

Table 15.10.1.1.4: Summary Statistics and Statistical Comparisons of Plasma Pharmacokinetic Parameters
All PK Analysis Sets

PK Parameters	Mean (% CV)		% GLSM Ratio (90% CI)
	Test	Reference	
Cohort 1, Analyte: SOF			
	Treatment B (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	1255.7 (36.5)	1924.9 (26.7)	62.11 (55.98, 68.91)
AUCinf (h*ng/mL)	1287.8 (37.9)	1938.6 (26.6)	62.97 (56.79, 69.82)
Cmax (ng/mL)	906.6 (43.6)	1558.1 (32.1)	55.00 (48.19, 62.78)
Cohort 2, Analyte: SOF			
	Treatment C (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	1598.3 (45.6)	1730.4 (54.5)	93.86 (86.41, 101.95)
AUCinf (h*ng/mL)	1640.4 (44.2)	1744.5 (54.3)	94.01 (86.36, 102.33)
Cmax (ng/mL)	1171.8 (44.8)	1474.6 (49.9)	80.36 (71.91, 89.80)

CV = coefficient of variation; GLSM = geometric least-squares mean; CI = confidence interval.

n represents the number of subjects in the PK analysis set.

Means presented are unadjusted arithmetic means.

= median (Q1, Q3)

Treatment code: A= SOF/VEL fixed dose combination (FDC) tablet, fasted; B= granules FDC1, fasted; C= granules FDC2, fasted; G= granules FDC2, fed.

Data Extracted: CRF data: 30MAR2018

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	Test	Reference	
Cohort 2, Analyte: SOF			
	Treatment G (N=56)	Treatment C (N=56)	
AUClast (h*ng/mL)	2494.5 (36.1)	1598.3 (45.6)	167.69 (150.62, 186.70)
AUCinf (h*ng/mL)	2523.7 (35.8)	1640.4 (44.2)	164.11 (147.95, 182.03)
Cmax (ng/mL)	1194.1 (43.0)	1171.8 (44.8)	105.26 (91.41, 121.20)
Cohort 1, Analyte: GS-331007			
	Treatment B (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	11264.0 (23.3)	11822.5 (21.0)	94.80 (91.79, 97.91)
AUCinf (h*ng/mL)	11864.5 (22.7)	12396.5 (20.2)	95.19 (92.24, 98.24)
Cmax (ng/mL)	1105.0 (27.5)	944.3 (32.7)	118.00 (112.02, 124.30)

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Cohort 2, Analyte: GS-331007			
	Treatment C (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	11315.9 (23.9)	11077.1 (25.6)	102.26 (99.55, 105.05)
AUCinf (h*ng/mL)	11910.3 (22.3)	11721.6 (24.4)	101.83 (99.29, 104.45)
Cmax (ng/mL)	988.2 (24.4)	910.3 (29.2)	109.43 (103.95, 115.20)
	Treatment G (N=56)	Treatment C (N=56)	
AUClast (h*ng/mL)	11678.3 (22.0)	11315.9 (23.9)	103.80 (100.23, 107.51)
AUCinf (h*ng/mL)	12341.7 (21.9)	11910.3 (22.3)	103.82 (100.45, 107.31)
Cmax (ng/mL)	621.9 (20.3)	988.2 (24.4)	63.59 (60.57, 66.76)

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PK Parameters	Mean (% CV)		% GLSM Ratio (90% CI)
	Test	Reference	
Cohort 1, Analyte: GS-566500			
	Treatment B (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	1575.7 (32.7)	2120.5 (22.4)	71.63 (66.26, 77.44)
AUCinf (h*ng/mL)	1626.1 (32.1)	2174.8 (22.2)	72.23 (66.95, 77.93)
Cmax (ng/mL)	395.6 (31.2)	548.7 (22.1)	70.13 (65.30, 75.31)
Cohort 2, Analyte: GS-566500			
	Treatment C (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	1868.2 (35.4)	1912.3 (37.2)	97.46 (91.99, 103.27)
AUCinf (h*ng/mL)	1917.2 (34.7)	1968.8 (36.6)	97.24 (91.92, 102.86)
Cmax (ng/mL)	468.8 (35.5)	491.8 (39.1)	95.61 (89.41, 102.23)

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Treatment code: A= SOF/VEL fixed dose combination (FDC) tablet, fasted; B= granules FDC1, fasted; C= granules FDC2, fasted; G= granules FDC2, fed.

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	Test	Reference	
Cohort 2, Analyte: GS-566500			
	Treatment G (N=56)	Treatment C (N=56)	
AUClast (h*ng/mL)	2719.5 (19.0)	1868.2 (35.4)	154.39 (142.37, 167.43)
AUCinf (h*ng/mL)	2777.5 (18.6)	1917.2 (34.7)	153.19 (141.65, 165.68)
Cmax (ng/mL)	530.1 (21.2)	468.8 (35.5)	118.91 (109.19, 129.49)
Cohort 1, Analyte: VEL			
	Treatment B (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	2951.8 (46.7)	4250.9 (37.3)	67.19 (60.23, 74.96)
AUCinf (h*ng/mL)	2991.7 (46.5)	4294.8 (37.1)	67.47 (60.57, 75.16)
Cmax (ng/mL)	359.2 (40.3)	533.9 (36.4)	66.10 (59.23, 73.76)

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Treatment code: A= SOF/VEL fixed dose combination (FDC) tablet, fasted; B= granules FDC1, fasted; C= granules FDC2, fasted; G= granules FDC2, fed.

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	Test	Reference	
Cohort 2, Analyte: VEL			
	Treatment C (N=56)	Treatment A (N=56)	
AUClast (h*ng/mL)	3740.3 (56.5)	4068.8 (62.4)	93.56 (82.00, 106.74)
AUCinf (h*ng/mL)	3782.7 (56.0)	4113.1 (62.1)	94.01 (82.75, 106.81)
Cmax (ng/mL)	476.5 (51.9)	497.3 (57.9)	97.25 (85.83, 110.19)
Cohort 2, Analyte: VEL			
	Treatment G (N=56)	Treatment C (N=56)	
AUClast (h*ng/mL)	3906.8 (44.0)	3740.3 (56.5)	122.33 (101.35, 147.65)
AUCinf (h*ng/mL)	3957.5 (44.0)	3782.7 (56.0)	121.16 (101.06, 145.25)
Cmax (ng/mL)	407.1 (32.8)	476.5 (51.9)	100.88 (84.94, 119.81)

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