

Table 14.2.1.1
Summary of Hepatitis D RNA (log10 IU/mL) by Dose Level and Visit
(Efficacy Analysis Set)

Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
Baseline				
N	13			13
Mean (SD)	4.58 (1.093)			4.58 (1.093)
Median	4.44			4.44
Min, Max	2.76, 6.28			2.76, 6.28
Week 1				
N	13			13
Mean (SD)	3.55 (1.040)			3.55 (1.040)
Median	3.55			3.55
Min, Max	2.13, 5.50			2.13, 5.50
Change from Baseline to Week 1				
N	13			13
Mean (SD)	-1.03 (0.599)			-1.03 (0.599)
Median	-1.03			-1.03
Min, Max	-1.89, -0.07			-1.89, -0.07

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.
Patients are summarized under the dose received at the corresponding visit.
Patients during the follow-up period, after Week 24, are summarized under the last dose level received.

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Week 2				
N	13			13
Mean (SD)	3.57 (1.125)			3.57 (1.125)
Median	3.62			3.62
Min, Max	1.89, 5.39			1.89, 5.39
Change from Baseline to Week 2				
N	13			13
Mean (SD)	-1.01 (0.935)			-1.01 (0.935)
Median	-0.80			-0.80
Min, Max	-2.32, 0.84			-2.32, 0.84
Week 4				
N	1	12		13
Mean (SD)	3.01 ()	3.13 (1.283)		3.12 (1.229)
Median	3.01	3.14		3.01
Min, Max	3.01, 3.01	1.11, 5.33		1.11, 5.33
Change from Baseline to Week 4				
N	1	12		13
Mean (SD)	-1.43 ()	-1.47 (0.929)		-1.47 (0.890)
Median	-1.43	-1.40		-1.43
Min, Max	-1.43, -1.43	-2.91, -0.05		-2.91, -0.05

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Week 6				
N	2	4	7	13
Mean (SD)	3.09 (1.025)	3.27 (1.310)	2.60 (0.856)	2.88 (0.994)
Median	3.09	3.29	2.38	2.73
Min, Max	2.36, 3.81	1.75, 4.76	1.30, 3.82	1.30, 4.76
Change from Baseline to Week 6				
N	2	4	7	13
Mean (SD)	-2.27 (0.276)	-1.43 (0.634)	-1.70 (1.393)	-1.70 (1.075)
Median	-2.27	-1.32	-1.64	-1.64
Min, Max	-2.47, -2.08	-2.29, -0.81	-3.17, 1.07	-3.17, 1.07
Week 8				
N	2	2	9	13
Mean (SD)	3.12 (0.813)	3.22 (0.247)	2.62 (1.174)	2.79 (1.024)
Median	3.12	3.22	2.44	3.04
Min, Max	2.54, 3.69	3.04, 3.39	1.11, 4.57	1.11, 4.57
Change from Baseline to Week 8				
N	2	2	9	13
Mean (SD)	-2.24 (0.488)	-1.96 (1.591)	-1.66 (0.746)	-1.80 (0.808)
Median	-2.24	-1.96	-1.63	-1.79
Min, Max	-2.59, -1.90	-3.09, -0.84	-2.87, -0.32	-3.09, -0.32

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.
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Week 12				
N	3	2	8	13
Mean (SD)	2.71 (0.928)	3.04 (0.785)	2.46 (1.397)	2.60 (1.175)
Median	2.95	3.04	1.76	2.48
Min, Max	1.69, 3.50	2.48, 3.59	1.11, 4.82	1.11, 4.82
Change from Baseline to Week 12				
N	3	2	8	13
Mean (SD)	-2.47 (0.508)	-2.14 (0.559)	-1.76 (0.634)	-1.98 (0.633)
Median	-2.75	-2.14	-1.84	-1.90
Min, Max	-2.78, -1.88	-2.54, -1.75	-2.45, -0.75	-2.78, -0.75
Week 16				
N	3	3	7	13
Mean (SD)	2.59 (1.074)	2.82 (0.248)	2.34 (1.244)	2.51 (1.009)
Median	2.94	2.71	1.67	2.71
Min, Max	1.38, 3.44	2.64, 3.10	1.11, 4.37	1.11, 4.37
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-2.59 (0.619)	-1.60 (1.700)	-2.06 (0.656)	-2.08 (0.941)
Median	-2.84	-1.13	-2.17	-2.17
Min, Max	-3.06, -1.89	-3.49, -0.19	-2.92, -1.20	-3.49, -0.19

