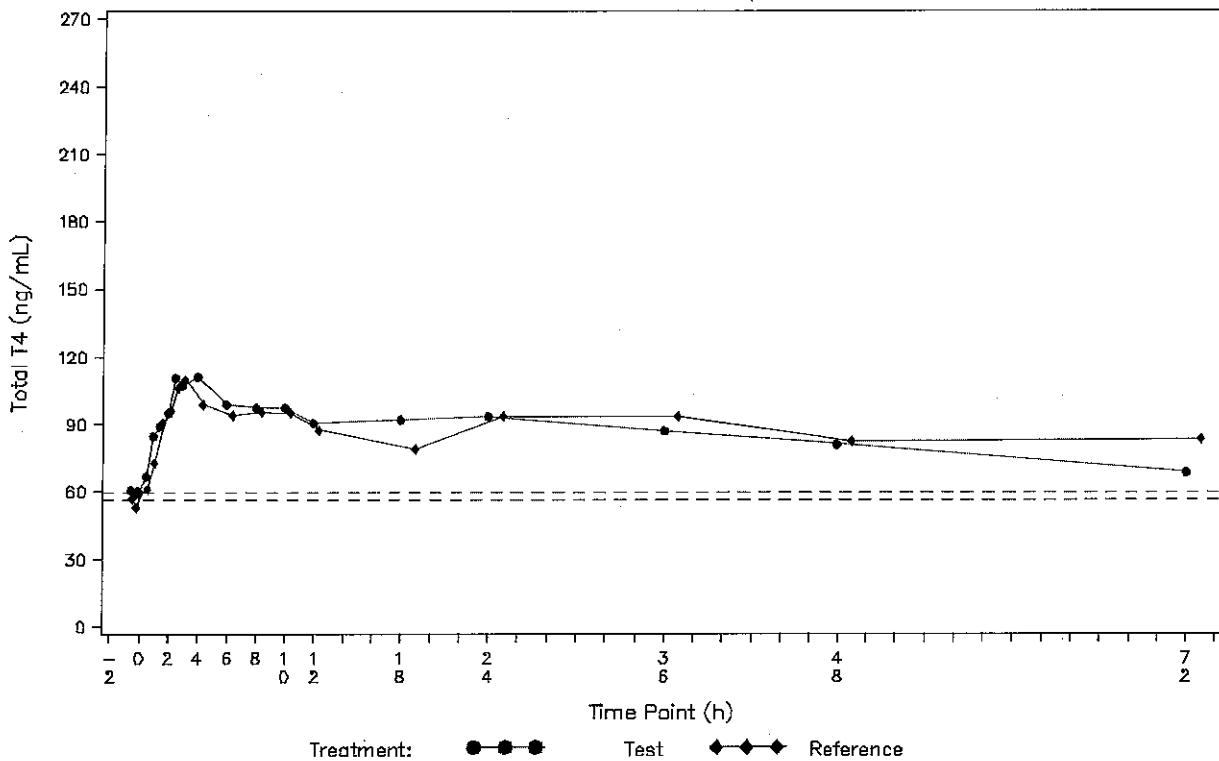
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Merck Serono
EMR 200125-001
Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

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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 16.2.5.2

