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## ***TA-65<sup>®</sup> for Skin* Reduces the Appearance of Aging Effects by Increasing Firmness and Reducing Wrinkles and Redness**

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## Abstract:

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TA-65<sup>®</sup> *for Skin* is a topical cream that has been developed as a novel product containing the active ingredient TA-65<sup>®</sup>, which is a pure molecule extracted from the Chinese herb, Astragalus. TA-65<sup>®</sup> has been extensively studied both experimentally and clinically for its impact on health and lifestyle. TA-65<sup>®</sup> *for Skin* has been tested in a pilot clinical study for its impact on skin's appearance. The study suggests that TA-65<sup>®</sup> *for Skin* improves the skin's appearance by increasing firmness, reducing wrinkles and erythema.

## Introduction:

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Skin undergoes age-related decline in regenerative capacity resulting in compromised homeostatic imbalance and severe skin conditions (Pillai, Oresajo et al. 2005). Senescence, a state of replicative arrest, has been shown to increase with age in dermal fibroblasts and epidermal keratinocytes in human (Dimri, Lee et al. 1995). Senescence limits replicative potential of cells and fuels inflammation in aging (Campisi 2013).

In the current study, topical formulation of TA-65<sup>®</sup> (*TA-65<sup>®</sup> for Skin*) is investigated as a novel product for skin improvement. The pilot study suggests significant improvement in skin firmness, reduction in fine lines and wrinkles and reduction in erythema following the use of *TA-65<sup>®</sup> for Skin*.

## Objective:

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The objective of this study was to determine the effect of *TA-65<sup>®</sup> for Skin* on the appearance of Crow's feet fine lines/wrinkles, skin firmness and the appearance of red/inflamed skin in a panel of 54 female subjects, aged 35-60 years, after 2, 4, 8 and 12 weeks' application of *TA-65<sup>®</sup> for Skin* or other skin care formulations.

## Methodology:

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This study was conducted in compliance with U.S. Code of Federal Regulations (CFR), Title 21 and informed consent was obtained from each subject. Fifty-four (54) female subjects, aged between 36 and 60 were enrolled in this 12 weeks' study.

Twenty subjects were instructed to apply *TA-65<sup>®</sup> for Skin* twice daily for 12 weeks and were instructed to report to the Testing Facility following 2, 4, 8 and 12 weeks of product use for visual evaluations, instrumental measurements and digital photographs. Additionally, at the final visit, subjects were required to respond to a questionnaire. Evaluations of efficacy were based on a comparison of baseline vs. each observation period for each product individually.

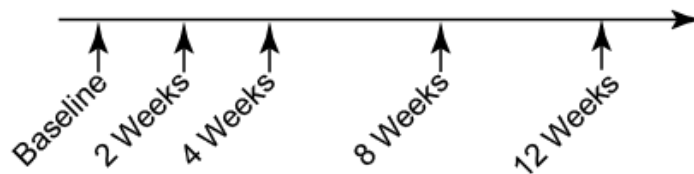


Figure 1: Study design

Subjects reported to the Testing Facility for the baseline visit. A Cutometer<sup>®</sup> measurement was taken on the face to measure skin's firmness. Digital photographs were taken of the face of each subject to determine changes in Crow's feet, fine lines/wrinkles, and redness. Digital imaging was done using Visia CR<sup>®</sup>, and ImagePro<sup>®</sup> software was used to analyze the changes in Crow's feet fine lines/wrinkles. Additionally, evaluation of irritation was conducted for safety purposes.

## Results and Discussion- Safety:

A trained technician evaluated the face of each subject for irritation at baseline and after 2, 4, 8 and 12 weeks. The mean score of irritation was zero for all products tested in this study, which indicate that *TA-65<sup>®</sup> for Skin* did not cause any irritation on the face of any subject at any time during the study.

