

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
		Trt	Phase	Dose**	Study Start	Period						
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
GASTROINTESTINAL DISORDERS	Constipation*/ CONSTIPATION	B	Active	0	93/ 100	5/ 12	0.33	173.00	MILD/ Resolved (16APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Diarrhoea*/ LOOSE STOOL	C	Active	0	2/ 3	2/ 3		5	22.00	MILD/ Resolved (10JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Oral disorder*/ PASTY MOUTH	A	Active	200 MG	47/ 51	12/ 16		0	83.00	MILD/ Resolved (27FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
INFECTIONS AND INFESTATIONS	Folliculitis*/ FOLLICULITIS	B	Active	0	100/ 104	12/ 16	5.33	88.00	MILD/ Resolved (20APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Arthropod bite*/ INSECT BITE	A	Active	200 MG	65/ 93	30/ 54		390	570.67	MODERATE/ Resolved (09APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other-insect bite	NO

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* Treatment-emergent

** Dose at onset of adverse event.

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

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Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 17SEP2016 (21:58)

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				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period					Duration (Hrs)
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Arthropod bite/ INSECT BITE	B	Active				1/ 5		93.33	MODERATE/ Resolved (09APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other-insect bite	NO	
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	C	Active	0	14/ 14	14/ 14		7	1.00	MILD/ Resolved (21JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Headache*/ HEADACHE	C	Active	0	35/ 39	35/ 36		504	24.00	MODERATE/ Resolved (15FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	
	Headache/ HEADACHE	A	Active				1/ 4		71.00	MODERATE/ Resolved (15FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	
	Headache/ INTERMITTENT HEADACHE	A	Active	200 MG	43/ 44	8/ 9		6	32.50	MODERATE/ Resolved (20FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	
	Headache/ INTERMITTENT HEADACHE	A	Active	200 MG	88/ 93	53/ 54		945.83	14.83	MODERATE/ Resolved (09APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	

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				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Headache/ INTERMITTENT HEADACHE	B	Active			1/ 5		93.33	MODERATE/ Resolved (09APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO		
	Paraesthesia*/ INTERMITTENT PARESTHESIA	A	Active	50 MG	38/ 50	3/ 15	10	289.00	MILD/ Resolved (26FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Oropharyngeal pain*/ THROAT PAIN	C	Active	0	30/ 36	30/ 36	383	143.00	MILD/ Resolved (12FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Dry skin*/ DRY SKIN LEGS	C	Active	0	10/ 15	10/ 15	11	124.00	MILD/ Resolved (22JAN2016)	Other-viral infection STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
[REDACTED]													
GASTROINTESTINAL DISORDERS	Constipation*/ CONSTIPATION	A	Active	50 MG	91/ 100	3/ 12	10.25	223.00	MILD/ Resolved (16APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

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System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day+/ Stop Day++					Time Post Dose (Hrs)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Application site irritati on*/ CONTACT IRRITATION ON CHEST FROM ECG ELECTRODES	A	Active	50 MG	90/ 93	2/ 5	21.25	72.00	MILD/ Resolved (09APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-due to ecg electrodes	NO
	Fatigue*/ INTERMITTENT FATIGUE	B	Active	0	7/ 15	7/ 15	0.92	194.00	MILD/ Resolved (22JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Vessel puncture site eryt hema*/ ERYTHEMA AT VENIPUNCTURE SITE	A	Active	50 MG	89/ 92	1/ 4	2.25	68.00	MILD/ Resolved (08APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Injection/procedure related-venipuncture	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	C	Active	0	48/ 49	13/ 14	1.92	20.00	MODERATE/ Resolved (25FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Headache*/ HEADACHE	A	Active	50 MG	91/ 92	3/ 4	9.75	8.50	MODERATE/ Resolved (08APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Headache*/ HEADACHE	A	Active	200 MG	95/ 96	7/ 8	1.02	8.23	MODERATE/ Resolved (12APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO

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System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++					Time Post Dose (Hrs)
NERVOUS SYSTEM DISORDERS	Headache*/ INTERMITTENT HEADACHE	B	Active	0	3/ 8	3/ 8	8.92	119.67	MODERATE/ Resolved (15JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Headache*/ INTERMITTENT HEADACHE	B	Active	0	11/ 15	11/ 15	9.92	96.00	MILD/ Resolved (22JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ INTERMITTENT HEADACHE	C	Active	0	40/ 43	5/ 8	6.92	63.00	MODERATE/ Resolved (19FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	100 MG	91/ 103	3/ 15	0.25	273.00	MILD/ Resolved (19APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Intertrigo*/ INTERTRIGO BREAST	C	Active	0	45/ 53	10/ 18	11.5	179.42	MODERATE/ Resolved (29FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/	NO
	Rash macular*/ SPOTS ON ARM	A	Active	50 MG	89/ 92	1/ 4	10.25	59.00	MILD/ Resolved (08APR2016)	Other-mycotic infection STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

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				Trt	Phase	Dose**	Study Start		Period				Duration (Hrs)	
							Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
GASTROINTESTINAL DISORDERS	Abdominal pain lower*/ LOW ABDOMINAL PAIN	C	Active	0	85/ 85	16/ 16	48.17	1.33	MILD/ Resolved (01APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-premenstrual syndrome	NO			
	Dry mouth*/ DRY MOUTH	A	Active	200 MG	9/ 36	9/ 36	2.83	643.00	MILD/ Resolved (12FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Nausea*/ INTERMITTENT NAUSEA	B	Active	0	38/ 43	3/ 8	10.83	119.00	MILD/ Resolved (19FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Nausea*/ NAUSEA	B	Active	400 MG	49/ 49	14/ 14	0.83	4.00	MILD/ Resolved (25FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Asthenia*/ WEAKNESS	B	Active	0	38/ 40	3/ 5	10.83	35.00	MILD/ Resolved (16FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

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				Trt	Phase	Dose**	Study				Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Study Day+	Start Day+/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chest discomfort*/ THORACIC OPPRESSION	A	Active	200 MG	7/ 8	7/ 8	2.83	23.00	MILD/ Resolved (15JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Chest discomfort*/ THORACIC OPPRESSION	A	Active	200 MG	13/ 15	13/ 15	3.83	47.00	MILD/ Resolved (22JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Fatigue*/ INTERMITTENT FATIGUE	A	Active	50 MG	2/ 10	2/ 10	10.83	180.00	MILD/ Resolved (17JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
INFECTIONS AND INFESTATIONS	Gastroenteritis*/ GASTRO ENTERITIS	A	Active	200 MG	18/ 36	18/ 36	98.83	427.00	MILD/ Resolved (12FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASMS	A	Active	100 MG	5/ 36	5/ 36	2.83	739.00	MILD/ Resolved (12FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Myalgia*/ MUSCULAR DISCOMFORT	A	Active	100 MG	4/ 6	4/ 6	1.33	44.50	MILD/ Resolved (13JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

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				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	A	Active	200 MG	12/ 12	12/ 12	1.33	3.50	MILD/ Resolved (19JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	50 MG	1/ 15	1/ 15	13.83	336.00	MILD/ Resolved (22JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
[REDACTED]													
EYE DISORDERS	Ocular discomfort*/ DISCOMFORT LEFT EYE	B	Active	400 MG	103/ 103	15/ 15	33.67	0.50	MODERATE/ Resolved (19APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GASTROINTESTINAL DISORDERS	Diarrhoea*/ LOOSE STOOL	C	Active	0	37/ 40	2/ 5	22.75	75.50	MILD/ Resolved (16FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Dysphagia*/ DIFFICULTY TO SWALLOW	A	Active	200 MG	7/ 8	7/ 8	1.75	8.00	MILD/ Resolved (15JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

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				Trt	Phase	Dose**	Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++					Time Post Dose (Hrs)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	200 MG	12/ 15	12/ 15	1.75	68.00	MILD/ Resolved (22JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
INFECTIONS AND INFESTATIONS	Fungal infection*/ MYCOTIC INFECTION	C	Active	0	50/ 57	15/ 22	36.25	154.50	MODERATE/ Resolved (04MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other illness-mycotic infection	NO			
PSYCHIATRIC DISORDERS	Insomnia*/ DIFFICULTY TO SLEEP	A	Active	50 MG	1/ 8	1/ 8	13.75	152.00	MILD/ Resolved (15JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
[REDACTED]														
GASTROINTESTINAL DISORDERS	Gingival pain*/ GUM IRRITATION	C	Active	0	73/ 77	4/ 8	10.92	95.00	MILD/ Resolved (24MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	A	Active	50 MG	38/ 50	3/ 15	0.67	286.00	MILD/ Resolved (26FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

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		Trt	Phase	Dose**	Day+/ Study Day+	Day++/ Stop Day++	Time Post Dose (Hrs)	Start	Time					
										Day				
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	200 MG	42/ 43	7/ 8		4.67	17.00	MILD/ Resolved (19FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Headache*/ HEADACHE	A	Active	200 MG	46/ 47	11/ 12		6.67	15.00	MILD/ Resolved (23FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Headache*/ HEADACHE	C	Active	0	73/ 76	4/ 7		8.92	62.00	MODERATE/ Resolved (23MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO		
	Paraesthesia*/ TINGLING	A	Active	50 MG	36/ 38	1/ 3		8.67	38.00	MILD/ Resolved (14FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Somnolence*/ INTERMITTENT SOMNOLENCE	A	Active	50 MG	37/ 50	2/ 15		21.67	313.00	MILD/ Resolved (26FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Tremor*/ BILATERAL HAND TREMOR	A	Active	50 MG	38/ 51	3/ 16		0.67	320.00	MILD/ Resolved (27FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

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		Trt	Phase	Dose**	Day+/ Study Day+	Day++/ Stop Day++	Time Post Dose (Hrs)	Start	Time					
										Day+/ Study Day+				
PSYCHIATRIC DISORDERS	Affect lability*/ EMOTIONAL INSTABILITY	C	Active	0	79/ 80	10/ 11	10.92	24.00	MILD/ Resolved (27MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		
	Insomnia*/ INTERMITTENT INSOMNIA	B	Active	0	1/ 38	1/ 36	13.67	826.33	MILD/ Resolved (14FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		
	Insomnia*/ INTERMITTENT INSOMNIA	A	Active			1/ 3		46.67	MILD/ Resolved (14FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Dry skin*/ DRY SKIN	A	Active	200 MG	44/ 48	9/ 13	9.67	96.00	MILD/ Resolved (24FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		
[REDACTED]														
EYE DISORDERS	Ocular hyperaemia*/ EYE REDNESS	B	Active	0	59/ 62	7/ 10	1.25	57.00	MILD/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		

