

IN VITRO EVALUATION OF HERBAL ACTIVE ENRICHED HAIR CREAM FOR COMMON DANDRUFF TREATMENT AND HAIR NOURISHMENT

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ABSTRACT

In everyday life we suffer with the deposition of dirt on the scalp. It start sticking and cannot go off without using a good cleansing products like shampoos and soaps. The sticking of dirt is due to oil present in our scalp called sebum. It works as a food to microbe and when the microbe start growing, it will hardly be controlled without right treatments. Malassezia breaks the sebum oil in to fatty acid specifically in oleic acid and hence the dandruff started. This is the beginning and if it is not stopped it will continue to be worsen. As almost half of the world population are affected by Dandruff. Overall clinical study results revealed that usage of tested anti – dandruff hair cream is effective and significantly reduce the dandruff fungi in scalp if used regularly. Also increase hair strength and shine with no itching as an observation. Based on the results obtained, test product has shown a significant reduction in dandruff by instrumental evaluation using Dandruff meter DA20 and visual scoring using dandruff scoring scale by Dermatologist. Reduction in scoring using Dandruff meter DA20 observed from baseline to each time points with improvement in hair nourishment also confirmed by instrument evaluation.

Clinical evaluation showed that 66.67% subjects reported excellent improvement and 25.00% subjects reported fair improvement in strength of hair after usage of test product for 15 days and 66.67% subjects reported mild improvement and 33.33% subjects reported moderate improvement in shininess of hair after usage of test product for 15 days. Subject perception evaluation showed that, 100% subjects felt no erythema and 95.83% subjects experienced no itchiness on scalp after usage of test product for 15 Days.

Subjective evaluation shows that, 100% subjects agreed on test product does not compromise the hair softness, does not causes any hypersensitivity reactions such as erythema, edema, pain, pruritus, and urticarial occurs, 95.83 % subjects agreed that hair are not damaged after application of test product, 100 % subjects agreed that they liked the test product and the fragrance also satisfied with the test product after using of 15 days.

In general, Naturals Styling Hair Cream Dandruff Guard (Test product) is safe and strengthen the hair with better shine and efficacious in reducing dandruff after usage of 15 days.

Formula efficacy is drawn high due to tea tree oil, lemon oil, Henna Powder, Green Almond powder, Aloe Vera Extract, Coconut oil, Pro-Vitamin of B5 in the formula these ingredients act as a carrier to carry the actives in to the deeper part of the scalp; synergistic combination of natural and synthetic chemicals helps to control the dandruff and nourishing the hairs. Overall study confirmed that the synergistic combination of synthetic anti-dandruff and natural ingredients plays a crucial role in control the anti-fungal, anti-inflammatory and local immune stimulatory actions.

Keywords: Dandruff, Lemon oil, Tea tree oil, Climbazole

INTRODUCTION

Malassezia globosa is a fungi and monophyletic genus. It is very common and found in all warm-blooded mammals and humans. It contributes to the dandruff, atopic eczema/dermatitis, pityriasis, versicolor, seborrheic dermatitis and folliculitis etc. When the fungus grows rapidly it disturbs new cell generation. Around 50% of people's bodies have a negative reaction to the presence of this fungus, causing dandruff.

Natural oils are present in our scalp called as a sebum; Dandruff-causing microbes utilize it as a food. *Malassezia* feeds off these oils, breaking it down into by-products, including oleic acid; formation of oleic acid is a starting/kick point of dandruff. Approximately half of the global population in the world is sensitive to the oleic acid and affected by the dandruff. The body reacts to the presence of oleic acid by increasing the speed at which your skin cells renew. It's an attempt to 'shed' the irritant and is the mechanism that causes flakes. There's more to the body's response to *Malassezia* and oleic acid than just flaking. Dandruff causes the itchy scalp, dry scalp, inflammation, a red scalp etc. There are so many options to control the situation. Sometime one needs to have more than one option to get rid of Dandruff. These options are shampoos, hair creams, different hair treatment techniques etc. Anti-dandruff hair cream can be an option to control the dandruff. Its unique pH of the products, solubility of actives, and deposition of actives play a critical role during anti-dandruff treatment. Varieties of antidandruff agents are used widely in various antidandruff preparations. There are different molecules synthetically derived and naturally occurred. Some of these are such as salicylic acid, climbazole, zinc pyrithione, octopirox, ketoconazole, selenium sulphide, coal tar etc. Climbazole is known as a very strong and good anti-dandruff agent. It is an imidazole radical which has very good anti-fungal activity.

