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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	22-03-2014/ 12:04	5.6 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	22-03-2014/ 12:04	26.9 (H, ncs)		1.6 - 17.6
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	23-03-2014/ 9:30	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	23-03-2014/ 9:30	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	23-03-2014/ 9:30	73.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	23-03-2014/ 9:30	100.00 (H, ncs)		0.00 - 9.00
		Nitrite	Period 1,Day -1/ 24 H Predose	23-03-2014/ 9:30	POSITIVE (H, ncs)		
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	23-03-2014/ 9:32	65.0 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	23-03-2014/ 9:32	2.57 (L, ncs)		2.80 - 7.20
		Bacteria	Period 1,Day -1/ 24 H Predose	23-03-2014/ 15:25	POSITIVE (H, ncs)		
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	23-03-2014/ 15:25	25.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 8:37	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
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 8:43	60.8 (L, ncs)		62.7 - 150.8
		Potassium (mmol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 8:43	3.47 (L, ncs)		3.50 - 5.10
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 8:43	33.1 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 8:43	5.3 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 8:43	27.8 (H, ncs)		1.6 - 17.6
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 8:43	134.9 (L, ncs)		136.0 - 146.0
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 18:35	22.0 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 18:35	3.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	28-04-2014/ 18:35	18.5 (H, ncs)		1.6 - 17.6
		Protein (g/L)	Follow-Up	13-05-2014/ 8:58	64.1 (L, ncs)	1.9	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	13-05-2014/ 8:58	60.4 (L, ncs)	-8.6	62.7 - 150.8
		Bilirubin (umol/L)	Follow-Up	13-05-2014/ 8:58	31.9 (H, ncs)	-0.6	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
		Chloride (mmol/L)	Follow-Up	13-05-2014/ 8:58	100.4 (L, ncs)	-5.9	101.0 - 109.0
		Direct Bilirubin (umol/L)	Follow-Up	13-05-2014/ 8:58	5.2 (H, ncs)	-0.4	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	13-05-2014/ 8:58	26.7 (H, ncs)	-0.2	1.6 - 17.6
		Sodium (mmol/L)	Follow-Up	13-05-2014/ 8:58	135.0 (L, ncs)	-6.3	136.0 - 146.0
	Treatment Sequence 2	Amylase (IU/L)	Screening	24-03-2014/ 8:25	25.2 (L, ncs)		28.0 - 100.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 8:08	25.2 (L, ncs)		28.0 - 100.0
		Leukocytes (/HPF)	Period 2,Day -1/ 24 H Predose	05-05-2014/ 9:16	198.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	05-05-2014/ 9:16	100.00 (H, ncs)		0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Period 2,Day -1/ 24 H Predose	05-05-2014/ 9:16	27 (H, ncs)		0 - 15
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	05-05-2014/ 18:53	100.00 (H, ncs)		0.00 - 9.00
		Bacteria	Follow-Up	20-05-2014/ 8:13	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Follow-Up	20-05-2014/ 8:13	6.00 (H, ncs)		0.00 - 4.00

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
		Leukocytes (uL)	Follow-Up	20-05-2014/ 8:13	500.00 (H, ncs)	500	0.00 - 9.00
		Leukocytes (/HPF)	Follow-Up	25-05-2014/ 8:34	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	25-05-2014/ 8:34	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 2	Amylase (IU/L)	Screening	25-03-2014/ 7:46	102.0 (H, ncs)		28.0 - 100.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	26-03-2014/ 8:25	102.5 (H, ncs)		28.0 - 100.0
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	26-03-2014/ 8:25	0.03 (L, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	26-03-2014/ 8:25	0.4 (L, ncs)		0.6 - 7.9
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	01-05-2014/ 8:08	108.9 (H, ncs)		28.0 - 100.0
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	01-05-2014/ 8:08	4.7 (L, ncs)		5.3 - 14.2
		Monocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	01-05-2014/ 8:08	0.25 (L, ncs)		0.27 - 0.91
		Amylase (IU/L)	Follow-Up	16-05-2014/ 7:55	101.9 (H, ncs)	-0.1	28.0 - 100.0
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	25-03-2014/ 10:22	205.0 (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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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	02-04-2014/ 8:15	1292.1 (H, ncs)		0.0 - 171.0
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 8:15	381 (H, ncs)		155 - 342
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 16:52	1015.7 (H, ncs)		0.0 - 171.0
		Creatine Kinase MB (IU/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 16:52	27.5 (H, ncs)		0.0 - 24.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 8:15	193.3 (H, ncs)		0.0 - 171.0
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 8:15	391 (H, ncs)		155 - 342
		Creatine Kinase (IU/L)	Follow-Up	23-05-2014/ 10:07	178.0 (H, ncs)	-27	0.0 - 171.0
		Platelets (10^9/L)	Follow-Up	23-05-2014/ 10:07	375 (H, ncs)	37	155 - 342
		Thyrotropin (mU/L)	Follow-Up	23-05-2014/ 10:07	0.10 (L, ncs)	-1.59	0.35 - 4.94
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	25-03-2014/ 10:59	1820.0 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Screening	25-03-2014/ 10:59	55.3 (H, ncs)		0.0 - 50.0
		Aspartate Aminotransferase (U/L)	Screening	25-03-2014/ 10:59	82.8 (H, ncs)		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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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 MB (IU/L)	Screening	25-03-2014/ 10:59	28.1 (H, ncs)		0.0 - 24.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 8:54	275.2 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Follow-Up	23-05-2014/ 8:17	465.8 (H, ncs)	304.4	0.0 - 171.0
		Creatine Kinase (IU/L)	Follow-Up	03-06-2014/ 8:11	327.2 (H, ncs)	165.8	0.0 - 171.0
	Treatment Sequence 1	Eosinophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	05-05-2014/ 8:54	8.9 (H, ncs)		0.6 - 8.4
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	05-05-2014/ 8:54	1.1 (H, ncs)		0.0 - 1.0
		Basophils/Leukocytes (%)	Follow-Up	19-05-2014/ 9:11	1.2 (H, ncs)	0.3	0.0 - 1.0
	Treatment Sequence 1	Amylase (IU/L)	Screening	26-03-2014/ 11:22	113.0 (H, ncs)		28.0 - 100.0
		Thyroxine (nmol/L)	Screening	26-03-2014/ 11:22	60.1 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Screening	26-03-2014/ 11:22	2.53 (L, ncs)		2.80 - 7.20
		Amylase (IU/L)	Screening	27-03-2014/ 11:23	108.0 (H, ncs)		28.0 - 100.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 7:41	113.0 (H, ncs)		28.0 - 100.0

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
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 7:41	1.90 (L, ncs)		2.80 - 7.20
		Creatinine (umol/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 7:41	41.7 (L, ncs)		45.0 - 84.0
		Amylase (IU/L)	Follow-Up	05-05-2014/ 10:38	106.7 (H, ncs)	-1.3	28.0 - 100.0
	Treatment Sequence 1	Chloride (mmol/L)	Screening	27-03-2014/ 12:06	100.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	27-03-2014/ 12:06	135.7 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 8:22	98.3 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 8:22	132.1 (L, ncs)		136.0 - 146.0
		Creatinine (umol/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 8:22	41.7 (L, ncs)		45.0 - 84.0
		Erythrocytes (uL)	Follow-Up	20-05-2014/ 9:28	10.00 (H, ncs)	10	0.00 - 5.00
		Sodium (mmol/L)	Follow-Up	20-05-2014/ 9:32	135.5 (L, ncs)	-0.2	136.0 - 146.0
	Treatment Sequence 1	Amylase (IU/L)	Screening	28-03-2014/ 8:51	114.0 (H, ncs)		28.0 - 100.0
		Protein (g/L)	Screening	28-03-2014/ 8:51	65.5 (L, ncs)		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
		Chloride (mmol/L)	Screening	28-03-2014/ 8:51	100.5 (L, ncs)		101.0 - 109.0
		Monocytes (10^9/L)	Screening	28-03-2014/ 8:51	0.29 (L, ncs)		0.30 - 0.92
		Sodium (mmol/L)	Screening	28-03-2014/ 8:51	135.6 (L, ncs)		136.0 - 146.0
		Amylase (IU/L)	Screening	01-04-2014/ 13:03	125.1 (H, ncs)		28.0 - 100.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 8:48	119.0 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 8:48	194.0 (H, ncs)		0.0 - 171.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 12:03	117.3 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 12:03	193.9 (H, ncs)		0.0 - 171.0
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 8:42	127.6 (H, ncs)		28.0 - 100.0
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 8:42	62.6 (L, ncs)		66.0 - 83.0
		Erythrocytes (uL)	Follow-Up	27-05-2014/ 7:22	10.00 (H, ncs)	10	0.00 - 5.00
		Amylase (IU/L)	Follow-Up	27-05-2014/ 7:25	136.0 (H, ncs)	10.9	28.0 - 100.0

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
		Protein (g/L)	Follow-Up	27-05-2014/ 7:25	65.6 (L, ncs)	0.1	66.0 - 83.0
		Creatine Kinase (IU/L)	Follow-Up	27-05-2014/ 7:25	176.9 (H, ncs)	22.4	0.0 - 171.0
	Treatment Sequence 2	Neutrophils (10^9/L)	Screening	28-03-2014/ 8:55	1.60 (L, ncs)		1.61 - 6.45
		Chloride (mmol/L)	Screening	28-03-2014/ 8:55	95.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	28-03-2014/ 8:55	131.9 (L, ncs)		136.0 - 146.0
		Lymphocytes/Leukocytes (%)	Screening	28-03-2014/ 8:55	50.4 (H, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Screening	28-03-2014/ 8:55	37.5 (L, ncs)		37.9 - 70.5
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 7:42	100.1 (L, ncs)		101.0 - 109.0
		Lymphocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	30-03-2014/ 7:42	51.2 (H, ncs)		17.8 - 48.5
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	05-05-2014/ 9:50	65.9 (L, ncs)		66.0 - 83.0
	Treatment Sequence 1	Chloride (mmol/L)	Screening	28-03-2014/ 11:09	100.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	28-03-2014/ 11:09	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
		Monocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 8:31	15.7 (H, ncs)		5.3 - 14.2
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 8:31	133.8 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:03	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:03	8.00 (H, ncs)		0.00 - 3.00
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:06	2.69 (L, ncs)		2.80 - 7.20
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:06	15.1 (H, ncs)		5.3 - 14.2
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:06	4.00 (L, ncs)		4.02 - 5.08
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:06	134.5 (L, ncs)		136.0 - 146.0
		Erythrocytes (10^12/L)	Follow-Up	26-05-2014/ 9:55	3.96 (L, ncs)	-0.21	4.02 - 5.08
		Sodium (mmol/L)	Follow-Up	26-05-2014/ 9:55	134.8 (L, ncs)	0.2	136.0 - 146.0
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	28-03-2014/ 12:28	225.4 (H, ncs)		0.0 - 171.0
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	13-04-2014/ 8:18	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
		Neutrophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	13-04-2014/ 8:23	37.9 (L, ncs)		38.2 - 71.5
		Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	19-05-2014/ 9:42	0.5 (H, ncs)		0.0 - 0.5
		Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	19-05-2014/ 9:44	4.07 (L, ncs)		4.10 - 5.90
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	28-03-2014/ 12:20	148.5 (H, ncs)		0.0 - 145.0
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 8:04	65.8 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 8:04	2.71 (L, ncs)		2.80 - 7.20
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:42	64.4 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:42	2.40 (L, ncs)		2.80 - 7.20
		Ketones (mmol/L)	Follow-Up	26-05-2014/ 11:50	100.0 (H, ncs)	100	0.0 - 0.5
		Erythrocytes (uL)	Follow-Up	26-05-2014/ 11:50	10.00 (H, ncs)	10	0.00 - 5.00
		Leukocytes (/HPF)	Follow-Up	26-05-2014/ 11:50	33.00 (H, ncs)		0.00 - 4.00
		Squamous Epithelial Cells (/HPF)	Follow-Up	26-05-2014/ 11:50	37 (H, ncs)		0 - 15