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* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE		
				Trt	Phase	Dose**	Study Start Day+/ Study Stop Day+	Period		Duration (Hrs)		SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE INTERMITTENT	A	Active	50 MG	108/ 110	3/ 5	5	1.25	45.00	MILD/ Resolved (26APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
INFECTIONS AND INFESTATIONS	Fungal infection*/ MYCOTIC INFECTION	B	Active	400 MG	82/ 99	30/ 47	47	381.25	408.00	MODERATE/ Resolved (15APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other illness-mycotic infection	NO	
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	C	Active	0	7/ 8	7/ 8	8	0.58	21.00	MILD/ Resolved (15JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Headache*/ HEADACHE	A	Active	50 MG	107/ 108	2/ 3	3	1.25	23.00	MILD/ Resolved (24APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Tremor*/ TREMOR BOTH ARMS	A	Active	200 MG	115/ 118	10/ 13	13	4.58	65.00	MILD/ Resolved (04MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	Menstruation irregular*/ IRREGULAR MENSTRUATION	C	Active	0	11/ 16	11/ 16	16	9.58	120.00	MILD/ Resolved (23JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
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 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Dry skin*/ DRY SKIN	C	Active	0	53/ 57	53/ 53	933.58	2.75	MILD/ Resolved (04MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Dry skin/ DRY SKIN	B	Active			1/ 5		93.25	MILD/ Resolved (04MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Dry skin/ DRY SKIN FOREHEAD	B	Active	0	65/ 68	13/ 16	10.25	59.00	MILD/ Resolved (15MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Eczema*/ ACUTE ECZEMA	C	Active	0	36/ 53	36/ 53	525.58	408.00	MODERATE/ Resolved (29FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	
	Skin irritation*/ BREAST IRRITATION	B	Active	0	62/ 82	10/ 30	11.25	478.00	MILD/ Resolved (29MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Skin irritation*/ BREAST IRRITATION	A	Active	200 MG	114/ 125	9/ 20	10.58	251.00	MODERATE/ Resolved (11MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE				
				Trt	Phase	Dose**	Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++					Time Post Dose (Hrs)
EAR AND LABYRINTH DISORDERS	Vertigo*/ INTERMITTENT VERTIGO	A	Active	200 MG	42/ 44	8/ 10	6.25	53.00	MODERATE/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
EYE DISORDERS	Vision blurred*/ BLURRED VISION	A	Active	200 MG	42/ 46	8/ 12	1.75	80.50	MILD/ Resolved (11MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
GASTROINTESTINAL DISORDERS	Abdominal distension*/ FEELING BLOATED	A	Active	200 MG	44/ 47	10/ 13	35.25	72.00	MILD/ Resolved (12MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Abdominal pain upper*/ STOMACH PAIN	A	Active	200 MG	42/ 46	8/ 12	6.25	100.00	MODERATE/ Resolved (11MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Gastrointestinal sounds abnormal*/ BORBORYGMI	A	Active	100 MG	38/ 39	4/ 5	10.25	24.00	MILD/ Resolved (04MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	B	Active	0	1/ 1	1/ 1	3.75	3.25	MODERATE/ Resolved (26JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Nausea*/ NAUSEA	A	Active	200 MG	42/ 44	8/ 10	5.25	54.00	MODERATE/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Vomiting*/ VOMITING	A	Active	200 MG	42/ 42	8/ 8	6.25	0.17	MODERATE/ Resolved (07MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Paraesthesia*/ MUSCLE TINGLING	A	Active	200 MG	42/ 44	8/ 10	0.17	45.00	MODERATE/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
GASTROINTESTINAL DISORDERS	Change of bowel habit*/ DECREASED BOWEL MOVEMENTS	A	Active	100 MG	76/ 79	6/ 9	1.25	81.00	MILD/ Resolved (13APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE	
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Asthenia*/ WEAKNESS	A	Active	50 MG	3/ 5	3/ 5	9.83	38.00	MILD/ Resolved (30JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Chest discomfort*/ THORACIC OPPRESSION	A	Active	100 MG	4/ 12	4/ 12	10.83	192.00	MILD/ Resolved (06FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscular weakness*/ LEGS WEAKNESS	B	Active	0	78/ 82	8/ 12	2.17	100.00	MILD/ Resolved (16APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	B	Active	0	71/ 71	1/ 1	1.17	6.00	MILD/ Resolved (05APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Tremor*/ HANDS TREMOR	B	Active	0	78/ 81	8/ 11	2.17	68.00	MILD/ Resolved (15APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Tremor*/ TREMOR HANDS	A	Active	100 MG	4/ 4	4/ 4	10.83	14.00	MILD/ Resolved (29JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE		
				Trt	Phase	Dose**	Study Start Day+/ Study Stop Day+	Period		Duration (Hrs)		SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
EAR AND LABYRINTH DISORDERS	Hyperacusis*/ NOISE SENSITIVITY	C	Active	0	41/ 47	7/ 13	9.92	144.00	MILD/ Resolved (12MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
EYE DISORDERS	Photophobia*/ LIGHT SENSITIVITY TO EYE	C	Active	0	40/ 44	6/ 10	9.92	96.00	MILD/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL CRAMPS	B	Active	0	7/ 7	7/ 7	4.17	0.50	MILD/ Resolved (01FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Cheilitis*/ LIP IRRITATION	C	Active	0	40/ 40	6/ 6	4.92	0.83	MILD/ Resolved (05MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Diarrhoea*/ LOOSE STOOL	B	Active	0	7/ 7	7/ 7	4.25	0.08	MILD/ Resolved (01FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE		
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period		Duration (Hrs)		SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Diarrhoea*/ WATERY STOOL	A	Active	50 MG	71/ 71	1/ 1		2	4.50	MILD/ Resolved (05APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Glossodynia*/ TONGUE SENSITIVE	C	Active	0	41/ 44	7/ 10		0	75.92	MILD/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chest discomfort*/ CHEST OPPRESSION	A	Active	200 MG	79/ 80	9/ 10		10	25.00	MILD/ Resolved (14APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Hangover*/ HANGOVER	C	Active	0	42/ 47	8/ 13		7.92	110.00	MILD/ Resolved (12MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Musculoskeletal stiffness */ STIFF NECK	A	Active	200 MG	79/ 80	9/ 10		10	25.00	MILD/ Resolved (14APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Musculoskeletal stiffness */ STIFFNESS	C	Active	0	40/ 44	6/ 10		11.92	83.00	MILD/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
						Start Day++/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Freezing phenomenon*/ FREEZING PHENOMENON	A	Active	100 MG	75/ 80	5/ 10	10	109.00	MILD/ Resolved (14APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Hypogeusia*/ DECREASED TASTE	C	Active	0	41/ 44	7/ 10	0.92	69.00	MILD/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Tremor*/ TREMOR	A	Active	50 MG	73/ 81	3/ 11	11	191.00	MILD/ Resolved (15APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	C	Active	0	36/ 39	2/ 5	20.42	73.50	MILD/ Resolved (04MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Insomnia*/ INSOMNIA	C	Active	0	40/ 44	6/ 10	1.42	79.50	MODERATE/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Pruritus*/ PRURITUS	C	Active	0	40/ 47	6/ 13	0.92	153.00	MILD/ Resolved (12MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Class	Organ	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
			Trt	Phase	Dose**	Study Start	Period					
						Day+/ Study Stop Day+	Start Day+/ Stop Day++	Time Post Dose (Hrs)				
[REDACTED]												
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Musculoskeletal stiffness */ MUSCLE STIFFNESS	A	Active	200 MG	42/ 43	8/ 9	3.83	31.00	MILD/ Resolved (08MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS		Insomnia*/ INSOMNIA	A	Active	50 MG	37/ 44	3/ 10	3.83	172.00	MILD/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
RENAL AND URINARY DISORDERS		Dysuria*/ DYSURIA	A	Active	200 MG	41/ 41	7/ 7	0.83	2.00	MILD/ Resolved (06MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]												
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Oropharyngeal pain*/ SORE THROAT	C	Active	0	74/ 82	4/ 12	5.75	185.00	MILD/ Resolved (20MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other illness-viral infection	NO
[REDACTED]												

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 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event					SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)			
					Day+/ Study Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Feeling hot*/ WARM SENSATION ON FEET	A	Active	200 MG	9/ 9	9/ 9	3.67	5.00	MILD/ Resolved (08MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
INFECTIONS AND INFESTATIONS	Nasopharyngitis/ COMMON COLD		Pre	0	-39/ -34	-39/ -34	-962.33	128.00	MILD/ Resolved (25JAN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASMS	A	Active	200 MG	9/ 15	9/ 15	3.67	163.00	MILD/ Resolved (14MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Disturbance in attention* / CONCENTRATION IMPAIRED	A	Active	200 MG	8/ 12	8/ 12	10.67	95.00	MILD/ Resolved (11MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	200 MG	8/ 10	8/ 10	1.67	31.00	MILD/ Resolved (09MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ SWEATING FEET	A	Active	200 MG	9/ 17	9/ 17	9.67	193.00	MILD/ Resolved (16MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SEVERITY/ Outcome	ACTION/ Causality	SAE	
				Trt	Phase	Dose**	Study Start Day+/ Study Stop Day+	Period					Duration (Hrs)
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Skin haemorrhage*/ BLEEDING (CUTANEOUS)	A	Active	200 MG	13/ 16	13/ 16	11.17	58.50	MILD/ Resolved (15MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
[REDACTED]													
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ ABDOMINAL DISCOMFORT	C	Active	0	4/ 12	4/ 12	0.83	185.75	MILD/ Resolved (11MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Asthenia*/ FEELING WEAK	A	Active	100 MG	41/ 48	5/ 12	0.67	173.00	MILD/ Resolved (16APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Vessel puncture site pain */ VENIPUNCTURE SITE PAIN	B	Active	400 MG	165/ 173	23/ 31	214.25	192.00	MILD/ Resolved (19AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-venipuncture	NO		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASM	B	Active	400 MG	171/ 180	29/ 38	358.25	215.00	MILD/ Resolved (26AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

[] Values in brackets are imputed from incomplete dates and times.

SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	200 MG	46/ 48	10/ 12	2.83	62.83	MODERATE/ Resolved (16APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	200 MG	48/ 71	12/ 35	3.67	558.00	MILD/ Resolved (09MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Libido increased*/ INCREASED LIBIDO	C	Active	0	13/ 16	13/ 16	0.58	69.00	MILD/ Resolved (15MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	C	Active	0	46/ 48	10/ 12	1.58	40.00	MILD/ Resolved (16APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Erythema*/ ERYTHEMA CHEST AREA	B	Active	0	1/ 1	1/ 1	11.83	0.67	MILD/ Resolved (29FEB2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

[] Values in brackets are imputed from incomplete dates and times.

SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day+/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ ABDOMINAL DISCOMFORT	B	Active	0	4/ 6	4/ 6	0.42	33.00	MILD/ Resolved (05MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Abdominal discomfort*/ STOMACH DISCOMFORT	A	Active	50 MG	37/ 37	1/ 1	2.5	8.00	MILD/ Resolved (05APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea*/ LOOSE STOOLS	A	Active	200 MG	46/ 47	10/ 11	2.67	30.83	MILD/ Resolved (15APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea*/ WATERY STOOLS	A	Active	50 MG	37/ 37	1/ 1	2.5	8.00	MILD/ Resolved (05APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea*/ WATERY STOOLS	C	Active	0	79/ 79	9/ 9	4.92	0.50	MILD/ Resolved (17MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Asthenia*/ WEAKNESS	A	Active	50 MG	37/ 37	1/ 1	2.5	8.00	MILD/ Resolved (05APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

[] Values in brackets are imputed from incomplete dates and times.

SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event				SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start Day+/ Study Stop Day+	Period		Duration (Hrs)			
						Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Vessel puncture site eryt hema*/ ERYTHEMA AT VENIPUNCTURE SITE	B	Active	0	7/ 7	7/ 7	10.83	1.08	MILD/ Resolved (06MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Injection/procedure related-venipuncture	NO
	Vessel puncture site pain */ VENIPUNCTURE SITE PAIN	C	Active	0	85/ 87	15/ 17	24.42	46.00	MILD/ Resolved (25MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-due to venipuncture	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Musculoskeletal stiffness */ STIFFNESS	B	Active	0	4/ 12	4/ 12	9.42	192.00	MILD/ Resolved (11MAR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	A	Active	100 MG	41/ 42	5/ 6	6	27.50	MILD/ Resolved (10APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	100 MG	40/ 71	4/ 35	0.5	729.00	MILD/ Resolved (09MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Nervousness*/ FEELING SHAKY - NO TREMOR OBSERVED	A	Active	200 MG	45/ 46	9/ 10	5	28.50	MILD/ Resolved (14APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
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 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event						SAE
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
RENAL AND URINARY DISORDERS	Polyuria*/ POLYURIA	A	Active	200 MG	44/ 53	8/ 17	9.5	216.00	MILD/ Resolved (21APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Erythema*/ ERYTHEMA	C	Active	0	75/ 75	5/ 5	7.92	0.35	MILD/ Resolved (13MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Hyperhidrosis*/ SWEATING	A	Active	100 MG	41/ 71	5/ 35	6	723.50	MILD/ Resolved (09MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	B	Active	0	45/ 45	9/ 9	4.42	5.00	MILD/ Resolved (13APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
10011019 (M/ 47(YEARS)/ WHITE/ 80.1(kg))											
EYE DISORDERS	Visual impairment*/ TROUBLE VISION	B	Active	0	37/ 37	3/ 3	0.25	11.50	MILD/ Resolved (28MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
 [] Values in brackets are imputed from incomplete dates and times.
 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Study Stop		Adverse Event Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/	Day+/	Start	Time						
					Day+	Day++	Day++	Post Dose (Hrs)						
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ HEAVY STOMACH	B	Active	0	40/ 42	6/ 8	10.75	48.00	MILD/ Resolved (02JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		
	Abdominal distension*/ INTERMITTENT BLOATING	C	Active	0	6/ 9	6/ 9	9.42	74.00	MILD/ Resolved (30APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		
	Diarrhoea*/ DIARRHEA	B	Active	400 MG	70/ 89	36/ 36	528.25	0.50	MODERATE/ Resolved (19JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug		NO		
	Diarrhoea/ DIARRHEA	A	Active			1/ 20		467.00	MODERATE/ Resolved (19JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug		NO		
	Diarrhoea*/ LOOSE STOOLS	C	Active	0	17/ 35	17/ 35	68.42	434.00	MILD/ Resolved (26MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		
	Dry mouth*/ DRY MOUTH	A	Active	200 MG	79/ 89	10/ 20	11	240.00	MILD/ Resolved (19JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug		NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Application site erythema */ ERYTHEMA AT ECG ELECTRODE SITES	B	Active	0	35/ 37	1/ 3	1.75	55.00	MILD/ Resolved (28MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-due to ecg electrode	NO
	Application site erythema */ ERYTHEMA AT ECG ELECTRODE SITES	B	Active	0	48/ 49	14/ 15	10.75	27.00	MILD/ Resolved (09JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-due to ecg electrode	NO
	Fatigue*/ FATIGUE	B	Active	0	35/ 48	1/ 14	5.75	305.00	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Fatigue*/ FATIGUE	A	Active	100 MG	73/ 85	4/ 16	10	289.00	MILD/ Resolved (15JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Vessel puncture site eryt hema*/ VENIPUNCTURE SITE REDNESS	A	Active	200 MG	83/ 85	14/ 16	6	41.00	MILD/ Resolved (15JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-venipuncture	NO
INFECTIONS AND INFESTATIONS	Fungal infection*/ MYCOTIC INFECTION	C	Active	0	9/ 16	9/ 16	11.42	155.00	MODERATE/ Resolved (07MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other illness-mycotic infection	NO

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
 [] Values in brackets are imputed from incomplete dates and times.
 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Study Stop		Adverse Event Period		SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/	Day+/	Start	Time	Duration (Hrs)	Post Dose (Hrs)			
					Study Day+	Study Day+	Day++/	Day++/					
INFECTIONS AND INFESTATIONS	Nasopharyngitis*/ COMMON COLD	B	Active	0	41/ 43	7/ 9	8.75	40.50	MILD/ Resolved (03JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASM	A	Active	200 MG	78/ 88	9/ 19	8	255.00	MILD/ Resolved (18JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
NERVOUS SYSTEM DISORDERS	Disturbance in attention* / CONCENTRATION IMPAIRMENT	C	Active	0	13/ 14	13/ 14	10.42	24.00	MILD/ Resolved (05MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Disturbance in attention* / DIFFICULT TO CONCENTRATE	B	Active	0	36/ 48	2/ 14	0.75	286.00	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Head discomfort*/ INTERMITTENT PRESSURE IN HEAD	C	Active	0	6/ 11	6/ 11	0.42	107.00	MILD/ Resolved (02MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Headache*/ HEADACHE	A	Active	200 MG	79/ 80	10/ 11	5	22.50	MODERATE/ Resolved (10JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE			
				Trt	Phase	Dose**	Study Start		Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++	Time Post Dose (Hrs)				
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Acne*/ ACNE FACE	A	Active	200 MG	81/ 86	12/ 17		0	119.00	MILD/ Resolved (16JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Dry skin*/ DRY SKIN FACE	B	Active	400 MG	48/ 54	14/ 20		3.75	140.00	MILD/ Resolved (14JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Night sweats*/ NIGHT SWEATING	A	Active	200 MG	79/ 96	10/ 27		10	410.00	MILD/ Resolved (26JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
VASCULAR DISORDERS	Hot flush*/ INTERMITTENT HOT FLUSH	B	Active	0	41/ 84	7/ 36		8.75	688.00	MILD/ Resolved (14JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Hot flush/ INTERMITTENT HOT FLUSH	A	Active			1/ 15			334.00	MILD/ Resolved (14JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

(M/ 53(YEARS)/ WHITE/ 90.5(kg))