There is a natural active hunt which is attracting to the researchers to research on natural and herbal compounds. It is also been proven that some of these compounds are very effective for anti-fungal treatment against the *Malassezia* fungi. There are so many studies that have been done on antidandruff activity of rosemary oil, basil oil, lemon oil, tea tree oil and on different herbal natural oils. One study conducted on shampoo by Sudhir Sawarkar, Vinay Deshmukh, Sankar Jayaganesh and Ovureddiar Perumal. 2018, Clinical Evaluation of Herbal Active Enriched Shampoo in Anti Dandruff Treatment. Also Cox, S., Mann, C., Markham, J., Bell, H., Gustafson, J., Warmington, J. and Wyllie, S. (2001). The mode of antimicrobial action of the essential oil of *Melaleuca alternifolia* (tea tree oil) exclusively studied on Tea tree oil. Many researchers found that *Melaleuca alternifolia* oil having very high efficacy against common dandruff exclusively and when it conjunct with *Citrus Limonum* the efficacy is enhanced tremendously.

There is an opportunity to get better understanding and generate data for the synergistic effect of synthetic and herbal materials against the dandruff-caused fungi. In this study we are using a hair cream format, having a particular solution for common dandruff problem. We also aimed to generate authentic data for hair strengthening, shining ease of combing etc. This is also to show off convenience to the consumer when using the product in routine.

MATERIALS AND METHODS

The objective of the present study was to evaluate in vitro efficacy and safety assessment of herbal actives anti-dandruff cream for the management of dandruff treatment.

SAMPLE PREPARATION

Tested preparation (Anti-Dandruff Cream) and process is summarized in the Table 1. The subjected preparation contained, Citrus limonum (lemon) oil; Melaleuca alternifolia (tea tree) oil; Trigonella foenum-graecum (Methi) dried additionally used of climbazole that is important to play a better role for the pathogenesis of dandruff.

Table 1. Antidandruff Cream ingredients and manufacturing details

RM Description	Method of manufacturing
Water	Water Phase: Add Di-sodium EDTA and Herbal extract @ 65°C and above Add the thickener in water phase and stir for 30 minutes
Disodium EDTA – IP Grade	
Herbal Extract	
Trigonella foenum-graecum (Methi) Powder	
Lawsonia inermis (Henna) Powder Prunus amygdalus (Almond Green) Powder	
Thickeners	Oil Phase: In another vessel mix all oil phase material @ 75°C Add the antidandruff synthetic active pre-dissolved in Propylene Glycol and natural active at 60 degree
Cocos nucifera Coconut oil	
Arlamol	
Capric triglyceride	
Liquid Paraffin	
Arlacel	
Cresmor	
Prunus amygdalus (SweetAlmond oil)	
Cety Alcohol	
Climbazole	
Lemon oil	Mix oil phase and water phase together
Tea tree oil	
Alovera extract	Premix d-penthenol in warm water And add in main mix after that add Aloe Vera powder mix
D-penthenol	
Triethanol amine	Adjust pH with tri-ethanol amine and then add preservative and fragrance
Preservative	
Fragrance	

STUDY DESIGN

This was an open-label, evaluator blinded, randomized, half-head, control arm, efficacy and safety study of anti-dandruff test product i.e. Naturals Styling Hair Cream Dandruff Guard involving a 2-week conditioning phase followed by a 2-week treatment phase. There were 24 subjects. The potential subjects were screened as per the inclusion and exclusion criteria only after obtaining written informed consent from the subjects. There were total 04 visits during the conduct of the study.

Clinical evaluations were conducted at baseline (i.e. before product application) and after 1 and 2 weeks of treatment with same restrictions throughout the study period.

The study duration of this study was approximately 4 weeks from conditioning period until last visit. The main focus is to evaluate the efficacy and safety of test product for anti-dandruff in terms of change in quantity of dandruff and the overall quality of hair i.e. strength and shininess etc. The safety of hair was assessed by treatment emergent adverse events such as erythema, itching, edema, pain, pruritus, and urticarial. Twenty-four (24) subjects completed the study.

