

Levothyroxine  
EMR 200125-001

Bioequivalence trial of new levothyroxine formulation vs. old formulation

Merck Serono  
EMR 200125-001

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Alanine Aminotransferase (U/L)	Screening	13-01-2014/ 8:45	35.5 (H, ncs)		0.0 - 35.0
		Creatine Kinase (IU/L)	Screening	17-01-2014/ 7:13	363.2 (H, ncs)		0.0 - 145.0
		Thyroxine (nmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:35	62.6 (L, ncs)		62.7 - 150.8
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:16	10.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:19	61.9 (L, ncs)		62.7 - 150.8
		Monocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:19	15.5 (H, ncs)		5.3 - 14.2
		Monocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:19	1.16 (H, ncs)		0.27 - 0.91
		Neutrophils (10 <sup>9</sup> /L)	Follow-Up	14-03-2014/ 9:23	7.19 (H, ncs)	3.63	1.61 - 6.45
		Thyroxine (nmol/L)	Follow-Up	14-03-2014/ 9:23	61.8 (L, ncs)	-13.7	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	14-03-2014/ 9:23	157.4 (H, ncs)	-205.8	0.0 - 145.0
		Lymphocytes/Leukocytes (%)	Follow-Up	14-03-2014/ 9:23	16.9 (L, ncs)	-13.5	17.8 - 48.5
		Neutrophils/Leukocytes (%)	Follow-Up	14-03-2014/ 9:23	75.6 (H, ncs)	15.2	37.9 - 70.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 2	Erythrocytes (uL)	Screening	13-01-2014/ 11:18	10.00 (H, ncs)		0.00 - 5.00
		Sodium (mmol/L)	Screening	13-01-2014/ 11:21	135.1 (L, ncs)		136.0 - 146.0
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	18-01-2014/ 8:18	4.7 (L, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	18-01-2014/ 8:18	100.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	18-01-2014/ 8:18	133.3 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Follow-Up	12-02-2014/ 7:36	146.0 (H, ncs)	6.5	0.0 - 145.0
		Bilirubin (umol/L)	Follow-Up	12-02-2014/ 7:36	4.8 (L, ncs)	-1.5	5.0 - 21.0
	Treatment Sequence 1	Monocytes/Leukocytes (%)	Follow-Up	12-02-2014/ 7:36	14.3 (H, ncs)	6.6	5.3 - 14.2
		Sodium (mmol/L)	Follow-Up	12-02-2014/ 7:36	135.0 (L, ncs)	-0.1	136.0 - 146.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:30	10.00 (H, ncs)		0.00 - 5.00
		Hematocrit (L/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:33	0.33 (L, ncs)		0.35 - 0.44
		Hemoglobin (g/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:33	105 (L, ncs)		111 - 146

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Eosinophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:33	8.2 (H, ncs)		0.6 - 7.9
		Ketones (mmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:27	0.5 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:27	10.00 (H, ncs)		0.00 - 5.00
		Calcium (mmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:29	2.17 (L, ncs)		2.20 - 2.65
		Hematocrit (L/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:29	0.33 (L, ncs)		0.35 - 0.44
		Hemoglobin (g/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:29	104 (L, ncs)		111 - 146
		Ketones (mmol/L)	Follow-Up	25-03-2014/ 10:26	0.5 (H, ncs)	0.5	0.0 - 0.5
		Erythrocytes (uL)	Follow-Up	25-03-2014/ 10:26	25.00 (H, ncs)	25	0.00 - 5.00
		Hematocrit (L/L)	Follow-Up	25-03-2014/ 10:29	0.33 (L, ncs)	-0.04	0.35 - 0.44
		Hemoglobin (g/L)	Follow-Up	25-03-2014/ 10:29	103 (L, ncs)	-16	111 - 146
	Treatment Sequence 1	Thyroxine (nmol/L)	Screening	13-01-2014/ 12:19	60.2 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:21	7.32 (H, ncs)		2.80 - 7.20

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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	27-02-2014/ 9:05	62.5 (L, ncs)		62.7 - 150.8
		Thyroxine (nmol/L)	Follow-Up	14-03-2014/ 12:35	59.5 (L, ncs)	-6.3	62.7 - 150.8
		Glucose (mmol/L)	Follow-Up	14-03-2014/ 12:35	3.96 (L, ncs)	-0.78	4.10 - 5.90
		pH	Follow-Up	14-03-2014/ 12:35	8.0 (H, ncs)	1.5	4.8 - 7.4
	Treatment Sequence 1	Chloride (mmol/L)	Screening	14-01-2014/ 9:57	99.9 (L, ncs)		101.0 - 109.0
		Neutrophils/Leukocytes (%)	Screening	14-01-2014/ 9:57	73.1 (H, ncs)		38.2 - 71.5
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:16	100.5 (L, ncs)		101.0 - 109.0
		Potassium (mmol/L)	Follow-Up	14-03-2014/ 8:52	5.22 (H, ncs)	1.03	3.50 - 5.10
		Bilirubin (umol/L)	Follow-Up	14-03-2014/ 8:52	21.8 (H, ncs)	4.7	5.0 - 21.0
		Indirect Bilirubin (umol/L)	Follow-Up	14-03-2014/ 8:52	18.7 (H, ncs)		1.6 - 17.6
	Treatment Sequence 2	Urea (mmol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:31	2.64 (L, ncs)		2.80 - 7.20
		Hematocrit (L/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:11	0.34 (L, ncs)		0.35 - 0.44

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.

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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
		Hemoglobin (g/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:11	108 (L, ncs)		111 - 146
		Leukocytes (10 <sup>9</sup> /L)	Follow-Up	19-03-2014/ 10:07	10.75 (H, ncs)	3.48	3.69 - 10.04
		Neutrophils (10 <sup>9</sup> /L)	Follow-Up	19-03-2014/ 10:07	8.19 (H, ncs)	3.51	1.61 - 6.45
		Thyroxine (nmol/L)	Follow-Up	19-03-2014/ 10:07	59.7 (L, ncs)	-10	62.7 - 150.8
		Lymphocytes/Leukocytes (%)	Follow-Up	19-03-2014/ 10:07	15.2 (L, ncs)	-10.4	17.8 - 48.5
		Neutrophils/Leukocytes (%)	Follow-Up	19-03-2014/ 10:07	76.1 (H, ncs)	11.7	37.9 - 70.5
		Eosinophils/Leukocytes (%)	Follow-Up	19-03-2014/ 10:07	0.5 (L, ncs)	-0.3	0.6 - 7.9
1	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	14-01-2014/ 11:47	179.1 (H, ncs)		0.0 - 145.0
		Sodium (mmol/L)	Screening	14-01-2014/ 11:47	134.3 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Screening	17-01-2014/ 11:00	171.0 (H, ncs)		0.0 - 145.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:25	191.4 (H, ncs)		0.0 - 145.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 17:54	179.0 (H, ncs)		0.0 - 145.0

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Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:25	65.2 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:25	207.5 (H, ncs)		0.0 - 145.0
		Calcium (mmol/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:25	2.15 (L, ncs)		2.20 - 2.65
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	28-02-2014/ 8:50	159.6 (H, ncs)		0.0 - 145.0
		Creatine Kinase (IU/L)	Follow-Up	14-03-2014/ 11:59	199.8 (H, ncs)	28.8	0.0 - 145.0
	Treatment Sequence 2	Leukocytes (uL)	Screening	15-01-2014/ 8:52	25.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:38	10.00 (H, ncs)		0.00 - 5.00
		Urea (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:40	2.57 (L, ncs)		2.80 - 7.20
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:40	135.9 (L, ncs)		136.0 - 146.0
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:49	10.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:49	25.00 (H, ncs)		0.00 - 9.00
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:51	61.6 (L, ncs)		62.7 - 150.8

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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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	27-02-2014/ 9:51	2.26 (L, ncs)		2.80 - 7.20
		Thyroxine (nmol/L)	Follow-Up	17-03-2014/ 10:34	56.8 (L, ncs)	-24.8	62.7 - 150.8
		Urea (mmol/L)	Follow-Up	17-03-2014/ 10:34	2.56 (L, ncs)	-0.35	2.80 - 7.20
	Treatment Sequence 1	Urea (mmol/L)	Screening	15-01-2014/ 10:10	2.61 (L, ncs)		2.80 - 7.20
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:49	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:49	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:49	25.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:49	100.00 (H, ncs)		0.00 - 9.00
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 9:02	134.6 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Follow-Up	19-03-2014/ 8:27	1575.2 (H, ncs)	1512.4	0.0 - 145.0
		Alanine Aminotransferase (U/L)	Follow-Up	19-03-2014/ 8:27	40.9 (H, ncs)	31.6	0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Follow-Up	19-03-2014/ 8:27	72.0 (H, ncs)	56.2	0.0 - 35.0

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Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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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	
1238/282	Treatment Sequence 2	Erythrocytes (uL)	Screening	15-01-2014/ 11:00	10.00 (H, ncs)		0.00 - 5.00	
		Gamma Glutamyl Transferase (U/L)	Screening	15-01-2014/ 11:03	41.8 (H, ncs)		0.0 - 38.0	
			Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	10.00 (H, ncs)		0.00 - 5.00
			Ketones (mmol/L)	Follow-Up	06-03-2014/ 11:30	15.0 (H, ncs)	15	0.0 - 0.5
			Erythrocytes (uL)	Follow-Up	06-03-2014/ 11:30	10.00 (H, ncs)	0	0.00 - 5.00
			Erythrocytes (uL)	Follow-Up	10-03-2014/ 10:05	10.00 (H, ncs)	0	0.00 - 5.00
	Treatment Sequence 1		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	18-01-2014/ 8:26	100.2 (L, ncs)		101.0 - 109.0
			Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	18-01-2014/ 8:26	135.6 (L, ncs)		136.0 - 146.0
			Basophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	18-01-2014/ 8:26	1.1 (H, ncs)		0.0 - 1.0
			Amylase (IU/L)	Follow-Up	10-03-2014/ 7:55	103.6 (H, ncs)	47.6	28.0 - 100.0
			Chloride (mmol/L)	Follow-Up	10-03-2014/ 7:55	99.7 (L, ncs)	-2.3	101.0 - 109.0
			Monocytes/Leukocytes (%)	Follow-Up	10-03-2014/ 7:55	15.0 (H, ncs)	7.6	5.6 - 14.8

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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 2	Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:06	150.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:06	POSITIVE (H, ncs)		
		Erythrocytes (/HPF)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:06	6.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:06	20.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:06	100.00 (H, ncs)		0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:06	80 (H, ncs)		0 - 15
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:15	60.0 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:15	152.0 (H, ncs)		0.0 - 145.0
		Lymphocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:15	16.4 (L, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:15	71.9 (H, ncs)		37.9 - 70.5
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 16:45	25.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Follow-Up	20-03-2014/ 10:47	60.8 (L, ncs)	-3.1	62.7 - 150.8

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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	20-03-2014/ 10:47	100.6 (L, ncs)	-3.4	101.0 - 109.0
		Glucose (mmol/L)	Follow-Up	20-03-2014/ 10:47	3.74 (L, ncs)	-0.53	4.10 - 5.90
	Treatment Sequence 1	Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:05	186.0 (H, ncs)		0.0 - 171.0
		pH	Follow-Up	13-03-2014/ 10:19	8.0 (H, ncs)	1	4.8 - 7.4
		Protein (g/L)	Follow-Up	13-03-2014/ 10:20	64.0 (L, ncs)	-3.6	66.0 - 83.0
	Treatment Sequence 1	Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	18-01-2014/ 8:46	145.2 (H, ncs)		0.0 - 145.0
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	23-02-2014/ 11:01	62.9 (L, ncs)		66.0 - 83.0
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	23-02-2014/ 11:01	60.9 (L, ncs)		62.7 - 150.8
		Basophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	23-02-2014/ 11:01	0.1 (L, ncs)		0.2 - 1.3
		Thyroxine (nmol/L)	Follow-Up	14-03-2014/ 12:38	57.5 (L, ncs)	-14.4	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	14-03-2014/ 12:38	188.3 (H, ncs)	75.4	0.0 - 145.0
		pH	Follow-Up	14-03-2014/ 12:39	8.0 (H, ncs)	3	4.8 - 7.4

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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	Chloride (mmol/L)	Screening	17-01-2014/ 11:15	97.0 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	17-01-2014/ 11:15	131.1 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:41	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:41	25.00 (H, ncs)		0.00 - 9.00
		Leukocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	3.31 (L, ncs)		3.69 - 10.04
		Neutrophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	1.40 (L, ncs)		1.61 - 6.45
		Urea (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	2.67 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	99.4 (L, ncs)		101.0 - 109.0
		Monocytes/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	18.4 (H, ncs)		5.3 - 14.2
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	132.2 (L, ncs)		136.0 - 146.0
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:43	0.03 (L, ncs)		0.04 - 0.43
		Leukocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 17:45	3.04 (L, ncs)		3.69 - 10.04

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 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 17:45	1.11 (L, ncs)		1.61 - 6.45
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:56	65.5 (L, ncs)		66.0 - 83.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:56	100.2 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:56	129.7 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Follow-Up	14-03-2014/ 11:56	100.8 (L, ncs)	3.8	101.0 - 109.0
		Sodium (mmol/L)	Follow-Up	14-03-2014/ 11:56	134.5 (L, ncs)	3.4	136.0 - 146.0
		Calcium (mmol/L)	Follow-Up	14-03-2014/ 11:56	2.70 (H, ncs)	0.24	2.20 - 2.65
	Treatment Sequence 1	Chloride (mmol/L)	Screening	20-01-2014/ 9:43	100.8 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	20-01-2014/ 9:43	4.03 (L, ncs)		4.10 - 5.90
		Lymphocytes/Leukocytes (%)	Screening	20-01-2014/ 9:43	17.5 (L, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Screening	20-01-2014/ 9:43	72.3 (H, ncs)		38.2 - 71.5
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:24	10.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Protein (g/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:27	65.6 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:27	2.75 (L, ncs)		2.80 - 7.20
		Basophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:27	1.1 (H, ncs)		0.0 - 1.0
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 8:57	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Follow-Up	19-03-2014/ 10:14	10.00 (H, ncs)	10	0.00 - 5.00
		Urea (mmol/L)	Follow-Up	19-03-2014/ 10:17	2.75 (L, ncs)	-0.53	2.80 - 7.20
		Triacylglycerol Lipase (IU/L)	Follow-Up	19-03-2014/ 10:17	78.8 (H, ncs)	30.3	0.0 - 67.0
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	20-01-2014/ 10:08	217.0 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	20-01-2014/ 10:08	99.7 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	20-01-2014/ 10:08	133.7 (L, ncs)		136.0 - 146.0
		Basophils/Leukocytes (%)	Screening	20-01-2014/ 10:08	1.2 (H, ncs)		0.0 - 1.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:39	100.8 (L, ncs)		101.0 - 109.0

