
Supplementary Materials**Table S1.** Drug compliance.

Parameter/Statistics	Active	Placebo
Overall IP Compliance %		
n	20	20
Mean (SD)	100.0(0.00)	100.0(0.00)
Median	100.0	100.0
Min, Max	100,100	100,100

Table S2. Descriptive statistics for physical examination.

Parameter/Statistics	Visit	Active	Placebo
General Appearance			
Normal	Screening	20(100.0)	20(100.0)
Abnormal	Screening	0(0.0)	0(0.0)
Not Done	Screening	0(0.0)	0(0.0)
Normal	Visit 3	20(100.0)	20(100.0)
Abnormal	Visit 3	0(0.0)	0(0.0)
Not Done	Visit 3	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Head, Eyes, Ears, Nose, and Throat			
Normal	Screening	20(100.0)	20(100.0)
Abnormal	Screening	0(0.0)	0(0.0)
Not Done	Screening	0(0.0)	0(0.0)
Normal	Visit 3	20(100.0)	20(100.0)
Abnormal	Visit 3	0(0.0)	0(0.0)
Not Done	Visit 3	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Abdomen			
Normal	Screening	20(100.0)	20(100.0)
Abnormal	Screening	0(0.0)	0(0.0)
Not Done	Screening	0(0.0)	0(0.0)
Normal	Visit 3	20(100.0)	20(100.0)
Abnormal	Visit 3	0(0.0)	0(0.0)
Not Done	Visit 3	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Abnormal	Screening	0(0.0)	0(0.0)
Not Done	Screening	0(0.0)	0(0.0)
Normal	Visit 3	20(100.0)	20(100.0)
Abnormal	Visit 3	0(0.0)	0(0.0)
Not Done	Visit 3	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Gastrointestinal			
Normal	Screening	20(100.0)	20(100.0)
Abnormal	Screening	0(0.0)	0(0.0)
Not Done	Screening	0(0.0)	0(0.0)
Normal	Visit 3	20(100.0)	20(100.0)
Abnormal	Visit 3	0(0.0)	0(0.0)
Not Done	Visit 3	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)

Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Musculoskeletal			
Normal	Screening	20(100.0)	20(100.0)
Abnormal	Screening	0(0.0)	0(0.0)
Not Done	Screening	0(0.0)	0(0.0)
Normal	Visit 3	20(100.0)	20(100.0)
Abnormal	Visit 3	0(0.0)	0(0.0)
Not Done	Visit 3	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Neurological			
Normal	Screening	20(100.0)	20(100.0)
Abnormal	Screening	0(0.0)	0(0.0)
Not Done	Screening	0(0.0)	0(0.0)
Normal	Visit 3	20(100.0)	20(100.0)
Abnormal	Visit 3	0(0.0)	0(0.0)
Not Done	Visit 3	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)
Normal	Visit 4	20(100.0)	20(100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)
Not Done	Visit 4	0(0.0)	0(0.0)