

**A DOUBLE-BLIND, HOME-USE STUDY IN APPROXIMATELY 45 HEALTHY VOLUNTEERS WITH AGEING, NON-FIRM SKIN TO ASSESS THE EFFICACY OF DIFFERENT TREATMENT DOSAGES OF A VITAMIN C DIETARY SUPPLEMENT COMPARED TO A PLACEBO CONTROL GROUP.**

**Primary Sponsor:**

Abundance & Health Limited, % ProfitPal, 1  
Maritana Gate, Canada Street, Waterford.  
Dublin. Ireland

**Co-Sponsor:**

LivOn Laboratories Inc.  
2654 W. Horizon Ridge Pkwy Ste B5-108  
Henderson, NV 89052

**Study Center:**

Princeton Consumer Research Ltd  
Harbour House  
23 Chandlers Quay  
Maldon  
Essex CM9 4LF  
United Kingdom

Draft Report v1: 12<sup>th</sup> December 2014

Final Report: 31<sup>st</sup> December 2014

**A DOUBLE-BLIND, HOME-USE STUDY IN APPROXIMATELY 45 HEALTHY VOLUNTEERS WITH AGEING, NON-FIRM SKIN TO ASSESS THE EFFICACY OF DIFFERENT TREATMENT DOSAGES OF A VITAMIN C DIETARY SUPPLEMENT COMPARED TO A PLACEBO CONTROL GROUP.**

**PRINCETON CONSUMER RESEARCH LTD REPORT NO: ABUCLII**

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by Princeton Consumer Research Ltd were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Danny McCamlie  
(Principal Investigator)

  
.....  
Date 12-1-2015

**QUALITY ASSURANCE STATEMENT**

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

Daniella Smith  
(Quality Assurance Manager)

  
.....  
Date 12-1-2015

## CONTENTS

<b>SUMMARY .....</b>	<b>5</b>
<b>KEY STUDY PERSONNEL AND RESPONSIBILITIES .....</b>	<b>6</b>
<b>STUDY FLOW CHART .....</b>	<b>7</b>
<b>INTRODUCTION &amp; OBJECTIVE .....</b>	<b>8</b>
<b>MATERIALS AND METHODS .....</b>	<b>9</b>
<b>1 STUDY DESIGN .....</b>	<b>9</b>
<b>2 SELECTION OF SUBJECTS .....</b>	<b>9</b>
<b>3 METHOD .....</b>	<b>10</b>
3.1 TEST ARTICLE .....	10
3.2 STUDY PROCEDURE .....	10
3.3 CUTOMETER® MPA 580 .....	11
3.4 PROFILOMETERY .....	11
<b>4 ADVERSE EVENTS .....</b>	<b>12</b>
4.1 CLASSIFICATION .....	12
4.2 REPORTING OF ADVERSE EVENTS .....	13
4.3 WITHDRAWALS .....	13
<b>5 STUDY ETHICS .....</b>	<b>14</b>
5.1 AMENDMENTS TO PROTOCOL .....	14
5.2 DECLARATION OF HELSINKI .....	14
5.3 SUBJECT CONSENT .....	14
5.4 INDEMNITY PROVISION .....	14
<b>6 QUALITY ASSURANCE .....</b>	<b>15</b>
<b>7 RETENTION OF DATA .....</b>	<b>15</b>
<b>8 REFERENCES .....</b>	<b>15</b>
<b>R E S U L T S .....</b>	<b>16</b>
<b>1 LOCATION AND DATES OF THE STUDY .....</b>	<b>16</b>
<b>2 SUBJECTS .....</b>	<b>16</b>
<b>FIGURE 1: AGE COMPOSITION OF THE SUBJECTS COMPLETING THE STUDY .....</b>	<b>16</b>
<b>3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY .....</b>	<b>16</b>
<b>4 ASSESSMENTS .....</b>	<b>17</b>
<b>TABLE 1 – MEAN CUTOMETER READINGS BEFORE, DURING AND AFTER 16 WEEKS USE OF THE TEST ARTICLE .....</b>	<b>17</b>
<b>TABLE 2 – STATISTICAL ANALYSIS OF CUTOMETER DATA COMPARED TO BASELINE VALUES .....</b>	<b>17</b>

---

**TABLE 3 – PERCENTAGE CHANGE OF SKIN VISCOELASTICITY COMPARED TO BASELINE..... 17**

**TABLE 1 – PROFILOMETERY VALUES BEFORE, DURING AND AFTER 16 WEEKS USE OF THE TEST ARTICLE ..... 18**

**TABLE 2 – STATISTICAL ANALYSIS OF PROFILOMETERY DATA COMPARED TO BASELINE VALUES..... 18**

**TABLE 3 – PERCENTAGE CHANGE OF FINE LINES AND WRINKLES COMPARED TO BASELINE..... 18**

**CONCLUSION..... 19**

**APPENDICES ..... 3620**

PRINCETON CONSUMER RESEARCH

## SUMMARY

1. A home-use study in 41 healthy volunteers with ageing, non-firm skin to assess the efficacy of different treatment dosages of a Vitamin C dietary supplement compared to a placebo control group.
2. At Week 0 Subjects underwent cutometry and profilometry assessments on the peri-orbital area of the face, after which they were issued with an instruction sheet, diary cards and their group allocated product regime. Subjects were asked to use the article supplied to them as per the usage instructions with one sachet to be taken in the morning, one in the day, and one in the evening. 4 subjects in each group underwent DIC (Digital Image Capture).
3. At weeks 4, 8 and 12 subjects returned to the study centre for further Cutometry and Profilometry assessments. The same 4 subjects of each group underwent further DIC.
4. At Week 16 Subjects returned to the Test Centre on where they underwent post-treatment cutometry and profilometry assessments. Final DIC was undertaken on the 4 selected subjects of each group. Subjects then returned their completed diary cards and were compensated for their time.
5. Individual scores, mean scores and standard deviations for cutometry and profilometry assessments at Weeks 0, 4, 8, 12 and 16 are presented in this report for the forty-one subjects who completed the study.
6. It can be concluded that both treatment groups A and C showed statistically significant increases in skin firmness at all time-points and reduced the appearance of fine lines and wrinkles. Treatment group B showed no statistical change for any assessment type.

