Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Basophils (/uL)			
Baseline			
n	4	6	10
Mean (SD)	25.0 (50.00)	66.7 (51.64)	50.0 (52.70)
Median	0.0	100.0	50.0
Min, Max	0, 100	0, 100	0, 100
46 hr			
n	4	6	10
Mean (SD)	25.0 (50.00)	33.3 (51.64)	30.0 (48.30)
Median	0.0	0.0	0.0
Min, Max	0, 100	0, 100	0, 100
Change from Baseline:			
n	4	6	10
Mean (SD)	0.0 (81.65)	-33.3 (51.64)	-20.0 (63.25)
Median	0.0	0.0	0.0
Min, Max	-100, 100	-100, 0	-100, 100

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Basophils/Leukocytes (%)			
Baseline			
n	4	6	10
Mean (SD)	0.8 (0.50)	1.0 (0.00)	0.9 (0.32)
Median	1.0	1.0	1.0
Min, Max	0, 1	1, 1	0, 1
46 hr			
n	4	6	10
Mean (SD)	0.5 (0.58)	0.5 (0.55)	0.5 (0.53)
Median	0.5	0.5	0.5
Min, Max	0, 1	0, 1	0, 1
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.3 (0.96)	-0.5 (0.55)	-0.4 (0.70)
Median	-0.5	-0.5	-0.5
Min, Max	-1, 1	-1, 0	-1, 1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Eosinophils (/uL)			
Baseline			
n	4	6	10
Mean (SD)	150.0 (57.74)	250.0 (216.79)	210.0 (172.88)
Median	150.0	200.0	200.0
Min, Max	100, 200	0, 600	0, 600
46 hr			
n	4	6	10
Mean (SD)	150.0 (57.74)	250.0 (187.08)	210.0 (152.39)
Median	150.0	200.0	200.0
Min, Max	100, 200	100, 600	100, 600
Change from Baseline:			
n	4	6	10
Mean (SD)	0.0 (81.65)	0.0 (63.25)	0.0 (66.67)
Median	0.0	0.0	0.0
Min, Max	-100, 100	-100, 100	-100, 100

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Eosinophils/Leukocytes (%)			
Baseline			
n	4	6	10
Mean (SD)	2.5 (0.58)	3.7 (2.94)	3.2 (2.30)
Median	2.5	2.5	2.5
Min, Max	2, 3	1, 9	1, 9
46 hr			
n	4	6	10
Mean (SD)	2.3 (0.50)	3.0 (1.79)	2.7 (1.42)
Median	2.0	2.5	2.0
Min, Max	2, 3	1, 6	1, 6
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.3 (0.50)	-0.7 (1.37)	-0.5 (1.08)
Median	0.0	-0.5	0.0
Min, Max	-1, 0	-3, 1	-3, 1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Hematocrit (%)			
Baseline			
n	4	6	10
Mean (SD)	42.8 (2.50)	38.2 (1.17)	40.0 (2.91)
Median	42.5	38.5	39.0
Min, Max	40, 46	36, 39	36, 46
46 hr			
n	4	6	10
Mean (SD)	40.0 (1.83)	36.8 (3.43)	38.1 (3.21)
Median	40.0	36.5	38.5
Min, Max	38, 42	32, 42	32, 42
Change from Baseline:			
n	4	6	10
Mean (SD)	-2.8 (3.86)	-1.3 (4.37)	-1.9 (4.01)
Median	-2.0	-1.5	-1.5
Min, Max	-8, 1	-7, 6	-8, 6

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Hemoglobin (g/dL)			
Baseline			
n	4	6	10
Mean (SD)	13.18 (0.670)	12.37 (0.703)	12.69 (0.774)
Median	13.25	12.15	12.60
Min, Max	12.3, 13.9	11.7, 13.5	11.7, 13.9
46 hr			
n	4	6	10
Mean (SD)	13.65 (0.624)	12.60 (1.506)	13.02 (1.298)
Median	13.70	12.35	13.15
Min, Max	12.9, 14.3	10.6, 14.8	10.6, 14.8
Change from Baseline:			
n	4	6	10
Mean (SD)	0.48 (1.138)	0.23 (1.485)	0.33 (1.294)
Median	0.60	-0.25	0.05
Min, Max	-1.0, 1.7	-1.2, 3.1	-1.2, 3.1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Lymphocytes (/uL)			
Baseline			
n	4	6	10
Mean (SD)	2050.0 (331.66)	1900.0 (442.72)	1960.0 (389.30)
Median	1950.0	1950.0	1950.0
Min, Max	1800, 2500	1200, 2300	1200, 2500
46 hr			
n	4	6	10
Mean (SD)	2050.0 (369.68)	2033.3 (602.22)	2040.0 (497.10)
Median	2050.0	1900.0	2000.0
Min, Max	1600, 2500	1300, 2800	1300, 2800
Change from Baseline:			
n	4	6	10
Mean (SD)	0.0 (424.26)	133.3 (326.60)	80.0 (352.14)
Median	50.0	100.0	100.0
Min, Max	-500, 400	-300, 600	-500, 600

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Lymphocytes/Leukocytes (%)			
Baseline			
n	4	6	10
Mean (SD)	33.3 (6.24)	28.5 (4.68)	30.4 (5.58)
Median	33.0	28.5	29.5
Min, Max	27, 40	22, 34	22, 40
46 hr			
n	4	6	10
Mean (SD)	29.8 (6.85)	29.8 (7.41)	29.8 (6.80)
Median	26.5	28.5	27.5
Min, Max	26, 40	21, 43	21, 43
Change from Baseline:			
n	4	6	10
Mean (SD)	-3.5 (7.33)	1.3 (7.17)	-0.6 (7.26)
Median	-1.5	2.5	-1.5
Min, Max	-14, 3	-7, 9	-14, 9

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Monocytes (/uL)			
Baseline			
n	4	6	10
Mean (SD)	475.0 (150.00)	466.7 (196.64)	470.0 (170.29)
Median	500.0	500.0	500.0
Min, Max	300, 600	200, 700	200, 700
46 hr			
n	4	6	10
Mean (SD)	450.0 (173.21)	416.7 (222.86)	430.0 (194.65)
Median	450.0	300.0	300.0
Min, Max	300, 600	200, 700	200, 700
Change from Baseline:			
n	4	6	10
Mean (SD)	-25.0 (206.16)	-50.0 (137.84)	-40.0 (157.76)
Median	0.0	0.0	0.0
Min, Max	-300, 200	-300, 100	-300, 200