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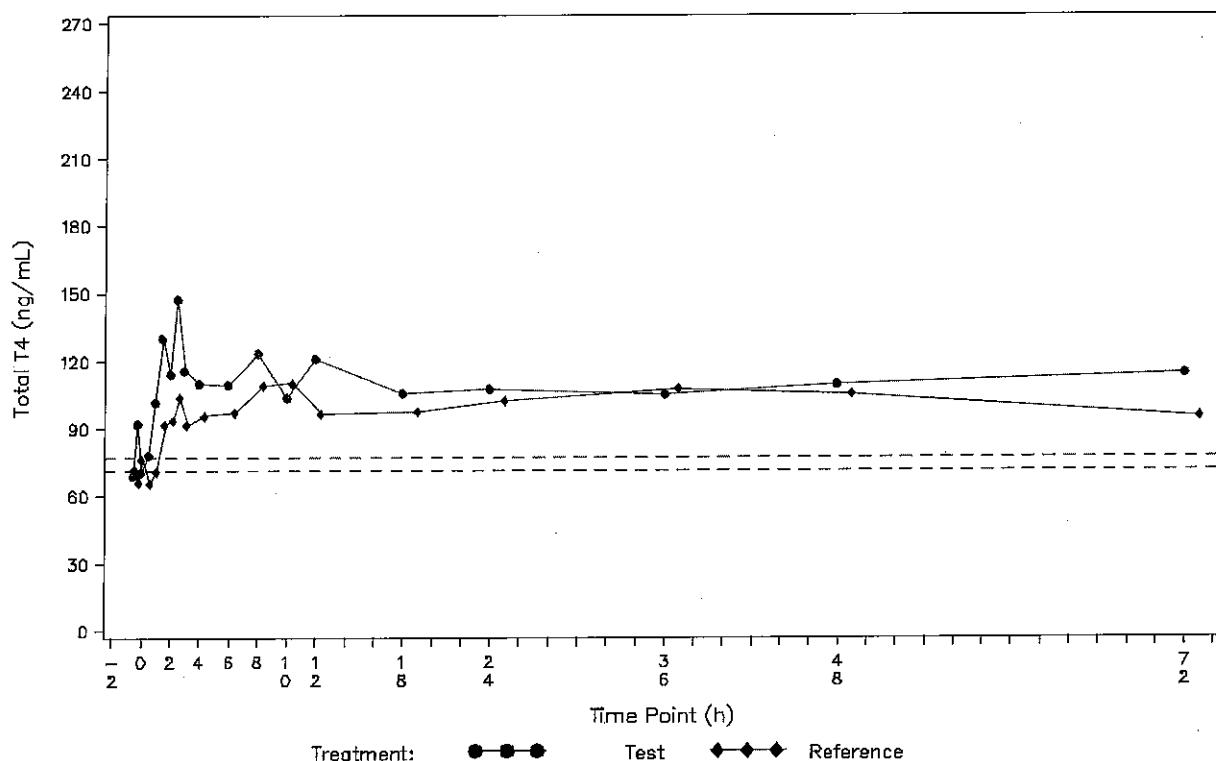
**Levothyroxine
EMR 200125-001**

Bioequiv: EMR200125-001 Page 896 of 1628 ualuation vs. old formulation

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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:



