Concentration vs Time

Data Tables

Concentration vs Time Data Tables

Table P1: Omeprazole Concentration-Time Data after the Administration of PRILOSEC OTC Tablets

Treatment	Subject	Period	Sequence	Time (hr) 0.00	0.25	0.50	1.00	1.33	1.67	2.00	2.33	2.67	3.00	3.33	3.67	4.00	4.50	5.00	5.50	6.00	7.00	8.00	9.00	10.00	11.00	12.00	14.00	16.00
A	1	2	BA	a	a	2.84	152	815	773	495	460	319	259	204	157	124	82.8	48.9	31.7	22.4	9.27	5.49	2.83	1.44	a	a	a	a
	2	1	AB	a	a	3.04	250	598	480	314	220	142	109	69.8	48.6	35.4	23.1	13.6	9.09	5.84	3.38	1.81	a	a	a	a	a	a
	3	2	BA	a	a	a	a	a	1.06	18.9	25.5	84.8	242	363	231	114	52.3	40.3	17.1	9.08	4.35	2.17	1.07	a	a	a	a	a
	4	1	AB	a	a	3.93	262	235	127	74.2	43.5	27.6	16.3	11.2	9.36	5.91	3.21	1.56	1.06	a	a	a	a	a	a	a	a	a
	5	1	AB	a	a	a	a	14.4	41.0	259	344	258	218	176	123	83.9	46.0	27.0	14.4	9.03	3.38	1.69	a	a	a	a	a	a
	7	1	AB	a	a	1.33	6.75	8.31	11.5	14.9	15.9	141	1120	1660	1420	1330	1050	780	594	505	331	226	144	97.0	64.4	42.5	21.1	11.6
	8	1	AB	a	a	a	138	271	104	52.9	37.3	21.5	12.5	7.77	5.64	3.75	2.90	1.29	1.08	a	a	a	a	a	a	a	a	a
	9	1	AB	a	a	a	a	a	a	1.25	1.63	1.62	1.61	1.48	1.80	4.84	390	594	374	230	120	67.2	36.1	21.2	11.7	6.07	1.94	a
	10	1	AB	a	a	a	16.2	30.9	53.6	98.3	68.8	112	142	76.6	50.6	30.1	12.6	6.62	3.97	2.40	1.27	a	a	a	a	a	a	a
	11	1	AB	a	a	38.1	60.4	35.5	159	162	91.3	46.7	26.5	17.9	10.9	7.10	3.36	1.56	a	a	a	a	a	a	a	a	a	a
	12	2	BA	a	a	a	a	a	30.2	356	294	159	94.9	109	70.2	44.9	26.6	11.7	6.75	4.22	1.82	a	a	a	a	a	a	a
	13	2	BA	a	a	1.58	167	427	421	258	164	107	76.8	50.7	34.2	25.9	13.7	7.11	4.71	2.78	1.25	a	a	a	a	a	a	a
	14	2	BA	a	a	a	11.9	28.4	174	172	161	385	901	798	516	384	256	164	102	68.4	31.8	16.6	8.06	4.21	2.42	1.18	a	a
	15	1	AB	a	a	a	19.1	35.1	20.1	13.1	9.77	66.1	256	302	251	176	99.8	44.6	24.4	15.6	5.67	2.18	1.00	a	a	a	a	a
	16	1	AB	a	a	1.83	344	293	196	126	84.6	52.0	31.4	24.9	16.8	11.8	7.42	3.74	2.14	1.44	a	a	a	a	a	a	a	a
	18	2	BA	a	1.21	18.2	575	1130	977	813	747	654	491	481	462	401	330	241	200	165	118	79.6	55.4	42.0	24.5	19.2	9.86	7.82
	19	1	AB	a	a	a	a	a	a	a	a	a	a	a	a	a	17.4	66.5	85.1	144	61.7	23.9	36.0	40.1	24.0	8.06	1.66	a
	20	2	BA	a	a	a	a	a	a	a	39.4	138	141	392	284	161	80.4	36.5	16.3	9.82	3.12	1.11	a	a	a	a	a	a
	21	2	BA	a	a	a	a	1.22	9.07	32.2	268	359	262	148	88.6	50.5	23.1	11.4	7.40	4.52	2.18	a	a	a	a	a	a	a
	22	2	BA	a	a	a	8.61	9.42	6.47	9.47	7.45	4.34	14.5	80.7	84.1	90.5	481	344	163	88.1	32.0	14.6	5.31	2.49	1.22	a	a	a
	23	2	BA	a	a	a	a	a	7.61	99.2	400	351	203	133	85.7	60.6	32.7	17.7	8.88	5.97	2.26	1.06	a	a	a	a	a	a
	24	2	BA	a	a	a	a	a	a	a	a	a	2.37	4.64	31.1	150	169	108	38.9	18.8	5.34	1.73	a	a	a	a	a	a
	25	2	BA	a	a	a	98.3	128	86.1	77.9	85.2	95.4	71.2	42.4	34.1	87.1	128	49.4	22.7	11.7	4.26	1.57	a	a	a	a	a	a
	26	1	AB	a	a	a	209	667	807	1030	937	822	793	680	555	519	422	356	299	259	174	134	98.3	75.0	51.5	11.5	20.3	37.4
	27	2	BA	a	a	a	81.3	235	139	72.3	41.2	23.6	17.8	9.98	6.99	5.57	2.75	1.35	a	a	a	a	a	a	a	a	a	a