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Monocytes/Leukocytes (%)			
Baseline			
n	4	6	10
Mean (SD)	7.8 (2.06)	6.8 (2.32)	7.2 (2.15)
Median	7.5	6.5	6.5
Min, Max	6, 10	4, 10	4, 10
46 hr			
n	4	6	10
Mean (SD)	6.0 (1.83)	5.5 (2.17)	5.7 (1.95)
Median	6.0	5.0	5.5
Min, Max	4, 8	3, 8	3, 8
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.8 (2.99)	-1.3 (1.75)	-1.5 (2.17)
Median	-1.0	-1.5	-1.0
Min, Max	-6, 1	-4, 1	-6, 1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Neutrophils (/uL)			
Baseline			
n	4	6	10
Mean (SD)	3475.0 (699.40)	4016.7 (893.12)	3800.0 (827.31)
Median	3400.0	3750.0	3750.0
Min, Max	2800, 4300	3400, 5800	2800, 5800
46 hr			
n	4	6	10
Mean (SD)	4375.0 (842.12)	4250.0 (1094.99)	4300.0 (952.19)
Median	4400.0	4250.0	4400.0
Min, Max	3400, 5300	2900, 5500	2900, 5500
Change from Baseline:			
n	4	6	10
Mean (SD)	900.0 (683.13)	233.3 (1206.10)	500.0 (1040.30)
Median	800.0	-250.0	400.0
Min, Max	200, 1800	-1000, 2100	-1000, 2100

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Neutrophils/Leukocytes (%)			
Baseline			
n	4	6	10
Mean (SD)	55.8 (7.85)	60.0 (7.38)	58.3 (7.45)
Median	56.0	60.0	59.5
Min, Max	48, 63	51, 71	48, 71
46 hr			
n	4	6	10
Mean (SD)	61.5 (5.07)	61.2 (5.71)	61.3 (5.17)
Median	63.5	63.0	63.0
Min, Max	54, 65	50, 66	50, 66
Change from Baseline:			
n	4	6	10
Mean (SD)	5.8 (6.29)	1.2 (7.94)	3.0 (7.33)
Median	3.5	1.0	3.0
Min, Max	1, 15	-8, 10	-8, 15

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Platelets (10^3/uL)			
Baseline			
n	4	6	10
Mean (SD)	311.5 (35.97)	367.2 (72.91)	344.9 (64.89)
Median	309.5	384.0	357.0
Min, Max	277, 350	228, 440	228, 440
46 hr			
n	4	6	10
Mean (SD)	298.8 (54.57)	362.3 (72.47)	336.9 (70.63)
Median	283.0	340.0	307.0
Min, Max	252, 377	298, 479	252, 479
Change from Baseline:			
n	4	6	10
Mean (SD)	-12.8 (60.82)	-4.8 (75.97)	-8.0 (66.75)
Median	2.0	-13.0	2.0
Min, Max	-98, 43	-91, 79	-98, 79

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Erythrocytes (10^6/uL)			
Baseline			
n	4	6	10
Mean (SD)	5.070 (0.4163)	4.458 (0.3595)	4.703 (0.4789)
Median	5.000	4.515	4.695
Min, Max	4.64, 5.64	4.01, 4.90	4.01, 5.64
46 hr			
n	4	6	10
Mean (SD)	4.758 (0.0877)	4.355 (0.2847)	4.516 (0.3013)
Median	4.750	4.260	4.660
Min, Max	4.66, 4.87	4.05, 4.75	4.05, 4.87
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.312 (0.4759)	-0.103 (0.5205)	-0.187 (0.4875)
Median	-0.200	-0.155	-0.170
Min, Max	-0.98, 0.13	-0.85, 0.74	-0.98, 0.74

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.1
Summary of Mean and Mean Change from Baseline in Laboratory Hematology Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Leukocytes (/uL)			
Baseline			
n	4	6	10
Mean (SD)	6225.0 (486.79)	6668.3 (1224.51)	6491.0 (982.04)
Median	6260.0	6430.0	6285.0
Min, Max	5600, 6780	5450, 8930	5450, 8930
46 hr			
n	4	6	10
Mean (SD)	7087.5 (1072.89)	6951.7 (1640.18)	7006.0 (1372.28)
Median	6965.0	7230.0	7115.0
Min, Max	6090, 8330	4580, 8670	4580, 8670
Change from Baseline:			
n	4	6	10
Mean (SD)	862.5 (734.14)	283.3 (1219.14)	515.0 (1046.34)
Median	1000.0	-140.0	340.0
Min, Max	-100, 1550	-870, 2430	-870, 2430

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-1-lb-hema.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Albumin (g/dL)			
Baseline			
n	4	6	10
Mean (SD)	5.23 (0.403)	5.17 (0.484)	5.19 (0.431)
Median	5.10	5.20	5.10
Min, Max	4.9, 5.8	4.5, 5.8	4.5, 5.8
46 hr			
n	4	6	10
Mean (SD)	4.90 (0.432)	5.12 (0.214)	5.03 (0.316)
Median	5.00	5.05	5.05
Min, Max	4.3, 5.3	4.9, 5.5	4.3, 5.5
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.33 (0.785)	-0.05 (0.418)	-0.16 (0.568)
Median	0.05	0.05	0.05
Min, Max	-1.5, 0.1	-0.8, 0.4	-1.5, 0.4

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Alkaline Phosphatase (U/L)			
Baseline			
n	4	6	10
Mean (SD)	140.8 (42.77)	86.5 (16.08)	108.2 (39.22)
Median	136.5	91.0	97.0
Min, Max	96, 194	64, 105	64, 194
46 hr			
n	4	6	10
Mean (SD)	126.8 (46.21)	89.0 (16.05)	104.1 (35.14)
Median	117.5	84.5	95.5
Min, Max	81, 191	69, 112	69, 191
Change from Baseline:			
n	4	6	10
Mean (SD)	-14.0 (18.00)	2.5 (12.77)	-4.1 (16.47)
Median	-9.0	2.0	-2.0
Min, Max	-39, 1	-11, 21	-39, 21

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Alanine Aminotransferase (U/L)			
Baseline			
n	4	6	10
Mean (SD)	10.5 (3.00)	11.2 (2.64)	10.9 (2.64)
Median	11.0	11.5	11.5
Min, Max	7, 13	7, 15	7, 15
46 hr			
n	4	6	10
Mean (SD)	13.5 (6.66)	15.2 (4.83)	14.5 (5.34)
Median	11.5	16.0	15.0
Min, Max	8, 23	7, 22	7, 23
Change from Baseline:			
n	4	6	10
Mean (SD)	3.0 (6.06)	4.0 (2.61)	3.6 (4.03)
Median	2.5	4.5	4.5
Min, Max	-3, 10	0, 7	-3, 10

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Aspartate Aminotransferase (U/L)			
Baseline			
n	4	6	10
Mean (SD)	20.0 (2.83)	23.2 (3.82)	21.9 (3.67)
Median	19.0	23.0	22.0
Min, Max	18, 24	17, 28	17, 28
46 hr			
n	4	6	10
Mean (SD)	24.5 (1.91)	23.7 (1.86)	24.0 (1.83)
Median	24.0	24.0	24.0
Min, Max	23, 27	21, 26	21, 27
Change from Baseline:			
n	4	6	10
Mean (SD)	4.5 (3.42)	0.5 (4.72)	2.1 (4.53)
Median	4.0	0.5	2.0
Min, Max	1, 9	-6, 8	-6, 9