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	26-05-2014/ 11:52	179.2 (H, ncs)	30.7	0.0 - 145.0
		Leukocytes (/HPF)	Follow-Up	16-06-2014/ 11:00	7.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	16-06-2014/ 11:00	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 2	Erythrocytes (uL)	Screening	28-03-2014/ 13:01	25.00 (H, ncs)		0.00 - 5.00
		Amylase (IU/L)	Screening	28-03-2014/ 13:07	20.0 (L, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Screening	28-03-2014/ 13:07	228.7 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	28-03-2014/ 13:07	99.9 (L, ncs)		101.0 - 109.0
		Alanine Aminotransferase (U/L)	Screening	28-03-2014/ 13:07	51.0 (H, ncs)		0.0 - 50.0
		Creatinine (umol/L)	Screening	28-03-2014/ 13:07	49.4 (L, ncs)		59.0 - 104.0
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 7:57	25.00 (H, ncs)		0.00 - 9.00
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 8:00	16.8 (L, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	02-04-2014/ 8:00	204.6 (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
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:00	16.8 (L, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:00	190.1 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:00	100.4 (L, ncs)		101.0 - 109.0
		Creatine Kinase MB (IU/L)	Period 2,Day -1/ 24 H Predose	08-05-2014/ 9:00	28.8 (H, ncs)		0.0 - 24.0
		Amylase (IU/L)	Follow-Up	27-05-2014/ 8:24	17.7 (L, ncs)	-2.3	28.0 - 100.0
		Thyroxine (nmol/L)	Follow-Up	27-05-2014/ 8:24	60.9 (L, ncs)	-9.4	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	27-05-2014/ 8:24	179.6 (H, ncs)	-49.1	0.0 - 171.0
	Treatment Sequence 1	Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:28	59.2 (L, ncs)		62.7 - 150.8
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:28	35.2 (H, ncs)		0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:28	40.8 (H, ncs)		0.0 - 35.0
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 17:57	37.2 (H, ncs)		0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 17:57	36.8 (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
		Thyroxine (nmol/L)	Follow-Up	28-05-2014/ 8:16	57.4 (L, ncs)	-18	62.7 - 150.8
		Sodium (mmol/L)	Follow-Up	28-05-2014/ 8:16	134.1 (L, ncs)	-2.6	136.0 - 146.0
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	03-04-2014/ 8:05	443.6 (H, ncs)		0.0 - 171.0
		Monocytes (10^9/L)	Screening	03-04-2014/ 8:05	0.98 (H, ncs)		0.30 - 0.92
		Platelets (10^9/L)	Screening	03-04-2014/ 8:05	363 (H, ncs)		155 - 342
		Alanine Aminotransferase (U/L)	Screening	03-04-2014/ 8:05	57.3 (H, ncs)		0.0 - 50.0
		Aspartate Aminotransferase (U/L)	Screening	03-04-2014/ 8:05	54.3 (H, ncs)		0.0 - 50.0
		Creatine Kinase (IU/L)	Screening	04-04-2014/ 8:33	232.4 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Screening	04-04-2014/ 8:33	51.1 (H, ncs)		0.0 - 50.0
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 7:03	390 (H, ncs)		155 - 342
		Monocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 7:36	1.02 (H, ncs)		0.30 - 0.92
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 7:36	364 (H, ncs)		155 - 342

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 (10^9/L)	Follow-Up	27-05-2014/ 7:48	8.80 (H, ncs)	0.49	3.19 - 8.71
		Platelets (10^9/L)	Follow-Up	27-05-2014/ 7:48	354 (H, ncs)	-9	155 - 342
		Bacteria	Follow-Up	27-05-2014/ 7:49	POSITIVE (H, ncs)		
		Nitrite	Follow-Up	27-05-2014/ 7:49	POSITIVE (H, ncs)		
		Bacteria	Follow-Up	07-06-2014/ 6:55	POSITIVE (H, ncs)		
	Treatment Sequence 1	Protein (g/L)	Screening	03-04-2014/ 8:22	62.3 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Screening	03-04-2014/ 8:22	197.5 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	03-04-2014/ 8:22	100.5 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	03-04-2014/ 8:22	134.3 (L, ncs)		136.0 - 146.0
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 8:11	62.8 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 8:11	188.9 (H, ncs)		0.0 - 171.0
		Protein (g/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:22	62.2 (L, ncs)		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)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:22	187.2 (H, ncs)		0.0 - 171.0
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:22	135.8 (L, ncs)		136.0 - 146.0
		Protein (g/L)	Follow-Up	27-05-2014/ 7:50	61.5 (L, ncs)	-0.8	66.0 - 83.0
		Creatine Kinase (IU/L)	Follow-Up	27-05-2014/ 7:50	186.8 (H, ncs)	-10.7	0.0 - 171.0
	Treatment Sequence 1	Leukocytes (uL)	Screening	03-04-2014/ 10:50	25.00 (H, ncs)		0.00 - 9.00
		Chloride (mmol/L)	Screening	03-04-2014/ 10:53	97.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	03-04-2014/ 10:53	134.6 (L, ncs)		136.0 - 146.0
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 8:30	25.00 (H, ncs)		0.00 - 9.00
		Thyroxine (nmol/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 8:32	62.4 (L, ncs)		62.7 - 150.8
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	06-04-2014/ 8:32	142 (L, ncs)		155 - 342
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:22	100.9 (L, ncs)		101.0 - 109.0
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	12-05-2014/ 9:22	146 (L, ncs)		155 - 342

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
		Leukocytes (/HPF)	Follow-Up	30-05-2014/ 9:34	6.00 (H, ncs)	4	0.00 - 4.00
		Leukocytes (uL)	Follow-Up	30-05-2014/ 9:34	25.00 (H, ncs)	0	0.00 - 9.00
		Thyroxine (nmol/L)	Follow-Up	30-05-2014/ 9:39	62.5 (L, ncs)	-23.1	62.7 - 150.8
	Treatment Sequence 2	Bilirubin (umol/L)	Screening	15-04-2014/ 8:01	25.9 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	15-04-2014/ 8:01	4.2 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	15-04-2014/ 8:01	21.7 (H, ncs)		1.6 - 17.6
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	16-04-2014/ 8:50	10.00 (H, ncs)		0.00 - 5.00
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	16-04-2014/ 8:54	26.4 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	16-04-2014/ 8:54	5.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	16-04-2014/ 8:54	20.9 (H, ncs)		1.6 - 17.6
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	22-05-2014/ 9:54	25.00 (H, ncs)		0.00 - 9.00
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	22-05-2014/ 9:56	34.9 (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)	Period 2,Day -1/ 24 H Predose	22-05-2014/ 9:56	5.3 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	22-05-2014/ 9:56	29.6 (H, ncs)		1.6 - 17.6
		Ketones (mmol/L)	Follow-Up	06-06-2014/ 9:41	5.0 (H, ncs)	5	0.0 - 0.5
		Creatine Kinase (IU/L)	Follow-Up	06-06-2014/ 9:42	189.9 (H, ncs)	78.6	0.0 - 171.0
		Bilirubin (umol/L)	Follow-Up	06-06-2014/ 9:42	35.9 (H, ncs)	10	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	06-06-2014/ 9:42	6.6 (H, ncs)	2.4	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	06-06-2014/ 9:42	29.3 (H, ncs)	7.6	1.6 - 17.6
		Bilirubin (umol/L)	Follow-Up	16-06-2014/ 7:13	33.9 (H, ncs)	8	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	16-06-2014/ 7:13	6.2 (H, ncs)	2	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	16-06-2014/ 7:13	27.7 (H, ncs)	6	1.6 - 17.6
	Treatment Sequence 2	Chloride (mmol/L)	Screening	15-04-2014/ 10:22	100.4 (L, ncs)		101.0 - 109.0
		Monocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:54	15.1 (H, ncs)		5.6 - 14.8

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
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 10:40	471.0 (H, ncs)		0.0 - 171.0
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 10:40	22.7 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 10:40	100.3 (L, ncs)		101.0 - 109.0
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 10:40	19.5 (H, ncs)		1.6 - 17.6
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 20:23	336.1 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Follow-Up	27-06-2014/ 8:02	284.5 (H, ncs)	175.4	0.0 - 171.0
		Chloride (mmol/L)	Follow-Up	27-06-2014/ 8:02	100.5 (L, ncs)	0.1	101.0 - 109.0
		Glucose (mmol/L)	Follow-Up	27-06-2014/ 8:02	6.10 (H, ncs)	1.53	4.10 - 5.90
	Treatment Sequence 2	Amylase (IU/L)	Screening	16-04-2014/ 8:10	111.3 (H, ncs)		28.0 - 100.0
		Bilirubin (umol/L)	Screening	16-04-2014/ 8:10	4.6 (L, ncs)		5.0 - 21.0
		Erythrocytes (uL)	Screening	16-04-2014/ 8:10	10.00 (H, ncs)		0.00 - 5.00
		Basophils (10^9/L)	Screening	16-04-2014/ 8:10	0.12 (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
		Eosinophils (10^9/L)	Screening	16-04-2014/ 8:10	0.58 (H, ncs)		0.04 - 0.43
		Basophils/Leukocytes (%)	Screening	16-04-2014/ 8:10	1.6 (H, ncs)		0.2 - 1.3
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:20	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:20	POSITIVE (H, ncs)		
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:22	106.1 (H, ncs)		28.0 - 100.0
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:22	4.7 (L, ncs)		5.0 - 21.0
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:22	370 (H, ncs)		173 - 369
		Basophils (10^9/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:22	0.10 (H, ncs)		0.01 - 0.07
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:22	1.03 (H, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 9:22	12.4 (H, ncs)		0.6 - 7.9
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 9:35	10.00 (H, ncs)		0.00 - 5.00
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 9:45	110.0 (H, ncs)		28.0 - 100.0