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/	Start	Time	Post				
					Study Day+	Day++/ Stop Day++	Post Dose (Hrs)	Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ STOMACH DISCOMFORT	C	Active	0	72/ 72	3/ 3	0.92	2.00	MILD/ Resolved (02JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Dry mouth*/ DRY MOUTH	B	Active	0	35/ 48	1/ 14	1.67	309.00	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Application site erythema */ ERYTHEMA AT ECG ELECTRODE SITES	B	Active	0	35/ 35	1/ 1	1.67	1.75	MILD/ Resolved (26MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-due to ecg electrode	NO	
INVESTIGATIONS	Weight decreased*/ WEIGHT DECREASE	B	Active	0	47/ 48	13/ 14	11.67	23.00	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	B	Active	0	38/ 38	4/ 4	3.67	2.00	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Headache*/ HEADACHE	C	Active	0	71/ 72	2/ 3	1.92	21.00	MILD/ Resolved (02JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	C	Active	0	42/ 45	7/ 10	11	68.00	MILD/ Resolved (22JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Arthralgia*/ PAIN BOTH KNEES	C	Active	0	47/ 47	12/ 12	2	1.25	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	100 MG	5/ 6	5/ 6	10.25	25.00	MILD/ Resolved (14MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ HEADACHE	B	Active	0	80/ 86	10/ 16	0	134.50	MODERATE/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Dysphonia*/ CHANGE IN VOICE	A	Active	200 MG	26/ 37	26/ 36	287.25	241.00	MILD/ Resolved (14JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE			
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Dysphonia/ CHANGE IN VOICE	C	Active				1/ 2		22.00	MILD/ Resolved (14JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Oropharyngeal pain*/ THROAT PAIN	B	Active	0	82/ 86	12/ 16		10	100.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Acne*/ ACNE	B	Active	0	75/ 80	5/ 10		0	118.00	MILD/ Resolved (27JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Intertrigo*/ INTERTRIGO	B	Active	0	81/ 93	11/ 23		11	275.00	MODERATE/ Resolved (09AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other-mycotic infection	NO	
	Seborrhoea*/ OILY SKIN	C	Active	0	40/ 55	5/ 20		6	353.00	MILD/ Resolved (02JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE		
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period		Duration (Hrs)		SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
METABOLISM AND NUTRITION DISORDERS	Decreased appetite*/ DECREASED APPETITE	A	Active	100 MG	40/ 48	5/ 13		2.92	187.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Neck pain*/ NECK PAIN	C	Active	0	11/ 11	11/ 11		5.17	2.00	MILD/ Resolved (19MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	C	Active	0	8/ 8	8/ 8		2.17	4.00	MILD/ Resolved (16MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	100 MG	40/ 51	5/ 16		3.92	270.00	MILD/ Resolved (28JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Cough*/ COUGH	A	Active	200 MG	65/ 71	30/ 36		394.92	140.00	MILD/ Resolved (18JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ SWEATING	A	Active	200 MG	44/ 52	9/ 17		1.92	176.00	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SEVERITY/ Outcome	ACTION/ Causality	SAE	
				Trt	Phase	Dose**	Study Start	Period					Duration (Hrs)
							Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
CARDIAC DISORDERS	Atrioventricular block first degree*/ INTERMITTENT FIRST DEGREE AV BLOCK	A	Active	50 MG	35/ 35	1/ 1	0.88	2.00	MILD/ Resolved (26MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GASTROINTESTINAL DISORDERS	Dry mouth*/ DRY MOUTH	A	Active	100 MG	38/ 38	4/ 4	1.08	8.50	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	B	Active	0	1/ 1	1/ 1	1	10.17	MILD/ Resolved (22APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Fatigue*/ FATIGUE	A	Active	200 MG	47/ 54	13/ 20	11.58	168.00	MILD/ Resolved (14JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Hunger*/ FEELING OF HUNGER	B	Active	0	7/ 10	7/ 10	10.75	85.50	MILD/ Resolved (01MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Dry throat*/ DRY THROAT	B	Active	0	2/ 2	2/ 2	23.17	14.00	MILD/ Resolved (23APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
EYE DISORDERS	Visual impairment*/ VISION TROUBLE	A	Active	100 MG	74/ 79	5/ 10	9.75	124.00	MILD/ Resolved (09JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GASTROINTESTINAL DISORDERS	Diarrhoea*/ LOOSE STOOLS	B	Active	400 MG	15/ 35	15/ 35	36.17	466.00	MILD/ Resolved (26MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Dyspepsia*/ INTERMITTENT PYROSIS	B	Active	0	2/ 15	2/ 15	0.88	309.20	MILD/ Resolved (06MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Gastroesophageal reflux disease*/ GASTROESOPHAGEAL REFLUX	C	Active	0	38/ 38	4/ 4	1	2.50	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Gastroesophageal reflux disease*/ INTERMITTENT GASTROESOPHAGEAL REFLUX	C	Active	0	43/ 48	9/ 14	0.5	118.00	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Vomiting*/ VOMITING	C	Active	0	44/ 44	10/ 10	5.5	0.25	MODERATE/ Resolved (04JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
METABOLISM AND NUTRITION DISORDERS	Decreased appetite*/ INAPPETENCE	C	Active	0	44/ 50	10/ 16	10.5	144.00	MILD/ Resolved (10JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Limb discomfort*/ HEAVY SENSATION THIGHS	A	Active	200 MG	78/ 79	9/ 10	9.75	28.00	MILD/ Resolved (09JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Muscle spasms*/ MUSCULAR SPASM	A	Active	50 MG	72/ 85	3/ 16	4.75	306.00	MILD/ Resolved (15JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Headache*/ INTERMITTENT HEADACHE	C	Active	0	44/ 82	10/ 36	11	625.75	MILD/ Resolved (12JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE			
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
								Start Day+ / Stop Day+	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Headache/ INTERMITTENT HEADACHE	A	Active				1/ 13		287.75	MILD/ Resolved (12JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO	
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	200 MG	77/ 80	8/ 11	5.75	81.50	MILD/ Resolved (10JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO		
VASCULAR DISORDERS	Hot flush*/ INTERMITTENT HOT FLUSH	B	Active	0	1/ 84	1/ 35	12.08	803.50	MILD/ Resolved (14JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO		
	Hot flush/ INTERMITTENT HOT FLUSH	C	Active				1/ 36	840.75	MILD/ Resolved (14JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO		
	Hot flush/ INTERMITTENT HOT FLUSH	A	Active				1/ 15	333.75	MILD/ Resolved (14JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Stop Day+	Day++/ Stop Day++	Time Post Dose (Hrs)					
EYE DISORDERS	Photophobia*/ BILATERAL EYES SENSITIVE TO LIGHT	C	Active	0	47/ 50	13/ 16	10.42	73.00	MILD/ Resolved (10JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Visual impairment*/ VISION TROUBLE	A	Active	100 MG	74/ 76	5/ 7	9.67	48.00	MILD/ Resolved (06JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
GASTROINTESTINAL DISORDERS	Abdominal distension*/ INTERMITTENT BLOATING	B	Active	0	1/ 51	1/ 35	11	804.58	MILD/ Resolved (11JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Abdominal distension/ INTERMITTENT BLOATING	C	Active			1/ 17		392.42	MILD/ Resolved (11JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Flatulence*/ FLATULENCE	B	Active	0	2/ 16	2/ 16	6	328.00	MILD/ Resolved (07MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Feeling cold*/ COLD FEELING	A	Active	100 MG	74/ 82	5/ 13	9.67	194.00	MILD/ Resolved (12JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Phase	Dose**	Study Start Day+/ Study Day+	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
						Start Day++/ Stop Day++	Time Post Dose (Hrs)				
INFECTIONS AND INFESTATIONS	Hordeolum*/ STYE	B	Active	400 MG	15/ 16	15/ 16	22.08	24.00	MILD/ Resolved (07MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other illness-bacterial infection	NO
INVESTIGATIONS	Weight decreased*/ WEIGHT LOSS	A	Active	200 MG	78/ 82	9/ 13	9.67	98.00	MILD/ Resolved (12JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASM	A	Active	50 MG	72/ 84	3/ 15	5.67	291.00	MILD/ Resolved (14JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Myalgia*/ INTERMITTENT MUSCLE PAIN	B	Active	0	5/ 50	5/ 35	11	720.58	MODERATE/ Resolved (10JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Myalgia/ INTERMITTENT MUSCLE PAIN	C	Active			1/ 16		358.42	MODERATE/ Resolved (10JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ INTERMITTENT LIGHTHEADNESS	A	Active	200 MG	76/ 82	7/ 13	9.67	146.00	MILD/ Resolved (12JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
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 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SEVERITY/ Outcome	ACTION/ Causality	SAE	
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period					Duration (Hrs)
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Tremor*/ HANDS TREMOR	A	Active	200 MG	82/ 84	13/ 15	1.67	44.00	MILD/ Resolved (14JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
[REDACTED]													
EYE DISORDERS	Visual impairment*/ VISION TROUBLE	A	Active	200 MG	12/ 15	12/ 15	10	72.00	MILD/ Resolved (06MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	A	Active	200 MG	13/ 13	13/ 13	7	7.00	MILD/ Resolved (04MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Diarrhoea*/ LOOSE STOOLS	A	Active	100 MG	6/ 8	6/ 8	10	61.00	MILD/ Resolved (29APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Flatulence*/ FLATULENCE	B	Active	0	37/ 40	3/ 6	11.33	71.00	MILD/ Resolved (31MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE			
				Trt	Phase	Dose**	Study				Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Study Day+	Start Day+/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Gastrointestinal sounds abnormal*/ BORBORYGMI	A	Active	200 MG	7/ 8	7/ 8	10	24.00	MILD/ Resolved (29APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Nausea*/ NAUSEA	A	Active	50 MG	1/ 3	1/ 3	14.42	38.50	MODERATE/ Resolved (24APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Vomiting*/ VOMITING	A	Active	50 MG	2/ 2	2/ 2	15.92	0.08	MODERATE/ Resolved (23APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chest discomfort*/ CHEST DISCOMFORT	C	Active	0	82/ 85	13/ 16	9.5	72.08	MILD/ Resolved (15JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Fatigue*/ INTERMITTENT FATIGUE	A	Active	200 MG	9/ 16	9/ 16	10.5	155.50	MILD/ Resolved (07MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Back pain*/ BACK PAIN	B	Active	0	35/ 38	1/ 4	7.33	66.00	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ INTERMITTENT MUSCULAR CRAMPS	A	Active	200 MG	13/ 16	13/ 16	5	65.00	MILD/ Resolved (07MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Pain in extremity*/ INTERMITTENT LEG PAIN	C	Active	0	72/ 74	3/ 5	11.33	46.25	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	50 MG	2/ 4	2/ 4	15.92	65.00	MILD/ Resolved (25APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ HEADACHE	A	Active	200 MG	7/ 7	7/ 7	3	8.00	MILD/ Resolved (28APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ INTERMITTENT HEADACHE	A	Active	200 MG	11/ 14	11/ 14	7.5	62.50	MILD/ Resolved (05MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ INTERMITTENT HEADACHE	B	Active	0	35/ 38	1/ 4	7.33	65.50	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++					Time Post Dose (Hrs)
NERVOUS SYSTEM DISORDERS	Headache*/ INTERMITTENT HEADACHE	B	Active	0	44/ 48	10/ 14	5.83	88.50	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ INTERMITTENT HEADACHE	C	Active	0	70/ 74	1/ 5	5.58	88.00	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Poor quality sleep*/ NOT SLEEPING WELL	B	Active	0	44/ 48	10/ 14	11.33	95.00	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Somnolence*/ SLEEPINESS	C	Active	0	84/ 85	15/ 16	35.58	10.00	MILD/ Resolved (15JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Tremor*/ LEG TREMOR	A	Active	200 MG	9/ 13	9/ 13	4	90.00	MILD/ Resolved (04MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	B	Active	400 MG	55/ 74	21/ 36	180.33	348.42	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE			
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
PSYCHIATRIC DISORDERS	Insomnia/ INSOMNIA	C	Active				1/ 5		93.58	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Nervousness*/ NERVOSITY	B	Active	400 MG	55/ 74	21/ 36	167.33	361.42	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Nervousness/ NERVOSITY	C	Active				1/ 5		93.58	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Nightmare*/ NIGHTMARE	B	Active	0	46/ 46	12/ 12	5.33	2.50	MILD/ Resolved (06JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ INTERMITTENT SWEATING	A	Active	200 MG	10/ 42	10/ 35	10	601.67	MILD/ Resolved (02JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Hyperhidrosis/ INTERMITTENT SWEATING	B	Active				1/ 8		171.33	MILD/ Resolved (02JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event						SAE			
					Trt	Phase	Dose**	Study Start Day+/ Study Stop Day+	Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
									Start Day++/ Stop Day++	Time Post Dose (Hrs)				
[REDACTED]														
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	B	Active	0	77/ 77	7/ 7	10.83	1.00	MILD/ Resolved (24JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Fatigue*/ INTERMITTENT FATIGUE	A	Active	50 MG	38/ 46	3/ 11	5.83	185.00	MILD/ Resolved (23JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	A	Active	200 MG	42/ 43	7/ 8	10.83	26.00	MILD/ Resolved (20JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Tremor*/ TREMOR	A	Active	200 MG	44/ 45	9/ 10	9.83	33.00	MILD/ Resolved (22JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
[REDACTED]														
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ STOMACH DISCOMFORT	C	Active	0	75/ 79	6/ 10	0.5	97.00	MILD/ Resolved (09JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
 [] Values in brackets are imputed from incomplete dates and times.
 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event					Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
				Trt	Phase	Dose**	Study Start						Period
							Day+/ Stop Day+	Start Day++/ Stop Day++					Time Post Dose (Hrs)
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	A	Active	50 MG	36/ 49	2/ 15	3.25	308.00	MILD/ Resolved (09JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Constipation*/ CONSTIPATION	B	Active	0	8/ 15	8/ 15	9.92	168.00	MILD/ Resolved (06MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Dyspepsia*/ PYROSIS	B	Active	0	8/ 17	8/ 17	9.92	216.00	MILD/ Resolved (08MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Gastrointestinal sounds abnormal*/ BORBORYGMI	B	Active	0	7/ 7	7/ 7	9.92	1.00	MILD/ Resolved (28APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Nausea*/ NAUSEA	A	Active	50 MG	36/ 37	2/ 3	1.25	31.00	MILD/ Resolved (28MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	50 MG	37/ 61	3/ 27	2.25	577.00	MILD/ Resolved (21JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
INFECTIONS AND INFESTATIONS	Gingivitis*/ GINGIVITIS	B	Active	400 MG	15/ 17	15/ 17	21.92	48.00	MILD/ Resolved (08MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Nasopharyngitis*/ COMMON COLD	C	Active	0	70/ 72	1/ 3	7.75	50.75	MILD/ Resolved (02JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscular weakness*/ INTERMITTENT MUSCLE WEAKNESS	A	Active	50 MG	36/ 46	2/ 12	0.25	238.00	MILD/ Resolved (06JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Disturbance in attention* / CONCENTRATION IMPAIRMENT	B	Active	0	2/ 14	2/ 14	1.75	287.00	MILD/ Resolved (05MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ HEADACHE	B	Active	0	2/ 2	2/ 2	1.75	6.00	MILD/ Resolved (23APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ HEADACHE	B	Active	0	7/ 10	7/ 10	1.92	69.00	MILD/ Resolved (01MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	B	Active	0	13/ 14	13/ 14	0.92	21.00	MILD/ Resolved (05MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ HEADACHE	A	Active	200 MG	49/ 49	15/ 15	25.25	10.00	MILD/ Resolved (09JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ INTERMITTENT HEADACHE	A	Active	50 MG	35/ 38	1/ 4	7.25	66.00	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Tremor*/ TREMOR BOTH HANDS	A	Active	50 MG	36/ 49	2/ 15	0.25	323.00	MILD/ Resolved (09JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Affect lability*/ EMOTIONAL LABILITY	A	Active	50 MG	37/ 61	3/ 27	11.25	568.00	MILD/ Resolved (21JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Oropharyngeal pain*/ SORE THROAT	B	Active	400 MG	35/ 38	35/ 35	501.92	1.75	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-air conditioning	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
		Trt	Phase	Dose**	Study Start	Period						
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Oropharyngeal pain/ SORE THROAT	A	Active		1/ 4		78.25	MILD/ Resolved (29MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-air conditioning	NO		
[REDACTED]												
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ HEAVY STOMACH	C	Active	0	4/ 4	4/ 4	10.5	1.50	MILD/ Resolved (12MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Abdominal pain*/ ABDOMINAL PAIN	C	Active	0	9/ 9	9/ 9		6	1.00	MILD/ Resolved (17MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Flatulence*/ FLATULENCE	C	Active	0	8/ 9	8/ 9		2	2.00	MILD/ Resolved (17MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Gingival bleeding*/ INTERMITTENT GUM BLEEDING	B	Active	0	36/ 38	1/ 3	12.25	34.50	MILD/ Resolved (15JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE			
				Trt	Phase	Dose**	Study Start		Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	A	Active	100 MG	76/ 80	6/ 10	10.75	95.00	MILD/ Resolved (27JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	50 MG	73/ 87	3/ 17	2.75	331.00	MILD/ Resolved (03AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR CRAMPS IN LEGS	C	Active	0	13/ 22	13/ 22	11	204.00	MILD/ Resolved (30MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Muscle spasms*/ MUSCULAR SPASM	A	Active	200 MG	79/ 83	9/ 13	7.75	98.00	MILD/ Resolved (30JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
NERVOUS SYSTEM DISORDERS	Head discomfort*/ PRESSURE IN HEAD	A	Active	200 MG	79/ 81	9/ 11	7.75	61.00	MILD/ Resolved (28JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Headache*/ HEADACHE	B	Active	0	36/ 37	1/ 2	12.75	9.00	MILD/ Resolved (14JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/	Day++/	Start	Time				
					Study Day+	Stop Day++	Day+	Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	200 MG	76/ 76	6/ 6	0.25	1.50	MILD/ Resolved (23JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Paraesthesia*/ PARESTHESIA FINGERS	A	Active	200 MG	77/ 81	7/ 11	4.75	102.00	MILD/ Resolved (28JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Restless legs syndrome*/ RESTLESS LEGS	B	Active	0	36/ 48	1/ 13	2.75	283.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Restless legs syndrome*/ RESTLESS LEGS	B	Active	400 MG	50/ 52	15/ 17	23.75	46.00	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Somnolence*/ SLEEPINESS	C	Active	0	6/ 10	6/ 10	11	96.00	MILD/ Resolved (18MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Tremor*/ LEFT HAND TREMOR	A	Active	200 MG	82/ 84	12/ 14	5.75	40.00	MILD/ Resolved (31JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE			
				Trt	Phase	Dose**	Study Start		Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Tremor*/ TREMOR LEGS	C	Active	0	5/ 11	5/ 11	11	158.00	MILD/ Resolved (19MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
PSYCHIATRIC DISORDERS	Insomnia*/ INTERMITTENT INSOMNIA	A	Active	50 MG	72/ 83	2/ 13	10.75	251.00	MILD/ Resolved (30JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Libido decreased*/ DECREASED LIBIDO	A	Active	200 MG	86/ 87	16/ 17	46.75	38.00	MILD/ Resolved (03AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Cough*/ COUGH	A	Active	200 MG	85/ 86	15/ 16	22.75	27.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Epistaxis*/ EPISTAXIS	A	Active	200 MG	84/ 87	14/ 17	10.75	59.00	MILD/ Resolved (03AUG2016)	Other-viral infection STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Nasal congestion*/ BLOCKED NOSE	C	Active	0	2/ 13	2/ 13	23	265.25	MILD/ Resolved (21MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Acne*/ ACNE	A	Active	100 MG	74/ 76	4/ 6	0.75	47.00	MILD/ Resolved (23JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ STOMACHACHE	A	Active	50 MG	3/ 8	3/ 8	1.57	116.00	MILD/ Resolved (29APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Constipation*/ CONSTIPATION	A	Active	100 MG	6/ 8	6/ 8	9.83	48.00	MILD/ Resolved (29APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Dyspepsia*/ INTERMITTENT PYROSIS	A	Active	100 MG	4/ 13	4/ 13	10.57	215.00	MILD/ Resolved (04MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Haematochezia*/ BLOOD IN STOOLS	A	Active	100 MG	4/ 5	4/ 5	7.58	24.25	MILD/ Resolved (26APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start Day+/ Study Stop Day+	Period					
						Start Day++/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	50 MG	1/ 1	1/ 1	0.58	4.00	MILD/ Resolved (22APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ INTERMITTENT HEADACHE	A	Active	100 MG	4/ 16	4/ 16	0.58	297.00	MODERATE/ Resolved (07MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Asthma*/ ASTHMA EXACERBATION	A	Active	200 MG	32/ 39	32/ 39	430.83	168.00	MODERATE/ Resolved (30MAY2016)	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (TREATMENT GIVEN,D/C STUDY) / Other-pre existing condition	NO
[REDACTED]											
GASTROINTESTINAL DISORDERS	Constipation*/ CONSTIPATION	B	Active	0	9/ 11	9/ 11	10.92	35.00	MILD/ Resolved (19MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Gingival bleeding*/ GUMS BLEEDING	A	Active	200 MG	48/ 50	13/ 15	9.67	49.00	MILD/ Resolved (27JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
 [] Values in brackets are imputed from incomplete dates and times.
 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE				
				Trt	Phase	Dose**	Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++					Time Post Dose (Hrs)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	C	Active	0	71/ 72	1/ 2	3.67	20.00	MILD/ Resolved (19JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Fatigue*/ INTERMITTENT FATIGUE	B	Active	0	9/ 52	9/ 36	0.42	647.83	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Fatigue/ INTERMITTENT FATIGUE	A	Active			1/ 17		381.67	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Neck pain*/ PAIN NECK	A	Active	100 MG	41/ 44	6/ 9	10.83	58.83	MILD/ Resolved (21JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	200 MG	70/ 70	35/ 35	509.17	5.00	MILD/ Resolved (17JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	200 MG	47/ 48	12/ 13	5.67	28.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Study Stop		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Study Day+	Day++/ Stop Day++	Time Post Dose (Hrs)	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	C	Active	0	81/ 83	11/ 13		3.67	54.00	MILD/ Resolved (30JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Rhinorrhoea*/ RUNNY NOSE	A	Active	50 MG	36/ 38	1/ 3		0.67	46.00	MILD/ Resolved (15JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Dry skin*/ DRY SKIN FACE	C	Active	0	79/ 90	9/ 20		9.67	265.00	MILD/ Resolved (06AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
VASCULAR DISORDERS	Hot flush*/ INTERMITTENT HOT FLUSHES	A	Active	200 MG	43/ 49	8/ 14		10.67	143.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue/ FATIGUE	B	Active	0	1/ 1	1/ 1		-2.5	7.00	MILD/ Resolved (22APR2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
EYE DISORDERS	Visual impairment*/ TROUBLE OF VISION	B	Active	0	71/ 73	1/ 3	8.08	41.25	MILD/ Resolved (20JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Visual impairment*/ TROUBLE VISION	A	Active	200 MG	43/ 47	8/ 12	8.83	87.60	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GASTROINTESTINAL DISORDERS	Abdominal pain*/ PAIN LEFT ABDOMEN	C	Active	0	9/ 9	9/ 9	0.08	0.25	MILD/ Resolved (17MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chest discomfort*/ LEFT THORACIC DISCOMFORT	C	Active	0	15/ 15	15/ 15	23.88	0.03	MILD/ Resolved (23MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Fatigue*/ FATIGUE	A	Active	100 MG	39/ 47	4/ 12	0.58	189.00	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Feeling hot*/ HOT FEELING	A	Active	200 MG	45/ 47	10/ 12	0.58	33.00	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