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:39	134.9 (L, ncs)		136.0 - 146.0
		Basophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:39	0.09 (H, ncs)		0.01 - 0.07
		Basophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:39	1.7 (H, ncs)		0.0 - 1.0
		Amylase (IU/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:22	109.7 (H, ncs)		28.0 - 100.0
	Treatment Sequence 1	Sodium (mmol/L)	Screening	21-01-2014/ 9:20	134.8 (L, ncs)		136.0 - 146.0
		Calcium (mmol/L)	Screening	21-01-2014/ 9:20	2.17 (L, ncs)		2.20 - 2.65
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:17	120.0 (H, ncs)		28.0 - 100.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:17	100.8 (L, ncs)		101.0 - 109.0
		Triacylglycerol Lipase (IU/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:17	110.0 (H, ncs)		0.0 - 67.0
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 8:04	62.8 (L, ncs)		66.0 - 83.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 8:04	135.0 (L, ncs)		136.0 - 146.0
		Calcium (mmol/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 8:04	2.15 (L, ncs)		2.20 - 2.65

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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	20-03-2014/ 8:34	10.00 (H, ncs)	10	0.00 - 5.00
		Protein (g/L)	Follow-Up	20-03-2014/ 8:35	65.3 (L, ncs)	-1.5	66.0 - 83.0
		Urea (mmol/L)	Follow-Up	20-03-2014/ 8:35	7.81 (H, ncs)	2.07	2.80 - 7.20
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	21-01-2014/ 9:19	293.7 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	21-01-2014/ 9:19	99.2 (L, ncs)		101.0 - 109.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:58	299.4 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 8:58	97.7 (L, ncs)		101.0 - 109.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	22-01-2014/ 17:50	252.8 (H, ncs)		0.0 - 171.0
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:11	61.2 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:11	210.4 (H, ncs)		0.0 - 171.0
		Glucose (mmol/L)	Period 2, Day -1/ 24 H Predose	27-02-2014/ 9:11	6.11 (H, ncs)		4.10 - 5.90
		pH	Follow-Up	14-03-2014/ 11:44	8.0 (H, ncs)	1	4.8 - 7.4

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

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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)	Follow-Up	14-03-2014/ 11:45	56.5 (L, ncs)	-11.7	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	14-03-2014/ 11:45	177.7 (H, ncs)	-116	0.0 - 171.0
		Chloride (mmol/L)	Follow-Up	14-03-2014/ 11:45	100.9 (L, ncs)	1.7	101.0 - 109.0
	Treatment Sequence 1	Bilirubin (umol/L)	Screening	21-01-2014/ 11:15	27.4 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Screening	21-01-2014/ 11:15	100.8 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Screening	21-01-2014/ 11:15	4.6 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	21-01-2014/ 11:15	22.8 (H, ncs)		1.6 - 17.6
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:37	21.4 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:37	99.9 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:37	3.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:37	17.9 (H, ncs)		1.6 - 17.6
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 9:05	61.2 (L, ncs)		62.7 - 150.8

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Thyroxine (nmol/L)	Follow-Up	19-03-2014/ 11:25	57.9 (L, ncs)	-6.4	62.7 - 150.8
	Treatment Sequence 2	Erythrocytes (uL)	Screening	21-01-2014/ 11:20	10.00 (H, ncs)		0.00 - 5.00
		Sodium (mmol/L)	Screening	21-01-2014/ 11:22	135.2 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:50	25.00 (H, ncs)		0.00 - 5.00
		Protein (g/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:52	63.5 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:52	157.1 (H, ncs)		0.0 - 145.0
		Monocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:52	0.26 (L, ncs)		0.27 - 0.91
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:52	135.5 (L, ncs)		136.0 - 146.0
		Calcium (mmol/L)	Period 1, Day -1/ 24 H Predose	27-01-2014/ 8:52	2.18 (L, ncs)		2.20 - 2.65
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 8:35	10.00 (H, ncs)		0.00 - 5.00
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	04-03-2014/ 8:37	64.8 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Follow-Up	21-03-2014/ 10:37	178.5 (H, ncs)	67	0.0 - 145.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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	21-03-2014/ 10:37	25.00 (H, ncs)	15	0.00 - 5.00
	Treatment Sequence 2	pH	Screening	23-01-2014/ 8:49	8.0 (H, ncs)		4.8 - 7.4
		Thyroxine (nmol/L)	Screening	23-01-2014/ 8:50	59.7 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Screening	23-01-2014/ 8:50	173.7 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Screening	24-01-2014/ 7:53	177.6 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:51	199.5 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 13:58	192.0 (H, ncs)		0.0 - 171.0
		pH	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:12	8.0 (H, ncs)		4.8 - 7.4
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:14	61.7 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:14	207.4 (H, ncs)		0.0 - 171.0
		Thyroxine (nmol/L)	Follow-Up	26-03-2014/ 9:48	52.5 (L, ncs)	-11.4	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	26-03-2014/ 9:48	224.1 (H, ncs)	46.5	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
	Treatment Sequence 1	Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:55	184.1 (H, ncs)		0.0 - 171.0
		Hemoglobin (g/L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:55	166 (H, ncs)		126 - 165
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:35	100.4 (L, ncs)		101.0 - 109.0
		Thyroxine (nmol/L)	Follow-Up	28-03-2014/ 7:09	58.8 (L, ncs)	-15	62.7 - 150.8
		Chloride (mmol/L)	Follow-Up	28-03-2014/ 7:09	99.6 (L, ncs)	-1.9	101.0 - 109.0
		Sodium (mmol/L)	Follow-Up	28-03-2014/ 7:09	135.6 (L, ncs)	-0.9	136.0 - 146.0
	Treatment Sequence 1	Bilirubin (umol/L)	Screening	27-01-2014/ 8:42	21.5 (H, ncs)		5.0 - 21.0
		Indirect Bilirubin (umol/L)	Screening	27-01-2014/ 8:42	18.2 (H, ncs)		1.6 - 17.6
		Platelets (10 <sup>9</sup> /L)	Screening	27-01-2014/ 8:42	144 (L, ncs)		155 - 342
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:34	22.7 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:34	3.7 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:34	19.0 (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
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:34	151 (L, ncs)		155 - 342
	Treatment Sequence 1	Erythrocytes (uL)	Screening	27-01-2014/ 8:21	10.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Screening	27-01-2014/ 8:50	210.2 (H, ncs)		0.0 - 171.0
		Lymphocytes (10 <sup>9</sup> /L)	Screening	27-01-2014/ 8:50	3.69 (H, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Screening	27-01-2014/ 8:50	99.5 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:39	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:58	25.00 (H, ncs)		0.00 - 5.00
		Lymphocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:00	3.83 (H, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:00	99.5 (L, ncs)		101.0 - 109.0
		Lymphocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:00	52.6 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:00	36.5 (L, ncs)		38.2 - 71.5
		Erythrocytes (uL)	Follow-Up	31-03-2014/ 9:04	10.00 (H, ncs)	0	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
		Lymphocytes (10 <sup>9</sup> /L)	Follow-Up	31-03-2014/ 9:08	3.83 (H, ncs)	0.14	1.08 - 3.00
		Lymphocytes/Leukocytes (%)	Follow-Up	31-03-2014/ 9:08	52.9 (H, ncs)	8.9	18.3 - 48.1
		Neutrophils/Leukocytes (%)	Follow-Up	31-03-2014/ 9:08	34.8 (L, ncs)	-11.7	38.2 - 71.5
		Creatinine (umol/L)	Follow-Up	31-03-2014/ 9:08	49.2 (L, ncs)	-21.5	59.0 - 104.0
	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	27-01-2014/ 9:25	358.8 (H, ncs)		0.0 - 171.0
		Basophils (10 <sup>9</sup> /L)	Screening	27-01-2014/ 9:25	0.10 (H, ncs)		0.01 - 0.07
		Eosinophils/Leukocytes (%)	Screening	27-01-2014/ 9:25	9.8 (H, ncs)		0.6 - 8.4
		Alanine Aminotransferase (U/L)	Screening	27-01-2014/ 9:25	71.5 (H, ncs)		0.0 - 50.0
		Basophils/Leukocytes (%)	Screening	27-01-2014/ 9:25	2.1 (H, ncs)		0.0 - 1.0
		Creatine Kinase (IU/L)	Screening	05-02-2014/ 8:16	466.8 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Screening	05-02-2014/ 8:16	54.5 (H, ncs)		0.0 - 50.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:30	496.4 (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
		Basophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:30	0.11 (H, ncs)		0.01 - 0.07
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:30	0.53 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:30	10.5 (H, ncs)		0.6 - 8.4
		Alanine Aminotransferase (U/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:30	59.9 (H, ncs)		0.0 - 50.0
		Basophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:30	2.2 (H, ncs)		0.0 - 1.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 18:42	382.9 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 18:42	53.6 (H, ncs)		0.0 - 50.0
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:06	56.4 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:06	1167.5 (H, ncs)		0.0 - 171.0
		Basophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:06	0.08 (H, ncs)		0.01 - 0.07
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:06	70.4 (H, ncs)		0.0 - 50.0
		Aspartate Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:06	61.3 (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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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 (%)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:06	1.9 (H, ncs)		0.0 - 1.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 16:13	927.0 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 16:13	61.5 (H, ncs)		0.0 - 50.0
		Aspartate Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 16:13	52.6 (H, ncs)		0.0 - 50.0
		Creatine Kinase (IU/L)	Follow-Up	11-04-2014/ 9:08	297.2 (H, ncs)	-169.6	0.0 - 171.0
	Treatment Sequence 1	Erythrocytes (uL)	Screening	27-01-2014/ 9:55	10.00 (H, ncs)		0.00 - 5.00
		Urea (mmol/L)	Screening	27-01-2014/ 9:59	2.29 (L, ncs)		2.80 - 7.20
		Hepatitis C Virus Antibody	Screening	27-01-2014/ 9:59	POSITIVE (H, ncs)		
		Glucose (mmol/L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:56	4.00 (L, ncs)		4.10 - 5.90
		pH	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:56	8.0 (H, ncs)		4.8 - 7.4
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:17	25.00 (H, ncs)		0.00 - 5.00
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:17	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)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:17	100.00 (H, ncs)		0.00 - 9.00
		Leukocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:25	10.33 (H, ncs)		3.69 - 10.04
		Neutrophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:25	7.40 (H, ncs)		1.61 - 6.45
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:25	2.42 (L, ncs)		2.80 - 7.20
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:25	71.6 (H, ncs)		37.9 - 70.5
		Urea (mmol/L)	Follow-Up	31-03-2014/ 12:07	2.62 (L, ncs)	0.33	2.80 - 7.20
	Treatment Sequence 1	Urea (mmol/L)	Screening	27-01-2014/ 10:57	2.50 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Screening	27-01-2014/ 10:57	100.3 (L, ncs)		101.0 - 109.0
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:18	2.73 (L, ncs)		2.80 - 7.20
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	28-01-2014/ 9:34	198.2 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 7:59	205.3 (H, ncs)		0.0 - 171.0
		Hemoglobin (g/L)	Follow-Up	27-03-2014/ 8:59	167 (H, ncs)	8	126 - 165

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 2	Creatine Kinase (IU/L)	Screening	28-01-2014/ 11:04	450.9 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	28-01-2014/ 11:04	98.0 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	28-01-2014/ 11:04	133.3 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Screening	31-01-2014/ 9:59	176.7 (H, ncs)		0.0 - 171.0
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:55	110.8 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:55	180.0 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:55	98.3 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:55	135.7 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 13:56	178.8 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:17	229.1 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:17	99.3 (L, ncs)		101.0 - 109.0
		Chloride (mmol/L)	Follow-Up	26-03-2014/ 8:53	99.9 (L, ncs)	1.9	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
1	Treatment Sequence 2	Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 7:46	100.5 (L, ncs)		101.0 - 109.0
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 7:46	0.58 (H, ncs)		0.03 - 0.50
	Treatment Sequence 1	Chloride (mmol/L)	Follow-Up	28-03-2014/ 11:02	100.2 (L, ncs)	-1.6	101.0 - 109.0
		Neutrophils (10 <sup>9</sup> /L)	Screening	29-01-2014/ 7:57	1.27 (L, ncs)		1.46 - 5.85
		Protein (g/L)	Screening	29-01-2014/ 7:57	60.4 (L, ncs)		66.0 - 83.0
		Thyroxine (nmol/L)	Screening	29-01-2014/ 7:57	59.8 (L, ncs)		62.7 - 150.8
		Lymphocytes/Leukocytes (%)	Screening	29-01-2014/ 7:57	51.1 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Screening	29-01-2014/ 7:57	34.7 (L, ncs)		38.2 - 71.5
		Neutrophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:49	1.08 (L, ncs)		1.46 - 5.85
		Protein (g/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:49	63.0 (L, ncs)		66.0 - 83.0
		Lymphocytes/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:49	53.7 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 7:49	33.3 (L, ncs)		38.2 - 71.5