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Bicarbonate (mEq/L)			
Baseline			
n	4	6	10
Mean (SD)	27.3 (1.50)	25.7 (1.63)	26.3 (1.70)
Median	28.0	26.0	26.0
Min, Max	25, 28	23, 28	23, 28
46 hr			
n	4	6	10
Mean (SD)	24.5 (1.29)	26.2 (2.14)	25.5 (1.96)
Median	24.5	27.0	25.5
Min, Max	23, 26	23, 28	23, 28
Change from Baseline:			
n	4	6	10
Mean (SD)	-2.8 (0.96)	0.5 (2.07)	-0.8 (2.35)
Median	-2.5	1.5	-1.5
Min, Max	-4, -2	-3, 2	-4, 2

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Bilirubin (mg/dL)			
Baseline			
n	4	6	10
Mean (SD)	0.720 (0.0000)	0.720 (0.0000)	0.720 (0.0000)
Median	0.720	0.720	0.720
Min, Max	0.72, 0.72	0.72, 0.72	0.72, 0.72
46 hr			
n	4	6	10
Mean (SD)	0.720 (0.0000)	0.710 (0.0590)	0.714 (0.0443)
Median	0.720	0.720	0.720
Min, Max	0.72, 0.72	0.60, 0.78	0.60, 0.78
Change from Baseline:			
n	4	6	10
Mean (SD)	0.000 (0.0000)	-0.010 (0.0590)	-0.006 (0.0443)
Median	0.000	0.000	0.000
Min, Max	0.00, 0.00	-0.12, 0.06	-0.12, 0.06

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Calcium (mg/dL)			
Baseline			
n	4	6	10
Mean (SD)	9.820 (0.3370)	9.760 (0.4685)	9.784 (0.4010)
Median	9.840	9.860	9.860
Min, Max	9.44, 10.16	8.88, 10.16	8.88, 10.16
46 hr			
n	4	6	10
Mean (SD)	9.620 (0.3141)	9.607 (0.2522)	9.612 (0.2613)
Median	9.740	9.540	9.640
Min, Max	9.16, 9.84	9.28, 9.96	9.16, 9.96
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.200 (0.6205)	-0.153 (0.3987)	-0.172 (0.4661)
Median	-0.100	-0.220	-0.220
Min, Max	-1.00, 0.40	-0.52, 0.60	-1.00, 0.60

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Cholesterol (mg/dL)			
Baseline			
n	4	6	10
Mean (SD)	148.6 (18.25)	172.5 (25.34)	162.9 (24.88)
Median	154.4	169.9	158.3
Min, Max	123.6, 162.2	146.7, 208.5	123.6, 208.5
46 hr			
n	4	6	10
Mean (SD)	136.1 (22.15)	164.1 (16.70)	152.9 (22.96)
Median	133.2	160.2	152.5
Min, Max	115.8, 162.2	146.7, 189.2	115.8, 189.2
Change from Baseline:			
n	4	6	10
Mean (SD)	-12.55 (11.53)	-8.366 (22.57)	-10.04 (18.22)
Median	-11.58	-9.652	-11.58
Min, Max	-27.03, 0	-38.61, 27.03	-38.61, 27.03

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Chloride (mEq/L)			
Baseline			
n	4	6	10
Mean (SD)	98.8 (0.50)	98.7 (0.82)	98.7 (0.67)
Median	99.0	98.5	99.0
Min, Max	98, 99	98, 100	98, 100
46 hr			
n	4	6	10
Mean (SD)	97.0 (1.41)	98.2 (0.98)	97.7 (1.25)
Median	96.5	98.5	97.5
Min, Max	96, 99	97, 99	96, 99
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.8 (1.26)	-0.5 (1.05)	-1.0 (1.25)
Median	-2.0	-0.5	-1.0
Min, Max	-3, 0	-2, 1	-3, 1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Creatinine Phosphokinase (U/L)			
Baseline			
n	4	6	10
Mean (SD)	100.3 (28.94)	126.5 (75.60)	116.0 (60.31)
Median	90.5	109.0	97.5
Min, Max	78, 142	45, 266	45, 266
46 hr			
n	4	6	10
Mean (SD)	106.0 (36.04)	133.8 (45.08)	122.7 (42.05)
Median	103.0	124.5	117.0
Min, Max	66, 152	95, 222	66, 222
Change from Baseline:			
n	4	6	10
Mean (SD)	5.8 (46.82)	7.3 (44.40)	6.7 (42.74)
Median	-10.5	-1.0	-7.5
Min, Max	-30, 74	-44, 77	-44, 77

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Creatinine (mg/dL)			
Baseline			
n	4	6	10
Mean (SD)	0.800 (0.0804)	0.793 (0.0993)	0.796 (0.0875)
Median	0.785	0.810	0.785
Min, Max	0.72, 0.91	0.66, 0.89	0.66, 0.91
46 hr			
n	4	6	10
Mean (SD)	0.780 (0.0469)	0.827 (0.0799)	0.808 (0.0697)
Median	0.800	0.800	0.800
Min, Max	0.71, 0.81	0.74, 0.97	0.71, 0.97
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.020 (0.1257)	0.033 (0.0985)	0.012 (0.1069)
Median	0.015	0.060	0.030
Min, Max	-0.20, 0.09	-0.09, 0.14	-0.20, 0.14

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Gamma Glutamyl Transferase (U/L)			
Baseline			
n	4	6	10
Mean (SD)	16.5 (4.12)	17.2 (4.58)	16.9 (4.18)
Median	17.0	16.0	16.0
Min, Max	12, 20	11, 23	11, 23
46 hr			
n	4	6	10
Mean (SD)	15.5 (2.38)	18.7 (2.73)	17.4 (2.95)
Median	15.5	17.5	17.0
Min, Max	13, 18	16, 23	13, 23
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.0 (4.55)	1.5 (2.59)	0.5 (3.50)
Median	-1.5	0.5	0.0
Min, Max	-6, 5	-1, 6	-6, 6

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Glucose (mg/dL)			
Baseline			
n	4	6	10
Mean (SD)	79.29 (1.471)	82.29 (4.365)	81.09 (3.703)
Median	79.29	81.99	80.19
Min, Max	77.49, 81.09	77.49, 90.10	77.49, 90.10
46 hr			
n	4	6	10
Mean (SD)	79.74 (4.505)	81.39 (6.181)	80.73 (5.359)
Median	80.19	80.19	80.19
Min, Max	73.88, 84.69	73.88, 90.10	73.88, 90.10
Change from Baseline:			
n	4	6	10
Mean (SD)	0.4505 (5.954)	-0.9010 (5.436)	-0.3604 (5.359)
Median	0.9010	-1.802	0
Min, Max	-7.208, 7.208	-5.406, 9.010	-7.208, 9.010

