Merck Serono
EMR 200125-001
Table 15.1.1 Summary of Subject Disposition

	Status	Treatment Sequence 1 (N=108) n (%)	Treatment Sequence 2 (N=108) n (%)	Total (N=216) n (%)
Subjects who terminated the study prematurely	Yes	5 (4.6)	7 (6.5)	12 (5.6)
	No	103 (95.4)	101 (93.5)	204 (94.4)
Reasons of withdrawal from the study prematurely	Adverse Event	2 (1.9)	2 (1.9)	4 (1.9)
	Protocol Non-Compliance	2 (1.9)	3 (2.8)	5 (2.3)
	Withdrawal By Subject	1 (0.9)	2 (1.9)	3 (1.4)
Safety Analysis Population	Yes	108 (100.0)	108 (100.0)	216 (100.0)
PK Analysis Population	Yes	103 (95.4)	101 (93.5)	204 (94.4)
	No	5 (4.6)	7 (6.5)	12 (5.6)

N: The number of subjects dosed with at least one treatment in that treatment sequence, or the number subjects in the safety population for the total summary; n: The number of subjects in the specific category.
%: calculated using the number of subjects dosed with at least one treatment for each treatment sequence, or the number of subjects in the safety population for the total summary.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Levothyroxine
EMR 200125-001

Bioequivalence trial of new levothyroxine formulation vs. old formulation

Merck Serono
EMR 200125-001
Table 15.1.2 Demographic Data (Safety Population)

Demographic characteristic	Statistics	Treatment Sequence 1 (N=108)	Treatment Sequence 2 (N=108)	Total (N=216)
Age (yr)	n (missing)	108 (0)	108 (0)	216 (0)
	Mean (SD)	35.0 (9.56)	34.1 (9.09)	34.5 (9.32)
	Median	34.0	33.0	33.0
	Min; Max	18; 50	18; 50	18; 50
Sex, n (%)	n (missing)	108 (0)	108 (0)	216 (0)
	Male	64 (59.3)	64 (59.3)	128 (59.3)
	Female	44 (40.7)	44 (40.7)	88 (40.7)
Race, n (%)	n (missing)	108 (0)	108 (0)	216 (0)
	White	108 (100.0)	106 (98.1)	214 (99.1)
	Black Or African American	0	2 (1.9)	2 (0.9)
Ethnicity, n (%)	n (missing)	108 (0)	108 (0)	216 (0)
	Not Hispanic Or Latino	108 (100.0)	108 (100.0)	216 (100.0)
Height (cm)	n (missing)	108 (0)	108 (0)	216 (0)
	Mean (SD)	174.9 (8.08)	174.1 (8.16)	174.5 (8.11)
	Median	175.0	174.5	175.0
	Min; Max	153; 191	153; 191	153; 191

Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with at least one treatment in that treatment sequence, or the number subjects in the safety population for the total summary; n: The number of subjects in the specific category. %: calculated using the number of subjects dosed with at least one treatment for each treatment sequence, or the number of subjects in the safety population for the total summary; SD: Standard deviation.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Merck Serono
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Table 15.1.2 Demographic Data (Safety Population)

Demographic characteristic	Statistics	Treatment Sequence 1 (N=108)	Treatment Sequence 2 (N=108)	Total (N=216)
Weight (kg)	n (missing)	108 (0)	108 (0)	216 (0)
	Mean (SD)	71.84 (9.245)	71.43 (9.717)	71.64 (9.464)
	Median	71.75	71.60	71.75
	Min; Max	52.0; 90.6	52.2; 93.5	52.0; 93.5
BMI (kg/m²)	n (missing)	108 (0)	108 (0)	216 (0)
	Mean (SD)	23.42 (1.998)	23.51 (2.311)	23.47 (2.156)
	Median	23.20	23.70	23.40
	Min; Max	19.2; 27.3	18.9; 28.2	18.9; 28.2

Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with at least one treatment in that treatment sequence, or the number subjects in the safety population for the total summary; n: The number of subjects in the specific category. %: calculated using the number of subjects dosed with at least one treatment for each treatment sequence, or the number of subjects in the safety population for the total summary; SD: Standard deviation.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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15.2 Efficacy Data

There were no efficacy assessments performed during the trial.

15.3 Safety Data

15.3.1 Display of Adverse Events

Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Intensity (Safety Population)

Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Intensity (Safety Population)

Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Causality (Safety Population)

Table 15.3.1.4 Summary of Treatment-Emergent Adverse Events Leading to Withdrawal, by System Organ Class and Preferred Term (Safety Population)

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Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Test (N=209) Subjects n (%)	 Events n	Reference (N=211) Subjects n (%)	 Events n	Total (N=216) Subjects n (%)	 Events n
Subjects with events and total events	63 (30.1)	118	61 (28.9)	165	98 (45.4)	283
Blood And Lymphatic System Disorders	0	0	1 (0.5)	1	1 (0.5)	1
Lymphadenopathy	0	0	1 (0.5)	1	1 (0.5)	1
Cardiac Disorders	2 (1.0)	3	4 (1.9)	5	6 (2.8)	8
Palpitations	2 (1.0)	3	3 (1.4)	4	5 (2.3)	7
Sinus Tachycardia	0	0	1 (0.5)	1	1 (0.5)	1
Ear And Labyrinth Disorders	0	0	1 (0.5)	1	1 (0.5)	1
Hearing Impaired	0	0	1 (0.5)	1	1 (0.5)	1
Gastrointestinal Disorders	14 (6.7)	22	14 (6.6)	29	24 (11.1)	51
Abdominal Discomfort	1 (0.5)	1	0	0	1 (0.5)	1
Abdominal Pain	5 (2.4)	9	3 (1.4)	7	7 (3.2)	16
Abdominal Pain Lower	1 (0.5)	1	0	0	1 (0.5)	1
Constipation	1 (0.5)	1	0	0	1 (0.5)	1
Diarrhoea	6 (2.9)	6	9 (4.3)	10	13 (6.0)	16
Dry Mouth	0	0	1 (0.5)	1	1 (0.5)	1
Dyspepsia	0	0	1 (0.5)	1	1 (0.5)	1
Epigastric Discomfort	0	0	1 (0.5)	1	1 (0.5)	1

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

	Test (N=209)		Reference (N=211)		Total (N=216)	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Eructation	1 (0.5)	1	0	0	1 (0.5)	1
Nausea	3 (1.4)	3	4 (1.9)	5	7 (3.2)	8
Vomiting	0	0	3 (1.4)	4	3 (1.4)	4
General Disorders And Administration Site Conditions	8 (3.8)	8	6 (2.8)	8	13 (6.0)	16
Asthenia	0	0	1 (0.5)	1	1 (0.5)	1
Axillary Pain	0	0	1 (0.5)	1	1 (0.5)	1
Catheter Site Phlebitis	3 (1.4)	3	1 (0.5)	1	4 (1.9)	4
Fatigue	2 (1.0)	2	1 (0.5)	1	3 (1.4)	3
Feeling Hot	2 (1.0)	2	1 (0.5)	1	3 (1.4)	3
Malaise	0	0	1 (0.5)	1	1 (0.5)	1
Sensation Of Pressure	1 (0.5)	1	1 (0.5)	2	1 (0.5)	3
Immune System Disorders	1 (0.5)	1	0	0	1 (0.5)	1
Seasonal Allergy	1 (0.5)	1	0	0	1 (0.5)	1
Infections And Infestations	17 (8.1)	19	18 (8.5)	20	33 (15.3)	39
Folliculitis	0	0	1 (0.5)	1	1 (0.5)	1
Nasopharyngitis	10 (4.8)	11	12 (5.7)	14	22 (10.2)	25
Oral Herpes	1 (0.5)	1	2 (0.9)	2	3 (1.4)	3
Otitis Media	1 (0.5)	1	0	0	1 (0.5)	1

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
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Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Test (N=209) Subjects n (%)	Test (N=209) Events n	Reference (N=211) Subjects n (%)	Reference (N=211) Events n	Total (N=216) Subjects n (%)	Total (N=216) Events n
Pharyngitis	1 (0.5)	1	0	0	1 (0.5)	1
Rhinitis	2 (1.0)	2	3 (1.4)	3	5 (2.3)	5
Tonsillitis	3 (1.4)	3	0	0	3 (1.4)	3
Injury, Poisoning And Procedural Complications	1 (0.5)	1	1 (0.5)	1	2 (0.9)	2
Animal Bite	0	0	1 (0.5)	1	1 (0.5)	1
Radius Fracture	1 (0.5)	1	0	0	1 (0.5)	1
Investigations	1 (0.5)	1	0	0	1 (0.5)	1
Blood Creatine Phosphokinase Increased	1 (0.5)	1	0	0	1 (0.5)	1
Metabolism And Nutrition Disorders	1 (0.5)	1	0	0	1 (0.5)	1
Hypokalaemia	1 (0.5)	1	0	0	1 (0.5)	1
Musculoskeletal And Connective Tissue Disorders	3 (1.4)	4	7 (3.3)	16	9 (4.2)	20
Arthralgia	0	0	2 (0.9)	5	2 (0.9)	5
Back Pain	2 (1.0)	2	2 (0.9)	2	4 (1.9)	4
Musculoskeletal Discomfort	0	0	1 (0.5)	2	1 (0.5)	2
Musculoskeletal Pain	1 (0.5)	1	0	0	1 (0.5)	1
Myalgia	0	0	2 (0.9)	2	2 (0.9)	2
Neck Pain	0	0	1 (0.5)	2	1 (0.5)	2

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
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Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

	Test (N=209)		Reference (N=211)		Total (N=216)	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Pain In Extremity	0	0	3 (1.4)	3	3 (1.4)	3
Sensation Of Heaviness	1 (0.5)	1	0	0	1 (0.5)	1
Nervous System Disorders	27 (12.9)	43	34 (16.1)	56	54 (25.0)	99
Disturbance In Attention	1 (0.5)	1	0	0	1 (0.5)	1
Dizziness	3 (1.4)	4	7 (3.3)	7	9 (4.2)	11
Dysgeusia	1 (0.5)	1	0	0	1 (0.5)	1
Headache	24 (11.5)	35	26 (12.3)	44	45 (20.8)	79
Paraesthesia	1 (0.5)	1	0	0	1 (0.5)	1
Somnolence	1 (0.5)	1	3 (1.4)	5	4 (1.9)	6
Psychiatric Disorders	5 (2.4)	5	2 (0.9)	6	7 (3.2)	11
Agitation	2 (1.0)	2	1 (0.5)	3	3 (1.4)	5
Apathy	1 (0.5)	1	0	0	1 (0.5)	1
Depressed Mood	1 (0.5)	1	1 (0.5)	1	2 (0.9)	2
Euphoric Mood	0	0	1 (0.5)	2	1 (0.5)	2
Libido Decreased	1 (0.5)	1	0	0	1 (0.5)	1
Reproductive System And Breast Disorders	1 (0.5)	1	5 (2.4)	5	6 (2.8)	6
Breast Pain	1 (0.5)	1	0	0	1 (0.5)	1
Menstruation Delayed	0	0	3 (1.4)	3	3 (1.4)	3

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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EMR 200125-001
Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Test (N=209) Subjects n (%)	Test (N=209) Events n	Reference (N=211) Subjects n (%)	Reference (N=211) Events n	Total (N=216) Subjects n (%)	Total (N=216) Events n
Menstruation Irregular	0	0	2 (0.9)	2	2 (0.9)	2
Respiratory, Thoracic And Mediastinal Disorders	3 (1.4)	3	8 (3.8)	9	10 (4.6)	12
Cough	1 (0.5)	1	1 (0.5)	1	2 (0.9)	2
Dyspnoea	0	0	1 (0.5)	1	1 (0.5)	1
Epistaxis	1 (0.5)	1	1 (0.5)	1	2 (0.9)	2
Oropharyngeal Pain	1 (0.5)	1	5 (2.4)	5	6 (2.8)	6
Throat Irritation	0	0	1 (0.5)	1	1 (0.5)	1
Skin And Subcutaneous Tissue Disorders	4 (1.9)	4	6 (2.8)	7	10 (4.6)	11
Angioedema	0	0	1 (0.5)	1	1 (0.5)	1
Dry Skin	0	0	2 (0.9)	2	2 (0.9)	2
Hyperhidrosis	1 (0.5)	1	2 (0.9)	2	3 (1.4)	3
Rash	1 (0.5)	1	2 (0.9)	2	3 (1.4)	3
Rash Papular	1 (0.5)	1	0	0	1 (0.5)	1
Swelling Face	1 (0.5)	1	0	0	1 (0.5)	1
Vascular Disorders	2 (1.0)	2	1 (0.5)	1	3 (1.4)	3
Hot Flush	2 (1.0)	2	1 (0.5)	1	3 (1.4)	3

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
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Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Levothyroxine
EMR 200125-001