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 (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 13:58	1.22 (L, ncs)		1.46 - 5.85
		Lymphocytes/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 13:58	50.8 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 13:58	37.5 (L, ncs)		38.2 - 71.5
		Neutrophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:03	1.29 (L, ncs)		1.46 - 5.85
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:03	61.3 (L, ncs)		66.0 - 83.0
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:03	51.0 (L, ncs)		62.7 - 150.8
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:03	36.9 (L, ncs)		38.2 - 71.5
		Protein (g/L)	Follow-Up	26-03-2014/ 7:30	63.8 (L, ncs)	3.4	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	26-03-2014/ 7:30	55.9 (L, ncs)	-10.8	62.7 - 150.8
	Treatment Sequence 2	pH	Screening	29-01-2014/ 8:17	8.0 (H, ncs)		4.8 - 7.4
		Creatine Kinase (IU/L)	Screening	29-01-2014/ 8:20	202.9 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	29-01-2014/ 8:20	100.4 (L, ncs)		101.0 - 109.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:00	204.0 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:00	99.1 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:00	3.90 (L, ncs)		4.10 - 5.90
		Erythrocytes (10 <sup>12</sup> /L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:00	5.88 (H, ncs)		4.12 - 5.74
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:00	135.8 (L, ncs)		136.0 - 146.0
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:00	0.51 (H, ncs)		0.03 - 0.50
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 14:16	172.5 (H, ncs)		0.0 - 171.0
		Glucose (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 14:16	7.73 (H, ncs)		4.10 - 5.90
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 14:16	0.55 (H, ncs)		0.03 - 0.50
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 7:34	285.5 (H, ncs)		0.0 - 171.0
		Monocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 7:34	5.5 (L, ncs)		5.6 - 14.8
		Erythrocytes (10 <sup>12</sup> /L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 7:34	5.79 (H, ncs)		4.12 - 5.74

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	26-03-2014/ 10:09	339.9 (H, ncs)	137	0.0 - 171.0
		Monocytes/Leukocytes (%)	Follow-Up	26-03-2014/ 10:09	5.5 (L, ncs)	-0.5	5.6 - 14.8
		Creatine Kinase (IU/L)	Follow-Up	02-04-2014/ 8:21	261.0 (H, ncs)	58.1	0.0 - 171.0
	Treatment Sequence 1	Protein (g/L)	Screening	30-01-2014/ 11:04	65.0 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Screening	30-01-2014/ 11:04	204.2 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:28	100.5 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:28	134.6 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:36	171.6 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:36	99.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:36	134.9 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Follow-Up	25-03-2014/ 9:33	99.4 (L, ncs)	-3.3	101.0 - 109.0
	Treatment Sequence 2	Erythrocytes (uL)	Screening	30-01-2014/ 11:08	10.00 (H, ncs)		0.00 - 5.00

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:17	10.00 (H, ncs)		0.00 - 5.00
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:18	136.3 (H, ncs)		28.0 - 100.0
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:11	10.00 (H, ncs)		0.00 - 5.00
		Amylase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:13	103.8 (H, ncs)		28.0 - 100.0
		Amylase (IU/L)	Follow-Up	25-03-2014/ 12:11	147.3 (H, ncs)	52.3	28.0 - 100.0
	Treatment Sequence 2	Erythrocytes (uL)	Screening	30-01-2014/ 11:27	10.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Screening	30-01-2014/ 11:30	61.8 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Screening	30-01-2014/ 11:30	98.9 (L, ncs)		101.0 - 109.0
		Platelets (10 <sup>9</sup> /L)	Screening	30-01-2014/ 11:30	127 (L, ncs)		155 - 342
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:29	25.00 (H, ncs)		0.00 - 5.00
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:32	126 (L, ncs)		155 - 342
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:28	61.8 (L, ncs)		62.7 - 150.8

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:28	21.1 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:28	96.8 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:28	3.9 (H, ncs)		0.0 - 3.4
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:28	141 (L, ncs)		155 - 342
		Thyroxine (nmol/L)	Follow-Up	28-03-2014/ 12:55	53.6 (L, ncs)	-15.3	62.7 - 150.8
		Bilirubin (umol/L)	Follow-Up	28-03-2014/ 12:55	21.1 (H, ncs)	7.5	5.0 - 21.0
		Chloride (mmol/L)	Follow-Up	28-03-2014/ 12:55	99.5 (L, ncs)	0.6	101.0 - 109.0
		Direct Bilirubin (umol/L)	Follow-Up	28-03-2014/ 12:55	3.6 (H, ncs)		0.0 - 3.4
		Sodium (mmol/L)	Follow-Up	28-03-2014/ 12:55	135.8 (L, ncs)	-0.6	136.0 - 146.0
		Platelets (10 <sup>9</sup> /L)	Follow-Up	28-03-2014/ 12:55	146 (L, ncs)	19	155 - 342
		Creatinine (umol/L)	Follow-Up	28-03-2014/ 12:55	52.5 (L, ncs)	-14	59.0 - 104.0
	Treatment Sequence 1	Urea (mmol/L)	Screening	30-01-2014/ 12:59	2.40 (L, ncs)		2.80 - 7.20

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Chloride (mmol/L)	Screening	30-01-2014/ 12:59	100.9 (L, ncs)		101.0 - 109.0
		Monocytes (10 <sup>9</sup> /L)	Screening	30-01-2014/ 12:59	0.27 (L, ncs)		0.30 - 0.92
		Sodium (mmol/L)	Screening	30-01-2014/ 12:59	135.4 (L, ncs)		136.0 - 146.0
		Basophils/Leukocytes (%)	Screening	30-01-2014/ 12:59	1.2 (H, ncs)		0.0 - 1.0
		pH	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:57	8.0 (H, ncs)		4.8 - 7.4
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	01-02-2014/ 8:59	135.6 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:19	25.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:22	577.2 (H, ncs)		0.0 - 171.0
		Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:22	4.2 (L, ncs)		5.0 - 21.0
		Triacylglycerol Lipase (IU/L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:22	71.5 (H, ncs)		0.0 - 67.0
		Basophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:22	0.08 (H, ncs)		0.01 - 0.07
		Basophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	09-03-2014/ 8:22	1.5 (H, ncs)		0.0 - 1.0

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

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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	09-03-2014/ 14:33	609.2 (H, ncs)		0.0 - 171.0
		pH	Follow-Up	26-03-2014/ 10:37	8.0 (H, ncs)	1	4.8 - 7.4
	Treatment Sequence 2	Erythrocytes (uL)	Screening	31-01-2014/ 8:29	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Screening	31-01-2014/ 8:29	6.00 (H, ncs)		0.00 - 3.00
		pH	Screening	31-01-2014/ 8:29	8.0 (H, ncs)		4.8 - 7.4
		pH	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:10	8.0 (H, ncs)		4.8 - 7.4
		Thyroxine (nmol/L)	Follow-Up	31-03-2014/ 10:48	58.9 (L, ncs)	-5.2	62.7 - 150.8
		Leukocytes (uL)	Follow-Up	31-03-2014/ 10:48	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 2	Chloride (mmol/L)	Screening	31-01-2014/ 11:06	99.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	31-01-2014/ 11:06	133.7 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:04	100.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:04	135.7 (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
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:05	52.4 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:05	97.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:05	134.3 (L, ncs)		136.0 - 146.0
		Basophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:05	0.09 (H, ncs)		0.01 - 0.07
		Basophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:05	1.6 (H, ncs)		0.0 - 1.0
		Thyroxine (nmol/L)	Follow-Up	28-03-2014/ 9:19	59.2 (L, ncs)	-4.3	62.7 - 150.8
		Sodium (mmol/L)	Follow-Up	28-03-2014/ 9:19	135.0 (L, ncs)	1.3	136.0 - 146.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	28-03-2014/ 9:19	60.2 (H, ncs)	13.6	0.0 - 55.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	09-04-2014/ 8:53	57.9 (H, ncs)	11.3	0.0 - 55.0
	Treatment Sequence 1	Erythrocytes (uL)	Screening	03-02-2014/ 10:19	10.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Screening	03-02-2014/ 10:20	146.0 (H, ncs)		0.0 - 145.0
		Erythrocytes (10 <sup>12</sup> /L)	Screening	03-02-2014/ 10:20	3.81 (L, ncs)		4.02 - 5.08

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Sodium (mmol/L)	Screening	03-02-2014/ 10:20	134.8 (L, ncs)		136.0 - 146.0
		Hematocrit (L/L)	Screening	03-02-2014/ 10:20	0.34 (L, ncs)		0.35 - 0.44
		Basophils/Leukocytes (%)	Screening	03-02-2014/ 10:20	0.1 (L, ncs)		0.2 - 1.3
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 8:06	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:21	50.00 (H, ncs)		0.00 - 5.00
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:23	98.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 9:23	135.2 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Follow-Up	28-03-2014/ 9:20	25.00 (H, ncs)	15	0.00 - 5.00
		Erythrocytes (/HPF)	Follow-Up	28-03-2014/ 9:20	15.00 (H, ncs)	15	0.00 - 3.00
		Thyroxine (nmol/L)	Follow-Up	28-03-2014/ 9:31	60.5 (L, ncs)	-3.3	62.7 - 150.8
		Erythrocytes (10 <sup>12</sup> /L)	Follow-Up	28-03-2014/ 9:31	3.92 (L, ncs)	0.11	4.02 - 5.08
		Sodium (mmol/L)	Follow-Up	28-03-2014/ 9:31	135.3 (L, ncs)	0.5	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
1342/271	Treatment Sequence 1	Neutrophils (10 <sup>9</sup> /L)	Screening	03-02-2014/ 11:50	6.59 (H, ncs)		1.61 - 6.45
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 7:54	10.00 (H, ncs)		0.00 - 5.00
		Glucose (mmol/L)	Period 1, Day -1/ 24 H Predose	05-02-2014/ 7:56	4.06 (L, ncs)		4.10 - 5.90
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	13-03-2014/ 8:22	40.5 (H, ncs)		0.0 - 35.0
		Sodium (mmol/L)	Follow-Up	28-03-2014/ 12:17	135.0 (L, ncs)	-1.6	136.0 - 146.0
	Treatment Sequence 2	Urea (mmol/L)	Screening	05-02-2014/ 8:29	2.06 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Screening	05-02-2014/ 8:29	97.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	05-02-2014/ 8:29	133.1 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 8:45	99.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 8:45	134.0 (L, ncs)		136.0 - 146.0
		pH	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:13	8.0 (H, ncs)		4.8 - 7.4
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:15	2.72 (L, ncs)		2.80 - 7.20

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:15	98.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:15	134.6 (L, ncs)		136.0 - 146.0
		pH	Follow-Up	11-04-2014/ 8:46	8.0 (H, ncs)	1	4.8 - 7.4
		Urea (mmol/L)	Follow-Up	11-04-2014/ 8:49	2.61 (L, ncs)	0.55	2.80 - 7.20
		Chloride (mmol/L)	Follow-Up	11-04-2014/ 8:49	99.2 (L, ncs)	1.8	101.0 - 109.0
	Treatment Sequence 2	Thyroxine (nmol/L)	Screening	05-02-2014/ 9:15	62.2 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Screening	05-02-2014/ 9:15	178.7 (H, ncs)		0.0 - 171.0
		Ketones (mmol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:40	0.5 (H, ncs)		0.0 - 0.5
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:28	354 (H, ncs)		155 - 342
	Treatment Sequence 2	Erythrocytes (uL)	Screening	05-02-2014/ 9:21	10.00 (H, ncs)		0.00 - 5.00
		Glucose (mmol/L)	Screening	05-02-2014/ 9:26	3.76 (L, ncs)		4.10 - 5.90
		Eosinophils (10 <sup>9</sup> /L)	Screening	05-02-2014/ 9:26	0.52 (H, ncs)		0.03 - 0.50

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Eosinophils/Leukocytes (%)	Screening	05-02-2014/ 9:26	8.6 (H, ncs)		0.6 - 8.4
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:42	25.00 (H, ncs)		0.00 - 5.00
		Eosinophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:44	9.7 (H, ncs)		0.6 - 8.4
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:11	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:11	8.00 (H, ncs)		0.00 - 3.00
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:18	54.3 (L, ncs)		62.7 - 150.8
		Eosinophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:18	9.8 (H, ncs)		0.6 - 8.4
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 15:37	10.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 15:54	59.5 (L, ncs)		62.7 - 150.8
		Erythrocytes (uL)	Follow-Up	03-04-2014/ 11:32	10.00 (H, ncs)	0	0.00 - 5.00
		pH	Follow-Up	03-04-2014/ 11:32	8.0 (H, ncs)	1	4.8 - 7.4
		Chloride (mmol/L)	Follow-Up	03-04-2014/ 11:37	100.3 (L, ncs)	-0.9	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
		Eosinophils/Leukocytes (%)	Follow-Up	03-04-2014/ 11:37	9.5 (H, ncs)	0.9	0.6 - 8.4
	Treatment Sequence 2	Urea (mmol/L)	Screening	05-02-2014/ 10:24	2.75 (L, ncs)		2.80 - 7.20
		Bilirubin (umol/L)	Screening	05-02-2014/ 10:24	21.4 (H, ncs)		5.0 - 21.0
		Indirect Bilirubin (umol/L)	Screening	05-02-2014/ 10:24	18.4 (H, ncs)		1.6 - 17.6
		Erythrocytes (10 <sup>12</sup> /L)	Screening	05-02-2014/ 10:24	5.13 (H, ncs)		4.02 - 5.08
		Bacteria	Period 2, Day -1/ 24 H Predose	19-03-2014/ 7:33	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 7:33	18.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 7:33	100.00 (H, ncs)		0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 7:33	25 (H, ncs)		0 - 15
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 7:36	2.60 (L, ncs)		2.80 - 7.20
		Lymphocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 7:36	14.7 (L, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 7:36	75.5 (H, ncs)		37.9 - 70.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 15:39	36.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 15:39	100.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Follow-Up	03-04-2014/ 10:44	10.00 (H, ncs)	10	0.00 - 5.00
		Bacteria	Follow-Up	03-04-2014/ 10:44	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Follow-Up	03-04-2014/ 10:44	40.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	03-04-2014/ 10:44	500.00 (H, ncs)	500	0.00 - 9.00
		pH	Follow-Up	03-04-2014/ 10:44	8.0 (H, ncs)	1	4.8 - 7.4
		Leukocytes (/HPF)	Follow-Up	09-04-2014/ 10:33	7.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	09-04-2014/ 10:33	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 2	Sodium (mmol/L)	Screening	05-02-2014/ 11:43	135.8 (L, ncs)		136.0 - 146.0
		Platelets (10 <sup>9</sup> /L)	Screening	05-02-2014/ 11:43	411 (H, ncs)		173 - 369
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:47	4.3 (L, 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
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:47	99.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:47	131.4 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:47	257.2 (H, ncs)		0.0 - 145.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:47	100.0 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:47	133.1 (L, ncs)		136.0 - 146.0
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:47	371 (H, ncs)		173 - 369
		Hematocrit (L/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:47	0.34 (L, ncs)		0.35 - 0.44
		Chloride (mmol/L)	Follow-Up	03-04-2014/ 11:14	100.0 (L, ncs)	-2.7	101.0 - 109.0
		Sodium (mmol/L)	Follow-Up	03-04-2014/ 11:14	131.7 (L, ncs)	-4.1	136.0 - 146.0
		Platelets (10 <sup>9</sup> /L)	Follow-Up	03-04-2014/ 11:14	411 (H, ncs)	0	173 - 369
		Hematocrit (L/L)	Follow-Up	03-04-2014/ 11:14	0.33 (L, ncs)	-0.02	0.35 - 0.44
		Hemoglobin (g/L)	Follow-Up	03-04-2014/ 11:14	103 (L, ncs)	-8	111 - 146