Screening Phase [Before 14 days from start of Conditioning Period]: After obtaining the informed consent, the subjects were screened as per the inclusion/exclusion criteria. Subjects were acclimatized at room temperature for at least 15 minutes prior to having any clinical and instrumental assessments for each visit during the study period. Subjects were assessed for abbreviated physical examination, demography (age and gender) and medical history. Urine pregnancy test was performed for females of childbearing potential only. Dermatological evaluation of dandruff on scalp was performed by using visual dandruff scoring scale. Qualifying subjects were provided shampoo for conditioning phase, Subjects were instructed to use this shampoo at least three times per week instead of their regular shampoo. Restriction and instruction were provided to each subject. Subjects were instructed not to wash their hair within 24 hours (± 2 hours) prior to the baseline visit. In addition, subjects were also instructed not to wet their hair within 8 hours of the baseline visit. Subjects were informed telephonically by screening personnel regarding the same. On enrolment day (Day 1), subjects who followed and completed the conditioning period, the inclusion/exclusion criteria were checked and only qualifying subjects enrolled. Study restrictions and instructions were provided to subject and asked to follow study Instructions. Subjects were informed about their next visit.

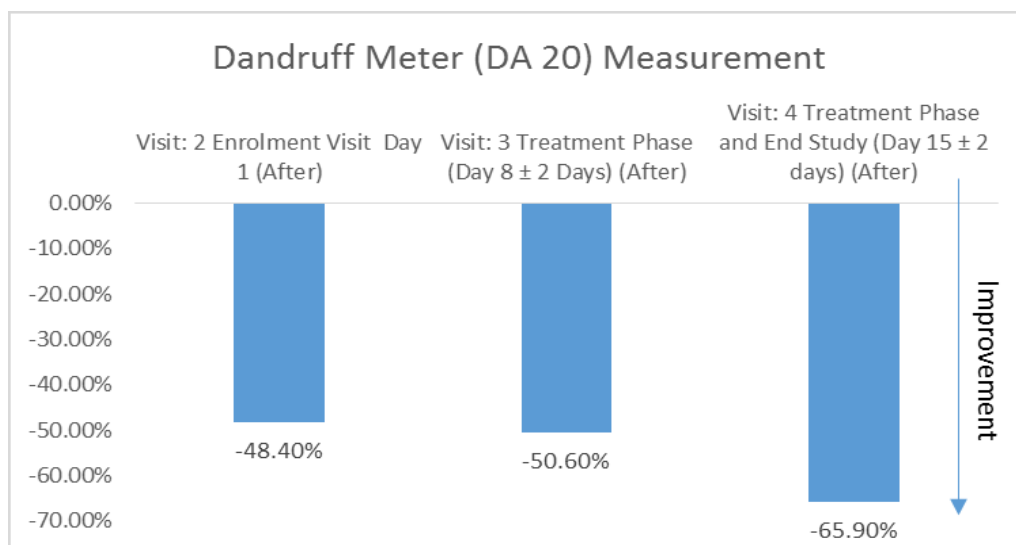
Enrolment Phase [Visit 2 (Day 1)]: Upon arrival, subjects were acclimatized at room temperature for at least 15 minutes prior to having any clinical and instrumental assessments. Inclusion/exclusion, well-being questionnaires were asked to subjects by study personnel and the answers were recorded along with the concomitant medications details. Urine pregnancy test was performed for females of childbearing potential. Subject's compliance for restrictions were ensured prior to any assessments. Dermatological evaluation of dandruff on scalp by using visual dandruff scoring scale and dandruff Meter DA 20 before application of test product on Day 1 was considered as baseline value. Digital photograph of petri dish with collected dandruff was taken prior to application of test product. The strength of hair by pull test was assessed by the scale (refer section 7.5.5) before application of test product on Day 1 and was considered as baseline value. The itchiness on scalp was assessed by scale (refer section 7.5.5) before application of test product on Day 1 according to subject perception evaluation and was considered as baseline value. Subjective evaluations were done by asking questions to subject before application on Day 1 and was considered as baseline value. Study staff dispensed and distributed test product to the subject for application. Based on dosage and administration, study personnel applied the test product to the subject's hair as per randomization schedule/ subjects number. Dermatological evaluation of dandruff on scalp was performed by using visual dandruff scoring scale after application of test product on Day 1. Dandruff was evaluated by using Dandruff Meter DA 20 after application of test product on Day 1. The strength of hair by pull test was assessed by the scale (refer section 7.5.5) after application of test product on Day 1. The shininess of hair was assessed by the scale (refer section 7.5.5) after application of test product on Day 1. The itchiness and erythema on scalp were assessed by scale (refer section 7.5.5) after application of test product on Day 1

according to subject perception evaluation. Subjective evaluations were done by asking questions to subject after application on Day 1.

