COVID-19 AA
Protocol: 043
Table 14.1.8 Treatment Emergent Adverse Events by Treatment, System Organ Class and Preferred Term (safety Population)

	Treatment	
MedDRA® System Organ Class| MedDRA® Preferred Term	DRUG A|(N=43)	DRUG B|(N=43)
Number of Subjects with TEAEs	8(18.6)	4(9.3)
Cardiac disorders	0	1(2.3)
Bradycardia	0	1(2.3)
Gastrointestinal disorders	2(4.7)	1(2.3)
Abdominal pain upper	0	1(2.3)
Diarrhoea	2(4.7)	0
Vomiting	1(2.3)	0
Infections and infestations	2(4.7)	2(4.7)
Bronchitis	0	1(2.3)
COVID-19 pneumonia	2(4.7)	1(2.3)
Investigations	2(4.7)	1(2.3)
Alanine aminotransferase increased	0	1(2.3)
Haematocrit decreased	1(2.3)	0
Haemoglobin decreased	1(2.3)	0
Red blood cell count decreased	1(2.3)	0

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	Treatment	
MedDRA® System Organ Class| MedDRA® Preferred Term	DRUG A|(N=43)	DRUG B|(N=43)
Transaminases increased	1(2.3)	0
Metabolism and nutrition disorders	1(2.3)	0
Hypokalaemia	1(2.3)	0
Nervous system disorders	1(2.3)	1(2.3)
Dizziness	1(2.3)	0
Syncope	0	1(2.3)
Psychiatric disorders	0	1(2.3)
Panic attack	0	1(2.3)
Respiratory, thoracic and mediastinal disorders	2(4.7)	1(2.3)
Dyspnoea	1(2.3)	0
Epistaxis	0	1(2.3)
Sinus congestion	1(2.3)	0
Skin and subcutaneous tissue disorders	1(2.3)	0
Rash	1(2.3)	0
UNCODED	2(4.7)	0

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		Treatment	
MedDRA® System Organ Class	MedDRA® Preferred Term	DRUG A (N=43)	DRUG B (N=43)
	UNCODED	2 (4.7)	0
Vascular disorders		2 (4.7)	0
	Hypertension	1 (2.3)	0
	Hypotension	1 (2.3)	0