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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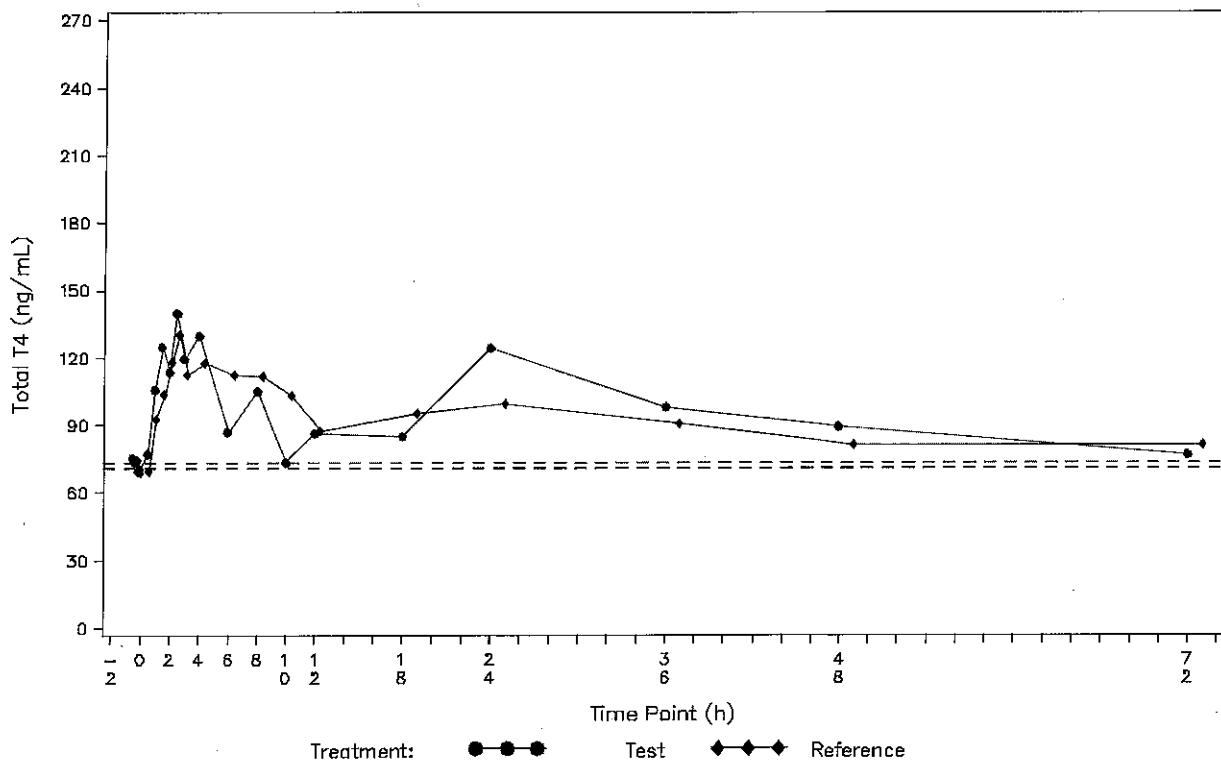
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Merck Serono
EMR 200125-001

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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:



*: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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**Levothyroxine
EMR 200125-001**

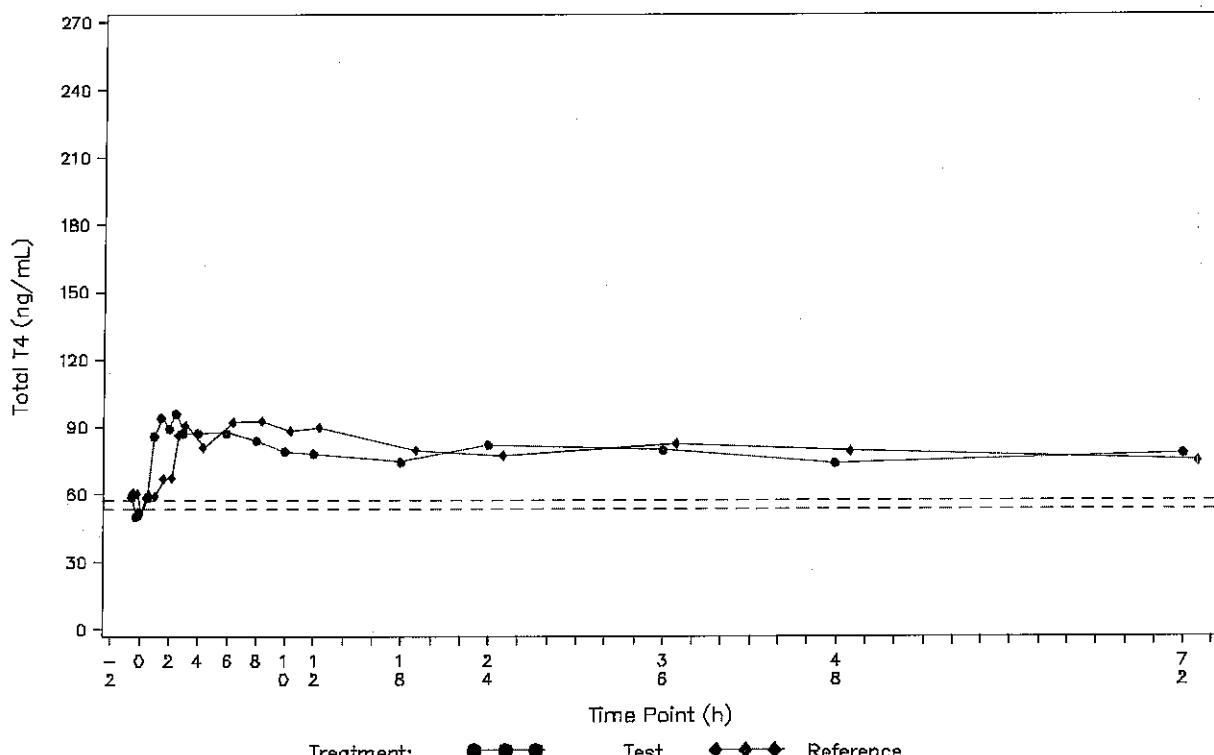
Bioequivalence EMR200125-001 Page 898 of 1628