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 2,Day -1/ 24 H Predose	28-05-2014/ 9:45	135.1 (L, ncs)		136.0 - 146.0
		Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 9:45	0.54 (H, ncs)		0.04 - 0.43
		Erythrocytes (uL)	Follow-Up	17-06-2014/ 8:03	10.00 (H, ncs)	0	0.00 - 5.00
		Amylase (IU/L)	Follow-Up	17-06-2014/ 8:06	103.7 (H, ncs)	11.2	28.0 - 100.0
		Leukocytes (10^9/L)	Follow-Up	17-06-2014/ 8:06	10.51 (H, ncs)	3.15	3.69 - 10.04
		Bilirubin (umol/L)	Follow-Up	17-06-2014/ 8:06	4.3 (L, ncs)	-0.3	5.0 - 21.0
		Eosinophils (10^9/L)	Follow-Up	17-06-2014/ 8:06	1.12 (H, ncs)	0.54	0.04 - 0.43
		Eosinophils/Leukocytes (%)	Follow-Up	17-06-2014/ 8:06	10.7 (H, ncs)	2.8	0.6 - 7.9
	Treatment Sequence 2	Urea (mmol/L)	Screening	16-04-2014/ 9:20	2.44 (L, ncs)		2.80 - 7.20
		Bilirubin (umol/L)	Screening	16-04-2014/ 9:20	22.1 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	16-04-2014/ 9:20	3.9 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	16-04-2014/ 9:20	18.2 (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
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 8:26	23.3 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 8:26	3.8 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 8:26	19.5 (H, ncs)		1.6 - 17.6
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 10:02	2.69 (L, ncs)		2.80 - 7.20
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 10:02	5.10 (H, ncs)		4.02 - 5.08
		Leukocytes (/HPF)	Follow-Up	12-06-2014/ 6:54	7.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	12-06-2014/ 6:54	25.00 (H, ncs)	25	0.00 - 9.00
		Thyroxine (nmol/L)	Follow-Up	12-06-2014/ 6:58	57.4 (L, ncs)	-10.4	62.7 - 150.8
		Bilirubin (umol/L)	Follow-Up	12-06-2014/ 6:58	24.7 (H, ncs)	2.6	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	12-06-2014/ 6:58	4.2 (H, ncs)	0.3	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	12-06-2014/ 6:58	20.5 (H, ncs)	2.3	1.6 - 17.6
	Treatment Sequence 1	Leukocytes (10^9/L)	Screening	16-04-2014/ 10:05	10.10 (H, ncs)		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)	Screening	16-04-2014/ 10:05	7.34 (H, ncs)		1.46 - 5.85
		Neutrophils/Leukocytes (%)	Screening	16-04-2014/ 10:05	72.7 (H, ncs)		38.2 - 71.5
		Leukocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 10:07	10.89 (H, ncs)		3.19 - 8.71
		Neutrophils (10^9/L)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 10:07	8.40 (H, ncs)		1.46 - 5.85
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 10:07	60.5 (L, ncs)		62.7 - 150.8
		Lymphocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 10:07	16.1 (L, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 10:07	77.1 (H, ncs)		38.2 - 71.5
		Leukocytes (10^9/L)	Follow-Up	12-06-2014/ 8:42	9.30 (H, ncs)	-0.8	3.19 - 8.71
		Neutrophils (10^9/L)	Follow-Up	12-06-2014/ 8:42	6.64 (H, ncs)	-0.7	1.46 - 5.85
		Protein (g/L)	Follow-Up	12-06-2014/ 8:42	64.2 (L, ncs)	-4.9	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	12-06-2014/ 8:42	61.2 (L, ncs)	-6.1	62.7 - 150.8
		Lymphocytes/Leukocytes (%)	Follow-Up	12-06-2014/ 8:42	18.2 (L, ncs)	-0.5	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	Bacteria	Screening	17-04-2014/ 9:39	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Screening	17-04-2014/ 9:39	80.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Screening	17-04-2014/ 9:39	100.00 (H, ncs)		0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Screening	17-04-2014/ 9:39	30 (H, ncs)		0 - 15
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 7:49	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	22-04-2014/ 7:49	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 7:49	45.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 7:49	500.00 (H, ncs)		0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 7:49	30 (H, ncs)		0 - 15
		Leukocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 8:25	10.23 (H, ncs)		3.69 - 10.04
		Neutrophils (10^9/L)	Period 1,Day -1/ 24 H Predose	22-04-2014/ 8:25	6.63 (H, ncs)		1.61 - 6.45
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	28-05-2014/ 9:16	150.00 (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	28-05-2014/ 10:00	2.36 (L, ncs)		2.80 - 7.20
		Amylase (IU/L)	Follow-Up	13-06-2014/ 7:21	27.1 (L, ncs)	-5.5	28.0 - 100.0
		Urea (mmol/L)	Follow-Up	13-06-2014/ 7:21	1.91 (L, ncs)	-1.18	2.80 - 7.20
	Treatment Sequence 2	Leukocytes (10^9/L)	Screening	22-04-2014/ 7:45	8.96 (H, ncs)		3.19 - 8.71
		Neutrophils (10^9/L)	Screening	22-04-2014/ 7:45	6.15 (H, ncs)		1.46 - 5.85
		Basophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 7:53	1.1 (H, ncs)		0.0 - 1.0
		Gamma Glutamyl Transferase (U/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:18	63.5 (H, ncs)		0.0 - 55.0
		Leukocytes (10^9/L)	Follow-Up	23-06-2014/ 6:58	9.46 (H, ncs)	0.5	3.19 - 8.71
		Neutrophils (10^9/L)	Follow-Up	23-06-2014/ 6:58	6.22 (H, ncs)	0.07	1.46 - 5.85
		Platelets (10^9/L)	Follow-Up	23-06-2014/ 6:58	151 (L, ncs)	-21	155 - 342
		Eosinophils (10^9/L)	Follow-Up	23-06-2014/ 6:58	0.59 (H, ncs)	0.2	0.03 - 0.50
		Gamma Glutamyl Transferase (U/L)	Follow-Up	23-06-2014/ 6:58	72.9 (H, ncs)	20.8	0.0 - 55.0

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
		Gamma Glutamyl Transferase (U/L)	Follow-Up	01-07-2014/ 7:10	76.3 (H, ncs)	24.2	0.0 - 55.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	11-07-2014/ 6:54	65.0 (H, ncs)	12.9	0.0 - 55.0
	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	22-04-2014/ 10:00	278.7 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	22-04-2014/ 10:00	97.7 (L, ncs)		101.0 - 109.0
		Platelets (10^9/L)	Screening	22-04-2014/ 10:00	344 (H, ncs)		155 - 342
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:33	135.5 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:33	303.6 (H, ncs)		0.0 - 171.0
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:33	1.07 (L, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:33	97.9 (L, ncs)		101.0 - 109.0
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:33	0.53 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:33	10.5 (H, ncs)		0.6 - 8.4
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 17:52	123.4 (H, ncs)		28.0 - 100.0

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 1,Day -1/ 24 H Predose	27-04-2014/ 17:52	245.7 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 8:07	97.8 (L, ncs)		101.0 - 109.0
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 8:07	350 (H, ncs)		155 - 342
		Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 8:07	0.60 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 8:07	12.0 (H, ncs)		0.6 - 8.4
		Erythrocytes (uL)	Follow-Up	17-06-2014/ 10:43	10.00 (H, ncs)	10	0.00 - 5.00
		Erythrocytes (/HPF)	Follow-Up	17-06-2014/ 10:43	6.00 (H, ncs)		0.00 - 3.00
		Creatine Kinase (IU/L)	Follow-Up	17-06-2014/ 10:46	296.8 (H, ncs)	18.1	0.0 - 171.0
		Chloride (mmol/L)	Follow-Up	17-06-2014/ 10:46	98.1 (L, ncs)	0.4	101.0 - 109.0
		Eosinophils (10^9/L)	Follow-Up	17-06-2014/ 10:46	0.54 (H, ncs)	0.09	0.03 - 0.50
		Eosinophils/Leukocytes (%)	Follow-Up	17-06-2014/ 10:46	9.6 (H, ncs)	1.5	0.6 - 8.4
	Treatment Sequence 1	Bilirubin (umol/L)	Screening	22-04-2014/ 12:04	26.0 (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	22-04-2014/ 12:04	3.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	22-04-2014/ 12:04	22.5 (H, ncs)		1.6 - 17.6
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:35	108.8 (H, ncs)		28.0 - 100.0
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:35	62.4 (L, ncs)		66.0 - 83.0
		Triacylglycerol Lipase (IU/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:35	81.5 (H, ncs)		0.0 - 67.0
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:35	0.54 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:35	10.8 (H, ncs)		0.6 - 8.4
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:18	224.6 (H, ncs)		0.0 - 171.0
		Triacylglycerol Lipase (IU/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:18	69.4 (H, ncs)		0.0 - 67.0
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:18	1.3 (H, ncs)		0.0 - 1.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 17:54	184.2 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Follow-Up	17-06-2014/ 8:28	257.1 (H, ncs)	142.1	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
		Bilirubin (umol/L)	Follow-Up	17-06-2014/ 8:28	41.2 (H, ncs)	24.4	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	17-06-2014/ 8:28	4.6 (H, ncs)	1.1	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	17-06-2014/ 8:28	36.6 (H, ncs)	14.1	1.6 - 17.6
		Bilirubin (umol/L)	Follow-Up	23-06-2014/ 8:25	25.1 (H, ncs)	8.3	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	23-06-2014/ 8:25	3.8 (H, ncs)	0.3	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	23-06-2014/ 8:25	21.3 (H, ncs)	-1.2	1.6 - 17.6
	Treatment Sequence 2	Ketones (mmol/L)	Screening	23-04-2014/ 10:02	5.0 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Screening	23-04-2014/ 10:02	10.00 (H, ncs)		0.00 - 5.00
		Hematocrit (L/L)	Screening	23-04-2014/ 10:05	0.37 (L, ncs)		0.38 - 0.48
		Hemoglobin (g/L)	Screening	23-04-2014/ 10:05	121 (L, ncs)		126 - 165
		Eosinophils (10^9/L)	Screening	23-04-2014/ 10:05	0.52 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Screening	23-04-2014/ 10:05	11.8 (H, ncs)		0.6 - 8.4

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.

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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
		Basophils/Leukocytes (%)	Screening	23-04-2014/ 10:05	1.4 (H, ncs)		0.0 - 1.0
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:10	5.0 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:10	25.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:13	271.8 (H, ncs)		0.0 - 171.0
		Basophils (10^9/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:13	0.08 (H, ncs)		0.01 - 0.07
		Hematocrit (L/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:13	0.36 (L, ncs)		0.38 - 0.48
		Hemoglobin (g/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:13	116 (L, ncs)		126 - 165
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:13	0.90 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:13	15.1 (H, ncs)		0.6 - 8.4
		Basophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 10:13	1.3 (H, ncs)		0.0 - 1.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 17:52	225.3 (H, ncs)		0.0 - 171.0
		Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:21	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
		Hematocrit (L/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:23	0.36 (L, ncs)		0.38 - 0.48
		Hemoglobin (g/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:23	117 (L, ncs)		126 - 165
		Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:23	0.53 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:23	9.9 (H, ncs)		0.6 - 8.4
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:23	1.1 (H, ncs)		0.0 - 1.0
		Thyroxine (nmol/L)	Follow-Up	17-06-2014/ 7:47	56.5 (L, ncs)	-7	62.7 - 150.8
		Basophils (10^9/L)	Follow-Up	17-06-2014/ 7:47	0.10 (H, ncs)	0.04	0.01 - 0.07
		Hematocrit (L/L)	Follow-Up	17-06-2014/ 7:47	0.36 (L, ncs)	-0.01	0.38 - 0.48
		Hemoglobin (g/L)	Follow-Up	17-06-2014/ 7:47	114 (L, ncs)	-7	126 - 165
		Eosinophils (10^9/L)	Follow-Up	17-06-2014/ 7:47	0.98 (H, ncs)	0.46	0.03 - 0.50
		Eosinophils/Leukocytes (%)	Follow-Up	17-06-2014/ 7:47	15.3 (H, ncs)	3.5	0.6 - 8.4
		Basophils/Leukocytes (%)	Follow-Up	17-06-2014/ 7:47	1.6 (H, ncs)	0.2	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.

