Levothyroxine **Bioequivalence trial of new levothyroxine formulation versus old formulation**

EMR 200125-001

Table 11.3 Summary Statistics of Primary Baseline-Adjusted Total T4 Pharmacokinetic Parameters (Pharmacokinetic Population)

	Statistic	$AUC_{0-72,adj}$ * (hr*ng/mL)	$C_{max,adj}$ (ng/mL)
Test	n (missing)	204 (0)	204 (0)
	Mean (SD)	1975.81 (626.137)	55.3788 (15.93241)
	Geo Mean (95% CI)	1851.94 (1751.43;1958.22)	53.5498 (51.7064;55.4589)
	Geo CV (CV%)	42.1 (31.7)	25.8 (28.8)
	SEM	43.838	1.11549
	Median	1944.15	53.6550
	Min; Max	140.4; 3749.7	27.520; 191.233
Reference	n (missing)	204 (0)	204 (0)
	Mean (SD)	1976.87 (619.892)	54.1358 (12.72064)
	Geo Mean (95% CI)	1865.11 (1772.77;1962.25)	52.6806 (50.9997;54.4170)
	Geo CV (CV%)	38.1 (31.4)	23.8 (23.5)
	SEM	43.401	0.89062
	Median	1915.95	52.4765
	Min; Max	253.5; 3466.1	28.300; 102.830

CI = Confidence Interval; CV% = Coefficient of Variation Percentage; GeoCV = Geometric Coefficient of Variation; GeoMean = Geometric Mean; Max = Maximum Value; Min = Minimum Value; n = The number of subjects with specific parameter calculable; SD = Standard Deviation; SEM = Standard Error of the Mean; T4 = thyroxine

* $AUC_{(0-tlast)}$ was used for Test subjec and Reference Subjects . Normalization to exactly 72 hours was not possible because of invalid λz.

Test: levothyroxine new formulation.
Reference: levothyroxine old formulation.

Source: Section 15.4, Table 15.4.1.1.2