



## PREPARATION AND EVALUATION OF DERMAL GEL CONTAINING OCIMUM BASILICUM FOR ACNE VULGARIS TREATMENT

Rama Al Mouslli<sup>1</sup>, Ghina Obaid<sup>1</sup>, Nour Al Assal<sup>1</sup>, Kinda Al Yaseen<sup>1</sup>, Rama Aziz<sup>1,2</sup> and \*Bassel Hussein<sup>1,3</sup>

<sup>1</sup>Faculty of pharmacy, Al-Sham Private University (ASPU), Damascus, Syria

<sup>1,2</sup>Faculty of agriculture, Damascus university. Al-Sham Private University (ASPU), Damascus, Syria

<sup>1,3</sup>Faculty of pharmacy, Al-Sham Private University (ASPU), Damascus, Syria

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### Abstract

Acne vulgaris is one of the most common problems in skin diseases, especially in teenagers. It is usually seen on the face, upper part of the chest, and the back of subjects who possess greater numbers of oil glands. In this study, the efficacy and safety of gel products containing Ocimum Basilicum (OB) essential oil were investigated for treating acne. The prepared gels were applied alone on twenty volunteers suffering from acne vulgaris. It was found that the prepared gels have been effectively treated acne vulgaris without side effects. The dry leaves of OB extract have the faster effect compared with the fresh OB leaves extract.

**Keywords:** Acne vulgaris, Skin diseases, Ocimum Basilicum (OB), Volunteers, Treatment, Product, Gel.

### INTRODUCTION

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous unit and is among the most common dermatological conditions worldwide<sup>(1-2)</sup>. It is a common skin disorder affecting most individuals in the teenage years. It has been estimated that acne affects 650 million people globally and is the eighth most common diseases in the world<sup>(3)</sup>. Acne commonly affects young people at a time when they are undergoing maximum psychological, social, and physical change. A high incidence of acne is found in girls aged about 14 to 17 and in boys aged about 16 to 19<sup>(3-4)</sup>. The lesions occur primarily on the face, neck, upper back and chest<sup>(5-6)</sup>. Studies have revealed the burden of acne to diminish adolescents' quality of life and to impact their global self-esteem<sup>(7-8)</sup>. Acne pathogenesis is multifactorial, resulting from excess of androgen induced sebaceous secretion, hypermenorrhea, abnormal follicle keratinization, colonization by *Propionibacterium acnes*, and inflammation process<sup>(9)</sup>. The bacteria mainly reside in pilosebaceous follicles and play a crucial role in stimulating host inflammatory responses, which are essential for acne pathogenesis<sup>(10)</sup>. Several medications that have been devised to target these pathogenic mechanisms have demonstrated modest efficacy, but their use is also accompanied by potentially serious side effects<sup>(11-12)</sup>. A wide variety of treatment regimens exist for acne vulgaris including benzoyl peroxide, retinoids, isotretinoids, keratolytic soaps, alpha hydroxy acids, azelaic acid, salicylic acid as well as hormonal, anti-androgen, antibiotics or anti-seborrheic treatments<sup>(13-14)</sup>. However, none of these regimens, as mentioned before, is free of side effects, and acne recurrence may be occurred when treatment is stopped, so over the last few decades, there has been a growing interest in the use of medicinal plants as an alternative or adjuvant therapy in the treatment of acne vulgaris<sup>(15-16)</sup>. Medicinal plants have been used as traditional treatments for numerous human diseases for thousands of years<sup>(16)</sup>.