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MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE	
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
IMMUNE SYSTEM DISORDERS	Seasonal allergy*/ EXACERBATION OF SEASONAL ALLERGY	C	Active	0	22/ 37	22/ 36	191.83	336.42	MODERATE/ Resolved (14JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other-seasonal allergy	NO
	Seasonal allergy*/ EXACERBATION OF SEASONAL ALLERGY	A	Active			1/ 2		23.58	MODERATE/ Resolved (14JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other-seasonal allergy	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ INTERMITTENT MUSCULAR SPASM	A	Active	200 MG	44/ 98	9/ 36	9.58	650.42	MILD/ Resolved (14AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Muscle spasms*/ INTERMITTENT MUSCULAR SPASM	B	Active			1/ 28		658.58	MILD/ Resolved (14AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	C	Active	0	15/ 15	15/ 15	23.98	0.02	MILD/ Resolved (23MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ HEADACHE	A	Active	50 MG	37/ 47	2/ 12	23.58	238.00	MODERATE/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	B	Active	0	79/ 80	9/ 10	6.58	28.00	MILD/ Resolved (27JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	50 MG	36/ 38	1/ 3	12.58	35.00	MILD/ Resolved (15JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia*/ INSOMNIA	B	Active	0	75/ 83	5/ 13	3.58	192.00	MILD/ Resolved (30JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Libido decreased*/ DECREASE LIBIDO	A	Active	100 MG	39/ 62	4/ 27	9.58	552.00	MILD/ Resolved (09JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	Erectile dysfunction*/ ERECTION/TROUBLE DISORDER	B	Active	0	74/ 74	4/ 4	1.58	1.50	MILD/ Resolved (21JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ SWEATING	A	Active	200 MG	43/ 48	8/ 13	9.58	120.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
[REDACTED]											
GASTROINTESTINAL DISORDERS	Abdominal pain*/ RIGHT SIDE ABDOMEN PAIN	C	Active	0	7/ 7	7/ 7	5.75	1.00	MILD/ Resolved (15MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea*/ INTERMITTENT LOOSE STOOLS	C	Active	0	10/ 43	10/ 36	5.75	618.50	MILD/ Resolved (20JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea/ INTERMITTENT LOOSE STOOLS	B	Active			1/ 8		168.50	MILD/ Resolved (20JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea/ INTERMITTENT LOOSE STOOLS	B	Active	400 MG	50/ 81	15/ 36	25.5	502.50	MILD/ Resolved (28JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea/ INTERMITTENT LOOSE STOOLS	A	Active			1/ 11		238.50	MILD/ Resolved (28JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

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+ Day relative to start of study treatment. First day of study treatment = day 1

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[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Study Stop		Adverse Event Period		SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Study Day+	Day++/ Stop Day++	Time Post Dose (Hrs)	Duration (Hrs)					
GASTROINTESTINAL DISORDERS	Diarrhoea/ LOOSE STOOLS	A	Active	200 MG	84/ 92	14/ 22		9.5	193.00	MILD/ Resolved (08AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Dry mouth*/ DRY MOUTH	A	Active	200 MG	79/ 92	9/ 22		9.5	313.00	MILD/ Resolved (08AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Dyspepsia*/ PYROSIS	B	Active	0	45/ 47	10/ 12		0.5	33.00	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	
	Functional gastrointestinal disorder*/ SLOW BOWEL FUNCTION	B	Active	0	44/ 48	9/ 13		2.5	91.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	100 MG	74/ 86	4/ 16		10.5	291.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Fatigue*/ INTERMITTENT FATIGUE	C	Active	0	2/ 47	2/ 36		2.75	813.50	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

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+ Day relative to start of study treatment. First day of study treatment = day 1

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event					Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE		
				Trt	Phase	Dose**	Study						Period	
							Day+/ Study Day+	Start Day+/ Stop Day+					Time Post Dose (Hrs)	Start Day+/ Stop Day+
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue/ INTERMITTENT FATIGUE	B	Active				1/ 12		261.50	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Vessel puncture site pain */ VENIPUNCTURE SITE PAIN	C	Active	0	14/ 17	14/ 17		4.75	65.00	MILD/ Resolved (25MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASM	A	Active	100 MG	74/ 87	4/ 17		10.5	311.00	MILD/ Resolved (03AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Pain in extremity*/ RIGHT FOOT PAINFUL	B	Active	400 MG	49/ 49	14/ 14		2	6.50	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	A	Active	100 MG	75/ 75	5/ 5		6	0.50	MILD/ Resolved (22JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Tremor*/ HANDS TREMOR	A	Active	200 MG	77/ 86	7/ 16		5.5	212.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE			
				Trt	Phase	Dose**	Study Start		Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++	Time Post Dose (Hrs)				
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	B	Active	0	46/ 47	11/ 12	7.5	26.00	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Libido decreased*/ DECREASED LIBIDO	A	Active	200 MG	86/ 87	16/ 17	46.5	23.00	MILD/ Resolved (03AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ SWEATING	A	Active	200 MG	79/ 83	9/ 13	7.5	91.00	MILD/ Resolved (30JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
[REDACTED]														
GASTROINTESTINAL DISORDERS	Diarrhoea*/ LOOSE STOOLS	A	Active	50 MG	1/ 4	1/ 4	2.67	72.00	MILD/ Resolved (12MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
NERVOUS SYSTEM DISORDERS	Dizziness*/ FEELING DIZZY	A	Active	50 MG	3/ 7	3/ 7	0.67	96.00	MODERATE/ Resolved (15MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

