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Enhanced efficacy of radiant skin serum in subjects with moderate to severe, dry and sensitive skin

Abstract

Background: Dry skin is an uncomfortable condition marked by scaling, itching, and cracking.

Objectives: To evaluate the safety and efficacy of Primrose E Radiant Skin Serum in subjects with moderate to severely dry skin and sensitive skin.

Methods: The study was conducted on 24 healthy female subjects, aged≥30 to≤55 years. Each subject applied a test product on face BID for consecutive 45 days. Effect of test product was evaluated for facial skin hydration/moisture by Corneometer® CM 825, radiance/glow by Skin-Glossymeter GL 200, subjective evaluation. Subject perception about the product was also evaluated.

Results: There was a statistically significant ($p<0.001$) increase observed in skin hydration through Corneometer evaluation on both cheeks on Day 1, Day 21, at 24 hours after Day 21 and Day 45, statistically significant ($p<0.001$) increase observed in glow by Skin-Glossymeter GL 200onboth cheeks on Day 1, t Day 21, at 24 hours after Day 21 and Day 45 and no apparent adverse event was observed.

Conclusions: Primrose E Radiant Skin Serum is safe and efficacious in increasing the skin hydration/moisturisation level. It was important to test the skin hydrating and glossiness effects of Primrose E over 24 hours. This was done during Visits 2 (Day 21) and Visit 3 (at 24 hours from Day 21) of the study. The clinical results showed that Primrose E provides up to 24hours of continuous hydration/moisturisation and glow/ radiance protection. There is an increase in the skin's radiance and it gives off a beautiful glow for subjects with moderate to even a severe dry skin condition. Primrose E is suitable for people with sensitive dry skin and found to be safe and effective.

Keywords: dry skin, xerodermatic, sensitive, dull skin

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Abbreviations: AE, adverse event; LED, light-emitting diode; ICD, informed consent document; OTC, over-the-Counter; BID, bis in die

Introduction

Healthy, young vital skin is usually able to maintain sufficient moisture. In dry skin, the barrier function may be insufficient owing to a variety of reasons. Although anyone can develop dry skin, the condition is more prone in the 50 years and older age groups; in those who live in dry, cold, or low-humidity climates, also high humidity climate with sun exposure or prolong air conditioning environment and in those who bathe or shower very frequently. Although most cases of dry skin are caused by environmental exposures, certain diseases can also significantly alter the function and appearance of the skin. Potential causes of dry skin include the conditions like weather, Central heating and air conditioning, wood-burning stoves, space heaters, and fireplaces, harsh soaps, sun exposure, aging, etc.[1]

Sensitive skin is self-diagnosed and typically unaccompanied by any obvious physical signs of irritation, and the number of individuals who claim sensitivity has risen steadily with the number of consumer products. It affects a large part of the population and is accompanied by great interest by the cosmetic industry. Sensitive skin is a subject of intense research work. Approximately, 50% of women and 40% of men surveyed regarded themselves as having sensitive skin, creating a sizable demand for products designed to minimize skin sensitivity. Some studies have suggested that sensitive skin is a result of impaired barrier function, which leads to the exposure of immune system cells and sensitive nerves, resulting in marked cutaneous responses to otherwise harmless stimuli.[2]

The objective of the present research to observe the effect of Radiant Skin Serum in subjects with having moderate to severely dry and sensitive skin by measuring the skin hydration level using Corneometer CM 825 instrument on the left and right cheeks of the subjects; skin radiance/glow measured by Skin-Glossymeter GL 200 instrument on the left and right cheeks of the subjects; subjective evaluation by asking questions to subjects about the skin dryness and glossiness; subject response index i.e. consumer perception about a product also assessed.

The radiant skin serum contains Evening Primrose Oil that moisturizes and soothes the skin, hence the study was conducted on volunteers with moderate to severely dry skin and sensitive skin to know the effect of Radiant skin Serum on skin hydration and skin radiance/glow.