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Potassium (mEq/L)			
Baseline			
n	4	6	10
Mean (SD)	3.95 (0.129)	4.02 (0.248)	3.99 (0.202)
Median	3.95	4.05	4.00
Min, Max	3.8, 4.1	3.6, 4.3	3.6, 4.3
46 hr			
n	4	6	10
Mean (SD)	3.90 (0.082)	4.18 (0.467)	4.07 (0.380)
Median	3.90	4.00	3.90
Min, Max	3.8, 4.0	3.7, 4.9	3.7, 4.9
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.05 (0.129)	0.17 (0.468)	0.08 (0.374)
Median	-0.05	0.20	0.05
Min, Max	-0.2, 0.1	-0.6, 0.8	-0.6, 0.8

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Magnesium (mEq/L)			
Baseline			
n	4	6	10
Mean (SD)	1.895 (0.2042)	1.770 (0.1307)	1.820 (0.1660)
Median	1.940	1.770	1.820
Min, Max	1.64, 2.06	1.64, 1.98	1.64, 2.06
46 hr			
n	4	6	10
Mean (SD)	1.725 (0.1821)	1.717 (0.1483)	1.720 (0.1526)
Median	1.680	1.730	1.680
Min, Max	1.56, 1.98	1.56, 1.90	1.56, 1.98
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.170 (0.3380)	-0.053 (0.1677)	-0.100 (0.2394)
Median	-0.170	-0.120	-0.120
Min, Max	-0.50, 0.16	-0.18, 0.26	-0.50, 0.26

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Phosphate (mg/dL)			
Baseline			
n	4	6	10
Mean (SD)	3.736 (0.1174)	3.260 (0.4604)	3.450 (0.4273)
Median	3.782	3.178	3.627
Min, Max	3.565, 3.813	2.728, 3.875	2.728, 3.875
46 hr			
n	4	6	10
Mean (SD)	3.333 (0.6603)	3.767 (0.4281)	3.593 (0.5453)
Median	3.054	3.813	3.767
Min, Max	2.914, 4.309	2.976, 4.247	2.914, 4.309
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.4030 (0.6796)	0.5063 (0.5789)	0.1426 (0.7487)
Median	-0.6355	0.5735	0.2635
Min, Max	-0.8990, 0.5580	-0.4030, 1.085	-0.8990, 1.085

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Protein (g/dL)			
Baseline			
n	4	6	10
Mean (SD)	7.68 (0.640)	8.00 (0.775)	7.87 (0.706)
Median	7.60	8.00	7.95
Min, Max	7.0, 8.5	6.7, 9.1	6.7, 9.1
46 hr			
n	4	6	10
Mean (SD)	7.53 (0.655)	7.92 (0.232)	7.76 (0.462)
Median	7.55	7.95	7.80
Min, Max	6.7, 8.3	7.6, 8.2	6.7, 8.3
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.15 (1.109)	-0.08 (0.640)	-0.11 (0.799)
Median	0.35	-0.10	0.00
Min, Max	-1.8, 0.5	-1.1, 0.9	-1.8, 0.9

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Sodium (mEq/L)			
Baseline			
n	4	6	10
Mean (SD)	138.5 (0.58)	138.3 (1.37)	138.4 (1.07)
Median	138.5	138.0	138.0
Min, Max	138, 139	137, 140	137, 140
46 hr			
n	4	6	10
Mean (SD)	136.8 (0.50)	137.5 (0.84)	137.2 (0.79)
Median	137.0	138.0	137.0
Min, Max	136, 137	136, 138	136, 138
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.8 (0.50)	-0.8 (1.17)	-1.2 (1.03)
Median	-2.0	-1.0	-1.5
Min, Max	-2, -1	-2, 1	-2, 1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Triglycerides (mg/dL)			
Baseline			
n	4	6	10
Mean (SD)	77.44 (28.33)	64.90 (19.92)	69.92 (23.02)
Median	88.50	66.38	79.65
Min, Max	35.40, 97.35	44.25, 88.50	35.40, 97.35
46 hr			
n	4	6	10
Mean (SD)	92.93 (30.23)	78.18 (29.31)	84.08 (28.98)
Median	88.50	75.23	84.08
Min, Max	61.95, 132.8	44.25, 115.1	44.25, 132.8
Change from Baseline:			
n	4	6	10
Mean (SD)	15.49 (19.62)	13.28 (19.99)	14.16 (18.75)
Median	17.70	17.70	17.70
Min, Max	-8.850, 35.40	-17.70, 35.40	-17.70, 35.40

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.2
Summary of Mean and Mean Change from Baseline in Laboratory Chemistry Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Urea (mmol/L)			
Baseline			
n	4	6	10
Mean (SD)	3.13 (0.877)	2.90 (0.657)	2.99 (0.714)
Median	3.20	2.95	3.00
Min, Max	2.0, 4.1	1.8, 3.8	1.8, 4.1
46 hr			
n	4	6	10
Mean (SD)	3.20 (0.707)	4.00 (0.590)	3.68 (0.728)
Median	3.25	3.90	3.60
Min, Max	2.3, 4.0	3.4, 4.7	2.3, 4.7
Change from Baseline:			
n	4	6	10
Mean (SD)	0.08 (0.750)	1.10 (0.405)	0.69 (0.748)
Median	-0.05	1.05	0.95
Min, Max	-0.7, 1.1	0.5, 1.6	-0.7, 1.6

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-2-lb-chem.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.3
Summary of Mean and Mean Change from Baseline in Laboratory Coagulation Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Activated Partial Thromboplastin Time (sec)			
Baseline			
n	4	6	10
Mean (SD)	30.20 (2.618)	33.92 (4.631)	32.43 (4.228)
Median	30.50	33.40	32.70
Min, Max	27.0, 32.8	27.7, 42.0	27.0, 42.0
46 hr			
n	4	6	10
Mean (SD)	33.90 (4.938)	32.42 (2.391)	33.01 (3.448)
Median	33.20	32.40	32.40
Min, Max	28.8, 40.4	28.7, 36.1	28.7, 40.4
Change from Baseline:			
n	4	6	10
Mean (SD)	3.70 (6.537)	-1.50 (2.553)	0.58 (5.008)
Median	0.90	-1.10	0.00
Min, Max	-0.4, 13.4	-5.9, 1.0	-5.9, 13.4

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-3-lb-coag.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.3
Summary of Mean and Mean Change from Baseline in Laboratory Coagulation Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Prothrombin Intl. Normalized Ratio			
Baseline			
n	4	6	10
Mean (SD)	1.03 (0.050)	1.02 (0.041)	1.02 (0.042)
Median	1.00	1.00	1.00
Min, Max	1.0, 1.1	1.0, 1.1	1.0, 1.1
46 hr			
n	4	6	10
Mean (SD)	1.00 (0.000)	1.00 (0.000)	1.00 (0.000)
Median	1.00	1.00	1.00
Min, Max	1.0, 1.0	1.0, 1.0	1.0, 1.0
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.03 (0.050)	-0.02 (0.041)	-0.02 (0.042)
Median	0.00	0.00	0.00
Min, Max	-0.1, 0.0	-0.1, 0.0	-0.1, 0.0

