Journal of Current Pharma Research
(An Official Publication of Human Journals)
An International Peer Reviewed Journal For Pharmacy, Medical & Biological Science
DOI: 10.25166 CODEN: JCPRD6 NLM ID: 101744065
ISSN: Print: 2230-7834 Online: 2230-7842
SJIF Impact Factor: 6.913

Human Journals
Research Article
April 2023 Vol.:17, Issue:3

Safety and Efficacy of iGlow (Poly Herbal Preparation) on Overall Skin Health Among Healthy Adult Volunteers - A Randomized, Double Blind, Placebo-Controlled, Two Arm Study

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Submitted: 03 April 2023
Accepted: 14 April 2023
Published: 25 April 2023

HUMAN JOURNALS
www.jcpr.humanjournals.com

Keywords: iGlow, Skin, photodamage, sunscreen, anti-ageing

ABSTRACT

Nutritional status plays an important role in the maintenance of healthy skin. Conditions that adversely affect the biological functions of skin often correspond to a less attractive appearance of skin. Sunscreens are the most commonly used photoprotective agents. However, use of sunscreens may only provide limited sun protection, expose the skin to chemicals that might otherwise damage or disrupt barrier function, or induce inflammatory reactions in the skin. The study's goal was to assess the safety and efficacy of iGlow for the effect on overall skin health in male and female subjects. The study included 90 healthy adult male and female subjects who were instructed to take twice daily preferably 15 minutes after lunch and dinner daily. The investigational product, either active or placebo, was given for a period of 3 months (90 days). All were randomized into active and placebo groups (2:1 ratio). These vital sign parameters were found to be normal for all the study subjects and did not have any clinically or statistically significant abnormal values when compared between and within groups, implying that the test product has no safety issues observed after 90 days of oral administration. The measured laboratory parameters were found to be completely normal before and after the treatment periods across all the study groups. There were no protocol deviations observed during the course of the trial. In this study iGlow has demonstrated a remarkable safety profile when administered orally as liquid dosage form. It showed significant improvement in visual dermatological erythema better than the placebo group arm at the end of the study (Day 90). These results corroborate even with various biomarkers (procollagen, collagen, elastin, HAS1, hydration, TEWL and elasticity) showed that the subjects had a significant improvement in the overall skin health in the iGlow receiving group. This study clearly indicates that iGlow has significant anti- and anti-ageing effects in the study subjects. Therefore, it is concluded that iGlow has a definite role in improving the overall skin health when the subjects administered the product orally for 90 consecutive days.

INTRODUCTION

According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, keeping the skin healthy ensures protecting the body against germs as well as damage to your bones, muscles and internal organs. Besides protecting skin from microbes, skin also prevent dehydration to keep fluids inside the body. Nutritional status plays an important role in the maintenance of healthy skin (1-4). Macronutrients (carbohydrates, proteins, and lipids) and micronutrients (vitamins and nutritionally essential minerals) work together to maintain the barrier functions of skin. Changes in nutritional status that alter skin structure and function can also directly affect skin appearance. Unlike many organs, skin nutrition may be enhanced directly through topical applications. Topical application of micronutrients can complement dietary consumption, leading to a stronger, healthier protective barrier for the body. Conditions that adversely affect the biological functions of skin often correspond to a less attractive appearance of skin (5-8).

Primary exposures to ultraviolet (UV) light are through sunlight and tanning beds. Although UV penetration of skin aids in vitamin D synthesis, it has the potential to damage the cells and extracellular components of the skin (9-11). Free radicals are produced when light energy is absorbed by cellular components (10, 11). While the skin has endogenous antioxidant systems to combat free radicals and repair proteins, excessive exposures may overwhelm these defenses and lead to permanent damage referred as photodamage (11-13). Sunburn is the most common form of acute photodamage, where the damage caused by excessive exposure of UV light leads to a large inflammatory response (erythema) (13). Prolonged or repeated exposures to UV light may cause permanent damage referred as ‘photoaging’ (12-13). While skin laxity, wrinkling, and thickening are the most apparent signs of photodamage, changes in skin texture, abnormal skin growths, and impaired wound healing are also possible (13-15). Skin discoloration may also occur with chronic UV exposure, especially in the form of solar lentigines, also known as liver spots.

Prevention of photodamage begins with limiting exposure to UV light. Because avoidance of sunlight is not always practical, photoprotective agents are often used to limit exposure (9, 12). Sunscreens are the most commonly used photoprotective agents. However, use of sunscreens may only provide limited sun protection, expose the skin to chemicals that might otherwise damage or disrupt barrier function, or induce inflammatory reactions in the skin. Therefore, care must be taken in their use (12).

iGlow is a poly herbal juice composed of extracts of *Musa paradisiaca, Carica papaya, Citrus sinensis, Aloe barbadensi, Pyrus malus, Pterocarpus marsupium, Vitis vinifera, Spinacia oleracea, Crocus sativus* and *Cocus nucifera*. The present study was aimed to assess the safety and efficacy of iGlow for the effect on overall skin health in male and female subjects.