**KEY STUDY PERSONNEL AND RESPONSIBILITIES**

<b>Key personnel</b>	<b>General responsibilities</b>
<p><b>Principal Investigator (PI)</b>            Danny McCamlie            Princeton Consumer Research            Harbour House            23 Chandlers Quay            Maldon            Essex CM9 4LF            United Kingdom              Tel: 01621 859230            Fax: 01621 851537</p>	<p>The Principal Investigator (PI) was responsible for ensuring sufficient resources are available to conduct the study according to Good Clinical Practice (GCP), for reporting any serious adverse events to the Sponsor.</p>
<p><b>Project Supervisors (PS)</b>            Mandie Mayes            Princeton Consumer Research Ltd            Harbour House            23 Chandlers Quay            Maldon            Essex CM9 4LF            United Kingdom              Tel: 01621 859230            Fax: 01621 851537</p>	<p>The Project Supervisor (PS) was responsible for the conduct of the study on a daily basis.</p>
<p><b>Project Co-ordinator (PC)</b>            Jonathan Orchard            Abundance &amp; Health Ltd            22 Northumberland Rd            Ballsbridge            Dublin            Dublin 4            Ireland</p>	<p>The Project Co-ordinator (PC) was the primary point of contact on behalf of the Sponsor of this project and represented the Sponsor (Abundance &amp; Health Ltd) of this study.</p>
<p><b>Co-Project Co-ordinator (CPC)</b>            Shari Paulsen            2654 W. Horizon Ridge Pkwy Ste B5-108            Henderson,            NV 89052</p>	<p>The Co-Project Co-ordinator (CPC) was the secondary point of contact on behalf of the Sponsor of this project and represented the Co-Sponsor (LivOn Laboratories) of this study, should the PC have been unavailable for contact.</p>

**STUDY FLOW CHART**

<b>VISIT</b>	<b>Visit 1 Week 0</b>	<b>Visit 2 Week 4</b>	<b>Visit 3 Week 8</b>	<b>Visit 4 Week 12</b>	<b>Visit 5 Week 16</b>
Issue of Diary cards and instruction sheet.	√				
Issue of the test article to use at home for the following 16 weeks	√				
Cutometry® assessments of the cheek area of the face	√	√	√	√	√
Profilometry assessments of the periorbital area of the face	√	√	√	√	√
Digital Image Capture (DIC) of the cheek and periorbital area of the face	√	√	√	√	√
Return to test centre with any unused test articles and Diary Sheet.					√

### INTRODUCTION & OBJECTIVE

The objective of this study was to assess the anti-ageing efficacy of varying dosage amounts of the test article in healthy volunteers with aging, non-firm skin when compared to a placebo product under blind conditions.

PRINCETON CONSUMER RESEARCH

## MATERIALS AND METHODS

### **1** STUDY DESIGN

A double-blind, randomised, placebo controlled, single centre, home-use study with assessments before, during, and after treatment.

### **2** SELECTION OF SUBJECTS

#### **2.1** Screening

Forty-five subjects were recruited into the study. Subjects had to satisfy the following inclusion and exclusion criteria, had to be prepared to accept the prohibitions and restrictions and give written informed consent (Appendices 1 and 2).

At the time of recruiting, subjects were advised that no products should be applied to the face the night before and on the days of the study.

The suitability of each potential subject was confirmed before his or her acceptance by review of a study specific pre-treatment questionnaire (Appendix 3).

#### **2.2** Inclusion criteria

- 2.2.1 Healthy volunteers with aging, non-firm skin, of either sex, aged over 18 years.
- 2.2.2 Completed written informed consent.

#### **2.3** Exclusion criteria

- 2.3.1 Pregnancy or lactation.
- 2.3.2 Inadequate precaution or procedure to prevent pregnancy (women of child bearing potential only).
- 2.3.3 A current skin disease of any type at the test site (e.g. acne, eczema, psoriasis).
- 2.3.4 Open cuts and abrasions on facial area.
- 2.3.5 Heavy alcohol consumption in the opinion of the investigator.
- 2.3.6 A fever in the last 12 hours, prior to start of the study.
- 2.3.7 Significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological, locomotor or psychiatric disease, which in the opinion of the Investigator would compromise the safety of the subject.
- 2.3.8 History of malignant disease.
- 2.3.9 Insulin-dependent diabetes.
- 2.3.10 Concurrent medication likely to affect the response to the test article or confuse the results of the study.
- 2.3.11 Allergic to any vitamin supplements or Soy and its derivatives
- 2.3.12 Participation in an anti-ageing study in the last 28 days.
- 2.3.13 Suffers of the genetic condition, hemochromatosis.
- 2.3.14 Users of Vitamin C supplements for up to and including 2 months prior to study start date.

#### **2.4** Prohibitions and restrictions – for the duration of the study

- 2.4.1 No deliberate exposure of the facial area to natural sunlight or to other sources of UV light, tanning booths or sun beds and no sun bathing during the study.
- 2.4.2 No use of any current facial care products, other than those issued, for duration of the study.

### **3** METHOD

#### **3.1** Test article

To the best of the Sponsor's knowledge, the test article did not contain any substances at levels of concentration requiring label declaration by the relevant regulatory authorities and was formulated and tested to comply with applicable regulations. Based on the information available, Princeton Consumer Research considered the test article to be safe for use in man.

Approximately 6,800 sachet samples of the test article and 8,500 sachets of the placebo were supplied by the Sponsor in a blinded fashion labelled as follows:

Group A	Group B	Group C
A1	B1	C1
A2	B2	C2
A3	B3	C3

The test articles was used as supplied by the Sponsor with each group taking one sachet X1 in the morning, one sachet of X2 in the daytime, and one sachet of X3 in the evening (where X was the group number). It was the responsibility of the Sponsor that the test articles met all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods or equipment, and that any costs including tax/duty were fully met by the Sponsor prior to receipt of the test article at Princeton Consumer Research. No liability with regard to safe receipt or costs involved in the carriage of goods or equipment to any Princeton Consumer Research site was accepted. At the end of the study period any unused test articles was disposed of after 28 days, unless requested otherwise by the Sponsor.

#### **3.2** Study procedure

Subjects attended the Test Centre on week 0 when they underwent cutometry (see Section 3.3) and profilometry (see Section 3.4) after which they will be issued with an instruction sheet, diary card and the test article, subjects were assigned test articles according to a randomisation which followed an adaptive biased randomisation design. They were instructed to use the issued test article at home for the following sixteen weeks as per the user instructions. On weeks 4, 8, 12 and 16 subjects returned to the Test Centre when they underwent post-treatment cutometry and profilometry assessments. On week 16 they returned any unused test article and their completed diary cards.