Bioequivalence trial of new levothyroxine formulation vs. old formulation

Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Test Subjects (N=209) Events (n=118)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	51 (24.4)	76	27 (12.9)	40	2 (1.0)	2
Blood And Lymphatic System Disorders	0	0	0	0	0	0
Lymphadenopathy	0	0	0	0	0	0
Cardiac Disorders	2 (1.0)	3	0	0	0	0
Palpitations	2 (1.0)	3	0	0	0	0
Sinus Tachycardia	0	0	0	0	0	0
Ear And Labyrinth Disorders	0	0	0	0	0	0
Hearing Impaired	0	0	0	0	0	0
Gastrointestinal Disorders	13 (6.2)	18	4 (1.9)	4	0	0
Abdominal Discomfort	1 (0.5)	1	0	0	0	0
Abdominal Pain	4 (1.9)	5	4 (1.9)	4	0	0
Abdominal Pain Lower	1 (0.5)	1	0	0	0	0
Constipation	1 (0.5)	1	0	0	0	0
Diarrhoea	6 (2.9)	6	0	0	0	0
Dry Mouth	0	0	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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	Test Subjects (N=209) Events (n=118)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Dyspepsia	0	0	0	0	0	0
Epigastric Discomfort	0	0	0	0	0	0
Eructation	1 (0.5)	1	0	0	0	0
Nausea	3 (1.4)	3	0	0	0	0
Vomiting	0	0	0	0	0	0
General Disorders And Administration Site Conditions	6 (2.9)	6	2 (1.0)	2	0	0
Asthenia	0	0	0	0	0	0
Axillary Pain	0	0	0	0	0	0
Catheter Site Phlebitis	3 (1.4)	3	0	0	0	0
Fatigue	2 (1.0)	2	0	0	0	0
Feeling Hot	0	0	2 (1.0)	2	0	0
Malaise	0	0	0	0	0	0
Sensation Of Pressure	1 (0.5)	1	0	0	0	0
Immune System Disorders	1 (0.5)	1	0	0	0	0
Seasonal Allergy	1 (0.5)	1	0	0	0	0
Infections And Infestations	9 (4.3)	9	9 (4.3)	10	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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	Test Subjects (N=209) Events (n=118)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Folliculitis	0	0	0	0	0	0
Nasopharyngitis	5 (2.4)	5	6 (2.9)	6	0	0
Oral Herpes	1 (0.5)	1	0	0	0	0
Otitis Media	0	0	1 (0.5)	1	0	0
Pharyngitis	1 (0.5)	1	0	0	0	0
Rhinitis	2 (1.0)	2	0	0	0	0
Tonsillitis	0	0	3 (1.4)	3	0	0
Injury, Poisoning And Procedural Complications	0	0	0	0	1 (0.5)	1
Animal Bite	0	0	0	0	0	0
Radius Fracture	0	0	0	0	1 (0.5)	1
Investigations	0	0	0	0	1 (0.5)	1
Blood Creatine Phosphokinase Increased	0	0	0	0	1 (0.5)	1
Metabolism And Nutrition Disorders	1 (0.5)	1	0	0	0	0
Hypokalaemia	1 (0.5)	1	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	0	0	3 (1.4)	4	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Test Subjects (N=209) Events (n=118)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Arthralgia	0	0	0	0	0	0
Back Pain	0	0	2 (1.0)	2	0	0
Musculoskeletal Discomfort	0	0	0	0	0	0
Musculoskeletal Pain	0	0	1 (0.5)	1	0	0
Myalgia	0	0	0	0	0	0
Neck Pain	0	0	0	0	0	0
Pain In Extremity	0	0	0	0	0	0
Sensation Of Heaviness	0	0	1 (0.5)	1	0	0
Nervous System Disorders	22 (10.5)	27	11 (5.3)	16	0	0
Disturbance In Attention	0	0	1 (0.5)	1	0	0
Dizziness	3 (1.4)	3	1 (0.5)	1	0	0
Dysgeusia	1 (0.5)	1	0	0	0	0
Headache	19 (9.1)	22	10 (4.8)	13	0	0
Paraesthesia	1 (0.5)	1	0	0	0	0
Somnolence	0	0	1 (0.5)	1	0	0
Psychiatric Disorders	2 (1.0)	2	3 (1.4)	3	0	0
Agitation	1 (0.5)	1	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.2.sas

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Test Subjects (N=209) Events (n=118)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Apathy	0	0	1 (0.5)	1	0	0
Depressed Mood	0	0	1 (0.5)	1	0	0
Euphoric Mood	0	0	0	0	0	0
Libido Decreased	1 (0.5)	1	0	0	0	0
Reproductive System And Breast Disorders	1 (0.5)	1	0	0	0	0
Breast Pain	1 (0.5)	1	0	0	0	0
Menstruation Delayed	0	0	0	0	0	0
Menstruation Irregular	0	0	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	2 (1.0)	2	1 (0.5)	1	0	0
Cough	1 (0.5)	1	0	0	0	0
Dyspnoea	0	0	0	0	0	0
Epistaxis	1 (0.5)	1	0	0	0	0
Oropharyngeal Pain	0	0	1 (0.5)	1	0	0
Throat Irritation	0	0	0	0	0	0
Skin And Subcutaneous Tissue Disorders	4 (1.9)	4	0	0	0	0
Angioedema	0	0	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Test Subjects (N=209) Events (n=118)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Dry Skin	0	0	0	0	0	0
Hyperhidrosis	1 (0.5)	1	0	0	0	0
Rash	1 (0.5)	1	0	0	0	0
Rash Papular	1 (0.5)	1	0	0	0	0
Swelling Face	1 (0.5)	1	0	0	0	0
Vascular Disorders	2 (1.0)	2	0	0	0	0
Hot Flush	2 (1.0)	2	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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	Reference Subjects (N=211) Events (n=165)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	54 (25.6)	115	31 (14.7)	50	0	0
Blood And Lymphatic System Disorders	1 (0.5)	1	0	0	0	0
Lymphadenopathy	1 (0.5)	1	0	0	0	0
Cardiac Disorders	2 (0.9)	3	2 (0.9)	2	0	0
Palpitations	2 (0.9)	3	1 (0.5)	1	0	0
Sinus Tachycardia	0	0	1 (0.5)	1	0	0
Ear And Labyrinth Disorders	1 (0.5)	1	0	0	0	0
Hearing Impaired	1 (0.5)	1	0	0	0	0
Gastrointestinal Disorders	13 (6.2)	20	5 (2.4)	9	0	0
Abdominal Discomfort	0	0	0	0	0	0
Abdominal Pain	2 (0.9)	4	3 (1.4)	3	0	0
Abdominal Pain Lower	0	0	0	0	0	0
Constipation	0	0	0	0	0	0
Diarrhoea	8 (3.8)	9	1 (0.5)	1	0	0
Dry Mouth	1 (0.5)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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	Reference Subjects (N=211) Events (n=165)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Dyspepsia	0	0	1 (0.5)	1	0	0
Epigastric Discomfort	1 (0.5)	1	0	0	0	0
Eructation	0	0	0	0	0	0
Nausea	3 (1.4)	3	1 (0.5)	2	0	0
Vomiting	2 (0.9)	2	2 (0.9)	2	0	0
General Disorders And Administration Site Conditions	4 (1.9)	6	2 (0.9)	2	0	0
Asthenia	1 (0.5)	1	0	0	0	0
Axillary Pain	1 (0.5)	1	0	0	0	0
Catheter Site Phlebitis	1 (0.5)	1	0	0	0	0
Fatigue	0	0	1 (0.5)	1	0	0
Feeling Hot	0	0	1 (0.5)	1	0	0
Malaise	1 (0.5)	1	0	0	0	0
Sensation Of Pressure	1 (0.5)	2	0	0	0	0
Immune System Disorders	0	0	0	0	0	0
Seasonal Allergy	0	0	0	0	0	0
Infections And Infestations	11 (5.2)	12	8 (3.8)	8	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Reference Subjects (N=211) Events (n=165)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Folliculitis	0	0	1 (0.5)	1	0	0
Nasopharyngitis	9 (4.3)	10	4 (1.9)	4	0	0
Oral Herpes	1 (0.5)	1	1 (0.5)	1	0	0
Otitis Media	0	0	0	0	0	0
Pharyngitis	0	0	0	0	0	0
Rhinitis	1 (0.5)	1	2 (0.9)	2	0	0
Tonsillitis	0	0	0	0	0	0
Injury, Poisoning And Procedural Complications	1 (0.5)	1	0	0	0	0
Animal Bite	1 (0.5)	1	0	0	0	0
Radius Fracture	0	0	0	0	0	0
Investigations	0	0	0	0	0	0
Blood Creatine Phosphokinase Increased	0	0	0	0	0	0
Metabolism And Nutrition Disorders	0	0	0	0	0	0
Hypokalaemia	0	0	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	4 (1.9)	11	5 (2.4)	5	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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	Reference Subjects (N=211) Events (n=165)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Arthralgia	1 (0.5)	3	2 (0.9)	2	0	0
Back Pain	1 (0.5)	1	1 (0.5)	1	0	0
Musculoskeletal Discomfort	1 (0.5)	2	0	0	0	0
Musculoskeletal Pain	0	0	0	0	0	0
Myalgia	1 (0.5)	1	1 (0.5)	1	0	0
Neck Pain	1 (0.5)	2	0	0	0	0
Pain In Extremity	2 (0.9)	2	1 (0.5)	1	0	0
Sensation Of Heaviness	0	0	0	0	0	0
Nervous System Disorders	27 (12.8)	38	15 (7.1)	18	0	0
Disturbance In Attention	0	0	0	0	0	0
Dizziness	6 (2.8)	6	1 (0.5)	1	0	0
Dysgeusia	0	0	0	0	0	0
Headache	20 (9.5)	28	14 (6.6)	16	0	0
Paraesthesia	0	0	0	0	0	0
Somnolence	2 (0.9)	4	1 (0.5)	1	0	0
Psychiatric Disorders	2 (0.9)	6	0	0	0	0
Agitation	1 (0.5)	3	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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	Reference Subjects (N=211) Events (n=165)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Apathy	0	0	0	0	0	0
Depressed Mood	1 (0.5)	1	0	0	0	0
Euphoric Mood	1 (0.5)	2	0	0	0	0
Libido Decreased	0	0	0	0	0	0
Reproductive System And Breast Disorders	5 (2.4)	5	0	0	0	0
Breast Pain	0	0	0	0	0	0
Menstruation Delayed	3 (1.4)	3	0	0	0	0
Menstruation Irregular	2 (0.9)	2	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	6 (2.8)	6	3 (1.4)	3	0	0
Cough	0	0	1 (0.5)	1	0	0
Dyspnoea	0	0	1 (0.5)	1	0	0
Epistaxis	1 (0.5)	1	0	0	0	0
Oropharyngeal Pain	4 (1.9)	4	1 (0.5)	1	0	0
Throat Irritation	1 (0.5)	1	0	0	0	0
Skin And Subcutaneous Tissue Disorders	4 (1.9)	5	2 (0.9)	2	0	0
Angioedema	1 (0.5)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Reference Subjects (N=211) Events (n=165)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Dry Skin	2 (0.9)	2	0	0	0	0
Hyperhidrosis	0	0	2 (0.9)	2	0	0
Rash	2 (0.9)	2	0	0	0	0
Rash Papular	0	0	0	0	0	0
Swelling Face	0	0	0	0	0	0
Vascular Disorders	0	0	1 (0.5)	1	0	0
Hot Flush	0	0	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Total Subjects (N=216) Events (n=283)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	86 (39.8)	191	50 (23.1)	90	2 (0.9)	2
Blood And Lymphatic System Disorders	1 (0.5)	1	0	0	0	0
Lymphadenopathy	1 (0.5)	1	0	0	0	0
Cardiac Disorders	4 (1.9)	6	2 (0.9)	2	0	0
Palpitations	4 (1.9)	6	1 (0.5)	1	0	0
Sinus Tachycardia	0	0	1 (0.5)	1	0	0
Ear And Labyrinth Disorders	1 (0.5)	1	0	0	0	0
Hearing Impaired	1 (0.5)	1	0	0	0	0
Gastrointestinal Disorders	23 (10.6)	38	7 (3.2)	13	0	0
Abdominal Discomfort	1 (0.5)	1	0	0	0	0
Abdominal Pain	6 (2.8)	9	6 (2.8)	7	0	0
Abdominal Pain Lower	1 (0.5)	1	0	0	0	0
Constipation	1 (0.5)	1	0	0	0	0
Diarrhoea	12 (5.6)	15	1 (0.5)	1	0	0
Dry Mouth	1 (0.5)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Total Subjects (N=216) Events (n=283)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Dyspepsia	0	0	1 (0.5)	1	0	0
Epigastric Discomfort	1 (0.5)	1	0	0	0	0
Eructation	1 (0.5)	1	0	0	0	0
Nausea	6 (2.8)	6	1 (0.5)	2	0	0
Vomiting	2 (0.9)	2	2 (0.9)	2	0	0
General Disorders And Administration Site Conditions	9 (4.2)	12	4 (1.9)	4	0	0
Asthenia	1 (0.5)	1	0	0	0	0
Axillary Pain	1 (0.5)	1	0	0	0	0
Catheter Site Phlebitis	4 (1.9)	4	0	0	0	0
Fatigue	2 (0.9)	2	1 (0.5)	1	0	0
Feeling Hot	0	0	3 (1.4)	3	0	0
Malaise	1 (0.5)	1	0	0	0	0
Sensation Of Pressure	1 (0.5)	3	0	0	0	0
Immune System Disorders	1 (0.5)	1	0	0	0	0
Seasonal Allergy	1 (0.5)	1	0	0	0	0
Infections And Infestations	20 (9.3)	21	16 (7.4)	18	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