Extracts of Kadali (*Musa paradisiaca*) has anti-oxidant activity and thus exhibit favorable effects in causing the skin glow, and may play an effective role in the wound healing (17). Karataki (*Carica papaya*) constituents exhibit alkaline combination, as with borax or potassium carbonate and they have showed good results in treatment of warts, corns, eczema, cutaneous tubercles and other hardness of the skin, and also injected into indolent glandular tumors to promote their absorption (18). Narangi (*Citrus sinensis*) have a high content of citric acid which aids in skin exfoliation and helps to dry out acne, improving the overall look of your skin. Orange peel has a higher content of Vitamin C than the orange itself, so grind orange peel and use as a body scrub in your daily beauty regime for a healthy-looking glow (19). Mucopolysaccharides help in binding moisture into the skin. Aloe stimulates fibroblast which produces the collagen and elastin fibers making the skin more elastic and less wrinkled. The use of apple extract (*Pyrus malus* extract) in skin care has grown steadily since 2003. In the first half of 2008, it increased by nearly 30% over the same period in 2007. This acidic, vitamin-rich fruit appears in face and body care in both mass-market and selective distribution. Apple fruit, juice and seeds are found in recent launches of antiaging, anti-acne and brightening products. The use of *Pterocarpus marsupium* in the Ayurveda system of traditional medicine is thousands of years old. The aerial seeds are the most commonly used parts of the tree, including the wood, flowers and leaves. The leaves are often applied externally as a remedy for skin diseases. Owing to the profound nutritional value, grape skins (*Vitis vinifera*), the juice, and the seeds offer incredible skin-care benefits ranging from protection against environmental factors, brightening due to the high level of antioxidants, firming, and nourishing due to the bounty of omega acids. There are also dozens of naturally-occurring chemical compounds that aid in everything from skin repair and rejuvenation to cellular turnover, detoxification, and evening of skin tone. A member of the Amaranthaceae plant family, *Spinacia oleracea* (spinach) is packed full of valuable nutrients to rejuvenate and nourish skin. Its potent antioxidants Vitamins C and E, along with Vitamin A promoting skin cell turnover, revitalize skin by evening and brightening, giving a radiant youthful appearance. *Crocus sativus* works as an amazing anti-solar agent and shields the skin from

harmful UV rays of the sun and protects the skin. Regular use fades away the dark spots, blemishes and brightens the skin tone by enhancing the complexion. *Cocus nucifera* extract is widely used in natural skin care and beauty products. As an excellent humectant, topically applied coconut has moisturizing effect and prevents water loss. It works on all kinds of skins and protects the skin in all seasons. It is effective in the fight against a number of bacterial infections because of its anti-fungal, antiviral, as well as anti-bacterial qualities. Due to its high nutrient values, Coconut extract helps diminish the appearance of acne scars. Furthermore, it also helps to prevent new acne scars from forming. It also detoxifies the skin by pulling out toxins that helps get rid of acne. It has antibacterial, antifungal, antioxidant and antimicrobial properties that help soothe inflammation, fight acne infections and palliates red dry skin that can cause acne. It also helps in removing the surface layer of dead skin cells, making the skin smoother. It will also prevent premature aging of your skin. The other ingredients of the juice like Asana, Darksha, Palakya, Shodhita etc have beneficial effect in overall health of human skin. iGlow is a poly herbal juice meant to be ingested orally b.i.d (twice a day) after lunch and dinner daily.

STUDY OBJECTIVES

1. The primary objective was to evaluate the safety of iGlow from baseline to end of the trial in male or female subjects.

2. The secondary objective was to evaluate of iGlow on overall improvement of skin health with regard to photo aging and skin hydration from baseline to end of the trial in male or female subjects.

STUDY DESIGN

Design: Randomized, double-blind, placebo-controlled, two arm study.

Study Treatment Allocation: All 90 subjects were randomized into active and placebo groups (2:1 ratio) and given the following treatment:

Group I-iG

Group II-Pb

Number of Subjects: 90 subjects (60:30) healthy adult male and female subjects.

Randomization: Investigational products duly labelled with randomization codes were provided to the investigators by the sponsor through Radiant Research. As per the randomization schedule the investigator / designee dispensed IP sachets, two for each subject/day. The IP sachets were kept by the investigator in a safe but accessible place.

Overall Study Plan

After obtaining the Ethics committee approval subjects were asked to visit the site. Informed consent was administered to study volunteers, and after obtaining their consent in writing, the subjects were asked about their medical history and the Investigator or his/her designee will conduct a physical examination. Demographics and vital signs were recorded. Blood sample were drawn from each subject for analysis of hematology, biochemistry and virology. Subjects were enrolled into the study after all the IC/EC criteria are met. Once the subject was found to be eligible, he or she was asked to visit the site as baseline visit (Day 0) where the IPs was dispensed sufficient until next scheduled visit. Blood samples for objective evaluations (biomarkers) will be collected on Day 0 and Day 90. Subjective evaluations (instrumental analysis) and Dermatologist's visual assessments were done on Day 0, 30 and 90.

Inclusion Criteria

Subjects fulfilling following criteria were included in the study:

1. Subjects in generally good health
2. Subjects age group 18-55 years
3. Subjects willing to follow the suggested diet plan.
4. Subjects willing to give a written informed consent and come for a regular follow up
5. Subject willing to abide by and comply with the study protocol
6. Subject has not participated in a similar investigation in the past four weeks.
7. Subjects having visible fine lines and wrinkles in periorbital area (Crow's feet), nasolabial areas, forehead, and perioral regions of the face

8. Subjects having mild to moderate naso-labial folds
9. Subjects having apparent mild to moderate crow's feet in unanimated face
10. Subjects who have not under gone any facial anti-ageing procedures (e.g. Botulinum dermal filler injections, laser resurfacing) in the past 3 months.
11. Subject should be willing to abstain from spa treatments/facials during the study period.

