

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-001	Urea Nitrogen (mmol/L)	UNSCHEDULED 4.03	0.999-3.33	20MAY2019	4.329	HIGH
	Glucose (mmol/L)	UNSCHEDULED 4.03	4.107-6.0495	20MAY2019	7.6035	HIGH
		UNSCHEDULED 4.01	4.107-6.0495	17MAY2019	7.437	HIGH
	Chloride (mmol/L)	UNSCHEDULED 4.03	98-107	20MAY2019	97	LOW
	Albumin (g/L)	UNSCHEDULED 4.03	35-52	20MAY2019	32	LOW
		UNSCHEDULED 4.01	35-52	17MAY2019	31	LOW
	Sodium (mmol/L)	UNSCHEDULED 4.03	135-145	20MAY2019	133	LOW
	Calcium (mmol/L)	UNSCHEDULED 4.03	2.1457-2.5449	20MAY2019	2.12075	LOW
		UNSCHEDULED 4.01	2.1457-2.5449	17MAY2019	2.07085	LOW
	Bilirubin (umol/L)	UNSCHEDULED 4.03	1.71-20.52	20MAY2019	41.04	HIGH
		UNSCHEDULED 4.01	1.71-20.52	17MAY2019	47.88	HIGH
		SCREENING	1.71-20.52	06MAY2019	22.23	HIGH
	Direct Bilirubin (umol/L)	UNSCHEDULED 1.01	0-6.84	06MAY2019	12.483	HIGH
		UNSCHEDULED 4.02	0-6.84	17MAY2019	21.546	HIGH
		UNSCHEDULED 4.04	0-6.84	20MAY2019	25.479	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-001	Aspartate Aminotransferase (U/L)	UNSCHEDULED 4.03	10-40	20MAY2019	185	HIGH
		UNSCHEDULED 4.01	10-40	17MAY2019	46	HIGH
		SCREENING	10-40	06MAY2019	52	HIGH
	Alanine Aminotransferase (U/L)	UNSCHEDULED 4.03	10-41	20MAY2019	64	HIGH
		SCREENING	10-41	06MAY2019	47	HIGH
	Alkaline Phosphatase (U/L)	UNSCHEDULED 4.03	40-129	20MAY2019	248	HIGH
		UNSCHEDULED 4.01	40-129	17MAY2019	341	HIGH
		SCREENING	40-129	06MAY2019	428	HIGH
	Protein (g/L)	UNSCHEDULED 4.03	64-83	20MAY2019	61	LOW
		UNSCHEDULED 4.01	64-83	17MAY2019	62	LOW
043-18101-74001-002	Lactate Dehydrogenase (U/L)	SCREENING	135-225	06MAY2019	427	HIGH
	Glucose (mmol/L)	SCREENING	4.107-6.0495	08MAY2019	8.4915	HIGH
	Creatinine (umol/L)	UNSCHEDULED 4.01	61.88-106.08	22MAY2019	44.2	LOW
		END OF TREATMENT	61.88-106.08	29MAY2019	53.04	LOW
		SAFETY FOLLOW-UP	61.88-106.08	24JUN2019	53.04	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-002	Glucose (mmol/L)	UNSCHEDULED 4.01	4.107-6.0495	22MAY2019	6.327	HIGH
		END OF TREATMENT	4.107-6.0495	29MAY2019	7.1595	HIGH
		SAFETY FOLLOW-UP	4.107-6.0495	24JUN2019	6.8265	HIGH
		CYCLE 1 DAY 1	4.107-6.0495	14MAY2019	7.8255	HIGH
	Alanine Aminotransferase (U/L)	END OF TREATMENT	10-41	29MAY2019	44	HIGH
		SAFETY FOLLOW-UP	10-41	24JUN2019	48	HIGH
	Alkaline Phosphatase (U/L)	SCREENING	40-129	08MAY2019	134	HIGH