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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	Urea (mmol/L)	Screening	24-04-2014/ 12:13	1.78 (L, ncs)		2.80 - 7.20
		Eosinophils (10^9/L)	Screening	24-04-2014/ 12:13	0.03 (L, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Screening	24-04-2014/ 12:13	0.5 (L, ncs)		0.6 - 7.9
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	27-04-2014/ 8:41	2.49 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:25	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:25	5.00 (H, ncs)		0.00 - 3.00
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	02-06-2014/ 9:28	2.38 (L, ncs)		2.80 - 7.20
	Treatment Sequence 1	Leukocytes (10^9/L)	Screening	28-04-2014/ 8:54	3.15 (L, ncs)		3.19 - 8.71
		Lymphocytes (10^9/L)	Screening	28-04-2014/ 8:54	0.98 (L, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Screening	28-04-2014/ 8:54	98.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	28-04-2014/ 8:54	133.5 (L, ncs)		136.0 - 146.0
		Leukocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:19	9.29 (H, ncs)		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)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:19	7.35 (H, ncs)		1.46 - 5.85
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:19	100.0 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:19	135.6 (L, ncs)		136.0 - 146.0
		Lymphocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:19	12.6 (L, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:19	79.1 (H, ncs)		38.2 - 71.5
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:19	0.3 (L, ncs)		0.6 - 8.4
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 7:54	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 7:54	11.00 (H, ncs)		0.00 - 3.00
		Lymphocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 7:56	0.99 (L, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 7:56	96.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 7:56	133.6 (L, ncs)		136.0 - 146.0
		Leukocytes (10^9/L)	Follow-Up	24-06-2014/ 7:48	2.90 (L, ncs)	-0.25	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
		Lymphocytes (10^9/L)	Follow-Up	24-06-2014/ 7:48	0.84 (L, ncs)	-0.14	1.08 - 3.00
	Treatment Sequence 1	Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 8:12	21.6 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 8:12	4.9 (H, ncs)		0.0 - 3.4
	Treatment Sequence 2	Erythrocytes (uL)	Screening	28-04-2014/ 9:12	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:59	150.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 7:59	9.00 (H, ncs)		0.00 - 3.00
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 8:02	184.7 (H, ncs)		0.0 - 171.0
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 8:02	11.32 (H, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 16:53	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 16:53	6.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Follow-Up	25-06-2014/ 11:01	25.00 (H, ncs)	0	0.00 - 5.00
	Treatment Sequence 1	Leukocytes (uL)	Screening	28-04-2014/ 11:12	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
		Protein (g/L)	Screening	28-04-2014/ 11:49	65.3 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Screening	28-04-2014/ 11:49	2.47 (L, ncs)		2.80 - 7.20
		Bacteria	Period 1,Day -1/ 24 H Predose	29-04-2014/ 8:00	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	29-04-2014/ 8:00	60.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	29-04-2014/ 8:00	500.00 (H, ncs)		0.00 - 9.00
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	29-04-2014/ 8:03	64.6 (L, ncs)		66.0 - 83.0
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	29-04-2014/ 18:40	100.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	04-06-2014/ 9:09	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	04-06-2014/ 9:09	25.00 (H, ncs)		0.00 - 9.00
		Bacteria	Follow-Up	20-06-2014/ 13:27	POSITIVE (H, ncs)		
		Leukocytes (uL)	Follow-Up	20-06-2014/ 13:27	25.00 (H, ncs)	0	0.00 - 9.00
	Treatment Sequence 1	Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 8:11	187.0 (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
		Protein (g/L)	Follow-Up	28-06-2014/ 11:10	64.3 (L, ncs)	-5.7	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	28-06-2014/ 11:10	57.5 (L, ncs)	-10.8	62.7 - 150.8
	Treatment Sequence 2	Leukocytes (/HPF)	Screening	30-04-2014/ 9:04	9.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Screening	30-04-2014/ 9:04	100.00 (H, ncs)		0.00 - 9.00
		Bilirubin (umol/L)	Screening	30-04-2014/ 9:09	23.8 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	30-04-2014/ 9:09	3.6 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	30-04-2014/ 9:09	20.2 (H, ncs)		1.6 - 17.6
		Lymphocytes/Leukocytes (%)	Screening	30-04-2014/ 9:09	17.3 (L, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Screening	30-04-2014/ 9:09	73.4 (H, ncs)		38.2 - 71.5
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 9:52	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 9:52	32.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 9:52	100.00 (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
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 9:54	106.5 (H, ncs)		28.0 - 100.0
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 16:53	9.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 16:53	100.00 (H, ncs)		0.00 - 9.00
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	04-05-2014/ 16:56	109.2 (H, ncs)		28.0 - 100.0
		Leukocytes (/HPF)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 8:38	26.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 8:38	100.00 (H, ncs)		0.00 - 9.00
		Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 8:41	3.99 (L, ncs)		4.10 - 5.90
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 8:41	135.6 (L, ncs)		136.0 - 146.0
		Leukocytes (/HPF)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 17:50	42.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	09-06-2014/ 17:50	100.00 (H, ncs)		0.00 - 9.00
		Leukocytes (uL)	Follow-Up	24-06-2014/ 7:50	25.00 (H, ncs)	-75	0.00 - 9.00
		Amylase (IU/L)	Follow-Up	24-06-2014/ 7:56	107.3 (H, ncs)	12.6	28.0 - 100.0

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	24-06-2014/ 7:56	368.0 (H, ncs)	254.2	0.0 - 171.0
	Treatment Sequence 1	Monocytes/Leukocytes (%)	Screening	30-04-2014/ 9:46	14.3 (H, ncs)		5.3 - 14.2
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 8:30	3.96 (L, ncs)		4.02 - 5.08
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	13-06-2014/ 9:08	3.88 (L, ncs)		4.02 - 5.08
		Erythrocytes (uL)	Follow-Up	02-07-2014/ 10:32	10.00 (H, ncs)	10	0.00 - 5.00
		Leukocytes (uL)	Follow-Up	02-07-2014/ 10:32	25.00 (H, ncs)	25	0.00 - 9.00
		Erythrocytes (10^12/L)	Follow-Up	02-07-2014/ 10:35	3.79 (L, ncs)	-0.23	4.02 - 5.08
	Treatment Sequence 1	Urea (mmol/L)	Screening	30-04-2014/ 10:28	2.50 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 7:20	10.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 7:22	60.1 (L, ncs)		62.7 - 150.8
		Basophils (10^9/L)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 7:22	0.00 (L, ncs)		0.01 - 0.07
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	13-06-2014/ 9:04	100.7 (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
		Erythrocytes (uL)	Follow-Up	30-06-2014/ 11:08	10.00 (H, ncs)	10	0.00 - 5.00
		Leukocytes (/HPF)	Follow-Up	30-06-2014/ 11:08	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	30-06-2014/ 11:08	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 2	Platelets (10^9/L)	Screening	02-05-2014/ 12:24	401 (H, ncs)		173 - 369
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 9:14	375 (H, ncs)		173 - 369
		Basophils (10^9/L)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 9:14	0.08 (H, ncs)		0.01 - 0.07
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	13-06-2014/ 11:22	168.2 (H, ncs)		0.0 - 145.0
		Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	13-06-2014/ 11:22	385 (H, ncs)		173 - 369
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	13-06-2014/ 11:22	25.00 (H, ncs)		0.00 - 9.00
		Thyroxine (nmol/L)	Follow-Up	30-06-2014/ 11:48	62.3 (L, ncs)	-7.6	62.7 - 150.8
		Basophils (10^9/L)	Follow-Up	30-06-2014/ 11:48	0.08 (H, ncs)	0.01	0.01 - 0.07
		Leukocytes (/HPF)	Follow-Up	30-06-2014/ 11:49	21.00 (H, ncs)		0.00 - 4.00

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
		Leukocytes (uL)	Follow-Up	30-06-2014/ 11:49	100.00 (H, ncs)	100	0.00 - 9.00
	Treatment Sequence 1	Lymphocytes (10^9/L)	Screening	05-05-2014/ 11:32	1.06 (L, ncs)		1.08 - 3.00
		Eosinophils (10^9/L)	Screening	05-05-2014/ 11:32	0.02 (L, ncs)		0.03 - 0.50
		Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:07	23.5 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:07	99.3 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:07	4.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:07	19.0 (H, ncs)		1.6 - 17.6
		Monocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:07	15.4 (H, ncs)		5.6 - 14.8
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:07	134.7 (L, ncs)		136.0 - 146.0
		Alkaline Phosphatase (U/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:07	120.5 (H, ncs)		30.0 - 120.0
		Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 9:59	5.0 (H, ncs)		0.0 - 0.5
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 9:59	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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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	11-06-2014/ 10:01	25.3 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 10:01	97.6 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 10:01	4.9 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 10:01	20.4 (H, ncs)		1.6 - 17.6
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 10:01	18.0 (H, ncs)		5.6 - 14.8
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 10:01	134.1 (L, ncs)		136.0 - 146.0
		Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 10:01	0.02 (L, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 10:01	0.5 (L, ncs)		0.6 - 8.4
		Creatine Kinase (IU/L)	Follow-Up	26-06-2014/ 11:14	3332.5 (H, ncs)	3196	0.0 - 171.0
		Chloride (mmol/L)	Follow-Up	26-06-2014/ 11:14	100.1 (L, ncs)	-1.7	101.0 - 109.0
		Eosinophils (10^9/L)	Follow-Up	26-06-2014/ 11:14	0.02 (L, ncs)	0	0.03 - 0.50
		Eosinophils/Leukocytes (%)	Follow-Up	26-06-2014/ 11:14	0.5 (L, ncs)	-0.1	0.6 - 8.4

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.

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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 MB (IU/L)	Follow-Up	26-06-2014/ 11:14	77.9 (H, ncs)		0.0 - 24.0
		Creatine Kinase (IU/L)	Follow-Up	02-07-2014/ 11:08	171.4 (H, ncs)	34.9	0.0 - 171.0
	Treatment Sequence 2	Lymphocytes (10^9/L)	Screening	05-05-2014/ 11:38	0.64 (L, ncs)		1.08 - 3.00
		Lymphocytes/Leukocytes (%)	Screening	05-05-2014/ 11:38	16.3 (L, ncs)		18.3 - 48.1
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:05	104.6 (H, ncs)		28.0 - 100.0
		Thyroxine (nmol/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:05	61.4 (L, ncs)		62.7 - 150.8
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:05	0.74 (L, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:05	100.6 (L, ncs)		101.0 - 109.0
		Monocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:05	17.8 (H, ncs)		5.6 - 14.8
		Lymphocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	06-05-2014/ 8:05	16.7 (L, ncs)		18.3 - 48.1
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 8:56	104.7 (H, ncs)		28.0 - 100.0
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	11-06-2014/ 8:56	99.7 (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
		Leukocytes (10^9/L)	Follow-Up	26-06-2014/ 13:26	3.09 (L, ncs)	-0.83	3.19 - 8.71
		Creatine Kinase (IU/L)	Follow-Up	26-06-2014/ 13:26	196.3 (H, ncs)	47.5	0.0 - 171.0
		Monocytes (10^9/L)	Follow-Up	26-06-2014/ 13:26	0.23 (L, ncs)	-0.29	0.30 - 0.92
	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	05-05-2014/ 12:35	171.1 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	05-05-2014/ 12:35	100.8 (L, ncs)		101.0 - 109.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	08-05-2014/ 8:05	100.8 (L, ncs)		101.0 - 109.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	13-06-2014/ 9:38	193.9 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Follow-Up	03-07-2014/ 11:28	210.6 (H, ncs)	39.5	0.0 - 171.0
		Monocytes (10^9/L)	Follow-Up	03-07-2014/ 11:28	0.28 (L, ncs)	-0.16	0.30 - 0.92
	Treatment Sequence 2	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	13-05-2014/ 7:35	99.9 (L, ncs)		101.0 - 109.0
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	09-05-2014/ 11:42	185.0 (H, ncs)		0.0 - 171.0
		Monocytes/Leukocytes (%)	Screening	09-05-2014/ 11:42	16.6 (H, ncs)		5.6 - 14.8

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
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	13-05-2014/ 7:44	99.3 (L, ncs)		101.0 - 109.0
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	18-06-2014/ 10:11	61.5 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	18-06-2014/ 10:11	100.9 (L, ncs)		101.0 - 109.0
		Monocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	18-06-2014/ 10:11	0.95 (H, ncs)		0.30 - 0.92
		Chloride (mmol/L)	Follow-Up	03-07-2014/ 8:14	100.1 (L, ncs)	-2.4	101.0 - 109.0
		Monocytes (10^9/L)	Follow-Up	03-07-2014/ 8:14	0.93 (H, ncs)	0.18	0.30 - 0.92
	Treatment Sequence 2	Urea (mmol/L)	Screening	10-05-2014/ 10:03	2.76 (L, ncs)		2.80 - 7.20
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	13-05-2014/ 9:42	2.79 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	13-05-2014/ 9:42	98.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	13-05-2014/ 9:42	133.9 (L, ncs)		136.0 - 146.0
	Treatment Sequence 1	Amylase (IU/L)	Screening	20-05-2014/ 8:50	121.2 (H, ncs)		28.0 - 100.0
		Chloride (mmol/L)	Screening	20-05-2014/ 8:50	99.7 (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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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)	Screening	20-05-2014/ 8:50	134.4 (L, ncs)		136.0 - 146.0
		Amylase (IU/L)	Screening	22-05-2014/ 7:23	114.4 (H, ncs)		28.0 - 100.0
		Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	23-05-2014/ 7:57	114.7 (H, ncs)		28.0 - 100.0
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 8:04	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 8:04	25.00 (H, ncs)		0.00 - 9.00
		Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 8:06	109.6 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 8:06	270.7 (H, ncs)		0.0 - 145.0
		Amylase (IU/L)	Follow-Up	14-07-2014/ 8:03	133.1 (H, ncs)	18.7	28.0 - 100.0
	Treatment Sequence 2	Erythrocytes (uL)	Screening	20-05-2014/ 12:36	250.00 (H, ncs)		0.00 - 5.00
		Bacteria	Screening	20-05-2014/ 12:36	POSITIVE (H, ncs)		
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 9:46	2.12 (L, ncs)		2.80 - 7.20
		Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 9:46	4.06 (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.