	28	1	AB	a	a	a	a	9.55	184	454	386	302	221	188	110	98.5	59.2	35.3	23.7	14.4	8.19	3.61	1.82	a	a	a	a	a
	29	1	AB	a	a	a	70.4	508	581	391	312	250	170	136	101	78.4	66.6	45.8	24.8	22.0	9.54	5.42	2.95	1.89	a	a	a	a
	30	2	BA	a	a	a	1.43	60.3	132	258	308	196	111	55.3	39.9	25.4	13.2	6.55	3.21	2.18	a	a	a	a	a	a	a	a
	31	1	AB	a	a	a	1.86	7.70	84.1	289	450	431	333	247	182	132	72.0	42.5	31.2	21.2	10.0	5.27	2.21	a	a	a	a	a
	32	2	BA	a	a	a	99.1	400	666	489	322	251	175	133	107	78.2	45.7	28.7	23.3	12.1	6.59	3.69	1.55	a	a	a	a	a
	33	1	AB	a	a	a	a	a	a	a	49.3	88.1	282	270	178	71.6	28.0	15.1	6.21	4.31	1.24	a	a	a	a	a	a	a
	34	2	BA	a	a	a	5.04	7.70	4.90	26.8	159	292	162	153	241	204	85.5	45.5	24.1	13.8	5.07	1.93	a	a	a	a	a	a
	35	1	AB	a	a	a	a	1.47	71.6	170	308	261	159	103	68.4	46.7	29.1	15.7	8.19	4.71	2.08	a	a	a	a	a	a	a
	36	1	AB	a	a	a	6.74	20.5	19.8	24.3	89.4	91.5	84.0	90.5	96.5	89.0	60.5	32.4	16.8	9.45	2.97	1.54	a	a	a	a	a	a
	37	2	BA	a	a	a	35.0	52.1	125	333	748	478	347	235	162	137	78.0	45.4	28.9	17.3	8.12	3.50	1.67	a	a	a	a	a
	38	1	AB	a	a	32.3	311	214	107	64.1	43.0	27.4	18.8	13.7	9.31	6.22	3.64	1.89	a	a	a	a	a	a	a	a	a	a
	39	2	BA	a	a	a	40.6	89.3	194	279	220	189	101	71.8	59.8	31.6	21.0	10.2	7.26	4.30	1.61	a	a	a	a	a	a	a
	40	1	AB	a	a	a	a	15.7	146	196	197	165	84.5	55.6	39.0	23.5	15.2	8.71	4.93	3.08	1.46	a	a	a	a	a	a	a
	41	1	AB	a	a	1.90	12.3	44.3	63.8	26.0	14.5	129	71.5	30.2	17.8	9.78	16.4	9.63	3.10	1.75	a	a	a	a	a	a	a	a
	42	1	AB	a	a	a	1.43	8.24	6.96	195	270	138	64.8	44.1	31.0	23.6	6.64	4.24	2.41	1.25	a	a	a	a	a	a	a	a
	43	1	AB	a	a	9.91	702	403	262	166	99.6	74.8	47.7	33.7	23.3	17.2	10.1	5.82	3.29	1.83	a	a	a	a	a	a	a	a
	44	2	BA	a	a	a	162	422	349	252	164	103	73.2	51.0	37.5	28.1	16.9	9.72	6.31	4.30	2.00	1.05	a	a	a	a	a	a
	45	2	BA	a	a	a	a	8.63	24.0	25.1	21.0	72.1	213	155	90.7	57.8	22.2	11.2	5.31	3.75	1.37	a	a	a	a	a	a	a
	47	2	BA	a	a	5.57	35.2	33.6	20.5	13.6	10.5	9.44	11.4	12.6	19.8	21.0	312	116	69.1	49.9	18.0	6.03	2.77	1.15	a	a	a	a
	48	2	BA	a	a	a	171	394	277	159	95.7	59.2	41.2	24.9	17.4	11.5	7.32	4.59	2.63	2.06	a	a	a	a	a	a	a	a
			n	0	1	12	31	37	40	41	43	43	44	44	44	44	45	45	42	40	34	25	16	10	7	6	5	3
			Mean	b	1.21	10.1	131	207	199	204	205	185	188	181	141	116	105	77.2	55.2	44.4	29.3	24.5	25.1	28.7	25.7	14.7	11.0	18.9
			SD	b	b	12.8	168	269	248	218	216	175	235	287	237	217	188	156.5	115.9	96.4	66.6	52.5	41.8	34.5	24.2	14.9	9.5	16.1
			Min	b	1.21	1.33	1.43	1.22	1.06	1.25	1.63	1.62	1.61	1.48	1.80	3.75	2.75	1.29	1.06	1.25	1.24	1.05	1.00	1.15	1.22	1.18	1.66	7.82
			Median	b	1.21	3.49	70.4	52.1	116	162	159	138	110	85.6	69.3	54.2	29.1	17.7	15.3	9.27	4.71	3.61	2.89	12.7	24.0	9.76	9.86	11.6
			Max	b	1.21	38.1	702	1130	977	1030	937	822	1120	1660	1420	1330	1050	780	594	505	331	226	144	97.0	64.4	42.5	21.1	37.4
			CV%	b	b	127	129	130	125	107	105	94.7	125	159	168	187	179	203	210	217	227	214	167	120	94.1	101	86.4	85.1