### 3.3 Cutometer® MPA 580

Measurements to study any changes in the viscoelastic properties of the skin by the test article were performed using the Cutometer® MPA 580 (Courage and Khazaka, Germany). The measuring principle is based on the suction method. Negative pressure is created in the device and the skin is drawn into the aperture of the probe. Inside the probe, the penetration depth is determined by a non-contact optical measuring system. This optical measuring system consists of a light source and a light receptor, as well as two prisms facing each other, which project the light from transmitter to receptor. The light intensity varies due to the penetration depth of the skin. The resistance of the skin to be sucked up by the negative pressure (firmness) and its ability to return into its original position (elasticity) are displayed as curves at the end of each measurement using Windows® based software.

### 3.4 Profilometry

Subjects were positioned on their backs with their head in line with the midline of their body. They were asked to close their eyes and maintain a neutral expression. Test sites were located using replica locating rings ensuring that each ring lies flat on the skin. The skin was not stretched or pulled during ring placement. Each ring was placed on the left and right periorbital areas of the face with the tab directed towards the back of the head. The foam and paper portions of each ring was aligned. Subjects were asked to turn their head so that the side of the head being evaluated is as horizontal as possible. The transparency film was then placed over the subject's face. Full locating rings, with centres, were then placed onto the film exactly over the site which had been selected. Landmarks were then traced onto the film using an indelible marker pen. The film was then removed from the face and labelled to identify the subject. The film was then stored in a cool, dry location until next use.

#### **Replica generation**

A skin marker pen was used to make dots through the film onto the face of the subject to enable exact location of the test sites. The ring was then positioned on the face and the replicas generated by filling the well in the centre of the ring with Silflo® (JS Davis, Hert) material. Once the replica had set completely (approximately 5 minutes) it was removed from the skin, allowed to dry skin side up for a few minutes, and then placed in a storage sleeve.

#### **Profilometric analysis**

The following equipment and software will be used:

PC: IBM compatible Pentium III 500 MHz with 256 MB memory running under Windows 2000 Professional.

Video: Cohu solid state B&W camera, 50mm lens/30mm extension, Coreco TCI Ultra frame grabber.

OPTIMAS v6.5, Microsoft EXCEL 2000, StatSoft STATISTICA 6.

A collimated light source directed at a 25° angle from the plane of the replica will be used. The replica will be placed in a holder that fixes the direction of the tab position of the replica so that the replica can be rotated to align the tab direction normal or parallel to the incident light direction. The replicas will be taken from the crow's feet area adjacent to each eye with the tab direction pointing toward the ear. The NORMAL sampling orientation provides texture measurements sensitive to the MAJOR, expression-induced lines (crow's feet). The PARALLEL sampling orientation provides texture measurements sensitive to the MINOR, fine lines.

The general background gradient of light intensity will be adjusted by applying a 1st order correction in the direction of the light propagation. The shadow texture produced by the oblique lighting of the negative replica will be analyzed by two types of assay methods:

##### **Method A**

Measuring the luminance along a set of 10 equal length parallel lines (passes) running across the replica parallel to the lighting direction. The variations in luminance will be treated as indicative of the roughness and analyzed by traditional surface roughness statistics:

**Rz** - the average maximum difference in luminance value for five equal length segments in each of the 10 lines traversing the sample.

**Ra** - the average deviation of the luminance curve about the mean luminance for the same 10 lines.

The "R" parameters are reported in the units of brightness (Grey Levels) ranging from 0 to 255.

**FSpace** - distance between markers placed on the lines at luminance changes indicative of fine lines.

**FNum** - number markers per mm placed on the lines at luminance changes indicative of fine lines.

#### **Method B**

The replica image area will then be divided into 10 equal width bands or sub-areas. The shadow-like features will be detected in each of these bands according to their luminance values being less than the detection threshold. Four parameters will be determined from the detected features.

**Spacing** - the mean distance in millimetres between adjacent detected features (i.e. spacing between the midpoints of adjacent shadowy features).

**Breadth** - the average breadth in millimetres of the detected features in millimetres. This parameter is proportional to the depth of the wrinkle producing the shadow.

**Shadows** - percent of the sampled replica area with luminance values less than the detection threshold. This is the relative area of shadows cast by the wrinkles and fine lines in the replica.

**NumWr** - the total number of features detected in the 10 bands or sub-areas used to calculate spacing and breadth

## 4 ADVERSE EVENTS

An adverse event would have been anything untoward that happened to a subject during the study, whether or not it was related to the administration of the test article.

An adverse reaction to test article would have been an adverse event occurring after the administration of the articles that was, or may have been, causally related to the test articles. If an adverse reaction had occurred, then macrophotographs would have been taken to record the reaction.

Every adverse event would have been recorded and then classified as Serious or Non-Serious.

### 4.1 Classification

An adverse event would be NON-SERIOUS (sub-classified as Mild, Moderate or Severe) unless it fell into one or more of the following categories when it would be classified as SERIOUS.

The event:

- resulted in death.
- was life threatening.
- required in-patient hospitalisation or prolongation of existing hospitalisation.
- resulted in persistent or significant disability /incapacity.
- was a congenital anomaly/birth defect.

Maximum intensity of NON-SERIOUS adverse events would be assigned to one of the following categories:

**Mild:** For example, an adverse event which was easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: For example, an adverse event which was sufficiently discomforting to interfere with normal everyday activities.

Severe: For example, an adverse event which prevented normal everyday activities.

#### **4.2 Reporting of adverse events**

In the event of a SERIOUS adverse event, the type, onset, severity, duration and outcome would have been recorded on a Serious Adverse Event Form and the Sponsor would have been notified within one working day, with a written report following within three working days. The significance of the event would have been discussed between the PI and the Sponsor, with the PI reserving the right to withhold further administration pending further information and discussion. The subject's General Practitioner would have also been informed as soon as it was reasonably practicable to do so.

All adverse events would have been listed in the results section of this report.

#### **4.3 Withdrawals**

The participation of a subject in this study may have been discontinued for any of the following reasons:

- the subject wished to withdraw.
- if, in the opinion of the Principal Investigator/Project Manager, it was in the best interests of the subject.
- suspected adverse effects from the test articles.
- inter-current illness.
- violation of the prohibitions and restrictions (see Section 2.4).
- development of an exclusion criterion.

