

Table 15.10.1.5: Summary of PK Exposures from Pediatric Subjects in Study 334-1112 Compared to the Adult Subjects in SOF Program
 Intensive PK Analysis Set
 Cohort 1 in PK Lead-in Phase

12 to < 18 Years Old: SOF(400mg)+REV

GS-331007	
Subject Population	AUCtau (h*ng/mL)
Pediatric Population	
N	10
Mean (SD)	9106.0 (2601.96)
CV (%)	28.6
Median	8508.1
Min, Max	5209.9, 14929.4
Geometric Mean	8795.4
SOF NDA Adult Population	
N	1695
Mean (SD)	7122.6 (2185.14)
CV (%)	30.7
Median	6880.9
Min, Max	1663.5, 18789.3
Geometric Mean	6792.6
GMR (%): Pediatric Population/ SOF NDA Adult Population	129.48
90% CI (%)	(109.96, 152.48)

Note: SOF Adult Population = HCV-infected adult subjects administered SOF/REV +/- PEG in Phase 2 and 3 studies.
 Note: GMR = Geometric Mean Ratio.

Data Extracted: 04Oct2018

Source: .../svr24_final/version1/prog/t-pkcomp.sas v9.4 Output file: t-pkcomp-p-a-cl.out 10OCT2018:11:03

Table 15.10.2.5: Summary of PK Exposures from Pediatric Subjects in Study 334-1112 Compared to the Adult Subjects in SOF Program
 Intensive PK Analysis Set
 Cohort 2 in PK Lead-in Phase

6 to < 12 Years Old: SOF(200mg)+RBV

GS-331007	
Subject Population	AUCtau (h*ng/mL)
Pediatric Population	
N	10
Mean (SD)	7651.2 (1723.32)
CV (%)	22.5
Median	8027.2
Min, Max	4777.2, 10105.6
Geometric Mean	7458.1
SOF NDA Adult Population	
N	1695
Mean (SD)	7122.6 (2185.14)
CV (%)	30.7
Median	6880.9
Min, Max	1663.5, 18789.3
Geometric Mean	6792.6
GMR (%): Pediatric Population/ SOF NDA Adult Population	109.80
90% CI (%)	(93.25, 129.29)

Note: SOF Adult Population = HCV-infected adult subjects administered SOF/RBV +/- PEG in Phase 2 and 3 studies.
 Note: GMR = Geometric Mean Ratio.

Data Extracted: 04Oct2018

Source: .../svr24_final/version1/prog/t-pkcomp.sas v9.4 Output file: t-pkcomp-p-a-c2.out 10OCT2018:11:03

Table 15.10.3.5: Summary of PK Exposures from Pediatric Subjects in Study 334-1112 Compared to the Adult Subjects in SOF Program
 Intensive PK Analysis Set
 Cohort 3 in PK Lead-in Phase

3 to < 6 Years Old: SOF(200mg or 150mg)+RBV

GS-331007	
Subject Population	AUCtau (h*ng/mL)
Pediatric Population	
N	10
Mean (SD)	10293.7 (1860.57)
CV (%)	18.1
Median	9915.0
Min, Max	8821.6, 15115.5
Geometric Mean	10166.1
SOF NDA Adult Population	
N	1695
Mean (SD)	7122.6 (2185.14)
CV (%)	30.7
Median	6880.9
Min, Max	1663.5, 18789.3
Geometric Mean	6792.6
GMR (%): Pediatric Population/ SOF NDA Adult Population	149.67
90% CI (%)	(127.12, 176.21)

Note: SOF Adult Population = HCV-infected adult subjects administered SOF/RBV +/- PEG in Phase 2 and 3 studies.
 Note: GMR = Geometric Mean Ratio.

Data Extracted: 04Oct2018

Source: .../svr24_final/version1/prog/t-pkcomp.sas v9.4 Output file: t-pkcomp-p-a-c3.out 10OCT2018:11:03