

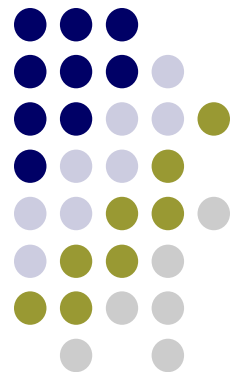


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HUMAN NUTRITION

Minerals • Science • Chelates

DiCALCIUM MALATE



DiCalcium Malate Bioavailability

Albion has developed a new, patented form of calcium—DiCalcium Malate. As the name suggests, it is comprised of 2 moles of calcium attached to one mole of malic acid. DiCalcium Malate was developed to give manufacturers of dietary supplements a better alternative to calcium carbonate and other salt forms. Most other calcium forms have a much lower elemental calcium content, while DiCalcium Malate is 29% elemental calcium. In addition to having significantly higher calcium content than the other alternatives to calcium carbonate, factors like bioavailability and gastric tolerance are issues that need to be evaluated to compare DiCalcium Malate to calcium carbonate, and there were 2 absorption studies completed over the last two years, in which the absorption of these two calcium forms were compared.

The first study tested the absorption of DiCalcium Malate and calcium carbonate at a high dose level, 900 mg elemental calcium (Chatuvedi, et al; FASEB, April 2006). The study was performed on healthy adults, and each adult served as his/her own controls as each adult consumed each product, separated by one week, and under similar dietary conditions. The main data gathered were serum calcium's area under the curve (AUC, a concentration-time line), half life, time to achieve maximum concentration, and maximum concentration achieved. The key data gathered in this study are depicted in the "900 mg Calcium Study Overview" below.

The study found that DiCalcium Malate was significantly better absorbed than calcium carbonate and it maintained an elevation in serum calcium for a much longer period of time, indicating a greater half life, this could be a reflection of the higher presence of the calcium in an absorbable form for a longer time period which could be related to the chemistry of this patented mineral form.

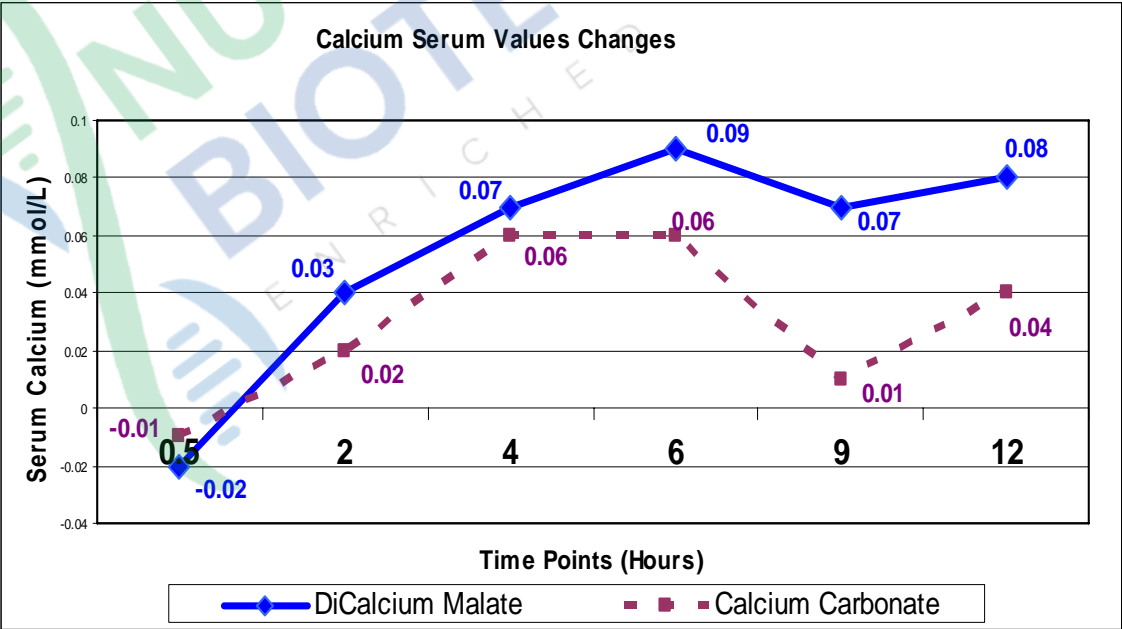
900 mg Calcium Study Overview

The following tables show the analysis within the treatment of calcium serum values. It was noted that beginning at hour 4, there was a significant difference in Calcium serum values for all points in the DiCalcium Malate compared to the carbonate. There was no statistical significance at any time point in the calcium carbonate treatment.