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-3-lb-coag.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.3
Summary of Mean and Mean Change from Baseline in Laboratory Coagulation Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Prothrombin Time (sec)			
Baseline			
n	4	6	10
Mean (SD)	14.50 (0.408)	13.52 (1.351)	13.91 (1.152)
Median	14.35	13.50	14.25
Min, Max	14.2, 15.1	11.7, 15.2	11.7, 15.2
46 hr			
n	4	6	10
Mean (SD)	13.33 (0.250)	13.42 (0.873)	13.38 (0.668)
Median	13.35	13.40	13.35
Min, Max	13.0, 13.6	12.1, 14.7	12.1, 14.7
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.17 (0.411)	-0.10 (1.460)	-0.53 (1.245)
Median	-1.10	-0.15	-0.85
Min, Max	-1.7, -0.8	-2.2, 1.9	-2.2, 1.9

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Table 14.3.4.4
Summary of Mean and Mean Change from Baseline in Laboratory Urinalysis Results
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Urine pH			
Baseline			
n	4	6	10
Mean (SD)	6.0 (0.00)	6.0 (0.63)	6.0 (0.47)
Median	6.0	6.0	6.0
Min, Max	6, 6	5, 7	5, 7
46 hr			
n	4	6	10
Mean (SD)	5.8 (0.50)	5.8 (0.41)	5.8 (0.42)
Median	6.0	6.0	6.0
Min, Max	5, 6	5, 6	5, 6
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.3 (0.50)	-0.2 (0.75)	-0.2 (0.63)
Median	0.0	0.0	0.0
Min, Max	-1, 0	-1, 1	-1, 1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-4-lb-urine.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Weight (kg)			
Baseline			
n	4	6	10
Mean (SD)	50.98 (13.152)	55.65 (12.878)	53.78 (12.475)
Median	46.15	52.60	50.25
Min, Max	41.4, 70.2	43.2, 79.5	41.4, 79.5
24 hr			
n	4	6	10
Mean (SD)	50.98 (13.091)	56.03 (12.834)	54.01 (12.468)
Median	46.25	53.30	50.85
Min, Max	41.3, 70.1	43.3, 79.8	41.3, 79.8
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.00 (0.141)	0.38 (0.436)	0.23 (0.389)
Median	-0.05	0.25	0.15
Min, Max	-0.1, 0.2	0.0, 1.2	-0.1, 1.2

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Weight (kg), CONT'D			
Post-Study			
n	4	6	10
Mean (SD)	51.15 (12.962)	56.10 (12.377)	54.12 (12.151)
Median	46.65	53.30	50.55
Min, Max	41.2, 70.1	43.5, 79.0	41.2, 79.0
Change from Baseline:			
n	4	6	10
Mean (SD)	0.17 (0.685)	0.45 (0.689)	0.34 (0.664)
Median	-0.15	0.45	0.15
Min, Max	-0.2, 1.2	-0.5, 1.5	-0.5, 1.5
Systolic Blood Pressure (mmHg)			
Baseline			
n	4	6	10
Mean (SD)	102.0 (7.16)	111.3 (15.46)	107.6 (13.16)
Median	103.5	108.5	105.5
Min, Max	92, 109	92, 132	92, 132

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Systolic Blood Pressure (mmHg), CONT'D			
2 hr			
n	4	6	10
Mean (SD)	104.8 (10.34)	117.8 (11.32)	112.6 (12.35)
Median	102.5	115.0	112.0
Min, Max	95, 119	105, 137	95, 137
Change from Baseline:			
n	4	6	10
Mean (SD)	2.8 (5.44)	6.5 (7.42)	5.0 (6.65)
Median	2.0	5.0	4.0
Min, Max	-3, 10	-3, 19	-3, 19
4 hr			
n	4	6	10
Mean (SD)	106.5 (10.54)	113.7 (10.23)	110.8 (10.43)
Median	110.5	110.5	110.5
Min, Max	91, 114	102, 129	91, 129

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Systolic Blood Pressure (mmHg), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	4.5 (3.87)	2.3 (6.89)	3.2 (5.71)
Median	5.5	1.0	3.0
Min, Max	-1, 8	-4, 15	-4, 15
13 hr			
n	4	6	10
Mean (SD)	103.5 (4.51)	117.7 (10.31)	112.0 (10.92)
Median	103.5	115.5	110.0
Min, Max	98, 109	105, 132	98, 132
Change from Baseline:			
n	4	6	10
Mean (SD)	1.5 (5.45)	6.3 (5.57)	4.4 (5.78)
Median	3.0	7.0	5.0
Min, Max	-6, 6	0, 13	-6, 13

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Systolic Blood Pressure (mmHg), CONT'D			
16 hr			
n	4	6	10
Mean (SD)	104.3 (11.53)	111.2 (9.54)	108.4 (10.37)
Median	106.5	108.5	108.5
Min, Max	89, 115	100, 127	89, 127
Change from Baseline:			
n	4	6	10
Mean (SD)	2.3 (4.99)	-0.2 (8.01)	0.8 (6.75)
Median	2.5	0.0	0.0
Min, Max	-3, 7	-10, 14	-10, 14
24 hr			
n	4	6	10
Mean (SD)	104.0 (11.92)	112.8 (10.94)	109.3 (11.61)
Median	104.5	108.5	108.5
Min, Max	91, 116	103, 129	91, 129

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Systolic Blood Pressure (mmHg), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	2.0 (6.68)	1.5 (5.36)	1.7 (5.56)
Median	3.0	0.0	0.0
Min, Max	-6, 8	-3, 11	-6, 11
30 hr			
n	4	6	10
Mean (SD)	109.8 (9.43)	117.0 (10.86)	114.1 (10.45)
Median	111.5	117.0	115.5
Min, Max	97, 119	105, 136	97, 136
Change from Baseline:			
n	4	6	10
Mean (SD)	7.8 (3.20)	5.7 (9.63)	6.5 (7.49)
Median	7.5	6.5	7.0
Min, Max	5, 11	-10, 17	-10, 17

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Systolic Blood Pressure (mmHg), CONT'D			
Post-Study			
n	4	6	10
Mean (SD)	106.5 (5.80)	111.7 (8.52)	109.6 (7.66)
Median	104.5	112.5	110.5
Min, Max	102, 115	97, 123	97, 123
Change from Baseline:			
n	4	6	10
Mean (SD)	4.5 (4.36)	0.3 (12.80)	2.0 (10.10)
Median	3.5	0.5	2.5
Min, Max	1, 10	-17, 19	-17, 19
Diastolic Blood Pressure (mmHg)			
Baseline			
n	4	6	10
Mean (SD)	64.0 (7.62)	68.5 (8.87)	66.7 (8.27)
Median	64.5	67.5	67.0
Min, Max	56, 71	58, 79	56, 79