Material and methods

Study design and participants

The study was a single-arm, open-label, safety and efficacy study of dry and sensitive skincare formulation Primrose E Radiant Skin Serum in terms of reduction in skin dryness by improving skin

hydration/moisture level along with skin glow in healthy adult female subjects. This study comprised of screening phase (within 14 days before Day 1), Enrolment Phase (Visit 2, Day 01) baseline before test product application, Treatment Phase (Visit 3, Day 21 and Visit 4, 24 hours ±2 hours after day 21±2 days), and End of study (Visit 5, Day 45) after test product application.

The potential subjects were screened as per inclusion and exclusion criteria only after obtaining a signed written informed consent from the subject. A total of 89 subjects were screened and signed the informed consent document for the study. Out of these 89 subjects, 24 subjects who met the study criteria were enrolled in the study. A total of 24 subjects (24 Females) completed all the phases of the study.

The before application readings were considered as a baseline to see the effect of Primrose E Radiant Skin Serumon after application of product on each visit before application reading was compared with each visit reading data to see the difference in observations and result concluded on that findings.

Inclusion criteria

Healthy female subjects aged ≥30 to ≤55 years, having moderate to severe dry facial skin i.e. dryness grade in between 2-4 with sensitive skin determined by Dermatologist on basis of skin sensitivity questionnaires during screening visit and positive lactic acid stinging test' at screening, Other enrolment criteria include subject's permission to take facial photographs and agreement in writing to allow the sponsor to use photographs; female subjects with childbearing potential must have negative urine pregnancy test; subjects who are willing to refrain from the use of new personal care products and treatments (cleansers/cosmetics, etc.), cleaning products, soap, and body wash, moisturizing products like bath oils, creams, lotions during the study period.

Exclusion criteria

Subjects were excluded from the study for the reasons as follows: Skin disease (e.g. psoriasis or any other skin condition as per Investigator's discretion), which would interfere with the test readings; subjects taking medications (e.g. steroids or antihistamines), which would compromise the study; a subject who is on any medication for skin disorder or applying any topical medication (including cosmetic) to face during the duration of the study; subject concurrently taking any medications as determined by the Investigator to potentially influence the study outcome; subject not willing to abstain from spa treatments throughout the study period; currently or has been undergoing dermatologist facial treatments or procedures within the last 1 month; any additional condition(s) that in the Investigator's opinion would warrant exclusion from the study or prevent the subject from completing the study.

Study product

All subjects received Primrose E Radiant Skin Serum for application on facial skin. Subjects were advised to clean the skin before application and then take one drop of Primrose E Radiant Skin Serum on one of the fingertips and rubbed with the thumb, then applied to the affected parts of facial skin twice a day for a consecutive 45 days.

Safety assessments

Subjects were enquired about AEs at each clinic visit and were informed to contact the Investigator at any time to report the possible AEs. However, no AEs occurred in the study. Also, no clinically significant changes were observed in the assessment of the vital signs. The Primrose E Radiant Skin Serum was found to be safe and well-tolerated during the study.

Instrumental measurements

Measurement of skin hydration level was done using Corneometer® CM-825. The Corneometer® works on the principle of capacitance. This measurement is based on the completely different di-electrical constant of water (81) and other substances (mostly<7). The measuring capacitor shows changes incapacitance according to the moisture content of the sample.

Measurement of skin glossiness was done using Glossymeter GL 200. Glossymeter GL 200 measurement is based on reflection. Parallel white light is created by the LEDs in the Skin-Glossymeter GL 200 probe head and sent via a mirror ata 60° angle onto the skin surface. One of the two sensors measures via a mirror directly reflected light, the other measures the diffuse reflected light vertically above the skin surface. So the Skin-Glossymeter GL 200 measures both, the portion of directly reflected light which is related to the gloss, and the scattered portion from the surface.

