

Protocol No.

Qualification Discrimination

Subject ID: 9999

Site: S999

Drug Discrimination Table

Measures	Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8	23	Peak	Emax >=65
Drug Liking	Placebo	-	50	1	50	0	50	50	50	50	50	-	50	
Drug Liking	Treatment	-	50	64	68	50	64	49	64	51	63	-	68	Yes
High	Placebo	1	0	1	0	1	0	0	1	1	0	-	1	
High	Treatment	1	0	65	63	56	69	21	26	6	15	-	69	
Good Drug Effects	Placebo	-	1	1	1	0	0	0	0	0	0	-	1	
Good Drug Effects	Treatment	-	1	73	59	71	60	2	38	2	49	-	73	
Bad Drug Effects	Placebo	-	0	1	0	0	1	0	0	0	0	-	1	
Bad Drug Effects	Treatment	-	1	1	1	2	2	3	1	1	1	-	3	
Any Drug Effects	Placebo	-	0	1	0	1	0	1	0	0	0	-	1	
Any Drug Effects	Treatment	-	1	52	46	22	44	33	40	12	29	-	52	
Drowsiness/Alertness	Placebo	50	50	50	51	50	50	50	51	50	50	-	51	
Drowsiness/Alertness	Treatment		50	50	39	33	34	43	50	50	50	-	50	
Overall Drug Liking	Placebo	-	-	-	-	-	-	-	-	-	0	1	1	
Overall Drug Liking	Treatment	-	-	-	-	-	-	-	-	-	73	75	75	
Take Drug Again	Placebo	-	-	-	-	-	-	-	-	-	0	1	1	
Take Drug Again	Treatment	-	-	-	-	-	-	-	-	-	78	90	90	
Relaxation/Agitation	Placebo	51	50	51	50	51	51	50	50	50	51	-	51	
Relaxation/Agitation	Treatment	50	51	30	29	29	37	53	50	50	50	-	53	
Feeling Drunk	Placebo	1	1	1	0	0	0	1	0	0	0	-	1	
Feeling Drunk	Treatment	0	1	1	1	3	1	2	0	2	2	-	3	
Dizziness	Placebo	1	1	1	0	0	0	1	0	0	0	-	1	
Dizziness	Treatment	1	1	1	3	2	1	1	1	1	1	-	3	

Drug Discrimination Summary

Peak score in response to Treatment is greater than that of placebo on Drug Liking (difference of at least 15 points)	Yes	Comments:
Peak score of at least 65 points for Treatment on Drug Liking	Yes	
Acceptable placebo response based on Drug Liking (score between 40 and 60 points, inclusive)	Yes	
Ability to complete the PD assessments and have acceptable overall responses as judged by the investigator or designee		
Able to tolerate Treatment as judged by the investigator or designee based on available safety data (e.g no emesis within 6 hours following doing or unarousable sedation within the first 3 hours postdose [i.e. Score of 1 on the OAA/S]).		
General behaviour suggests that the subject could successfully complete the study, as judged by the research site staff		

Subject Status after Qualification Phase:

- Subject meets eligibility criteria necessary to participate in the Treatment Phase
- Subject does not meet eligibility criteria

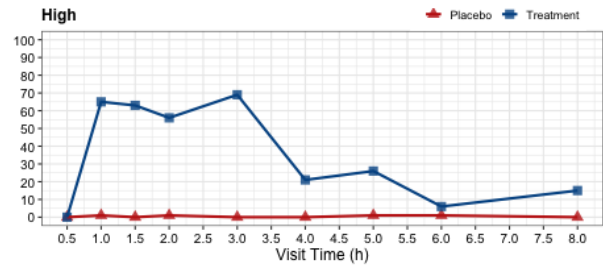
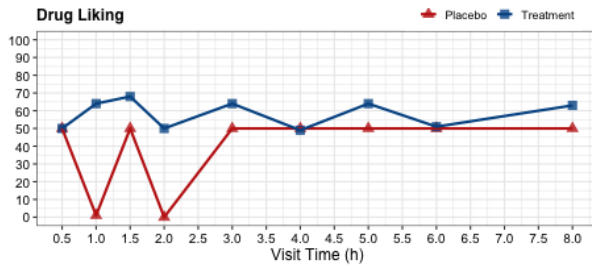
Lead Investigator: _____
Signature Date (dd-mmm-yyy)

Second Investigator: _____
Signature Date (dd-mmm-yyy)

Quality Control Review: _____
Signature Date (dd-mmm-yyy)

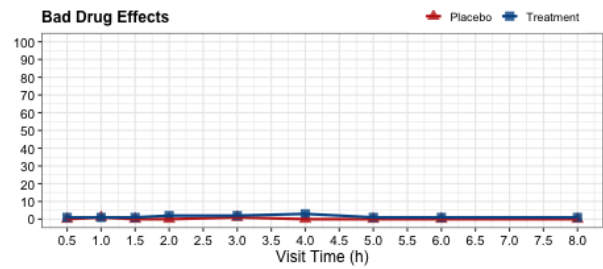
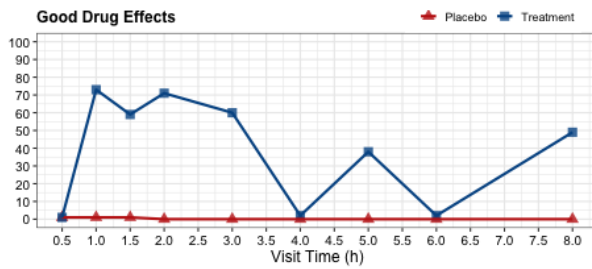
Subject ID: 9999