Subjects were free to withdraw at any time and need not have given a reason, but every reasonable attempt would have been made to ascertain such reasons. The data for any subjects who were withdrawn from the study would have been included in this report but may have been excluded from final data analysis.

Subjects would not have been followed up after their withdrawal from the study, except in the case of a Serious Adverse Event. Withdrawn subjects would not have been replaced.

## **5 STUDY ETHICS**

### **5.1 Amendments to protocol**

Proposed changes or additions to the authorised protocol would have been subject to approval by the Principal Investigator and the Sponsor before implementation, except and insofar as Princeton Consumer Research Ltd reserved the right to make unilateral departure from the protocol to eliminate an apparent immediate hazard to subject health.

### **5.2 Declaration of Helsinki**

The study conformed to the requirements of the Declaration of Helsinki and its subsequent amendments (Appendix 6).

### **5.3 Subject consent**

Subjects were informed of the nature, purpose and known risk of the study both orally and in writing and gave their written informed consent before participating in the study (Appendices 1 and 2). Subjects were advised that they were free to withdraw from the study at any time without being obliged to give a reason. They were compensated for their time and inconvenience.

### **5.4 Indemnity provision**

The Sponsor was responsible, without regard to legal liability, and indemnified Princeton Consumer Research Ltd, or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration in health or well-being as a result of participation in this study, except and insofar as such claims arose as a result of any negligent act or omission on the part of Princeton Consumer Research Ltd employees or any persons undertaking or involved in the study by arrangement with Princeton Consumer Research Ltd.

## 6 QUALITY ASSURANCE

The study was carried out within the spirit of the ICH Guidelines on Good Clinical Practice (1996) and other recognised guidelines. The draft report has been peer reviewed for accuracy and completeness of presentation. Additionally, the study may also have been subject to the following Quality Assurance procedures:

- Review of protocol and protocol amendments for completeness, clarity and adequacy.
- Inspection and/or audit of critical phases of study conduct for compliance with protocol and Princeton Consumer Research Ltd procedures.

The Princeton Consumer Research Ltd Quality Assurance Manager would have informed Princeton Consumer Research Ltd management of any findings that may have affected the integrity of the study.

## 7 RETENTION OF DATA

All raw data generated by Princeton Consumer Research Ltd during the course of the study, and including protocol and final report, will be retained in the Princeton Consumer Research Ltd Archive for a minimum period of fifteen years from study completion. In the event of original data being transferred to the Sponsor at their request, exact copies will be so retained. At no time will archived data be destroyed without prior written approval of the Sponsor. All study data will be available at any time, by appointment, for inspection by the Sponsor or their authorised representative.

## 8 REFERENCES

1. International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use. Note for Guidance on Good Clinical Practice, Consolidated Guideline. Step 4, Consolidated Guideline, 1/5/96. CPMP/ICH/135/95.

**RESULTS**

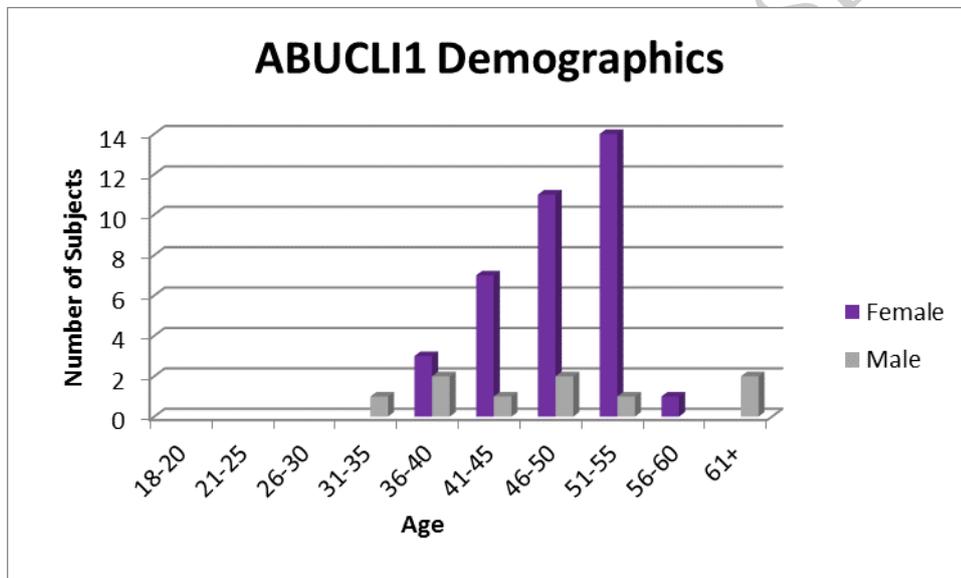
**1 LOCATION AND DATES OF THE STUDY**

The study was performed at Princeton Consumer Research Ltd, Harbour House, 23 Chandlers Quay, Maldon, Essex, CM9 4LF, United Kingdom between 4<sup>th</sup> August 2014 and 28<sup>th</sup> November 2014.

**2 SUBJECTS**

45 subjects were recruited into the study, 41 subjects completed the study. The age and sex composition of the subjects who completed the study is presented in Figure 1.

FIGURE 1: AGE COMPOSITION OF THE SUBJECTS COMPLETING THE STUDY



**3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY**

No adverse events were recorded. 4 subjects withdrew from the study for reasons unrelated to the test articles.

#### 4 ASSESSMENTS

Following data collection and receipt of raw data the study was unblinded by the Sponsor for reporting purposes. The blinding procedure is outlined in the appendices. Group A were dosed with one sachet of active product and two of placebo per day. Group B was the placebo control group. Group C were dosed with three sachets of active product per day.

##### 4.1 Cutometer readings

Mean assessment scores and their standard deviations are presented in Table 1. A Student t-test was performed on the Cutometer data to establish if a significant improvement in skin viscoelasticity (firmness and elasticity) had occurred after the use of the product at either dosage level. The statistical findings are presented in Table 2.

Differences were considered statistical significance when  $P < 0.05$ , therefore, the use of the test product in both low and high dose volumes showed a statistically significant improvement to skin viscoelasticity, with Group C performed to the highest level of efficacy. The Placebo control group showed no change in skin viscoelasticity, validating the findings.

Individual Cutometer readings before and after use of the test article are presented in Appendix 7.