		SAFETY FOLLOW-UP	40-129	24JUN2019	182	HIGH
		CYCLE 1 DAY 1	40-129	14MAY2019	141	HIGH
	Lactate Dehydrogenase (U/L)	END OF TREATMENT	135-225	29MAY2019	233	HIGH
043-18101-74001-003		CYCLE 1 DAY 1	135-225	14MAY2019	251	HIGH
	Urea Nitrogen (mmol/L)	END OF TREATMENT	0.999-3.33	20MAY2019	4.8285	HIGH
	Glucose (mmol/L)	SCREENING	4.107-6.0495	13MAY2019	6.2715	HIGH
	Albumin (g/L)	SCREENING	35-52	13MAY2019	30	LOW
		END OF TREATMENT	35-52	20MAY2019	25	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-003	Calcium (mmol/L)	END OF TREATMENT	2.1457-2.5449	20MAY2019	1.87125	LOW
	Bilirubin (umol/L)	SCREENING	1.71-20.52	13MAY2019	22.23	HIGH
		END OF TREATMENT	1.71-20.52	20MAY2019	51.3	HIGH
		UNSCHEDULED 14.01	0-17.1	20MAY2019	53.01	HIGH
		UNSCHEDULED 14.02	0-17.1	21MAY2019	53.01	HIGH
		UNSCHEDULED 14.03	0-17.1	22MAY2019	78.66	HIGH
		UNSCHEDULED 14.04	0-17.1	23MAY2019	136.8	HIGH
		UNSCHEDULED 14.05	0-17.1	24MAY2019	196.65	HIGH
		UNSCHEDULED 14.06	0-17.1	25MAY2019	213.75	HIGH
	Direct Bilirubin (umol/L)	UNSCHEDULED 1.01	0-6.84	13MAY2019	13.338	HIGH
	Aspartate Aminotransferase (U/L)	SCREENING	10-40	13MAY2019	45	HIGH
		END OF TREATMENT	10-40	20MAY2019	121	HIGH
	Alanine Aminotransferase (U/L)	END OF TREATMENT	10-41	20MAY2019	61	HIGH
		SCREENING	40-129	13MAY2019	432	HIGH
	Alkaline Phosphatase (U/L)	END OF TREATMENT	40-129	20MAY2019	248	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-003	Protein (g/L)	SCREENING	64-83	13MAY2019	62	LOW
		END OF TREATMENT	64-83	20MAY2019	50	LOW
043-18101-74001-004	Glucose (mmol/L)	SAFETY FOLLOW-UP	4.107-5.883	31JAN2020	6.1605	HIGH
		CYCLE 1 DAY 22	4.107-5.883	04OCT2019	6.66	HIGH
		CYCLE 2 DAY 15	4.107-5.883	24OCT2019	7.7145	HIGH
		CYCLE 3 DAY 1	4.107-5.883	06NOV2019	6.4935	HIGH
		CYCLE 3 DAY 15	4.107-5.883	22NOV2019	7.0485	HIGH
	Urate (umol/L)	SCREENING	154.648-356.8	10SEP2019	440.152	HIGH
			8			
		SAFETY FOLLOW-UP	154.648-356.8	31JAN2020	362.828	HIGH
			8			
		CYCLE 1 DAY 8	154.648-356.8	20SEP2019	422.308	HIGH
			8			
		CYCLE 1 DAY 15	154.648-356.8	27SEP2019	410.412	HIGH
			8			
		CYCLE 1 DAY 22	154.648-356.8	04OCT2019	457.996	HIGH
			8			
		CYCLE 2 DAY 1	154.648-356.8	11OCT2019	457.996	HIGH
			8			
		CYCLE 2 DAY 8	154.648-356.8	18OCT2019	362.828	HIGH
			8			
	Potassium (mmol/L)	CYCLE 1 DAY 15	3.5-5.1	27SEP2019	3.4	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-004	Albumin (g/L)	SCREENING	34-50	10SEP2019	31	LOW