Concentrations reported to 3 significant figures; Full precision data used in all pharmacokinetic and statistical analyses

a: Concentration below limit of quantification (1.00 ng/mL)

b. Not calculable due to lack of sufficient data

Table P2: Omeprazole Concentration-Time Data after the Administration of PRILOSEC Capsules

				Time (hr)																									
Treatment	Subject	Period	Sequence	0.00	0.25	0.50	1.00	1.33	1.67	2.00	2.33	2.67	3.00	3.33	3.67	4.00	4.50	5.00	5.50	6.00	7.00	8.00	9.00	10.00	11.00	12.00	14.00	16.00
B	1	1	BA	a	a	a	3.46	208	404	448	430	426	371	280	219	195	116	78.6	53.8	40.0	19.1	10.8	6.73	4.81	1.93	1.33	a	a
	2	2	AB	a	a	a	1.26	7.92	90.6	226	148	186	493	374	252	171	88.2	53.2	30.1	18.0	6.47	3.67	1.92	1.14	a	a	a	a
	3	1	BA	a	a	1.10	10.3	7.96	5.79	6.77	c	71.5	84.7	142	313	273	176	79.2	35.0	19.3	5.75	2.05	1.27	a	a	a	a	a
	4	2	AB	a	a	11.6	72.2	78.8	55.7	85.3	97.2	114	77.8	47.5	32.8	23.2	10.9	4.98	2.93	2.06	1.08	a	a	a	a	a	a	a
	5	2	AB	a	a	a	19.2	124	188	176	218	151	155	137	109	84.9	57.3	39.3	25.0	17.0	6.69	2.86	2.07	a	a	a	a	a
	7	2	AB	a	1.49	3.29	28.5	208	310	441	485	657	1030	1230	1310	1270	1030	762	945	499	352	241	167	112	75.3	53.9	30.2	18.6
	8	2	AB	a	a	a	11.3	58.0	82.7	104	66.7	45.8	62.6	85.5	63.8	33.6	14.9	6.18	3.30	1.71	a	3.56	a	a	a	a	a	a
	9	2	AB	a	a	a	a	4.67	42.2	84.1	112	98.0	97.4	140	179	185	206	462	250	204	108	55.1	29.3	21.3	10.3	5.44	1.62	a
	10	2	AB	a	a	a	29.0	31.0	76.0	103	160	164	102	48.1	32.0	24.6	13.5	9.24	5.61	2.64	1.23	a	a	a	a	a	a	a
	11	2	AB	a	a	2.34	22.5	85.2	88.6	81.1	68.1	42.2	35.0	27.1	24.5	27.4	41.7	32.4	11.5	4.69	1.75	a	a	a	a	a	a	a
	12	1	BA	a	a	a	a	4.73	7.80	12.2	226	263	181	146	121	87.2	68.7	44.6	23.6	14.4	4.98	2.24	1.21	a	a	a	a	a
	13	1	BA	a	a	a	51.6	104	188	196	176	169	120	86.9	69 2	55.0	32.6	13.8	7.17	4.26	1.56	a	a	a	a	a	a	a
	14	1	BA	a	a	26.7	429	987	863	652	472	379	290	212	137	140	104	71.3	38.1	27 2	13.0	6.43	3.43	2.07	1.08	a	a	a
	15	2	AB	a	a	a	a	a	9.99	22.2	27.5	28.5	33.3	79.6	128	123	172	197	112	64.7	32.9	14.0	6.52	2.83	1.70	a	a	a
	16	2	AB	a	a	a	108	247	203	138	95.3	68.1	45.6	30 9	22.4	17.1	9.05	5.57	3.39	2.42	1.17	a	a	a	a	a	a	a