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	Chloride (mmol/L)	Screening	06-02-2014/ 10:18	99.4 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:49	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:49	25.00 (H, ncs)		0.00 - 9.00
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:51	100.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:51	135.5 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:09	10.00 (H, ncs)		0.00 - 5.00
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:11	64.4 (L, ncs)		66.0 - 83.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 9:11	135.7 (L, ncs)		136.0 - 146.0
	Treatment Sequence 1	Urea (mmol/L)	Screening	07-02-2014/ 9:56	1.83 (L, ncs)		2.80 - 7.20
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:32	176.2 (H, ncs)		0.0 - 171.0
		Urea (mmol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:32	2.26 (L, ncs)		2.80 - 7.20
		Creatinine (umol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:32	55.4 (L, ncs)		59.0 - 104.0

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
		Creatinine (umol/L)	Period 2, Day -1/ 24 H Predose	19-03-2014/ 8:18	58.7 (L, ncs)		59.0 - 104.0
		Chloride (mmol/L)	Follow-Up	03-04-2014/ 11:15	100.3 (L, ncs)	-2.5	101.0 - 109.0
		Glucose (mmol/L)	Follow-Up	03-04-2014/ 11:15	4.02 (L, ncs)	-0.09	4.10 - 5.90
		Creatinine (umol/L)	Follow-Up	03-04-2014/ 11:15	55.7 (L, ncs)	-3.7	59.0 - 104.0
	Treatment Sequence 2	Glucose (mmol/L)	Screening	10-02-2014/ 10:34	4.01 (L, ncs)		4.10 - 5.90
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	11-02-2014/ 8:38	25.0 (H, ncs)		0.0 - 3.4
		pH	Follow-Up	04-04-2014/ 10:20	8.0 (H, ncs)	1.5	4.8 - 7.4
		Bilirubin (umol/L)	Follow-Up	04-04-2014/ 10:22	23.7 (H, ncs)	5.7	5.0 - 21.0
		Chloride (mmol/L)	Follow-Up	04-04-2014/ 10:22	100.5 (L, ncs)	-4.1	101.0 - 109.0
		Direct Bilirubin (umol/L)	Follow-Up	04-04-2014/ 10:22	5.0 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	04-04-2014/ 10:22	18.7 (H, ncs)		1.6 - 17.6
	Treatment Sequence 2	Erythrocytes (uL)	Screening	10-02-2014/ 10:42	10.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Glucose (mmol/L)	Screening	10-02-2014/ 10:45	3.87 (L, ncs)		4.10 - 5.90
		Platelets (10 <sup>9</sup> /L)	Screening	10-02-2014/ 10:45	142 (L, ncs)		173 - 369
		Eosinophils (10 <sup>9</sup> /L)	Screening	10-02-2014/ 10:45	0.03 (L, ncs)		0.04 - 0.43
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:17	250.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:17	8.00 (H, ncs)		0.00 - 3.00
		Monocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:19	0.24 (L, ncs)		0.27 - 0.91
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:19	126 (L, ncs)		173 - 369
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:30	143 (L, ncs)		173 - 369
		Monocytes (10 <sup>9</sup> /L)	Follow-Up	07-04-2014/ 10:09	0.25 (L, ncs)	-0.04	0.27 - 0.91
		Sodium (mmol/L)	Follow-Up	07-04-2014/ 10:09	135.5 (L, ncs)	-5.4	136.0 - 146.0
		Platelets (10 <sup>9</sup> /L)	Follow-Up	07-04-2014/ 10:09	131 (L, ncs)	-11	173 - 369
		Eosinophils (10 <sup>9</sup> /L)	Follow-Up	07-04-2014/ 10:09	0.03 (L, ncs)	0	0.04 - 0.43

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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
		Thyrotropin (mIU/L)	Follow-Up	07-04-2014/ 10:09	0.32 (L, ncs)	-0.92	0.35 - 4.94
	Treatment Sequence 2	Bilirubin (umol/L)	Screening	10-02-2014/ 12:23	21.6 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	10-02-2014/ 12:23	4.4 (H, ncs)		0.0 - 3.4
		Protein (g/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:33	65.6 (L, ncs)		66.0 - 83.0
		Thyroxine (nmol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:33	58.4 (L, ncs)		62.7 - 150.8
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 8:14	58.7 (L, ncs)		62.7 - 150.8
		Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 8:14	23.2 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 8:14	4.3 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 8:14	18.9 (H, ncs)		1.6 - 17.6
		Protein (g/L)	Follow-Up	08-04-2014/ 9:35	57.5 (L, ncs)	-10.5	66.0 - 83.0
		Creatine Kinase (IU/L)	Follow-Up	08-04-2014/ 9:35	180.0 (H, ncs)	72.8	0.0 - 171.0
		Bilirubin (umol/L)	Follow-Up	08-04-2014/ 9:35	27.7 (H, ncs)	6.1	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
7	Treatment Sequence 1	Direct Bilirubin (umol/L)	Follow-Up	08-04-2014/ 9:35	5.1 (H, ncs)	0.7	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	08-04-2014/ 9:35	22.6 (H, ncs)	5.4	1.6 - 17.6
		Platelets (10 <sup>9</sup> /L)	Follow-Up	08-04-2014/ 9:35	153 (L, ncs)	-15	155 - 342
		Creatine Kinase (IU/L)	Screening	11-02-2014/ 11:17	198.5 (H, ncs)		0.0 - 145.0
		Chloride (mmol/L)	Screening	11-02-2014/ 11:17	99.3 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	11-02-2014/ 11:17	133.1 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:37	100.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:37	132.1 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Follow-Up	07-04-2014/ 9:29	99.5 (L, ncs)	0.2	101.0 - 109.0
		Sodium (mmol/L)	Follow-Up	07-04-2014/ 9:29	133.6 (L, ncs)	0.5	136.0 - 146.0
		Basophils (10 <sup>9</sup> /L)	Follow-Up	07-04-2014/ 9:29	0.10 (H, ncs)	0.04	0.01 - 0.07
		Basophils/Leukocytes (%)	Follow-Up	07-04-2014/ 9:29	1.4 (H, ncs)	0.6	0.2 - 1.3

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Leukocytes (uL)	Follow-Up	07-04-2014/ 9:30	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 1	Leukocytes (10 <sup>9</sup> /L)	Screening	13-02-2014/ 8:04	3.46 (L, ncs)		3.69 - 10.04
		Neutrophils (10 <sup>9</sup> /L)	Screening	13-02-2014/ 8:04	1.52 (L, ncs)		1.61 - 6.45
		Monocytes/Leukocytes (%)	Screening	13-02-2014/ 8:04	20.5 (H, ncs)		5.3 - 14.2
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:26	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:26	5.00 (H, ncs)		0.00 - 3.00
		Neutrophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:29	1.55 (L, ncs)		1.61 - 6.45
		Erythrocytes (uL)	Follow-Up	07-04-2014/ 8:19	150.00 (H, ncs)	150	0.00 - 5.00
		Erythrocytes (/HPF)	Follow-Up	07-04-2014/ 8:19	12.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPF)	Follow-Up	07-04-2014/ 8:19	6.00 (H, ncs)		0.00 - 4.00
		Creatine Kinase (IU/L)	Follow-Up	07-04-2014/ 8:24	147.5 (H, ncs)	5.6	0.0 - 145.0
		Erythrocytes (10 <sup>12</sup> /L)	Follow-Up	07-04-2014/ 8:24	3.87 (L, ncs)	-0.3	4.02 - 5.08

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Hematocrit (L/L)	Follow-Up	07-04-2014/ 8:24	0.34 (L, ncs)	-0.02	0.35 - 0.44
	Treatment Sequence 1	Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:18	61.4 (L, ncs)		62.7 - 150.8
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	13-02-2014/ 11:07	275.7 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	13-02-2014/ 11:07	97.4 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	13-02-2014/ 11:07	3.76 (L, ncs)		4.10 - 5.90
		Erythrocytes (10 <sup>12</sup> /L)	Screening	13-02-2014/ 11:07	5.76 (H, ncs)		4.12 - 5.74
		Sodium (mmol/L)	Screening	13-02-2014/ 11:07	134.8 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:24	472.9 (H, ncs)		0.0 - 171.0
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:24	22.4 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:24	4.7 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:24	17.7 (H, ncs)		1.6 - 17.6
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 18:49	401.3 (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
		Opiate	Period 2, Day -1/ 24 H Predose	24-03-2014/ 7:55	POSITIVE (H, ncs)		
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 7:58	221.9 (H, ncs)		0.0 - 171.0
		Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 7:58	24.8 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 7:58	100.0 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 7:58	4.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 7:58	20.3 (H, ncs)		1.6 - 17.6
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 7:58	64.6 (H, ncs)		0.0 - 50.0
		Creatine Kinase (IU/L)	Follow-Up	02-05-2014/ 11:21	443.2 (H, ncs)	167.5	0.0 - 171.0
		Bilirubin (umol/L)	Follow-Up	02-05-2014/ 11:21	29.4 (H, ncs)	9	5.0 - 21.0
		Chloride (mmol/L)	Follow-Up	02-05-2014/ 11:21	97.2 (L, ncs)	-0.2	101.0 - 109.0
		Direct Bilirubin (umol/L)	Follow-Up	02-05-2014/ 11:21	5.6 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	02-05-2014/ 11:21	23.8 (H, ncs)		1.6 - 17.6

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (10 <sup>12</sup> /L)	Follow-Up	02-05-2014/ 11:21	5.89 (H, ncs)	0.13	4.12 - 5.74
		Hematocrit (L/L)	Follow-Up	02-05-2014/ 11:21	0.49 (H, ncs)	0.01	0.38 - 0.48
		Hemoglobin (g/L)	Follow-Up	02-05-2014/ 11:21	166 (H, ncs)	2	126 - 165
		Alanine Aminotransferase (U/L)	Follow-Up	02-05-2014/ 11:21	61.4 (H, ncs)	18	0.0 - 50.0
	Treatment Sequence 1	Urea (mmol/L)	Screening	14-02-2014/ 7:50	2.04 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Screening	14-02-2014/ 7:50	97.1 (L, ncs)		101.0 - 109.0
		Platelets (10 <sup>9</sup> /L)	Screening	14-02-2014/ 7:50	362 (H, ncs)		155 - 342
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 7:39	107.2 (H, ncs)		28.0 - 100.0
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 7:39	349 (H, ncs)		155 - 342
		pH	Period 2, Day -1/ 24 H Predose	28-03-2014/ 7:59	8.0 (H, ncs)		4.8 - 7.4
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:01	62.5 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:01	183.6 (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
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:01	100.3 (L, ncs)		101.0 - 109.0
		Amylase (IU/L)	Follow-Up	15-04-2014/ 8:13	131.9 (H, ncs)	32.6	28.0 - 100.0
		Thyroxine (nmol/L)	Follow-Up	15-04-2014/ 8:13	60.2 (L, ncs)	-9.4	62.7 - 150.8
		Potassium (mmol/L)	Follow-Up	15-04-2014/ 8:13	5.11 (H, ncs)	0.5	3.50 - 5.10
	Treatment Sequence 2	Urea (mmol/L)	Screening	14-02-2014/ 8:47	2.49 (L, ncs)		2.80 - 7.20
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 8:40	175.0 (H, ncs)		0.0 - 145.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 8:40	100.8 (L, ncs)		101.0 - 109.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 16:48	169.0 (H, ncs)		0.0 - 145.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 9:39	98.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 9:39	134.0 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Follow-Up	17-04-2014/ 11:20	224.6 (H, ncs)	109.8	0.0 - 145.0
		Creatine Kinase (IU/L)	Follow-Up	24-04-2014/ 11:04	181.2 (H, ncs)	66.4	0.0 - 145.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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	Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:42	0.52 (H, ncs)		0.03 - 0.50
		Chloride (mmol/L)	Follow-Up	10-04-2014/ 9:04	100.5 (L, ncs)	-1.6	101.0 - 109.0
		Eosinophils (10 <sup>9</sup> /L)	Follow-Up	10-04-2014/ 9:04	0.51 (H, ncs)	0.02	0.03 - 0.50
	Treatment Sequence 2	Chloride (mmol/L)	Screening	14-02-2014/ 9:50	96.7 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	14-02-2014/ 9:50	133.2 (L, ncs)		136.0 - 146.0
		Basophils (10 <sup>9</sup> /L)	Screening	14-02-2014/ 9:50	0.00 (L, ncs)		0.01 - 0.07
		Eosinophils (10 <sup>9</sup> /L)	Screening	14-02-2014/ 9:50	0.00 (L, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Screening	14-02-2014/ 9:50	0.0 (L, ncs)		0.6 - 7.9
		Basophils/Leukocytes (%)	Screening	14-02-2014/ 9:50	0.0 (L, ncs)		0.2 - 1.3
		Protein (g/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:15	65.6 (L, ncs)		66.0 - 83.0
		Lymphocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:15	0.86 (L, ncs)		0.99 - 2.89
		Monocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:15	0.26 (L, ncs)		0.27 - 0.91