Statistical analysis

The statistical analysis was done using SAS® statistical software (Version: 9.4; SAS Institute Inc., USA). For continuous variables, within-treatment differences for the change from baseline mean were analyzed utilizing Paired t-test. For categorical variables, the frequency and percentage of each category were provided. All statistical tests of the hypothesis employed a level of significance of 0.05.

Ethics

The clinical investigation, including the informed consent document (ICD), was reviewed by Riddhi Medical Nursing Home Institutional Ethics Committee following ICMR ethical guidelines, ICH-GCP, Schedule Y, and Declaration of Helsinki.

This study was conducted according to all the relevant SOP(s), the study protocol and protocol amendment(s), the ICMR ethical guidelines, The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) (Step 5) 'Guidance on Good Clinical Practice' (E6 R2) and Declaration of Helsinki.

Results

Subject disposition and demography

In this study, a total of 89 subjects were screened, out of them, 24 subjects were enrolled in the study. All 24 subjects (24 Females) completed all the phases of the study. All the subjects included in the study were of Asian Race.

Efficacy assessments

Primary efficacy parameters

Instrumental evaluation by corneometer CM 825 (Skin hydration level)

Efficacy of Primrose E Radiant Skin Serum skin hydration/moisture was measured by Corneometer® CM 825 change from baseline i.e. Day 1 before application to Day 1, 2 hours after application, Day 21, 24 hours ±2 hours after day 21, and Day 45 after application shown in table 1 and figure 1 for Right Cheek and Left Cheek.

Table 1 Summary of demographic characteristics

Summary of demographic characteristics		
	N	24
	Female	24 (100%)
Age (years)	Mean ± SD	44.7 (8.35)
	Median	48.5
	Min, Max.	29, 54

N= number of subjects.

There was a statistically significant increase observed in skin hydration level through Corneometer® CM 825 evaluation on both cheeks at Day 1 (P<0.001), Day 21 (P<0.001), Day 22 i.e. 24 hours from day 21 (P<0.001), and at Day 45 (P<0.001), which clinically indicates a significant increase in skin hydration level from baseline to Day 1, Day 21, at 24 hours after Day 21 and Day 45. Overall mean score was>40 which was considered as sufficiently moisturized skin.

Instrumental evaluation by skin-glossymeter GL 200 (Improvement in radiance/glow)

Efficacy of Primrose E Radiant Skin Serum on improvement in radiance/glow was measured by Skin-Glossymeter GL 200 change from baseline i.e. Day 1 before application to Day 1, 2 hours after application, Day 21, 24 hours ±2 hours after day 21, and Day 45 after application shown in table 2 and figure 2 for Right Cheek and Left Cheek.

