Human Clinical Trial
Evaluating the Safety and Efficacy of

A Randomized, Placebo Controlled, Double-Blind Cross-Over Trial

Products:
Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™
Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™

Manufacturer: Lily of the Desert
1.0 STUDY PURPOSE

To provide scientific data to support the statement: **When subjects take their good quality Vitamin C with Lily of the Desert aloe vera juice enhanced with Aloesorb™ they will approximately absorb 80% of that vitamin C product into this cellular system. Additionally, Lily of the Desert aloe vera juice enhanced with Aloesorb™ increases the quickness of absorption more than 20 times after the first hour compared to typical tap water and after six hours, it shows up to 7.6 times.**

2.0 STUDY OVERVIEW

*Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™ and Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™ are all natural, Certified Organic dietary supplements available at many natural food stores. This product is composed of Certified Organic Aloe Fillet Juice and citric acid. All products were taken orally for this study.*

It is a scientifically proven fact that most humans die from either malnutrition or dehydration. Vitamins and minerals are required for millions of necessary reactions to occur in our bodies. When the body is missing one or more of these required vitamins or minerals the body may fall out of Wellness and begin to move into a more vulnerable state of biochemistry of disease and unbalance. For the purpose of this study we evaluated Aloe Vera Juice’s ability to help absorb and utilize Vitamin C.
A very small sample of what Vitamin C is necessary for in the human body:

- Potent water-soluble antioxidant
- Essential for collagen formation
- Regulates iron metabolism
- Normal Adrenal functions
- Important for normal Immune system function
- Helps protect your body for the harmful affects of pollution
- Co-factor for cyt P450 enzymes
- Deficiency: petechiae, bleeding gums, impaired wound healing, scurvy

2.1 Study Design

This was a fifteen (15) subject 30-day study. The subjects were randomized into three groups of five (5) subjects, Group (A), Group (B), and Group (C).

Subjects cross-over was done in the following manner:

Baseline:

Group A- Product used- regular tap water
Group B- Product used *Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™*
Group C- Product used- *Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™*
Test #1:

Group A- Product used *Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™*
Group B- *Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™*
Group C- Product used- regular tap water

Test #2:

Group A- *Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™*
Group B- Product used- regular tap water
Group C- *Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™*

Test #3:

Group A- Product used- regular tap water
Group B- *Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™*
Group C- *Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™*
3.0 PROTOCOL

3.1 SCREENING AND TESTING PROCEDURES

The initial screening of all potential subjects included: screening to assess liver (AST, ALT), kidney (creatinine), thyroid (TSH) function as well as normal CBC labs. These tests were preformed at Fenestra Research Labs by healthcare professionals. Samples of blood and urine were taken from each subject for these screenings.

Following the initial screening at Visit 1 (week 0), subjects who met all inclusion criteria and none of the exclusion criteria during the intake at Visit 1 (week 0) were then entered into the study group. Subjects were randomized into three groups of five subjects. Subjects were tested on three separate days that were each one week apart.

3.2 Testing Procedure:

- Upon arrival each subject was assessed for general health and wellbeing
- A fasting blood draw was taken from each subject
- Subject either receives - Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™, Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™, or a placebo (tap water).
- Each of above named products included 500mg of vitamin C produced by the same manufacturer from the same test bottle, in a random order (on each of the 3 visits).
- The test product vitamin C’s label supplement facts were: vitamin C (as Ascorbic Acid) 500mg, Bio-Rose™ (Bioflavonoids Concentrate, Acerola Cherry, Rose Hips, Rutin Concentrate, Hesperidin Concentrate 50 mg
- In total seven samples of blood were drawn from each subject at each visit. At 0, 1, 2, 4, 6 hours in this 24 hour period.
At 2 hours, subjects were given a light breakfast (bagel and banana).

### 3.3 INCLUSION CRITERIA

- Subjects who have signed a written informed consent consistent with required guidelines and meet prior to participation in the trial.
- Subjects 40 years of age or older, either sex.
- Subjects who are not on any medication, antioxidant/herbal supplement.
- Subjects with normal glucose, lipids, kidney, liver and thyroid functions, normal CBC prior to the start date of this study.
- Subjects who were able to follow the protocol as designed by Lily of The Desert and Fenestra Research labs.
- In generally good health.