## Results and Discussion: Efficacy - Skin Firmness

Compared to the baseline measurements, there was improvement in the mean percent of skin firmness. The *TA-65 for Skin* significantly improved skin firmness by 42%, 93%, 101%, 89% after 2, 4, 8 and 12 weeks of daily application ( $p < 0.05$ ) (Table 1). A total of 89%, 83%, 83% and 83% of the subjects showed improvement after 2, 4, 8 and 12 weeks of *TA-65 for Skin* use (Table 1).

Time	Mean score $\pm$ S.D	<i>p</i> -value	Mean % change from baseline	% of subjects with improvement from baseline
Baseline	0.405 $\pm$ 0.159	-	-	-
Week 2	0.517 $\pm$ 0.135	0.002	42.2%	89%
Week 4	0.603 $\pm$ 0.090	<0.001	93.3%	83%
Week 8	0.629 $\pm$ 0.070	<0.001	100.6%	83%
Week 12	0.591 $\pm$ 0.082	<0.001	89.4%	83%

**Table 1: Evaluation of skin firmness by Cutometer<sup>®</sup>. Statistically significant differences from baseline,  $p \leq 0.05$**

## Results and Discussion: Efficacy - Crows' Feet Fine Lines/Wrinkles

Compared to baseline, there was improvement in the mean percent of Crow's feet fine lines/wrinkles. The mean percent improvement were 10.6%, 7.6%, 7.3% and 18.1% respectively at 2, 4, 8 and 12 weeks (Table 2). The improvements were statistically significant at 12 weeks (Table 2).

A total of 68%, 79%, 67%, and 78% of the subjects showed improvement from baseline after 2, 4, 8 and 12 weeks of *TA-65 for Skin* use, respectively (Table 2).

Time	Mean Score $\pm$ S.D	p-value	Mean % change from baseline	% of subjects with improvement from baseline
Baseline	1524.4 $\pm$ 1702.4	-	-	-
Week 2	1043.0 $\pm$ 430.1	0.145	-10.6%	68%
Week 4	1107.9 $\pm$ 706.4	0.169	-7.6%	79%
Week 8	1024.5 $\pm$ 446.2	0.108	-7.3%	67%
Week 12	929.8* $\pm$ 438.4	0.002	-18.1%	78%

**Table 2: Evaluation of Crow's Feet Fine Lines/Wrinkles by VISA CR<sup>®</sup> digital imaging.**

*\*Statistically significant differences from baseline,  $p \leq 0.05$ .*

## Results and Discussion: Efficacy - Evaluation of Skin Redness

Compared to baseline, there was improvement in the mean percent of skin redness. The mean percent improvements were 1.3 %, 4.5 %, 5.9% and 8.6% respectively at 2, 4, 8 and 12 weeks (Table 3). The decrease in redness were statistically significant at week 4, 8 and 12 ( $p < 0.05$ ). At the final visit (12 weeks), subjects responded to a questionnaire. The summary results are represented in the following table (Table 4). After 12 weeks of use, *TA-65<sup>®</sup> of Skin* was associated with a high level of subject acceptance.

A total of 58%, 63%, 72%, and 89% of the subjects showed improvement from baseline after 2, 4, 8 and 12 weeks of *TA-65 for Skin* use, respectively (Table 3).

Time	Mean Score $\pm$ S.D	<i>p</i> -value	Mean % change from baseline	% of Subjects with improvement from baseline
Baseline	13.4 $\pm$ 2.6	-	-	-
Week 2	13.1 $\pm$ 2.3	0.418	-1.3%	58%
Week 4	12.6 * $\pm$ 2.2	0.032	-4.5%	63%
Week 8	12.2* $\pm$ 2.1	0.003	-5.9%	72%
Week 12	11.8* $\pm$ 1.9	<0.001	-8.6%	89%