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.
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Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
Week 20				
N	4	3	6	13
Mean (SD)	2.81 (1.059)	3.10 (1.244)	2.69 (1.566)	2.82 (1.260)
Median	3.22	2.40	2.45	2.75
Min, Max	1.26, 3.54	2.37, 4.54	1.11, 4.91	1.11, 4.91
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-1.77 (0.647)	-1.31 (2.132)	-1.98 (0.970)	-1.76 (1.153)
Median	-1.47	-0.53	-2.13	-1.50
Min, Max	-2.74, -1.39	-3.73, 0.32	-3.22, -0.66	-3.73, 0.32
Week 24				
N	4	3	6	13
Mean (SD)	3.06 (1.099)	3.18 (1.143)	2.79 (1.616)	2.96 (1.280)
Median	3.23	3.34	2.98	3.34
Min, Max	1.67, 4.12	1.97, 4.24	0.85, 4.51	0.85, 4.51
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-1.51 (0.803)	-1.23 (2.766)	-1.88 (1.017)	-1.62 (1.394)
Median	-1.40	-0.89	-1.60	-1.41
Min, Max	-2.55, -0.71	-4.16, 1.35	-3.48, -0.71	-4.16, 1.35

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.
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Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
Week 28				
N	4	3	6	13
Mean (SD)	4.86 (1.955)	4.66 (1.476)	3.96 (2.065)	4.40 (1.811)
Median	4.67	4.29	4.67	4.29
Min, Max	2.92, 7.19	3.41, 6.29	1.26, 6.24	1.26, 7.19
Change from Baseline to Week 28				
N	4	3	6	13
Mean (SD)	0.29 (0.814)	0.25 (2.772)	-0.71 (1.551)	-0.18 (1.646)
Median	0.53	-0.82	-0.12	0.04
Min, Max	-0.82, 0.92	-1.84, 3.40	-3.07, 1.02	-3.07, 3.40
Week 32				
N	3	3	6	12
Mean (SD)	5.55 (2.218)	4.70 (0.315)	3.71 (1.940)	4.42 (1.807)
Median	5.69	4.87	3.68	4.31
Min, Max	3.26, 7.69	4.34, 4.90	1.11, 6.88	1.11, 7.69
Change from Baseline to Week 32				
N	3	3	6	12
Mean (SD)	0.37 (1.364)	0.29 (1.637)	-0.96 (1.698)	-0.32 (1.610)
Median	0.86	0.12	-1.22	-0.51
Min, Max	-1.18, 1.42	-1.26, 2.01	-3.22, 1.66	-3.22, 2.01

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Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
Week 36				
N	3	3	6	12
Mean (SD)	5.78 (1.878)	4.79 (1.058)	3.70 (1.747)	4.49 (1.748)
Median	6.04	4.69	3.84	4.18
Min, Max	3.79, 7.52	3.78, 5.89	1.18, 6.43	1.18, 7.52
Change from Baseline to Week 36				
N	3	3	6	12
Mean (SD)	0.60 (1.081)	0.37 (0.566)	-0.98 (1.509)	-0.24 (1.378)
Median	1.21	0.47	-1.23	-0.04
Min, Max	-0.65, 1.25	-0.24, 0.89	-3.15, 1.21	-3.15, 1.25
Week 40				
N	4	3	6	13
Mean (SD)	5.24 (0.946)	5.11 (1.193)	3.73 (1.852)	4.51 (1.569)
Median	5.08	5.31	3.88	4.60
Min, Max	4.30, 6.49	3.83, 6.19	1.18, 6.40	1.18, 6.49
Change from Baseline to Week 40				
N	4	3	6	13
Mean (SD)	0.66 (0.945)	0.70 (0.551)	-0.95 (1.599)	-0.07 (1.431)
Median	0.38	0.94	-1.22	0.22
Min, Max	-0.14, 2.02	0.07, 1.09	-2.60, 1.18	-2.60, 2.02

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Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
Week 44				
N	4	3	6	13
Mean (SD)	5.22 (1.632)	4.41 (0.823)	3.33 (1.710)	4.16 (1.653)
Median	4.93	4.87	3.20	3.91
Min, Max	3.85, 7.19	3.46, 4.90	1.15, 6.11	1.15, 7.19
Change from Baseline to Week 44				
N	4	3	6	13
Mean (SD)	0.65 (0.829)	-0.01 (1.057)	-1.34 (1.505)	-0.42 (1.467)
Median	1.01	0.57	-1.76	0.04
Min, Max	-0.59, 1.16	-1.23, 0.65	-2.85, 0.89	-2.85, 1.16
Week 48				
N	4	3	6	13
Mean (SD)	4.85 (1.539)	4.91 (1.432)	3.41 (1.770)	4.20 (1.679)
Median	4.52	5.70	3.47	4.45
Min, Max	3.39, 6.96	3.26, 5.78	1.11, 5.73	1.11, 6.96
Change from Baseline to Week 48				
N	4	3	6	13
Mean (SD)	0.27 (0.475)	0.50 (0.997)	-1.27 (1.595)	-0.39 (1.418)
Median	0.35	0.37	-1.40	0.07
Min, Max	-0.31, 0.69	-0.43, 1.56	-3.09, 0.51	-3.09, 1.56

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