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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/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 9:46	14.7 (H, ncs)		5.3 - 14.2
		Erythrocytes (uL)	Follow-Up	14-07-2014/ 11:47	10.00 (H, ncs)	-240	0.00 - 5.00
		Urea (mmol/L)	Follow-Up	14-07-2014/ 11:50	2.55 (L, ncs)	-0.33	2.80 - 7.20
		Eosinophils (10^9/L)	Follow-Up	14-07-2014/ 11:50	0.47 (H, ncs)	0.17	0.04 - 0.43
	Treatment Sequence 1	Lymphocytes (10^9/L)	Screening	20-05-2014/ 12:40	2.91 (H, ncs)		0.99 - 2.89
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	23-05-2014/ 9:56	65.1 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	23-05-2014/ 9:56	145.9 (H, ncs)		0.0 - 145.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	23-05-2014/ 9:56	135.6 (L, ncs)		136.0 - 146.0
		Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 9:52	4.5 (L, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 9:52	100.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 9:52	135.2 (L, ncs)		136.0 - 146.0
	Treatment Sequence 2	Protein (g/L)	Screening	20-05-2014/ 12:44	63.5 (L, ncs)		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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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
		Thyroxine (nmol/L)	Screening	20-05-2014/ 12:44	58.3 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Screening	20-05-2014/ 12:44	1.82 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Screening	20-05-2014/ 12:44	100.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	20-05-2014/ 12:44	132.2 (L, ncs)		136.0 - 146.0
		Calcium (mmol/L)	Screening	20-05-2014/ 12:44	2.19 (L, ncs)		2.20 - 2.65
		Thyrotropin (mU/L)	Screening	20-05-2014/ 12:44	0.22 (L, ncs)		0.35 - 4.94
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	23-05-2014/ 8:36	64.1 (L, ncs)		66.0 - 83.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	23-05-2014/ 8:36	135.7 (L, ncs)		136.0 - 146.0
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	28-06-2014/ 8:02	2.40 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Follow-Up	13-07-2014/ 6:41	10.00 (H, ncs)	10	0.00 - 5.00
		Leukocytes (/HPF)	Follow-Up	13-07-2014/ 6:41	34.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	13-07-2014/ 6:41	500.00 (H, ncs)	500	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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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
		Squamous Epithelial Cells (/HPF)	Follow-Up	13-07-2014/ 6:41	19 (H, ncs)		0 - 15
		Protein (g/L)	Follow-Up	13-07-2014/ 7:07	64.5 (L, ncs)	1	66.0 - 83.0
		Urea (mmol/L)	Follow-Up	13-07-2014/ 7:07	2.24 (L, ncs)	0.42	2.80 - 7.20
		Thyrotropin (mU/L)	Follow-Up	13-07-2014/ 7:07	0.08 (L, ncs)	-0.42	0.35 - 4.94

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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15.3.5 Other Displays of Laboratory Data

Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

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Table 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Basophils (10^9/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.029 (0.019)		0.031 (0.017)		0.030 (0.018)	
		Median	0.030		0.030		0.030	
		Min; Max	0.00; 0.13		0.00; 0.12		0.00; 0.13	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.031 (0.017)		0.032 (0.018)		0.032 (0.018)	
		Median	0.030		0.030		0.030	
		Min; Max	0.00; 0.11		0.00; 0.10		0.00; 0.11	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	0.030 (0.020)		0.032 (0.017)		0.031 (0.018)	
		Median	0.030		0.030		0.030	
		Min; Max	0.00; 0.15		0.00; 0.09		0.00; 0.15	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Basophils (10^9/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	0.029 (0.016)	0.000 (0.013)	0.032 (0.018)	0.001 (0.014)	0.031 (0.017)	0.000 (0.014)
		Median	0.030	0.000	0.030	0.000	0.030	0.000
		Min; Max	0.01; 0.10	-0.06; 0.04	0.00; 0.10	-0.05; 0.04	0.00; 0.10	-0.06; 0.04
Basophils/Leukocytes (%)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.53 (0.326)		0.54 (0.296)		0.53 (0.310)	
		Median	0.50		0.50		0.50	
		Min; Max	0.0; 2.1		0.0; 1.6		0.0; 2.1	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.57 (0.308)		0.54 (0.296)		0.56 (0.302)	
		Median	0.50		0.50		0.50	
		Min; Max	0.0; 2.2		0.0; 1.7		0.0; 2.2	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1.sas

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Table 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Basophils/Leukocytes (%)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	0.56 (0.342)		0.54 (0.295)		0.55 (0.319)	
		Median	0.50		0.50		0.50	
		Min; Max	0.0; 1.9		0.0; 1.6		0.0; 1.9	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	0.54 (0.286)	0.01 (0.247)	0.54 (0.292)	0.00 (0.276)	0.54 (0.288)	0.01 (0.261)
		Median	0.50	0.00	0.50	0.00	0.50	0.00
		Min; Max	0.1; 1.9	-1.1; 0.6	0.0; 1.6	-0.9; 0.6	0.0; 1.9	-1.1; 0.6
Eosinophils (10^9/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.139 (0.101)		0.172 (0.132)		0.155 (0.118)	
		Median	0.120		0.120		0.120	
		Min; Max	0.01; 0.49		0.00; 0.72		0.00; 0.72	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Eosinophils (10^9/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.161 (0.111)		0.202 (0.169)		0.181 (0.144)	
		Median	0.135		0.150		0.140	
		Min; Max	0.03; 0.54		0.00; 1.03		0.00; 1.03	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	0.158 (0.104)		0.184 (0.126)		0.171 (0.116)	
		Median	0.130		0.130		0.130	
		Min; Max	0.02; 0.60		0.01; 0.54		0.01; 0.60	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	0.146 (0.096)	0.007 (0.063)	0.191 (0.174)	0.019 (0.102)	0.168 (0.142)	0.013 (0.085)
		Median	0.120	0.010	0.125	0.000	0.120	0.010
		Min; Max	0.02; 0.54	-0.23; 0.20	0.01; 1.12	-0.21; 0.54	0.01; 1.12	-0.23; 0.54

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Eosinophils/L eukocytes (%)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	2.56 (1.913)		2.93 (2.041)		2.74 (1.982)	
		Median	2.20		2.35		2.20	
		Min; Max	0.1; 9.8		0.0; 11.8		0.0; 11.8	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	3.03 (2.173)		3.33 (2.418)		3.18 (2.298)	
		Median	2.50		2.70		2.60	
		Min; Max	0.3; 10.8		0.0; 15.1		0.0; 15.1	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	2.91 (1.967)		3.07 (2.040)		2.99 (2.001)	
		Median	2.20		2.30		2.30	
		Min; Max	0.2; 12.0		0.2; 9.9		0.2; 12.0	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Eosinophils/L eukocytes (%)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	2.67 (1.761)	0.11 (1.253)	3.15 (2.447)	0.22 (1.324)	2.91 (2.140)	0.16 (1.287)
		Median	2.10	0.20	2.30	0.10	2.20	0.10
		Min; Max	0.4; 9.6	-5.8; 4.2	0.2; 15.3	-3.8; 3.9	0.2; 15.3	-5.8; 4.2
Erythrocytes (10^12/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.778 (0.408)		4.807 (0.377)		4.792 (0.392)	
		Median	4.790		4.805		4.800	
		Min; Max	3.81; 5.66		3.99; 5.76		3.81; 5.76	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.797 (0.384)		4.842 (0.390)		4.819 (0.387)	
		Median	4.770		4.860		4.820	
		Min; Max	3.96; 5.64		3.92; 5.88		3.92; 5.88	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Erythrocytes (10^12/L)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	4.774 (0.419)		4.803 (0.398)		4.788 (0.408)	
		Median	4.760		4.840		4.775	
		Min; Max	3.88; 5.56		3.94; 5.79		3.88; 5.79	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	4.676 (0.417)	-0.102 (0.205)	4.706 (0.424)	-0.101 (0.228)	4.691 (0.420)	-0.101 (0.217)
		Median	4.670	-0.130	4.745	-0.080	4.700	-0.110
		Min; Max	3.73; 5.55	-0.54; 0.46	3.71; 5.89	-0.62; 0.49	3.71; 5.89	-0.62; 0.49
Hematocrit (L/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.415 (0.033)		0.417 (0.029)		0.416 (0.031)	
		Median	0.420		0.420		0.420	
		Min; Max	0.32; 0.47		0.35; 0.48		0.32; 0.48	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Hematocrit (L/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.415 (0.031)		0.418 (0.031)		0.416 (0.031)	
		Median	0.420		0.420		0.420	
		Min; Max	0.33; 0.48		0.34; 0.49		0.33; 0.49	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	0.414 (0.034)		0.416 (0.031)		0.415 (0.033)	
		Median	0.410		0.420		0.420	
		Min; Max	0.33; 0.47		0.34; 0.47		0.33; 0.47	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	0.407 (0.035)	-0.008 (0.018)	0.409 (0.034)	-0.008 (0.019)	0.408 (0.034)	-0.008 (0.018)
		Median	0.410	-0.010	0.410	-0.010	0.410	-0.010
		Min; Max	0.31; 0.46	-0.04; 0.05	0.32; 0.49	-0.05; 0.04	0.31; 0.49	-0.05; 0.05