TABLE 1 – MEAN CUTOMETER READINGS BEFORE, DURING AND AFTER 16 WEEKS USE OF THE TEST ARTICLE

	W0	W4	W8	W12	W16
Group A	0.557	0.609	0.653	0.711	0.752
Group B	0.558	0.560	0.559	0.559	0.559
Group C	0.552	0.662	0.773	0.888	0.892

TABLE 2 – STATISTICAL ANALYSIS OF CUTOMETER DATA COMPARED TO BASELINE VALUES.

	W4	W8	W12	W16
Group A	2.04E-04	3.91E-07	4.14E-09	3.96E-11
Group B	6.99E-01	8.89E-01	7.97E-01	8.76E-01
Group C	2.06E-10	5.35E-13	3.59E-14	1.52E-14

TABLE 3 – PERCENTAGE CHANGE OF SKIN VISCOELASTICITY COMPARED TO BASELINE.

	W4	W8	W12	W16
Group A	9.31%	17.32%	27.73%	34.99%
Group B	0.30%	0.08%	0.18%	0.12%
Group C	19.96%	40.02%	60.88%	61.47%

## 4.2 Profilometry Assessments

Mean assessment scores for Rz values are presented in Table 1. A Student t-test was performed on the Rz profilometry values to establish if a significant reduction in fine lines and wrinkles had occurred after the use of the product at either dosage level. The statistical findings are presented in Table 2.

Differences were considered statistical significance when  $P < 0.05$ , therefore, the use of the test product in both low and high dose volumes showed a statistically significant reduction in the appearance of fine lines and wrinkles, with Group C performing to the highest level of efficacy. The Placebo control group showed no change, validating the findings.

Individual profilometry assessments before and after use of the article are presented in Appendix 8.

TABLE 1 – PROFILOMETERY VALUES BEFORE, DURING AND AFTER 16 WEEKS USE OF THE TEST ARTICLE

	W0	W4	W8	W12	W16
Group A	114.0	110.8	108.9	106.7	105.4
Group B	112.4	112.2	113.0	111.9	112.6
Group C	113.2	109.5	103.5	98.6	97.9

TABLE 2 – STATISTICAL ANALYSIS OF PROFILOMETERY DATA COMPARED TO BASELINE VALUES.

	W4	W8	W12	W16
Group A	5.15E-09	7.70E-10	2.62E-10	1.70E-11
Group B	7.11E-01	1.93E-01	1.90E-01	6.21E-01
Group C	1.17E-09	3.06E-12	6.32E-14	6.18E-14

TABLE 3 – PERCENTAGE CHANGE OF FINE LINES AND WRINKLES COMPARED TO BASELINE.

	W4	W8	W12	W16
Group A	2.82%	4.45%	6.39%	7.52%
Group B	0.14%	-0.55%	0.41%	-0.21%
Group C	3.28%	8.58%	12.87%	13.56%

### CONCLUSION

It can be concluded that the use of the test article (Altrient C / LivOn Labs Liposomal Vitamin C) in either dosage tested shows a statistically significant improvement to the level of skin viscoelasticity and a statistically significant reduction in the appearance of fine lines and wrinkles. Following 16 weeks of regular routine usage the results continued to show an improvement with a slower rate of improvement being observed past 12 weeks of usage.

PRINCETON CONSUMER RESEARCH

APPENDIX 1: SUBJECT CONSENT FORM

Subject  
Number

**PRINCETON CONSUMER RESEARCH**  
**Harbour House**  
**23 Chandlers Quay**  
**Maldon CM9 4LF**  
**United Kingdom**

SUBJECT CONSENT for ABUCL11 (A HOME-USE STUDY)

Name of Subject:.....

The nature of the study and procedures required of the volunteers, together with possible hazards, have been described to me by the members of Princeton Consumer Research staff named below and I have had an opportunity to discuss these matters. Additionally I have been given a copy of the Subject Information Sheet for this study.

I understand that the study will be conducted in compliance with the Standard Operating Procedures of Princeton Consumer Research which are available to me at my request and that I may withdraw from the study at any time without having to give a reason.

I understand that every effort has been made and will continue to be made by the Sponsors of this study and by Princeton Consumer Research personnel to ensure that the health status of the volunteers will not be adversely affected by their participation in this study. I understand that in the unlikely event of a significant deterioration in health being caused by my participation in the study I will be given reasonable and appropriate treatment and may be compensated financially.

I also understand that all information given by me and all observations made on my health will be maintained in strictest confidence and in accordance with normal practice. This means the Sponsor of this study or an authorised representative of the Sponsor and/or representatives of regulatory authorities may request access to this information for checking purposes relevant to the study. Any such information will not identify me by name and this checking will be performed under the supervision of Princeton Consumer Research.

I agree to comply with the prohibitions and restrictions on the Subject Information Sheet and confirm that the information given on my questionnaires is true. I hereby consent to take part in the study and to carry out the procedures required of me. I also consent to my General Practitioner being informed of my participation and of any findings considered to require medical attention.

I consent to Princeton Consumer Research processing sensitive personal information that may be held by them or given by myself at the time of enrolment onto the above named study. This information will be treated as confidential to Princeton Consumer Research and will not be divulged to any third party unless required by Regulatory agencies. In all cases any information given will not identify me by name. This consent satisfies the requirement of the Data Protection Act 1998.

Signed: .....

Date: .....

I have explained the nature of the study to the above-named volunteer who has received a copy of the Subject Information Sheet.

Signed: .....

Date: .....

**APPENDIX 2: SUBJECT INFORMATION SHEET – ABUCLII**

Please read this sheet carefully. It is a written explanation of the way in which the study will be performed. You will also be given an oral explanation of the study from members of Princeton Consumer Research staff and an opportunity to ask questions. If any further questions occur to you, please either ring the office or ask at the test centre. The aim of the study is to assess the comparative effectiveness of different dosages of a test article on skin firmness and wrinkles.

Visit 1 (Week 0) On your visit to the Test Centre we will assess your cheek area to make sure that you have non-firm skin. We ask you not to wear any make-up on this day or to have used any facial skin care products and/or make-up the night before. We will perform two completely painless procedures where we will apply a small probe to your facial cheek area and take a plaster cast of your crow's feet area.

You will then be given a diary sheet and the test article and be asked to use as per the instruction leaflet for the following 16 weeks at home.

Visits 2, 3, 4 On weeks 4, 8, and 12, we will again perform the same procedures where we will apply a small probe to your cheek area and take a plaster mould of your crow's feet area.