System Organ Class Preferred Term	Total Subjects (N=216) Events (n=283) Mild Subjects n (%)	Events n	Moderate Subjects n (%)	Events n	Severe Subjects n (%)	Events n
Folliculitis	0	0	1 (0.5)	1	0	0
Nasopharyngitis	14 (6.5)	15	10 (4.6)	10	0	0
Oral Herpes	2 (0.9)	2	1 (0.5)	1	0	0
Otitis Media	0	0	1 (0.5)	1	0	0
Pharyngitis	1 (0.5)	1	0	0	0	0
Rhinitis	3 (1.4)	3	2 (0.9)	2	0	0
Tonsillitis	0	0	3 (1.4)	3	0	0
Injury, Poisoning And Procedural Complications	1 (0.5)	1	0	0	1 (0.5)	1
Animal Bite	1 (0.5)	1	0	0	0	0
Radius Fracture	0	0	0	0	1 (0.5)	1
Investigations	0	0	0	0	1 (0.5)	1
Blood Creatine Phosphokinase Increased	0	0	0	0	1 (0.5)	1
Metabolism And Nutrition Disorders	1 (0.5)	1	0	0	0	0
Hypokalaemia	1 (0.5)	1	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	4 (1.9)	11	8 (3.7)	9	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Total Subjects (N=216) Events (n=283)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Arthralgia	1 (0.5)	3	2 (0.9)	2	0	0
Back Pain	1 (0.5)	1	3 (1.4)	3	0	0
Musculoskeletal Discomfort	1 (0.5)	2	0	0	0	0
Musculoskeletal Pain	0	0	1 (0.5)	1	0	0
Myalgia	1 (0.5)	1	1 (0.5)	1	0	0
Neck Pain	1 (0.5)	2	0	0	0	0
Pain In Extremity	2 (0.9)	2	1 (0.5)	1	0	0
Sensation Of Heaviness	0	0	1 (0.5)	1	0	0
Nervous System Disorders	43 (19.9)	65	25 (11.6)	34	0	0
Disturbance In Attention	0	0	1 (0.5)	1	0	0
Dizziness	8 (3.7)	9	2 (0.9)	2	0	0
Dysgeusia	1 (0.5)	1	0	0	0	0
Headache	35 (16.2)	50	23 (10.6)	29	0	0
Paraesthesia	1 (0.5)	1	0	0	0	0
Somnolence	2 (0.9)	4	2 (0.9)	2	0	0
Psychiatric Disorders	4 (1.9)	8	3 (1.4)	3	0	0
Agitation	2 (0.9)	4	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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System Organ Class Preferred Term	Total Subjects (N=216) Events (n=283) Mild Subjects n (%)	Events n	Moderate Subjects n (%)	Events n	Severe Subjects n (%)	Events n
Apathy	0	0	1 (0.5)	1	0	0
Depressed Mood	1 (0.5)	1	1 (0.5)	1	0	0
Euphoric Mood	1 (0.5)	2	0	0	0	0
Libido Decreased	1 (0.5)	1	0	0	0	0
Reproductive System And Breast Disorders	6 (2.8)	6	0	0	0	0
Breast Pain	1 (0.5)	1	0	0	0	0
Menstruation Delayed	3 (1.4)	3	0	0	0	0
Menstruation Irregular	2 (0.9)	2	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	7 (3.2)	8	4 (1.9)	4	0	0
Cough	1 (0.5)	1	1 (0.5)	1	0	0
Dyspnoea	0	0	1 (0.5)	1	0	0
Epistaxis	2 (0.9)	2	0	0	0	0
Oropharyngeal Pain	4 (1.9)	4	2 (0.9)	2	0	0
Throat Irritation	1 (0.5)	1	0	0	0	0
Skin And Subcutaneous Tissue Disorders	8 (3.7)	9	2 (0.9)	2	0	0
Angioedema	1 (0.5)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Total Subjects (N=216) Events (n=283)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Dry Skin	2 (0.9)	2	0	0	0	0
Hyperhidrosis	1 (0.5)	1	2 (0.9)	2	0	0
Rash	3 (1.4)	3	0	0	0	0
Rash Papular	1 (0.5)	1	0	0	0	0
Swelling Face	1 (0.5)	1	0	0	0	0
Vascular Disorders	2 (0.9)	2	1 (0.5)	1	0	0
Hot Flush	2 (0.9)	2	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.2.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Test Subjects (N=209) Events (n=118)				Reference Subjects (N=211) Events (n=165)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	35 (16.7)	67	37 (17.7)	51	39 (18.5)	87	39 (18.5)	78
Blood And Lymphatic System Disorders	0	0	0	0	0	0	1 (0.5)	1
Lymphadenopathy	0	0	0	0	0	0	1 (0.5)	1
Cardiac Disorders	2 (1.0)	3	0	0	3 (1.4)	4	1 (0.5)	1
Palpitations	2 (1.0)	3	0	0	3 (1.4)	4	0	0
Sinus Tachycardia	0	0	0	0	0	0	1 (0.5)	1
Ear And Labyrinth Disorders	0	0	0	0	0	0	1 (0.5)	1
Hearing Impaired	0	0	0	0	0	0	1 (0.5)	1
Gastrointestinal Disorders	10 (4.8)	15	4 (1.9)	7	7 (3.3)	10	8 (3.8)	19
Abdominal Discomfort	1 (0.5)	1	0	0	0	0	0	0
Abdominal Pain	2 (1.0)	5	3 (1.4)	4	2 (0.9)	3	2 (0.9)	4
Abdominal Pain Lower	1 (0.5)	1	0	0	0	0	0	0
Constipation	1 (0.5)	1	0	0	0	0	0	0
Diarrhoea	5 (2.4)	5	1 (0.5)	1	5 (2.4)	5	5 (2.4)	5
Dry Mouth	0	0	0	0	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Test Subjects (N=209) Events (n=118)				Reference Subjects (N=211) Events (n=165)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Dyspepsia	0	0	0	0	0	0	1 (0.5)	1
Epigastric Discomfort	0	0	0	0	0	0	1 (0.5)	1
Eructation	1 (0.5)	1	0	0	0	0	0	0
Nausea	1 (0.5)	1	2 (1.0)	2	1 (0.5)	1	3 (1.4)	4
Vomiting	0	0	0	0	0	0	3 (1.4)	4
General Disorders And Administration Site Conditions	5 (2.4)	5	3 (1.4)	3	5 (2.4)	7	1 (0.5)	1
Asthenia	0	0	0	0	1 (0.5)	1	0	0
Axillary Pain	0	0	0	0	1 (0.5)	1	0	0
Catheter Site Phlebitis	0	0	3 (1.4)	3	0	0	1 (0.5)	1
Fatigue	2 (1.0)	2	0	0	1 (0.5)	1	0	0
Feeling Hot	2 (1.0)	2	0	0	1 (0.5)	1	0	0
Malaise	0	0	0	0	1 (0.5)	1	0	0
Sensation Of Pressure	1 (0.5)	1	0	0	1 (0.5)	2	0	0
Immune System Disorders	0	0	1 (0.5)	1	0	0	0	0
Seasonal Allergy	0	0	1 (0.5)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Test Subjects (N=209) Events (n=118)				Reference Subjects (N=211) Events (n=165)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Infections And Infestations	0	0	17 (8.1)	19	1 (0.5)	1	17 (8.1)	19
Folliculitis	0	0	0	0	1 (0.5)	1	0	0
Nasopharyngitis	0	0	10 (4.8)	11	0	0	12 (5.7)	14
Oral Herpes	0	0	1 (0.5)	1	0	0	2 (0.9)	2
Otitis Media	0	0	1 (0.5)	1	0	0	0	0
Pharyngitis	0	0	1 (0.5)	1	0	0	0	0
Rhinitis	0	0	2 (1.0)	2	0	0	3 (1.4)	3
Tonsillitis	0	0	3 (1.4)	3	0	0	0	0
Injury, Poisoning And Procedural Complications	0	0	1 (0.5)	1	0	0	1 (0.5)	1
Animal Bite	0	0	0	0	0	0	1 (0.5)	1
Radius Fracture	0	0	1 (0.5)	1	0	0	0	0
Investigations	0	0	1 (0.5)	1	0	0	0	0
Blood Creatine Phosphokinase Increased	0	0	1 (0.5)	1	0	0	0	0
Metabolism And Nutrition Disorders	0	0	1 (0.5)	1	0	0	0	0
Hypokalaemia	0	0	1 (0.5)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Test Subjects (N=209) Events (n=118)				Reference Subjects (N=211) Events (n=165)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Musculoskeletal And Connective Tissue Disorders	2 (1.0)	3	1 (0.5)	1	5 (2.4)	9	3 (1.4)	7
Arthralgia	0	0	0	0	2 (0.9)	4	1 (0.5)	1
Back Pain	1 (0.5)	1	1 (0.5)	1	0	0	2 (0.9)	2
Musculoskeletal Discomfort	0	0	0	0	0	0	1 (0.5)	2
Musculoskeletal Pain	1 (0.5)	1	0	0	0	0	0	0
Myalgia	0	0	0	0	2 (0.9)	2	0	0
Neck Pain	0	0	0	0	0	0	1 (0.5)	2
Pain In Extremity	0	0	0	0	3 (1.4)	3	0	0
Sensation Of Heaviness	1 (0.5)	1	0	0	0	0	0	0
Nervous System Disorders	19 (9.1)	30	10 (4.8)	13	22 (10.4)	36	15 (7.1)	20
Disturbance In Attention	1 (0.5)	1	0	0	0	0	0	0
Dizziness	3 (1.4)	4	0	0	5 (2.4)	5	2 (0.9)	2
Dysgeusia	1 (0.5)	1	0	0	0	0	0	0
Headache	16 (7.7)	22	10 (4.8)	13	16 (7.6)	26	13 (6.2)	18
Paraesthesia	1 (0.5)	1	0	0	0	0	0	0
Somnolence	1 (0.5)	1	0	0	3 (1.4)	5	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Test Subjects (N=209) Events (n=118)				Reference Subjects (N=211) Events (n=165)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Psychiatric Disorders	5 (2.4)	5	0	0	2 (0.9)	5	1 (0.5)	1
Agitation	2 (1.0)	2	0	0	1 (0.5)	3	0	0
Apathy	1 (0.5)	1	0	0	0	0	0	0
Depressed Mood	1 (0.5)	1	0	0	1 (0.5)	1	0	0
Euphoric Mood	0	0	0	0	1 (0.5)	1	1 (0.5)	1
Libido Decreased	1 (0.5)	1	0	0	0	0	0	0
Reproductive System And Breast Disorders	0	0	1 (0.5)	1	5 (2.4)	5	0	0
Breast Pain	0	0	1 (0.5)	1	0	0	0	0
Menstruation Delayed	0	0	0	0	3 (1.4)	3	0	0
Menstruation Irregular	0	0	0	0	2 (0.9)	2	0	0
Respiratory, Thoracic And Mediastinal Disorders	0	0	3 (1.4)	3	3 (1.4)	3	5 (2.4)	6
Cough	0	0	1 (0.5)	1	0	0	1 (0.5)	1
Dyspnoea	0	0	0	0	1 (0.5)	1	0	0
Epistaxis	0	0	1 (0.5)	1	1 (0.5)	1	0	0
Oropharyngeal Pain	0	0	1 (0.5)	1	0	0	5 (2.4)	5

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Test Subjects (N=209) Events (n=118)				Reference Subjects (N=211) Events (n=165)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Throat Irritation	0	0	0	0	1 (0.5)	1	0	0
Skin And Subcutaneous Tissue Disorders	4 (1.9)	4	0	0	5 (2.4)	6	1 (0.5)	1
Angioedema	0	0	0	0	1 (0.5)	1	0	0
Dry Skin	0	0	0	0	2 (0.9)	2	0	0
Hyperhidrosis	1 (0.5)	1	0	0	2 (0.9)	2	0	0
Rash	1 (0.5)	1	0	0	1 (0.5)	1	1 (0.5)	1
Rash Papular	1 (0.5)	1	0	0	0	0	0	0
Swelling Face	1 (0.5)	1	0	0	0	0	0	0
Vascular Disorders	2 (1.0)	2	0	0	1 (0.5)	1	0	0
Hot Flush	2 (1.0)	2	0	0	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

System Organ Class Preferred Term	Total Subjects (N=216) Events (n=283) Related Subjects n (%)	 Events n	 Not Related Subjects n (%)	 Events n
Subjects with events and total events	61 (28.2)	154	69 (31.9)	129
Blood And Lymphatic System Disorders	0	0	1 (0.5)	1
Lymphadenopathy	0	0	1 (0.5)	1
Cardiac Disorders	5 (2.3)	7	1 (0.5)	1
Palpitations	5 (2.3)	7	0	0
Sinus Tachycardia	0	0	1 (0.5)	1
Ear And Labyrinth Disorders	0	0	1 (0.5)	1
Hearing Impaired	0	0	1 (0.5)	1
Gastrointestinal Disorders	15 (6.9)	25	11 (5.1)	26
Abdominal Discomfort	1 (0.5)	1	0	0
Abdominal Pain	3 (1.4)	8	5 (2.3)	8
Abdominal Pain Lower	1 (0.5)	1	0	0
Constipation	1 (0.5)	1	0	0
Diarrhoea	8 (3.7)	10	6 (2.8)	6
Dry Mouth	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

System Organ Class Preferred Term	Total Subjects (N=216) Related Subjects n (%)	Total Events (n=283) Related Events n	Not Related Subjects n (%)	Not Related Events n
Dyspepsia	0	0	1 (0.5)	1
Epigastric Discomfort	0	0	1 (0.5)	1
Eructation	1 (0.5)	1	0	0
Nausea	2 (0.9)	2	5 (2.3)	6
Vomiting	0	0	3 (1.4)	4
General Disorders And Administration Site Conditions	9 (4.2)	12	4 (1.9)	4
Asthenia	1 (0.5)	1	0	0
Axillary Pain	1 (0.5)	1	0	0
Catheter Site Phlebitis	0	0	4 (1.9)	4
Fatigue	3 (1.4)	3	0	0
Feeling Hot	3 (1.4)	3	0	0
Malaise	1 (0.5)	1	0	0
Sensation Of Pressure	1 (0.5)	3	0	0
Immune System Disorders	0	0	1 (0.5)	1
Seasonal Allergy	0	0	1 (0.5)	1
Infections And Infestations	1 (0.5)	1	32 (14.8)	38

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

System Organ Class Preferred Term	Total Subjects (N=216) Events (n=283) Related Subjects n (%)	 Events n	 Not Related Subjects n (%)	 Events n
Folliculitis	1 (0.5)	1	0	0
Nasopharyngitis	0	0	22 (10.2)	25
Oral Herpes	0	0	3 (1.4)	3
Otitis Media	0	0	1 (0.5)	1
Pharyngitis	0	0	1 (0.5)	1
Rhinitis	0	0	5 (2.3)	5
Tonsillitis	0	0	3 (1.4)	3
Injury, Poisoning And Procedural Complications	0	0	2 (0.9)	2
Animal Bite	0	0	1 (0.5)	1
Radius Fracture	0	0	1 (0.5)	1
Investigations	0	0	1 (0.5)	1
Blood Creatine Phosphokinase Increased	0	0	1 (0.5)	1
Metabolism And Nutrition Disorders	0	0	1 (0.5)	1
Hypokalaemia	0	0	1 (0.5)	1
Musculoskeletal And Connective Tissue Disorders	6 (2.8)	12	4 (1.9)	8