		CYCLE 1 DAY 8	34-50	20SEP2019	29	LOW
		CYCLE 1 DAY 15	34-50	27SEP2019	29	LOW
		CYCLE 1 DAY 22	34-50	04OCT2019	30	LOW
	Potassium (mmol/L)	CYCLE 2 DAY 15	3.5-5.1	24OCT2019	3.3	LOW
		CYCLE 3 DAY 15	3.5-5.1	22NOV2019	3.4	LOW
	Bicarbonate (mmol/L)	END OF TREATMENT	21-32	06DEC2019	34.5	HIGH
		CYCLE 1 DAY 8	21-32	20SEP2019	35	HIGH
		CYCLE 1 DAY 22	21-32	04OCT2019	35.6	HIGH
		CYCLE 2 DAY 1	21-32	11OCT2019	35.5	HIGH
		CYCLE 2 DAY 8	21-32	18OCT2019	34	HIGH
		CYCLE 2 DAY 15	21-32	24OCT2019	34.1	HIGH
		CYCLE 3 DAY 1	21-32	06NOV2019	34.9	HIGH
		CYCLE 3 DAY 15	21-32	22NOV2019	33.1	HIGH
		CYCLE 3 DAY 8	21-32	14NOV2019	32.9	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-004	Albumin (g/L)	END OF TREATMENT	34-50	06DEC2019	21	LOW
		SAFETY FOLLOW-UP	34-50	31JAN2020	32	LOW
		CYCLE 2 DAY 1	34-50	11OCT2019	22	LOW
		CYCLE 2 DAY 8	34-50	18OCT2019	25	LOW
		CYCLE 2 DAY 15	34-50	24OCT2019	23	LOW
		CYCLE 3 DAY 1	34-50	06NOV2019	23	LOW
		CYCLE 3 DAY 15	34-50	22NOV2019	24	LOW
		CYCLE 3 DAY 8	34-50	14NOV2019	24	LOW
	Sodium (mmol/L)	SAFETY FOLLOW-UP	136-145	31JAN2020	135	LOW
	Magnesium (mmol/L)	SCREENING	0.7407-0.9876	10SEP2019	0.4938	LOW
		CYCLE 1 DAY 8	0.7407-0.9876	20SEP2019	0.5761	LOW
		CYCLE 1 DAY 15	0.7407-0.9876	27SEP2019	0.5761	LOW
		CYCLE 2 DAY 1	0.7407-0.9876	11OCT2019	0.61725	LOW
		CYCLE 2 DAY 8	0.7407-0.9876	18OCT2019	0.5761	LOW
		CYCLE 3 DAY 8	0.7407-0.9876	14NOV2019	0.6584	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-004	Calcium (mmol/L)	SAFETY FOLLOW-UP	2.12075-2.51995	31JAN2020	3.06885	HIGH
		CYCLE 2 DAY 8	2.12075-2.51995	18OCT2019	2.6447	HIGH
		CYCLE 2 DAY 15	2.12075-2.51995	24OCT2019	2.0459	LOW
		CYCLE 3 DAY 8	2.12075-2.51995	14NOV2019	2.5948	HIGH
	Bilirubin (umol/L)	END OF TREATMENT	3.42-17.1	06DEC2019	51.3	HIGH
	Direct Bilirubin (umol/L)	CYCLE 2 DAY 15	0-3.42	24OCT2019	5.13	HIGH
		CYCLE 3 DAY 1	0-3.42	06NOV2019	5.13	HIGH
		CYCLE 3 DAY 15	0-3.42	22NOV2019	6.84	HIGH
	Magnesium (mmol/L)	CYCLE 3 DAY 15	0.7407-0.9876	22NOV2019	0.53495	LOW
	Phosphate (mmol/L)	SCREENING	0.83954-1.51763	10SEP2019	0.77496	LOW
		END OF TREATMENT	0.83954-1.51763	06DEC2019	0.77496	LOW
		SAFETY FOLLOW-UP	0.83954-1.51763	31JAN2020	0.6458	LOW
		CYCLE 1 DAY 22	0.83954-1.51763	04OCT2019	0.71038	LOW
		CYCLE 2 DAY 1	0.83954-1.51763	11OCT2019	0.74267	LOW