DiCalcium Malate				
Time Points (hrs.)	Mean	SD	Difference from baseline	*P Value <0.05
0.5	2.29	0.08	-0.02	-
2	2.34	0.09	0.03	-
4	2.37	0.10	0.07	*
6	2.40	0.08	0.09	*
9	2.37	0.09	0.07	*
12	2.38	0.12	0.08	*

Calcium Carbonate				
Time Points (hrs.)	Mean	SD	Difference from baseline	*P Value <0.05
0.5	2.38	0.10	-0.01	-
2	2.40	0.08	0.02	-
4	2.45	0.10	0.06	-
6	2.45	0.10	0.06	-
9	2.40	0.07	0.01	-
12	2.43	0.09	0.04	-

The figure to the right visually summarizes the differences from baseline values of the DiCalcium Malate and calcium carbonate serum measurements.



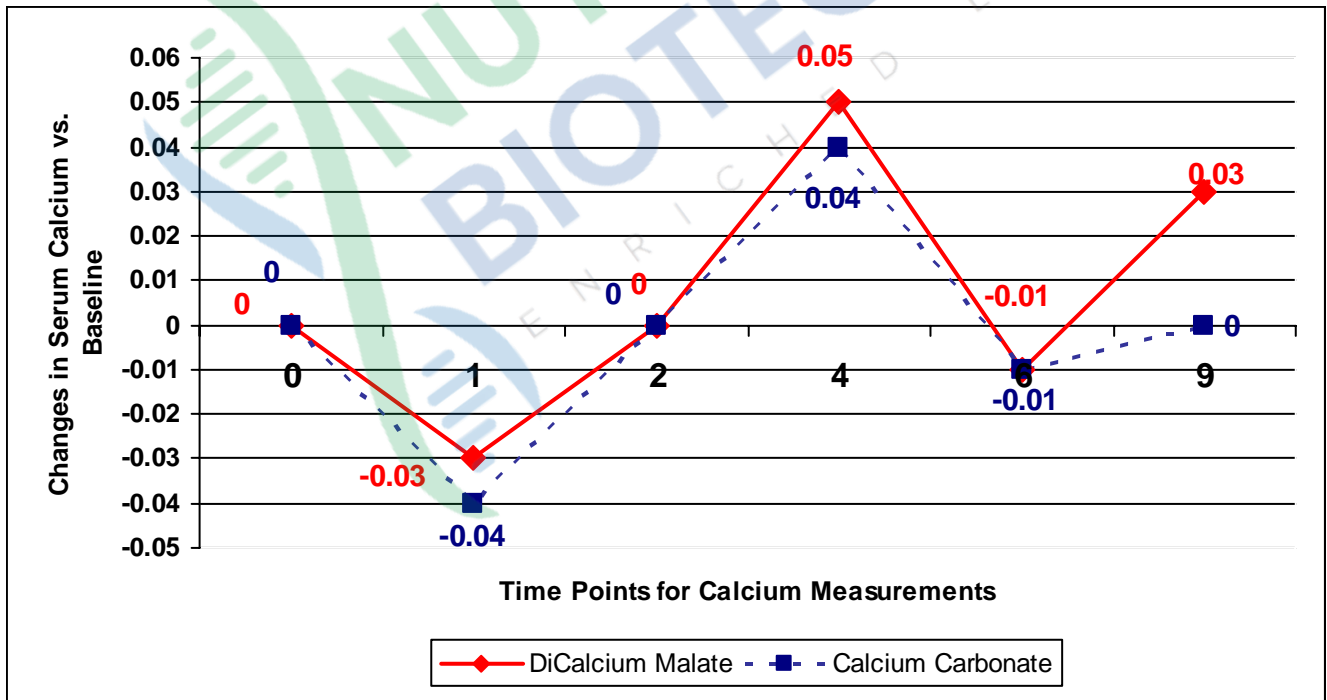
The area under the curve calculation for the changes in calcium serum for DiCalcium Malate is much greater than for calcium carbonate and indicates greater relative absorption for DiCalcium Malate.

In the second study, the absorption of DiCalcium Malate was compared to calcium carbonate at a moderate dose of 300mg elemental calcium (Crowley, et al, KGK Enterprises, in process). This study was done in similar fashion, but on healthy premenopausal women, and the same pharmacokinetic measurements were taken as in the 900mg study. At the 300mg dose of calcium, DiCalcium Malate was again absorbed at a better rate than the calcium carbonate form. The salient data from the 300mg calcium dose study is depicted in the “300mg Calcium Study Overview” below.

