Table 14.3.1.1: Treatment-Emergent Adverse Events
Occurring in ≥5% of Subjects in Any Treatment Group
Safety Population

		Number (%) of Subjects		
System Organ Class	**Preferred Term**	**Placebo(N=100)**	**Drug 50mg(N=101)**	**Drug 100mg(N=99)**
Gastrointestinal disorders				
	Constipation	10 (10.0)	8 (7.9)	5 (5.1)
	Diarrhea	12 (12.0)	18 (17.8)	19 (19.2)
	Nausea	15 (15.0)	22 (21.8)	27 (27.3)
	Vomiting	8 (8.0)	12 (11.9)	14 (14.1)
General disorders				
	Asthenia	6 (6.0)	8 (7.9)	9 (9.1)
	Fatigue	14 (14.0)	16 (15.8)	19 (19.2)
	Pyrexia	8 (8.0)	10 (9.9)	9 (9.1)
Nervous system disorders				
	Dizziness	10 (10.0)	15 (14.9)	17 (17.2)
	Headache	18 (18.0)	20 (19.8)	24 (24.2)
	Somnolence	5 (5.0)	10 (9.9)	11 (11.1)

Note: Subjects with multiple occurrences of an AE are counted only once per preferred term. Percentages are based on the number of subjects in each treatment group. MedDRA Version 24.1 was used for coding.

Source: ADAE SDTM Dataset, Data Cutoff: 31-DEC-2023