

## B12 Study - Comparative Absorption of Liposomal Liquid vs. Liposomal Powder-Filled Capsule

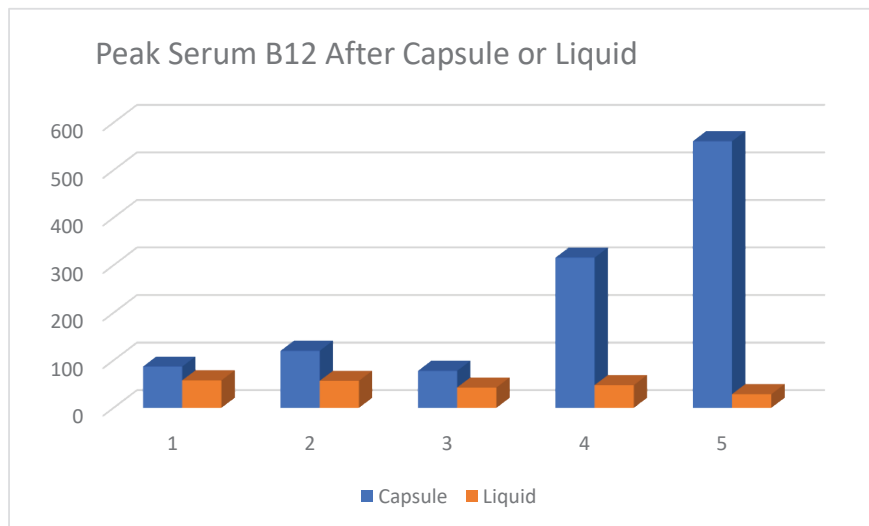
### ABSTRACT

We conducted a single-dose, crossover study in six human subjects of two dosage forms of vitamin B12 – a liposomal liquid and a liposomal powder-filled capsule. Equivalent doses were given one time. Serum B12 measurements were conducted at baseline, then at 45 minutes, 75 minutes, and 135 minutes after dosing. Each subject was given 3 mg of vitamin B12 in one dosage form, followed by a washout period of 14 days, then dosing with the other dosage form.

Baseline B12 levels were, as expected, different between subjects. All subjects (with one exception) had an increase above baseline at one or more time points. Comparing the different dosage forms, the capsule performed better than the liquid in five of six subjects. The one subject with an abnormally high baseline prior to liquid dosing was the only outlier.

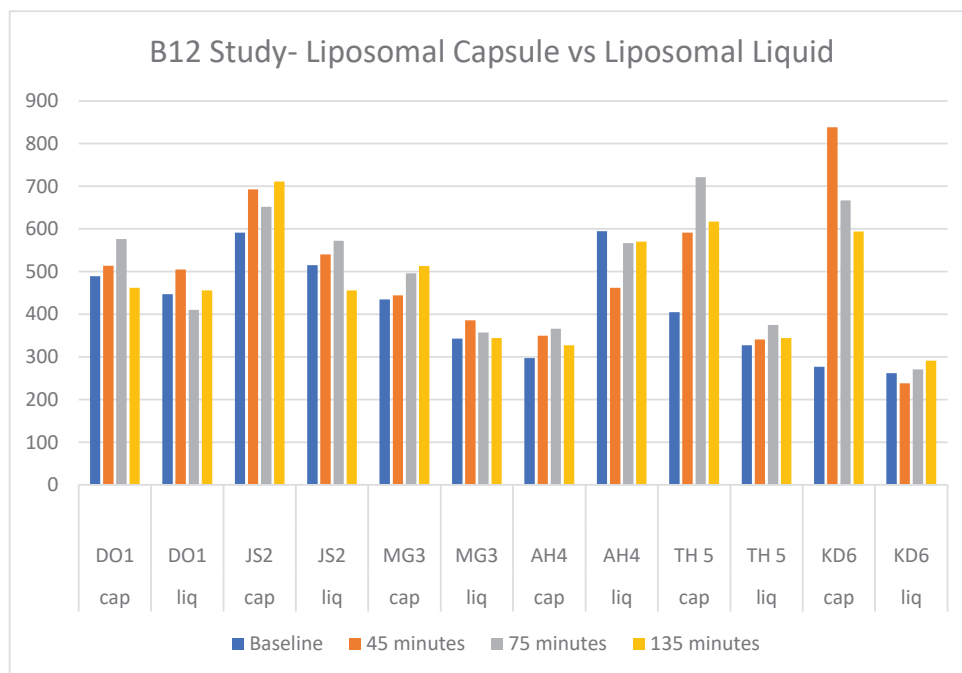
All subjects had serum B12 increases after taking the capsule formulation at T45, then all but one had increases at T75 and T135, but not in a linear fashion. This might be due to the normal pharmacokinetics of oral vitamin B12 intake, as there is a significant and complex intestinal enterocyte uptake, transport, and enterohepatic circulation of this vitamin.

On average, the serum B12 in five of six subjects in this study increased six-fold after taking a liposomal capsule compared to the liposomal liquid when comparing the highest peak of each subject's serum B12.



Average ratio between capsule and liquid peaks above baseline = 6.3

	Subject	Baseline	45 minutes	75 minutes	135 minutes
cap	DO1	489	514	576	462
liq	DO1	447	505	410	456
cap	JS2	591	693	652	711
liq	JS2	515	540	572	456
cap	MG3	435	444	496	513
liq	MG3	343	386	357	344
cap	AH4	297	350	366	327
liq	AH4	595	462	567	570
cap	TH 5	405	591	721	617
liq	TH 5	327	341	375	344
cap	KD6	277	838	667	594
liq	KD6	262	238	271	291



	Subject	0	45 min	75 min	135 min	45 min (-t0)	75 min (-t0)	135 min (-t0)	Highest in range	Ratio
cap	DO1	489	514	576	462	25	87	-27	87	1.5
liq	DO1	447	505	410	456	58	-37	9	58	
cap-liq		42	9	166	6					
cap	JS2	591	693	652	711	102	61	120	120	2.10526316
liq	JS2	515	540	572	456	25	57	-59	57	
cap-liq		76	153	80	255					
cap	MG3	435	444	496	513	9	61	78	78	1.81395349
liq	MG3	343	386	357	344	43	14	1	43	
cap-liq		92	58	139	169					
cap	AH4	297	350	366	327	53	69	30	69	
liq	AH4	595	462	567	570	-133	-28	-25	0	
cap-liq		-298	-112	-201	-243					
cap	TH 5	405	591	721	617	186	316	212	316	6.58333333
liq	TH 5	327	341	375	344	14	48	17	48	
cap-liq		78	250	346	273					
cap	KD6	277	838	667	594	561	390	317	561	19.3448276
liq	KD6	262	238	271	291	-24	9	29	29	
cap-liq		15	600	396	303					

6.26947551