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Research Article

**DESIGN, DEVELOPMENT AND EVALUATION OF HERBAL  
LIPBALM FOR TREATMENT OF ACTINIC CHEILITIS**Neetu P. Khatri<sup>1\*</sup>, Shilpa P. Chaudhari<sup>2</sup><sup>1</sup>Assistant Professor, Dr. D.Y. Patil College of Pharmacy, Akurdi, Pune., <sup>2</sup>Professor, Dr. D.Y. Patil College of Pharmacy, Akurdi, Pune.**Article Received:** September 2019    **Accepted:** October 2019    **Published:** November 2019**Abstract:**

*Now-a-days herbal formulations are gaining popularity because natural products are safe to use and easy to handle. Synthetic agents may cause allergic reactions and were found to be carcinogenic in nature. Aim of our study was to formulate and evaluate herbal lipbalm used for the treatment of actinic cheilitis. In this regard natural edible ingredient such as turmeric powder, hydrogenated vegetable oil, butter, coconut oil, olive oil, castor oil, Vanilla & rose essence and lemon juice were used to formulate herbal lipbalm. Prepared herbal lipbalm was evaluated for different evaluation test such as color, texture, pH, melting point, breaking point, softening point, surface anomalies and ageing stability etc. Results showed that, different evaluation parameters of prepared herbal lipbalm were resembled with standard values.*

**Keyword:** Actinic Cheilitis, Herbal Lipbalm, hydrogenated vegetable oil, allergic reactions.**Corresponding author:**

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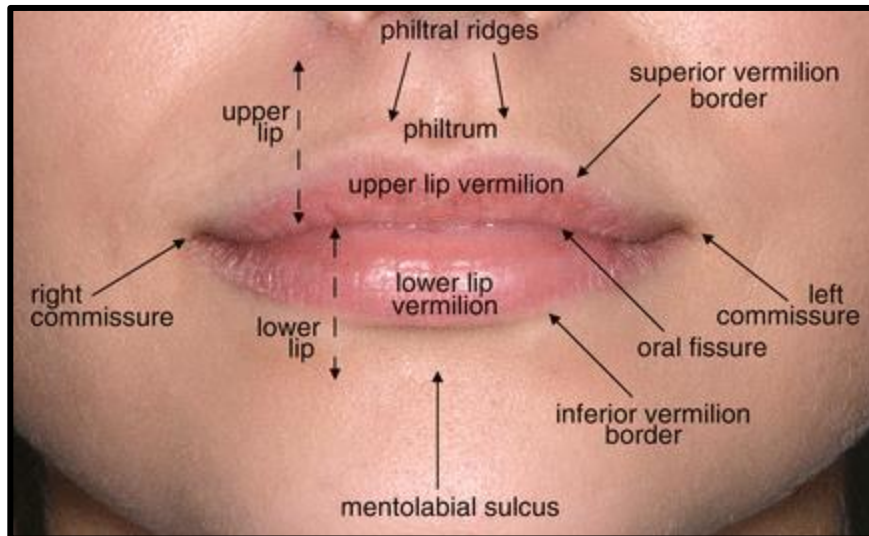


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**INTRODUCTION:**

Actinic cheilitis (AC) is a pre-invasive, malignant lesion of the lips that has the potential to develop into squamous cell carcinoma (SCC). It is well-known as cheilitis exfoliativa, solar cheilosis, solar keratosis, and actinic keratosis of the lips<sup>1</sup>. The word has been derived from the Greek words "aktis" meaning "ray" and "cheilos" meaning "lips". It manifests almost exclusively on the vermilion regions of the lower lip, as this area is more directly exposed to sunlight than the upper lip and its epithelium is thin, has a thin keratin layer and lower melanin content. The vermilion border is the transition zone between the dry skin and the wet mucosa of the lips and has no

secretory elements beneath it. Vermilion border of the lower lip is exposed to the environment and is more prone to develop various disorders than the upper lip. Actinic cheilitis is caused by excessive or chronic exposure to sunlight, which has, shortwave UV-B rays. It can damage lip cellular DNA and cause abnormalities [2]. It affects more usually in fair-skinned (primarily Caucasian) individuals and in outdoor workers [1]. In comparison with women, men have consistently been found to have higher rates of AC, and it is believed that women are less often affected as a result of the protective barrier effect associated with lip balm application [1].