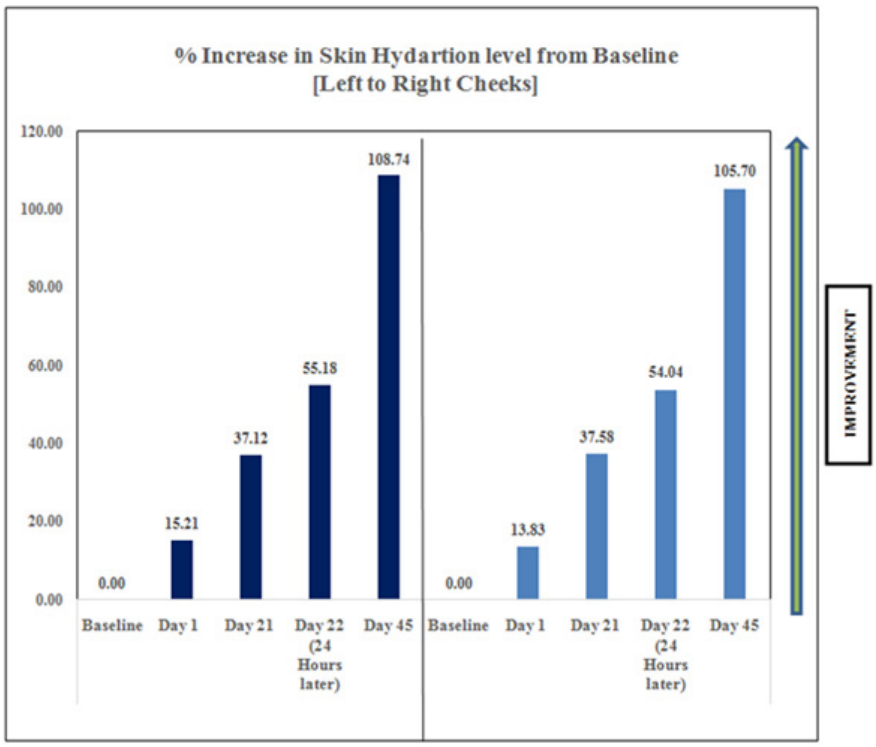

Figure 1 % Increase in skin Hydration level from baseline [Left to Right Cheek].

*P-value< 0.05.

Table 2 Skin Hydration level evaluation – Mean Value, p-Value and % change from Baseline for right and left cheek

Visits	Right cheek (Skin hydration)			Left cheek (Skin hydration)		
	Mean value	p-Value	% CFB	Mean value	p-Value	% CFB
Visit 02 (Day 1)	3.053	0.0000	13.83%	3.315	0.0000	15.21%
Visit 03 (Day 21)	8.301	0.0000	37.58%	8.085	0.0000	37.12%
Visit 04 (at 24 hours after Day 21)	11.893	0.0000	54.04%	11.938	0.0000	55.18%
Visit 05 (Day 45)	23.251	0.0000	105.70%	23.437	0.0000	108.74%

Citation: Gajjar T, Patel N, Patel M, et al. Enhanced efficacy of radiant skin serum in subjects with moderate to severe, dry and sensitive skin. *J Dermat Cosmetol.* 2021;5(1):6–11. DOI: 10.15406/jdc.2021.05.00173

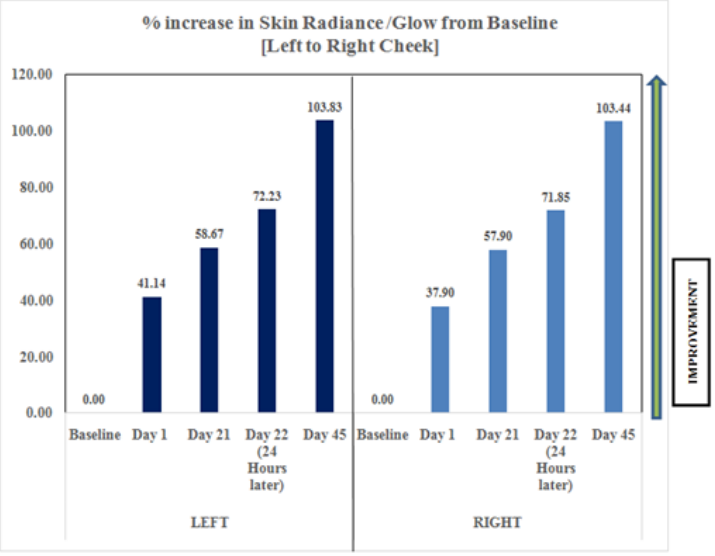

Figure 2 % Increase in Skin Radiance /Glow from Baseline [Left to Right Cheek].

*P-value < 0.05.

There was a statistically significant increase observed in skin radiance /glow level through Skin-Glossymeter GL 200 evaluation for right cheek and left cheek at Day 1 (P<0.001), Day 21 (P<0.001), Day 22 i.e. 24 hours from day 21 (P<0.001), and at Day 45 (P<0.001), which clinically indicates a significant increase in skin radiance/ glow level on both cheeks from baseline to Day 1, Day 21, at 24 hours after Day 21 and Day 45. It's important to note that skin radiance continued to improve over a 24 hour period even though there was no extra application of Primrose E radiance Skin serum. It can be concluded that this must be the carry over effect of the product from a full day earlier.