Visit 5 (Week 16) We will then perform the procedure where we will apply a small probe to the cheek area of the face. After this, we will ask you to complete a questionnaire about the test article. You will then be asked to return your diary sheet along with any unused test article.

**Possible unwanted effects**

In the very unlikely event that you are, "hypersensitive", to the test article you might experience some shortness of breath, flushing and possibly dizziness. If this does happen you should stop using the test article. Should the shortness of breath become severe and you feel unwell contact your own doctor without delay.

**Prohibitions and restrictions**

**Do not** use a sun bed, tanning booth or sunlamp during the study and keep your face out of natural sunlight before the study.

**Do not** sun bathe.

**PLEASE TURN OVER**

APPENDIX 2 - continued**SUMMARY INFORMATION SHEET – ABUCL11**

TEST ARTICLE:	An anti-ageing product.
REGISTRATION STATUS:	Not applicable - Consumer Products.
TITLE/PURPOSE OF TRIAL:	To assess how well the test article firms your skin and smoothes wrinkles.
BRIEF DESCRIPTION OF PROCEDURE:	See over.
ATTENDANCE:	5 visits (approximately 2 hours for the first visit and 1 hour for the remaining visits).
NUMBER OF PERSONS PARTICIPATING:	Approximately 48 subjects.
POSSIBLE RISKS/DISCOMFORTS:	Irritation or allergic reaction to the components of the test article. Skin reddening which would disappear shortly after the test is over. In the very unlikely event that you are, “hypersensitive”, to a component of the test article you might experience some shortness of breath, flushing and possibly dizziness.
PAYMENT DETAILS:	£xx for completion of the study (If subject is dropped due to a reaction that, in the opinion of Princeton Consumer Research, is related to the product, then £xx is paid).  Payments will only be made at the end of the study.

**PROHIBITIONS AND RESTRICTIONS:**

**Do not** use a sun bed, tanning booth or sunlamp during the study and keep your face out of natural sunlight before the study.

**Do not** sun bathe.

**Do not** use ANY of your current facial care products for duration of the study, e.g. toners, moisturisers, anti-ageing serums, or skin lightening creams.

**Do not** wear any facial skin care products and/or make-up the night before and on the day of all visits during the study.

THE PROJECT SUPERVISOR IN CHARGE OF THIS STUDY, MANDIE MAYES, MAY BE CONTACTED DURING NORMAL WORKING HOURS ON **01621 859230** (ANSWERPHONE OUT OF OFFICE HOURS).

APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE

FOR OFFICE USE ONLY

Subject's Initials

--	--	--

**STRICTLY CONFIDENTIAL**

In order for us to judge that you are healthy to take part in the study and that any medication you take is not likely to interfere with your test responses, we need information on your health. We may need to contact you again for further details but please answer all the questions as fully as possible.

**STUDY No: ABUCLII**

1. Do you have any skin problems at present on your face, e.g. acne, pigment changes, psoriasis, eczema, skin cancer? ..... **YES**  **NO**

**IF 'YES'** please give details of condition and/or treatment, eg ointment/cream.

\_\_\_\_\_

2. Are you regularly taking any medicines, drugs (including street drugs) or oral contraceptives at present? **YES**  **NO**

**IF 'YES'** please give details eg name, how often taken.

\_\_\_\_\_

3. Have you ever had any operations?..... **YES**  **NO**

**IF 'YES'**, please state when and for what.

\_\_\_\_\_

4. Have you ever had hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological, locomotor, immune deficiency or psychiatric disease? ..... **YES**  **NO**

**IF 'YES'**, please give details.

\_\_\_\_\_

5. Have you consulted your doctor within the last 6 months? ..... **YES**  **NO**

**IF 'YES'**, please state when and for what.

\_\_\_\_\_

6. Have you ever been examined for suspected cancer? ..... **YES**  **NO**

**IF 'YES'**, please state when and for what. Was this confirmed as malignant?

\_\_\_\_\_

7. Have you ever had a reaction to drugs, medicine or vitamin supplements?..... **YES**  **NO**

**IF 'YES'**, which drug and explain reaction and duration.

\_\_\_\_\_

8. Do you suffer from haemochromatosis type 1?..... **YES**  **NO**

9. Do you consider yourself to have wrinkled skin?..... **YES**  **NO**

**APPENDIX 3:** continued

10. How many units of alcohol do you consume **on average** in a week? \_\_\_\_\_  
 (A unit is ½ pint of beer or 1 glass of wine or 1 'short')

What is your maximum daily consumption? \_\_\_\_/units **OR** do you only drink on special occasions?

11.

a....Are you pregnant or breast feeding at present? **YES**  **NO**

b. ... Is it possible that you will become pregnant? **YES**  **NO**

c....**If NO** – Contraceptive Pill  Name: ..... Condoms  Sterilised   
 Abstinence  Vasectomy (partner)  Post Menopausal  Other\*  - please specify)

12. Have you ever had any skin problems related to the use of any of the following types of material?

Material	YES	NO	When? - Which products? – What happens?
Moisturiser Products			
Anti-wrinkle products			
Firming products			
Fruit Jucies such as Orange, Grapefruit etc			
Other-please specify			

13. Have you participated in an anti-wrinkle study in the last 28 days? ..... **YES**  **NO**

**If 'YES'**, which site was used? \_\_\_\_\_

14. a) Date of birth: \_\_\_\_\_ b) Age: \_\_\_\_\_

15. I confirm that to the best of my knowledge the information I have provided is correct.

16. Signature..... Date.....

**PLEASE HELP US TO PROCESS YOUR APPLICATION QUICKLY BY CHECKING THAT YOU HAVE ANSWERED ALL OF THE QUESTIONS. ALL INFORMATION IS CONFIDENTIAL**

**FOR OFFICE USE ONLY**

Questionnaire checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Medication checked by: \_\_\_\_\_ Date: \_\_\_\_\_

Subject can/cannot proceed with study. Reason for exclusion: \_\_\_\_\_

**TO BE COMPLETED WHEN BOOKING VOLUNTEER ONTO STUDY**

Has the volunteer had a fever in the last 12 hours? \_\_\_\_\_ **YES**  **NO**

Has the volunteer used self tanning lotion on the face in the last week? **YES**  **NO**

Has the volunteer taken any medication in the last 7 days? **YES**  **NO**

Comments: \_\_\_\_\_

Subject accepted onto study by: \_\_\_\_\_ Date: \_\_\_\_\_

Subject No:

APPENDIX 4: TEST ARTICLE INGREDIENT LISTING**1. ALTRIENT VITAMIN C**

WATER

VITAMIN C AS SODIUM ASCORBATE 1G

PHOSPHOLIPIDS (FROM SOY LECITHIN) 1G OF WHICH -

- PHOSPHATIDYLCHOLINE 500MG
- PHOSPHATIDYLETHANOLAMINE 144MG
- PHOSPHATIDYLINOSITOL 24MG

ALCOHOL(12% W/W)

XANTHAN GUM

EDTA

APPENDIX 5: USEAGE INSTRUCTIONS

Subjects will be given a set of usage instructions in the product packs.