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Total Subjects (N=216) Events (n=283)			
	Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n
Arthralgia	2 (0.9)	4	1 (0.5)	1
Back Pain	1 (0.5)	1	3 (1.4)	3
Musculoskeletal Discomfort	0	0	1 (0.5)	2
Musculoskeletal Pain	1 (0.5)	1	0	0
Myalgia	2 (0.9)	2	0	0
Neck Pain	0	0	1 (0.5)	2
Pain In Extremity	3 (1.4)	3	0	0
Sensation Of Heaviness	1 (0.5)	1	0	0
Nervous System Disorders	38 (17.6)	66	23 (10.6)	33
Disturbance In Attention	1 (0.5)	1	0	0
Dizziness	7 (3.2)	9	2 (0.9)	2
Dysgeusia	1 (0.5)	1	0	0
Headache	31 (14.4)	48	21 (9.7)	31
Paraesthesia	1 (0.5)	1	0	0
Somnolence	4 (1.9)	6	0	0
Psychiatric Disorders	7 (3.2)	10	1 (0.5)	1
Agitation	3 (1.4)	5	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

System Organ Class Preferred Term	Total Subjects (N=216) Related Subjects n (%)	Events (n=283) Related Events n	Not Related Subjects n (%)	Not Related Events n
Apathy	1 (0.5)	1	0	0
Depressed Mood	2 (0.9)	2	0	0
Euphoric Mood	1 (0.5)	1	1 (0.5)	1
Libido Decreased	1 (0.5)	1	0	0
Reproductive System And Breast Disorders	5 (2.3)	5	1 (0.5)	1
Breast Pain	0	0	1 (0.5)	1
Menstruation Delayed	3 (1.4)	3	0	0
Menstruation Irregular	2 (0.9)	2	0	0
Respiratory, Thoracic And Mediastinal Disorders	3 (1.4)	3	8 (3.7)	9
Cough	0	0	2 (0.9)	2
Dyspnoea	1 (0.5)	1	0	0
Epistaxis	1 (0.5)	1	1 (0.5)	1
Oropharyngeal Pain	0	0	6 (2.8)	6
Throat Irritation	1 (0.5)	1	0	0
Skin And Subcutaneous Tissue Disorders	9 (4.2)	10	1 (0.5)	1
Angioedema	1 (0.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Total Subjects (N=216) Events (n=283)			
	Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n
Dry Skin	2 (0.9)	2	0	0
Hyperhidrosis	3 (1.4)	3	0	0
Rash	2 (0.9)	2	1 (0.5)	1
Rash Papular	1 (0.5)	1	0	0
Swelling Face	1 (0.5)	1	0	0
Vascular Disorders	3 (1.4)	3	0	0
Hot Flush	3 (1.4)	3	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.4 Summary of Treatment-Emergent Adverse Events Leading to Discontinuation (Safety Population)

	Test (N=209)		Reference (N=211)		Total (N=216)	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	3 (1.4)	3	2 (0.9)	4	5 (2.3)	7
Cardiac Disorders	0	0	1 (0.5)	1	1 (0.5)	1
Sinus Tachycardia	0	0	1 (0.5)	1	1 (0.5)	1
Gastrointestinal Disorders	0	0	1 (0.5)	2	1 (0.5)	2
Diarrhoea	0	0	1 (0.5)	1	1 (0.5)	1
Nausea	0	0	1 (0.5)	1	1 (0.5)	1
Infections And Infestations	1 (0.5)	1	0	0	1 (0.5)	1
Otitis Media	1 (0.5)	1	0	0	1 (0.5)	1
Investigations	1 (0.5)	1	0	0	1 (0.5)	1
Blood Creatine Phosphokinase Increased	1 (0.5)	1	0	0	1 (0.5)	1
Nervous System Disorders	0	0	1 (0.5)	1	1 (0.5)	1
Dizziness	0	0	1 (0.5)	1	1 (0.5)	1
Psychiatric Disorders	1 (0.5)	1	0	0	1 (0.5)	1
Depressed Mood	1 (0.5)	1	0	0	1 (0.5)	1

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary.
n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.4.sas

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15.3.2 Listing of Deaths, Other Serious and Significant Adverse Events

Table 15.3.2.1 Serious Adverse Events with Outcome Death (Safety Population)

Table 15.3.2.2 Serious Adverse Events (Safety Population)

Table 15.3.2.3 Serious Adverse Events Leading to Study Discontinuation (Safety Population)

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Table 15.3.2.1 Serious Adverse Events with Outcome of Death (Safety Population)

Subject Number/ Random Number	System Org.Class/ Preferred Term/ Reported Term	Serious Criteria	Onset Date /Time	Resolution Date/ Time(AE Duration)	Severity	Relatio--nship	Action Taken with Study Treatment	Other Action Taken	Outcome	Treatment at Onset

There was no serious adverse event with Outcome of Death in this trial.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.2.1.sas

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Table 15.3.2.2 Serious Adverse Events (Safety Population)

Subject Number/ Random Number	System Org.Class/ Preferred Term/ Reported Term	Serious Criteria	Onset Date /Time	Resolution Date/ Time(AE Duration hh:mm)	Severity	Relatio--nship	Action Taken with Study Treatment	Other Action Taken	Outcome	Treatment at Onset
1	Injury, Poisoning And Procedural Complications / Radius Fracture / Dislocated Distal Radius Fracture Right Side	Yes	23-01-2014 /17:00	27-01-2014 (102:59)	Severe	Not Related	Not Applicable	Multiple	Recovered/Resolved	Test
	Infections And Infestations / Otitis Media / Otitis Media Left Ear	Yes	26-04-2014 /2:00	11-05-2014 /10:00 (368:00)	Moderate	Not Related	Drug Withdrawn	Multiple	Recovered/Resolved	Test

MedDRA: Medical Dictionary for Regulatory Activities; AE duration = AE Resolution date/time - Onset Date/time
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
All adverse events (AEs) are coded using MedDRA version 17.0.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.2.2.sas

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Merck Serono
EMR 200125-001
Table 15.3.2.3 Serious Adverse Events Leading to Study Discontinuation (Safety Population)

Subject Number/ Random Number	System Org.Class/ Preferred Term/ Reported Term	Serious Criteria	Onset Date /Time	Resolution Date/ Time(AE Duration hh:mm)	Severity	Relatio--nship	Action Taken with Study Treatment	Other Action Taken	Outcome	Treatment at Onset
-	Infections And Infestations / Otitis Media / Otitis Media Left Ear	Yes	26-04-2014 /2:00	11-05-2014 /10:00 (368:00)	Moderate	Not Related	Drug Withdrawn	Multiple	Recovered/Resolved	Test

MedDRA: Medical Dictionary for Regulatory Activities; AE duration = AE Resolution date/time - Onset Date/time
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.
All adverse events (AEs) are coded using MedDRA version 17.0.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.2.3.sas

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15.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

There were no deaths reported during this trial.

Two SAEs were reported during the trial:

- Subject had an SAE of severe radius fracture considered unrelated to IMP. The event of radius fracture also led to withdrawal of the subject from the trial.
- Subject had an SAE of moderate otitis media considered unrelated to IMP.

Five (5) subjects had either IMP withdrawn, or were withdrawn from trial entirely:

- Subject was withdrawn from the trial due to an AE of moderate sinus tachycardia considered unrelated to IMP.
- Subject was withdrawn from the trial due to AEs of mild dizziness, moderate diarrhoea, and mild nausea; all considered unrelated to IMP.
- Subject had IMP withdrawn due to moderate depressed mood considered related to IMP.
- Subject was withdrawn from the trial due to an AE of severe elevated blood creatinine phosphokinase considered unrelated to IMP.
- Subject had IMP withdrawn due to an SAE of moderate otitis media considered unrelated to IMP (see SAE narrative).

15.3.3.1 Serious Adverse Event Narratives

Subject Number:	
Age (years):	48
Gender:	Female
Race / Ethnicity	White / Not Hispanic or Latino
Weight (kg):	53.3
Height (cm):	160
BMI (kg/m^2):	20.8
Reason for Narrative:	SAE

Subject , a 48-year-old female, was randomized to Sequence 2 (Reference/Test) and received Reference treatment on 11 Dec 2013 at 12:15 and Test treatment on 16 Jan 2014 at 9:21. The subject had unremarkable medical history including herpes zoster (in 1980), tibia fracture (in 2007), dysmenorrhea (in 2007), limb operation (leg) (in 2007), and uterine dilation and curettage (in 2007).

On 23 Jan 2014 (at 17:00) (approximately 7 days after last IMP dose), the subject fell down and experienced a severe SAE of radius fracture (right arm) considered unrelated to IMP. On 24 Jan 2014, surgery (open reposition) was performed. The subject was discharged on 27 Jan 2014 and the SAE of radius fracture was considered resolved on the same day.

The subject received 600 mg ibuprofen orally three times daily from 24 Jan 2014 until 29 Jan 2014, 5 mg Oxygenic® orally as needed from 24 Jan 2014 until 25 Jan 2014, 10 mg Targin® orally as needed from 24 Jan 2014 until 25 Jan 2014, and 500 mg Novaminsulfon® orally as needed from 24 Jan 2014 until 27 Jan 2014; all as treatment for the event of radius fracture. As prophylaxis for gastric ulcer the subject also received 40 mg Pantoprazole® orally once daily from 24 Jan 2014 until 27 Jan 2014.

Subject Number:	
Age (years):	41
Gender:	Female
Race / Ethnicity	White / Not Hispanic or Latino
Weight (kg):	62.0
Height (cm):	165
BMI (kg/m^2):	22.8
Reason for Narrative:	SAE (IMP withdrawal)

Subject a 41-year-old female, was randomized to Sequence 1 (Test/Reference) and received only Test treatment on 31 Mar 2014 at 9:15. The subject had unremarkable medical history of developmental hip dysplasia (from 1972 until 1999), with hip surgery in 1998 and 1999, appendicitis and appendectomy (in 1996), spontaneous abortion (in 1999), and caesarean section (in 2000).

On 26 Apr 2014 (at 2:00) (approximately 26 days after last IMP dose), the subject experienced a moderate SAE of otitis media considered unrelated to IMP. Due to exacerbation the subject was hospitalized on 27 Apr 2014. Tympanic drainage of (left) middle ear for treatment of otitis media was performed on 30 Apr 2014 and the subject was discharged from hospital on 03 May 2014. The SAE of otitis media resolved on 11 May 2014 and the IMP was withdrawn on 20 May 2014.

Other AEs reported included mild hypokalaemia and moderate tonsillitis from 27 Apr 2014 until 11 May 2014. Both events were considered unrelated to IMP by the investigator.

The subject received 1000 mg Novaminsulfon® orally three times daily from 27 Apr 2014 until 1 May 2014 and 90 mg Cymbalta® orally once daily from 29 Apr 2014 until 11 May 2014 for otitis media, and 1500 mg Cefuroxim® intravenous (IV) three times daily from 27 Apr 2014 until 3 May 2014 for otitis media and tonsillitis. The subject received Propofol® as sedative during tympanic drainage on 30 Apr 2014. For the treatment of hypokalaemia the subject received 1 potassium tablet (unknown dose) orally three times daily from 27 Apr 2014 until 4 May 2014.

15.3.3.2 Adverse Event Withdrawal Narratives

Subject Number:	
Age (years):	34
Gender:	Female
Race / Ethnicity	White / Not Hispanic or Latino
Weight (kg):	60.0
Height (cm):	168
BMI (kg/m^2):	21.3
Reason for Narrative:	AE leading to withdrawal

Subject -, a 34-year-old female, was randomized to Sequence 2 (Reference/Test) and received only Reference treatment on 6 Dec 2013 at 9:15. The subject had no reported medical history.

On 10 Jan 2014 (approximately 35 days after last IMP dose), the subject presented with a moderate AE of sinus tachycardia (asymptomatic) considered unrelated to the IMP by the investigator. The event resolved on 16 Jan 2014 and the subject was withdrawn from the trial on the same day. No concomitant therapy was administered. A summary of relevant vital signs results is provided below.

Other AEs reported for this subject included mild angioedema and mild dry skin on 7 Dec 2013 and an event of mild delayed menstruation from 18 Dec 2013 until 15 Jan 2014; all three events were considered related to IMP by the investigator. The angioedema was treated with a local cooling pack before resolving, no other concomitant therapy was provided.

Time Point	SBP (mmHg)	DBP (mmHg)	Pulse (bpm)
Screening (22 Nov 2013)	138	87	78
Period 1, 24 hours predose (5 Dec 2013)	114	63	84
50 min predose (6 Dec 2013)	124	77	79
2 hours postdose (6 Dec 2013)	127	74	71
3 hours postdose (6 Dec 2013)	121	81	72
6 hours postdose (6 Dec 2013)	115	71	88
12 hours postdose (6 Dec 2013)	118	77	75
24 hours postdose (7 Dec 2013)	118	74	87
48 hours postdose (8 Dec 2013)	133	78	80
72 hours postdose (9 Dec 2013)	145	86	86 (Abnormal/NCS)
* Period 2, 24 hours predose (10 Jan 2014)	136	78	111 (Abnormal/NCS)
50 min predose (11 Jan 2014)	145	81	119 (Abnormal/NCS)
50 min predose (11 Jan 2014) (repeat)	153	91	112 (Abnormal/NCS)
Follow-up (15 Jan 2014)	151	83	108 (Abnormal/NCS)

Bpm = beats per minute; DBP = diastolic blood pressure; NCS = not clinically significant; SBP = systolic blood pressure
***Note:** Test treatment was not administered due to sinus tachycardia

Subject Number:	1
Age (years):	30
Gender:	Female
Race / Ethnicity	White / Not Hispanic or Latino
Weight (kg):	73.0
Height (cm):	171
BMI (kg/m^2):	25.0
Reason for Narrative:	AE leading to withdrawal

Subject [redacted] a 30-year-old female, was randomized to Sequence 2 (Reference/Test) and received only Reference treatment on 23 Jan 2014 at 9:33. The subject had unremarkable medical history of tonsillitis and tonsillectomy (in 1992), allergy to animals (since 1993), and upper limb (arm) fracture (in 1994).