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	16-02-2014/ 8:15	71.6 (H, ncs)		37.9 - 70.5
		Basophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:15	0.00 (L, ncs)		0.01 - 0.07
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:15	0.00 (L, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:15	0.0 (L, ncs)		0.6 - 7.9
		Basophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:15	0.0 (L, ncs)		0.2 - 1.3
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	65.2 (L, ncs)		66.0 - 83.0
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	58.4 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	99.0 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	135.5 (L, ncs)		136.0 - 146.0
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	73.8 (H, ncs)		37.9 - 70.5
		Basophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	0.00 (L, ncs)		0.01 - 0.07
		Eosinophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	0.01 (L, ncs)		0.04 - 0.43

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Eosinophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	0.2 (L, ncs)		0.6 - 7.9
		Basophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 10:39	0.0 (L, ncs)		0.2 - 1.3
		Protein (g/L)	Follow-Up	07-04-2014/ 7:23	63.4 (L, ncs)	-3.5	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	07-04-2014/ 7:23	52.1 (L, ncs)	-16.3	62.7 - 150.8
		Chloride (mmol/L)	Follow-Up	07-04-2014/ 7:23	100.5 (L, ncs)	3.8	101.0 - 109.0
		Erythrocytes (10 <sup>12</sup> /L)	Follow-Up	07-04-2014/ 7:23	3.71 (L, ncs)	-0.38	4.02 - 5.08
		Sodium (mmol/L)	Follow-Up	07-04-2014/ 7:23	135.1 (L, ncs)	1.9	136.0 - 146.0
		Basophils (10 <sup>9</sup> /L)	Follow-Up	07-04-2014/ 7:23	0.00 (L, ncs)	0	0.01 - 0.07
		Eosinophils (10 <sup>9</sup> /L)	Follow-Up	07-04-2014/ 7:23	0.01 (L, ncs)	0.01	0.04 - 0.43
		Eosinophils/Leukocytes (%)	Follow-Up	07-04-2014/ 7:23	0.2 (L, ncs)	0.2	0.6 - 7.9
		Basophils/Leukocytes (%)	Follow-Up	07-04-2014/ 7:23	0.0 (L, ncs)	0	0.2 - 1.3
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	14-02-2014/ 9:49	257.0 (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
		Bilirubin (umol/L)	Screening	14-02-2014/ 9:49	22.9 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	14-02-2014/ 9:49	4.2 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	14-02-2014/ 9:49	18.7 (H, ncs)		1.6 - 17.6
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-02-2014/ 8:05	257.1 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 9:25	328.3 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-03-2014/ 16:16	298.7 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Follow-Up	08-04-2014/ 9:21	342.3 (H, ncs)	85.3	0.0 - 171.0
		Monocytes/Leukocytes (%)	Follow-Up	08-04-2014/ 9:21	4.9 (L, ncs)	-4.3	5.6 - 14.8
		Monocytes (10 <sup>9</sup> /L)	Follow-Up	08-04-2014/ 9:21	0.28 (L, ncs)	-0.26	0.30 - 0.92
	Treatment Sequence 1	Chloride (mmol/L)	Screening	17-02-2014/ 9:06	100.7 (L, ncs)		101.0 - 109.0
		Neutrophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 9:07	1.32 (L, ncs)		1.46 - 5.85
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 9:07	100.6 (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
		Monocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 9:07	15.9 (H, ncs)		5.6 - 14.8
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 9:07	35.8 (L, ncs)		38.2 - 71.5
		Thyroxine (nmol/L)	Follow-Up	15-04-2014/ 8:52	56.4 (L, ncs)	-16.6	62.7 - 150.8
	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	17-02-2014/ 10:24	206.1 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	17-02-2014/ 10:24	96.2 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	17-02-2014/ 10:24	135.2 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:57	99.3 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:57	135.8 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:02	98.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:02	135.9 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Follow-Up	29-04-2014/ 8:27	100.4 (L, ncs)	4.2	101.0 - 109.0
		Triiodothyronine, Free (pmol/L)	Follow-Up	29-04-2014/ 8:27	5.84 (H, ncs)	0.48	2.63 - 5.70

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 2	Erythrocytes (uL)	Screening	17-02-2014/ 10:48	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Screening	17-02-2014/ 10:48	6.00 (H, ncs)		0.00 - 3.00
		Protein (g/L)	Screening	17-02-2014/ 10:51	63.4 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Screening	17-02-2014/ 10:51	151.6 (H, ncs)		0.0 - 145.0
		Monocytes/Leukocytes (%)	Screening	17-02-2014/ 10:51	4.7 (L, ncs)		5.3 - 14.2
		Neutrophils/Leukocytes (%)	Screening	17-02-2014/ 10:51	75.0 (H, ncs)		37.9 - 70.5
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:38	10.00 (H, ncs)		0.00 - 5.00
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:49	135.6 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:30	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:30	4.00 (H, ncs)		0.00 - 3.00
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:35	59.9 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:35	170.4 (H, ncs)		0.0 - 145.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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	11-04-2014/ 17:11	150.0 (H, ncs)		0.0 - 145.0
		Erythrocytes (uL)	Follow-Up	29-04-2014/ 10:33	10.00 (H, ncs)	-15	0.00 - 5.00
		Creatine Kinase (IU/L)	Follow-Up	29-04-2014/ 10:35	188.6 (H, ncs)	37	0.0 - 145.0
	Treatment Sequence 1	Chloride (mmol/L)	Screening	17-02-2014/ 11:46	98.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	17-02-2014/ 11:46	134.9 (L, ncs)		136.0 - 146.0
		pH	Screening	17-02-2014/ 11:46	8.0 (H, ncs)		4.8 - 7.4
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 7:44	99.3 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 7:44	135.7 (L, ncs)		136.0 - 146.0
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:53	57.1 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:53	195.2 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:53	98.1 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:53	134.4 (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
		Thyroxine (nmol/L)	Follow-Up	15-04-2014/ 10:09	55.5 (L, ncs)	-13.8	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	15-04-2014/ 10:09	202.3 (H, ncs)	36	0.0 - 171.0
		Chloride (mmol/L)	Follow-Up	15-04-2014/ 10:09	99.7 (L, ncs)	1.1	101.0 - 109.0
		Creatine Kinase (IU/L)	Follow-Up	22-04-2014/ 9:41	209.8 (H, ncs)	43.5	0.0 - 171.0
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	18-02-2014/ 11:20	198.1 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Screening	18-02-2014/ 11:20	99.7 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	18-02-2014/ 11:20	135.9 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 7:59	99.4 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	20-02-2014/ 7:59	135.8 (L, ncs)		136.0 - 146.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	28-03-2014/ 8:48	100.7 (L, ncs)		101.0 - 109.0
		Creatine Kinase (IU/L)	Follow-Up	15-04-2014/ 10:12	207.2 (H, ncs)	9.1	0.0 - 171.0
	Treatment Sequence 1	Amylase (IU/L)	Screening	20-02-2014/ 7:35	103.6 (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
		Leukocytes (10 <sup>9</sup> /L)	Screening	20-02-2014/ 7:35	2.68 (L, ncs)		3.19 - 8.71
		Neutrophils (10 <sup>9</sup> /L)	Screening	20-02-2014/ 7:35	1.30 (L, ncs)		1.46 - 5.85
		Lymphocytes (10 <sup>9</sup> /L)	Screening	20-02-2014/ 7:35	1.03 (L, ncs)		1.08 - 3.00
		Monocytes (10 <sup>9</sup> /L)	Screening	20-02-2014/ 7:35	0.22 (L, ncs)		0.30 - 0.92
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 9:25	107.0 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 9:25	172.3 (H, ncs)		0.0 - 171.0
		Potassium (mmol/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 9:25	5.28 (H, ncs)		3.50 - 5.10
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 18:13	110.7 (H, ncs)		28.0 - 100.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 18:13	185.8 (H, ncs)		0.0 - 171.0
		Lymphocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:08	1.00 (L, ncs)		1.08 - 3.00
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:08	135.1 (L, ncs)		136.0 - 146.0
		Amylase (IU/L)	Follow-Up	24-04-2014/ 8:20	106.0 (H, ncs)	2.4	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	24-04-2014/ 8:20	174.9 (H, ncs)	36.2	0.0 - 171.0
	Treatment Sequence 1	Urea (mmol/L)	Screening	20-02-2014/ 8:25	2.79 (L, ncs)		2.80 - 7.20
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:52	0.03 (L, ncs)		0.04 - 0.43
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:16	10.00 (H, ncs)		0.00 - 5.00
		pH	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:16	8.0 (H, ncs)		4.8 - 7.4
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:18	2.55 (L, ncs)		2.80 - 7.20
		Basophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:18	0.1 (L, ncs)		0.2 - 1.3
		Basophils/Leukocytes (%)	Follow-Up	30-04-2014/ 7:29	0.1 (L, ncs)	-0.1	0.2 - 1.3
	Treatment Sequence 2	Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:18	246.6 (H, ncs)		0.0 - 171.0
		Creatine Kinase MB (IU/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:18	24.8 (H, ncs)		0.0 - 24.0
		Lactate Dehydrogenase (IU/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:18	288.7 (H, ncs)		0.0 - 248.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 18:18	176.3 (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
	Treatment Sequence 2	Amylase (IU/L)	Screening	21-02-2014/ 8:01	100.4 (H, ncs)		28.0 - 100.0
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:23	102.9 (H, ncs)		28.0 - 100.0
		Amylase (IU/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 8:52	101.5 (H, ncs)		28.0 - 100.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 8:52	99.8 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 8:52	135.5 (L, ncs)		136.0 - 146.0
		Amylase (IU/L)	Follow-Up	23-04-2014/ 8:01	109.0 (H, ncs)	8.6	28.0 - 100.0
	Treatment Sequence 1	Neutrophils (10 <sup>9</sup> /L)	Screening	24-02-2014/ 9:25	1.31 (L, ncs)		1.46 - 5.85
		Chloride (mmol/L)	Screening	24-02-2014/ 9:25	100.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	24-02-2014/ 9:25	135.2 (L, ncs)		136.0 - 146.0
		Neutrophils/Leukocytes (%)	Screening	24-02-2014/ 9:25	37.9 (L, ncs)		38.2 - 71.5
		Ketones (mmol/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:55	0.5 (H, ncs)		0.0 - 0.5
	Treatment Sequence 1	Sodium (mmol/L)	Screening	24-02-2014/ 10:02	135.4 (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
		Leukocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:05	3.11 (L, ncs)		3.19 - 8.71
		Neutrophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:05	1.10 (L, ncs)		1.46 - 5.85
		Neutrophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:05	35.4 (L, ncs)		38.2 - 71.5
		Eosinophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:05	9.3 (H, ncs)		0.6 - 8.4
		Monocytes/Leukocytes (%)	Follow-Up	24-04-2014/ 7:11	16.2 (H, ncs)	3.1	5.6 - 14.8
	Treatment Sequence 1	Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 9:43	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 1	Thyroxine (nmol/L)	Screening	26-02-2014/ 8:23	60.9 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Screening	26-02-2014/ 8:23	223.7 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Screening	05-03-2014/ 7:33	258.7 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:12	250.7 (H, ncs)		0.0 - 171.0
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:12	68 (L, ncs)		155 - 342
		Hematocrit (L/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:12	0.37 (L, ncs)		0.38 - 0.48

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
		Hemoglobin (g/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:12	125 (L, ncs)		126 - 165
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 9:53	178.0 (H, ncs)		0.0 - 171.0
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 9:53	350 (H, ncs)		155 - 342
		Thyroxine (nmol/L)	Follow-Up	07-05-2014/ 8:29	58.8 (L, ncs)	-10.5	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	07-05-2014/ 8:29	195.9 (H, ncs)	-62.8	0.0 - 171.0
	Treatment Sequence 1	Chloride (mmol/L)	Screening	26-02-2014/ 8:32	99.3 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	26-02-2014/ 8:32	135.7 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 8:22	201.1 (H, ncs)		0.0 - 171.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 8:22	100.5 (L, ncs)		101.0 - 109.0
		Monocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 8:22	0.93 (H, ncs)		0.30 - 0.92
		Creatine Kinase (IU/L)	Follow-Up	05-05-2014/ 10:03	181.1 (H, ncs)	23.5	0.0 - 171.0
		Platelets (10 <sup>9</sup> /L)	Follow-Up	05-05-2014/ 10:03	129 (L, ncs)	-42	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
	Treatment Sequence 2	Chloride (mmol/L)	Screening	26-02-2014/ 8:42	100.7 (L, ncs)		101.0 - 109.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:08	99.0 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:08	132.8 (L, ncs)		136.0 - 146.0
		Erythrocytes (uL)	Follow-Up	23-04-2014/ 10:42	10.00 (H, ncs)	10	0.00 - 5.00
	Treatment Sequence 2	Alkaline Phosphatase (U/L)	Screening	26-02-2014/ 8:56	28.6 (L, ncs)		30.0 - 120.0
		Glucose (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:28	6.00 (H, ncs)		0.00 - 1.69
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:32	97.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:32	130.3 (L, ncs)		136.0 - 146.0
		Hematocrit (L/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:32	0.34 (L, ncs)		0.35 - 0.44
		Alkaline Phosphatase (U/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:32	28.6 (L, ncs)		30.0 - 120.0
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:06	2.64 (L, ncs)		2.80 - 7.20
		Hematocrit (L/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:06	0.34 (L, ncs)		0.35 - 0.44

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
		Hemoglobin (g/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:06	108 (L, ncs)		111 - 146
		Thyroxine (nmol/L)	Follow-Up	28-04-2014/ 9:30	62.2 (L, ncs)	-3.3	62.7 - 150.8
		Urea (mmol/L)	Follow-Up	28-04-2014/ 9:30	2.76 (L, ncs)	-1.04	2.80 - 7.20
		Hematocrit (L/L)	Follow-Up	28-04-2014/ 9:30	0.32 (L, ncs)	-0.04	0.35 - 0.44
		Hemoglobin (g/L)	Follow-Up	28-04-2014/ 9:30	100 (L, ncs)	-15	111 - 146
	Treatment Sequence 1	Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:35	134.5 (L, ncs)		136.0 - 146.0
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:13	65.8 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:13	2.73 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:13	99.1 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:13	132.9 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Follow-Up	30-04-2014/ 10:24	436.5 (H, ncs)	330.1	0.0 - 171.0
		Chloride (mmol/L)	Follow-Up	30-04-2014/ 10:24	100.6 (L, ncs)	-0.4	101.0 - 109.0