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Hemoglobin (g/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	141.6 (13.65)		142.0 (11.58)		141.8 (12.63)	
		Median	143.5		144.0		144.0	
		Min; Max	101; 165		111; 164		101; 165	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	141.8 (12.93)		143.1 (12.41)		142.5 (12.66)	
		Median	143.0		145.0		144.0	
		Min; Max	105; 166		111; 166		105; 166	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	141.0 (14.06)		141.8 (12.50)		141.4 (13.28)	
		Median	142.0		142.0		142.0	
		Min; Max	104; 164		108; 164		104; 164	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Hemoglobin (g/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	138.2 (14.52)	-3.3 (6.52)	138.7 (13.70)	-3.3 (6.50)	138.5 (14.08)	-3.3 (6.50)
		Median	140.0	-4.0	140.5	-3.0	140.0	-3.0
		Min; Max	96; 164	-18; 21	100; 167	-21; 15	96; 167	-21; 21
Leukocytes (10^9/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	5.618 (1.398)		5.891 (1.339)		5.755 (1.373)	
		Median	5.325		5.855		5.460	
		Min; Max	3.15; 10.10		3.36; 9.87		3.15; 10.10	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	5.499 (1.304)		5.986 (1.322)		5.743 (1.332)	
		Median	5.400		5.835		5.620	
		Min; Max	3.11; 10.23		2.93; 10.36		2.93; 10.36	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Leukocytes (10^9/L)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	5.648 (1.462)		6.132 (1.602)		5.890 (1.549)	
		Median	5.290		5.900		5.665	
		Min; Max	3.49; 12.23		3.78; 14.68		3.49; 14.68	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	5.591 (1.293)	-0.027 (1.135)	6.013 (1.502)	0.121 (1.200)	5.802 (1.414)	0.047 (1.167)
		Median	5.425	0.010	5.745	0.005	5.605	0.010
		Min; Max	2.90; 9.51	-3.38; 3.62	3.09; 10.75	-4.05; 3.48	2.90; 10.75	-4.05; 3.62
Lymphocytes (10^9/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	1.698 (0.415)		1.786 (0.382)		1.742 (0.400)	
		Median	1.645		1.805		1.730	
		Min; Max	0.98; 3.69		0.64; 2.83		0.64; 3.69	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Lymphocytes (10^9/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	1.792 (0.425)		1.925 (0.483)		1.859 (0.459)	
		Median	1.785		1.950		1.835	
		Min; Max	1.07; 3.32		0.74; 3.62		0.74; 3.62	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	1.724 (0.454)		1.918 (0.472)		1.821 (0.472)	
		Median	1.640		1.870		1.770	
		Min; Max	0.99; 3.83		0.85; 3.48		0.85; 3.83	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	1.740 (0.496)	0.042 (0.324)	1.838 (0.435)	0.051 (0.357)	1.789 (0.468)	0.047 (0.340)
		Median	1.660	0.035	1.730	0.060	1.690	0.040
		Min; Max	0.57; 3.83	-0.89; 1.11	1.04; 3.14	-0.83; 1.22	0.57; 3.83	-0.89; 1.22

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Lymphocytes/L eukocytes (%)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	31.21 (7.323)		30.98 (6.740)		31.09 (7.022)	
		Median	30.60		30.80		30.75	
		Min; Max	17.1; 51.1		16.3; 50.4		16.3; 51.1	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	33.41 (7.410)		32.74 (7.447)		33.08 (7.419)	
		Median	32.30		32.40		32.40	
		Min; Max	12.6; 53.7		14.6; 51.7		12.6; 53.7	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	31.48 (7.856)		32.32 (8.010)		31.90 (7.926)	
		Median	30.70		32.40		31.50	
		Min; Max	13.4; 52.6		13.4; 51.0		13.4; 52.6	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1.sas

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Table 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Lymphocytes/Leukocytes (%)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	31.70 (7.566)	0.49 (6.106)	31.48 (7.222)	0.50 (5.939)	31.59 (7.379)	0.49 (6.009)
		Median	30.75	0.85	30.90	0.35	30.80	0.50
		Min; Max	9.3; 52.9	-15.4; 13.6	15.2; 48.4	-23.0; 22.2	9.3; 52.9	-23.0; 22.2
Monocytes (10^9/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.523 (0.143)		0.514 (0.142)		0.518 (0.142)	
		Median	0.515		0.490		0.500	
		Min; Max	0.26; 0.88		0.24; 0.98		0.24; 0.98	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	0.534 (0.148)		0.546 (0.165)		0.540 (0.157)	
		Median	0.510		0.525		0.520	
		Min; Max	0.30; 1.16		0.24; 0.95		0.24; 1.16	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1.sas

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Table 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Monocytes (10^9/L)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	0.547 (0.167)		0.526 (0.143)		0.536 (0.155)	
		Median	0.530		0.530		0.530	
		Min; Max	0.31; 1.17		0.25; 1.02		0.25; 1.17	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	0.530 (0.147)	0.007 (0.121)	0.521 (0.158)	0.008 (0.115)	0.526 (0.153)	0.007 (0.118)
		Median	0.505	-0.005	0.520	0.000	0.510	0.000
		Min; Max	0.28; 0.92	-0.35; 0.34	0.23; 0.93	-0.29; 0.35	0.23; 0.93	-0.35; 0.35
Monocytes/Leukocytes (%)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	9.51 (2.445)		8.91 (2.319)		9.21 (2.396)	
		Median	9.15		8.45		8.65	
		Min; Max	5.8; 20.5		4.7; 16.6		4.7; 20.5	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1.sas

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Table 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Monocytes/Leukocytes (%)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	9.89 (2.427)		9.15 (2.243)		9.52 (2.361)	
		Median	9.15		9.15		9.15	
		Min; Max	6.0; 18.4		5.3; 17.8		5.3; 18.4	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	9.83 (2.446)		8.75 (2.088)		9.29 (2.331)	
		Median	9.50		8.60		9.20	
		Min; Max	5.4; 18.0		4.7; 14.7		4.7; 18.0	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	9.60 (2.137)	0.10 (2.033)	8.75 (2.016)	-0.16 (2.122)	9.17 (2.117)	-0.03 (2.077)
		Median	9.30	0.25	8.65	-0.30	8.85	0.00
		Min; Max	5.8; 16.2	-9.7; 7.6	4.6; 14.8	-6.4; 8.9	4.6; 16.2	-9.7; 8.9

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1.sas

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Table 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Neutrophils (10^9/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	3.238 (1.159)		3.400 (1.096)		3.319 (1.129)	
		Median	2.930		3.245		3.100	
		Min; Max	1.27; 7.34		1.60; 6.43		1.27; 7.34	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	2.982 (1.080)		3.281 (1.045)		3.131 (1.071)	
		Median	2.810		3.095		2.915	
		Min; Max	1.08; 7.35		1.61; 7.67		1.08; 7.67	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	3.188 (1.286)		3.471 (1.421)		3.330 (1.359)	
		Median	2.940		3.260		3.125	
		Min; Max	1.29; 9.40		1.44; 11.59		1.29; 11.59	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Neutrophils (10^9/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	3.145 (1.056)	-0.092 (1.040)	3.431 (1.218)	0.031 (1.021)	3.288 (1.146)	-0.030 (1.030)
		Median	2.985	-0.120	3.215	-0.045	3.110	-0.085
		Min; Max	1.30; 7.19	-2.96; 3.63	1.24; 8.19	-2.78; 3.51	1.24; 8.19	-2.96; 3.63
Neutrophils/L eukocytes (%)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	56.20 (8.395)		56.64 (7.938)		56.42 (8.154)	
		Median	55.90		56.00		55.90	
		Min; Max	34.7; 73.1		37.5; 75.0		34.7; 75.0	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	53.09 (8.308)		54.23 (8.337)		53.66 (8.323)	
		Median	53.10		53.95		53.25	
		Min; Max	33.3; 79.1		32.7; 77.0		32.7; 79.1	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Neutrophils/L eukocytes (%)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	55.23 (8.968)		55.31 (9.289)		55.27 (9.108)	
		Median	56.30		54.90		55.95	
		Min; Max	35.8; 77.1		35.0; 79.0		35.0; 79.0	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	55.50 (8.377)	-0.70 (7.816)	56.09 (8.216)	-0.56 (6.627)	55.79 (8.283)	-0.63 (7.229)
		Median	56.50	-1.30	57.00	-0.05	56.70	-1.20
		Min; Max	34.8; 76.0	-21.0; 21.0	37.3; 77.3	-18.2; 26.7	34.8; 77.3	-21.0; 26.7
Platelets (10^9/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	247.0 (46.85)		247.5 (53.45)		247.2 (50.14)	
		Median	240.5		242.0		241.5	
		Min; Max	144; 407		127; 411		127; 411	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1.sas

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Table 15.3.5.1.1 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Hematology (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Platelets (10^9/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	246.2 (51.09)		252.1 (55.27)		249.1 (53.18)	
		Median	240.0		250.0		246.0	
		Min; Max	68; 449		126; 414		68; 449	
	Period 2/ (Day -1)	n (missing)	104 (0)		105 (0)		209 (0)	
		Mean (SD)	249.4 (43.84)		255.3 (57.77)		252.4 (51.27)	
		Median	246.5		248.0		247.0	
		Min; Max	146; 391		141; 391		141; 391	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	256.7 (47.97)	9.7 (28.39)	256.1 (52.36)	8.7 (28.82)	256.4 (50.10)	9.2 (28.55)
		Median	257.5	6.0	255.0	9.5	256.0	7.0
		Min; Max	129; 378	-58; 97	131; 411	-101; 111	129; 411	-101; 111

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.1.sas

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Table 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Alanine Aminotransferase (U/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	22.01 (10.801)		21.93 (10.251)		21.97 (10.505)	
		Median	19.65		19.40		19.60	
		Min; Max	3.0; 54.5		6.4; 60.2		3.0; 60.2	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	21.69 (10.447)		21.74 (9.201)		21.71 (9.821)	
		Median	19.55		19.70		19.65	
		Min; Max	3.0; 59.9		7.0; 49.6		3.0; 59.9	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	23.01 (13.927)		23.54 (13.890)		23.28 (13.878)	
		Median	21.30		20.60		20.80	
		Min; Max	5.1; 74.2		4.0; 106.4		4.0; 106.4	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2.sas

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Table 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Alanine Aminotransferase (U/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	21.70 (10.794)	-0.30 (8.915)	21.48 (10.481)	-0.46 (8.415)	21.59 (10.614)	-0.38 (8.649)
		Median	19.55	-0.75	18.65	-0.50	19.20	-0.55
		Min; Max	5.4; 61.2	-23.1; 43.8	8.7; 61.4	-24.7; 24.4	5.4; 61.4	-24.7; 43.8
Alkaline Phosphatase (U/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	68.70 (18.521)		65.89 (18.576)		67.29 (18.559)	
		Median	68.40		63.50		65.05	
		Min; Max	35.7; 118.5		28.6; 118.4		28.6; 118.5	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	68.55 (18.779)		66.41 (17.973)		67.48 (18.369)	
		Median	66.30		62.95		64.40	
		Min; Max	34.7; 120.5		28.6; 113.5		28.6; 120.5	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Alkaline Phosphatase (U/L)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	69.60 (19.610)		66.09 (17.957)		67.85 (18.839)	
		Median	65.90		60.80		63.60	
		Min; Max	33.5; 134.6		33.3; 125.0		33.3; 134.6	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	68.87 (19.149)	0.17 (7.893)	64.91 (16.447)	-0.98 (8.449)	66.89 (17.918)	-0.40 (8.178)
		Median	67.20	-0.05	62.05	-0.10	64.10	-0.10
		Min; Max	34.2; 121.8	-20.9; 25.9	31.8; 106.4	-34.2; 17.2	31.8; 121.8	-34.2; 25.9
Amylase (IU/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	60.48 (18.681)		62.76 (19.279)		61.62 (18.972)	
		Median	57.65		61.60		59.35	
		Min; Max	28.1; 125.1		20.0; 104.8		20.0; 125.1	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Amylase (IU/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	62.06 (21.286)		65.17 (23.041)		63.61 (22.184)	
		Median	58.55		62.55		59.75	
		Min; Max	27.1; 135.5		16.8; 136.3		16.8; 136.3	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	60.79 (18.037)		65.44 (21.135)		63.11 (19.738)	
		Median	60.70		62.70		61.90	
		Min; Max	22.9; 127.6		16.8; 111.6		16.8; 127.6	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	62.78 (21.448)	2.30 (10.989)	65.47 (26.013)	2.71 (15.560)	64.12 (23.823)	2.51 (13.440)
		Median	60.00	1.15	62.35	1.10	60.75	1.15
		Min; Max	27.1; 136.0	-37.8; 47.6	17.7; 216.5	-23.2; 128.4	17.7; 216.5	-37.8; 128.4

