

**FAST-**



## Fast-C® Profile

Fast-C® is a premium form of Vitamin C developed to exhibit superior bioavailability without the stomach upset of pure ascorbic acid or “buffered” Vitamin C compositions.

- Ultra tolerable/rapid buffering
- Patented+ exclusive license (Bioperine®)
- Clinical research validated: crossover comparator trials
- Uniform, directly compressible granules – faster tableting!
- GMO-free, NO animal products or synthetic agents
- Kosher certified



## Fast-C<sup>®</sup>: Competitive Landscape

- Ester-C<sup>®</sup>
  - Market dominator
  - Premium Vitamin C market in flux due to NBTY buy-out
  - Original (active) patent expired (April '07)
  - Evidence based of superiority in humans is thin. Two published clinical trials showing:
    - Slightly *inferior* bioavailability compared to ascorbic acid or ascorbic acid + flavonoids
    - One published clinical showing greater tolerability (relative to ascorbic acid) but bioavailability was NOT assessed



# Fast-C®: Competitive Landscape

## Ester-C® - Absorption & Retention Issues

**Table**

Areas under the plasma vitamin C time-concentration curves, 24-hour urinary excretion of vitamin C, and ratios of area to urine<sup>a</sup>

Type of vitamin C	Area (arbitrary units)	Urinary excretion (mmol/24 hr)	Ratio of area to urine
Ascorbic acid	253 ± 20 <sup>b</sup>	1.16 ± 0.16	253 ± 40
Ester-C	214 ± 18	1.48 ± 0.28	188 ± 37
Ascorbic acid with bioflavonoids	259 ± 19	1.20 ± 0.18	252 ± 37
Placebo	11 ± 9 <sup>*</sup>	0.03 ± 0.02 <sup>*</sup>	...

<sup>a</sup>After ingestion of 500 mg synthetic vitamin C as ascorbic acid, ascorbic acid from Ester-C (Inter-Cal Corp, Prescott, Ariz), ascorbic acid with bioflavonoids, or a placebo.

<sup>b</sup>Mean ± standard error

<sup>\*</sup>Significantly different from all other values, *P* < .05.

- J Am Diet Assn, 1994



## Fast-C<sup>®</sup>: Clinical Trials

- Two clinical trials initiated in 2007
  - First study – Fast-C<sup>®</sup> vs. Ester-C<sup>®</sup>: completed
  - Second study – Fast-C<sup>®</sup> (dose escalation) vs Ester-C<sup>®</sup>: by late 2008
- Both studies are led by expert clinical investigators and executed by certified research professionals
  - Conducted in compliance with current Good Clinical Practices (cGCP)
  - Conducted by certified pharmaceutical research center in USA

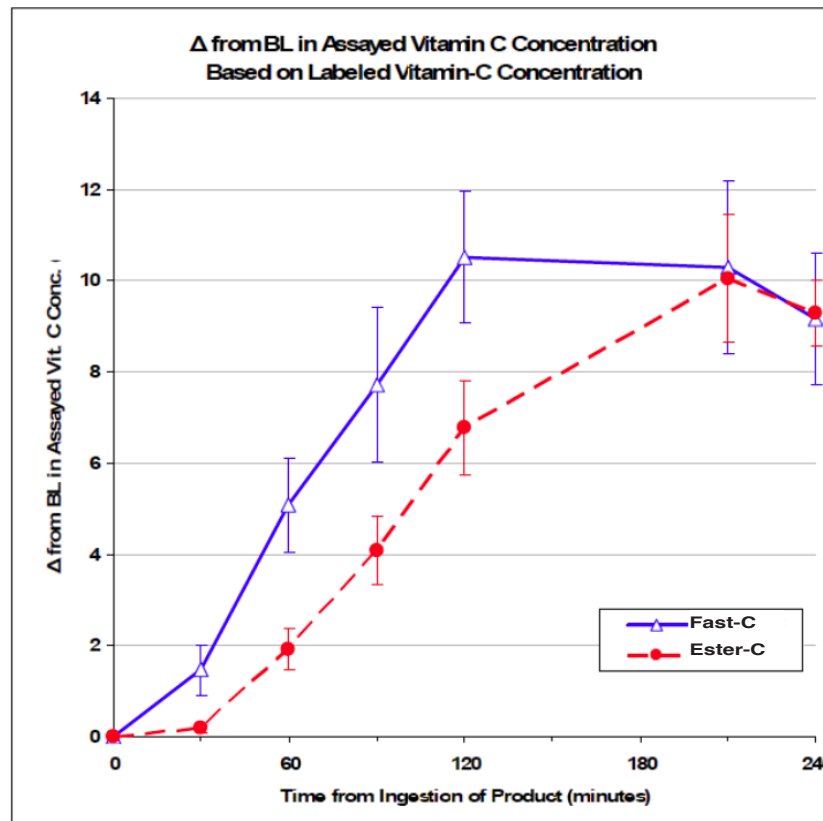


## Fast-C®: Clinical Data

- Study 1: Proof of Concept Clinical Trial (Study 1)
  - Fast-C® vs Ester-C®: **1 gram** of ascorbic acid
  - Prospective, comparator, double-blind, randomized, **crossover** trial
  - Five, healthy, non-smoking males (32 years avg.; 30.1 BMI avg)
- Outcome measures
  - 4 hour pharmacokinetics (HPLC)
  - 24 hour urine ascorbate (HPLC)



## Vitamin C Change From Baseline



Error-bars represent  $\pm 1$  Standard Error of the Mean

\* P = 0.06



## Faster Rise Yet Equal Urinary Losses

- Tmax (time to achieve peak blood vitamin C concentration):
  - Fast-C®: 180 minutes vs. Ester-C®: 216 minutes (p=0.346)
- AUC (4 hr.):
  - Fast-C®: 1,813 vs Ester-C®: 1,334 (35% greater; p=0.319)
- No difference in 24 hours urinary ascorbic acid excretion
- Preliminary interpretation: Fast-C® appears to deliver Vitamin C faster and to a greater extent than Ester-C® and exhibits equal apparent retention of the delivered dose
- **Presented at Experimental Biology 2008**





## Fast-C®: Follow Up Study

- Confirmatory, Dose Escalation Clinical Trial
  - Fast-C® (Bioperine lower dose) vs. Fast-C® (Bioperine higher dose) vs. Ester-C®
  - Prospective, comparator, double-blind, randomized, crossover trial
  - Ten health, non-smoking male subjects following a low Vitamin C diet
  - Single, 1 gram dose of AA (from each source)
  - 24 hour urine + 4 hour blood pharmacokinetics
  - cGCP at USA-based pharmaceutical research center

Study target completion date: June 2009





**Vigour**

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