**Table 3: Evaluation of Skin Redness.**

\*Statistically significant differences from baseline,  $p \leq 0.05$

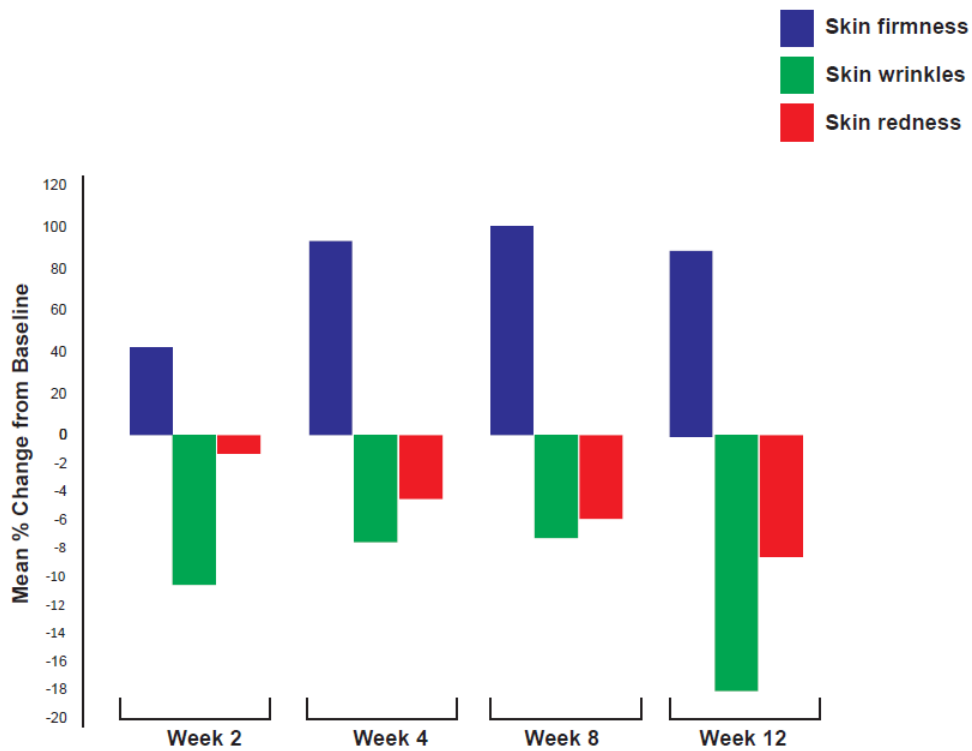


Figure 2: Cosmetic efficacy of *TA-65® for Skin*

## Results and Discussion: Efficacy - Evaluation of Irritation

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There was no irritation on the face of subjects at any time during the study.

## Results and Discussion: Efficacy - Subject Questionnaire

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At the final visit (12 weeks), subjects responded to a questionnaire. The summary results are represented in the following table (Table 4). After 12 weeks of use, *TA-65<sup>®</sup> of Skin* was associated with a high level of subject acceptance.

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Questions	Strongly agree or agree
This product reduces the appearance of Crow's feet fine lines.	83.3%
This product reduces the appearance of Crow's feet wrinkles.	77.8%
The signs of aging around my skin feel firmer.	83.3%
This product made my skin feel firmer.	94.4%
This product made my skin feel tighter.	88.9%
This product helped to reduce the appearance of red/inflamed skin.	72.2%
Overall, my skin appears healthier since using the test product	88.9%
Overall, my skin appears younger since using the test product.	83.3%
I would purchase this product.	77.8%
I would recommend this product to a friend	77.8%

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**Table 4: Subject Questionnaire summary.**

## Conclusions:

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The clinical efficacy study revealed that *TA-65<sup>®</sup> for Skin* helped to improve the appearance of Crow's feet fine lines/wrinkles, increase skin firmness and reduce the appearance of red/inflamed skin when used twice daily for 12 weeks.

## References:

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Campisi, J. (2013). "Aging, cellular senescence, and cancer." *Annu Rev Physiol* **75**: 685-705.

Dimri, G. P., X. Lee, G. Basile, M. Acosta, G. Scott, C. Roskelley, E. E. Medrano, M. Linskens, I. Rubelj, O. Pereira-Smith and et al. (1995). "A biomarker that identifies senescent human cells in culture and in aging skin in vivo." *Proc Natl Acad Sci U S A* **92**(20): 9363-9367.