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2.sas

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Table 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Aspartate Aminotransferase (U/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	23.25 (5.441)		23.56 (5.604)		23.41 (5.513)	
		Median	22.95		22.50		22.90	
		Min; Max	13.4; 39.5		9.6; 40.1		9.6; 40.1	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	23.05 (6.042)		23.18 (5.778)		23.11 (5.898)	
		Median	22.55		22.05		22.20	
		Min; Max	13.0; 44.5		10.3; 50.0		10.3; 50.0	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	25.44 (22.310)		23.75 (6.931)		24.59 (16.502)	
		Median	21.80		22.40		22.25	
		Min; Max	14.2; 240.6		11.7; 58.5		11.7; 240.6	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Aspartate Aminotransferase (U/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	23.95 (11.827)	0.70 (11.455)	23.73 (10.125)	0.17 (9.444)	23.84 (10.984)	0.43 (10.477)
		Median	21.80	-0.75	21.05	-0.80	21.40	-0.80
		Min; Max	12.9; 114.8	-17.8; 90.5	10.9; 97.6	-15.3; 70.3	10.9; 114.8	-17.8; 90.5
Bilirubin (umol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	12.94 (4.558)		13.14 (4.975)		13.04 (4.761)	
		Median	12.60		12.20		12.45	
		Min; Max	5.2; 30.7		4.6; 32.5		4.6; 32.5	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	12.20 (4.480)		12.63 (5.168)		12.42 (4.830)	
		Median	11.15		12.10		11.55	
		Min; Max	4.8; 24.8		4.3; 33.7		4.3; 33.7	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Bilirubin (umol/L)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	12.05 (4.817)		12.72 (5.510)		12.39 (5.174)	
		Median	11.20		11.50		11.30	
		Min; Max	4.2; 36.8		5.3; 34.9		4.2; 36.8	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	11.79 (5.037)	-1.16 (4.312)	12.06 (5.895)	-1.08 (4.373)	11.92 (5.472)	-1.12 (4.333)
		Median	11.50	-1.40	10.45	-1.30	10.90	-1.35
		Min; Max	3.4; 41.2	-10.7; 24.4	4.3; 35.9	-13.7; 10.0	3.4; 41.2	-13.7; 24.4
Calcium (mmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	2.378 (0.078)		2.394 (0.081)		2.386 (0.080)	
		Median	2.370		2.400		2.385	
		Min; Max	2.17; 2.59		2.19; 2.56		2.17; 2.59	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Calcium (mmol/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	2.371 (0.086)		2.384 (0.091)		2.377 (0.088)	
		Median	2.375		2.380		2.380	
		Min; Max	2.20; 2.59		2.18; 2.67		2.18; 2.67	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	2.364 (0.086)		2.387 (0.073)		2.375 (0.080)	
		Median	2.360		2.390		2.380	
		Min; Max	2.15; 2.51		2.17; 2.65		2.15; 2.65	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	2.363 (0.086)	-0.015 (0.075)	2.368 (0.085)	-0.027 (0.079)	2.365 (0.086)	-0.021 (0.077)
		Median	2.360	-0.010	2.375	-0.020	2.360	-0.020
		Min; Max	2.19; 2.70	-0.18; 0.24	2.13; 2.61	-0.23; 0.19	2.13; 2.70	-0.23; 0.24

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Chloride (mmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	101.72 (2.028)		102.22 (2.191)		101.97 (2.121)	
		Median	101.95		102.45		102.10	
		Min; Max	96.2; 105.6		95.4; 106.5		95.4; 106.5	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	102.68 (1.919)		102.67 (2.122)		102.67 (2.019)	
		Median	102.85		102.90		102.90	
		Min; Max	97.9; 107.0		97.7; 107.8		97.7; 107.8	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	102.52 (2.200)		102.68 (2.246)		102.60 (2.219)	
		Median	102.80		102.80		102.80	
		Min; Max	95.9; 108.8		96.8; 107.9		95.9; 108.8	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Chloride (mmol/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	102.84 (1.913)	1.12 (1.858)	102.99 (2.024)	0.77 (2.232)	102.92 (1.966)	0.95 (2.056)
		Median	102.90	1.10	103.00	0.80	102.90	0.90
		Min; Max	97.6; 107.1	-3.8; 5.7	97.2; 107.4	-5.9; 7.5	97.2; 107.4	-5.9; 7.5
Creatine Kinase (IU/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	120.69 (68.397)		120.37 (60.423)		120.53 (64.383)	
		Median	107.20		109.85		108.90	
		Min; Max	36.6; 466.8		30.9; 361.3		30.9; 466.8	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	132.51 (110.143)		135.50 (130.286)		134.01 (120.365)	
		Median	108.70		109.75		109.65	
		Min; Max	42.2; 965.1		35.2; 1292.1		35.2; 1292.1	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Creatine Kinase (IU/L)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	221.77 (888.514)		150.05 (160.664)		185.91 (637.947)	
		Median	107.70		106.70		106.90	
		Min; Max	32.4; 9146.7		39.4; 1564.9		32.4; 9146.7	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	195.06 (440.927)	74.36 (439.269)	174.10 (283.239)	53.74 (277.501)	184.58 (369.854)	64.05 (366.689)
		Median	107.50	1.90	108.10	2.00	107.50	2.00
		Min; Max	28.3; 3332.5	-267.0; 3196.0	33.0; 2666.8	-159.3; 2540.8	28.3; 3332.5	-267.0; 3196.0
Creatinine (umol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	67.50 (10.707)		67.39 (11.185)		67.44 (10.923)	
		Median	67.80		66.80		67.00	
		Min; Max	45.2; 90.6		45.6; 89.8		45.2; 90.6	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Creatinine (umol/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	70.47 (11.603)		69.65 (11.840)		70.06 (11.702)	
		Median	70.40		68.15		69.25	
		Min; Max	41.7; 94.6		40.9; 94.0		40.9; 94.6	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	70.89 (11.012)		69.99 (12.495)		70.44 (11.757)	
		Median	71.90		67.80		70.25	
		Min; Max	50.9; 98.9		46.2; 102.7		46.2; 102.7	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	68.97 (11.000)	1.47 (6.376)	69.66 (12.131)	2.28 (6.471)	69.32 (11.557)	1.88 (6.421)
		Median	68.80	1.20	68.85	1.45	68.80	1.35
		Min; Max	45.4; 96.3	-21.5; 19.2	43.1; 100.1	-14.0; 21.5	43.1; 100.1	-21.5; 21.5

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Creatinine Clearance (mL/min/1.73m2)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	106.0 (13.12)		106.9 (15.05)		106.5 (14.09)	
		Median	102.5		102.0		102.0	
		Min; Max	90; 151		90; 180		90; 180	
Direct Bilirubin (umol/L)	Screening	n (missing)	7 (0)		14 (0)		21 (0)	
		Mean (SD)	4.27 (0.894)		4.40 (0.762)		4.36 (0.788)	
		Median	4.20		4.25		4.20	
		Min; Max	3.3; 6.0		3.0; 5.9		3.0; 6.0	
	Period 1/ (Day -1)	n (missing)	6 (0)		8 (0)		14 (0)	
		Mean (SD)	4.52 (0.840)		4.15 (0.843)		4.31 (0.831)	
		Median	4.60		4.05		4.35	
		Min; Max	3.5; 5.8		2.8; 5.5		2.8; 5.8	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Direct Bilirubin (umol/L)	Period 2/ (Day -1)	n (missing)	3 (0)		8 (0)		11 (0)	
		Mean (SD)	3.73 (2.558)		4.54 (0.727)		4.32 (1.349)	
		Median	4.90		4.65		4.80	
		Min; Max	0.8; 5.5		3.2; 5.3		0.8; 5.5	
	Follow-Up	n (missing)	3 (0)	2 (1)	8 (0)	4 (4)	11 (0)	6 (5)
		Mean (SD)	3.67 (0.814)	NC	4.98 (0.911)	0.75 (1.190)	4.62 (1.043)	0.53 (1.167)
		Median	3.30	NC	5.05	0.50	4.60	0.50
		Min; Max	3.1; 4.6	NC	3.6; 6.6	-0.4; 2.4	3.1; 6.6	-0.9; 2.4
Gamma Glutamyl Transferase (U/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	19.22 (9.648)		20.60 (9.130)		19.91 (9.396)	
		Median	16.60		18.45		17.30	
		Min; Max	7.7; 62.0		7.2; 55.7		7.2; 62.0	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Gamma Glutamyl Transferase (U/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	18.15 (8.641)		20.08 (8.885)		19.12 (8.797)	
		Median	15.90		17.45		16.55	
		Min; Max	8.1; 63.1		7.9; 49.6		7.9; 63.1	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	18.60 (10.526)		21.02 (10.493)		19.81 (10.555)	
		Median	16.40		17.60		16.95	
		Min; Max	8.2; 91.5		7.2; 63.5		7.2; 91.5	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	18.53 (9.932)	-0.69 (5.724)	20.12 (10.173)	-0.49 (4.808)	19.32 (10.061)	-0.59 (5.274)
		Median	16.45	-0.20	17.45	-0.25	16.70	-0.20
		Min; Max	8.3; 79.3	-27.7; 20.3	7.7; 72.9	-17.5; 20.8	7.7; 79.3	-27.7; 20.8

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Glucose (mmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.646 (0.350)		4.572 (0.355)		4.609 (0.354)	
		Median	4.655		4.585		4.635	
		Min; Max	3.85; 5.76		3.71; 5.41		3.71; 5.76	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.854 (0.378)		4.839 (0.395)		4.846 (0.386)	
		Median	4.845		4.855		4.850	
		Min; Max	4.00; 5.80		3.72; 5.60		3.72; 5.80	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	4.856 (0.371)		4.747 (0.452)		4.801 (0.416)	
		Median	4.830		4.800		4.820	
		Min; Max	4.04; 5.77		1.92; 6.11		1.92; 6.11	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Glucose (mmol/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	4.760 (0.378)	0.114 (0.372)	4.707 (0.428)	0.135 (0.528)	4.734 (0.403)	0.124 (0.455)
		Median	4.775	0.135	4.640	0.065	4.700	0.100
		Min; Max	3.88; 5.75	-0.88; 1.17	3.74; 6.99	-0.84; 3.28	3.74; 6.99	-0.88; 3.28
Indirect Bilirubin (umol/L)	Screening	n (missing)	7 (0)		14 (0)		21 (0)	
		Mean (SD)	20.71 (2.607)		20.15 (2.642)		20.34 (2.579)	
		Median	19.90		19.65		19.90	
		Min; Max	18.2; 24.7		17.2; 26.9		17.2; 26.9	
	Period 1/ (Day -1)	n (missing)	6 (0)		8 (0)		14 (0)	
		Mean (SD)	18.15 (1.005)		20.10 (3.691)		19.26 (2.954)	
		Median	18.45		18.65		18.65	
		Min; Max	16.7; 19.0		17.7; 28.9		16.7; 28.9	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Indirect Bilirubin (umol/L)	Period 2/ (Day -1)	n (missing)	3 (0)		8 (0)		11 (0)	
		Mean (SD)	18.37 (14.061)		22.34 (4.366)		21.25 (7.505)	
		Median	20.40		21.35		20.40	
		Min; Max	3.4; 31.3		17.2; 29.6		3.4; 31.3	
	Follow-Up	n (missing)	3 (0)	2 (1)	8 (0)	4 (4)	11 (0)	6 (5)
		Mean (SD)	24.63 (10.364)	NC	22.84 (3.952)	3.78 (3.428)	23.33 (5.755)	4.93 (5.389)
		Median	18.70	NC	23.10	3.85	22.60	3.85
		Min; Max	18.6; 36.6	NC	17.5; 29.3	-0.2; 7.6	17.5; 36.6	-0.2; 14.1
Lactate Dehydrogenase (IU/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	158.37 (22.498)		165.03 (22.124)		161.70 (22.508)	
		Median	155.60		160.95		158.65	
		Min; Max	82.1; 220.6		127.7; 228.2		82.1; 228.2	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Lactate Dehydrogenase (IU/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	158.95 (23.664)		163.50 (22.253)		161.23 (23.030)	
		Median	157.35		161.45		159.70	
		Min; Max	84.7; 225.7		120.2; 231.2		84.7; 231.2	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	163.43 (32.495)		169.46 (25.216)		166.45 (29.171)	
		Median	160.10		164.50		162.15	
		Min; Max	89.6; 379.1		133.8; 288.7		89.6; 379.1	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	159.40 (25.150)	1.03 (19.435)	163.48 (20.007)	-1.55 (17.675)	161.44 (22.764)	-0.26 (18.578)
		Median	155.15	-0.05	162.60	-4.40	158.05	-1.60
		Min; Max	87.8; 238.2	-63.4; 80.5	121.0; 240.8	-55.7; 49.8	87.8; 240.8	-63.4; 80.5