On 26 Feb 2014 (approximately 34 days after last IMP dose), the subject presented with mild dizziness at 8:00. At 17:00 on the same day, the subject presented with moderate diarrhea and mild nausea. The diarrhea and nausea resolved on 2 Mar 2014 and the dizziness resolved on 4 Mar 2014. The subject was withdrawn from the trial on 2 Mar 2014. All three events were considered unrelated to IMP by the investigator. No concomitant therapy was administered.

No other AEs were reported.

Subject Number:	
Age (years):	26
Gender:	Female
Race / Ethnicity	White / Not Hispanic or Latino
Weight (kg):	71.3
Height (cm):	179
BMI (kg/m^2):	22.3
Reason for Narrative:	AE leading to withdrawal

Subject , a 26-year-old female, was randomized to Sequence 1 (Test/Reference) and received only Test treatment on 17 Feb 2014 at 9:39. The subject had no reported medical history.

On 22 Feb 2014 (approximately 5 days after last IMP dose), the subject presented with moderate depressed mood at 10:00. The depressed mood resolved on 24 Feb 2014 and the IMP was withdrawn on 7 Apr 2014. The depressed mood was considered related to IMP by the investigator. No concomitant therapy was administered.

No other AEs were reported.

Subject Number:	
Age (years):	46
Gender:	Male
Race / Ethnicity	White / Not Hispanic or Latino
Weight (kg):	77.5
Height (cm):	174
BMI (kg/m^2):	25.6
Reason for Narrative:	AE leading to withdrawal

Subject , a 46-year-old male, was randomized to Sequence 1 (Test/Reference) and received only Test treatment on 17 Mar 2014 at 9:45. The subject had unremarkable medical history of tendon rupture (in 2002), and ureteric stenosis and ureteric surgery (in 2009).

On 21 Apr 2014 (approximately 35 days after last IMP dose), the subject presented with severe elevated blood creatinine phosphokinase (CPK) and was withdrawn from the trial on the same day. The elevated blood CPK was considered unrelated to IMP by the investigator and resolved on 2 May 2014. The subject was asymptomatic and ECG results were within normal range. No other AEs were reported and no concomitant medication was administered.

A summary of relevant laboratory results are provided below.

Time Point	ALT (U/L) Range: 0 – 50	AST (U/L) Range: 0 – 50	CPK (U/L) Range: 0 – 171
Screening (11 Mar 2014)	17.4	24.3	162.7
Period 1, 24 hours predose (16 Mar 2014)	16.2	23.5	165.6
Period 2, 24 hours predose (21 Apr 2014) (10:15)	72.1 (H/NCS)	240.6 (H/NCS)	9146.7 (H/NCS)
Repeat (21 Apr 2014) (18:06)	64.6 (H/NCS)	209.4 (H/NCS)	7822.1 (H/NCS)
Follow-up (24 Apr 2014)	61.2 (H/NCS)	114.8 (H/NCS)	2988.1 (H/NCS)
Repeat (2 May 2014)	29.1	27.0	220.3 (H/NCS)

ALT = alanine aminotransferase, AST = aspartate aminotransferase; CPK = creatine phosphokinase
H = high (above normal range); NCS = not clinically significant

15.3.4 Abnormal Laboratory Value Listing (Each Subject)

Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Leukocytes (10^9/L)	Screening	18-11-2013/ 11:47	3.61 (L, ncs)		3.69 - 10.04
		Protein (g/L)	Screening	18-11-2013/ 11:47	65.7 (L, ncs)		66.0 - 83.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:10	101.2 (H, ncs)		28.0 - 100.0
		Leukocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:10	3.46 (L, ncs)		3.69 - 10.04
		Neutrophils (10^9/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:10	1.38 (L, ncs)		1.61 - 6.45
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 9:45	62.2 (L, ncs)		62.7 - 150.8
		Leukocytes (10^9/L)	Follow-Up	20-01-2014/ 11:22	3.06 (L, ncs)	-0.55	3.69 - 10.04
		Neutrophils (10^9/L)	Follow-Up	20-01-2014/ 11:22	1.30 (L, ncs)	-0.59	1.61 - 6.45
		Thyroxine (nmol/L)	Follow-Up	20-01-2014/ 11:22	55.7 (L, ncs)	-10.9	62.7 - 150.8
	Treatment Sequence 1	Lymphocytes (10^9/L)	Screening	20-11-2013/ 12:17	1.01 (L, ncs)		1.08 - 3.00
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 9:35	65.0 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 9:35	241.1 (H, ncs)		0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:12	0.5 (H, ncs)		0.0 - 0.5
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:21	2.69 (L, ncs)		2.80 - 7.20
	Treatment Sequence 1	Erythrocytes (uL)	Screening	21-11-2013/ 11:21	10.00 (H, ncs)		0.00 - 5.00
		Bilirubin (umol/L)	Screening	21-11-2013/ 11:24	22.4 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	21-11-2013/ 11:24	4.2 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	21-11-2013/ 11:24	18.2 (H, ncs)		1.6 - 17.6
		Monocytes/Leukocytes (%)	Screening	21-11-2013/ 11:24	14.6 (H, ncs)		5.3 - 14.2
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 8:47	10.00 (H, ncs)		0.00 - 5.00
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 8:50	36.8 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 8:50	5.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 8:50	31.3 (H, ncs)		1.6 - 17.6
		Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 8:50	4.04 (L, ncs)		4.10 - 5.90

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Potassium (mmol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 9:35	3.49 (L, ncs)		3.50 - 5.10
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 16:42	178.8 (H, ncs)		0.0 - 171.0
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:42	65.5 (L, ncs)		66.0 - 83.0
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:42	61.3 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:42	7.42 (H, ncs)		2.80 - 7.20
		Protein (g/L)	Follow-Up	27-01-2014/ 10:06	65.8 (L, ncs)	-1.2	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	27-01-2014/ 10:06	54.8 (L, ncs)	-18.4	62.7 - 150.8
		Urea (mmol/L)	Follow-Up	27-01-2014/ 10:06	8.17 (H, ncs)	3.35	2.80 - 7.20
	Treatment Sequence 1	Bilirubin (umol/L)	Screening	21-11-2013/ 8:43	24.3 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Screening	21-11-2013/ 8:43	98.7 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Screening	21-11-2013/ 8:43	4.4 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	21-11-2013/ 8:43	19.9 (H, ncs)		1.6 - 17.6

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Merck Serono
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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 15:59	22.9 (H, ncs)		5.0 - 21.0
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 15:59	19.9 (H, ncs)		1.6 - 17.6
		Bilirubin (umol/L)	Follow-Up	27-01-2014/ 10:46	21.9 (H, ncs)	-0.5	5.0 - 21.0
		Indirect Bilirubin (umol/L)	Follow-Up	27-01-2014/ 10:46	18.6 (H, ncs)	0.4	1.6 - 17.6
	Treatment Sequence 2	Leukocytes (10^9/L)	Screening	22-11-2013/ 8:21	12.01 (H, ncs)		3.19 - 8.71
		Neutrophils (10^9/L)	Screening	22-11-2013/ 8:21	7.71 (H, ncs)		1.46 - 5.85
		Creatine Kinase (IU/L)	Screening	22-11-2013/ 8:21	298.4 (H, ncs)		0.0 - 171.0
		Urea (mmol/L)	Screening	22-11-2013/ 8:21	2.79 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Screening	22-11-2013/ 8:21	99.5 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	22-11-2013/ 8:21	3.71 (L, ncs)		4.10 - 5.90
		Monocytes (10^9/L)	Screening	22-11-2013/ 8:21	1.23 (H, ncs)		0.30 - 0.92
		Creatine Kinase (IU/L)	Screening	27-11-2013/ 11:03	181.6 (H, ncs)		0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 9:05	107.7 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 9:05	212.5 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 9:05	100.8 (L, ncs)		101.0 - 109.0
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 9:05	5.77 (H, ncs)		4.12 - 5.74
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 9:05	133.5 (L, ncs)		136.0 - 146.0
		Triacylglycerol Lipase (IU/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 9:05	188.4 (H, ncs)		0.0 - 67.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 17:04	186.9 (H, ncs)		0.0 - 171.0
		Leukocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:08	9.02 (H, ncs)		3.19 - 8.71
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:08	1564.9 (H, ncs)		0.0 - 171.0
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:08	135.5 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 17:22	1167.7 (H, ncs)		0.0 - 171.0
		Protein (g/L)	Follow-Up	22-01-2014/ 9:54	65.7 (L, ncs)	-0.3	66.0 - 83.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Creatine Kinase (IU/L)	Follow-Up	22-01-2014/ 9:54	322.5 (H, ncs)	140.9	0.0 - 171.0
		Bilirubin (umol/L)	Follow-Up	22-01-2014/ 9:54	4.3 (L, ncs)	-2.7	5.0 - 21.0
		Glucose (mmol/L)	Follow-Up	22-01-2014/ 9:54	6.99 (H, ncs)	3.28	4.10 - 5.90
	Treatment Sequence 2	Leukocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 9:59	14.68 (H, ncs)		3.69 - 10.04
		Neutrophils (10^9/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 9:59	11.59 (H, ncs)		1.61 - 6.45
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 9:59	5.0 (L, ncs)		5.3 - 14.2
		Lymphocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 9:59	13.4 (L, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 9:59	79.0 (H, ncs)		37.9 - 70.5
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 9:59	374 (H, ncs)		173 - 369
		Erythrocytes (uL)	Follow-Up	22-01-2014/ 8:05	10.00 (H, ncs)	10	0.00 - 5.00
	Treatment Sequence 1	Urea (mmol/L)	Screening	22-11-2013/ 8:47	2.73 (L, ncs)		2.80 - 7.20
		Basophils (10^9/L)	Screening	22-11-2013/ 8:47	0.08 (H, ncs)		0.01 - 0.07

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	0.25 (H, ncs)		0.00 - 0.09
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	1.5 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	250.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	POSITIVE (H, ncs)		
		Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	10.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	20.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	100.00 (H, ncs)		0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:29	16 (H, ncs)		0 - 15
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 17:33	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 7:59	10.00 (H, ncs)		0.00 - 5.00
		Protein (g/L)	Follow-Up	03-02-2014/ 7:36	63.6 (L, ncs)	-2.6	66.0 - 83.0
		Urea (mmol/L)	Follow-Up	03-02-2014/ 7:36	2.61 (L, ncs)	-0.12	2.80 - 7.20

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Calcium (mmol/L)	Follow-Up	03-02-2014/ 7:36	2.19 (L, ncs)	-0.07	2.20 - 2.65
		Hematocrit (L/L)	Follow-Up	03-02-2014/ 7:36	0.34 (L, ncs)	-0.03	0.35 - 0.44
1	Treatment Sequence 2	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:35	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 2	Hemoglobin (g/L)	Follow-Up	21-01-2014/ 8:06	166 (H, ncs)	6	126 - 165
	Treatment Sequence 1	Monocytes (10^9/L)	Screening	22-11-2013/ 10:59	0.28 (L, ncs)		0.30 - 0.92
	Treatment Sequence 2	Erythrocytes (uL)	Screening	22-11-2013/ 11:12	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (10^12/L)	Screening	22-11-2013/ 11:15	3.99 (L, ncs)		4.02 - 5.08
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:44	25.00 (H, ncs)		0.00 - 5.00
		Neutrophils (10^9/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:46	7.67 (H, ncs)		1.61 - 6.45
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:46	22.6 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:46	4.2 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:46	18.4 (H, ncs)		1.6 - 17.6

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:46	3.92 (L, ncs)		4.02 - 5.08
		Lymphocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:46	16.3 (L, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:46	77.0 (H, ncs)		37.9 - 70.5
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:02	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:02	7.00 (H, ncs)		0.00 - 3.00
		Leukocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	11.19 (H, ncs)		3.69 - 10.04
		Neutrophils (10^9/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	8.40 (H, ncs)		1.61 - 6.45
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	27.2 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	4.8 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	22.4 (H, ncs)		1.6 - 17.6
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	5.1 (L, ncs)		5.3 - 14.2
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	3.99 (L, ncs)		4.02 - 5.08

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Neutrophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:04	75.0 (H, ncs)		37.9 - 70.5
		Ketones (mmol/L)	Follow-Up	15-01-2014/ 10:17	0.5 (H, ncs)	0.5	0.0 - 0.5
		Erythrocytes (uL)	Follow-Up	15-01-2014/ 10:17	50.00 (H, ncs)	40	0.00 - 5.00
		Neutrophils (10^9/L)	Follow-Up	15-01-2014/ 10:20	7.26 (H, ncs)	2.16	1.61 - 6.45
		Bilirubin (umol/L)	Follow-Up	15-01-2014/ 10:20	28.1 (H, ncs)	7.2	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	15-01-2014/ 10:20	4.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	15-01-2014/ 10:20	23.6 (H, ncs)		1.6 - 17.6
		Monocytes/Leukocytes (%)	Follow-Up	15-01-2014/ 10:20	4.6 (L, ncs)	-0.8	5.3 - 14.2
		Erythrocytes (10^12/L)	Follow-Up	15-01-2014/ 10:20	3.95 (L, ncs)	-0.04	4.02 - 5.08
		Lymphocytes/Leukocytes (%)	Follow-Up	15-01-2014/ 10:20	17.6 (L, ncs)	-7.5	17.8 - 48.5
		Neutrophils/Leukocytes (%)	Follow-Up	15-01-2014/ 10:20	77.3 (H, ncs)	8.8	37.9 - 70.5
		Eosinophils (10^9/L)	Follow-Up	15-01-2014/ 10:20	0.03 (L, ncs)	-0.02	0.04 - 0.43