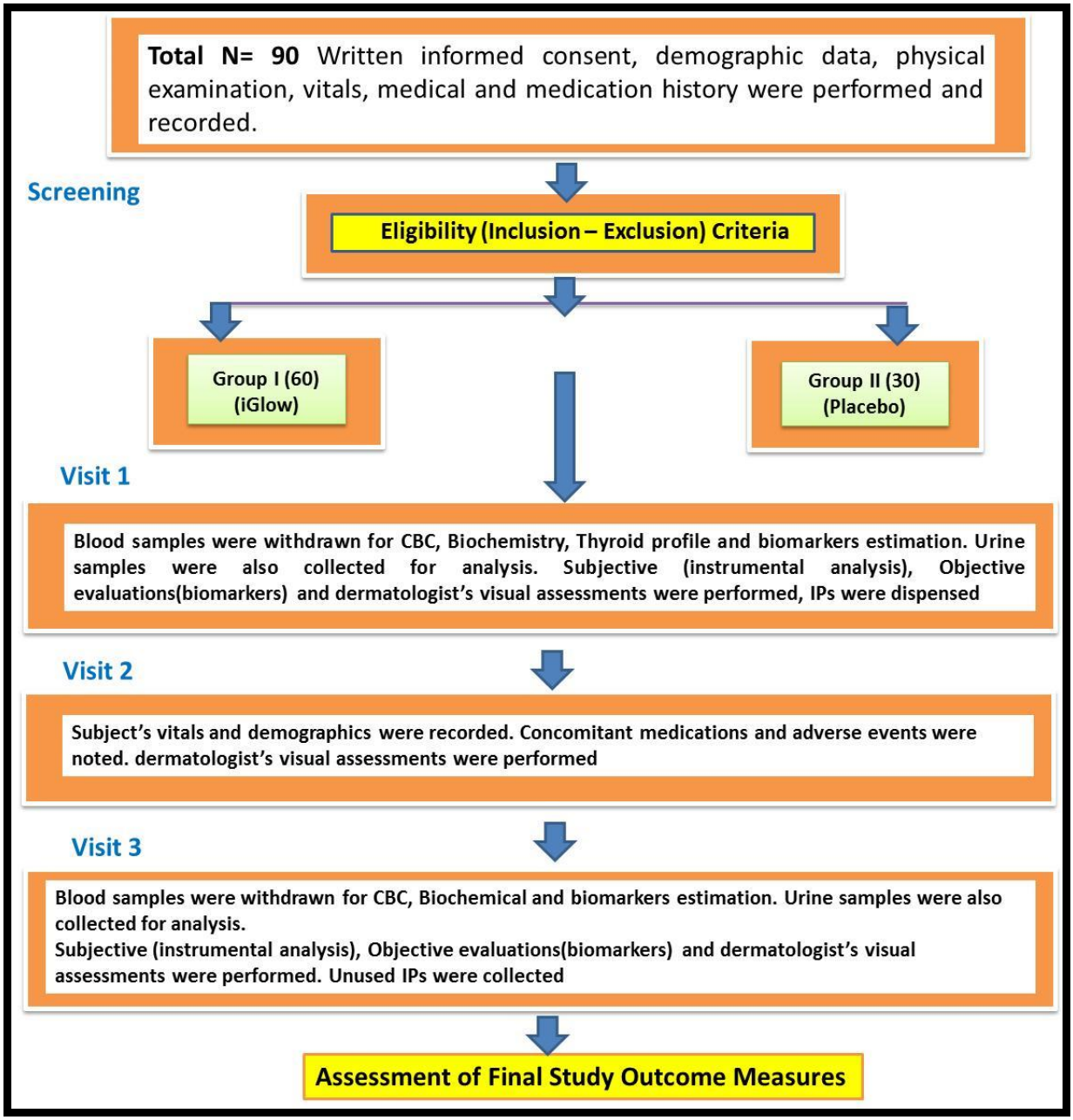
Exclusion criteria:

Subjects fulfilling any one of the following criteria were excluded from the study:

1. A known history or present condition of allergic response to any cosmetic products.
2. Subjects having severe photo-aging.
3. Subject having skin diseases (e.g. moderate to severe acne vulgaris face or nodulocystic acne, psoriasis, active atopic dermatitis, melasma, lichen planus pigmentosus/ Achy dermatosis, pigmented contact dermatitis or other cutaneous manifestations), which will interfere with the test readings.
4. Subjects on oral medications (e.g. steroids, anti-oxidant) or any skin supplement for skin care which will compromise the study.
5. Systemic treatment which may modify the cutaneous state on the day of inclusion or in the previous 30 days, including retinoid therapy.
6. Subjects not willing to discontinue other topical anti-ageing, anti- wrinkle facial products.
7. Subjects who are pregnant, and nursing.
8. Hypersensitivity to any component of the tested products.
9. History of intense sun exposure.
10. Chronic illness which may influence the cutaneous state.
11. Subject participating in any other cosmetic or therapeutic trial.
12. Any underlying uncontrolled medical illness including diabetes mellitus, hypertension,

liver disease or history of alcoholism, HIV, hepatitis, or any other serious medical illness.

Flow Chart of Study Activities



ASSESSMENT OF SAFETY

Specification of Safety Parameters

The study's safety parameters included vital signs and adverse events, which were compared from the subjects' baseline to the final visit of the subjects as per standard study guidelines.

Treatment of Subjects

iGlow is a poly herbal preparation with many kinds of natural herbal ingredients to be ingested twice daily preferably 15 minutes after lunch and dinner daily. The investigational product, either active or placebo was ingested for a period of 3 months (90 days).

Statistical Analysis

The data generated from individual CRFs were compared between groups from Day 0 till Day 90. Student T test was employed for analyzing efficacy values between different visits, while 'p' value <0.05 was considered as statistical significance for the study.

RESULTS

The IP codes for the 2 groups were un-blinded towards end of the study during statistical analysis and it was revealed that Group I /Treatment A – received iGlow, Group II/Treatment B – received Placebo products respectively.

Demographics and baseline characteristics

Table1 A: Descriptive statistics–Demographics: Age and Sex

Parameter/Statistics	Treatment A	Treatment B
Age (Years)		
N	60	30
Mean (SD)	42.5 (10.72)	38.4 (12.47)
Median	45.0	38.0
Min, Max	20, 60	18, 67
Sex, n (%)		
Female	28 (46.7)	15 (50.0)
Male	32 (53.3)	15 (50.0)
Smoking, n (%)		
Yes	6 (10.0)	0 (0.0)
No	54 (90.0)	30 (100.0)
Drug Abuse, n (%)		
Yes	0 (0.0)	0 (0.0)
No	60 (100.0)	30 (100.0)
Alcohol Abuse, n (%)		
Yes	0 (0.0)	0 (0.0)
No	60 (100.0)	30 (100.0)

Table 1 B: Descriptive statistics–Demographics (Height, Weight, Waist Circumference)