		CYCLE 2 DAY 15	0.83954-1.51763	24OCT2019	0.25832	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-004	Direct Bilirubin (umol/L)	END OF TREATMENT	0-3.42	06DEC2019	46.17	HIGH
	AspartateAminotransferase (U/L)	END OF TREATMENT	15-37	06DEC2019	52	HIGH
		CYCLE 1 DAY 22	15-37	04OCT2019	78	HIGH
		CYCLE 2 DAY 15	15-37	24OCT2019	113	HIGH
		CYCLE 3 DAY 1	15-37	06NOV2019	123	HIGH
		CYCLE 3 DAY 15	15-37	22NOV2019	136	HIGH
		CYCLE 3 DAY 8	15-37	14NOV2019	86	HIGH
	Alanine Aminotransferase (U/L)	CYCLE 1 DAY 15	14-59	27SEP2019	13	LOW
		CYCLE 1 DAY 22	14-59	04OCT2019	173	HIGH
		CYCLE 2 DAY 8	14-59	18OCT2019	10	LOW
		CYCLE 2 DAY 15	14-59	24OCT2019	66	HIGH
		CYCLE 3 DAY 1	14-59	06NOV2019	113	HIGH
		CYCLE 3 DAY 15	14-59	22NOV2019	140	HIGH
		CYCLE 3 DAY 8	14-59	14NOV2019	104	HIGH
	Alkaline Phosphatase (U/L)	CYCLE 2 DAY 15	46-116	24OCT2019	209	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-004	Alkaline Phosphatase (U/L)	END OF TREATMENT	46-116	06DEC2019	408	HIGH
		SAFETY FOLLOW-UP	46-116	31JAN2020	676	HIGH
		CYCLE 3 DAY 1	46-116	06NOV2019	366	HIGH
		CYCLE 3 DAY 15	46-116	22NOV2019	507	HIGH
		CYCLE 3 DAY 8	46-116	14NOV2019	442	HIGH
	Protein (g/L)	SCREENING	64-82	10SEP2019	85	HIGH
		SAFETY FOLLOW-UP	64-82	31JAN2020	90	HIGH
		CYCLE 1 DAY 22	64-82	04OCT2019	85	HIGH
	Lactate Dehydrogenase (U/L)	SCREENING	81-234	10SEP2019	260	HIGH
		CYCLE 1 DAY 8	81-234	20SEP2019	279	HIGH
		CYCLE 1 DAY 15	81-234	27SEP2019	308	HIGH
		CYCLE 1 DAY 22	81-234	04OCT2019	332	HIGH
		CYCLE 2 DAY 1	81-234	11OCT2019	311	HIGH
		CYCLE 2 DAY 8	81-234	18OCT2019	293	HIGH
		CYCLE 2 DAY 15	81-234	24OCT2019	380	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-004	Lactate Dehydrogenase (U/L)	END OF TREATMENT	81-234	06DEC2019	314	HIGH
		SAFETY FOLLOW-UP	81-234	31JAN2020	467	HIGH
		CYCLE 3 DAY 1	81-234	06NOV2019	342	HIGH
		CYCLE 3 DAY 15	81-234	22NOV2019	417	HIGH
		CYCLE 3 DAY 8	81-234	14NOV2019	279	HIGH
043-18101-74001-005	Glucose (mmol/L)	CYCLE 1 DAY 8	4.107-5.883	26DEC2019	7.215	HIGH
		CYCLE 3 DAY 15	4.107-5.883	02MAR2020	5.9385	HIGH
		CYCLE 3 DAY 8	4.107-5.883	24FEB2020	3.7185	LOW
	Chloride (mmol/L)	SCREENING	97-107	16DEC2019	108	HIGH
		CYCLE 3 DAY 1	97-107	17FEB2020	108	HIGH
	Albumin (g/L)	SCREENING	34-50	16DEC2019	30	LOW
		CYCLE 1 DAY 8	34-50	26DEC2019	33	LOW
		CYCLE 1 DAY 15	34-50	02JAN2020	32	LOW