**All Groups –**

Please consume one sachet of the product 3 times daily, once in the morning, afternoon and evening. The product can be consumed neat or mixed with water/juice depending on personal preference.

PRINCETON CONSUMER RESEARCH

APPENDIX 6: DECLARATION OF HELSINKI**WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI**  
**Ethical Principles for Medical Research Involving Human Subjects**

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:  
29th WMA General Assembly, Tokyo, Japan, October 1975  
35th WMA General Assembly, Venice, Italy, October 1983  
41st WMA General Assembly, Hong Kong, September 1989  
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996  
52nd WMA General Assembly, Edinburgh, Scotland, October 2000  
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)  
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)  
59th WMA General Assembly, Seoul, October 2008

**A. INTRODUCTION**

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.
6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
8. In medical practice and in medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.
10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

APPENDIX 6 - Continued**B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH**

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

APPENDIX 6 - Continued

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

APPENDIX 6 - Continued

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

**C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE**

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
- The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
  - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.
33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

APPENDIX 7: INDIVIDUAL CUTOMETER DATA FOR GROUP A (LOW DOSAGE)

Subject	Treatment A				
	Uv/Ue	Uv/Ue	Uv/Ue	Uv/Ue	Uv/Ue
	W0	W4	W8	W12	W16
1	0.542	0.568	0.614	0.673	0.709
2	0.516	0.570	0.616	0.674	0.707
3	0.569	0.620	0.652	0.744	0.774
4	-	-	-	-	-
5	0.536	0.586	0.633	0.707	0.745
6	0.521	0.605	0.648	0.727	0.764
7	0.558	0.630	0.662	0.716	0.752
8	0.548	0.593	0.631	0.672	0.728
9	0.557	0.653	0.708	0.750	0.775
10	0.526	0.664	0.707	0.765	0.805
11	0.580	0.634	0.685	0.748	0.782
12	0.597	0.597	0.649	0.706	0.751
13	0.581	0.592	0.643	0.701	0.755
14	0.588	0.635	0.688	0.718	0.766
15	0.577	0.575	0.610	0.657	0.711
<b>MEAN</b>	0.557	0.609	0.653	0.711	0.752
<b>St Dev</b>	0.026	0.031	0.033	0.034	0.029
<b>% Change</b>		9.31%	17.32%	27.73%	34.99%
<b>P-Value vs 0</b>		2.04E-04	3.91E-07	4.14E-09	3.96E-11

APPENDIX 7: INDIVIDUAL CUTOMETER DATA FOR GROUP B (PLACEBO)

Subject	Treatment B				
	Uv/Ue	Uv/Ue	Uv/Ue	Uv/Ue	Uv/Ue
	W0	W4	W8	W12	W16
1	-	-	-	-	-
2	0.585	0.568	0.591	0.584	0.597
3	0.507	0.492	0.516	0.517	0.521
4	0.512	0.499	0.528	0.489	0.517
5	0.532	0.543	0.522	0.535	0.521
6	0.568	0.552	0.562	0.556	0.579
7	0.552	0.550	0.575	0.548	0.539
8	0.544	0.554	0.525	0.543	0.534
9	0.507	0.530	0.508	0.518	0.495
10	0.585	0.568	0.580	0.570	0.610
11	0.595	0.615	0.583	0.618	0.572
12	0.596	0.609	0.595	0.605	0.584
13	0.599	0.615	0.606	0.620	0.624
14	-	-	-	-	-
15	0.576	0.585	0.573	0.568	0.574
<b>MEAN</b>	0.558	0.560	0.559	0.559	0.559
<b>St Dev</b>	0.035	0.040	0.034	0.040	0.040
<b>% Change</b>		0.30%	0.08%	0.18%	0.12%
<b>P-Value vs 0</b>		6.99E-01	8.89E-01	7.97E-01	8.76E-01

APPENDIX 7: INDIVIDUAL CUTOMETER DATA FOR GROUP C (HIGH DOSAGE)

Subject	Treatment C				
	Uv/Ue	Uv/Ue	Uv/Ue	Uv/Ue	Uv/Ue
	W0	W4	W8	W12	W16
1	0.555	0.640	0.730	0.859	0.872
2	0.563	0.646	0.780	0.921	0.926
3	0.537	0.642	0.775	0.922	0.922
4	0.593	0.728	0.826	0.940	0.938
5	0.565	0.688	0.812	0.934	0.931
6	-	-	-	-	-
7	0.565	0.643	0.751	0.886	0.895
8	0.535	0.640	0.751	0.847	0.837
9	0.592	0.707	0.811	0.942	0.954
10	0.554	0.699	0.813	0.890	0.883
11	0.503	0.602	0.682	0.783	0.797
12	0.573	0.687	0.819	0.924	0.931
13	0.550	0.684	0.811	0.910	0.898
14	0.538	0.617	0.723	0.798	0.807
15	0.508	0.651	0.741	0.882	0.892
<b>MEAN</b>	0.552	0.662	0.773	0.888	0.892
<b>St Dev</b>	0.027	0.036	0.044	0.051	0.049
<b>% Change</b>		19.96%	40.02%	60.88%	61.47%
<b>P-Value vs 0</b>		2.06E-10	5.35E-13	3.59E-14	1.52E-14

APPENDIX 8: INDIVIDUAL PROFILOMETERY DATA FOR GROUP A (LOW DOSAGE)