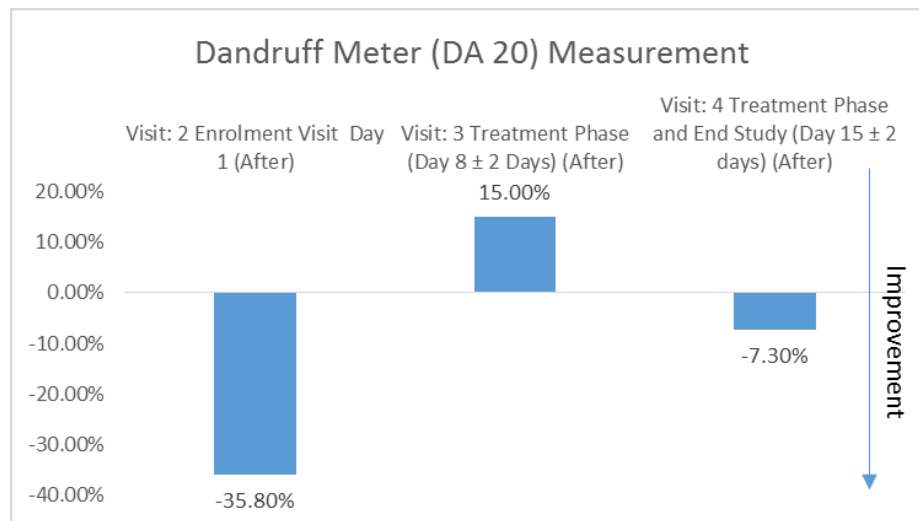
Treatment Phase [Visit 3 (Day 8 ± 2 days)]: Upon arrival, subjects were acclimatized at room temperature for at least 15 minutes prior to having any clinical and instrumental assessments. Well-being questionnaires and concomitant medications details were recorded. Subject's compliance for restrictions were ensured prior to any assessments. Dermatological evaluation of dandruff on scalp was performed by using visual dandruff scoring scale after application of test product on Day 8. Dandruff was evaluated by using Dandruff Meter DA 20 after application of test product on Day 8. The strength of hair by pull test was assessed by the scale (refer section 7.5.5) after application of test product on Day 8. The shininess of hair was assessed by the scale (refer section 7.5.5) after application of test product on Day 8. The itchiness and erythema on scalp were assessed by scale (refer section 7.5.5) after application of test product on Day 8 according to subject perception evaluation. Subjective evaluations were done by asking questions to subject after application on Day 8.

Treatment phase and End of Study [Visit 4 (Day 15 ± 2 days)]: Upon arrival, subjects were acclimatized at room temperature for at least 15 minutes prior to having any clinical and instrumental assessments. Well-being questionnaires and concomitant medications details were recorded. Subject's compliance for restrictions were ensured prior to any assessment. Dermatological evaluation of dandruff on scalp was performed by using visual dandruff scoring scale after application of test product on Day 15. Digital photograph of petri dish with collected dandruff was taken after application of test product. Dandruff was evaluated by using Dandruff Meter DA 20 after application of test product on Day 15. The strength of hair by pull test was assessed by the scale (refer section 7.5.5) after application of test product on Day 15. The shininess of hair was assessed by the scale (refer section 7.5.5) after application of test product on Day 15. The itchiness and erythema on scalp were assessed by scale (refer section 7.5.5) after application of test product on Day 15 according to subject perception evaluation. Subjective evaluations were done by asking questions to subject after application on Day 15. Once the subjective evaluation was completed, the subject's participation in the study was considered as complete.

Dandruff Meter (DA 20) Measurement- Change from Baseline- For Treatment A



Dandruff Meter (DA 20) Measurement- Change from Baseline for Treatment B



STATISTICAL ANALYSIS

Treatment A: Statistically significant reduction observed from baseline to Visit 2 (P-value=0.0002), Visit 3 (P-value=0.0001), Visit 4 (P-value=0.0000), which clinically shows significant reduction in dandruff as compare from baseline to Visit 2, Visit 3 and Visit 4.

Treatment B: Statistically significant reduction observed from baseline to Visit 2 (P-value=0.0004) and Visit 4 (P-value=0.0073), which clinically shows significant reduction in dandruff as compare from baseline to Visit 2 and Visit 4.

Statistically non-significant reduction observed from baseline to Visit 3 (P-value=0.0645) which clinically shows non-significant reduction in dandruff as compare from baseline to Visit 3.

RESULTS

In vitro study supported the claim of controlling and reducing dandruff fungi on scalp on regular usage of hair styling anti-dandruff cream. Efficacy was analyzed on the basis of hair fall verses base line in 15 days’ time frame. The observation was done using Dandruff meter and visual.