Parameter/ Statistics	Visit	Height (in Centimeters)		Weight (in Kilograms)		Waist Circumference	
		Treatment A	Treatment B	Treatment A	Treatment B	Treatment A	Treatment B
N	Screening	60	30	60	30	60	30
Mean (SD)	Screening	165.8(5.75)	165.4(3.60)	62.4(7.18)	61.3(6.40)	82.9(9.52)	81.9(9.76)
Median	Screening	165.0	166.0	62.0	63.0	88.0	81.5
Min, Max	Screening	157,183	158,171	48,80	49,78	70,94	70,95
N	Visit 3	60	30	60	30	60	30
Mean (SD)	Visit 3	165.8(5.75)	165.4(3.60)	62.4(7.30)	61.3(6.35)	82.9(9.51)	82.0(9.78)
Median	Visit 3	165.0	166.0	62.0	63.0	89.0	81.5
Min, Max	Visit 3	157,183	158,171	48,80	49,78	70,94	70,95

Safety Results:

Table 2 A: Descriptive statistics for vital signs: Temperature, Heart rate, Pulse rate and Respiratory rate

Parameter/ Statistics	Visit	Temperature (Fahrenheit)		Heart rate (beats/min)		Pulse rate (beats/min)		Respiratory rate (breaths /min)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Screening	60	30	60	30	60	30	60	30
Mean (SD)	Screening	96.90(0.760)	97.05(0.672)	74.6(1.06)	75.2(0.59)	74.7(1.18)	75.3(0.88)	14.6(0.62)	14.8(0.55)
Median	Screening	96.80	97.20	75.0	75.0	75.0	75.5	15.0	15.0
Min, Max	Screening	95.2,98.7	95.4,98.1	72,78	74,76	72,78	74,77	13,16	14,16
N	Visit 2	60	30	60	30	60	30	60	30
Mean (SD)	Visit 2	96.70(0.734)	96.98(0.679)	74.9(0.85)	75.2(0.61)	74.9(1.18)	75.2(0.86)	14.7(0.79)	14.8(0.43)
Median	Visit 2	96.70	96.95	75.0	75.0	75.0	75.0	15.0	15.0
Min, Max	Visit 2	94.0,98.6	95.3,98.0	73,78	74,76	72,77	74,77	13,16	14,15
N	Visit 3	60	30	60	30	60	30	60	30
Mean (SD)	Visit 3	96.83(0.570)	96.90(0.724)	74.7(0.84)	74.9(0.76)	74.7(1.06)	75.2(0.87)	14.7(0.63)	14.8(0.71)
Median	Visit 3	96.80	96.80	75.0	75.0	75.0	75.0	15.0	15.0
Min, Max	Visit 3	95.8,98.2	95.7,98.1	73,76	73,76	73,77	73,76	14,16	14,16

Table 2 B: Descriptive statistics for vital signs- Systolic and Diastolic Blood Pressure

Parameter/ Statistics	Visit	Systolic Blood Pressure (mmHg)		Diastolic Blood Pressure (mmHg)	
		Treatment A	Treatment B	Treatment A	Treatment B
N	Screening	60	30	60	30
Mean (SD)	Screening	121.5(4.44)	120.5(1.53)	82.3(5.16)	80.0(0.00)
Median	Screening	120.0	120.0	80.0	80.0
Min, Max	Screening	100,130	120,125	80,100	80,80
N	Visit 2	60	30	60	30
Mean (SD)	Visit 2	121.5(3.60)	120.3(3.92)	82.4(5.48)	81.3(3.46)
Median	Visit 2	120.0	120.0	80.0	80.0
Min, Max	Visit 2	110,130	110,130	80,100	80,90
N	Visit 3	60	30	60	30
Mean (SD)	Visit 3	122.4(8.00)	120.5(3.04)	81.9(4.61)	81.5(3.97)
Median	Visit 3	120.0	120.0	80.0	80.0
Min, Max	Visit 3	120,180	115,130	80,100	80,95

Table 3: Descriptive statistics for Medical History

Parameter/Statistics	Visit	Treatment A	Treatment B
Medical History Present?			
Yes	Screening	0(0.0)	0(0.0)
No	Screening	60(100.0)	30(100.0)
Currently consuming Medicines?			
Yes	Screening	0(0.0)	0(0.0)
No	Screening	60(100.0)	30(100.0)

Table 4 A: Descriptive statistics for Lab Data (RBC, WBC, Platelet Count and Basophil)

Parameter/ Statistics	Visit	RBC (mill/cumm)		WBC (Cells/Cumm)		Platelet Count (1akhs/cumm)		Basophil (%)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Visit 1	60	30	60	30	60	30	60	30
Mean (SD)	Visit 1	5.09(0.406)	4.97(0.382)	7639.2(1376.56)	7306.7(1740.18)	2.911(0.7877)	2.673(0.5609)	0.480(0.3972)	0.598(0.3887)
Median	Visit 1	5.08	4.90	7400.0	7450.0	2.930	2.765	0.425	0.650
Min, Max	Visit 1	4.1,6.4	4.4,5.9	5000,10800	4700,9900	1.02,5.98	1.00,3.84	0.00,1.00	0.00,1.00
N	Visit 4	60	30	60	30	60	30	60	30
Mean (SD)	Visit 4	4.94(0.391)	5.08(0.407)	7628.3(1392.97)	7303.3(847.50)	2.845(0.5468)	2.700(0.5527)	0.458(0.3914)	0.558(0.3634)
Median	Visit 4	4.90	5.16	7750.0	7200.0	2.795	2.575	0.400	0.600
Min, Max	Visit 4	4.1,5.6	4.3,5.7	4200,9400	5200,8700	1.45,3.92	1.88,3.82	0.00,1.00	0.00,1.00

Table 4 B: Descriptive statistics for Lab Data (Neutrophils, Lymphocytes, Monocytes and Eosinophils)