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Potassium (mmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.238 (0.300)		4.266 (0.271)		4.252 (0.286)	
		Median	4.240		4.255		4.240	
		Min; Max	3.53; 5.13		3.68; 4.84		3.53; 5.13	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.317 (0.337)		4.331 (0.331)		4.324 (0.333)	
		Median	4.285		4.290		4.290	
		Min; Max	3.49; 5.28		3.30; 5.08		3.30; 5.28	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	4.317 (0.326)		4.287 (0.332)		4.302 (0.328)	
		Median	4.300		4.270		4.295	
		Min; Max	3.58; 5.06		3.47; 5.06		3.47; 5.06	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Potassium (mmol/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	4.381 (0.326)	0.143 (0.321)	4.336 (0.255)	0.070 (0.329)	4.358 (0.293)	0.106 (0.326)
		Median	4.345	0.090	4.350	0.075	4.350	0.090
		Min; Max	3.65; 5.22	-0.57; 1.03	3.71; 4.91	-0.70; 0.77	3.65; 5.22	-0.70; 1.03
Protein (g/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	70.75 (3.366)		71.32 (3.478)		71.04 (3.426)	
		Median	70.85		71.75		71.20	
		Min; Max	60.4; 77.0		62.2; 79.0		60.4; 79.0	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	70.70 (3.469)		71.64 (3.820)		71.17 (3.670)	
		Median	70.50		72.10		71.25	
		Min; Max	62.4; 80.7		63.4; 80.1		62.4; 80.7	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Protein (g/L)	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	70.49 (3.907)		71.77 (3.599)		71.13 (3.802)	
		Median	70.90		71.90		71.40	
		Min; Max	61.3; 80.0		64.4; 81.4		61.3; 81.4	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	70.08 (3.430)	-0.68 (2.911)	70.40 (3.796)	-0.92 (3.038)	70.24 (3.613)	-0.80 (2.971)
		Median	69.90	-0.80	70.20	-0.70	70.10	-0.80
		Min; Max	61.5; 78.3	-7.6; 9.2	57.5; 83.0	-10.5; 7.3	57.5; 83.0	-10.5; 9.2
Sodium (mmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	137.41 (2.039)		137.79 (2.069)		137.60 (2.058)	
		Median	137.40		137.70		137.60	
		Min; Max	131.1; 143.6		131.9; 142.4		131.1; 143.6	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Sodium (mmol/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	137.44 (1.874)		137.43 (1.772)		137.43 (1.820)	
		Median	137.65		137.50		137.60	
		Min; Max	132.1; 141.3		130.3; 141.1		130.3; 141.3	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	137.56 (2.117)		137.69 (1.919)		137.62 (2.017)	
		Median	137.80		137.80		137.80	
		Min; Max	129.7; 141.5		132.8; 142.6		129.7; 142.6	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	137.75 (1.582)	0.34 (1.686)	137.98 (1.882)	0.19 (2.332)	137.86 (1.738)	0.26 (2.031)
		Median	137.85	0.35	137.90	0.05	137.90	0.20
		Min; Max	133.6; 141.9	-4.0; 4.6	131.7; 144.3	-6.3; 7.9	131.7; 144.3	-6.3; 7.9

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Thyrotropin (mU/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	1.426 (0.721)		1.342 (0.595)		1.384 (0.661)	
		Median	1.205		1.205		1.205	
		Min; Max	0.42; 4.13		0.35; 3.52		0.35; 4.13	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	1.456 (0.824)	0.030 (0.613)	1.301 (0.742)	-0.041 (0.579)	1.378 (0.786)	-0.006 (0.596)
		Median	1.260	0.010	1.110	-0.075	1.170	-0.040
		Min; Max	0.01; 4.07	-1.64; 2.30	0.08; 3.90	-1.59; 2.07	0.01; 4.07	-1.64; 2.30
Thyroxine (nmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	75.28 (9.211)		76.66 (12.931)		75.97 (11.222)	
		Median	73.45		71.95		72.80	
		Min; Max	63.0; 113.9		63.5; 133.5		63.0; 133.5	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Thyroxine (nmol/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	74.26 (8.063)		76.14 (10.567)		75.20 (9.424)	
		Median	73.50		73.85		73.75	
		Min; Max	60.1; 102.3		58.4; 111.1		58.4; 111.1	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	71.35 (8.555)		72.36 (10.438)		71.85 (9.534)	
		Median	71.20		70.30		70.60	
		Min; Max	51.0; 93.6		52.4; 115.3		51.0; 115.3	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	72.05 (13.298)	-3.23 (12.628)	72.08 (11.282)	-4.59 (10.833)	72.06 (12.303)	-3.91 (11.757)
		Median	69.80	-4.20	71.00	-3.35	70.50	-3.55
		Min; Max	54.8; 141.2	-31.8; 74.0	52.1; 107.3	-53.3; 16.4	52.1; 141.2	-53.3; 74.0

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Thyroxine, Free (pmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	13.693 (1.179)		13.740 (1.354)		13.717 (1.266)	
		Median	13.460		13.415		13.435	
		Min; Max	11.41; 17.62		11.01; 17.89		11.01; 17.89	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	13.340 (1.712)	-0.353 (1.681)	13.307 (1.254)	-0.433 (1.163)	13.323 (1.497)	-0.393 (1.442)
		Median	13.080	-0.405	13.115	-0.270	13.105	-0.380
		Min; Max	10.22; 25.13	-4.33; 12.13	10.60; 17.86	-4.89; 2.60	10.22; 25.13	-4.89; 12.13
Triacylglycerol Lipase (IU/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	21.90 (10.121)		22.24 (9.686)		22.07 (9.884)	
		Median	19.70		21.25		20.25	
		Min; Max	3.4; 59.6		7.3; 57.1		3.4; 59.6	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Triacylglycerol Lipase (IU/L)	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	24.37 (15.084)		25.63 (19.815)		25.00 (17.579)	
		Median	19.50		22.20		21.10	
		Min; Max	5.4; 110.0		7.3; 188.4		5.4; 188.4	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	22.76 (12.178)		23.81 (11.719)		23.28 (11.934)	
		Median	20.20		22.50		20.85	
		Min; Max	5.7; 71.5		7.2; 74.1		5.7; 74.1	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	23.17 (13.356)	1.28 (9.878)	22.59 (10.598)	0.35 (6.783)	22.88 (12.032)	0.81 (8.466)
		Median	19.30	0.20	21.20	0.70	20.10	0.25
		Min; Max	1.3; 78.8	-29.5; 46.3	5.3; 53.2	-19.7; 22.1	1.3; 78.8	-29.5; 46.3

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Triiodothyronine (nmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	1.629 (0.185)		1.583 (0.195)		1.606 (0.191)	
		Median	1.645		1.590		1.620	
		Min; Max	1.25; 2.12		1.16; 2.12		1.16; 2.12	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	1.661 (0.198)		1.624 (0.190)		1.643 (0.194)	
		Median	1.630		1.620		1.620	
		Min; Max	1.20; 2.45		1.24; 2.14		1.20; 2.45	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	1.620 (0.195)		1.591 (0.192)		1.605 (0.194)	
		Median	1.610		1.580		1.590	
		Min; Max	1.17; 2.29		1.05; 2.15		1.05; 2.29	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Triiodothyronine (nmol/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	1.650 (0.217)	0.021 (0.215)	1.568 (0.191)	-0.015 (0.189)	1.609 (0.208)	0.003 (0.202)
		Median	1.630	-0.010	1.555	-0.005	1.600	-0.010
		Min; Max	1.12; 2.35	-0.34; 0.97	1.05; 2.10	-0.57; 0.42	1.05; 2.35	-0.57; 0.97
Triiodothyronine, Free (pmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.302 (0.511)		4.180 (0.512)		4.241 (0.514)	
		Median	4.340		4.220		4.300	
		Min; Max	2.82; 5.36		2.82; 5.00		2.82; 5.36	
	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	4.387 (0.612)	0.086 (0.701)	4.212 (0.522)	0.033 (0.599)	4.300 (0.574)	0.059 (0.651)
		Median	4.325	0.095	4.220	0.000	4.275	0.055
		Min; Max	2.91; 6.94	-1.46; 3.87	2.78; 5.62	-1.53; 1.33	2.78; 6.94	-1.53; 3.87

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Urea (mmol/L)	Screening	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	3.823 (1.140)		3.819 (0.882)		3.821 (1.017)	
		Median	3.625		3.710		3.695	
		Min; Max	1.60; 6.77		1.82; 6.24		1.60; 6.77	
	Period 1/ (Day -1)	n (missing)	108 (0)		108 (0)		216 (0)	
		Mean (SD)	4.184 (1.186)		4.249 (1.194)		4.216 (1.188)	
		Median	3.935		4.045		4.020	
		Min; Max	1.90; 7.32		2.08; 11.32		1.90; 11.32	
	Period 2/ (Day -1)	n (missing)	105 (0)		105 (0)		210 (0)	
		Mean (SD)	4.192 (1.130)		4.324 (1.066)		4.258 (1.098)	
		Median	4.180		4.240		4.215	
		Min; Max	1.94; 7.42		2.12; 7.08		1.94; 7.42	

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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 15.3.5.1.2 Summary and Change from Screening to FU of Laboratory Data by Treatment Sequence and Time Point: Clinical Chemistry (Safety Population)

			Treatment Sequence 1 (N=108)		Treatment Sequence 2 (N=108)		Total (N=216)	
Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change
Urea (mmol/L)	Follow-Up	n (missing)	108 (0)	108 (0)	108 (0)	108 (0)	216 (0)	216 (0)
		Mean (SD)	4.333 (1.316)	0.510 (1.164)	4.116 (0.940)	0.298 (0.964)	4.225 (1.146)	0.404 (1.072)
		Median	4.150	0.385	3.995	0.305	4.045	0.345
		Min; Max	1.91; 9.42	-3.20; 4.71	2.24; 7.18	-3.01; 2.78	1.91; 9.42	-3.20; 4.71

Baseline defined as Screening for Follow-Up results; NC: Not Calculated.
Max: Maximum Value; Min: Minimum Value; 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 in specific laboratory tests.
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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