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Eosinophils/Leukocytes (%)	Follow-Up	15-01-2014/ 10:20	0.3 (L, ncs)	-0.4	0.6 - 7.9
	Treatment Sequence 1	Protein (g/L)	Screening	22-11-2013/ 12:16	65.5 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Screening	22-11-2013/ 12:16	2.61 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Screening	22-11-2013/ 12:16	98.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	22-11-2013/ 12:16	134.9 (L, ncs)		136.0 - 146.0
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:49	3.32 (H, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:49	98.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:49	133.9 (L, ncs)		136.0 - 146.0
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:07	65.9 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:07	350.1 (H, ncs)		0.0 - 171.0
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:07	2.58 (L, ncs)		2.80 - 7.20
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:07	134.6 (L, ncs)		136.0 - 146.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 17:25	383.6 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	07-01-2014/ 12:01	281.4 (H, ncs)		0.0 - 171.0
		Protein (g/L)	Follow-Up	22-01-2014/ 12:04	65.6 (L, ncs)	0.1	66.0 - 83.0
		Urea (mmol/L)	Follow-Up	22-01-2014/ 12:04	2.73 (L, ncs)	0.12	2.80 - 7.20
		Chloride (mmol/L)	Follow-Up	22-01-2014/ 12:04	100.2 (L, ncs)	1.8	101.0 - 109.0
	Treatment Sequence 1	Protein (g/L)	Screening	22-11-2013/ 12:22	65.1 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Screening	22-11-2013/ 12:22	1.60 (L, ncs)		2.80 - 7.20
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:41	134.7 (L, ncs)		136.0 - 146.0
		Protein (g/L)	Follow-Up	21-01-2014/ 9:06	64.8 (L, ncs)	-0.3	66.0 - 83.0
		Lymphocytes (10^9/L)	Follow-Up	21-01-2014/ 9:06	0.57 (L, ncs)	-0.84	0.99 - 2.89
		Lymphocytes/Leukocytes (%)	Follow-Up	21-01-2014/ 9:06	9.3 (L, ncs)	-13.6	17.8 - 48.5
		Neutrophils/Leukocytes (%)	Follow-Up	21-01-2014/ 9:06	76.0 (H, ncs)	8	37.9 - 70.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
1037/105	Treatment Sequence 2	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:22	10.00 (H, ncs)		0.00 - 5.00
		Ketones (mmol/L)	Follow-Up	23-12-2013/ 10:41	0.5 (H, ncs)	0.5	0.0 - 0.5
		Erythrocytes (uL)	Follow-Up	23-12-2013/ 10:41	10.00 (H, ncs)	10	0.00 - 5.00
		Creatine Kinase (IU/L)	Follow-Up	23-12-2013/ 10:45	491.2 (H, ncs)	391.7	0.0 - 171.0
	Treatment Sequence 2	Urea (mmol/L)	Screening	27-11-2013/ 8:12	2.67 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Screening	27-11-2013/ 8:12	100.2 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	27-11-2013/ 8:12	135.8 (L, ncs)		136.0 - 146.0
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:15	65.4 (L, ncs)		66.0 - 83.0
		Glucose (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:15	3.76 (L, ncs)		4.10 - 5.90
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:15	4.00 (L, ncs)		4.02 - 5.08
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:15	135.2 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:01	25.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:01	5.00 (H, ncs)		0.00 - 3.00
		Neutrophils (10^9/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:03	7.11 (H, ncs)		1.61 - 6.45
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:03	65.5 (L, ncs)		66.0 - 83.0
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:03	5.0 (L, ncs)		5.3 - 14.2
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:03	3.94 (L, ncs)		4.02 - 5.08
		Lymphocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:03	16.1 (L, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 10:03	78.0 (H, ncs)		37.9 - 70.5
		Erythrocytes (10^12/L)	Follow-Up	20-01-2014/ 7:56	3.88 (L, ncs)	-0.26	4.02 - 5.08
	Treatment Sequence 2	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:56	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:56	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:56	25.00 (H, ncs)		0.00 - 9.00
		Alanine Aminotransferase (U/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:59	39.9 (H, ncs)		0.0 - 35.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Alanine Aminotransferase (U/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 17:36	36.1 (H, ncs)		0.0 - 35.0
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:36	26.2 (L, ncs)		28.0 - 100.0
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:36	65.1 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:36	2.61 (L, ncs)		2.80 - 7.20
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:36	135.9 (L, ncs)		136.0 - 146.0
		Calcium (mmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:36	2.17 (L, ncs)		2.20 - 2.65
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:36	106.4 (H, ncs)		0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:36	58.5 (H, ncs)		0.0 - 35.0
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 16:32	102.7 (H, ncs)		0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 16:32	54.4 (H, ncs)		0.0 - 35.0
		Erythrocytes (uL)	Follow-Up	30-01-2014/ 8:51	25.00 (H, ncs)	25	0.00 - 5.00
		Erythrocytes (/HPF)	Follow-Up	30-01-2014/ 8:51	8.00 (H, ncs)		0.00 - 3.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Monocytes (10^9/L)	Follow-Up	30-01-2014/ 8:52	0.23 (L, ncs)	-0.05	0.27 - 0.91
	Treatment Sequence 2	Neutrophils (10^9/L)	Screening	28-11-2013/ 11:07	1.33 (L, ncs)		1.46 - 5.85
		Monocytes (10^9/L)	Screening	28-11-2013/ 11:07	0.28 (L, ncs)		0.30 - 0.92
		Glucose (mmol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:41	3.72 (L, ncs)		4.10 - 5.90
		Monocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:41	0.29 (L, ncs)		0.30 - 0.92
		Creatinine (umol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:41	56.4 (L, ncs)		59.0 - 104.0
		Neutrophils (10^9/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:00	1.44 (L, ncs)		1.46 - 5.85
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:00	2.78 (L, ncs)		2.80 - 7.20
		Lymphocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:00	49.3 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:00	38.0 (L, ncs)		38.2 - 71.5
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:00	1.1 (H, ncs)		0.0 - 1.0
		Leukocytes (10^9/L)	Follow-Up	29-01-2014/ 8:17	3.09 (L, ncs)	-0.27	3.19 - 8.71

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Neutrophils (10^9/L)	Follow-Up	29-01-2014/ 8:17	1.24 (L, ncs)	-0.64	1.46 - 5.85
		Monocytes (10^9/L)	Follow-Up	29-01-2014/ 8:17	0.28 (L, ncs)	0	0.30 - 0.92
		Creatinine (umol/L)	Follow-Up	29-01-2014/ 8:17	58.5 (L, ncs)	-2.6	59.0 - 104.0
	Treatment Sequence 2	Erythrocytes (uL)	Screening	28-11-2013/ 11:16	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Screening	28-11-2013/ 11:16	5.00 (H, ncs)		0.00 - 3.00
		Thyroxine (nmol/L)	Screening	28-11-2013/ 11:43	62.6 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Screening	28-11-2013/ 11:43	99.1 (L, ncs)		101.0 - 109.0
		Basophils/Leukocytes (%)	Screening	28-11-2013/ 11:43	0.1 (L, ncs)		0.2 - 1.3
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:03	10.00 (H, ncs)		0.00 - 5.00
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:29	0.01 (L, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:29	0.2 (L, ncs)		0.6 - 7.9
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:26	25.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (uL)	Follow-Up	30-01-2014/ 10:31	10.00 (H, ncs)	-15	0.00 - 5.00
		Bilirubin (umol/L)	Follow-Up	30-01-2014/ 10:34	4.6 (L, ncs)	-4.6	5.0 - 21.0
		Eosinophils (10^9/L)	Follow-Up	30-01-2014/ 10:34	0.03 (L, ncs)	-0.02	0.04 - 0.43
		Eosinophils/Leukocytes (%)	Follow-Up	30-01-2014/ 10:34	0.4 (L, ncs)	-0.2	0.6 - 7.9
		Basophils/Leukocytes (%)	Follow-Up	30-01-2014/ 10:34	0.1 (L, ncs)	0	0.2 - 1.3
	Treatment Sequence 1	Erythrocytes (uL)	Screening	29-11-2013/ 10:39	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (uL)	Screening	29-11-2013/ 10:39	25.00 (H, ncs)		0.00 - 9.00
		pH	Screening	29-11-2013/ 10:39	0.0 (L, ncs)		4.8 - 7.4
		Creatine Kinase (IU/L)	Screening	29-11-2013/ 10:42	282.1 (H, ncs)		0.0 - 145.0
		Chloride (mmol/L)	Screening	29-11-2013/ 10:42	100.1 (L, ncs)		101.0 - 109.0
		Erythrocytes (10^12/L)	Screening	29-11-2013/ 10:42	3.89 (L, ncs)		4.02 - 5.08
		Erythrocytes (uL)	Screening	09-12-2013/ 8:09	50.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (/HPF)	Screening	09-12-2013/ 8:09	8.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPF)	Screening	09-12-2013/ 8:09	8.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Screening	09-12-2013/ 8:09	25.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 8:33	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	19-12-2013/ 8:33	POSITIVE (H, ncs)		
		pH	Period 1,Day -1/ 24 H Predose	19-12-2013/ 8:33	8.0 (H, ncs)		4.8 - 7.4
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 8:36	3.96 (L, ncs)		4.02 - 5.08
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 7:58	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 8:00	3.90 (L, ncs)		4.02 - 5.08
		Erythrocytes (uL)	Follow-Up	07-02-2014/ 8:53	50.00 (H, ncs)	0	0.00 - 5.00
		Erythrocytes (/HPF)	Follow-Up	07-02-2014/ 8:53	7.00 (H, ncs)	-1	0.00 - 3.00
		Leukocytes (uL)	Follow-Up	07-02-2014/ 8:53	25.00 (H, ncs)	0	0.00 - 9.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Bilirubin (umol/L)	Follow-Up	07-02-2014/ 9:01	3.4 (L, ncs)	-5.3	5.0 - 21.0
		Erythrocytes (10^12/L)	Follow-Up	07-02-2014/ 9:01	3.73 (L, ncs)	-0.16	4.02 - 5.08
	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	29-11-2013/ 10:51	295.0 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	29-11-2013/ 10:51	99.5 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	29-11-2013/ 10:51	3.92 (L, ncs)		4.10 - 5.90
		Creatine Kinase (IU/L)	Screening	06-12-2013/ 11:40	260.2 (H, ncs)		0.0 - 171.0
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:18	0.5 (H, ncs)		0.0 - 0.5
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:21	317.4 (H, ncs)		0.0 - 171.0
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:21	2.73 (L, ncs)		2.80 - 7.20
		Glucose (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:21	4.09 (L, ncs)		4.10 - 5.90
		Lymphocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:21	50.3 (H, ncs)		18.3 - 48.1
		Lymphocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 9:20	3.46 (H, ncs)		1.08 - 3.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Lymphocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 9:20	48.2 (H, ncs)		18.3 - 48.1
		Protein (g/L)	Follow-Up	29-01-2014/ 11:00	64.7 (L, ncs)	-2.4	66.0 - 83.0
		Creatine Kinase (IU/L)	Follow-Up	29-01-2014/ 11:00	189.5 (H, ncs)	-70.7	0.0 - 171.0
	Treatment Sequence 1	Chloride (mmol/L)	Screening	29-11-2013/ 10:47	97.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	29-11-2013/ 10:47	135.9 (L, ncs)		136.0 - 146.0
		Basophils (10^9/L)	Screening	29-11-2013/ 10:47	0.13 (H, ncs)		0.01 - 0.07
		Eosinophils (10^9/L)	Screening	29-11-2013/ 10:47	0.01 (L, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Screening	29-11-2013/ 10:47	0.1 (L, ncs)		0.6 - 7.9
		Basophils/Leukocytes (%)	Screening	29-11-2013/ 10:47	1.8 (H, ncs)		0.2 - 1.3
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 9:13	99.0 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 9:13	135.6 (L, ncs)		136.0 - 146.0
		Basophils (10^9/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 9:13	0.10 (H, ncs)		0.01 - 0.07

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:53	97.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:53	132.7 (L, ncs)		136.0 - 146.0
		Basophils (10^9/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:53	0.15 (H, ncs)		0.01 - 0.07
		Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:53	0.03 (L, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:53	0.4 (L, ncs)		0.6 - 7.9
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:53	1.9 (H, ncs)		0.2 - 1.3
		Creatine Kinase (IU/L)	Follow-Up	27-01-2014/ 9:38	153.0 (H, ncs)	33	0.0 - 145.0
		Chloride (mmol/L)	Follow-Up	27-01-2014/ 9:38	100.3 (L, ncs)	2.7	101.0 - 109.0
		Basophils (10^9/L)	Follow-Up	27-01-2014/ 9:38	0.10 (H, ncs)	-0.03	0.01 - 0.07
		Eosinophils (10^9/L)	Follow-Up	27-01-2014/ 9:38	0.02 (L, ncs)	0.01	0.04 - 0.43
		Eosinophils/Leukocytes (%)	Follow-Up	27-01-2014/ 9:38	0.4 (L, ncs)	0.3	0.6 - 7.9
		Basophils/Leukocytes (%)	Follow-Up	27-01-2014/ 9:38	1.9 (H, ncs)	0.1	0.2 - 1.3

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Erythrocytes (uL)	Screening	29-11-2013/ 11:08	10.00 (H, ncs)		0.00 - 5.00
		Chloride (mmol/L)	Screening	29-11-2013/ 11:13	100.3 (L, ncs)		101.0 - 109.0
		Basophils/Leukocytes (%)	Screening	29-11-2013/ 11:13	1.4 (H, ncs)		0.2 - 1.3
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:18	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:18	POSITIVE (H, ncs)		
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:23	25.00 (H, ncs)		0.00 - 5.00
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:24	1.5 (H, ncs)		0.2 - 1.3
		Erythrocytes (uL)	Follow-Up	05-02-2014/ 9:55	10.00 (H, ncs)	0	0.00 - 5.00
	Treatment Sequence 1	Urea (mmol/L)	Screening	29-11-2013/ 11:33	2.33 (L, ncs)		2.80 - 7.20
		Erythrocytes (10^12/L)	Screening	29-11-2013/ 11:33	3.93 (L, ncs)		4.02 - 5.08
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:29	0.5 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:29	25.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:58	0.25 (H, ncs)		0.00 - 0.09
		Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:58	0.5 (H, ncs)		0.0 - 0.5
		Leukocytes (/HPF)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:58	8.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:58	25.00 (H, ncs)		0.00 - 9.00
		pH	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:58	9.0 (H, ncs)		4.8 - 7.4
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 10:01	22.9 (L, ncs)		28.0 - 100.0
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 10:01	1.94 (L, ncs)		2.80 - 7.20
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 10:01	135.1 (L, ncs)		136.0 - 146.0
		Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 17:22	1.5 (H, ncs)		0.0 - 0.5
		Leukocytes (/HPF)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 17:22	5.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 17:22	25.00 (H, ncs)		0.00 - 9.00
		pH	Follow-Up	27-01-2014/ 10:39	8.0 (H, ncs)	1	4.8 - 7.4