Parameter/ Statistics	Visit	Neutrophils (%)		Lymphocytes (%)		Monocytes (%)		Eosinophils (%)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Visit 1	60	30	60	30	60	30	60	30
Mean (SD)	Visit 1	60.8(7.67)	57.4(7.86)	30.5(4.20)	29.7(5.39)	3.8(1.65)	3.8(1.23)	3.8(1.24)	4.0(1.40)
Median	Visit 1	62.0	58.5	29.0	29.5	4.0	3.0	3.5	4.0
Min, Max	Visit 1	43,78	43,72	20,38	20,40	1,8	3,7	2,6	1,6
N	Visit 4	60	30	60	30	60	30	60	30
Mean (SD)	Visit 4	59.0(6.88)	60.3(7.30)	30.6(5.22)	30.0(3.19)	3.9(1.12)	3.8(1.24)	3.6(1.57)	4.0(1.58)
Median	Visit 4	60.0	60.0	30.0	30.0	4.0	4.0	3.0	4.0
Min,Max	Visit 4	49,75	49,72	20,40	20,35	2,7	2,7	1,6	1,6

Table 4 C: Descriptive statistics for Lab Data (Blood Urea, Creatinine, SGOT, SGPT and Alkaline Phosphatase)

Parameter/ Statistics	Visit	Blood Urea (mg/dl)		S. Creatinine (mg/d1)		SGOT (U/L)		SGPT (U/L)		Alkaline Phosphatase (u/l)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Visit 1	60	30	60	30	60	30	60	30	60	30
Mean (SD)	Visit 1	23.2(8.13)	20.5(4.81)	0.957(0.2384)	0.887(0.1525)	23.659(7.3454)	24.700(8.1162)	23.526(10.1985)	23.700(11.9803)	119.5(67.14)	124.0(65.43)
Median	Visit 1	21.5	21.0	0.900	0.850	23.000	23.000	21.000	21.500	84.5	90.0
Min, Max	Visit 1	12,46	13,29	0.60,1.56	0.70,1.20	8.45,41.00	13.00, 55.00	12.00,49.00	5.00,48.00	50,296	42,266
N	Visit 4	60	30	60	30	60	30	60	30	60	30
Mean (SD)	Visit 4	23.9(4.30)	21.3(3.43)	0.965(0.1400)	0.883(0.1621)	24.617(4.7339)	25.233(6.3933)	24.917(5.9839)	24.100(6.5197)	121.8(49.84)	124.9(45.32)
Median	Visit 4	22.0	21.0	0.900	0.850	23.000	24.000	23.000	22.000	94.5	100.0
Min, Max	Visit 4	15,32	18,31	0.70,1.30	0.70,1.20	18.00,38.00	13.00, 37.00	12.00,39.00	11.00,41.00	60,210	68,200

Table 4 D: Descriptive statistics for Lab Data (Total Cholesterol, Triglycerides, HDL Cholesterol and LDL Cholesterol)

Parameter/ Statistics	Visit	Total Cholesterol (mg/dl)		Triglycerides (mg/dl)		HDL Cholesterol (mg/dl)		LDL Cholesterol (mg/dl)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Visit 1	60	30	60	30	60	30	60	30
Mean (SD)	Visit 1	160.0(28.93)	160.2(21.35)	182.6(32.91)	180.2(25.73)	32.1(4.90)	34.2(4.45)	96.6(34.04)	98.7(22.81)
Median	Visit 1	163.0	161.0	183.5	179.0	32.0	34.5	101.0	103.5
Min, Max	Visit 1	15,200	125,200	111,248	119,221	3,40	27,40	24,182	64,140
N	Visit 4	60	30	60	30	60	30	60	30
Mean (SD)	Visit 4	161.7(22.14)	161.8(9.28)	182.0(41.61)	188.7(18.14)	32.7(3.23)	34.7(3.00)	96.5(22.72)	98.9(17.95)
Median	Visit 4	160.0	160.0	184.0	188.0	33.0	34.0	95.5	96.5
Min, Max	Visit 4	102,200	134,189	2,280	134,230	22,44	31,45	47,143	56,140

Table 4 E: Descriptive statistics for Lab Data (Fasting Blood Glucose and Hemoglobin)

Parameter / Statistics	Fasting Blood Glucose (mg/dl)			Hemoglobin (g/dL)		
	Visit	Treatment A	Treatment B	Visit	Treatment A	Treatment B
N	Visit 1	60	30	Screening	35	35
Mean (SD)	Visit 1	77.4(2.71)	76.6(1.56)	Screening	14.02(1.727)	13.82(1.896)
Median	Visit 1	77.5	76.0	Screening	13.50	14.00
Min, Max	Visit 1	65,81	73,80	Screening	11.7,18.0	10.7,18.0
N	Visit 4	60	30	Visit 3	35	35
Mean (SD)	Visit 4	77.4(2.57)	76.7(1.47)	Visit 3	14.58(1.646)	14.59(1.687)
Median	Visit 4	78.0	76.0	Visit 3	14.10	14.70
Min, Max	Visit 4	66,81	73,79	Visit 3	11.9,18.5	11.3,19.0

Table 4 F: Descriptive statistics for Lab Data (Total Bilirubin and Total Protein)

Parameter/ Statistics	Visit	Total Bilirubin mg/dl)		Total Protein	
		Treatment A	Treatment B	Treatment A	Treatment B
N	Visit 1	60	30	60	30
Mean (SD)	Visit 1	0.751(0.8804)	0.591(0.2946)	7.28(0.526)	6.79(0.671)
Median	Visit 1	0.600	0.500	7.30	6.55
Min, Max	Visit 1	0.30,7.30	0.30,1.50	6.0,8.2	5.9,8.2
N	Visit 4	60	30	60	30
Mean (SD)	Visit 4	0.767(0.0857)	0.593(0.2504)	7.32(0.526)	6.75(0.588)
Median	Visit 4	0.700	0.700	7.30	6.50
Min, Max	Visit 4	0.60,1.00	0.20,1.00	6.1,8.2	6.1,7.9