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Diastolic Blood Pressure (mmHg), CONT'D			
2 hr			
n	4	6	10
Mean (SD)	62.3 (6.24)	70.5 (6.28)	67.2 (7.28)
Median	63.0	70.0	69.0
Min, Max	54, 69	60, 77	54, 77
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.8 (5.44)	2.0 (5.29)	0.5 (5.40)
Median	-3.5	-1.0	-1.0
Min, Max	-6, 6	-2, 11	-6, 11
4 hr			
n	4	6	10
Mean (SD)	67.8 (10.50)	70.0 (7.92)	69.1 (8.54)
Median	64.5	71.0	68.0
Min, Max	59, 83	57, 80	57, 83

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Diastolic Blood Pressure (mmHg), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	3.8 (7.80)	1.5 (5.68)	2.4 (6.29)
Median	4.0	1.0	1.5
Min, Max	-6, 13	-4, 12	-6, 13
13 hr			
n	4	6	10
Mean (SD)	63.3 (6.99)	70.8 (6.11)	67.8 (7.24)
Median	64.0	70.5	67.0
Min, Max	54, 71	64, 80	54, 80
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.8 (6.40)	2.3 (3.78)	1.1 (4.91)
Median	-2.5	2.5	1.5
Min, Max	-6, 8	-4, 7	-6, 8

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Diastolic Blood Pressure (mmHg), CONT'D			
16 hr			
n	4	6	10
Mean (SD)	63.8 (8.54)	66.7 (10.71)	65.5 (9.50)
Median	66.0	66.5	66.5
Min, Max	52, 71	50, 79	50, 79
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.3 (3.50)	-1.8 (7.47)	-1.2 (5.98)
Median	-0.5	-0.5	-0.5
Min, Max	-4, 4	-11, 8	-11, 8
24 hr			
n	4	6	10
Mean (SD)	61.3 (6.55)	72.7 (8.89)	68.1 (9.64)
Median	58.5	72.0	66.0
Min, Max	57, 71	63, 85	57, 85

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Diastolic Blood Pressure (mmHg), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	-2.8 (5.74)	4.2 (2.48)	1.4 (5.21)
Median	-1.0	4.5	2.0
Min, Max	-11, 2	1, 7	-11, 7
30 hr			
n	4	6	10
Mean (SD)	64.8 (9.50)	68.7 (9.44)	67.1 (9.15)
Median	65.0	68.5	67.5
Min, Max	54, 75	58, 79	54, 79
Change from Baseline:			
n	4	6	10
Mean (SD)	0.8 (4.27)	0.2 (3.31)	0.4 (3.50)
Median	2.0	1.0	1.0
Min, Max	-5, 4	-6, 4	-6, 4

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Diastolic Blood Pressure (mmHg), CONT'D			
Post-Study			
n	4	6	10
Mean (SD)	61.3 (3.30)	72.0 (7.90)	67.7 (8.31)
Median	61.0	74.0	67.0
Min, Max	58, 65	58, 81	58, 81
Change from Baseline:			
n	4	6	10
Mean (SD)	-2.8 (4.79)	3.5 (6.47)	1.0 (6.43)
Median	-3.0	3.0	0.5
Min, Max	-8, 3	-3, 15	-8, 15
Heart Rate (beats/min)			
Baseline			
n	4	6	10
Mean (SD)	71.5 (8.54)	71.3 (10.82)	71.4 (9.45)
Median	71.0	71.5	71.0
Min, Max	62, 82	59, 85	59, 85

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Heart Rate (beats/min), CONT'D			
2 hr			
n	4	6	10
Mean (SD)	78.5 (9.85)	78.3 (11.74)	78.4 (10.44)
Median	75.0	81.0	76.5
Min, Max	71, 93	64, 93	64, 93
Change from Baseline:			
n	4	6	10
Mean (SD)	7.0 (4.32)	7.0 (4.10)	7.0 (3.94)
Median	8.0	7.5	8.0
Min, Max	1, 11	1, 12	1, 12
4 hr			
n	4	6	10
Mean (SD)	72.8 (9.95)	77.5 (14.98)	75.6 (12.79)
Median	73.0	78.0	73.5
Min, Max	61, 84	61, 98	61, 98

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Heart Rate (beats/min), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	1.3 (5.91)	6.2 (10.09)	4.2 (8.64)
Median	2.5	4.0	3.0
Min, Max	-7, 7	-7, 23	-7, 23
13 hr			
n	4	6	10
Mean (SD)	81.8 (5.91)	81.0 (13.33)	81.3 (10.51)
Median	81.0	84.5	82.5
Min, Max	76, 89	64, 96	64, 96
Change from Baseline:			
n	4	6	10
Mean (SD)	10.3 (4.03)	9.7 (6.68)	9.9 (5.51)
Median	9.0	8.5	9.0
Min, Max	7, 16	3, 21	3, 21

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Heart Rate (beats/min), CONT'D			
16 hr			
n	4	6	10
Mean (SD)	82.8 (7.14)	77.8 (12.62)	79.8 (10.58)
Median	84.0	77.0	83.0
Min, Max	73, 90	63, 94	63, 94
Change from Baseline:			
n	4	6	10
Mean (SD)	11.3 (7.32)	6.5 (6.28)	8.4 (6.77)
Median	13.5	5.5	9.5
Min, Max	1, 17	-2, 14	-2, 17
24 hr			
n	4	6	10
Mean (SD)	76.8 (15.95)	78.8 (9.70)	78.0 (11.76)
Median	71.5	80.0	73.5
Min, Max	64, 100	66, 89	64, 100

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Heart Rate (beats/min), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	5.3 (11.06)	7.5 (4.59)	6.6 (7.34)
Median	3.5	6.0	6.0
Min, Max	-4, 18	3, 15	-4, 18
30 hr			
n	4	6	10
Mean (SD)	75.0 (10.61)	77.8 (11.92)	76.7 (10.89)
Median	71.5	79.0	73.5
Min, Max	67, 90	63, 90	63, 90
Change from Baseline:			
n	4	6	10
Mean (SD)	3.5 (8.81)	6.5 (6.38)	5.3 (7.13)
Median	4.0	6.0	5.5
Min, Max	-7, 13	-1, 14	-7, 14

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Heart Rate (beats/min), CONT'D			
Post-Study			
n	4	6	10
Mean (SD)	81.0 (11.63)	81.2 (10.17)	81.1 (10.13)
Median	76.5	82.5	80.0
Min, Max	73, 98	63, 93	63, 98
Change from Baseline:			
n	4	6	10
Mean (SD)	9.5 (8.58)	9.8 (7.33)	9.7 (7.38)
Median	11.0	9.0	9.0
Min, Max	-1, 17	2, 20	-1, 20
Respiratory Rate (breaths/min)			
Baseline			
n	4	6	10
Mean (SD)	13.0 (1.15)	12.7 (1.03)	12.8 (1.03)
Median	13.0	12.0	12.0
Min, Max	12, 14	12, 14	12, 14