Herbal extracts have recently received considerable interest in acne therapy owing to their enhanced skin compatibility compared with antibiotics and synthetic agents<sup>(17)</sup>. Plants produce a wide range of chemical compounds which have biological effects such as anti-inflammatory, anticancer, contraceptive, and different effects on hematopoietic cells<sup>(18)</sup>. Essential oils are secondary plant metabolites that include a wide spectrum of synthetic compounds as well as therapeutic capabilities<sup>(18)</sup>. The anti-inflammatory effects of free fatty acids in sebum particularly linoleic and lauric acids were found to inhibit acne<sup>(19-20)</sup>, and the general antimicrobial activities of medicinal plants and plant products, such as essential oils have been reviewed previously<sup>(21-23)</sup>. The use of plants and essential oils still presents a curious case since they constitute a class of potent natural antimicrobial agents<sup>(24-25)</sup>. The purpose of this study is to prepare dermal products containing Ocimum Basilicum (OB) extracts as a medicinal plant for acne treatment and these products were applied on twenty volunteers with different acne cases. The efficacy of the product in treating acne was evaluated.

### MATERIALS AND METHODS

- Materials:** Carbopol, HPMC, Macrogol were purchased from Sigma- Germany. Triethanolamine, Ethanol, and other excipients were purchased from Merck- Germany. All other chemicals and reagents were of analytical grade and used as received.
- The botanical extracts, and the extraction method:** The extraction was performed in the horticulture department of the faculty of agriculture in Damascus university. The OB leaves were cut with a little of petioles left, they were placed in a big flask and hot water was poured on them, then distilled water was added in the capacitor entrance. Next, the oil was gathered, by using the scalp vein. The oil was put in dark glass bottles and stored in a refrigerator. The dry samples were extracted and stored in the same way of the fresh OB. Figure 1. shows the fresh plant and the obtained extracts.

\*Corresponding Author: Dr. Bassel Hussein

Faculty of pharmacy, Al-Sham Private University (ASPU), Damascus, Syria  
Email: b.h.foph@aspu.edu.sy

3. **Gels Preparation:** The gels were prepared using different jellifying agents, such as Carbopol, HPMC, and Macrogol. The gel has been fixed with suitable materials to give it a creamy texture and appropriate excipients have been added to stabilize the efficacy of the product. The chosen formulation of the gel was determined due to the homogeneity appearance, the ease to spread on skin, and the product stability. The prepared gels were applied on twenty volunteers. All the chosen volunteers were of medium or severe cases. They informed to use the gels topically on the affected acne areas, three times a day. In case of sun exposure, a sunscreen is needed. Volunteers filled a questionnaire about their sex, age, skin type, places where acne mainly spread, previous acne treatments and all past taken medicines. All the volunteers accepted to stop all medicines they were using and apply the prepared gel alone for at least one month.



Fig.1. Fresh OB, and the extracts

## RESULTS AND DISCUSSION

The prepared gels were applied on twenty volunteers with different acne cases. The results showed the effectiveness of the applied product in treating the most cases. The efficacy of the product included the improvement of volunteer's situations which assessed by decreasing the spread area of acne pimples (such as in face, back, chest...), decreasing the acne pimples size, and even in disappearing the acne pimples in some cases. Table 1. shows information of volunteers. In most of the twenty studied cases, the obtained results were great in curing acne. The treatment led in six cases (cases number 1, 2, 3, 9, 10, 18) to completely disappearance of acne pimples, and all their traces disappeared too. Only in two cases (cases number 17 and 19) the improvement was little. In the other cases the improvement was excellent or at least good. No side effects were observed in all studied cases during the period of using the OB gel product. Some more details about the cases number 1, and 2 will be explained, because the treatment in these two cases led to completely removing acnes.

### Case Number- 1

A 18-year-old male patient of oily skin type was suffering from severe acnes especially concentrated on the right cheek. He had not responded to systemic and topical Erythromycin and clindamycin treatment at the age of 14. At the age of 18, he used a drug prescribed by a specialist doctor containing: Glycolic acid 6% cream- Clindamycin 1% solution- Tretinoin 0.01% gel. The improvement was little and only during the use of drugs. This patient was convinced to stop this prescription and use only our prepared gel containing OB extracts. Figure. 2 shows the case number 1 before and after the treatment.