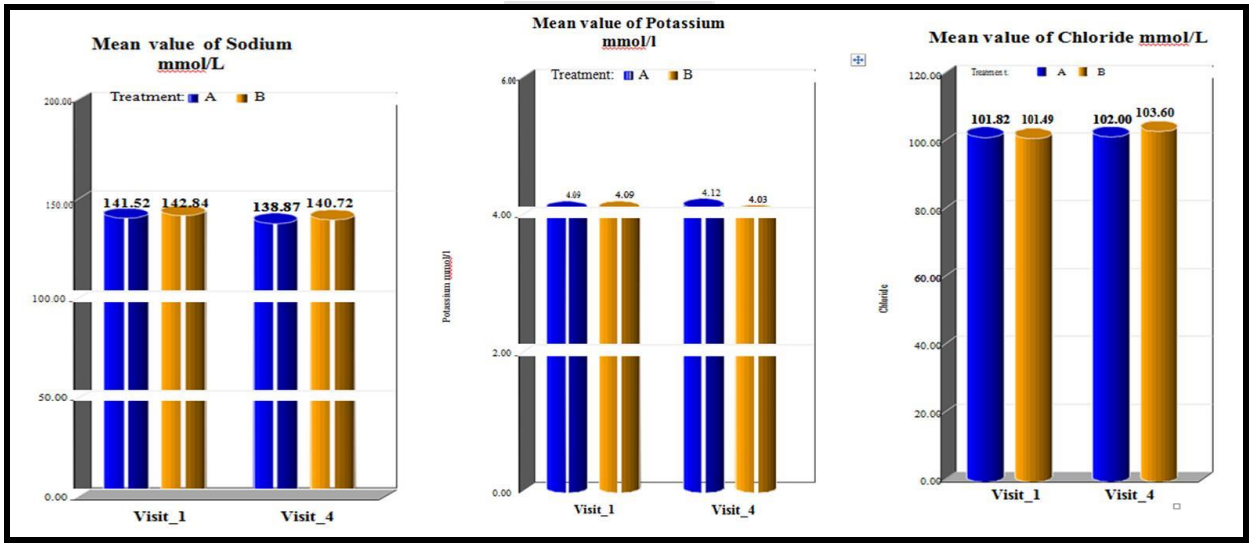


Fig 1: Descriptive statistics for Lab Data- Sodium (mmol/l), Potassium (mmol/l) and Chloride (mmol/l)

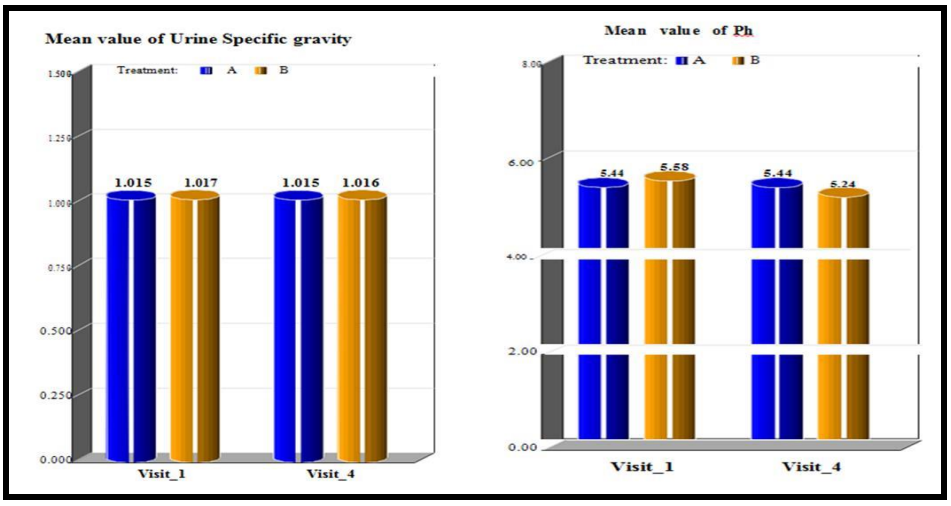


Fig 2: Comparative Descriptive Statistics for parameters Lab Data - Urine Specific Gravity and Urine pH

Table 4 G: Descriptive statistics for Lab Data- Urine Color & Appearance

Parameter/ Statistics	Visit	Color & Appearance		Pus Cells (hpf)		Epithelial cells (/hpf)		ECG	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
Normal	Visit 1	60 (100.0)	30 (100.0)	60 (100.0)	30 (100.0)	60 (100.0)	30 (100.0)	60 (100.0)	30 (100.0)
Abnormal	Visit 1	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Normal	Visit 4	60 (100.0)	30 (100.0)	0(0.0)	0(0.0)	60 (100.0)	30 (100.0)	0(0.0)	30 (100.0)
Abnormal	Visit 4	0(0.0)	0(0.0)	60(100.0)	30(100.0)	0(0.0)	0(0.0)	60(100.0)	0(0.0)

Table 4 H: Descriptive statistics for Lab Data- Protein, Urine Glucose, Bile Salts and Bile Pigment

Parameter/ Statistics	Visit	Protein		Urine Glucose		Bile Salts		Bile Pigment	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
Present	Visit 1	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Absent	Visit 1	60(100.0)	30(100.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)
Present	Visit 4	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Absent	Visit 4	60(100.0)	30(100.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)

Table 4 I: Descriptive statistics for Lab Data- Urine Bacteria, Urine RBCs, Urine Casts and Urine Crystals

Parameter/ Statistics	Visit	Urine Bacteria		Urine RBCs		Urine Casts		Urine Crystals	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
Present	Visit 1	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Absent	Visit 1	60(100.0)	30(100.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)
Present	Visit 4	60(100.0)	30(100.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Absent	Visit 4	0(0.0)	0(0.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)	60(100.0)	30(100.0)

ASSESSMENT OF EFFICACY

Efficacy variable(s)

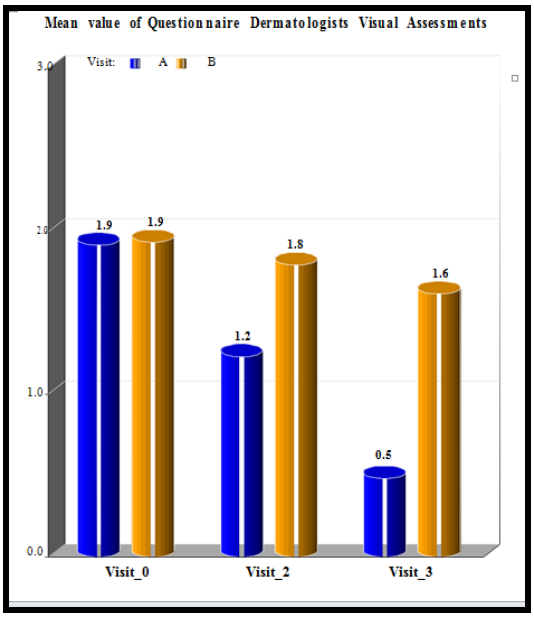


Fig 3: Comparative Descriptive Statistics for Efficacy parameters- Dermatologist's Visual Assessments