		CYCLE 1 DAY 22	34-50	09JAN2020	32	LOW
		CYCLE 2 DAY 15	34-50	30JAN2020	31	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-005	Sodium (mmol/L)	SCREENING	136-145	16DEC2019	146	HIGH
	Calcium (mmol/L)	CYCLE 1 DAY 22	2.12075-2.519	09JAN2020	2.07085	LOW
			95			
		CYCLE 2 DAY 15	2.12075-2.519	30JAN2020	2.02095	LOW
			95			
		CYCLE 3 DAY 8	2.12075-2.519	24FEB2020	2.07085	LOW
			95			
	Bilirubin (umol/L)	SCREENING	3.42-17.1	16DEC2019	1.71	LOW
		CYCLE 1 DAY 8	3.42-17.1	26DEC2019	1.71	LOW
		CYCLE 1 DAY 15	3.42-17.1	02JAN2020	1.71	LOW
	Aspartate Aminotransferase (U/L)	SCREENING	15-37	16DEC2019	40	HIGH
		CYCLE 2 DAY 1	15-37	16JAN2020	60	HIGH
	Alkaline Phosphatase (U/L)	SCREENING	46-116	16DEC2019	180	HIGH
	Magnesium (mmol/L)	CYCLE 2 DAY 15	0.7407-0.9876	30JAN2020	0.69955	LOW
		CYCLE 3 DAY 1	0.7407-0.9876	17FEB2020	0.69955	LOW
		CYCLE 3 DAY 15	0.7407-0.9876	02MAR2020	0.69955	LOW
		CYCLE 3 DAY 8	0.7407-0.9876	24FEB2020	0.69955	LOW
	Phosphate (mmol/L)	CYCLE 2 DAY 1	0.83954-1.517	16JAN2020	0.358419	LOW
			63			

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74001-005	Alkaline Phosphatase (U/L)	CYCLE 1 DAY 8	46-116	26DEC2019	134	HIGH
		CYCLE 2 DAY 1	46-116	16JAN2020	129	HIGH
		CYCLE 2 DAY 8	46-116	23JAN2020	119	HIGH
		CYCLE 3 DAY 8	46-116	24FEB2020	127	HIGH
	Protein (g/L)	SCREENING	64-82	16DEC2019	60	LOW
		CYCLE 1 DAY 8	64-82	26DEC2019	63	LOW
		CYCLE 1 DAY 15	64-82	02JAN2020	60	LOW
		CYCLE 1 DAY 22	64-82	09JAN2020	61	LOW
		CYCLE 2 DAY 15	64-82	30JAN2020	60	LOW
		CYCLE 3 DAY 15	64-82	02MAR2020	63	LOW
043-18101-74002-001	Urea Nitrogen (mmol/L)	CYCLE 1 DAY 1	0.999-3.996	06NOV2019	0.8325	LOW
		CYCLE 1 DAY 8	1.1655-2.997	14NOV2019	0.8325	LOW
		CYCLE 1 DAY 15	1.1655-2.997	21NOV2019	0.666	LOW
		CYCLE 2 DAY 1	1.1655-2.997	04DEC2019	0.4995	LOW
		CYCLE 2 DAY 8	1.1655-2.997	12DEC2019	0.4995	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74002-001	Urea Nitrogen (mmol/L)	CYCLE 2 DAY 15	1.1655-2.997	19DEC2019	0.4995	LOW
	Glucose (mmol/L)	SCREENING	3.885-5.8275	24OCT2019	6.327	HIGH
	Creatinine (umol/L)	SCREENING	53.04-114.92	24OCT2019	44.2	LOW
		CYCLE 1 DAY 1	50.388-88.4	06NOV2019	36.244	LOW
		CYCLE 1 DAY 8	53.04-114.92	14NOV2019	35.36	LOW
		CYCLE 1 DAY 15	53.04-114.92	21NOV2019	32.708	LOW
		CYCLE 2 DAY 1	53.04-114.92	04DEC2019	26.52	LOW
		CYCLE 2 DAY 8	53.04-114.92	12DEC2019	28.288	LOW