300 mg Calcium Study Overview

DiCalcium Malate serum readings (mmol/L)		
Time Points (hrs.)	Serum Level	Change
0	2.31	0
1	2.27	-.04
2	2.31	0
4	2.36	+.05
6	2.30	-.01
9	2.33	+.03

Calcium Carbonate serum readings (mmol/L)		
Time Points (hrs.)	Serum Level	Change
0	2.32	0
1	2.29	-.03
2	2.32	0
4	2.36	+.04
6	2.31	-.01
9	2.32	0



Summary

The measurement of AUC does not yield absolute bioavailability values, but is well suited for comparison of two (or more) preparations. It has a low signal to noise ratio, because unlike drugs, the studied substance (calcium) has a normal serum presence prior to dosing, and it is a tightly regulated value. Due to this, the absorption increments tend to be a small fraction of what is already present and the body's homeostatic forces actively dampen the absorptive rise (Heaney R, Journal of Nutrition; 131:1344S-1348S). This helps explain why the 900mg dose study exhibited a larger apparent margin in absorption in favor of the Di-Calcium Malate over calcium carbonate than what was seen in the 300mg dosage study. One of the problems that can be encountered with calcium carbonate is the phenomenon of acid rebound and gas after a larger dose of this substance. To compare DiCalcium Malate to calcium carbonate for this tendency, an in vitro test was performed. Equal elemental amounts of calcium from DiCalcium Malate and calcium carbonate were put into separate breakers and then equal amounts of simulated stomach acid was added to each beaker. The calcium carbonate foamed up forming gas bubbles, while the DiCalcium Malate did not. From this in vitro test, it appears that DiCalcium Malate would not have the gastric problems seen with calcium carbonate. Di Calcium Malate appears to be a high calcium containing ingredient that is better absorbed and potentially better tolerated than calcium carbonate. DiCalcium Malate (US patent #6706904) is available exclusively from Albion

It is of note that the gap in absorption between DiCalcium Malate over calcium carbonate was larger at the 900mg dose than at the 300mg dose. Previous calcium absorption studies have indicated that as you increase the dose of calcium, the relative absorption of the calcium decreases in terms of percentage of absorption. For DiCalcium Malate, this effect is not as evident as it is for calcium carbonate. DiCalcium Malate is a unique, patented form of calcium, which contains 2 moles of calcium bound to one mole of malic acid. It may very well be that the release of the calcium from the DiCalcium Malate molecule takes place at different rates for each of the calcium, thus decreasing the tendency for the calcium (especially at higher doses) to over clutter the absorption sites and transfer mechanism for calcium absorption, and allowing for a more efficient calcium absorption at higher doses.



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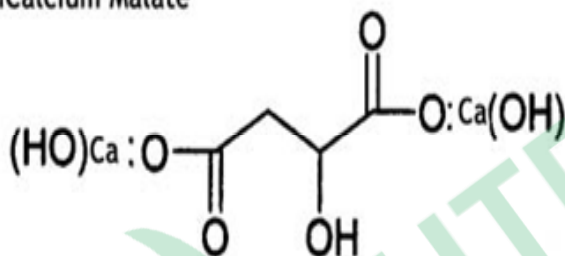
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DiCalcium Malate

29% Calcium
(#4049 & #4050)

DiCalcium Malate



DiCalcium Malate is an exclusive form of calcium from Albion Advanced Nutrition, which holds the composition and method of administration patent, US 6,706,904.

Dicalcium Malate is Kosher-Parve, GMO free, BSE free, and suitable for vegans, vegetarians, and lacto-ovo vegetarians.

Malic acid is a naturally occurring organic acid found in apples, watermelon, plums, lychees, and cherries in high concentration. It is more soluble than citric acid and forms metal compounds that are of low hygroscopicity allowing for easier storage and better shelf life. In addition to providing calcium in this compound, it contributes malic acid into the metabolism, as well. DiCalcium Malate is 64% malic acid w/w. Malic acid is part of the Krebs and Glyoxalate energy producing cycles in the human body. In vitro studies show that DiCalcium Malate, unlike calcium carbonate and some of the other alkali calcium forms does not cause the formation of gas when subjected to stomach acid and does not give rise to acid rebound seen with these other calcium forms. Malic acid is a natural buffering agent.

HUMAN NUTRITION DIVISION

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