Clinical evaluation showed that 66.67% subjects showed excellent improvement and 25.00% subjects showed fair improvement in strength of Hair. And 66.67% subjects showed mild improvement and 33.33% subjects showed moderate improvement in shining of the hair after usage of test product for 15 days,

Also Subject perception evaluation showed that, 100% subjects felt no erythema on scalp and 95.83% subjects experienced no itchiness on scalp after usage of test product for 15 Days.

Subjective evaluation shows that, 100% subjects agreed on test product does not compromise the hair softness, 100% subjects agreed on test product does not causes any hypersensitivity reactions such as erythema, edema, pain, pruritus, and urticarial occurs, 95.83 % subjects agreed that hair are not damaged after application of test product after usage of 15 days.

Change in Dandruff (Average) after 15 days.

Treatment A% Reduction Value						
Visit	None	Almost non/Slight	Mild	Moderate	Marked	Severe/heavy
Baseline	-	-	-	62.5	37.5	-
Visit 2 (Day 1)	16.67	25	33.33	20.83	4.17	-
Visit 3 (Day 8)	4.35	30.43	26.09	30.43	8.7	-
Visit 4 (Day 15)	4.17	58.33	29.17	8.33	-	-

Treatment B% Reduction Value						
Visit	None	Almost non/Slight	Mild	Moderate	Marked	Severe/heavy
Baseline	-	-	-	66.67	33.33	-
Visit 2 (Day 1)	-	29.17	50	16.67	4.17	-
Visit 3 (Day 8)	4.35	21.74	30.4 3	26.09	13.04	4.35
Visit 4 (Day 15)	-	20.83	50	25	4.17	-

Clinical evaluation showed that

- i. Strength of Hair showed that after usage of test product for 15 days,
- ii. 66.67% subjects showed excellent improvement and 25.00% subjects showed fair improvement.
- iii. Shininess of hair showed that after usage of test product for 15 days,
- iv. 66.67% subjects showed mild improvement and 33.33% subjects showed moderate improvement.

Subject perception evaluation showed that,

- i. 100% subjects felt no erythema on scalp after usage of test product for 15 Days.
- ii. 95.83% subjects experienced no itchiness on scalp after usage of test product for 15 Days.

Subjective evaluation shows that,

- i. 100% subjects agreed on test product does not compromise the hair softness after usage of 15 days.
- ii. 100% subjects agreed on test product does not causes any hypersensitivity reactions such as erythema, edema, pain, pruritus, and urticarial occurs after using of 15 days.
- iii. 95.83 % subjects agreed that hair are not damaged after application of test product for 15 days.
- iv. 100 % subjects agreed that they liked the test product after using of 15 days.

- v. 100% subjects liked the fragrance of this product after application of 15 days.
- vi. 100% subjects satisfied with the test product after using of 15 days.

DISCUSSION

The purpose of this study was to determine the effectiveness and safety of Vatika Naturals Styling Hair Cream Dandruff Guard.

Based on the results obtained, test product has shown a significant reduction in dandruff by instrumental evaluation using Dandruff meter DA20 and visual scoring using dandruff scoring scale by Dermatologist. Reduction in scoring using Dandruff meter DA20 observed from baseline to each time points, however at visit 3 mean value was increased from visit 2 but value was less than baseline reading. On visit 2 the reading was taken immediate after application of test product and on visit 3 subject used the product for 7 days and then reading taken this might be a reason for the difference.

Clinical evaluation showed that 66.67% subjects reported excellent improvement and 25.00% subjects reported fair improvement in strength of hair after usage of test product for 15 days and 66.67% subjects reported mild improvement and 33.33% subjects reported moderate improvement in shininess of hair after usage of test product for 15 days.

Subject perception evaluation showed that, 100% subjects felt no erythema and 95.83% subjects experienced no itchiness on scalp after usage of test product for 15 Days.

Subjective evaluation shows that, 100% subjects agreed on test product does not compromise the hair softness, does not causes any hypersensitivity reactions such as erythema, edema, pain, pruritus, and urticarial occurs, 95.83 % subjects agreed that hair are not damaged after application of test product, 100 % subjects agreed that they liked the test product and the fragrance also satisfied with the test product after using of 15 days.

In general, Vatika Naturals Styling Hair Cream Dandruff Guard (Test product) is safe and efficacious in reducing dandruff after usage of 15 days.

CONCLUSION

The data clearly reveals that the usage of Vatika Anti-Dandruff cream reduces the dandruff this is due to the combination of natural and synthetic ingredients. Also data endorsed that using Vatika hair styling anti-dandruff cream is safe for use.

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