

**A RANDOMIZED HOME USE STUDY IN TWO PARALLEL GROUPS, CONSISTING OF 30 HEALTHY SUBJECTS AGED 35-70, TO ASSESS THE EFFICACY OF ONE ANTI-WRINKLE REGIMEN COMPARED TO A PLACEBO REGIMEN.**

**R X G A W R 1**

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 were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Barrie Drewitt  
(Principal Investigator)



Date ..... 5th Aug 2015

Danny McCamlie  
(Project Manager)

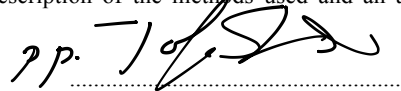


Date ..... 5th Aug 2015

**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.

Reece Statham  
(Quality Assurance Manager)



Date ..... 5th Aug 2015

Prepared for:  
RxGenesys  
175 SW 7th St  
Suite 2102  
Miami, FL 33130

Prepared by:  
Princeton Consumer Research  
Harbour House  
23 Chandlers Quay  
Maldon  
Essex CM9 4LF  
United Kingdom

Draft Report v1: 19<sup>th</sup> June 2015  
Draft Report v2: 25<sup>th</sup> June 2015  
Draft Report v3: 26<sup>th</sup> June 2015  
Draft Report v4: 6<sup>th</sup> July 2015  
Final Report: 23<sup>rd</sup> July 2015  
Final Report v2: 30<sup>th</sup> July 2015

## CONTENTS

1	SUMMARY .....	3
2	KEY STUDY PERSONNEL AND RESPONSIBILITIES.....	6
3	STUDY FLOW CHART .....	7
4	INTRODUCTION AND OBJECTIVE .....	7
5	STUDY DESIGN.....	8
6	SELECTION OF SUBJECTS.....	8
7	TEST ARTICLES .....	9
8	METHOD .....	10
9	STUDY ASSESSMENTS/INSTRUMENTATION .....	11
10	ADVERSE EVENTS.....	15
11	STUDY ETHICS.....	16
12	R E S U L T S .....	17
	APPENDIX 1: SUBJECT CONSENT FORM.....	24
	APPENDIX 2: SUBJECT INFORMATION SHEET .....	27
	APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE .....	28
	APPENDIX 4: USAGE INSTRUCTIONS .....	29
	APPENDIX 5: TEST ARTICLES INGREDIENT LISTING .....	30
	APPENDIX 6: TREATMENT SITE RANDOMISATION .....	33
	APPENDIX 7: SELF PERCEPTION QUESTIONNAIRE (SPQ).....	34
	APPENDIX 8: DECLARATION OF HELSINKI .....	38
	APPENDIX 10: RAW DATA .....	42

## 1 SUMMARY

Title:	A randomized home use study in two parallel groups, consisting of 30 healthy subjects aged 35-70, to assess the efficacy of one anti-wrinkle regimen compared to a placebo regimen.
Study design:	Double-blind study, using objective instrumental and visual assessments, and subjective perception assessments of 71 healthy subjects with aged skin over a usage period of 8 weeks, to compare the efficacy of one anti-ageing regime compared to a placebo regime using a bi-lateral facial design.
Test Groups:	1. Active Regimen – A1 Cleanser, A2 Moisturizer, A3 Illuminator, A4 Anti-Aging 2. Placebo Regimen – B1 Cleanser, B2 Moisturizer, B3 Illuminator, B4 Anti-Aging
Dose regime:	Each subject followed a 8-week usage schedule according to the usage instructions provided.
Duration of study:	8 week treatment period, with assessments at Baseline, Week 2, Week 4 and Week 8.
Number of subjects:	71 subjects enrolled onto the study with 68 subjects completing the study.
Type of subjects:	Healthy subjects of either sex aged 35 to 70 years who exhibited moderate to advanced photoaging according to the Glogau scale.
Observations:	<p>Profilometry assessments were taken on all study visits to assess the appearance of fine lines and wrinkles using the generated Silflo replicas of the periorbital area.</p> <p>VISIA photography was taken and analysed by Canfield for assessments of pores.</p> <p>Visual grading according to the Glogau scale of visible photodamage was conducted by a qualified assessor at all study time points.</p> <p>Cutometry assessments of skin firmness and elasticity were conducted using a Courage and Khazaka Cutometer MPA 580.</p> <p>Corneometer assessments of skin moisture content and the humectant properties of the regimes were conducted using a Courage and Khazaka Corneometer CM825.</p> <p>Chromameter assessments of skin tone and skin brightness were conducted using a Courage and Khazaka CR300.</p> <p>Self-perception Questionnaires were issued to each subject as designed by the sponsor to gather subjective opinions of the regimes used.</p>

Method:	At baseline, Informed Consent was obtained and verification of study eligibility was confirmed. Subjects underwent photography and instrumentation measurements/observations, with a subset of 10 subjects undergoing videography. Subjects were provided with the test articles that had been randomly assigned to them and a daily diary card to ensure compliance. Subjects were required to return to the testing facility for additional measurements/assessments on study days 14, 28, and 56.
Duration of study:	Study Started: w/c 23 <sup>rd</sup> February 2015 Study Ended: w/e 24 <sup>th</sup> April 2015
Location:	Princeton Consumer Research Ltd. Princeton Forrestal Center 307 College Road East Princeton New Jersey 08540
Adverse Events:	No adverse events were recorded for any subject during the study.
Conclusion:	Following between and within treatment data analysis the following claims have been supported by the study. The full discussion is presented in the results section of this report.