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Sodium (mmol/L)	Follow-Up	30-04-2014/ 10:24	135.3 (L, ncs)	-0.9	136.0 - 146.0
	Treatment Sequence 2	Chloride (mmol/L)	Screening	26-02-2014/ 10:56	100.5 (L, ncs)		101.0 - 109.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:21	100.2 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:21	135.6 (L, ncs)		136.0 - 146.0
	Treatment Sequence 2	Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:47	25.00 (H, ncs)		0.00 - 9.00
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:49	100.5 (H, ncs)		28.0 - 100.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:25	98.2 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:25	133.2 (L, ncs)		136.0 - 146.0
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:25	46.1 (H, ncs)		0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:25	38.6 (H, ncs)		0.0 - 35.0
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 18:11	41.1 (H, ncs)		0.0 - 35.0
		Leukocytes (uL)	Follow-Up	23-04-2014/ 12:20	25.00 (H, ncs)	25	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
/	Treatment Sequence 1	Alanine Aminotransferase (U/L)	Follow-Up	23-04-2014/ 12:22	46.5 (H, ncs)	24.4	0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Follow-Up	23-04-2014/ 12:22	36.6 (H, ncs)	14.2	0.0 - 35.0
		Protein (g/L)	Screening	27-02-2014/ 8:37	65.0 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Screening	27-02-2014/ 8:37	2.61 (L, ncs)		2.80 - 7.20
		Hematocrit (L/L)	Screening	27-02-2014/ 8:37	0.32 (L, ncs)		0.35 - 0.44
		Hemoglobin (g/L)	Screening	27-02-2014/ 8:37	101 (L, ncs)		111 - 146
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:31	132.3 (L, ncs)		136.0 - 146.0
		Hematocrit (L/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:31	0.34 (L, ncs)		0.35 - 0.44
		Hemoglobin (g/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:31	105 (L, ncs)		111 - 146
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:34	132.7 (L, ncs)		136.0 - 146.0
		Hematocrit (L/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:34	0.33 (L, ncs)		0.35 - 0.44
		Hemoglobin (g/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:34	104 (L, ncs)		111 - 146

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
		Hematocrit (L/L)	Follow-Up	23-04-2014/ 9:34	0.31 (L, ncs)	-0.01	0.35 - 0.44
		Hemoglobin (g/L)	Follow-Up	23-04-2014/ 9:34	96 (L, ncs)	-5	111 - 146
		Thyrotropin (mU/L)	Follow-Up	23-04-2014/ 9:34	0.01 (L, ncs)	-1.19	0.35 - 4.94
		Triiodothyronine, Free (pmol/L)	Follow-Up	23-04-2014/ 9:34	6.94 (H, ncs)	3.87	2.63 - 5.70
		Thyroxine, Free (pmol/L)	Follow-Up	23-04-2014/ 9:34	25.13 (H, ncs)	12.13	9.01 - 19.05
		Thyrotropin (mU/L)	Follow-Up	30-04-2014/ 10:17	0.01 (L, ncs)	-1.19	0.35 - 4.94
		Triiodothyronine, Free (pmol/L)	Follow-Up	30-04-2014/ 10:17	6.53 (H, ncs)	3.46	2.63 - 5.70
		Thyroxine, Free (pmol/L)	Follow-Up	30-04-2014/ 10:17	25.00 (H, ncs)	12	9.01 - 19.05
		Thyrotropin (mU/L)	Follow-Up	08-05-2014/ 8:23	0.01 (L, ncs)	-1.19	0.35 - 4.94
		Triiodothyronine, Free (pmol/L)	Follow-Up	08-05-2014/ 8:23	6.02 (H, ncs)	2.95	2.63 - 5.70
		Thyroxine, Free (pmol/L)	Follow-Up	08-05-2014/ 8:23	22.73 (H, ncs)	9.73	9.01 - 19.05
		Thyrotropin (mU/L)	Follow-Up	12-05-2014/ 10:24	0.01 (L, ncs)	-1.19	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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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
		Triiodothyronine, Free (pmol/L)	Follow-Up	12-05-2014/ 10:24	5.84 (H, ncs)	2.77	2.63 - 5.70
		Thyroxine, Free (pmol/L)	Follow-Up	12-05-2014/ 10:24	19.88 (H, ncs)	6.88	9.01 - 19.05
		Thyrotropin (mU/L)	Follow-Up	26-05-2014/ 9:36	0.01 (L, ncs)	-1.19	0.35 - 4.94
	Treatment Sequence 2	Thyroxine (nmol/L)	Screening	27-02-2014/ 8:56	61.2 (L, ncs)		62.7 - 150.8
		Urea (mmol/L)	Screening	27-02-2014/ 8:56	2.59 (L, ncs)		2.80 - 7.20
		Bilirubin (umol/L)	Screening	27-02-2014/ 8:56	29.4 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	27-02-2014/ 8:56	5.2 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	27-02-2014/ 8:56	24.2 (H, ncs)		1.6 - 17.6
		Basophils/Leukocytes (%)	Screening	27-02-2014/ 8:56	1.3 (H, ncs)		0.0 - 1.0
		pH	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:06	8.0 (H, ncs)		4.8 - 7.4
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:08	33.7 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:08	4.8 (H, ncs)		0.0 - 3.4

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
		Indirect Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:08	28.9 (H, ncs)		1.6 - 17.6
		Monocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:08	0.28 (L, ncs)		0.30 - 0.92
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 17:19	22.7 (H, ncs)		5.0 - 21.0
		Indirect Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 17:19	19.7 (H, ncs)		1.6 - 17.6
		Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:16	28.0 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:16	99.2 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:16	5.0 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:16	23.0 (H, ncs)		1.6 - 17.6
		Alkaline Phosphatase (U/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:16	125.0 (H, ncs)		30.0 - 120.0
		Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 18:11	21.9 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 18:11	3.7 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 18:11	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
		Thyroxine (nmol/L)	Follow-Up	06-05-2014/ 11:12	59.1 (L, ncs)	-5.9	62.7 - 150.8
		Monocytes (10 <sup>9</sup> /L)	Follow-Up	06-05-2014/ 11:12	0.27 (L, ncs)	-0.03	0.30 - 0.92
	Treatment Sequence 1	Gamma Glutamyl Transferase (U/L)	Screening	27-02-2014/ 10:09	64.6 (H, ncs)		0.0 - 55.0
		Thyrotropin (mU/L)	Screening	27-02-2014/ 10:09	0.30 (L, ncs)		0.35 - 4.94
		Gamma Glutamyl Transferase (U/L)	Screening	17-03-2014/ 10:17	62.0 (H, ncs)		0.0 - 55.0
		Gamma Glutamyl Transferase (U/L)	Period 1, Day -1/ 24 H Predose	19-03-2014/ 8:44	63.1 (H, ncs)		0.0 - 55.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 8:49	229.3 (H, ncs)		0.0 - 171.0
		Gamma Glutamyl Transferase (U/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 8:49	91.5 (H, ncs)		0.0 - 55.0
		Alkaline Phosphatase (U/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 8:49	134.6 (H, ncs)		30.0 - 120.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 16:49	173.6 (H, ncs)		0.0 - 171.0
		Gamma Glutamyl Transferase (U/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 16:49	80.5 (H, ncs)		0.0 - 55.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	09-05-2014/ 11:13	79.3 (H, ncs)	17.3	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
		Thyrotropin (mU/L)	Follow-Up	09-05-2014/ 11:13	0.26 (L, ncs)	-0.16	0.35 - 4.94
		Gamma Glutamyl Transferase (U/L)	Follow-Up	22-05-2014/ 10:29	77.4 (H, ncs)	15.4	0.0 - 55.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	03-06-2014/ 9:34	85.5 (H, ncs)	23.5	0.0 - 55.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	17-06-2014/ 10:05	81.1 (H, ncs)	19.1	0.0 - 55.0
		Gamma Glutamyl Transferase (U/L)	Follow-Up	13-07-2014/ 10:27	81.0 (H, ncs)	19	0.0 - 55.0
	Treatment Sequence 2	Chloride (mmol/L)	Screening	27-02-2014/ 11:15	99.0 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	27-02-2014/ 11:15	4.04 (L, ncs)		4.10 - 5.90
		Sodium (mmol/L)	Screening	27-02-2014/ 11:15	135.6 (L, ncs)		136.0 - 146.0
		Lymphocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:07	3.28 (H, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:07	100.4 (L, ncs)		101.0 - 109.0
		Lymphocytes/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:07	51.7 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	02-03-2014/ 8:07	32.7 (L, ncs)		38.2 - 71.5

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
		Amylase (IU/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:30	26.9 (L, ncs)		28.0 - 100.0
		Lymphocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:30	3.48 (H, ncs)		1.08 - 3.00
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:30	98.2 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:30	133.5 (L, ncs)		136.0 - 146.0
		Lymphocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:30	48.9 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	07-04-2014/ 9:30	36.7 (L, ncs)		38.2 - 71.5
		Amylase (IU/L)	Follow-Up	28-04-2014/ 9:42	25.7 (L, ncs)	-7.2	28.0 - 100.0
		Lymphocytes (10 <sup>9</sup> /L)	Follow-Up	28-04-2014/ 9:42	3.10 (H, ncs)	1.14	1.08 - 3.00
		Chloride (mmol/L)	Follow-Up	28-04-2014/ 9:42	100.1 (L, ncs)	1.1	101.0 - 109.0
		Platelets (10 <sup>9</sup> /L)	Follow-Up	28-04-2014/ 9:42	343 (H, ncs)	87	155 - 342
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	28-02-2014/ 8:32	180.0 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:12	339.5 (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
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:12	100.6 (L, ncs)		101.0 - 109.0
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:12	414 (H, ncs)		155 - 342
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 8:08	323.8 (H, ncs)		0.0 - 171.0
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 8:08	375 (H, ncs)		155 - 342
		Creatine Kinase (IU/L)	Follow-Up	07-05-2014/ 7:50	1033.8 (H, ncs)	853.8	0.0 - 171.0
		Chloride (mmol/L)	Follow-Up	07-05-2014/ 7:50	99.2 (L, ncs)	-2.2	101.0 - 109.0
		Sodium (mmol/L)	Follow-Up	07-05-2014/ 7:50	134.6 (L, ncs)	-2.4	136.0 - 146.0
		Platelets (10 <sup>9</sup> /L)	Follow-Up	07-05-2014/ 7:50	372 (H, ncs)	55	155 - 342
		Aspartate Aminotransferase (U/L)	Follow-Up	07-05-2014/ 7:50	54.3 (H, ncs)	27.2	0.0 - 50.0
		Creatine Kinase MB (IU/L)	Follow-Up	07-05-2014/ 7:50	29.7 (H, ncs)	12.2	0.0 - 24.0
		Creatine Kinase (IU/L)	Follow-Up	15-05-2014/ 7:50	265.2 (H, ncs)	85.2	0.0 - 171.0
	Treatment Sequence 1	Thyroxine (nmol/L)	Screening	28-02-2014/ 9:25	61.9 (L, ncs)		62.7 - 150.8

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:18	25.00 (H, ncs)		0.00 - 9.00
		pH	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:18	8.0 (H, ncs)		4.8 - 7.4
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:21	965.1 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 17:22	797.2 (H, ncs)		0.0 - 171.0
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 9:59	60.7 (L, ncs)		62.7 - 150.8
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 9:59	100.2 (L, ncs)		101.0 - 109.0
		Creatine Kinase (IU/L)	Follow-Up	05-05-2014/ 8:03	633.3 (H, ncs)	473.7	0.0 - 171.0
		Urea (mmol/L)	Follow-Up	05-05-2014/ 8:03	9.42 (H, ncs)	4.71	2.80 - 7.20
	Treatment Sequence 1	Creatine Kinase (IU/L)	Screening	03-03-2014/ 10:32	1518.1 (H, ncs)		0.0 - 145.0
		Glucose (mmol/L)	Screening	03-03-2014/ 10:32	4.09 (L, ncs)		4.10 - 5.90
		Aspartate Aminotransferase (U/L)	Screening	03-03-2014/ 10:32	63.6 (H, ncs)		0.0 - 35.0
		Creatine Kinase MB (IU/L)	Screening	03-03-2014/ 10:32	90.8 (H, ncs)		0.0 - 24.0

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)	Screening	05-03-2014/ 9:44	372.9 (H, ncs)		0.0 - 145.0
		Aspartate Aminotransferase (U/L)	Screening	05-03-2014/ 9:44	39.5 (H, ncs)		0.0 - 35.0
		Creatine Kinase MB (IU/L)	Screening	05-03-2014/ 9:44	68.6 (H, ncs)		0.0 - 24.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:40	201.5 (H, ncs)		0.0 - 145.0
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:40	4.8 (L, ncs)		5.0 - 21.0
		Sodium (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:40	134.5 (L, ncs)		136.0 - 146.0
		Creatine Kinase MB (IU/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:40	68.7 (H, ncs)		0.0 - 24.0
		Glucose (mmol/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 9:22	4.09 (L, ncs)		4.10 - 5.90
		Urea (mmol/L)	Follow-Up	28-04-2014/ 9:57	2.63 (L, ncs)	-0.49	2.80 - 7.20
	Treatment Sequence 2	Protein (g/L)	Screening	03-03-2014/ 11:11	65.6 (L, ncs)		66.0 - 83.0
		Sodium (mmol/L)	Screening	03-03-2014/ 11:11	135.8 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 9:16	186.1 (H, ncs)		0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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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 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 9:16	3.03 (H, ncs)		1.08 - 3.00
	Treatment Sequence 2	Creatinine (umol/L)	Screening	03-03-2014/ 11:58	58.7 (L, ncs)		59.0 - 104.0
		Ketones (mmol/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 9:00	0.5 (H, ncs)		0.0 - 0.5
		Leukocytes (/HPF)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 9:00	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 9:00	25.00 (H, ncs)		0.00 - 9.00
		Ketones (mmol/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:36	0.5 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:36	250.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:36	POSITIVE (H, ncs)		
		Erythrocytes (/HPF)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:36	236.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPP)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:36	18.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:36	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	04-03-2014/ 9:13	315.5 (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
		Bilirubin (umol/L)	Screening	04-03-2014/ 9:13	26.2 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	04-03-2014/ 9:13	5.9 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	04-03-2014/ 9:13	20.3 (H, ncs)		1.6 - 17.6
		Creatine Kinase (IU/L)	Screening	05-03-2014/ 9:27	214.2 (H, ncs)		0.0 - 171.0
		Amylase (IU/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:19	106.2 (H, ncs)		28.0 - 100.0
		Triacylglycerol Lipase (IU/L)	Period 1, Day -1/ 24 H Predose	06-03-2014/ 8:19	73.5 (H, ncs)		0.0 - 67.0
		Triacylglycerol Lipase (IU/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 8:44	74.1 (H, ncs)		0.0 - 67.0
		Triacylglycerol Lipase (IU/L)	Period 2, Day -1/ 24 H Predose	11-04-2014/ 16:17	82.8 (H, ncs)		0.0 - 67.0
		Triacylglycerol Lipase (IU/L)	Period 2, Day -1/ 24 H Predose	15-04-2014/ 8:19	71.4 (H, ncs)		0.0 - 67.0
		Thyroxine (nmol/L)	Follow-Up	25-04-2014/ 9:31	60.7 (L, ncs)	-6.1	62.7 - 150.8
	Treatment Sequence 1	Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:47	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:47	POSITIVE (H, ncs)		