		CYCLE 2 DAY 15	53.04-114.92	19DEC2019	17.68	LOW
	Urate (umol/L)	SCREENING	261.712-452.0	24OCT2019	196.284	LOW
			48			
		CYCLE 1 DAY 8	261.712-452.0	14NOV2019	220.076	LOW
			48			
		CYCLE 1 DAY 15	261.712-452.0	21NOV2019	220.076	LOW
			48			
		CYCLE 2 DAY 1	261.712-452.0	04DEC2019	160.596	LOW
			48			
		CYCLE 2 DAY 8	261.712-452.0	12DEC2019	154.648	LOW
			48			
		CYCLE 2 DAY 15	261.712-452.0	19DEC2019	142.752	LOW
			48			

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74002-001	Chloride (mmol/L)	SCREENING	98-107	24OCT2019	97	LOW
		CYCLE 1 DAY 1	97-106	06NOV2019	96	LOW
		CYCLE 1 DAY 15	98-107	21NOV2019	95	LOW
		CYCLE 2 DAY 1	98-107	04DEC2019	94	LOW
		CYCLE 2 DAY 8	98-107	12DEC2019	95	LOW
	Albumin (g/L)	CYCLE 1 DAY 8	34-50	14NOV2019	30	LOW
		CYCLE 2 DAY 8	34-50	12DEC2019	32	LOW
		CYCLE 2 DAY 15	34-50	19DEC2019	23	LOW
	Sodium (mmol/L)	SCREENING	136-145	24OCT2019	135	LOW
	Potassium (mmol/L)	CYCLE 1 DAY 15	3.5-5.1	21NOV2019	3.2	LOW
		CYCLE 2 DAY 1	3.5-5.1	04DEC2019	2.7	LOW
		CYCLE 2 DAY 15	3.5-5.1	19DEC2019	3.3	LOW
	Bicarbonate (mmol/L)	SCREENING	21-31	24OCT2019	34	HIGH
		CYCLE 2 DAY 1	21-31	04DEC2019	32	HIGH
		CYCLE 2 DAY 15	21-31	19DEC2019	35	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74002-001	Calcium (mmol/L)	CYCLE 1 DAY 15	2.12075-2.51995	21NOV2019	0.092315	LOW
		CYCLE 2 DAY 1	2.12075-2.51995	04DEC2019	2.0958	LOW
		CYCLE 2 DAY 8	2.12075-2.51995	12DEC2019	2.07085	LOW
		CYCLE 2 DAY 15	2.12075-2.51995	19DEC2019	1.97105	LOW
	Direct Bilirubin (umol/L)	CYCLE 1 DAY 15	0.513-3.078	21NOV2019	3.42	HIGH
		CYCLE 2 DAY 1	0.513-3.078	04DEC2019	3.42	HIGH
		CYCLE 2 DAY 8	0.513-3.078	12DEC2019	3.42	HIGH
		CYCLE 2 DAY 15	0.513-3.078	19DEC2019	3.42	HIGH
	Aspartate Aminotransferase (U/L)	SCREENING	13-37	24OCT2019	40	HIGH
		CYCLE 2 DAY 1	13-37	04DEC2019	49	HIGH
	Magnesium (mmol/L)	CYCLE 1 DAY 8	0.78185-1.11105	14NOV2019	0.7407	LOW
		CYCLE 1 DAY 15	0.78185-1.11105	21NOV2019	0.6584	LOW
		CYCLE 2 DAY 1	0.78185-1.11105	04DEC2019	0.7407	LOW
		CYCLE 2 DAY 8	0.78185-1.11105	12DEC2019	0.61725	LOW
		CYCLE 2 DAY 15	0.78185-1.11105	19DEC2019	0.5761	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74002-001	Aspartate Aminotransferase (U/L)	CYCLE 2 DAY 8	13-37	12DEC2019	46	HIGH
		CYCLE 2 DAY 15	13-37	19DEC2019	62	HIGH
	Alanine Aminotransferase (U/L)	CYCLE 2 DAY 1	13-56	04DEC2019	11	LOW