Subject	Treatment A				
	Rz (PARALLEL DIRECTION)				
	W0	W4	W8	W12	W16
1	100.0	96.0	95.0	93.0	93.0
2	111.0	108.0	107.0	105.0	103.0
3	124.0	120.0	119.0	117.0	117.0
4	-	-	-	-	-
5	125.0	121.0	120.0	118.0	116.0
6	101.0	99.0	98.0	95.0	93.0
7	110.0	106.0	103.0	101.0	100.0
8	125.0	121.0	118.0	115.0	115.0
9	113.0	110.0	107.0	105.0	103.0
10	104.0	101.0	100.0	98.0	96.0
11	124.0	120.0	118.0	115.0	115.0
12	109.0	107.0	104.0	101.0	99.0
13	106.0	102.0	100.0	97.0	95.0
14	119.0	117.0	115.0	114.0	113.0
15	125.0	123.0	121.0	120.0	118.0
<b>MEAN</b>	114.0	110.8	108.9	106.7	105.4
<b>St Dev</b>	9.5	9.4	9.2	9.5	9.7
<b>% Change</b>		2.82%	4.45%	6.39%	7.52%
<b>P-Value vs 0</b>		5.15E-09	7.70E-10	2.62E-10	1.70E-11

APPENDIX 8: INDIVIDUAL PROFILOMETERY DATA FOR GROUP B (PLACEBO)

Subject	Treatment B				
	Rz (PARALLEL DIRECTION)				
	W0	W4	W8	W12	W16
1	-	-	-	-	-
2	101.0	99.0	99.0	100.0	103.0
3	116.0	115.0	118.0	117.0	114.0
4	123.0	123.0	124.0	123.0	122.0
5	114.0	115.0	112.0	114.0	116.0
6	113.0	111.0	113.0	112.0	112.0
7	100.0	102.0	102.0	100.0	102.0
8	115.0	115.0	116.0	113.0	114.0
9	112.0	111.0	110.0	110.0	113.0
10	110.0	112.0	112.0	108.0	108.0
11	119.0	118.0	121.0	121.0	121.0
12	118.0	117.0	119.0	118.0	120.0
13	115.0	114.0	117.0	115.0	115.0
14	-	-	-	-	-
15	105.0	107.0	106.0	104.0	104.0
<b>MEAN</b>	112.4	112.2	113.0	111.9	112.6
<b>St Dev</b>	6.8	6.5	7.3	7.4	6.7
<b>% Change</b>		0.14%	-0.55%	0.41%	-0.21%
<b>P-Value vs 0</b>		7.11E-01	1.93E-01	1.90E-01	6.21E-01

APPENDIX 8: INDIVIDUAL PROFILOMETERY DATA FOR GROUP C (HIGH DOSAGE)

Subject	Treatment C				
	Rz (PARALLEL DIRECTION)				
	W0	W4	W8	W12	W16
1	117.000	114.000	109.000	105.000	104.000
2	113.000	108.000	101.000	96.000	96.000
3	114.000	111.000	105.000	99.000	97.000
4	109.000	106.000	101.000	97.000	97.000
5	116.000	112.000	106.000	100.000	98.000
6	-	-	-	-	-
7	101.000	98.000	91.000	85.000	85.000
8	106.000	103.000	96.000	92.000	90.000
9	115.000	112.000	107.000	102.000	102.000
10	120.000	115.000	108.000	104.000	104.000
11	101.000	98.000	93.000	87.000	86.000
12	111.000	106.000	101.000	97.000	96.000
13	121.000	116.000	109.000	104.000	104.000
14	122.000	119.000	112.000	108.000	107.000
15	119.000	115.000	110.000	105.000	104.000
<b>MEAN</b>	113.2	109.5	103.5	98.6	97.9
<b>St Dev</b>	6.9	6.6	6.5	6.9	6.9
<b>% Change</b>		3.28%	8.58%	12.87%	13.56%
<b>P-Value vs 0</b>		1.17E-09	3.06E-12	6.32E-14	6.18E-14

**Vitamin C Skin Firming Study sponsored by Abundance & Health LTD and LivOn Laboratories Inc.  
Study Product Information and Instructions**

ACTIVE: ACV0214/039 EXP 1215

PLACEBO: ACV0614/227 EXP 1215 & ACV0714/231 EXP 1215

- Study is 16 weeks, total of 112 days
- 3 Groups: A, B, C. Each group has 15 participants, taking 3 packets per day.
  - Group A = 1 Active + 2 Placebo per day
  - Group B = 3 Placebo per day
  - Group C = 3 Active per day

**Group A** = 1,800 packets ACTIVE + 3,600 packets PLACEBO

Package Group A, 15 Sets (total of 15 cases):

Box A1 = 4 cartons ACTIVE ACV0214/039

Box A2 = 4 cartons PLACEBO ACV0614/227

Box A3 = 4 cartons PLACEBO ACV0714/231

**Group B** = 5,400 packets of PLACEBO

Package Group B, 15 Sets (total of 15 cases):

Box B1 = 4 cartons PLACEBO ACV0614/227

Box B2 = 4 cartons PLACEBO ACV0614/227

Box B3 = 4 cartons PLACEBO ACV0614/227

**Group C** = 5,400 packets of ACTIVE

Package Group C, 15 Sets (total of 15 cases):

Box C1 = 4 cartons ACTIVE ACV0214/039

Box C2 = 4 cartons ACTIVE ACV0214/039

Box C3 = 4 cartons ACTIVE ACV0214/039

**Instructions:**

1. Separate the number of cartons you need from each Lot for each Group.
2. Print the box codes on stickers in a large font size (at least 50pt). You will need 60 stickers per box code, for a total of 540 stickers.
3. Label the top display panel of each carton with the appropriate box code (A1, A2, A3, B1, B2, B3, C1, C2, C3).
4. Have 1 person double-check the codes correspond to the correct Lot numbers.
5. For each participant, package 1 complete set of study product in a case. There will be a total of 15 cases for each group. For example, Group A will have 15 cases, and each case will include 4 cartons of A1, 4 cartons of A2, and 4 cartons of A3.
6. Cases must not include LivOn's Lot information. Label each case to say GROUP A, GROUP B or GROUP C in a large font. It is OK to overlabel existing LivOn cases with a permanent label.
7. Before sealing the cases, have at least 2 people check that each box includes the correct number of cartons per Lot/Box code. Do NOT rely on the Box codes for this count, check the actual Lot numbers.
8. Pack master shippers with no more than 6 cases. You will have 7 master shippers with 6 cases each, and 1 master shipped with 3 cases. Ship by FedEx Intl Economy to:

**F.A.O. Julia Wood**

**Aspen Clinical Research,**

**Harbour House,**

**23 Chandler Quay,**

**Maldon,**

**Essex CM9 4LF**