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[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Presyncope*/ VAGAL REACTION	A	Active	100 MG	4/ 4	4/ 4	10.67	0.08	MODERATE/ Resolved (12MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	200 MG	47/ 55	8/ 16	6.5	184.00	MILD/ Resolved (19JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	B	Active	0	10/ 14	10/ 14	3.92	101.00	MILD/ Resolved (08JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Insomnia*/ INTERMITTENT INSOMNIA	A	Active	100 MG	43/ 54	4/ 15	1.5	247.00	MILD/ Resolved (18JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ HEAD SWEATING	A	Active	200 MG	48/ 54	9/ 15	8.5	149.00	MILD/ Resolved (18JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
10011038 (M/ 33(YEARS)/ WHITE/ 81.3(kg))											

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++					Time Post Dose (Hrs)
CARDIAC DISORDERS	Atrioventricular block first degree*/ INTERMITTENT FIRST DEGREE AV BLOCK	C	Active	0	14/ 36	14/ 36	1.02	527.23	MILD/ Resolved (13JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Atrioventricular block first degree*/ INTERMITTENT FIRST DEGREE AV BLOCK	A	Active			1/ 1		4.88	MILD/ Resolved (13JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Atrioventricular block first degree*/ INTERMITTENT FIRST DEGREE AV BLOCK	B	Active	0	84/ 87	14/ 17	11.77	72.15	MILD/ Resolved (03AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
EAR AND LABYRINTH DISORDERS	Ear discomfort*/ LEFT EAR BLOCKED	C	Active	0	8/ 13	8/ 13	9.58	130.00	MILD/ Resolved (21MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GASTROINTESTINAL DISORDERS	Diarrhoea*/ LOOSE STOOLS	C	Active	0	9/ 9	9/ 9	5.58	0.08	MILD/ Resolved (17MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	C	Active	0	2/ 15	2/ 15		297.50	MILD/ Resolved (23MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SEVERITY/ Outcome	ACTION/ Causality	SAE	
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period					Duration (Hrs)
								Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	100 MG	40/ 49	5/ 14	10.33	215.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Fatigue*/ FATIGUE	A	Active	200 MG	50/ 53	15/ 18	23.33	70.00	MILD/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Feeling drunk*/ FEELING DRUNK	C	Active	0	2/ 15	2/ 15	5.5	304.00	MILD/ Resolved (23MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Feeling hot*/ WARM FEELING	C	Active	0	13/ 13	13/ 13	8.58	1.00	MILD/ Resolved (21MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	100 MG	41/ 42	6/ 7	2.33	19.00	MILD/ Resolved (19JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	200 MG	44/ 49	9/ 14	4.33	125.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
VASCULAR DISORDERS	Hot flush*/ INTERMITTENT HOT FLUSHES	A	Active	200 MG	42/ 49	7/ 14	10.33	167.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	100 MG	75/ 77	6/ 8	3.92	42.00	MILD/ Resolved (10AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Somnolence*/ SOMNOLENCE	A	Active	200 MG	83/ 83	14/ 14	9.92	9.00	MILD/ Resolved (16AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Tremor*/ HANDS TREMOR	A	Active	200 MG	84/ 84	15/ 15	33.92	4.00	MILD/ Resolved (17AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ DIFFICULTY TO SLEEP	A	Active	200 MG	82/ 83	13/ 14	1.92	7.00	MILD/ Resolved (16AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SEVERITY/ Outcome	ACTION/ Causality	SAE
				Study Start		Period		Duration (Hrs)	Dose (Hrs)			
				Day+/ Study Day+	Day+/ Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Oropharyngeal pain*/ THROAT PAIN	A	Active	50 MG	71/ 73	2/ 4	0.42	50.00	MILD/ Resolved (06AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO	
[REDACTED]												
GASTROINTESTINAL DISORDERS	Abdominal pain lower*/ PAIN LOWER ABDOMEN	A	Active	200 MG	87/ 89	17/ 19	72.83	45.50	MILD/ Resolved (05AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	B	Active	0	37/ 43	2/ 8	22.25	146.00	MILD/ Resolved (20JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Fatigue*/ FATIGUE	A	Active	50 MG	73/ 90	3/ 20	5.33	401.00	MILD/ Resolved (06AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Feeling drunk/ FEELING DRUNK	C	Active	0	0/ 15	0/ 15	-23.17	356.50	MILD/ Resolved (23MAY2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Study Stop		Adverse Event Period		SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Study Day+	Day++/ Stop Day++	Time Post Dose (Hrs)	Duration (Hrs)					
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASMS	A	Active	200 MG	82/ 95	12/ 25	1.08	309.25	MILD/ Resolved (11AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
NERVOUS SYSTEM DISORDERS	Dizziness*/ INTERMITTENT DIZZINESS	A	Active	50 MG	72/ 78	2/ 8	0.33	141.00	MILD/ Resolved (25JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Headache*/ HEADACHE	A	Active	100 MG	75/ 76	5/ 6	10.83	19.50	MODERATE/ Resolved (23JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO		
	Headache*/ HEADACHE	A	Active	200 MG	81/ 81	11/ 11	8.33	4.00	MODERATE/ Resolved (28JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO		
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	50 MG	72/ 90	2/ 20	0.33	418.00	MILD/ Resolved (06AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Libido decreased*/ DECREASED LIBIDO	A	Active	50 MG	72/ 92	2/ 22	22.33	492.00	MILD/ Resolved (08AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE	
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Stop Day+	Start Day++/ Stop Day++					Time Post Dose (Hrs)
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL CRAMPS	B	Active	0	53/ 54	14/ 15	6.33	31.00	MODERATE/ Resolved (18JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Nausea*/ NAUSEA	A	Active	200 MG	14/ 15	14/ 15	1.42	20.33	MILD/ Resolved (09JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	C	Active	0	78/ 86	9/ 17	9.83	194.00	MILD/ Resolved (19AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Fatigue*/ INTERMITTENT FATIGUE	A	Active	100 MG	4/ 41	4/ 40	0.75	862.67	MILD/ Resolved (05JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Fatigue/ INTERMITTENT FATIGUE	B	Active			1/ 2		24.83	MILD/ Resolved (05JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

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+ Day relative to start of study treatment. First day of study treatment = day 1

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Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/	Start	Time	Post				
					Study Day+	Day++/ Stop Day++	Post Dose (Hrs)	Dose				
METABOLISM AND NUTRITION DISORDERS	Decreased appetite*/ INTERMITTENT LOSS OF APPETITE	C	Active	0	76/ 91	7/ 22	10.33	360.50	MILD/ Resolved (24AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Trismus*/ JAW SPASMS	A	Active	100 MG	5/ 15	5/ 15	6.75	231.00	MILD/ Resolved (09JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	C	Active	0	71/ 73	2/ 4	0.33	49.50	MILD/ Resolved (06AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Insomnia*/ DIFFICULTY TO SLEEP	C	Active	0	72/ 74	3/ 5	4.83	56.00	MILD/ Resolved (07AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia*/ DIFFICULTY TO SLEEP	C	Active	0	75/ 92	6/ 23	1.83	393.00	MILD/ Resolved (25AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia*/ INTERMITTENT INSOMNIA	A	Active	50 MG	2/ 41	2/ 40	8.75	902.67	MILD/ Resolved (05JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event					SEVERITY/ Outcome	ACTION/ Causality	SAE		
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period				Duration (Hrs)	
								Start Day++/ Stop Day++					Time Post Dose (Hrs)
PSYCHIATRIC DISORDERS	Insomnia/ INTERMITTENT INSOMNIA	B	Active			1/ 2		24.83	MILD/ Resolved (05JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
[REDACTED]													
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Trismus*/ JAW SPASMS	A	Active	200 MG	8/ 8	8/ 8	4.67	0.50	MILD/ Resolved (02JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
PSYCHIATRIC DISORDERS	Insomnia*/ DIFFICULTY TO SLEEP	B	Active	0	72/ 74	3/ 5	3.75	57.00	MILD/ Resolved (07AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Night sweats*/ NIGHT SWEATING	A	Active	200 MG	11/ 15	11/ 15	3.67	102.00	MILD/ Resolved (09JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
10011043 (M/ 33(YEARS)/ WHITE/ 60.65(kg))													
GASTROINTESTINAL DISORDERS	Gingival pain*/ GUM PAIN	A	Active	200 MG	39/ 46	9/ 16	10	159.50	MILD/ Resolved (04AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
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 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Phase	Dose**	Study Start Day+/ Study Stop Day+	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
						Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Vessel puncture site haem atoma*/ VENIPUNCTURE SITE HEMATOMA	C	Active	0	16/ 34	16/ 31	48	360.00	MILD/ Resolved (23JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-venipuncture	NO
	Vessel puncture site haem atoma*/ VENIPUNCTURE SITE HEMATOMA	A	Active			1/ 4		72.00	MILD/ Resolved (23JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-venipuncture	NO
METABOLISM AND NUTRITION DISORDERS	Decreased appetite*/ LOSS OF APPETITE	B	Active	0	61/ 76	4/ 19	11	365.00	MILD/ Resolved (03SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	50 MG	31/ 47	1/ 17	15	368.00	MILD/ Resolved (05AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Insomnia*/ INSOMNIA	B	Active	0	59/ 72	2/ 15	18.28	319.72	MILD/ Resolved (30AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
RENAL AND URINARY DISORDERS	Dysuria*/ DIFFICULTY URINATING	A	Active	200 MG	44/ 47	14/ 17	0	71.00	MILD/ Resolved (05AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE				
				Trt	Phase	Dose**	Study		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	
							Day+/ Study Day+	Stop Day+	Start Day++/ Stop Day++					Time Post Dose (Hrs)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Cough*/ COUGH	A	Active	200 MG	54/ 72	24/ 28	252	84.00	MILD/ Resolved (30AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO			
	Cough/ COUGH	B	Active			1/ 15		338.00	MILD/ Resolved (30AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO			
	Oropharyngeal pain*/ SORE THROAT	C	Active	0	10/ 15	10/ 15	11	120.00	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-air conditioning	NO			
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ EXCESSIVE PERSPIRATION	A	Active	200 MG	44/ 47	14/ 17	6	77.00	MILD/ Resolved (05AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
[REDACTED]														
EYE DISORDERS	Ocular hyperaemia*/ RED EYES	B	Active	0	1/ 10	1/ 10	3.92	211.00	MODERATE/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other-lens	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE			
				Trt	Phase	Dose**	Study Start		Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
GASTROINTESTINAL DISORDERS	Diarrhoea*/ LOOSE STOOLS	A	Active	200 MG	45/ 68	15/ 38	22.92	553.00	MILD/ Resolved (26AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Dry mouth*/ DRY MOUTH	A	Active	200 MG	41/ 49	11/ 19	2.92	188.00	MILD/ Resolved (07AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Vessel puncture site eryt hema*/ ERYTHEMA AT VENIPUNCTURE SITE	A	Active	200 MG	39/ 49	9/ 19	11.42	239.50	MILD/ Resolved (07AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-venipuncture	NO			
INVESTIGATIONS	Weight decreased*/ WEIGHT LOSS	A	Active	200 MG	53/ 79	23/ 49	214.92	624.00	MILD/ Resolved (06SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Back pain*/ BACK PAIN	A	Active	200 MG	41/ 44	11/ 14	11.92	75.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Pain in jaw*/ CHIN PAIN	A	Active	200 MG	37/ 49	7/ 19	11.92	287.00	MILD/ Resolved (07AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

[] Values in brackets are imputed from incomplete dates and times.

SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/	Start	Time	Post				
					Study Day+	Day++/ Stop Day++	Dose (Hrs)	Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Muscle contractions involuntary*/ INVOLUNTARY MUSCLE CONTRACTIONS	A	Active	100 MG	36/ 49	6/ 19	11.92	311.00	MILD/ Resolved (07AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Abnormal behaviour*/ CHANGE IN BEHAVIOR	A	Active	200 MG	40/ 62	10/ 32	0.92	528.00	MODERATE/ Resolved (20AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia*/ INSOMNIA	B	Active	400 MG	31/ 50	31/ 31	400.42	7.58	MODERATE/ Resolved (08AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia/ INSOMNIA	A	Active			1/ 20		454.92	MODERATE/ Resolved (08AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Psychiatric decompensation*/ PSYCHOTIC DECOMPENSATION	A	Active	200 MG	45/ 47	15/ 17	22.92	48.00	SEVERE/ Resolved (05AUG2016)	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study Drug	YES	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Dyspnoea*/ DIFFICULTIES TO BREATHE	A	Active	100 MG	36/ 44	6/ 14	0.92	194.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Trt Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day+/ Stop Day++	Time Post Dose (Hrs)				
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Pruritus*/ PRURITUS FOREARM	A	Active	50 MG	33/ 35	3/ 5	11.92	48.00	MILD/ Resolved (24JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	50 MG	3/ 7	3/ 7	3.83	91.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ DIFFICULTY TO SLEEP	A	Active	100 MG	3/ 7	3/ 7	2.83	80.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ INTERMITTENT SWEATING	A	Active	50 MG	3/ 16	3/ 16	10	314.50	MILD/ Resolved (05JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
EYE DISORDERS	Photophobia*/ EYE LIGHT SENSITIVITY	A	Active	200 MG	68/ 74	11/ 17	11.42	143.50	MILD/ Resolved (01SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE				
				Trt	Phase	Dose**	Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	
							Day+/ Study Day+	Stop Day+	Start Day++/ Stop Day++					Time Post Dose (Hrs)
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL CRAMPS	B	Active	0	3/ 3	3/ 3	11.75	8.25	MILD/ Resolved (22JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Diarrhoea*/ WATERY STOOLS	B	Active	0	3/ 3	3/ 3	11.75	8.25	MILD/ Resolved (22JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	C	Active	0	35/ 47	5/ 17	11.75	287.00	MILD/ Resolved (05AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASMS	A	Active	200 MG	65/ 73	8/ 16	10.92	201.00	MILD/ Resolved (31AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Pain in jaw*/ INTERMITTENT JAW DISCOMFORT	A	Active	100 MG	61/ 77	4/ 20	10.92	385.00	MILD/ Resolved (04SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	C	Active	0	31/ 32	1/ 2	4.75	20.00	MILD/ Resolved (21JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE			
				Trt	Phase	Dose**	Study Start		Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Stop Day+	Day+/ Stop Day++	Time Post Dose (Hrs)					
NERVOUS SYSTEM DISORDERS	Somnolence*/ SLEEPINESS	C	Active	0	31/ 34	1/ 4	4.75	68.00	MILD/ Resolved (23JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Tremor*/ HANDS TREMOR	A	Active	200 MG	64/ 77	7/ 20	10.92	313.00	MILD/ Resolved (04SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
PSYCHIATRIC DISORDERS	Insomnia*/ DIFFICULTY TO SLEEP	A	Active	100 MG	60/ 73	3/ 16	2.92	296.00	MILD/ Resolved (31AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	Ejaculation failure*/ NO EJACULATION	A	Active	100 MG	62/ 78	5/ 21	8.92	375.00	MILD/ Resolved (05SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Throat irritation*/ IRRITATED THROAT	C	Active	0	42/ 44	12/ 14	10.75	52.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
						Start Day++/ Stop Day++	Time Post Dose (Hrs)				
CARDIAC DISORDERS	Palpitations*/ INTERMITTENT PALPITATION	A	Active	100 MG	6/ 15	6/ 15	6.67	208.00	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
EYE DISORDERS	Ocular discomfort*/ EYE DISCOMFORT	A	Active	100 MG	4/ 6	4/ 6	5.67	41.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Ocular discomfort*/ EYE DISCOMFORT	A	Active	200 MG	8/ 11	8/ 11	7	65.67	MODERATE/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	A	Active	100 MG	4/ 6	4/ 6	5.67	41.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Fatigue*/ FATIGUE	C	Active	0	67/ 68	10/ 11	10.83	27.00	MILD/ Resolved (26AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
INFESTATIONS AND INFESTATIONS	Nasopharyngitis*/ COMMON COLD	B	Active	0	35/ 44	5/ 14	10.67	220.50	MILD/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Other-viral infection	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE	
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ INTERMITTENT MUSCULAR CRAMPS	C	Active	0	65/ 68	8/ 11	0.83	73.00	MILD/ Resolved (26AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Muscle spasms*/ MUSCULAR SPASM	A	Active	100 MG	4/ 19	4/ 19	5.67	354.00	MILD/ Resolved (08JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Pain in jaw*/ INTERMITTENT JAW DISCOMFORT	C	Active	0	65/ 68	8/ 11	11.83	74.00	MILD/ Resolved (26AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	A	Active	100 MG	4/ 6	4/ 6	5.67	41.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Headache*/ HEADACHE INTERMITTENT	A	Active	100 MG	4/ 15	4/ 15	11.67	251.00	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	100 MG	4/ 6	4/ 6	5.67	41.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Trt Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Study Stop Day+	Start Day+ / Stop Day++	Time Post Dose (Hrs)				
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	A	Active	100 MG	4/ 15	4/ 15	1.67	246.00	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	Gynaecomastia*/ GYNECOMASTIA	C	Active	0	62/ 66	5/ 9	7.83	87.00	MILD/ Resolved (24AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO
	Testicular pain*/ BILATERAL TESTICULAR PAIN	C	Active	0	61/ 65	4/ 8	10.83	86.00	MILD/ Resolved (23AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Eczema*/ IRRITATIVE ECZEMA	A	Active	200 MG	14/ 32	14/ 31	2.67	406.08	MODERATE/ Resolved (21JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN) / Study Drug	NO
	Eczema/ IRRITATIVE ECZEMA	B	Active			1/ 2		22.92	MODERATE/ Resolved (21JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN) / Study Drug	NO
	Eczema/ IRRITATIVE ECZEMA	B	Active	0	40/ 58	10/ 28	10.67	420.00	MILD/ Resolved (16AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION) / Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE	
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Erythema*/ RED SPOT BELLY	A	Active	200 MG	14/ 24	14/ 24	11.67	240.00	MILD/ Resolved (13JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Hyperhidrosis*/ SWEATING	A	Active	100 MG	4/ 6	4/ 6	10.67	48.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
EYE DISORDERS	Dry eye*/ DRY EYES	C	Active	0	7/ 12	7/ 12	10.58	120.00	MILD/ Resolved (01JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	C	Active	0	3/ 12	3/ 12	3.58	211.00	MILD/ Resolved (01JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Limb discomfort*/ HEAVY LEGS	C	Active	0	3/ 7	3/ 7	3.58	91.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Synovial cyst*/ INGUINAL GANGLION	C	Active	0	16/ 23	16/ 23	47.58	168.00	MILD/ Resolved (12JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-infection	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	C	Active	0	30/ 31	30/ 31	398.58	9.42	MODERATE/ Resolved (20JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Headache/ HEADACHE	B	Active			1/ 1		4.58	MODERATE/ Resolved (20JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Somnolence*/ INTERMITTENT SLEEPINESS	C	Active	0	2/ 14	2/ 14	6.58	281.00	MILD/ Resolved (03JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Somnolence*/ SLEEPINESS	B	Active	0	33/ 45	3/ 15	5.58	281.00	MILD/ Resolved (03AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Oropharyngeal pain*/ SORE THROAT	B	Active	0	31/ 33	1/ 3	4.58	55.00	MILD/ Resolved (22JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-air conditioning	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
EYE DISORDERS	Vision blurred*/ INTERMITTENT BLURRED VISION	A	Active	200 MG	8/ 15	8/ 15	0.33	166.17	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Visual impairment*/ VISION TROUBLE	A	Active	100 MG	5/ 5	5/ 5	6.5	4.00	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL CRAMPS	A	Active	50 MG	3/ 6	3/ 6	3.5	67.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Change of bowel habit*/ DECREASED BOWEL MOVEMENT	A	Active	50 MG	2/ 12	2/ 12	3.5	235.00	MILD/ Resolved (01JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Diarrhoea*/ LOOSE STOOL	A	Active	50 MG	1/ 3	1/ 3	3.25	52.58	MILD/ Resolved (22JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event					SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)			
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Dysphagia*/ DIFFICULTY TO SWALLOW	A	Active	50 MG	2/ 2	2/ 2	2.5	1.00	MILD/ Resolved (21JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Haematochezia*/ BLOOD FECES	A	Active	200 MG	11/ 19	11/ 19	0	183.50	MILD/ Resolved (08JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-decreased bowel movement	NO
	Nausea*/ NAUSEA	A	Active	100 MG	5/ 5	5/ 5	6.5	4.00	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Nausea*/ NAUSEA	C	Active	0	59/ 59	2/ 2	5.17	0.17	MILD/ Resolved (17AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Fatigue*/ FATIGUE	B	Active	0	32/ 33	2/ 3	22.5	24.00	MILD/ Resolved (22JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Fatigue*/ FATIGUE	B	Active	0	35/ 45	5/ 15	10.5	240.00	MILD/ Resolved (03AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
 [] Values in brackets are imputed from incomplete dates and times.
 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event					SEVERITY/ Outcome	ACTION/ Causality	SAE		
				Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period				Duration (Hrs)	
								Start Day++/ Stop Day++					Time Post Dose (Hrs)
NERVOUS SYSTEM DISORDERS	Dizziness*/ INTERMITTENT DIZZINESS	A	Active	50 MG	2/ 7	2/ 7	2.5	116.00	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Dizziness*/ INTERMITTENT DIZZINESS	A	Active	200 MG	9/ 11	9/ 11	1.5	58.00	MILD/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Head discomfort*/ HEAVY HEAD	A	Active	100 MG	5/ 6	5/ 6	10.5	24.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Headache*/ INTERMITTENT HEADACHE	A	Active	100 MG	4/ 7	4/ 7	1.37	57.13	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Headache*/ INTERMITTENT HEADACHE	C	Active	0	59/ 62	2/ 5	0.67	70.00	MILD/ Resolved (20AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ SWEATING	A	Active	200 MG	7/ 8	7/ 8	6.5	31.00	MILD/ Resolved (27JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash macular*/ MACULAR ERUPTION	C	Active	0	60/ 78	3/ 21	11.67	431.00	MILD/ Resolved (05SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
VASCULAR DISORDERS	Hot flush*/ HOT FLUSHES	A	Active	200 MG	8/ 11	8/ 11	0.5	76.25	MILD/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
GASTROINTESTINAL DISORDERS	Change of bowel habit*/ DECREASED BOWEL MOVEMENT	B	Active	0	1/ 11	1/ 11	5.92	238.75	MILD/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	B	Active	0	6/ 10	6/ 10	10.42	96.00	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
[REDACTED]											
CARDIAC DISORDERS	Atrioventricular block first degree*/ INTERMITTENT FIRST DEGREE AV BLOCK	C	Active	0	71/ 73	14/ 16	0.75	46.97	MILD/ Resolved (31AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening
 * Treatment-emergent
 ** Dose at onset of adverse event.
 + Day relative to start of study treatment. First day of study treatment = day 1
 ++ Day relative to first day of each treatment period. First day of each treatment period = day 1
 [] Values in brackets are imputed from incomplete dates and times.
 SAE = Serious Adverse Event (according to Investigators assessment).
 Treatment (Trt) column gives study treatment at time of adverse event.
 MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event					SAE	
		Trt	Phase	Dose**	Study Start Day+/ Stop Day+	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
						Start Day++/ Stop Day++	Time Post Dose (Hrs)				
EYE DISORDERS	Ocular discomfort*/ RIGHT EYE DISCOMFORT	B	Active	0	8/ 10	8/ 10	6.92	39.42	MODERATE/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Cough*/ COUGH	A	Active	50 MG	31/ 58	1/ 28	6.33	640.00	MILD/ Resolved (16AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-viral infection	NO
	Cough*/ INTERMITTENT COUGH	C	Active	0	69/ 78	12/ 21	1.58	218.00	MILD/ Resolved (05SEP2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-air conditioning	NO
[REDACTED]											
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ STOMACH DISCOMFORT	A	Active	50 MG	32/ 33	2/ 3	21.92	37.33	MILD/ Resolved (22JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Chapped lips*/ CHAPPED LIPS	C	Active	0	1/ 13	1/ 13	1.25	287.00	MILD/ Resolved (02JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