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (10^12/L)	Follow-Up	27-01-2014/ 10:42	3.99 (L, ncs)	0.06	4.02 - 5.08
	Treatment Sequence 2	Erythrocytes (uL)	Screening	29-11-2013/ 12:40	10.00 (H, ncs)		0.00 - 5.00
		pH	Screening	29-11-2013/ 12:40	8.0 (H, ncs)		4.8 - 7.4
		Chloride (mmol/L)	Screening	29-11-2013/ 12:42	97.8 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:17	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:17	5.00 (H, ncs)		0.00 - 3.00
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:18	99.9 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 18:45	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:15	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:15	7.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Follow-Up	05-02-2014/ 10:29	10.00 (H, ncs)	0	0.00 - 5.00
		Chloride (mmol/L)	Follow-Up	05-02-2014/ 10:31	100.0 (L, ncs)	2.2	101.0 - 109.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 2	Amylase (IU/L)	Screening	02-12-2013/ 8:15	104.8 (H, ncs)		28.0 - 100.0
		Monocytes (10^9/L)	Screening	02-12-2013/ 8:15	0.24 (L, ncs)		0.30 - 0.92
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:52	103.9 (H, ncs)		28.0 - 100.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:52	99.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	05-12-2013/ 8:52	135.5 (L, ncs)		136.0 - 146.0
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	10-01-2014/ 9:24	111.6 (H, ncs)		28.0 - 100.0
		Lymphocytes (10^9/L)	Follow-Up	28-01-2014/ 11:58	1.04 (L, ncs)	-0.79	1.08 - 3.00
		Sodium (mmol/L)	Follow-Up	28-01-2014/ 11:58	135.5 (L, ncs)	-2.7	136.0 - 146.0
	Treatment Sequence 1	Erythrocytes (uL)	Screening	05-12-2013/ 9:24	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Screening	05-12-2013/ 9:24	7.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPF)	Screening	05-12-2013/ 9:24	7.00 (H, ncs)		0.00 - 4.00
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:01	25.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:01	8.00 (H, ncs)		0.00 - 3.00
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:04	2.73 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 7:55	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Follow-Up	30-01-2014/ 9:17	10.00 (H, ncs)	-40	0.00 - 5.00
		Glucose (mmol/L)	Follow-Up	30-01-2014/ 9:22	3.88 (L, ncs)	-0.79	4.10 - 5.90
		Erythrocytes (10^12/L)	Follow-Up	30-01-2014/ 9:22	3.90 (L, ncs)	-0.48	4.02 - 5.08
	Treatment Sequence 2	Thyroxine (nmol/L)	Screening	05-12-2013/ 11:36	58.1 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Screening	05-12-2013/ 11:36	2.25 (L, ncs)		2.80 - 7.20
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 9:20	209.2 (H, ncs)		0.0 - 145.0
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 9:20	0.80 (L, ncs)		0.99 - 2.89
		Monocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 9:20	0.25 (L, ncs)		0.27 - 0.91
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 9:20	135.6 (L, ncs)		136.0 - 146.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 18:07	184.0 (H, ncs)		0.0 - 145.0
		pH	Period 2,Day -1/ 24 H Predose	24-01-2014/ 9:57	8.0 (H, ncs)		4.8 - 7.4
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 10:00	257.0 (H, ncs)		0.0 - 145.0
		Lymphocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 10:00	0.85 (L, ncs)		0.99 - 2.89
		Protein (g/L)	Follow-Up	07-02-2014/ 10:29	61.8 (L, ncs)	-5.1	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	07-02-2014/ 10:29	59.0 (L, ncs)	-9.9	62.7 - 150.8
		Calcium (mmol/L)	Follow-Up	07-02-2014/ 10:29	2.13 (L, ncs)	-0.2	2.20 - 2.65
	Treatment Sequence 1	Bilirubin (umol/L)	Screening	09-12-2013/ 9:22	30.7 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Screening	09-12-2013/ 9:22	100.7 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Screening	09-12-2013/ 9:22	6.0 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	09-12-2013/ 9:22	24.7 (H, ncs)		1.6 - 17.6
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:32	0.5 (H, ncs)		0.0 - 0.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:34	24.8 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:34	5.8 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:34	19.0 (H, ncs)		1.6 - 17.6
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:25	72.1 (H, ncs)		0.0 - 50.0
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 16:27	65.0 (H, ncs)		0.0 - 50.0
	Treatment Sequence 1	Chloride (mmol/L)	Screening	09-12-2013/ 9:58	99.1 (L, ncs)		101.0 - 109.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:10	99.5 (L, ncs)		101.0 - 109.0
		Basophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:10	1.1 (H, ncs)		0.0 - 1.0
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:46	62.3 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:46	421.1 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:46	74.2 (H, ncs)		0.0 - 50.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 17:51	340.0 (H, ncs)		0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 17:51	65.8 (H, ncs)		0.0 - 50.0
		Chloride (mmol/L)	Follow-Up	03-02-2014/ 10:57	99.3 (L, ncs)	0.2	101.0 - 109.0
?	Treatment Sequence 2	Glucose (mmol/L)	Screening	09-12-2013/ 10:22	4.07 (L, ncs)		4.10 - 5.90
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:34	1.5 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:34	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:34	POSITIVE (H, ncs)		
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:36	3.62 (H, ncs)		0.99 - 2.89
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:36	2.61 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 18:44	10.00 (H, ncs)		0.00 - 5.00
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:42	103.2 (H, ncs)		28.0 - 100.0
		Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:42	4.06 (L, ncs)		4.10 - 5.90
		Erythrocytes (uL)	Follow-Up	03-02-2014/ 8:26	10.00 (H, ncs)	10	0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Leukocytes (uL)	Follow-Up	03-02-2014/ 8:26	25.00 (H, ncs)	25	0.00 - 9.00
		Protein (g/L)	Follow-Up	03-02-2014/ 8:29	64.4 (L, ncs)	-4.9	66.0 - 83.0
		Erythrocytes (10^12/L)	Follow-Up	03-02-2014/ 8:29	3.99 (L, ncs)	-0.34	4.02 - 5.08
		Neutrophils/Leukocytes (%)	Follow-Up	03-02-2014/ 8:29	37.3 (L, ncs)	-13.6	37.9 - 70.5
		Eosinophils (10^9/L)	Follow-Up	03-02-2014/ 8:29	0.51 (H, ncs)	0.21	0.04 - 0.43
		Eosinophils/Leukocytes (%)	Follow-Up	03-02-2014/ 8:29	9.4 (H, ncs)	3.9	0.6 - 7.9
	Treatment Sequence 2	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:52	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:52	POSITIVE (H, ncs)		
		Hematocrit (L/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:54	0.49 (H, ncs)		0.38 - 0.48
		Hemoglobin (g/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:54	166 (H, ncs)		126 - 165
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 10:14	10.00 (H, ncs)		0.00 - 5.00
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 10:22	1.1 (H, ncs)		0.0 - 1.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (uL)	Follow-Up	07-02-2014/ 9:25	25.00 (H, ncs)	25	0.00 - 5.00
		Basophils/Leukocytes (%)	Follow-Up	07-02-2014/ 9:27	1.1 (H, ncs)	0.6	0.0 - 1.0
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	10-12-2013/ 10:12	409.7 (H, ncs)		0.0 - 171.0
		Bilirubin (umol/L)	Screening	10-12-2013/ 10:12	21.9 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Screening	10-12-2013/ 10:12	100.9 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Screening	10-12-2013/ 10:12	4.1 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	10-12-2013/ 10:12	17.8 (H, ncs)		1.6 - 17.6
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:10	10.00 (H, ncs)		0.00 - 5.00
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:12	22.2 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:12	3.9 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:12	18.3 (H, ncs)		1.6 - 17.6
		Calcium (mmol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:12	2.67 (H, ncs)		2.20 - 2.65

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

/project24/ep/blinded/e210899_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.4.1.sas

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 9:29	10.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 9:31	62.2 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 9:31	100.6 (L, ncs)		101.0 - 109.0
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 18:11	53.9 (L, ncs)		62.7 - 150.8
		Erythrocytes (uL)	Follow-Up	10-02-2014/ 10:47	10.00 (H, ncs)	10	0.00 - 5.00
		Creatine Kinase (IU/L)	Follow-Up	10-02-2014/ 10:50	283.4 (H, ncs)	166.8	0.0 - 171.0
		Urea (mmol/L)	Follow-Up	10-02-2014/ 10:50	2.58 (L, ncs)	-3.01	2.80 - 7.20
		Monocytes/Leukocytes (%)	Follow-Up	10-02-2014/ 10:50	5.4 (L, ncs)	-1	5.6 - 14.8
		Monocytes (10^9/L)	Follow-Up	10-02-2014/ 10:50	0.26 (L, ncs)	-0.08	0.30 - 0.92
	Treatment Sequence 2	Ketones (mmol/L)	Screening	11-12-2013/ 10:18	5.0 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Screening	11-12-2013/ 10:18	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Screening	11-12-2013/ 10:18	6.00 (H, ncs)		0.00 - 3.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Leukocytes (/HPF)	Screening	11-12-2013/ 10:18	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Screening	11-12-2013/ 10:18	25.00 (H, ncs)		0.00 - 9.00
		Hemoglobin (g/L)	Screening	11-12-2013/ 10:24	148 (H, ncs)		111 - 146
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	50.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	POSITIVE (H, ncs)		
		Leukocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:22	10.36 (H, ncs)		3.69 - 10.04
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:22	189.7 (H, ncs)		0.0 - 145.0
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:22	2.91 (H, ncs)		0.99 - 2.89
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:25	145.9 (H, ncs)		0.0 - 145.0
		Lymphocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:25	3.16 (H, ncs)		0.99 - 2.89
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:25	99.1 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:25	133.2 (L, ncs)		136.0 - 146.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:25	371 (H, ncs)		173 - 369
		Creatine Kinase (IU/L)	Follow-Up	07-02-2014/ 9:41	965.9 (H, ncs)	847.3	0.0 - 145.0
		Chloride (mmol/L)	Follow-Up	07-02-2014/ 9:41	98.9 (L, ncs)	-3.8	101.0 - 109.0
		Sodium (mmol/L)	Follow-Up	07-02-2014/ 9:41	133.6 (L, ncs)	-4.2	136.0 - 146.0
		Alanine Aminotransferase (U/L)	Follow-Up	07-02-2014/ 9:41	37.2 (H, ncs)	18.4	0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Follow-Up	07-02-2014/ 9:41	52.9 (H, ncs)	26.6	0.0 - 35.0
	Treatment Sequence 1	Urea (mmol/L)	Screening	11-12-2013/ 11:38	2.51 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:11	10.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:13	58.5 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:13	2.54 (L, ncs)		2.80 - 7.20
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:13	134.7 (L, ncs)		136.0 - 146.0
		Neutrophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 8:13	71.9 (H, ncs)		37.9 - 70.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Urea (mmol/L)	Follow-Up	03-02-2014/ 10:44	2.11 (L, ncs)	-0.4	2.80 - 7.20
	Treatment Sequence 2	Chloride (mmol/L)	Screening	12-12-2013/ 11:05	99.9 (L, ncs)		101.0 - 109.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:28	104.3 (H, ncs)		28.0 - 100.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:28	100.9 (L, ncs)		101.0 - 109.0
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:50	25.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Follow-Up	05-02-2014/ 8:17	10.00 (H, ncs)	10	0.00 - 5.00
		Leukocytes (uL)	Follow-Up	05-02-2014/ 8:17	25.00 (H, ncs)	25	0.00 - 9.00
		Amylase (IU/L)	Follow-Up	05-02-2014/ 8:18	216.5 (H, ncs)	128.4	28.0 - 100.0
		Basophils/Leukocytes (%)	Follow-Up	05-02-2014/ 8:18	0.1 (L, ncs)	-0.1	0.2 - 1.3
	Treatment Sequence 1	Ketones (mmol/L)	Screening	13-12-2013/ 9:40	0.5 (H, ncs)		0.0 - 0.5
		Leukocytes (/HPF)	Screening	13-12-2013/ 9:40	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Screening	13-12-2013/ 9:40	25.00 (H, ncs)		0.00 - 9.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Creatine Kinase (IU/L)	Follow-Up	11-02-2014/ 8:55	404.1 (H, ncs)	322.3	0.0 - 171.0
		Glucose (mmol/L)	Follow-Up	11-02-2014/ 8:55	4.09 (L, ncs)	-0.34	4.10 - 5.90
	Treatment Sequence 2	Erythrocytes (uL)	Screening	16-12-2013/ 8:01	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 7:46	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	03-01-2014/ 7:46	POSITIVE (H, ncs)		
		Squamous Epithelial Cells (/HPF)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 7:46	20 (H, ncs)		0 - 15
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 7:48	63.6 (L, ncs)		66.0 - 83.0
		Potassium (mmol/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 7:48	3.30 (L, ncs)		3.50 - 5.10
		Creatinine (umol/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 7:48	40.9 (L, ncs)		45.0 - 84.0
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 16:11	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	03-01-2014/ 16:11	POSITIVE (H, ncs)		
		Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 16:11	5.00 (H, ncs)		0.00 - 3.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:33	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:33	4.00 (H, ncs)		0.00 - 3.00
		Hemoglobin (g/L)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:33	150 (H, ncs)		111 - 146
		Erythrocytes (uL)	Follow-Up	24-02-2014/ 8:28	25.00 (H, ncs)	15	0.00 - 5.00
		Protein (g/L)	Follow-Up	24-02-2014/ 8:31	65.9 (L, ncs)	-1.8	66.0 - 83.0
		Creatinine (umol/L)	Follow-Up	24-02-2014/ 8:31	43.1 (L, ncs)	-2.5	45.0 - 84.0
	Treatment Sequence 1	Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:48	370 (H, ncs)		173 - 369
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:49	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:49	4.00 (H, ncs)		0.00 - 3.00
	Treatment Sequence 1	Chloride (mmol/L)	Screening	16-12-2013/ 12:26	98.3 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	16-12-2013/ 12:26	135.3 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 9:42	100.4 (L, ncs)		101.0 - 109.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 9:42	134.7 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Follow-Up	07-02-2014/ 11:49	100.6 (L, ncs)	2.3	101.0 - 109.0
	Treatment Sequence 2	Erythrocytes (uL)	Screening	16-12-2013/ 12:40	10.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Screening	16-12-2013/ 12:43	59.0 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Screening	16-12-2013/ 12:43	100.4 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:45	10.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:57	216.1 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:57	99.1 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 11:21	25.00 (H, ncs)		0.00 - 5.00
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 11:23	369 (H, ncs)		155 - 342
		Chloride (mmol/L)	Follow-Up	07-02-2014/ 12:08	100.3 (L, ncs)	-0.1	101.0 - 109.0
		Erythrocytes (uL)	Follow-Up	07-02-2014/ 12:08	25.00 (H, ncs)	15	0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
5	Treatment Sequence 2	Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	24-01-2014/ 9:33	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Follow-Up	07-02-2014/ 9:38	10.00 (H, ncs)	10	0.00 - 5.00
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	18-12-2013/ 10:34	267.0 (H, ncs)		0.0 - 171.0
		Hemoglobin (g/L)	Screening	18-12-2013/ 10:34	123 (L, ncs)		126 - 165
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:24	63.4 (L, ncs)		66.0 - 83.0
		Hematocrit (L/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:24	0.36 (L, ncs)		0.38 - 0.48
		Hemoglobin (g/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:24	121 (L, ncs)		126 - 165
		Protein (g/L)	Follow-Up	25-02-2014/ 9:04	65.7 (L, ncs)	-1.3	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	25-02-2014/ 9:04	62.5 (L, ncs)	-8.5	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	25-02-2014/ 9:04	271.8 (H, ncs)	118.2	0.0 - 171.0
	Treatment Sequence 1	Hemoglobin (g/L)	Period 1,Day -1/ 24 H Predose	19-12-2013/ 10:27	166 (H, ncs)		126 - 165
		Lymphocytes/Leukocytes (%)	Follow-Up	11-02-2014/ 11:32	49.3 (H, ncs)	2.8	18.3 - 48.1