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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④ 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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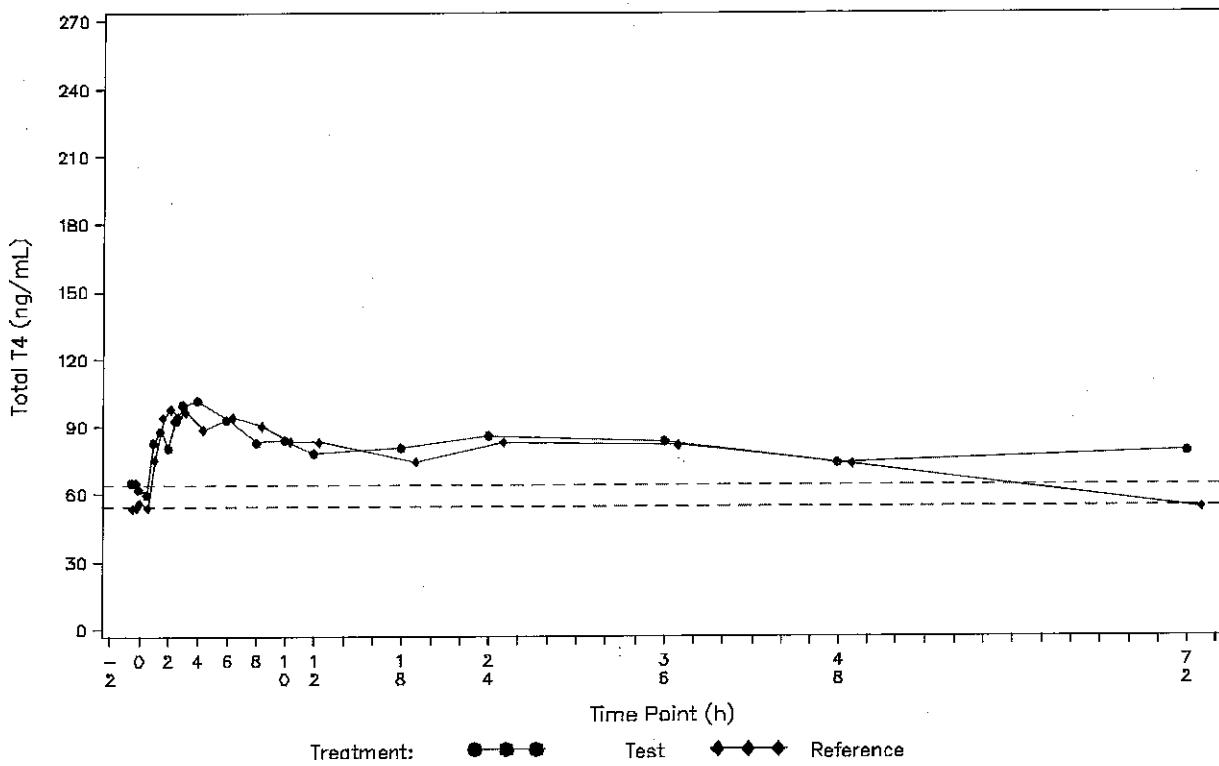
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Figure 15.4.2.9 Concentration-Time Profiles: Individual Concentration versus Actual Time in Linear Scale (for Total T4 Values)
(Safety Population)