### 3.4 EXCLUSION CRITERIA

- History of head trauma
- History of serious diseases or illness diagnosed at this time.
- Known moderate to severe renal insufficiency.
- Recent history (<6 months prior to Visit 1) of myocardial infarction.
- Subjects who regularly use oxygen therapy.
- Subjects with known active tuberculosis.
- Subjects with a history of cancer within the last 5 years.
- Subjects with treated basal cell carcinoma are allowed.
- Subjects who have undergone thoracotomy with pulmonary resection within 1 year prior to the trial.
- Subjects who are currently in a pulmonary rehabilitation program or who have completed a pulmonary rehabilitation program in the 6 weeks prior to the screening visit (Visit 1).
- Subjects currently prescribed diuretic medications, cardiac stimulants, or any
other prescribed or non-prescribed medication that may, in the opinion of the Fenestra research staff, alter testing results.

- Use of opiate analgesics prescribed or otherwise obtained for any treatment reason including migraine treatment, or for recreation.
- History of drug or alcohol addiction.
- Females who are pregnant, lactating, or nursing or who may become pregnant during the course of the study.
- Patients diagnosed as HIV-positive, diagnosed with AIDS, or with any neuromuscular condition including CP, MS, ALS, or Huntington's Chorea.
- Patients with uncontrolled hypertension (e.g. BP>150/100).
- Subjects who have used steroid therapy with-in the last 6-months.
- Subjects who currently or have with-in the last 6-months smoked cigarettes.
- Patients with any condition not previously named that, in the opinion of the investigators or intake staff, would jeopardize the safety of the patient or affect the validity of the data collected in this study.
4.0 Aloe Preparations used for this study

Group B - *Lily of the Desert Aloe Vera Fillet Juice enhanced with 60mg of Aloesorb™ per 2 ounce serving*

5.2 Group C - *Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with 60mg of Aloesorb™ per 2 ounce serving*

**CLINICAL DATA ANALYSIS**

5.0 General Information

- Mean Age: 48 ± 6 yrs
- Mean BMI: 23 ± 4 kg/sqm
- Male: Female- 5:10
### 6.0 Results