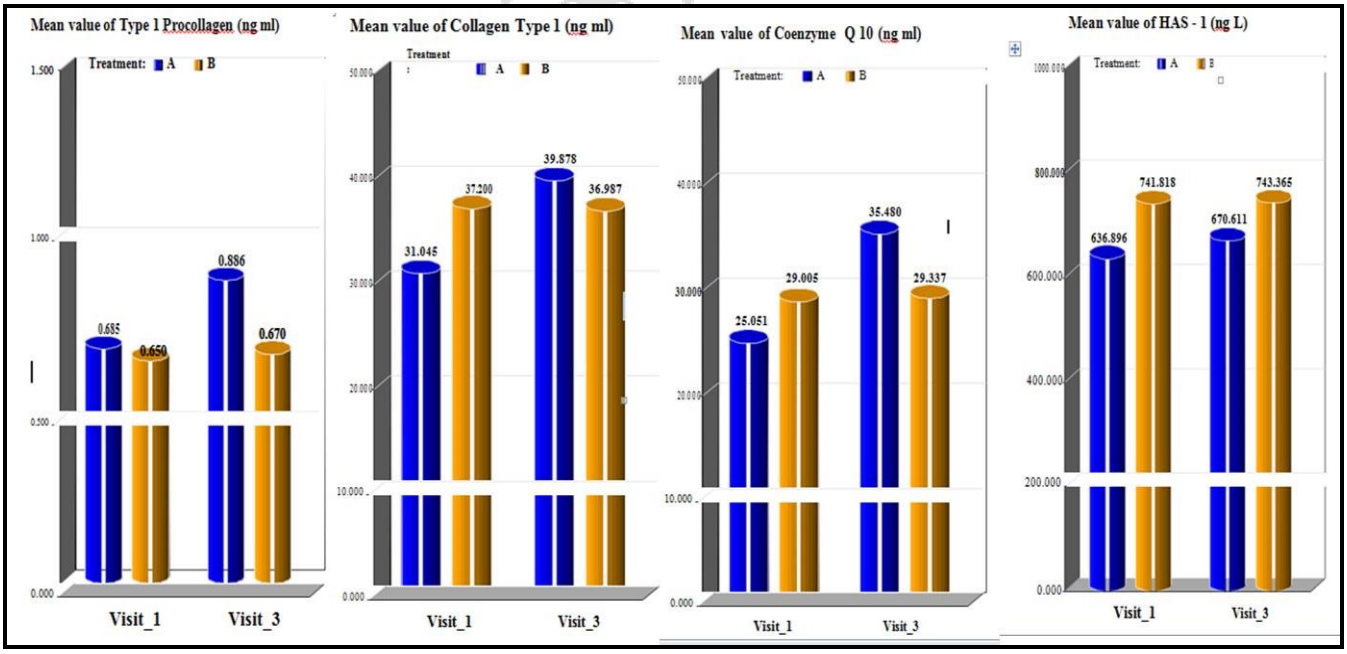


Fig 4: Comparative Descriptive Statistics for Efficacy parameters- Type 1 Procollagen, Collagen Type 1, Coenzyme Q 10 (ng/ml) and HAS-1 (ngL)