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Respiratory Rate (breaths/min), CONT'D			
2 hr			
n	4	6	10
Mean (SD)	12.0 (0.00)	12.7 (1.03)	12.4 (0.84)
Median	12.0	12.0	12.0
Min, Max	12, 12	12, 14	12, 14
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.0 (1.15)	0.0 (1.79)	-0.4 (1.58)
Median	-1.0	0.0	0.0
Min, Max	-2, 0	-2, 2	-2, 2
4 hr			
n	4	6	10
Mean (SD)	12.0 (0.00)	12.0 (0.00)	12.0 (0.00)
Median	12.0	12.0	12.0
Min, Max	12, 12	12, 12	12, 12

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Respiratory Rate (breaths/min), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.0 (1.15)	-0.7 (1.03)	-0.8 (1.03)
Median	-1.0	0.0	0.0
Min, Max	-2, 0	-2, 0	-2, 0
13 hr			
n	4	6	10
Mean (SD)	13.0 (1.15)	12.3 (0.82)	12.6 (0.97)
Median	13.0	12.0	12.0
Min, Max	12, 14	12, 14	12, 14
Change from Baseline:			
n	4	6	10
Mean (SD)	0.0 (1.63)	-0.3 (1.51)	-0.2 (1.48)
Median	0.0	0.0	0.0
Min, Max	-2, 2	-2, 2	-2, 2

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Respiratory Rate (breaths/min), CONT'D			
16 hr			
n	4	6	10
Mean (SD)	13.0 (1.15)	12.2 (0.41)	12.5 (0.85)
Median	13.0	12.0	12.0
Min, Max	12, 14	12, 13	12, 14
Change from Baseline:			
n	4	6	10
Mean (SD)	0.0 (1.63)	-0.5 (0.84)	-0.3 (1.16)
Median	0.0	0.0	0.0
Min, Max	-2, 2	-2, 0	-2, 2
24 hr			
n	4	6	10
Mean (SD)	12.0 (0.00)	12.0 (0.00)	12.0 (0.00)
Median	12.0	12.0	12.0
Min, Max	12, 12	12, 12	12, 12

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Respiratory Rate (breaths/min), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.0 (1.15)	-0.7 (1.03)	-0.8 (1.03)
Median	-1.0	0.0	0.0
Min, Max	-2, 0	-2, 0	-2, 0
30 hr			
n	4	6	10
Mean (SD)	12.5 (1.00)	12.7 (1.03)	12.6 (0.97)
Median	12.0	12.0	12.0
Min, Max	12, 14	12, 14	12, 14
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.5 (1.91)	0.0 (1.79)	-0.2 (1.75)
Median	-1.0	0.0	0.0
Min, Max	-2, 2	-2, 2	-2, 2

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Respiratory Rate (breaths/min), CONT'D			
Post-Study			
n	4	6	10
Mean (SD)	13.5 (1.00)	12.7 (0.82)	13.0 (0.94)
Median	14.0	12.5	13.0
Min, Max	12, 14	12, 14	12, 14
Change from Baseline:			
n	4	6	10
Mean (SD)	0.5 (1.91)	0.0 (1.41)	0.2 (1.55)
Median	1.0	0.0	0.0
Min, Max	-2, 2	-2, 2	-2, 2
Temperature (C)			
Baseline			
n	4	6	10
Mean (SD)	36.58 (0.096)	36.45 (0.055)	36.50 (0.094)
Median	36.55	36.45	36.50
Min, Max	36.5, 36.7	36.4, 36.5	36.4, 36.7

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Temperature (C), CONT'D			
2 hr			
n	4	6	10
Mean (SD)	36.48 (0.050)	36.50 (0.063)	36.49 (0.057)
Median	36.50	36.50	36.50
Min, Max	36.4, 36.5	36.4, 36.6	36.4, 36.6
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.10 (0.082)	0.05 (0.055)	-0.01 (0.099)
Median	-0.10	0.05	0.00
Min, Max	-0.2, 0.0	0.0, 0.1	-0.2, 0.1
4 hr			
n	4	6	10
Mean (SD)	36.40 (0.000)	36.42 (0.041)	36.41 (0.032)
Median	36.40	36.40	36.40
Min, Max	36.4, 36.4	36.4, 36.5	36.4, 36.5

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
Temperature (C), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.18 (0.096)	-0.03 (0.052)	-0.09 (0.099)
Median	-0.15	0.00	-0.10
Min, Max	-0.3, -0.1	-0.1, 0.0	-0.3, 0.0
13 hr			
n	4	6	10
Mean (SD)	36.45 (0.058)	36.45 (0.084)	36.45 (0.071)
Median	36.45	36.40	36.40
Min, Max	36.4, 36.5	36.4, 36.6	36.4, 36.6
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.13 (0.126)	0.00 (0.063)	-0.05 (0.108)
Median	-0.10	0.00	0.00
Min, Max	-0.3, 0.0	-0.1, 0.1	-0.3, 0.1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Temperature (C), CONT'D			
16 hr			
n	4	6	10
Mean (SD)	36.58 (0.126)	36.58 (0.098)	36.58 (0.103)
Median	36.60	36.55	36.60
Min, Max	36.4, 36.7	36.5, 36.7	36.4, 36.7
Change from Baseline:			
n	4	6	10
Mean (SD)	0.00 (0.082)	0.13 (0.137)	0.08 (0.132)
Median	0.00	0.10	0.05
Min, Max	-0.1, 0.1	0.0, 0.3	-0.1, 0.3
24 hr			
n	4	6	10
Mean (SD)	36.50 (0.115)	36.47 (0.082)	36.48 (0.092)
Median	36.50	36.45	36.45
Min, Max	36.4, 36.6	36.4, 36.6	36.4, 36.6

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Temperature (C), CONT'D			
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.08 (0.126)	0.02 (0.098)	-0.02 (0.114)
Median	-0.10	0.00	0.00
Min, Max	-0.2, 0.1	-0.1, 0.2	-0.2, 0.2
30 hr			
n	4	6	10
Mean (SD)	36.43 (0.050)	36.43 (0.052)	36.43 (0.048)
Median	36.40	36.40	36.40
Min, Max	36.4, 36.5	36.4, 36.5	36.4, 36.5
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.15 (0.058)	-0.02 (0.098)	-0.07 (0.106)
Median	-0.15	-0.05	-0.10
Min, Max	-0.2, -0.1	-0.1, 0.1	-0.2, 0.1

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Source: t-14-3-4-5-vs.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.5
Summary of Vital Signs
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

Temperature (C), CONT'D			
Post-Study			
n	4	6	10
Mean (SD)	36.50 (0.082)	36.47 (0.082)	36.48 (0.079)
Median	36.50	36.45	36.50
Min, Max	36.4, 36.6	36.4, 36.6	36.4, 36.6
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.08 (0.096)	0.02 (0.117)	-0.02 (0.114)
Median	-0.05	0.00	0.00
Min, Max	-0.2, 0.0	-0.1, 0.2	-0.2, 0.2

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
Baseline is defined as the last assessment prior to administration of study drug.