Table 1. Information of volunteers, and the progress of treatment

Volunteer N°	Volunteers Information				Estimation after 10 days of treatment	Estimation after 20 days	Estimation after 30 days or more
	Gender	Age	Acne spread area	Acne degree of infection			
1	M	18	Right cheek	Severe	Obvious improvement after 3 days	Excellent improvement	Complete disappearance of acne
2	F	18	Front and right cheek	Medium	Immediate improvement	Excellent improvement	Complete disappearance of acne
3	F	22	Forehead and left cheek	Severe	Little improvement	Improvement	Decrease in acne size and in count
4	F	37	Face and shoulders	Medium	Improvement	Inflammation disappeared	Decrease in acne size and in count
5	F	20	Left cheek	Medium	Improvement	Noticeable improvement	Complete disappearance of acne
6	M	17	Right cheek	Severe	Improvement	Noticeable improvement	Acne traces disappeared
7	M	22	Forehead	Medium	No improvement	Little improvement	Pimples traces remained
8	F	20	Face and hands	Medium	Little improvement	Improvement	Noticeable improvement
9	F	20	All the face	Severe	Excellent improvement	Excellent improvement	Great improvement most acne disappeared in 6 days
10	M	23	Face	Medium	Excellent improvement	Excellent improvement	Complete disappearance of acne
11	F	19	Face and hands	Medium	Little improvement	Improvement	Noticeable improvement, but few of acnes remained
12	M	20	Forehead and cheeks	Severe	Little improvement	Improvement	Noticeable improvement, very little of acnes remained
13	M	23	Face and back	Severe	Little improvement	Improvement	A few acnes remained
14	F	20	Face	Medium	Little improvement	Improvement	Excellent improvement
15	F	38	Forehead and cheeks	Medium	Rapid improvement in less than a week	Good improvement	Excellent improvement
16	F	22	Left cheek	Medium	Improvement in 7 days	Good improvement	Excellent improvement
17	F	19	Forehead and hands	Medium	No improvement	Little improvement	Little improvement
18	F	18	Face and forehead	Medium	Little improvement	Improvement	Complete disappearance of acne without traces
19	F	21	Face	Medium	No improvement	Little improvement	Little improvement
20	M	20	Chest	Medium	Little improvement	Improvement	Most pimples disappeared

## Case Number-2

A 18-year-old female patient of oily skin type with mild-to-moderate papulopustular acne concentrated on the front of the face and the right cheek. She had not sufficiently improved by the treatment of systemic Erythromycin, Benzyl peroxide 5% gel, and Sulfur soap at the age of 16. At the age of 18, she used Clindamycin 1% solution- Tretinoin 0.01% gel, and Panthenol 2% cream. The improvement was relating using these products and was not satisfied. The patient was convinced to stop all drugs and use only the prepared gel containing OB extracts. Figure. 3 shows the case number 2 before and after the treatment.



Fig. 2. Case Number 1. Before and after the treatment



Fig. 3. Case Number 2. Before and after the treatment

## Conclusion

The efficacy and safety of topical gels containing OB extracts were studied and successfully proved in the treatment of acne vulgaris. The number of inflammatory lesions and the number of non-inflammatory lesions were significantly reduced at 1- to 4 weeks after treatment. The twenty patients treated with the lonely gels had excellent or at least good responses at maximum four weeks. The results of this study showed that topically applied gels are both effective and safe in reducing the clinical manifestation of acne in patients with moderate or even severe cases. OB extract-based gels showed excellent efficacy in acne treatment, may be due to the principal active ingredients existed in the plant, such as Linalool, Eugenol, Cineole which have antioxidant and antibacterial effects, however dry basil leaves extract has a faster improvement effect than the fresh green leaves basil extract, this may be due to the higher concentration of active substances in the dry leaves compared with the fresh ones. This study proved that

basil oil could be an excellent candidate for acne treatment. This research is the first research in Syria which proved the benefits of the use of OB extracts in acne treatment in a gel pharmaceutical form. More investigations and experiments are needed in future to ascertain our results.

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