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Erythrocytes (uL)	Screening	18-12-2013/ 11:17	50.00 (H, ncs)		0.00 - 5.00
		Bacteria	Screening	18-12-2013/ 11:17	POSITIVE (H, ncs)		
		Thyroxine (nmol/L)	Screening	18-12-2013/ 11:19	60.5 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Screening	18-12-2013/ 11:19	2.65 (L, ncs)		2.80 - 7.20
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:22	27.1 (L, ncs)		28.0 - 100.0
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:22	2.35 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:45	10.00 (H, ncs)		0.00 - 5.00
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:47	2.55 (L, ncs)		2.80 - 7.20
		Thyroxine (nmol/L)	Follow-Up	24-02-2014/ 10:06	58.5 (L, ncs)	-16	62.7 - 150.8
		Sodium (mmol/L)	Follow-Up	24-02-2014/ 10:06	135.7 (L, ncs)	-4	136.0 - 146.0
	Treatment Sequence 2	Sodium (mmol/L)	Screening	20-12-2013/ 8:24	135.6 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:53	250.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:56	2.73 (L, ncs)		2.80 - 7.20
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	23-12-2013/ 11:23	958.1 (H, ncs)		0.0 - 171.0
		Bilirubin (umol/L)	Screening	23-12-2013/ 11:23	23.0 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	23-12-2013/ 11:23	4.3 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	23-12-2013/ 11:23	18.7 (H, ncs)		1.6 - 17.6
		Glucose (mmol/L)	Screening	23-12-2013/ 11:23	3.95 (L, ncs)		4.10 - 5.90
		Aspartate Aminotransferase (U/L)	Screening	23-12-2013/ 11:23	53.7 (H, ncs)		0.0 - 50.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:13	100.9 (L, ncs)		101.0 - 109.0
		Thyroxine (nmol/L)	Follow-Up	24-02-2014/ 9:53	55.6 (L, ncs)	-9.6	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	24-02-2014/ 9:53	2666.8 (H, ncs)	2540.8	0.0 - 171.0
		Eosinophils/Leukocytes (%)	Follow-Up	24-02-2014/ 9:53	8.7 (H, ncs)	2.5	0.6 - 8.4
		Alanine Aminotransferase (U/L)	Follow-Up	24-02-2014/ 9:53	52.4 (H, ncs)	7.7	0.0 - 50.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Aspartate Aminotransferase (U/L)	Follow-Up	24-02-2014/ 9:53	97.6 (H, ncs)	70.3	0.0 - 50.0
		Creatine Kinase MB (IU/L)	Follow-Up	24-02-2014/ 9:53	38.7 (H, ncs)	19.4	0.0 - 24.0
	Treatment Sequence 1	Potassium (mmol/L)	Screening	30-12-2013/ 7:32	5.13 (H, ncs)		3.50 - 5.10
		Platelets (10^9/L)	Screening	30-12-2013/ 7:32	407 (H, ncs)		155 - 342
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:48	1.5 (H, ncs)		0.0 - 0.5
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:53	292.1 (H, ncs)		0.0 - 171.0
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:53	449 (H, ncs)		155 - 342
		Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 9:15	0.5 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 9:15	10.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 9:17	359.8 (H, ncs)		0.0 - 171.0
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 9:17	391 (H, ncs)		155 - 342
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	24-02-2014/ 8:14	189.6 (H, ncs)		0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (uL)	Follow-Up	11-03-2014/ 7:49	10.00 (H, ncs)	10	0.00 - 5.00
		Platelets (10^9/L)	Follow-Up	11-03-2014/ 7:53	378 (H, ncs)	-29	155 - 342
	Treatment Sequence 2	Ketones (mmol/L)	Screening	30-12-2013/ 7:34	0.5 (H, ncs)		0.0 - 0.5
		Bilirubin (umol/L)	Screening	30-12-2013/ 7:37	23.3 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	30-12-2013/ 7:37	4.1 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	30-12-2013/ 7:37	19.2 (H, ncs)		1.6 - 17.6
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:59	3.10 (H, ncs)		1.08 - 3.00
	Treatment Sequence 1	Erythrocytes (uL)	Screening	30-12-2013/ 7:44	10.00 (H, ncs)		0.00 - 5.00
		Lymphocytes/Leukocytes (%)	Screening	30-12-2013/ 7:48	17.1 (L, ncs)		17.8 - 48.5
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:29	165.8 (H, ncs)		0.0 - 145.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	03-01-2014/ 8:29	100.1 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	08-02-2014/ 8:17	10.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Neutrophils (10^9/L)	Follow-Up	24-02-2014/ 9:53	6.49 (H, ncs)	0.9	1.61 - 6.45
		Creatine Kinase (IU/L)	Follow-Up	24-02-2014/ 9:53	152.2 (H, ncs)	31	0.0 - 145.0
		Sodium (mmol/L)	Follow-Up	24-02-2014/ 9:53	135.5 (L, ncs)	-2.5	136.0 - 146.0
		Lymphocytes/Leukocytes (%)	Follow-Up	24-02-2014/ 9:53	14.0 (L, ncs)	-3.1	17.8 - 48.5
		Neutrophils/Leukocytes (%)	Follow-Up	24-02-2014/ 9:53	76.0 (H, ncs)	6.3	37.9 - 70.5
	Treatment Sequence 2	Bilirubin (umol/L)	Screening	03-01-2014/ 11:50	26.3 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Screening	03-01-2014/ 11:50	99.7 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Screening	03-01-2014/ 11:50	4.0 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	03-01-2014/ 11:50	22.3 (H, ncs)		1.6 - 17.6
		Alanine Aminotransferase (U/L)	Screening	03-01-2014/ 11:50	58.6 (H, ncs)		0.0 - 50.0
		Gamma Glutamyl Transferase (U/L)	Screening	03-01-2014/ 11:50	62.7 (H, ncs)		0.0 - 55.0
		Bilirubin (umol/L)	Screening	09-01-2014/ 7:19	24.8 (H, ncs)		5.0 - 21.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Direct Bilirubin (umol/L)	Screening	09-01-2014/ 7:19	4.7 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	09-01-2014/ 7:19	20.1 (H, ncs)		1.6 - 17.6
		Alanine Aminotransferase (U/L)	Screening	09-01-2014/ 7:19	60.2 (H, ncs)		0.0 - 50.0
		Gamma Glutamyl Transferase (U/L)	Screening	09-01-2014/ 7:19	55.7 (H, ncs)		0.0 - 55.0
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 8:06	2.08 (L, ncs)		2.80 - 7.20
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 8:06	21.7 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 8:06	3.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 8:06	18.2 (H, ncs)		1.6 - 17.6
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 8:47	100.1 (L, ncs)		101.0 - 109.0
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 8:47	61.6 (H, ncs)		0.0 - 50.0
		Erythrocytes (uL)	Follow-Up	25-02-2014/ 8:15	10.00 (H, ncs)	10	0.00 - 5.00
		Thyroxine (nmol/L)	Follow-Up	25-02-2014/ 8:21	54.3 (L, ncs)	-10.4	62.7 - 150.8

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Alanine Aminotransferase (U/L)	Follow-Up	25-02-2014/ 8:21	58.1 (H, ncs)	-2.1	0.0 - 50.0
	Treatment Sequence 1	Monocytes/Leukocytes (%)	Screening	06-01-2014/ 9:07	15.0 (H, ncs)		5.3 - 14.2
		Neutrophils (10^9/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:39	6.59 (H, ncs)		1.61 - 6.45
		Monocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:39	1.16 (H, ncs)		0.27 - 0.91
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 9:44	4.5 (L, ncs)		5.0 - 21.0
		Thyroxine (nmol/L)	Follow-Up	10-03-2014/ 8:47	60.1 (L, ncs)	-5.5	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	10-03-2014/ 8:47	265.0 (H, ncs)	204.1	0.0 - 145.0
		Monocytes/Leukocytes (%)	Follow-Up	10-03-2014/ 8:47	14.7 (H, ncs)	-0.3	5.3 - 14.2
		Monocytes (10^9/L)	Follow-Up	10-03-2014/ 8:47	0.92 (H, ncs)	0.12	0.27 - 0.91
	Treatment Sequence 2	Chloride (mmol/L)	Screening	07-01-2014/ 10:21	100.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	07-01-2014/ 10:21	135.6 (L, ncs)		136.0 - 146.0
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:30	21.7 (H, ncs)		5.0 - 21.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	18-01-2014/ 7:30	18.9 (H, ncs)		1.6 - 17.6
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 9:52	135.5 (L, ncs)		136.0 - 146.0
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	23-02-2014/ 9:52	160 (L, ncs)		173 - 369
		Erythrocytes (10^12/L)	Follow-Up	10-03-2014/ 11:08	3.99 (L, ncs)	-0.62	4.02 - 5.08
	Treatment Sequence 2	Amylase (IU/L)	Screening	13-01-2014/ 8:42	104.5 (H, ncs)		28.0 - 100.0
		Platelets (10^9/L)	Screening	13-01-2014/ 8:42	140 (L, ncs)		173 - 369
		Alanine Aminotransferase (U/L)	Screening	13-01-2014/ 8:42	40.0 (H, ncs)		0.0 - 35.0
		Platelets (10^9/L)	Screening	17-01-2014/ 7:30	140 (L, ncs)		173 - 369
		Alanine Aminotransferase (U/L)	Screening	17-01-2014/ 7:30	36.0 (H, ncs)		0.0 - 35.0
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	22-01-2014/ 8:34	10.00 (H, ncs)		0.00 - 5.00
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	22-01-2014/ 8:36	100.7 (H, ncs)		28.0 - 100.0
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	22-01-2014/ 8:36	161 (L, ncs)		173 - 369

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Alanine Aminotransferase (U/L)	Period 1,Day -1/ 24 H Predose	22-01-2014/ 8:36	47.2 (H, ncs)		0.0 - 35.0
		Gamma Glutamyl Transferase (U/L)	Period 1,Day -1/ 24 H Predose	22-01-2014/ 8:36	38.9 (H, ncs)		0.0 - 38.0
		Alanine Aminotransferase (U/L)	Period 1,Day -1/ 24 H Predose	22-01-2014/ 17:46	39.2 (H, ncs)		0.0 - 35.0
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	27-02-2014/ 9:15	150 (L, ncs)		173 - 369
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	27-02-2014/ 9:15	49.1 (H, ncs)		0.0 - 35.0
		Gamma Glutamyl Transferase (U/L)	Period 2,Day -1/ 24 H Predose	27-02-2014/ 9:15	57.7 (H, ncs)		0.0 - 38.0
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	28-02-2014/ 8:40	40.8 (H, ncs)		0.0 - 35.0
		Gamma Glutamyl Transferase (U/L)	Period 2,Day -1/ 24 H Predose	28-02-2014/ 8:40	50.6 (H, ncs)		0.0 - 38.0
		Amylase (IU/L)	Follow-Up	14-03-2014/ 9:21	106.0 (H, ncs)	1.5	28.0 - 100.0
		Alanine Aminotransferase (U/L)	Follow-Up	14-03-2014/ 9:21	43.1 (H, ncs)	7.1	0.0 - 35.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	14-03-2014/ 9:21	44.9 (H, ncs)	11.8	0.0 - 38.0
	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	13-01-2014/ 8:45	186.2 (H, ncs)		0.0 - 145.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.
Test: 600 µg (3*200 µg tablets) levothyroxine new formulation.
Reference: 600 µg (3*200 µg tablets) levothyroxine old formulation.

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