- Visibly reduces the appearance of fine lines & wrinkles by up to 19.27% in 2 weeks
- Visibly reduces the appearance of fine lines & wrinkles by up to 38.32% in 4 weeks
- Visibly reduces the appearance of fine lines & wrinkles by up to 56.34% in 8 weeks
- Reduces the appearance of crow's feet fine lines and wrinkles by up to 4.75% in 2 weeks
- Reduces the appearance of crow's feet fine lines and wrinkles by up to 8.57% in 4 weeks
- Reduces the appearance of crow's feet fine lines and wrinkles by up to 13.99% in 8 weeks
- Reduces the visible signs of photoageing by 19.27% in 2 weeks
- Reduces the visible signs of photoageing by 38.32% in 4 weeks
- Reduces the visible signs of photoageing by 56.34% in 8 weeks
- Increases skin's elasticity by up to 25.22% in 4 weeks
- Increases skin's elasticity by up to 43.12% in 8 weeks
- Increases skin's firmness by up to 25.22% in 4 weeks
- Increases skin's firmness by up to 43.12% in 8 weeks
- Helps to maintain 122.24% of normal level of moisturization and hydration over 2 weeks
- Helps to maintain 106.38% of normal level of moisturization and hydration over 4 weeks
- Helps to maintain 108.93% of normal level of moisturization and hydration over 8 weeks
- Reduction of 6.69% of pigment by 14 days
- Anti-wrinkle
- Visibly increases the appearance of skin smoothness, softness, radiance, firmness, and tone
- Visibly reduces the appearance of fine lines & wrinkles
- Improves elasticity over time
- Skin complexion becomes more luminous and radiant over time
- Brightens skin tone over time
- Lightens skin tone over time
- Promotes even skin tone over time
- Promotes a glowing complexion over time
- Maintains and enhances moisturization
- Moisturizes over time
- Combats dehydration over time
- Promotes and maintains optimal hydration levels in the skin

For SPQ data any claim qualified by the relevant time point and percentage of respondents answering favourably is substantiated, such as shown below for exemplar claims based on Week 8 assessments.

- 94% Noticed a reduction in the appearance of deep wrinkles\*
- 100% Noticed a reduction in the appearance of fine lines\*
- 81% Noticed a reduction in the appearance of age spots\*
- 88% Noticed a reduction in the appearance of pores\*
- 100% Noticed an improvement in the level of moisture of their skin\*
- 91% Noticed a visible improvement of their skin's glow\*
- 84% Noticed a visible improvement of their skin's radiance\*
- 94% Noticed a visible improvement in their skin's evenness\*
- 94% Noticed a visible improvement of their skin's radiance\*

- 94% Noticed a visible improvement of their overall complexion\*
- 88% Noticed a visible improvement of their skin's elasticity\*
- 91% Noticed a visible improvement of their skin's texture\*
- 65% of people who use makeup Noticed Makeup application was easier\*
- 88% Noticed a visible improvement of their skin's smoothness\*
- 91% Noticed a visible improvement of their skin's softness\*
- 94% Would recommend the regimen to a friend\*

\*X% of 32 users following 8 weeks use.

PRINCETON CONSUMER RESEARCH

## 2 KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key personnel	General responsibilities
<p><b>Principal Investigator (PI)</b>            Barrie Drewitt            Princeton Consumer Research            Princeton Forrestal Center            307 College Road East            Princeton            New Jersey            08540            Tel: 609-455-1112</p>	<p>The Principal Investigator (PI) will be responsible for ensuring sufficient resources are available to conduct the study according to Good Clinical Practice (GCP), for the study design, compiling the results and writing the clinical report.</p>
<p><b>Project Supervisor (PS)</b>            Diane Benevento            Princeton Consumer Research            Princeton Forrestal Center            307 College Road East            Princeton            New Jersey            08540            Tel: 609-455-1112</p>	<p>The Project Supervisor (PS) will be responsible for the conduct of the study on a daily basis.</p>
<p><b>Project Manager (PM)</b>            Danny McCamlie            Director of Project Management            Princeton Consumer Research Inc.            Harbour House            23 Chandlers Quay            Maldon            Essex CM9 4LF            United Kingdom</p>	<p>The Project Manager (PM) will be involved with the study design, compiling the results and writing the clinical report.</p>
<p><b>Project Co-ordinator (PC)</b>            Kirsty Barany            RxGenesys            175 SW 7th St            Suite 2102            Miami, FL 33130             kbarany@rxgenesys.com</p>	<p>The Project Co-ordinator (PC) will be the primary point of contact on behalf of the Sponsor of this project and will represent the Sponsor (RxGenesys) of this study.</p>