		CYCLE 2 DAY 8	13-56	12DEC2019	11	LOW
	Alkaline Phosphatase (U/L)	SCREENING	45-117	24OCT2019	235	HIGH
		CYCLE 1 DAY 1	39-117	06NOV2019	188	HIGH
		CYCLE 1 DAY 8	45-117	14NOV2019	165	HIGH
		CYCLE 1 DAY 15	45-117	21NOV2019	118	HIGH
		CYCLE 2 DAY 15	45-117	19DEC2019	126	HIGH
	Protein (g/L)	CYCLE 1 DAY 8	64-89	14NOV2019	63	LOW
		CYCLE 1 DAY 15	64-89	21NOV2019	61	LOW
		CYCLE 2 DAY 1	64-89	04DEC2019	57	LOW
		CYCLE 2 DAY 8	64-89	12DEC2019	54	LOW
		CYCLE 2 DAY 15	64-89	19DEC2019	55	LOW
	Lactate Dehydrogenase (U/L)	SCREENING	140-271	24OCT2019	581	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74002-001	Lactate Dehydrogenase (U/L)	CYCLE 1 DAY 1	119-226	06NOV2019	945	HIGH
		CYCLE 1 DAY 8	140-271	14NOV2019	801	HIGH
		CYCLE 1 DAY 15	140-271	21NOV2019	856	HIGH
		CYCLE 2 DAY 1	140-271	04DEC2019	1094	HIGH
		CYCLE 2 DAY 8	140-271	12DEC2019	9.71	LOW
		CYCLE 2 DAY 15	140-271	19DEC2019	738	HIGH
043-18101-74003-004	Chloride (mmol/L)	END OF TREATMENT	97-108	15JAN2020	94	LOW
		CYCLE 3 DAY 1	97-108	30DEC2019	95	LOW
		CYCLE 3 DAY 15	97-108	15JAN2020	94	LOW
	Albumin (g/L)	END OF TREATMENT	35-48	15JAN2020	31	LOW
		CYCLE 2 DAY 1	35-48	05DEC2019	33	LOW
		CYCLE 2 DAY 8	35-48	11DEC2019	33	LOW
		CYCLE 3 DAY 15	35-48	15JAN2020	31	LOW
		CYCLE 3 DAY 8	35-48	08JAN2020	34	LOW
	Creatinine (umol/L)	CYCLE 2 DAY 1	38.896-88.4	05DEC2019	97.24	HIGH

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74003-004	Sodium (mmol/L)	END OF TREATMENT	135-145	15JAN2020	134	LOW
		CYCLE 2 DAY 1	135-145	05DEC2019	132	LOW
		CYCLE 3 DAY 1	135-145	30DEC2019	132	LOW
		CYCLE 3 DAY 15	135-145	15JAN2020	134	LOW
	Calcium (mmol/L)	CYCLE 2 DAY 1	2.1956-2.5698	05DEC2019	2.17065	LOW
			5			
	Bilirubin (umol/L)	CYCLE 3 DAY 1	3.42-22.23	30DEC2019	23.94	HIGH
	Aspartate Aminotransferase (U/L)	END OF TREATMENT	17-42	15JAN2020	52	HIGH
		CYCLE 2 DAY 1	17-42	05DEC2019	16	LOW
		CYCLE 3 DAY 15	17-42	15JAN2020	52	HIGH
	Alanine Aminotransferase (U/L)	CYCLE 1 DAY 1	11-50	07NOV2019	10	LOW
		CYCLE 2 DAY 1	11-50	05DEC2019	10	LOW
		CYCLE 2 DAY 15	11-50	18DEC2019	10	LOW
	Magnesium (mmol/L)	END OF TREATMENT	0.7407-0.9876	15JAN2020	0.69955	LOW
		CYCLE 3 DAY 1	0.7407-0.9876	30DEC2019	0.69955	LOW
		CYCLE 3 DAY 15	0.7407-0.9876	15JAN2020	0.69955	LOW