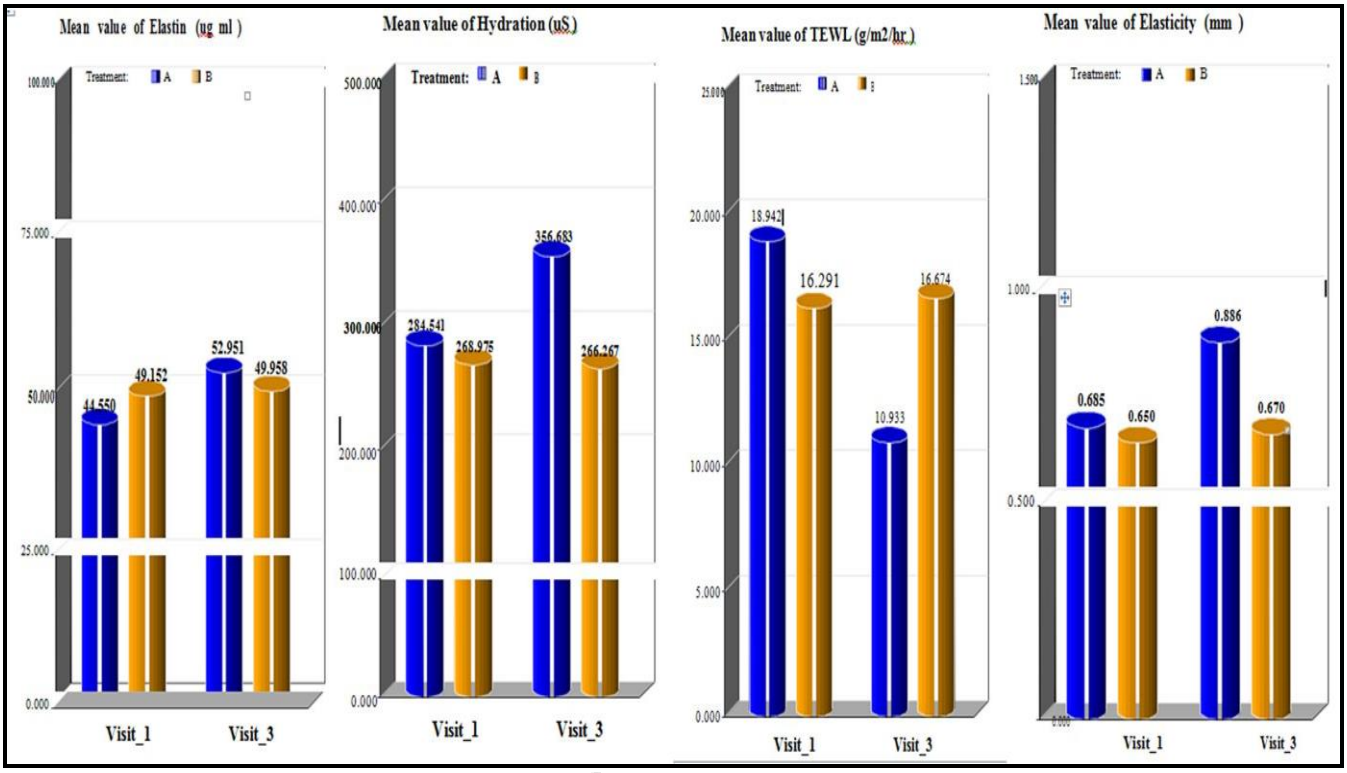


Fig 5: Comparative Descriptive Statistics for Efficacy parameters- Elastin, Hydration (µS), TEWL (gn/m2/hr) and Elasticity (mm)

DISCUSSION

iGlow polyherbal formulation is a proprietary formula designed for improving overall skin health. It is enriched with time tested herbal extracts, powders and naturally derived proteins that provide necessary nutrients to the wellbeing of human skin.

The trial was conducted in Sri Venkateshwara Hospital, Rashtra Kuvempu Nagara, Bangalore, Karnataka- 560076, post Institutional Ethics Committee approval /favorable opinion on the trial proposal.

Eligible subjects were enrolled into the study only after obtaining their consent in writing. The randomization was done in 2:1 ratio. The first patient's first visit was on 26 Oct 2021, last patient's first visit was on 02 Dec 2021 and last patient's last visit was on 07 Mar 2022.

Demographics: Subjects of mean age group of 42.5 and 38.4 years and weight of 62.4 and 61.3 kgs were included randomly between the active and placebo groups respectively. More females were enrolled than males and active group had a greater number of female subjects (Table 1A).

Safety Parameters: Vital signs for the 2 treatment group subjects were measured at all the study visits. Table 2A shows average temperature of study subjects across all the visits. Similarly other vital parameters like heart rate, pulse rate, respiratory rate, systolic blood pressure and diastolic blood pressure were measured and recorded (Table 2A and 2B). These vital sign parameters were found to be normal for all the study subjects and did not have any clinical or statistically significant abnormal values when compared between and within groups, implying that the test product has no safety issues post 90 days of oral administration.

Physical examination was performed, medical history, were completely normal across all the treatment groups across all the study visits. None of these safety lab data has any statistically significant changes from baseline (Day 0) visit values to that of their respective last (Day 90) visit values. This indicates that the product under testing is completely safe for oral consumption. Medical history (Table 3) and Physical examination on screening visit was found to be normal for all the volunteers.

Laboratory safety Data: Hematology parameters like fasting blood glucose (Table 4E), Hemoglobin (Table 4E), WBC (Table 4A), Neutrophils, Lymphocytes, Monocytes, Eosinophils (Table 4B), Basophils, RBC, Platelet count (Table 4A), were normal throughout all the visits.

Serum biochemistry: Parameters like Serum Creatinine (Table 4C), Blood urea (Table 4C), Total Bilirubin (Table 4F), Total protein (Table 4F), SGOT, SGPT, Alkaline phosphatase (Table 4C), Total cholesterol, HDL, LDL, TG (Table 4D) are completely normal before and after the treatment periods across all the study groups. Sodium, Potassium and Chloride (Fig 1) were normal for all the study subjects.

Urinalysis: Specific gravity (Fig 2), pH (Fig 2), Urine color & appearance (Table 4G), urine protein, Urine glucose, Bile salts, Bile pigment, Pus cells, Epithelial Cells, Urine bacteria, Red cells, Urine casts, Urine crystals (Table 4H and 4I) had no major changes between the screening and last visit and also between the two treatment groups.

Urine pregnancy test was performed at the time of screening to ensure no women of child bearing potential were enrolled into the trial.

ECG was performed on screening and last visit and no abnormalities were observed.

Efficacy parameters: Dermatologist's visual assessments for erythema showed statistically significant changes between the two treatment groups by Day 90 (Fig 3). Biomarkers like Type 1 procollagen, collagen, co-enzyme Q10, HAS1, Elastin, Hydration, TEWL and Elasticity (Fig 4 and 5) showed that all these efficacy parameters showed statistically significant change in the treatment group when compared to placebo group by Day 90.

Instrumental analysis showed a clear change in the dermatological changes from Day 0 to Day 90 for the first 60 subjects who received active product whereas the remaining graphs starting from 061 to 090 did not show clinically significant change. These parameters had left an extremely remarkable change in the iGlow group of subjects from screening to last visit (day 90), not only within the group but also when compared to placebo group values.

There were no Adverse OR Serious Adverse Events reported in this trial.

There was no protocol deviations observed during the course of the trial. The compliance of investigational product is 100% by all the completed study subjects.

CONCLUSION:

In the present study iGlow has demonstrated a remarkable safety profile when administered orally as liquid dosage form. Subjects who had visible fine lines and wrinkles in periorbital area (Crow's feet), nasolabial areas, forehead and perioral regions of the face; mild to moderate naso-labial folds and crow's feet when received iGlow showed significant improvement in their visual dermatological erythema better than the placebo group arm at the end of the study (Day 90). These results corroborate even with various biomarkers (procollagen, collagen, elastin, HAS1, hydration, TEWL and elasticity) showed that the subjects had a significant improvement in the overall skin health in the iGlow receiving group. This study clearly indicates that iGlow has significant anti-ageing effects in the study subjects. Therefore, it is concluded that iGlow has a definite role in improving the overall skin health when the subjects administered the product orally for 90 consecutive days.

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