Secondary efficacy parameters

The subjective evaluation was assessed by asking questions to subjects by study personnel at Day 21, 24 hours±2 hours after day 21, and Day 45 after application.

Before application of Primrose E Radiant Skin Serum, 100% of subjects responded that they had dull skin and their skin was lack lustre at visit 2.

After application of Primrose E Radiant Skin Serum, 100% of subjects responded that their skin dullness improved after 45 days usage, in which 3 (12.50%) subjects felt moderate improvement and 21 (87.85%) subjects felt marked improvement.

After application of Primrose E Radiant Skin Serum, 100% of subjects responded that their skin brilliance/radiance improved after 45 days of use of the product, in which 5 (20.83%) subjects felt moderate improvement and 19 (79.17%) subjects felt marked improvement.

After application of Primrose E Radiant Skin Serum, 95.83% of subjects with sensitive skin responded that their skin sensitivity reduced after 45 days usage.

After application of Primrose E Radiant Skin Serum, 100% of subjects responded that the product did not cause any reaction to their skin after 45 days usage.

After application of Primrose E Radiant Skin Serum, 100% of subjects agreed that their skin is normal after 45 days of usage.

After application of Primrose E Radiant Skin Serum, 95.83% of subjects with sensitive skin responded that their skin is less sensitive to hot and cold weather after 45 days of usage.

Subject response index [consumer perception about the product] was asked and filled by study personnel at Day 45 end of the study.

- 100% of subjects like the product and agreed that the product is easy to use and apply.
- 100% of subjects responded that the product has an appealing fragrance and it makes the skin soft and smooth.
- 100% of subjects responded that the product suited their skin and gives moisturisation. (Table 3) (Figure 3&4).

Table 3 Skin Radiance / Glow evaluation – Mean Value, p-Value and % Change from Baseline for Right and Left Cheek

Visits	Right cheek (Skin Radiance / Glow)			Left cheek (Skin radiance / Glow)		
	Mean value	P-Value	% CFB	Mean value	P-Value	% CFB
Visit 02 (Day 1)	0.838	0.0000	37.90%	0.888	0.0000	41.14%
Visit 03 (Day 21)	1.260	0.0000	57.90%	1.267	0.0000	58.67 %
Visit 04 (at 24 hours after Day 21)	1.569	0.0000	71.85 %	1.558	0.0000	72.23%
Visit 05 (Day 45)	2.254	0.0000	103.44%	2.225	0.0000	103.83%

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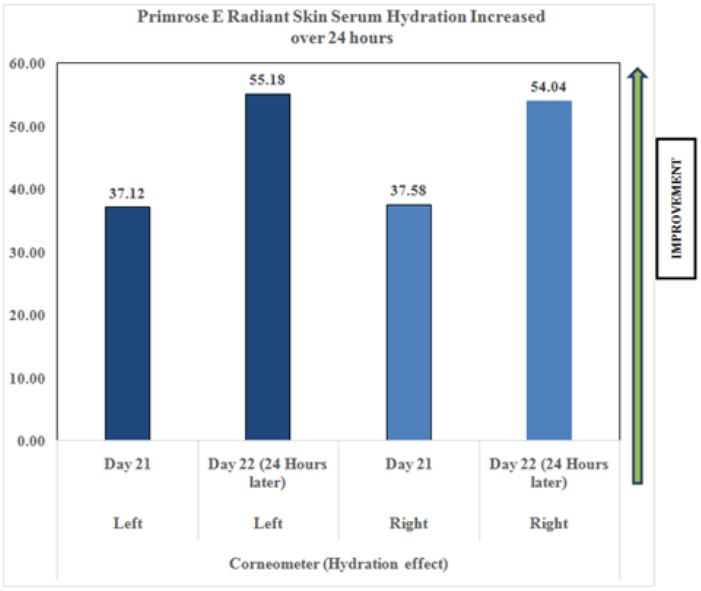

Figure 3 Graphical Representation for Primrose E hydration increased over 24 hours.