Subject ID/Random Number:



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 16.2.5.2

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Levothyroxine
EMR 200125-001

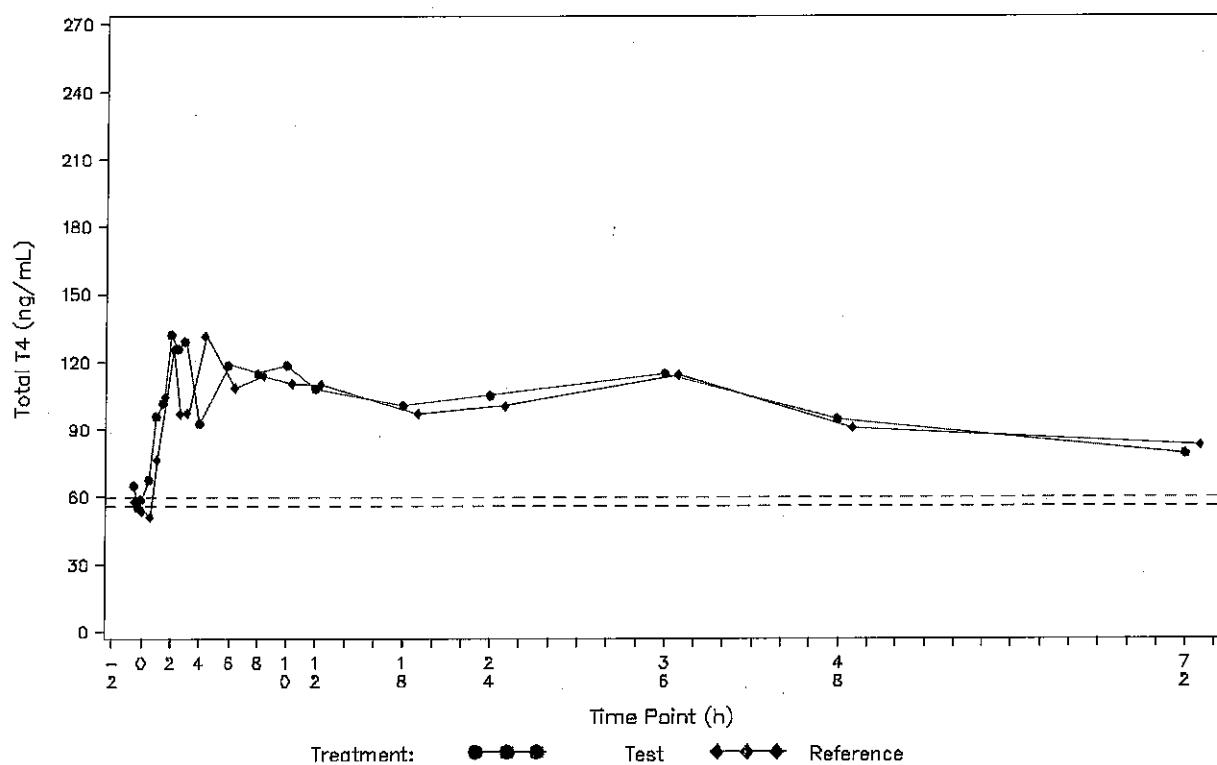
Bioequivalence EMR200125-001 Page 900 of 1628 New formulation vs. old formulation

Merck Serono
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: 7



@: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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