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)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:47	25.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 13:40	50.00 (H, ncs)		0.00 - 5.00
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:19	9.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:19	100.00 (H, ncs)		0.00 - 9.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 17:02	100.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Follow-Up	05-05-2014/ 7:16	50.00 (H, ncs)	50	0.00 - 5.00
		Bacteria	Follow-Up	05-05-2014/ 7:16	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Follow-Up	05-05-2014/ 7:16	28.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	05-05-2014/ 7:16	100.00 (H, ncs)	100	0.00 - 9.00
		Erythrocytes (10 <sup>12</sup> /L)	Follow-Up	05-05-2014/ 7:20	3.97 (L, ncs)	-0.41	4.02 - 5.08
	Treatment Sequence 2	Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:17	172.5 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:21	332.8 (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
		Eosinophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:21	0.4 (L, ncs)		0.6 - 8.4
	Treatment Sequence 2	Erythrocytes (uL)	Screening	05-03-2014/ 8:35	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Screening	05-03-2014/ 8:35	6.00 (H, ncs)		0.00 - 3.00
		Urea (mmol/L)	Screening	05-03-2014/ 8:42	2.79 (L, ncs)		2.80 - 7.20
		Glucose (mmol/L)	Screening	05-03-2014/ 8:42	4.07 (L, ncs)		4.10 - 5.90
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:59	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 9:41	25.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 9:46	364.1 (H, ncs)		0.0 - 145.0
		Erythrocytes (uL)	Follow-Up	06-05-2014/ 7:38	25.00 (H, ncs)	0	0.00 - 5.00
		Erythrocytes (/HPF)	Follow-Up	06-05-2014/ 7:38	4.00 (H, ncs)	-2	0.00 - 3.00
	Treatment Sequence 1	Bilirubin (umol/L)	Screening	05-03-2014/ 10:35	22.6 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	05-03-2014/ 10:35	3.9 (H, ncs)		0.0 - 3.4

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
		Indirect Bilirubin (umol/L)	Screening	05-03-2014/ 10:35	18.7 (H, ncs)		1.6 - 17.6
		Eosinophils (10 <sup>9</sup> /L)	Screening	05-03-2014/ 10:35	0.02 (L, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Screening	05-03-2014/ 10:35	0.5 (L, ncs)		0.6 - 8.4
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:45	25.00 (H, ncs)		0.00 - 5.00
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:07	60.1 (L, ncs)		62.7 - 150.8
		Eosinophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:07	0.02 (L, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:07	0.3 (L, ncs)		0.6 - 8.4
	Treatment Sequence 1	Erythrocytes (uL)	Screening	10-03-2014/ 8:09	10.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	26-03-2014/ 7:53	25.00 (H, ncs)		0.00 - 5.00
		Basophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	26-03-2014/ 7:55	0.1 (L, ncs)		0.2 - 1.3
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	01-05-2014/ 8:45	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Follow-Up	16-05-2014/ 7:52	25.00 (H, ncs)	15	0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 2	Thyroxine (nmol/L)	Screening	10-03-2014/ 8:47	61.7 (L, ncs)		62.7 - 150.8
		Lymphocytes (10 <sup>9</sup> /L)	Screening	10-03-2014/ 8:47	1.07 (L, ncs)		1.08 - 3.00
		Leukocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	30-03-2014/ 8:58	2.93 (L, ncs)		3.19 - 8.71
		Lymphocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	30-03-2014/ 8:58	0.97 (L, ncs)		1.08 - 3.00
		Monocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	30-03-2014/ 8:58	0.24 (L, ncs)		0.30 - 0.92
		Protein (g/L)	Follow-Up	19-05-2014/ 11:05	65.6 (L, ncs)	-2.9	66.0 - 83.0
		Thyroxine (nmol/L)	Follow-Up	19-05-2014/ 11:05	59.7 (L, ncs)	-7.8	62.7 - 150.8
		Monocytes (10 <sup>9</sup> /L)	Follow-Up	19-05-2014/ 11:05	0.29 (L, ncs)	-0.05	0.30 - 0.92
	Treatment Sequence 1	Urea (mmol/L)	Screening	10-03-2014/ 9:03	2.68 (L, ncs)		2.80 - 7.20
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	05-05-2014/ 11:07	182.3 (H, ncs)		0.0 - 171.0
	Treatment Sequence 2	Protein (g/L)	Screening	10-03-2014/ 9:38	62.6 (L, ncs)		66.0 - 83.0
		Platelets (10 <sup>9</sup> /L)	Screening	10-03-2014/ 9:38	166 (L, ncs)		173 - 369

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Eosinophils (10 <sup>9</sup> /L)	Screening	10-03-2014/ 9:38	0.63 (H, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Screening	10-03-2014/ 9:38	8.7 (H, ncs)		0.6 - 7.9
		pH	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:03	8.0 (H, ncs)		4.8 - 7.4
		Protein (g/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:05	65.4 (L, ncs)		66.0 - 83.0
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:05	151 (L, ncs)		173 - 369
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:05	0.58 (H, ncs)		0.04 - 0.43
		Potassium (mmol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:02	3.47 (L, ncs)		3.50 - 5.10
		Glucose (mmol/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:02	1.92 (L, ncs)		4.10 - 5.90
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:02	147 (L, ncs)		173 - 369
		Eosinophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:02	0.53 (H, ncs)		0.04 - 0.43
		pH	Follow-Up	06-05-2014/ 9:37	8.0 (H, ncs)	1	4.8 - 7.4
		Leukocytes (10 <sup>9</sup> /L)	Follow-Up	06-05-2014/ 9:41	10.68 (H, ncs)	3.41	3.69 - 10.04

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 <sup>9</sup> /L)	Follow-Up	06-05-2014/ 9:41	6.98 (H, ncs)	2.87	1.61 - 6.45
		Protein (g/L)	Follow-Up	06-05-2014/ 9:41	64.9 (L, ncs)	2.3	66.0 - 83.0
		Urea (mmol/L)	Follow-Up	06-05-2014/ 9:41	2.27 (L, ncs)	-0.66	2.80 - 7.20
		Glucose (mmol/L)	Follow-Up	06-05-2014/ 9:41	4.00 (L, ncs)	-0.64	4.10 - 5.90
		Platelets (10 <sup>9</sup> /L)	Follow-Up	06-05-2014/ 9:41	163 (L, ncs)	-3	173 - 369
		Eosinophils (10 <sup>9</sup> /L)	Follow-Up	06-05-2014/ 9:41	0.52 (H, ncs)	-0.11	0.04 - 0.43
	Treatment Sequence 2	Ketones (mmol/L)	Screening	10-03-2014/ 11:29	5.0 (H, ncs)		0.0 - 0.5
		Erythrocytes (uL)	Screening	10-03-2014/ 11:29	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Screening	10-03-2014/ 11:29	8.00 (H, ncs)		0.00 - 3.00
		Leukocytes (uL)	Screening	10-03-2014/ 11:29	25.00 (H, ncs)		0.00 - 9.00
		Creatine Kinase (IU/L)	Screening	10-03-2014/ 11:34	172.5 (H, ncs)		0.0 - 171.0
		Bilirubin (umol/L)	Screening	10-03-2014/ 11:34	24.9 (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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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	10-03-2014/ 11:34	4.4 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	10-03-2014/ 11:34	20.5 (H, ncs)		1.6 - 17.6
		Alanine Aminotransferase (U/L)	Screening	10-03-2014/ 11:34	53.6 (H, ncs)		0.0 - 50.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:29	150.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (/HPF)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:29	9.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPF)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:29	7.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:29	25.00 (H, ncs)		0.00 - 9.00
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 9:31	232.8 (H, ncs)		0.0 - 171.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 13:40	25.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:14	25.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:29	172.7 (H, ncs)		0.0 - 171.0
		Erythrocytes (uL)	Follow-Up	05-05-2014/ 12:03	250.00 (H, ncs)	200	0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (/HPF)	Follow-Up	05-05-2014/ 12:03	124.00 (H, ncs)	116	0.00 - 3.00
		Leukocytes (/HPF)	Follow-Up	05-05-2014/ 12:03	5.00 (H, ncs)	2	0.00 - 4.00
		Protein (g/L)	Follow-Up	08-05-2014/ 11:31	0.25 (H, ncs)	0.25	0.00 - 0.09
		Ketones (mmol/L)	Follow-Up	08-05-2014/ 11:31	1.5 (H, ncs)	-3.5	0.0 - 0.5
		Erythrocytes (uL)	Follow-Up	08-05-2014/ 11:31	250.00 (H, ncs)	200	0.00 - 5.00
		Bacteria	Follow-Up	08-05-2014/ 11:31	POSITIVE (H, ncs)		
		Erythrocytes (/HPF)	Follow-Up	08-05-2014/ 11:31	196.00 (H, ncs)	188	0.00 - 3.00
		Erythrocytes (uL)	Follow-Up	14-05-2014/ 12:55	250.00 (H, ncs)	200	0.00 - 5.00
		Erythrocytes (/HPF)	Follow-Up	14-05-2014/ 12:55	13.00 (H, ncs)	5	0.00 - 3.00
	Treatment Sequence 1	Lymphocytes/Leukocytes (%)	Screening	11-03-2014/ 8:05	49.8 (H, ncs)		18.3 - 48.1
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:28	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:28	POSITIVE (H, ncs)		

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (/HPF)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:28	6.00 (H, ncs)		0.00 - 3.00
		Leukocytes (/HPF)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:28	50.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:28	500.00 (H, ncs)		0.00 - 9.00
		Lymphocytes/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:30	52.9 (H, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 8:30	37.7 (L, ncs)		38.2 - 71.5
		Leukocytes (/HPF)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 13:40	30.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 13:40	500.00 (H, ncs)		0.00 - 9.00
		Erythrocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:13	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:13	122.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:13	100.00 (H, ncs)		0.00 - 9.00
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:15	9146.7 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:15	72.1 (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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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Aspartate Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:15	240.6 (H, ncs)		0.0 - 50.0
		Creatine Kinase MB (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:15	85.7 (H, ncs)		0.0 - 24.0
		Lactate Dehydrogenase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:15	379.1 (H, ncs)		0.0 - 248.0
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 17:01	18.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 17:01	500.00 (H, ncs)		0.00 - 9.00
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 18:06	7822.1 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 18:06	64.6 (H, ncs)		0.0 - 50.0
		Aspartate Aminotransferase (U/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 18:06	209.4 (H, ncs)		0.0 - 50.0
		Creatine Kinase MB (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 18:06	74.3 (H, ncs)		0.0 - 24.0
		Erythrocytes (uL)	Follow-Up	24-04-2014/ 10:52	10.00 (H, ncs)	10	0.00 - 5.00
		Leukocytes (uL)	Follow-Up	24-04-2014/ 10:52	25.00 (H, ncs)	25	0.00 - 9.00
		Protein (g/L)	Follow-Up	24-04-2014/ 10:54	65.9 (L, ncs)	-2.1	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
		Creatine Kinase (IU/L)	Follow-Up	24-04-2014/ 10:54	2988.1 (H, ncs)	2825.4	0.0 - 171.0
		Lymphocytes/Leukocytes (%)	Follow-Up	24-04-2014/ 10:54	51.2 (H, ncs)	1.4	18.3 - 48.1
		Neutrophils/Leukocytes (%)	Follow-Up	24-04-2014/ 10:54	38.1 (L, ncs)	-1.7	38.2 - 71.5
		Alanine Aminotransferase (U/L)	Follow-Up	24-04-2014/ 10:54	61.2 (H, ncs)	43.8	0.0 - 50.0
		Aspartate Aminotransferase (U/E)	Follow-Up	24-04-2014/ 10:54	114.8 (H, ncs)	90.5	0.0 - 50.0
		Creatine Kinase MB (IU/L)	Follow-Up	24-04-2014/ 10:54	36.3 (H, ncs)		0.0 - 24.0
		Creatine Kinase (IU/L)	Follow-Up	02-05-2014/ 9:01	220.3 (H, ncs)	57.6	0.0 - 171.0
	Treatment Sequence 2	Hemoglobin (g/L)	Period 1, Day -1/ 24 H Predose	26-03-2014/ 7:55	166 (H, ncs)		126 - 165
		Erythrocytes (uL)	Follow-Up	15-05-2014/ 8:13	10.00 (H, ncs)	10	0.00 - 5.00
	Treatment Sequence 1	Leukocytes (uL)	Screening	12-03-2014/ 8:20	25.00 (H, ncs)		0.00 - 9.00
		Neutrophils (10 <sup>9</sup> /L)	Screening	12-03-2014/ 8:24	1.58 (L, ncs)		1.61 - 6.45
		Protein (g/L)	Screening	12-03-2014/ 8:24	63.0 (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
		Bacteria	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:54	POSITIVE (H, ncs)		
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 7:54	25.00 (H, ncs)		0.00 - 9.00
		Bacteria	Period 1, Day -1/ 24 H Predose	16-03-2014/ 13:40	POSITIVE (H, ncs)		
		Leukocytes (uL)	Period 1, Day -1/ 24 H Predose	16-03-2014/ 13:40	25.00 (H, ncs)		0.00 - 9.00
		Bacteria	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:17	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:17	5.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:17	25.00 (H, ncs)		0.00 - 9.00
		Amylase (IU/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:19	24.3 (L, ncs)		28.0 - 100.0
		Protein (g/L)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 10:19	63.8 (L, ncs)		66.0 - 83.0
		Bacteria	Period 2, Day -1/ 24 H Predose	21-04-2014/ 17:01	POSITIVE (H, ncs)		
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	21-04-2014/ 17:01	25.00 (H, ncs)		0.00 - 9.00
		Crystals	Period 2, Day -1/ 24 H Predose	21-04-2014/ 17:01	POSITIVE (H, ncs)		