Interpretation: Primrose E Radiant Skin Serum provides continuous hydration/ moisturisation even after 24 hours.

It's important to note that skin radiance continued to improve over a 24 hour period even though there was no extra application of Primrose E Radiance Skin Serum. It can be concluded that this must be the carry over effect of the product from a full day earlier.

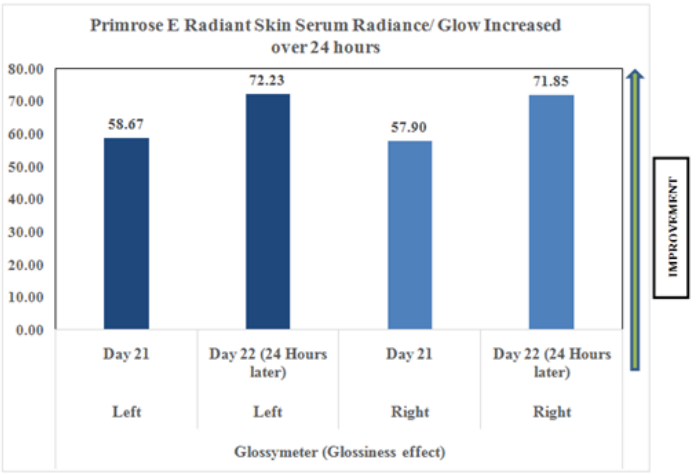

Figure 4 Graphical Representation for Primrose E Radiance/Glow Increased over 24 hours.

Interpretation: Primrose E Radiant Skin Serum provides continuous glow /radiance even after 24 hours.

Results

Primrose E Radiant Skin Serum is safe to use topically as there were no adverse events (AEs) reported by the Investigator nor self-reported by the subjects, during the conduct of the study. It was important to test the hydration/moisturisation and glow /radiance efficacy of Primrose E over 24 hours and this was provided for on Visit 2 (Day 21) and 24 hours later on Visit 3. There was a statistically significant increase observed in skin hydration level through Corneometer® CM 825 evaluation on both cheeks at Day 1 ($P<0.001$), Day 21 ($P<0.001$), Day 22 i.e. 24 hours from day 21 ($P<0.001$), and at Day 45 ($P<0.001$), which clinically indicates a significant increase in skin hydration level from baseline to Day 1, Day 21, at 24 hours after Day 21 and Day 45. An overall mean score was >40 which is considered as sufficiently moisturized skin. Skin radiance/glow through Skin-Glossymeter GL 200 evaluation shows for both Cheeks: A statistically significant increase was observed in Skin radiance/ glow at Day 1 ($P<0.001$),Day 21 ($P<0.001$), Day 22 i.e. 24 hours from day 21 ($P<0.001$), and at Day 45 ($P<0.001$), which clinically indicates a significant increase in the skin radiance/glow after usage. Furthermore, the product usage was well received. Overall the subjects were satisfied with the effects shown by the Primrose E Radiant Skin Serum.

Discussion

People may experience dry skin on their face as a result of many factors, including changes in temperature or humidity, using soaps with harsh chemicals, and skin conditions, such as eczema. In most cases, people can get rid of dry skin using home remedies and over-the-counter (OTC) treatments.

The skin naturally produces an oil called sebum. When the skin produces too much oil, this can lead to pimples. However, having some

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sebum on the skin is important for keeping it hydrated and protecting the cells from infection. Skin that is not creating or replenishing enough sebum can become dry. Dry skin can be itchy, and it may look flaky and bumpy or have red patches. Dehydrated skin lacks water and appears dull or rough.