	18	1	BA	a	a	a	6.87	70.6	82.8	72.5	93 9	105	117	271	441	994	835	575	457	347	254	162	122	104	61.4	43.1	22 2	13.8
	19	2	AB	a	a	a	a	a	a	a	a	a	a	2.27	59.1	222	615	323	154	81.0	32.5	12.3	4.43	2.82	1.59	a	a	a
	20	1	BA	a	a	3.19	10.6	26.9	19.5	14.9	13.3	144	195	221	157	96.2	62.7	36.1	18.8	10.1	2.84	1.19	a	4.31	a	a	a	a
	21	1	BA	a	a	a	138	322	211	125	89.7	70.0	50.5	40.2	28.2	19.0	13.6	7.76	3.17	1.98	a	a	a	a	a	a	a	a
	22	1	BA	a	a	4.68	3.65	10.1	9 44	12.3	32.5	82.7	388	512	425	292	202	86.8	46.3	24.9	9.79	3.85	1.74	a	a	a	a	a
	23	1	BA	a	a	a	a	a	6 56	62.8	64.5	87.5	198	154	141	88.9	139	62.1	31.9	18.2	7.02	2.78	1.25	a	a	a	a	a
	24	1	BA	a	a	43.0	56.4	49.4	27.5	17.3	30.7	24.8	17.4	23.3	62.2	129	99.7	47.9	27.7	15.7	5.09	1.87	a	a	a	a	a	a
	25	1	BA	a	a	1.39	22.6	15.8	11.1	7.65	4.80	3.13	2.55	1.80	1.44	1.01	128	83.2	198	137	58.7	31.1	19.1	5.41	1.28	a	a	a
	26	2	AB	a	a	2.18	223	848	922	906	1020	984	487	782	405	647	566	463	384	330	241	175	121	90.2	14.4	23 8	23.8	63.1
	27	1	BA	a	a	9.92	178	164	86.0	53.1	29.8	18.9	11.9	11.9	8.54	6.12	3.43	1.02	3.76	1.79	a	a	a	a	a	a	a	a
	28	2	AB	a	a	1.67	11.2	36.4	254	365	330	261	186	152	133	86.8	60.0	33.8	17.3	12.8	5.13	2.46	1.31	a	a	a	a	a
	29	2	AB	a	a	a	1.79	16.5	37.3	74.0	88.2	67.1	75.6	151	238	208	206	138	94.8	62.5	38.2	23.1	15.8	10.3	7.29	4.85	2.49	1.31
	30	1	BA	a	a	a	1.02	1.90	15.2	30.3	87.0	321	264	137	95.6	63.8	39.1	19.0	10.0	7.04	2 96	a	a	a	a	a	a	a
	31	2	AB	a	a	4.04	89.0	310	342	326	258	215	165	133	119	101	72.6	50 8	34.5	29.6	16.9	6.52	4.12	2.05	1.52	a	a	a
	32	1	BA	a	a	a	a	8.44	167	461	483	433	301	239	172	143	85.9	47.9	30.9	20.4	9.97	6.47	2.78	a	a	a	a	a
	33	2	AB	a	a	a	a	a	a	a	a	17.9	37.3	63.4	97 8	101	237	83.3	32.0	18.2	2.98	a	a	a	a	a	a	a
	34	1	BA	a	a	3.01	330	319	232	209	151	101	64 3	50.3	36.5	25.8	16.0	7.51	4.89	2.64	a	a	a	a	a	a	a	a
	35	2	AB	a	a	a	10 3	16.2	44.3	81 5	185	148	158	129	88.8	63.3	37.5	21.9	12.5	9.42	5.75	2.58	2.45	a	2.13	a	a	a
	36	2	AB	a	a	2.13	4.76	16 2	48.5	102	91.7	110	96.1	93.9	72.2	69.1	75.4	38.6	17 2	10.8	4.40	1.90	a	a	a	a	a	a
	37	1	BA	a	a	a	12.7	7.09	4.94	8.02	95.7	237	1160	683	389	261	156	95.9	53.5	33.5	14.4	6.31	2.97	1.66	1.05	a	a	a