Site: S999



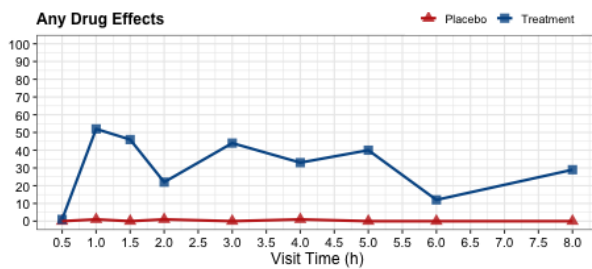
Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo		50	1	50	0	50	50	50	50	50
Treatment		50	64	68	50	64	49	64	51	63

Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8	
Placebo		1	0	1	0	1	0	0	1	1	0
Treatment		1	0	65	63	56	69	21	26	6	15



Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo		1	1	1	0	0	0	0	0	0
Treatment		1	73	59	71	60	2	38	2	49

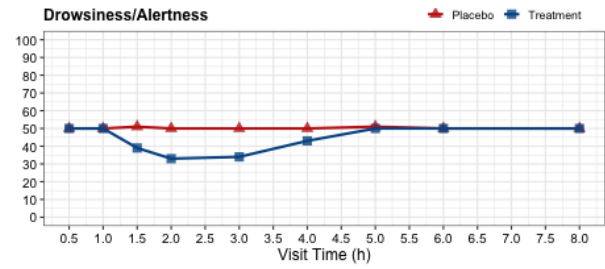
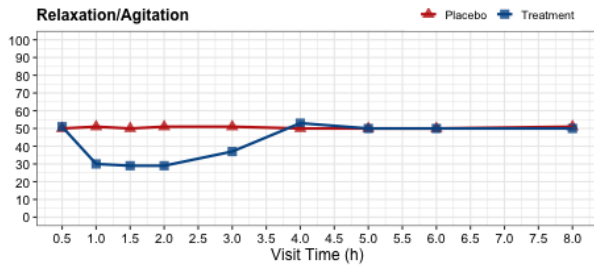
Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo		0	1	0	0	1	0	0	0	0
Treatment		1	1	1	2	2	3	1	1	1



Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo		0	1	0	1	0	1	0	0	0
Treatment		1	52	46	22	44	33	40	12	29

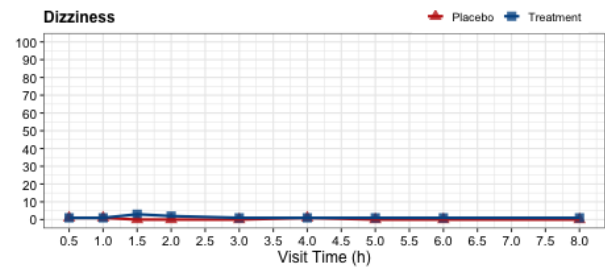
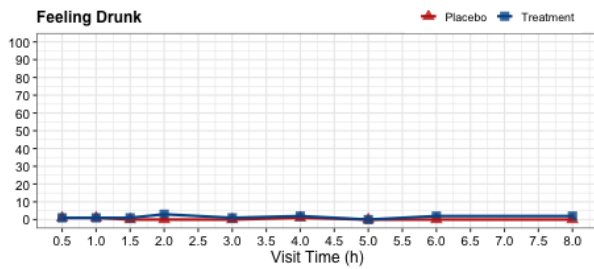
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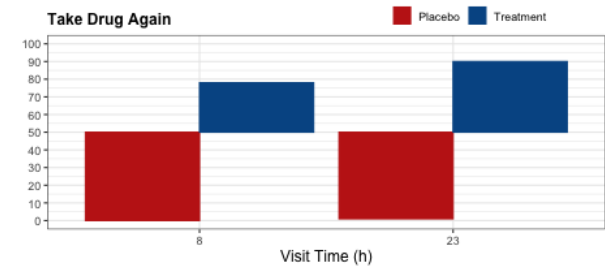
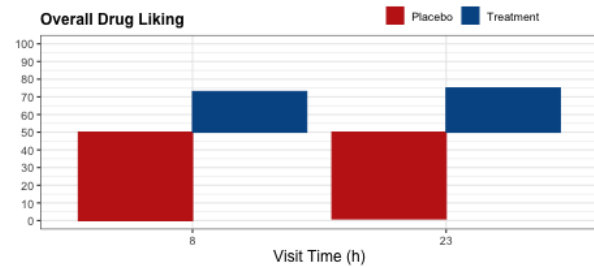
Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo	51	50	51	50	51	51	50	50	50	51
Treatment	50	51	30	29	29	37	53	50	50	50

Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo	50	50	50	51	50	50	50	51	50	50
Treatment		50	50	39	33	34	43	50	50	50



Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo	1	1	1	0	0	0	1	0	0	0
Treatment	0	1	1	1	3	1	2	0	2	2

Treatment	Pre dose	0.5	1	1.5	2	3	4	5	6	8
Placebo	1	1	1	0	0	0	1	0	0	0
Treatment	1	1	1	3	2	1	1	1	1	1



Treatment	8	23
Placebo	0	1
Treatment	73	75

Treatment	8	23
Placebo	0	1
Treatment	78	90