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74003-004	Alanine Aminotransferase (U/L)	CYCLE 3 DAY 1	11-50	30DEC2019	9	LOW
	Alkaline Phosphatase (U/L)	END OF TREATMENT	31-95	15JAN2020	316	HIGH
		CYCLE 3 DAY 15	31-95	15JAN2020	316	HIGH
	Lactate Dehydrogenase (U/L)	CYCLE 3 DAY 1	102-199	30DEC2019	238	HIGH
043-18101-74003-007	Alkaline Phosphatase (U/L)	SCREENING	31-95	03MAR2020	104	HIGH
		CYCLE 1 DAY 1	31-95	19MAR2020	97	HIGH
043-18101-74004-002	Sodium (mmol/L)	CYCLE 2 DAY 1	135-145	10FEB2020	134	LOW
	Magnesium (mmol/L)	CYCLE 1 DAY 8	0.6584-0.9876	21JAN2020	1.02875	HIGH
		UNSCHEDULED 3.01	0.6584-0.9876	13JAN2020	1.11105	HIGH
	Phosphate (mmol/L)	CYCLE 1 DAY 8	0.80725-1.453	21JAN2020	0.41977	LOW
			05			
		CYCLE 1 DAY 15	0.80725-1.453	28JAN2020	0.48435	LOW
			05			
		CYCLE 1 DAY 22	0.80725-1.453	04FEB2020	0.48435	LOW
			05			
		CYCLE 2 DAY 1	0.80725-1.453	10FEB2020	0.51664	LOW
			05			
		CYCLE 2 DAY 8	0.80725-1.453	18FEB2020	0.58122	LOW
			05			
		UNSCHEDULED 3.01	0.80725-1.453	13JAN2020	0.61351	LOW
			05			

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of Measurement	Result	Flag
043-18101-74004-002	Calcium (mmol/L)	CYCLE 1 DAY 8	2.12075-2.61975	21JAN2020	2.0459	LOW
		CYCLE 2 DAY 8	2.12075-2.61975	18FEB2020	2.02095	LOW
		CYCLE 2 DAY 15	2.12075-2.61975	25FEB2020	1.996	LOW
	Direct Bilirubin (umol/L)	CYCLE 1 DAY 1	3.42-6.84	06JAN2020	0.342	LOW
	Aspartate Aminotransferase (U/L)	CYCLE 2 DAY 15	10-40	25FEB2020	158	HIGH
	Alanine Aminotransferase (U/L)	CYCLE 2 DAY 15	10-60	25FEB2020	132	HIGH
	Alkaline Phosphatase (U/L)	CYCLE 2 DAY 15	40-130	25FEB2020	196	HIGH
	Lactate Dehydrogenase (U/L)	CYCLE 2 DAY 15	135-225	25FEB2020	230	HIGH
	Phosphate (mmol/L)	CYCLE 2 DAY 15	0.80725-1.45305	25FEB2020	0.41977	LOW
043-18101-74004-003	Lactate Dehydrogenase (U/L)	SCREENING	135-225	14JAN2020	302	HIGH
		CYCLE 1 DAY 1	135-225	27JAN2020	246	HIGH
		CYCLE 1 DAY 8	135-225	03FEB2020	243	HIGH
		CYCLE 1 DAY 15	135-225	10FEB2020	241	HIGH
		CYCLE 1 DAY 22	135-225	18FEB2020	280	HIGH
043-18101-74004-004	Lactate Dehydrogenase (U/L)	SCREENING	135-214	03MAR2020	235	HIGH

02:25 Monday, March 20, 2023 22

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.1.7 Abnormal Biochemistry Values

Subject Number	Test	Visit	Normal Range	Date/Time of		Flag
				Measurement	Result	
043-18101-74004-004	Lactate Dehydrogenase (U/L)	CYCLE 1 DAY 1	135-214	16MAR2020	219	HIGH