

# **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

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### **CONDFIDENTIAL INFORMATION**

Any part or all of the information in this report may be unpublished material.

### 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: petechae, 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™

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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.

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> 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

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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:  $48 \pm 6$  yrs

• Mean BMI:  $23 \pm 4 \text{ kg/sqm}$ 

• Male: Female- 5:10

### 6.0 Results

### MILLIGRAMS OF VITAMIN C FOUND IN BLOOD SAMPLE

Subject #	Gel	Picbo	Leaf	Gel	Picbo	Leaf	Gel	Plcbo	Leaf	Gel	Picbo	Leaf	Gel	Picbo	Leaf
 Hours	Begin	Begin	Begin	1	1	1	2	2	2	4	4	4	6	6	6
1	0	0	0	175	15	160	299	125	406	376	90	408	90	15	288
2	0	0	0	176	6	164	299	90	387	299	94	388	143	27	300
3	2	0	0	155	10	156	399	88	411	438	91	406	120	90	402
4	2	0	2	197	15	190	410	20	410	400	35	400	99	24	385
5	0	0	0	178	8	177	410	102	408	407	86	410	40	64	396
6	0	0	0	177	6	156	289	66	408	399	70	389	100	44	371
7	0	0	0	175	12	172	385	96	383	400	94	394	25	94	299
8	3	2	2	166	4	174	299	14	395	399	88	341	150	33	318
9	0	0	0	168	12	155	401	105	427	406	107	406	270	2	383
10	0	0	0	175	10	170	386	127	488	387	99	488	44	93	400
11	0	0	0	174	4	166	332	9	335	399	27	339	194	4	305
12	1	1	1	168	2	164	375	27	364	400	33	399	66	18	274
13	0	0	0	175	10	169	404	44	402	431	51	400	37	47	280
14	0	0	0	172	3	169	396	81	388	401	80	391	157	22	283
15	0	0	0	159	7	170	407	110	402	408	92	405	83	71	280
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	392	457	169.1
Placebo vs Gel&Leaf Percent				1989%		1926%	397%		445%	423%		425%	150%		666%
Placebo vs Gel&Leaf Times				20.887		20.258	4.974		5.45	5.23		5.245	2.5		7.66

<sup>\*</sup>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* \*\*Mand *Lily of the Desert Aloe Vera Whole Leaf Juice enhanced with Aloesorb* \*\*M), this product was shown to be a safe and highly effective. Using theses 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.