Thirty-three (33) subjects, ages 25-60 years with moderate facial dyspigmentation, were enrolled in this 32-week single center study. Each subject was given a cleanser and a moisturizing SPF 30 sunscreen for daily use and generic 4% hydroquinone cream to be used in combination with generic 0.025% tretinoin cream at bedtime for a total of 12 weeks. After 12 weeks of therapy, the prescription combination was discontinued and subjects were provided with a cosmeceutical formulation for skin lightening to use twice daily.

Evaluation assessments included dark spot size, and intensity, hyperpigmentation, visual and tactile smoothness, skin tone, clarity, and evenness, radiance, blotchiness, and overall appearance. Tolerability assessment included erythema, edema, dryness, and peeling while the subjects assessed stinging, tingling, itching, and burning. Biinstrumentation measurements and digital photographs were obtained at weeks 12, 24, and 32.

There was an improvement in moisturization and reduction in skin dryness with the use of the cosmeceutical formulation containing hydroxyphenoxoy propionic acid, ellagic acid, yeast extract, and salicylic acid, considering the fact that hydroquinone/tretinoin combination usually causes skin dryness and irritation which often leads to premature termination of the prescription therapy. Corneometer measurements, showed statistically significant increase after week 32 (p=0.004) as compared to baseline.

There was continued statistically significant improvement in visual smoothness (p<0.001) and tactile smoothness (p<0.001) with a reduction in erythema, peeling, and dryness at week 32 compared to the baseline assessment (week 12). Moreover, statistically significant improvement was seen in clarity (p=0.007) (Figure 1), imperfections (p<0.005), radiance/brightness (p=0.001), and firmness (p=0.009). The improvement in all of these facial parameters was reflected in an overall highly statistically significant improvement at week 32 (p=0.001).

Improvement in skin pigmentation continued after the prescription regimen was discontinued followed by 20 weeks of cosmeceutical formulation use. Statistically significant improvements were also observed in even skin tone (p=0.019) and overall hyperpigmentation (p=0.032).

The cosmeceutical formulation improved skin feel and overall appearance while maintaining the pigment lightening results achieved with the hydroquinone/tretinoin combination, 20 weeks after the prescription treatment has been discontinued.

Improvements in skin moisturization, quality, and continued reduction in hyper pigmentation confirmed the complementary benefits offered by the cosmeceutical formula when used following the recommended 12 week use of the prescription hydroquinone/tretinoin combination.

No tolerability issues were noted by the investigator or the subjects with the novel skin lightening preparation.