**MILLIGRAMS OF VITAMIN C FOUND IN BLOOD SAMPLE**

| Subject # | Gel Begin | Plcbo Begin | Leaf Begin | Gel 1 | Plcbo 1 | Leaf 1 | Gel 2 | Plcbo 2 | Leaf 2 | Gel 3 | Plcbo 3 | Leaf 3 | Gel 4 | Plcbo 4 | Leaf 4 | Gel 5 | Plcbo 5 | Leaf 5 | Gel 6 | Plcbo 6 | Leaf 6 | Gel 7 | Plcbo 7 | Leaf 7 | Gel 8 | Plcbo 8 | Leaf 8 | Gel 9 | Plcbo 9 | Leaf 9 | Gel 10 | Plcbo 10 | Leaf 10 | Gel 11 | Plcbo 11 | Leaf 11 | Gel 12 | Plcbo 12 | Leaf 12 | Gel 13 | Plcbo 13 | Leaf 13 | Gel 14 | Plcbo 14 | Leaf 14 | Gel 15 | Plcbo 15 | Leaf 15 |
|-----------|-----------|-------------|------------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|-------|---------|--------|
| Hours     | Begin     | Begin       | Begin      |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |         |        |       |
| 1         | 0         | 0           | 0          | 175   | 15      | 160    | 299   | 125     | 406    | 376   | 90      | 408    | 90    | 15      | 288    | 2      | 1       |
| 2         | 0         | 0           | 0          | 176   | 6       | 164    | 299   | 90      | 387    | 299   | 94      | 388    | 143   | 27      | 300    | 0.95   | 0.2     |
| 3         | 2         | 0           | 0          | 155   | 10      | 156    | 399   | 88      | 411    | 438   | 91      | 406    | 120   | 90      | 402    | 1      | 0.2     |
| 4         | 2         | 0           | 2          | 197   | 15      | 190    | 410   | 20      | 410    | 400   | 35      | 400    | 99    | 24      | 385    | 1      | 0.2     |
| 5         | 0         | 0           | 0          | 178   | 8       | 177    | 410   | 102     | 408    | 407   | 86      | 410    | 40   | 64      | 396    | 1      | 0.2     |
| 6         | 0         | 0           | 0          | 177   | 6       | 156    | 289   | 66      | 408    | 399   | 70      | 389    | 100   | 44      | 371    | 1      | 0.2     |
| 7         | 0         | 0           | 0          | 175   | 12      | 172    | 385   | 96      | 383    | 400   | 94      | 394    | 25    | 94      | 299    | 1      | 0.2     |
| 8         | 3         | 2           | 2          | 166   | 4       | 174    | 299   | 14      | 395    | 399   | 88      | 341    | 150   | 33      | 318    | 1      | 0.2     |
| 9         | 0         | 0           | 0          | 168   | 12      | 155    | 401   | 105     | 427    | 406   | 107     | 406    | 270   | 2       | 383    | 1      | 0.2     |
| 10        | 0         | 0           | 0          | 175   | 10      | 170    | 386   | 127     | 488    | 387   | 99      | 488    | 44    | 93      | 400    | 1      | 0.2     |
| 11        | 0         | 0           | 0          | 174   | 4       | 166    | 332   | 9       | 335    | 399   | 27      | 339    | 194   | 4       | 305    | 1      | 0.2     |
| 12        | 1         | 1           | 1          | 168   | 2       | 164    | 375   | 27      | 364    | 400   | 33      | 399    | 66    | 18      | 274    | 1      | 0.2     |
| 13        | 0         | 0           | 0          | 175   | 10      | 169    | 404   | 44      | 402    | 431   | 51      | 400    | 37    | 47      | 280    | 1      | 0.2     |
| 14        | 0         | 0           | 0          | 172   | 3       | 169    | 396   | 81      | 388    | 401   | 80      | 391    | 157   | 22      | 283    | 1      | 0.2     |
| 15        | 0         | 0           | 0          | 159   | 7       | 170    | 407   | 110     | 402    | 408   | 92      | 405    | 83    | 71      | 280    | 1      | 0.2     |

Mean: 0.53 0.2 0.333333 172.67 8.27 167.47 366.1 73.6 401 397 75.8 397.6 108 43.2 330.9
SD: 499 499.8 499.6667 327.33 492 332.53 133.9 426 99.1 103 424 102.4 457 169.1

**Placebo vs Gel&Leaf Percent**
- 1989%
- 1926%
- 397%
- 445%
- 423%
- 425%
- 1989%

**Placebo vs Gel&Leaf Times**
- 20.887
- 20.258
- 4.974
- 5.45
- 5.23
- 5.245
- 2.5
- 7.66

*p<0.01
CONCLUSION

Based on these clinical comparisons and the complete lack of known adverse side effects, interactions, or contra-indications from the herbal ingredients in the Study Products (Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™ and Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™), this product was shown to be a safe and highly effective. Using these products on a daily bases can increase the bioavailability for the vitamin C more than any other product this laboratory has tested.

Based on the data obtained in this study several statements can be made:

1. *Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™* when given with vitamin C can significantly increase plasma ORAC at both 1,2,4 and 6 hrs intervals at the cellular level.

2. *Lily of the Desert Aloe Vera Fillet Juice enhanced with Aloesorb™* when given with vitamins C can significantly increase plasma vitamin C at 1, 2, 4 and 6 hrs intervals at the cellular level. Showing 20.8 times better than water at 1 hour, 5.0 times at 2 hours, 5.2 times at 4 hours and 2.5 times at 6 hours.

3. *Aloesorb™ and Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb™* when given with vitamin C can significantly increase plasma vitamin C at 1, 2, 4 and 6 hrs intervals at the cellular level. Showing 20.3 times better than water at 1 hour, 5.4 times at 2 hours, 5.2 times at 4 hours and 7.7 times at 6 hours.