[] Values in brackets are imputed from incomplete dates and times.

SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE	
		Trt	Phase	Dose**	Study Start	Period		Duration (Hrs)	SEVERITY/ Outcome		ACTION/ Causality
					Day+/ Study Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)				
GASTROINTESTINAL DISORDERS	Diarrhoea*/ LOOSE STOOLS	A	Active	50 MG	32/ 40	2/ 10	3.25	191.00	MILD/ Resolved (29JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Nausea*/ INTERMITTENT NAUSEA	C	Active	0	5/ 10	5/ 10	0.92	118.33	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Nausea*/ INTERMITTENT NAUSEA	A	Active	50 MG	32/ 43	2/ 13	21.92	265.33	MILD/ Resolved (01AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Toothache*/ DENTAL PAIN	A	Active	200 MG	38/ 44	8/ 14	8.25	138.50	MODERATE/ Resolved (02AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Asthenia*/ FEELING WEAK	A	Active	50 MG	32/ 36	2/ 6	3.25	91.00	MILD/ Resolved (25JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Chest discomfort*/ THORACIC OPPRESSION	C	Active	0	5/ 10	5/ 10	0.58	117.67	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event							SAE			
				Trt	Phase	Dose**	Study Start		Period			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++	Time Post Dose (Hrs)				
METABOLISM AND NUTRITION DISORDERS	Decreased appetite*/ LACK OF APPETITE	A	Active	50 MG	32/ 47	2/ 17	23.25	359.00	MILD/ Resolved (05AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Back pain*/ PAIN LOWER BACK	C	Active	0	29/ 31	29/ 31	367.75	40.25	MILD/ Resolved (20JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Back pain/ PAIN LOWER BACK	A	Active			1/ 1		4.25	MILD/ Resolved (20JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-awkward movement	NO			
	Muscular weakness*/ HAND WEAKNESS	C	Active	0	5/ 6	5/ 6	0.5	21.75	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Torticollis*/ TORTICOLLIS	C	Active	0	10/ 11	10/ 11	10.25	30.25	MILD/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	B	Active	0	61/ 62	4/ 5	6.5	16.00	MILD/ Resolved (20AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Adverse Event			Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Study Start	Period					
					Day+/ Study Day+	Start Day+/ Stop Day++	Time Post Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Headache*/ INTERMITTENT HEADACHE	C	Active	0	1/ 8	1/ 8	1.75	167.50	MODERATE/ Resolved (27JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO
	Paraesthesia*/ LEFT HAND TINGLING	C	Active	0	9/ 10	9/ 10	1.33	20.92	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
PSYCHIATRIC DISORDERS	Insomnia*/ INSOMNIA	C	Active	0	31/ 58	31/ 31	400.25	7.75	MILD/ Resolved (16AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
	Insomnia/ INSOMNIA	A	Active			1/ 28		646.25	MILD/ Resolved (16AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	Vaginal haemorrhage*/ INTERMITTENT SPOTTING	C	Active	0	12/ 14	12/ 14	10.25	63.00	MILD/ Resolved (03JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Acne*/ ACNE SPOTS	C	Active	0	13/ 17	13/ 17	8.25	86.00	MILD/ Resolved (06JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Study Stop		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Study Day+	Day++/ Stop Day++	Time Post Dose (Hrs)	Start	Time					
										Day+				
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Erythema*/ ERYTHEMA RIGHT THUMB	B	Active	0	71/ 72	14/ 15		11.5	24.00	MILD/ Resolved (30AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Hyperhidrosis*/ SWEATING	C	Active	0	3/ 11	3/ 11		10.25	198.25	MILD/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
	Seborrhoea*/ OILY SKIN	C	Active	0	3/ 16	3/ 16		10.25	317.00	MILD/ Resolved (05JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
VASCULAR DISORDERS	Hot flush*/ INTERMITTENT HOT FLUSHES	C	Active	0	7/ 10	7/ 10		11.25	74.00	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		
[REDACTED]														
GASTROINTESTINAL DISORDERS	Change of bowel habit*/ DECREASED BOWEL MOVEMENT	A	Active	50 MG	2/ 5	2/ 5		3.17	67.00	MILD/ Resolved (24JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO		

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE				
				Trt	Phase	Dose**	Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	
							Day+/ Study Day+	Day+/ Stop Day+	Start Day++					Time Post Dose (Hrs)
GASTROINTESTINAL DISORDERS	Diarrhoea*/ LOOSE STOOLS	A	Active	50 MG	1/ 1	1/ 1	3.17	8.00	MILD/ Resolved (20JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Paraesthesia oral*/ MOUTH PARESTHESIA	A	Active	200 MG	7/ 11	7/ 11	3.17	106.00	MILD/ Resolved (30JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Feeling drunk*/ FEELING DRUNK	A	Active	100 MG	4/ 4	4/ 4	4.67	2.50	MILD/ Resolved (23JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
INFECTIONS AND INFESTATIONS	Asymptomatic bacteriuria* / ASYMPTOMATIC BACTERIURIA	B	Active	0	64/ 72	7/ 15	10.42	192.00	MILD/ Resolved (30AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other-bacterial infection	NO			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscle spasms*/ MUSCULAR SPASMS	A	Active	200 MG	12/ 17	12/ 17	10.17	120.00	MILD/ Resolved (06JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Muscular weakness*/ MUSCULAR WEAKNESS	A	Active	100 MG	4/ 8	4/ 8	5.17	92.00	MILD/ Resolved (27JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/	Start	Time	Post				
					Study Day+	Day++/	Stop Day++	Dose (Hrs)				
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	A	Active	200 MG	8/ 8	8/ 8	3.17	2.00	MILD/ Resolved (27JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Insomnia*/ DIFFICULTY TO SLEEP	B	Active	0	60/ 62	3/ 5	8.42	50.00	MILD/ Resolved (20AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia*/ INSOMNIA	A	Active	100 MG	6/ 13	6/ 13	10.17	169.00	MILD/ Resolved (02JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Nervousness*/ FEELING NERVOUS	A	Active	200 MG	11/ 15	11/ 15	3.17	97.00	MILD/ Resolved (04JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Restlessness*/ RESTLESS LIMBS	A	Active	200 MG	9/ 10	9/ 10	5.17	29.00	MILD/ Resolved (29JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Hyperhidrosis*/ INTERMITTENT SWEATING	A	Active	200 MG	14/ 31	14/ 31	14.17	392.00	MILD/ Resolved (20JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Table 16.2.7.1
 SERTRALINE Protocol A0501104
 Adverse Events

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment		Adverse Event						SAE				
				Trt	Phase	Dose**	Study Start				Period		SEVERITY/ Outcome	ACTION/ Causality
							Study Day+	Day+/ Stop Day+	Time Post Dose (Hrs)		Duration (Hrs)	SEVERITY/ Outcome		
VASCULAR DISORDERS	Hot flush*/ HOT FLUSH	A	Active	200 MG	7/ 7	7/ 7	8.17	0.50	MILD/ Resolved (26JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
[REDACTED]														
GASTROINTESTINAL DISORDERS	Nausea*/ INTERMITTENT NAUSEA	A	Active	50 MG	60/ 66	3/ 9	3.33	139.00	MILD/ Resolved (24AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
METABOLISM AND NUTRITION DISORDERS	Decreased appetite*/ LOSS OF APPETITE	A	Active	50 MG	60/ 65	3/ 8	11.83	110.00	MILD/ Resolved (23AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Neck pain*/ NECK PAIN	B	Active	0	33/ 37	3/ 7	11.08	83.00	MILD/ Resolved (26JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			
	Pain in extremity*/ PAIN RIGHT LEG	C	Active	0	2/ 6	2/ 6	2.05	92.00	MILD/ Resolved (25JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO			

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

[] Values in brackets are imputed from incomplete dates and times.

SAE = Serious Adverse Event (according to Investigators assessment).

Treatment (Trt) column gives study treatment at time of adverse event.

MedDRA (v19.0) coding dictionary applied.

[REDACTED] Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 17SEP2016 (21:58)

Treatment Group: A=Sertraline, B=Moxifloxacin, C=Placebo

System Organ Class	MedDRA (v19.0) Preferred Term/ INVESTIGATOR ENTRY	Treatment			Study Start		Period		Duration (Hrs)	SEVERITY/ Outcome	ACTION/ Causality	SAE
		Trt	Phase	Dose**	Day+/ Stop Day+	Start Day++/ Stop Day++	Time Post Dose (Hrs)					
NERVOUS SYSTEM DISORDERS	Dizziness*/ INTERMITTENT DIZZINESS	A	Active	200 MG	65/ 71	8/ 14	0.33	144.00	MILD/ Resolved (29AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Headache*/ HEADACHE	B	Active	0	31/ 37	1/ 7	11.08	131.00	MODERATE/ Resolved (26JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (TREATMENT GIVEN)/ Study Drug	NO	
	Headache*/ HEADACHE	A	Active	50 MG	58/ 63	1/ 6	6.33	112.00	MILD/ Resolved (21AUG2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
PSYCHIATRIC DISORDERS	Emotional disorder*/ CHANGES IN EMOTIONAL STATUS	B	Active	0	34/ 37	4/ 7	11.08	71.00	MILD/ Resolved (26JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia*/ INTERMITTENT INSOMNIA	C	Active	0	4/ 8	4/ 8	5.08	104.00	MILD/ Resolved (27JUN2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	
	Insomnia*/ LACK OF SLEEP	B	Active	0	33/ 37	3/ 7	2.08	80.00	MILD/ Resolved (26JUL2016)	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study Drug	NO	

Age and weight are at Screening

* Treatment-emergent

** Dose at onset of adverse event.

+ Day relative to start of study treatment. First day of study treatment = day 1

++ Day relative to first day of each treatment period. First day of each treatment period = day 1

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SAE = Serious Adverse Event (according to Investigators assessment).

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MedDRA (v19.0) coding dictionary applied.

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