	38	2	AB	a	a	2.53	100	206	184	126	79.5	58.0	36.5	27.3	18.1	13.5	7.88	4.14	2.53	1.39	a	a	a	a	a	a	a	a
	39	1	BA	a	a	a	a	8.22	6.90	6.83	12.2	18.8	66 0	92.7	141	201	145	83.1	41.0	23.3	7.71	3.21	1.46	a	a	a	a	a
	40	2	AB	a	a	a	72.6	137	202	160	118	68.3	55.1	35 4	26.0	18 3	12.7	7.98	4.58	2.77	1.71	a	a	a	a	a	a	a
	41	2	AB	a	a	a	37.1	38.8	56.0	74.3	64.0	44.0	30.1	22.5	12.1	10.6	5.98	2.73	1.41	a	1.92	a	a	a	a	a	a	a
	42	2	AB	a	a	a	1.66	8.67	17.6	23.5	84.1	102	68.0	68.6	61.7	46 0	29.0	22.9	12.1	7.73	3.32	1.53	a	a	a	a	a	a
	43	2	AB	a	a	a	a	2 23	17.7	15.2	51.8	188	272	299	225	168	127	59.5	30.1	15 2	5.64	2.51	1.46	a	a	a	a	a
	44	1	BA	a	a	2.85	202	236	185	154	125	106	80.0	62.6	49.8	38.1	24.0	15.1	8.71	5.12	2.53	1.27	a	a	a	a	a	a
	45	1	BA	a	a	20.6	78.3	141	120	84.5	55.3	46.8	29.4	18.2	14.6	10.6	6.64	3.24	1.98	1.60	a	a	a	a	a	a	a	a
	47	1	BA	a	a	a	a	1.01	2.44	1.37	a	a	3.74	5.24	3.83	25.5	213	157	103	70.3	21.3	7.18	3.04	1.23	a	a	a	a
	48	1	BA	a	a	1.19	62.8	222	376	249	152	87.3	53.9	39.1	30.0	20.4	10.8	6.28	3.91	2.42	1.27	a	a	a	a	a	a	a
			n	0	1	19	35	41	43	43	41	43	44	45	45	45	45	45	45	44	39	30	24	15	13	6	5	4
			Mean	b	1.49	7.75	69.8	132	147	153	163	163	178	169	150	153	142	98.7	75.3	50.6	33.7	26.5	21 9	24.4	13.9	22.1	16.1	24.2
			SD	b	b	11.00	97.9	206	200	189	188	185	238	232	213	244	215	163.0	163.4	102.9	76 7	58.4	45 5	40.8	24.7	22.2	13.1	26.9
			Min	b	1.49	1.10	1.02	1.01	2.44	1.37	4.80	3.13	2.55	1.80	1.44	1.01	3.43	1.02	1.41	1.39	1.08	1.19	1.21	1.14	1.05	1.33	1.62	1.31
			Median	b	1.49	3.01	28.5	49.4	82.7	84.5	95.3	102	90.4	92.7	95.6	86.8	72.6	44.6	25.0	15.4	5.75	3.76	3.01	4.31	1.93	14.6	22.2	16.2
			Max	b	1.49	43.0	429	987	922	906	1020	984	1160	1230	1310	1270	1030	762	945	499	352	241	167	112	75.3	53.9	30.2	63.1
			CV%	b	b	142	140	157	136	123	116	114	133	138	142	159	152	165	217	203	228	220	208	167	177	101	81.8	111

Concentrations reported to 3 significant figures; Full precision data used in all pharmacokinetic and statistical analyses

a: Concentration below limit of quantification (1.00 ng/mL)

b: Not calculable due to lack of sufficient data

c: No sample