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	
J	Treatment Sequence 2	Triacylglycerol Lipase (IU/L)	Period 1, Day -1/ 24 H Predose	19-03-2014/ 8:06	67.9 (H, ncs)		0.0 - 67.0	
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 9:12	391.7 (H, ncs)		0.0 - 171.0	
		Treatment Sequence 2	Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 16:52	308.6 (H, ncs)		0.0 - 171.0
			Creatine Kinase (IU/L)	Follow-Up	09-05-2014/ 10:07	179.2 (H, ncs)	61.1	0.0 - 171.0
		Treatment Sequence 2	Monocytes (10 <sup>9</sup> /L)	Follow-Up	09-05-2014/ 10:07	0.29 (L, ncs)	-0.02	0.30 - 0.92
			Sodium (mmol/L)	Follow-Up	09-05-2014/ 10:07	135.4 (L, ncs)	-2.3	136.0 - 146.0
		Treatment Sequence 2	Basophils/Leukocytes (%)	Follow-Up	09-05-2014/ 10:07	1.1 (H, ncs)	0.5	0.0 - 1.0
			Leukocytes (10 <sup>9</sup> /L)	Screening	14-03-2014/ 8:37	9.87 (H, ncs)		3.19 - 8.71
		Treatment Sequence 2	Neutrophils (10 <sup>9</sup> /L)	Screening	14-03-2014/ 8:37	6.11 (H, ncs)		1.46 - 5.85
			Creatine Kinase (IU/L)	Screening	14-03-2014/ 8:37	274.9 (H, ncs)		0.0 - 171.0
		Treatment Sequence 2	Eosinophils (10 <sup>9</sup> /L)	Screening	14-03-2014/ 8:37	0.72 (H, ncs)		0.03 - 0.50
			Leukocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:39	9.42 (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 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:39	6.31 (H, ncs)		1.46 - 5.85
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:39	188.6 (H, ncs)		0.0 - 171.0
		Monocytes (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:39	0.95 (H, ncs)		0.30 - 0.92
		Lymphocytes/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:39	14.6 (L, ncs)		18.3 - 48.1
		Eosinophils (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:39	0.73 (H, ncs)		0.03 - 0.50
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 9:29	224.6 (H, ncs)		0.0 - 171.0
		Thyroxine (nmol/L)	Follow-Up	13-05-2014/ 7:55	54.8 (L, ncs)	-9.7	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	13-05-2014/ 7:55	235.9 (H, ncs)	-39	0.0 - 171.0
		Eosinophils (10 <sup>9</sup> /L)	Follow-Up	13-05-2014/ 7:55	0.51 (H, ncs)	-0.21	0.03 - 0.50
		Eosinophils/Leukocytes (%)	Follow-Up	13-05-2014/ 7:55	8.8 (H, ncs)	1.5	0.6 - 8.4
	Treatment Sequence 1	Urea (mmol/L)	Screening	14-03-2014/ 8:59	2.47 (L, ncs)		2.80 - 7.20
		Basophils (10 <sup>9</sup> /L)	Screening	14-03-2014/ 8:59	0.00 (L, 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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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	23-03-2014/ 8:30	100.4 (L, ncs)		101.0 - 109.0
		Leukocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	12.23 (H, ncs)		3.19 - 8.71
		Neutrophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	9.40 (H, ncs)		1.46 - 5.85
		Urea (mmol/L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	2.30 (L, ncs)		2.80 - 7.20
		Chloride (mmol/L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	95.9 (L, ncs)		101.0 - 109.0
		Monocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	1.17 (H, ncs)		0.30 - 0.92
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	133.3 (L, ncs)		136.0 - 146.0
		Lymphocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	13.4 (L, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	76.8 (H, ncs)		38.2 - 71.5
		Basophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	0.00 (L, ncs)		0.01 - 0.07
		Eosinophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	0.02 (L, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:24	0.2 (L, 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
		Leukocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 18:24	9.99 (H, ncs)		3.19 - 8.71
		Neutrophils (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 18:24	5.96 (H, ncs)		1.46 - 5.85
		Monocytes (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 18:24	1.25 (H, ncs)		0.30 - 0.92
		Chloride (mmol/L)	Follow-Up	13-05-2014/ 7:13	97.6 (L, ncs)	-3.8	101.0 - 109.0
		Sodium (mmol/L)	Follow-Up	13-05-2014/ 7:13	135.2 (L, ncs)	-2.1	136.0 - 146.0
	Treatment Sequence 1	Chloride (mmol/L)	Screening	14-03-2014/ 12:11	100.3 (L, ncs)		101.0 - 109.0
		Lymphocytes/Leukocytes (%)	Screening	14-03-2014/ 12:11	17.5 (L, ncs)		18.3 - 48.1
		Neutrophils/Leukocytes (%)	Screening	14-03-2014/ 12:11	73.0 (H, ncs)		38.2 - 71.5
		Eosinophils/Leukocytes (%)	Screening	14-03-2014/ 12:11	0.4 (L, ncs)		0.6 - 8.4
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	02-04-2014/ 7:55	504.4 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	02-04-2014/ 16:50	377.9 (H, ncs)		0.0 - 171.0
		Monocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	08-05-2014/ 7:54	15.5 (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
1581/242	Treatment Sequence 2	Chloride (mmol/L)	Screening	17-03-2014/ 8:52	100.8 (L, ncs)		101.0 - 109.0
		Monocytes/Leukocytes (%)	Screening	17-03-2014/ 8:52	16.5 (H, ncs)		5.3 - 14.2
		Ketones (mmol/L)	Period 1, Day -1/ 24 H Predose	06-04-2014/ 8:02	0.5 (H, ncs)		0.0 - 0.5
		Lymphocytes/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	06-04-2014/ 8:04	50.9 (H, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Period 1, Day -1/ 24 H Predose	06-04-2014/ 8:04	37.5 (L, ncs)		37.9 - 70.5
		Platelets (10 <sup>9</sup> /L)	Period 1, Day -1/ 24 H Predose	06-04-2014/ 8:04	393 (H, ncs)		173 - 369
		Ketones (mmol/L)	Period 2, Day -1/ 24 H Predose	12-05-2014/ 8:08	0.5 (H, ncs)		0.0 - 0.5
		Leukocytes (uL)	Period 2, Day -1/ 24 H Predose	12-05-2014/ 8:08	25.00 (H, ncs)		0.00 - 9.00
		Sodium (mmol/L)	Period 2, Day -1/ 24 H Predose	12-05-2014/ 8:09	135.4 (L, ncs)		136.0 - 146.0
		Lymphocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	12-05-2014/ 8:09	51.0 (H, ncs)		17.8 - 48.5
		Neutrophils/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	12-05-2014/ 8:09	35.0 (L, ncs)		37.9 - 70.5
		Platelets (10 <sup>9</sup> /L)	Period 2, Day -1/ 24 H Predose	12-05-2014/ 8:09	389 (H, ncs)		173 - 369

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant; Baseline defined as Screening for Follow-Up results.

Treatment Sequence 1: Test/Reference; Treatment Sequence 2: Reference/Test.

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

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/Random Number	Treatment Sequence	Lab Test (Unit)	Visit/Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Thyroxine (nmol/L)	Follow-Up	28-05-2014/ 7:23	56.1 (L, ncs)	-13.1	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	28-05-2014/ 7:23	161.9 (H, ncs)	111.2	0.0 - 145.0
		Urea (mmol/L)	Follow-Up	28-05-2014/ 7:23	2.66 (L, ncs)	-1.61	2.80 - 7.20
		Sodium (mmol/L)	Follow-Up	28-05-2014/ 7:23	134.9 (L, ncs)	-1.2	136.0 - 146.0
	Treatment Sequence 1	Glucose (mmol/L)	Screening	17-03-2014/ 12:01	3.85 (L, ncs)		4.10 - 5.90
		Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	19-03-2014/ 8:26	22.0 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1, Day -1/ 24 H Predose	19-03-2014/ 8:26	4.7 (H, ncs)		0.0 - 3.4
		Lymphocytes/Leukocytes (%)	Period 2, Day -1/ 24 H Predose	24-04-2014/ 8:15	17.5 (L, ncs)		18.3 - 48.1
		Thyroxine (nmol/L)	Follow-Up	09-05-2014/ 10:50	61.7 (L, ncs)	-1.3	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	09-05-2014/ 10:50	210.3 (H, ncs)	73.4	0.0 - 171.0
		Glucose (mmol/L)	Follow-Up	09-05-2014/ 10:50	4.02 (L, ncs)	0.17	4.10 - 5.90
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	20-03-2014/ 8:32	392.0 (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
		Chloride (mmol/L)	Screening	20-03-2014/ 8:32	99.8 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	20-03-2014/ 8:32	3.71 (L, ncs)		4.10 - 5.90
		Sodium (mmol/L)	Screening	20-03-2014/ 8:32	135.3 (L, ncs)		136.0 - 146.0
		Creatine Kinase (IU/L)	Screening	21-03-2014/ 7:25	361.3 (H, ncs)		0.0 - 171.0
		Erythrocytes (uL)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:37	25.00 (H, ncs)		0.00 - 5.00
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:39	275.0 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 15:42	256.4 (H, ncs)		0.0 - 171.0
		Creatine Kinase (IU/L)	Period 2, Day -1/ 24 H Predose	30-04-2014/ 8:05	251.5 (H, ncs)		0.0 - 171.0
		Amylase (IU/L)	Follow-Up	15-05-2014/ 8:38	104.1 (H, ncs)	10.9	28.0 - 100.0
		Thyroxine (nmol/L)	Follow-Up	15-05-2014/ 8:38	61.8 (L, ncs)	-25	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	15-05-2014/ 8:38	237.1 (H, ncs)	-124.2	0.0 - 171.0
		Lymphocytes (10 <sup>9</sup> /L)	Follow-Up	15-05-2014/ 8:38	3.14 (H, ncs)	1.22	1.08 - 3.00

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

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High	
/	Treatment Sequence 1	Chloride (mmol/L)	Screening	20-03-2014/ 9:23	97.2 (L, ncs)		101.0 - 109.0	
		Sodium (mmol/L)	Screening	20-03-2014/ 9:23	132.4 (L, ncs)		136.0 - 146.0	
		Chloride (mmol/L)	Period 1, Day -1/ 24 H Predose	23-03-2014/ 8:43	100.7 (L, ncs)		101.0 - 109.0	
		Thyroxine (nmol/L)	Period 2, Day -1/ 24 H Predose	28-04-2014/ 8:23	55.5 (L, ncs)		62.7 - 150.8	
		Chloride (mmol/L)	Follow-Up	13-05-2014/ 8:34	99.1 (L, ncs)	1.9	101.0 - 109.0	
		Sodium (mmol/L)	Follow-Up	13-05-2014/ 8:34	134.8 (L, ncs)	2.4	136.0 - 146.0	
		Alanine Aminotransferase (U/L)	Follow-Up	13-05-2014/ 8:34	50.7 (H, ncs)	22.4	0.0 - 50.0	
		Alkaline Phosphatase (U/L)	Follow-Up	13-05-2014/ 8:34	121.8 (H, ncs)	10.9	30.0 - 120.0	
		Alanine Aminotransferase (U/L)	Follow-Up	18-05-2014/ 9:15	54.8 (H, ncs)	26.5	0.0 - 50.0	
		Alkaline Phosphatase (U/L)	Follow-Up	18-05-2014/ 9:15	123.5 (H, ncs)	12.6	30.0 - 120.0	
		Alkaline Phosphatase (U/L)	Follow-Up	23-05-2014/ 10:40	122.2 (H, ncs)	11.3	30.0 - 120.0	
		Treatment Sequence 1	Monocytes (10 <sup>9</sup> /L)	Screening	20-03-2014/ 11:04	0.26 (L, ncs)		0.27 - 0.91

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
		Eosinophils (10 <sup>9</sup> /L)	Screening	20-03-2014/ 11:04	0.03 (L, ncs)		0.04 - 0.43
		Triiodothyronine (nmol/L)	Period 1, Day -1/ 24 H Predose	26-03-2014/ 8:00	2.45 (H, ncs)		0.89 - 2.44
		Eosinophils (10 <sup>9</sup> /L)	Follow-Up	16-05-2014/ 10:29	0.03 (L, ncs)	0	0.04 - 0.43
	Treatment Sequence 2	Bacteria	Screening	21-03-2014/ 8:14	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Screening	21-03-2014/ 8:14	7.00 (H, ncs)		0.00 - 4.00
		Nitrite	Screening	21-03-2014/ 8:14	POSITIVE (H, ncs)		
		Protein (g/L)	Screening	21-03-2014/ 8:17	62.2 (L, ncs)		66.0 - 83.0
		Urea (mmol/L)	Screening	21-03-2014/ 8:17	2.48 (L, ncs)		2.80 - 7.20
		Bilirubin (umol/L)	Screening	21-03-2014/ 8:17	26.6 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	21-03-2014/ 8:17	5.4 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	21-03-2014/ 8:17	21.2 (H, ncs)		1.6 - 17.6
		Bilirubin (umol/L)	Screening	22-03-2014/ 12:04	32.5 (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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