Table 14.3.4.6
Summary of Electrocardiogram (ECG) Parameters
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

ECG Mean Ventricular Rate (bpm)			
Baseline			
n	4	6	10
Mean (SD)	69.43 (9.625)	74.27 (11.896)	72.33 (10.759)
Median	67.65	74.65	70.65
Min, Max	59.7, 82.7	60.3, 91.0	59.7, 91.0
Day 2			
n	4	6	10
Mean (SD)	73.50 (13.077)	76.67 (15.332)	75.40 (13.794)
Median	72.50	75.50	74.50
Min, Max	61.0, 88.0	60.0, 94.0	60.0, 94.0
Change from Baseline:			
n	4	6	10
Mean (SD)	4.08 (6.675)	2.40 (7.553)	3.07 (6.877)
Median	3.30	0.85	1.50
Min, Max	-3.0, 12.7	-5.0, 16.7	-5.0, 16.7

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
The predose baseline ECG will be done within 2 hours prior to study drug administration and will be repeated 3 times with
approximately 1 to 2 minute intervals between ECGs, the average will be used as the ECG baseline.

Source: t-14-3-4-6-ecg.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.6
Summary of Electrocardiogram (ECG) Parameters
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

PR Interval, Aggregate (msec)			
Baseline			
n	4	6	10
Mean (SD)	148.65 (32.367)	137.43 (21.981)	141.92 (25.518)
Median	141.65	142.00	141.65
Min, Max	117.3, 194.0	100.0, 158.0	100.0, 194.0
Day 2			
n	4	6	10
Mean (SD)	147.50 (32.182)	136.67 (18.052)	141.00 (23.613)
Median	138.00	143.00	140.00
Min, Max	120.0, 194.0	102.0, 152.0	102.0, 194.0
Change from Baseline:			
n	4	6	10
Mean (SD)	-1.15 (3.103)	-0.77 (10.244)	-0.92 (7.845)
Median	-1.65	-1.65	-1.65
Min, Max	-4.0, 2.7	-12.0, 14.7	-12.0, 14.7

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
The predose baseline ECG will be done within 2 hours prior to study drug administration and will be repeated 3 times with
approximately 1 to 2 minute intervals between ECGs, the average will be used as the ECG baseline.

Table 14.3.4.6
Summary of Electrocardiogram (ECG) Parameters
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
RR Interval, Aggregate (msec)			
Baseline			
n	4	6	10
Mean (SD)	877.83 (116.827)	823.87 (132.635)	845.45 (122.879)
Median	886.00	803.30	849.30
Min, Max	727.3, 1012.0	657.3, 993.3	657.3, 1012.0
Day 2			
n	4	6	10
Mean (SD)	836.00 (147.919)	810.33 (163.190)	820.60 (149.211)
Median	835.00	804.00	812.00
Min, Max	684.0, 990.0	636.0, 1002.0	636.0, 1002.0
Change from Baseline:			
n	4	6	10
Mean (SD)	-41.82 (73.388)	-13.53 (70.615)	-24.85 (69.130)
Median	-32.65	-10.65	-21.65
Min, Max	-139.3, 37.3	-139.3, 64.7	-139.3, 64.7

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
The predose baseline ECG will be done within 2 hours prior to study drug administration and will be repeated 3 times with
approximately 1 to 2 minute intervals between ECGs, the average will be used as the ECG baseline.

Table 14.3.4.6
Summary of Electrocardiogram (ECG) Parameters
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

QRS Duration, Aggregate (msec)			
Baseline			
n	4	6	10
Mean (SD)	76.35 (4.784)	83.53 (8.398)	80.66 (7.783)
Median	75.70	80.30	78.65
Min, Max	71.3, 82.7	75.3, 97.3	71.3, 97.3
Day 2			
n	4	6	10
Mean (SD)	75.50 (6.191)	82.67 (6.154)	79.80 (6.893)
Median	74.00	81.00	79.00
Min, Max	70.0, 84.0	76.0, 92.0	70.0, 92.0
Change from Baseline:			
n	4	6	10
Mean (SD)	-0.85 (1.660)	-0.87 (2.617)	-0.86 (2.174)
Median	-1.00	-0.30	-1.00
Min, Max	-2.7, 1.3	-5.3, 2.0	-5.3, 2.0

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
The predose baseline ECG will be done within 2 hours prior to study drug administration and will be repeated 3 times with
approximately 1 to 2 minute intervals between ECGs, the average will be used as the ECG baseline.

Table 14.3.4.6
Summary of Electrocardiogram (ECG) Parameters
Safety Population

Parameter Visit Statistic	Cohort A (N=4)	Cohort B (N=6)	All Subjects (N=10)
QT Interval, Aggregate (msec)			
Baseline			
n	4	6	10
Mean (SD)	401.33 (21.166)	395.68 (29.716)	397.94 (25.464)
Median	398.00	398.35	398.00
Min, Max	379.3, 430.0	350.0, 432.7	350.0, 432.7
Day 2			
n	4	6	10
Mean (SD)	376.50 (24.076)	380.00 (23.967)	378.60 (22.707)
Median	373.00	383.00	379.00
Min, Max	354.0, 406.0	352.0, 404.0	352.0, 406.0
Change from Baseline:			
n	4	6	10
Mean (SD)	-24.83 (12.832)	-15.68 (16.152)	-19.34 (14.903)
Median	-24.65	-11.35	-19.35
Min, Max	-40.7, -9.3	-40.7, 2.0	-40.7, 2.0

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
The predose baseline ECG will be done within 2 hours prior to study drug administration and will be repeated 3 times with
approximately 1 to 2 minute intervals between ECGs, the average will be used as the ECG baseline.

Source: t-14-3-4-6-ecg.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42

Table 14.3.4.6
Summary of Electrocardiogram (ECG) Parameters
Safety Population

Parameter
  Visit
    Statistic
	Cohort A
	(N=4)
		Cohort B
		(N=6)
			All Subjects
			(N=10)

QTcF Interval, Aggregate (msec)			
Baseline			
n	4	6	10
Mean (SD)	419.65 (7.489)	422.17 (11.212)	421.16 (9.499)
Median	420.00	425.15	422.35
Min, Max	410.3, 428.3	401.7, 433.3	401.7, 433.3
Day 2			
n	4	6	10
Mean (SD)	400.25 (6.131)	409.17 (3.371)	405.60 (6.328)
Median	399.50	409.00	408.00
Min, Max	394.0, 408.0	404.0, 414.0	394.0, 414.0
Change from Baseline:			
n	4	6	10
Mean (SD)	-19.40 (2.169)	-13.00 (11.594)	-15.56 (9.337)
Median	-20.00	-17.65	-18.50
Min, Max	-21.3, -16.3	-25.3, 6.3	-25.3, 6.3

Cohort A: Adolescent female subjects Ages 12 - 14 years; Cohort B: Adolescent female subjects Ages 15 - 17 years.
The predose baseline ECG will be done within 2 hours prior to study drug administration and will be repeated 3 times with
approximately 1 to 2 minute intervals between ECGs, the average will be used as the ECG baseline.

Source: t-14-3-4-6-ecg.sas   Data Cutoff: 29JAN2021   Run Date: 08MAR2021 09:42