Some potential causes of dry or dehydrated skin on the face include cold weather, dry air, exposure to harsh chemicals in soaps or other products, washing the skin excessively, unbalanced skin pH, skin conditions, such as atopic dermatitis, seborrheic dermatitis, and psoriasis, diabetes, hypothyroidism, smoking, spending too much time in direct sunlight, People can treat dry skin using several different methods. The best treatment option will depend on the cause of someone's dry skin and its severity. Treatments also vary among different skin types, which can be normal, dry, oily, or a combination.[3]

Moisturizing or hydrating agents are important components in a basic skincare regimen. They protect the skin from daily insults of the environment and assist in preventing premature skin aging. The combination of novel ingredients in the Primrose E Radiant Skin Serum was designed to provide rapid and long-lasting benefits in maintaining skin hydration and skin radiance/glow. The Primrose E Radiant Skin Serum contains Simmondsia Chinensis (Jojoba Oil), Evening Primrose Oil, d-alpha-Tocopherol, Grape Seed Oil, Capric/ Caprylic Triglycerides, Isopropyl myristate & Lavendula Angustifolia.

Thus, the study was conducted to determine the effectiveness and safety of Primrose E Radiant Skin Serum in subjects with moderate to severely dry skin and sensitive skin.

Each ingredient have its own benefits i.e. Evening Primrose Oil moisturizes and soothes the skin, it can enhance the texture and elasticity of skin, addressing dryness, irritation, roughness, and wrinkles. Applying Primrose E Radiant Skin Serum daily can result in a clear and healthy complexion.[4] Linoleic acid which is found in evening primrose oil is an omega-6 fatty acid that promotes skin health by reinforcing the skin barrier, preserving water in the epidermis, and regulating sebum production, reduction of inflammation, dryness, scaling, and overall severity of atopic dermatitis or eczema. If your skin is deficient inessential fatty acids it can lead to dry, rough, or scaly skin. Linoleic acid is an essential building block for ceramides which is one of the skin's key moisturizing elements.[5–7] Here, Grape Seed Oil contains linoleic acid and that helps to moisturize the skin. D-alpha Tocopherol is the most active form of Natural Vitamin E helps to prevent damage to the skin caused by free radicals from UV exposure. Vitamin E may also have an anti-inflammatory effect on the skin. Grape Seed Oil has high in linoleic acid, also known as omega-6 fatty acid, which in addition to fortifying the skin's barrier and helping to reduce water loss from the skin.

After usage of Primrose E Radiant Skin Serum for 45 days, none of the subjects reported any adverse event. During the study conduct, it was observed that Primrose E Radiant Skin Serum helps in increasing the skin hydration level and provides continuous 24-hour hydration/ moisturisation and glow/ radiance protection. The subjective evaluation also suggests the same. Moreover, it has the added benefits of being hydrating, gives a glow to skin in subjects with moderate to severely dry skin and sensitive skin. Also, no adverse event was observed during the conduct of the study.[8–11]

Conclusion

Overall, evaluation of the Botanical based Primrose E Radiant Skin Serum based on skin hydration level, using Corneometer® CM 825 and skin radiance/ glow, using Skin-Glossymeter GL 200, along with subjective evaluation parameters and response index, suggests that the Primrose E Radiant Skin Serum is safe and efficacious in increasing the skin hydration level. It was important to test the skin hydrating and glossiness effects of Primrose E Radiant Skin Serum over 24 hours. This was done during Visits 2 (Day 21) and Visit 3 (at 24 hours from Day 21) of the study. The clinical results showed that Primrose E Radiant Skin Serum provides up to 24 hours of continuous hydration/moisturisation and glow/radiance protection. There is an increase in the skin's radiance and it gives off a beautiful glow for subjects with moderate to even a severe dry skin condition. Primrose E Radiant Skin Serum is a botanical product suitable for people with Dry and Sensitive skin. And was found to be safe.

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None.

Conflicts of interest

The authors involved with the development of this journal have no conflict of interest to declare.

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