

Table 15.10.1.4.1: Statistical Comparisons of Pharmacokinetic Parameter Estimates Between Test and Reference Groups  
 BIC, FTC, TAF PK Analysis Sets

Parameters	Visit				Statistical Comparison			
	Test		Reference		GLSM Ratio (%)	90% CI	Model	
	n	GLSM	n	GLSM			rMSE	rInter
-----								
Analyte: BIC, Second Trimester (Test) vs Week 12 Post-partum (Reference)								
AUCtau (h*ng/mL)	20	58923.61	32	142893.91	41.24	(36.71,46.32)	0.225	0.214
Ctau (ng/mL)	20	898.34	32	3432.91	26.17	(21.45,31.93)	0.390	0.305
Cmax (ng/mL)	21	5564.51	32	10719.39	51.91	(46.48,57.97)	0.220	0.178
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Analyte: BIC, Second Trimester (Test) vs Week 6 Post-partum (Reference)								
AUCtau (h*ng/mL)	20	58074.50	31	130063.52	44.65	(40.04,49.79)	0.208	0.236
Ctau (ng/mL)	20	891.06	31	3301.08	26.99	(22.23,32.78)	0.375	0.337
Cmax (ng/mL)	21	5468.61	31	9483.08	57.67	(52.48,63.36)	0.183	0.225
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Analyte: BIC, Third Trimester (Test) vs Week 12 Post-partum (Reference)								
AUCtau (h*ng/mL)	30	57966.25	32	142893.91	40.57	(36.77,44.76)	0.226	0.167
Ctau (ng/mL)	30	996.45	32	3432.91	29.03	(25.74,32.74)	0.277	0.250
Cmax (ng/mL)	30	5164.70	32	10719.39	48.18	(43.03,53.94)	0.261	0.088

n represents the number of adult participants in the PK Analysis Sets with the corresponding PK parameter available.  
 CI = confidence interval; GLSM = geometric least-squares mean. ANOVA model includes visit as a fixed effect and participant as a random effect.  
 Mixed model covariance parameter estimates: rMSE = square root of mean square error; rInter = Square Root of Interparticipant Variance.

Data Extracted: CRF Data, Lab Data: 21NOV2022, PK Data: 14OCT2022

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	Test		Reference		GLSM Ratio (%)	90% CI	Model	
	n	GLSM	n	GLSM			rMSE	rInter
----- Analyte: BIC, Third Trimester (Test) vs Week 6 Post-partum (Reference) -----								
AUCtau (h*ng/mL)	30	57750.82	31	130063.52	44.40	(39.95,49.34)	0.242	0.147
Ctau (ng/mL)	30	989.34	31	3301.08	29.97	(26.47,33.93)	0.284	0.252
Cmax (ng/mL)	30	5161.15	31	9483.08	54.42	(48.39,61.21)	0.270	0.088
----- Analyte: TAF, Second Trimester (Test) vs Week 12 Post-partum (Reference) -----								
AUCtau (h*ng/mL)	15	219.23	30	282.43	77.62	(65.40,92.14)	0.298	0.170
Cmax (ng/mL)	21	301.69	32	431.59	69.90	(56.16,87.00)	0.440	0.277
----- Analyte: TAF, Second Trimester (Test) vs Week 6 Post-partum (Reference) -----								
AUCtau (h*ng/mL)	15	217.61	27	348.17	62.50	(50.76,76.96)	0.347	0.173
Cmax (ng/mL)	21	296.95	31	446.19	66.55	(53.79,82.34)	0.425	0.281
----- Analyte: TAF, Third Trimester (Test) vs Week 12 Post-partum (Reference) -----								
AUCtau (h*ng/mL)	17	196.78	30	282.43	69.67	(58.57,82.88)	0.341	0.000
Cmax (ng/mL)	30	246.60	32	431.59	57.14	(46.04,70.91)	0.509	0.000

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	Test		Reference		GLSM Ratio (%)	90% CI	Model	
	n	GLSM	n	GLSM			rMSE	rInter
-----								
Analyte: TAF, Third Trimester (Test) vs Week 6 Post-partum (Reference)								
-----								
AUCtau (h*ng/mL)	17	196.78	27	348.17	56.52	(46.32,68.96)	0.382	0.000
Cmax (ng/mL)	30	246.60	31	446.19	55.27	(44.65,68.42)	0.499	0.000
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Analyte: FTC, Second Trimester (Test) vs Week 12 Post-partum (Reference)								
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AUCtau (h*ng/mL)	21	10089.14	32	14972.79	67.38	(63.45,71.56)	0.115	0.177
Ctau (ng/mL)	21	49.28	32	76.73	64.22	(54.63,75.49)	0.321	0.278
Cmax (ng/mL)	21	2449.63	32	3239.98	75.61	(66.70,85.70)	0.249	0.215
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Analyte: FTC, Second Trimester (Test) vs Week 6 Post-partum (Reference)								
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AUCtau (h*ng/mL)	21	10168.91	31	15824.72	64.26	(60.95,67.75)	0.100	0.208
Ctau (ng/mL)	21	45.09	31	105.13	42.89	(36.55,50.34)	0.308	0.497
Cmax (ng/mL)	21	2535.08	31	3258.07	77.81	(68.76,88.05)	0.243	0.237
-----								
Analyte: FTC, Third Trimester (Test) vs Week 12 Post-partum (Reference)								
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AUCtau (h*ng/mL)	30	10359.29	32	14972.79	69.19	(65.88,72.66)	0.112	0.181
Ctau (ng/mL)	30	49.65	32	76.73	64.71	(59.30,70.61)	0.200	0.251
Cmax (ng/mL)	30	2509.31	32	3239.98	77.45	(70.33,85.29)	0.222	0.154

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	n	GLSM	n	GLSM			rMSE	rInter
----- Analyte: FTC, Third Trimester (Test) vs Week 6 Post-partum (Reference) -----								
AUCtau (h*ng/mL)	30	10300.34	31	15824.72	65.09	(61.79,68.57)	0.119	0.192
Ctau (ng/mL)	30	49.33	31	105.13	46.92	(39.57,55.64)	0.391	0.311
Cmax (ng/mL)	30	2511.45	31	3258.07	77.08	(69.78,85.15)	0.228	0.166

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