

Gilead Sciences, Inc.
Study GS-US-236-0112 (Week 24 Analysis)

Table 44.1: Statistical Comparison of Pharmacokinetics Parameter Estimates Between Test and Historical Reference Treatment for EVG
PK Substudy Analysis Set: EVG

Parameters	Treatment				Statistical Comparison				
	Test		Reference		Ratio		90% Confidence Interval (%)	Model	
	n	GLS Mean	n	GLS Mean	Test/Reference	(%)		rMSE	rInter
----- Analyte: EVG, Adolescents in GS-US-236-0112 (Test) vs. Adults from Historical Studies (Reference) -----									
AUCtau (ng*h/mL)	14	28529.11	419	21896.87	Test/Reference	130.29	(104.79,162.00)	0.308	0.383
Cmax (ng/mL)	14	2390.01	419	1689.04	Test/Reference	141.50	(116.06,172.52)	0.224	0.388
Ctau (ng/mL)	14	410.08	419	387.42	Test/Reference	105.85	(69.99,160.09)	0.570	0.739

GLS Mean = Geometric Least Squares Mean. rMSE = square root of mean square error.

PK parameters for the test group were from Study 236-0112.

PK parameters for the reference group were estimated from the population PK modeling in HIV-infected subjects (Stribild treated subjects in studies GS-US-236-0103 and GS-US-236-104, and Stribild treated subjects who participated in PK substudy in study GS-US-236-0102).

Data Extracted: CRF Data, Lab Data: 25Jul2014, DXA Data: 18Jul2014, PK Concentration Data: 02Aug2013, PK Parameter Data: 16Aug2013

Source: .../s2360112/wk_24/version2/prog/t-pkstat-test-hist.sas v9.2 Output file: t-pkstat-test-hist-evg.out 05AUG2014:10:42

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