**Figure1: Anatomy of Lip**

Common signs of actinic cheilitis include: overall dryness, scaly plaques or scab-like lesions, thin, delicate patches of skin, loss of the demarcation between the lower lip and surrounding skin, inflammation, tenderness or soreness, fissuring or

skin breakage and separation, leukokeratosis or white scaly patches, discoloration, more noticeable or prominent lip folds or lines tightness and wrinkled skin [2].



**Figure 2: Actinic Cheilitis**

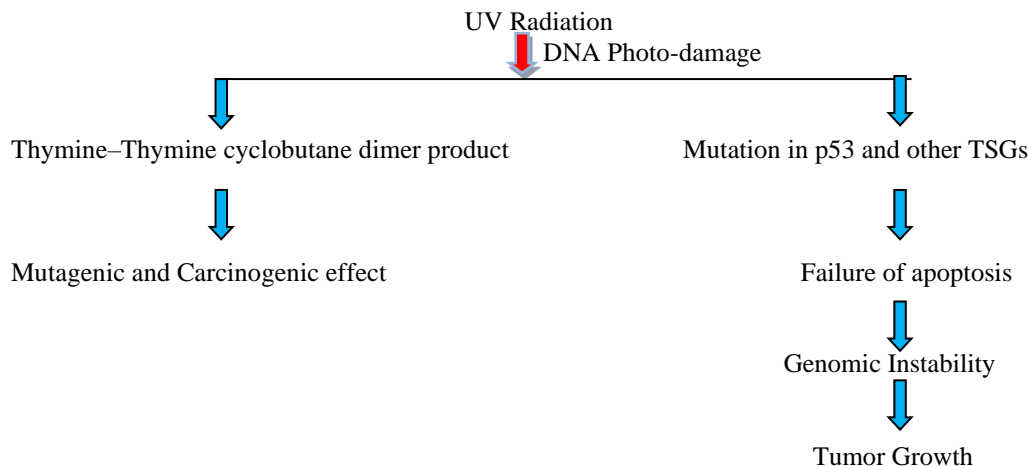
**PATHOGENESIS:**

Actinic cheilitis is a reflection of abnormal skin cell development because of exposure to chronic ultraviolet light (both UVB -290-320 nm and UVA -320-400 nm) [3]. Direct exposure to sunlight, Covalent dimerization of adjacent thymines through a photochemical reaction happens. The subsequent thymine–thymine cyclobutane dimer product as the major DNA lesion formed by UV irradiation of cells and associated with the mutagenic and carcinogenic effects of solar irradiation [4]. If there is no appropriate restoration method, these DNA changes are the starting phase of Actinic cheilitis, mutations which can progress into the development of Actinic cheilitis. UV radiations are not only the initiators but also the promoters. [3]

If there is only limited exposure to UVB, tumor suppressor gene *TP53* can retain sufficient functionality to arrest the cell cycle, permitting

activation of repair processes of cellular DNA before the cell enters the phase of DNA synthesis. A cell with repaired DNA can then proceed through the rest of the cell cycle to cell division. But chronic exposure of UVB rays can damage the DNA sufficiently to render it beyond repair, and p53 then activates cellular pathways leading to programmed cell death (apoptosis).

UVB-induced dysregulation of the function of the tumour-suppressor gene p53 results in genomic instability, making the cells susceptible to further critical UVB-induced genetic alterations with ultimate malignant transformation of the affected cells. It is evident that UVB is a complete carcinogen since it not only initiates the genetic alteration of epithelial cells but also subsequently promotes the expansion of clones of transformed cells, which then display all the characteristics of malignancy[5].



**Figure 3: Pathogenesis of Actinic Cheilitis**

**TREATMENT:**

Limit sun exposure  
Wear a hat with a wide brim  
Apply sunscreen-containing lip balm frequently

**Topical therapies for actinic cheilitis are unapproved. They include:**

Topical retinoids  
5-fluorouracil cream  
Imiquimod cream  
Photodynamic therapy

**Physical treatments for actinic cheilitis include:**

Cryotherapy  
Electrocautery  
Vermilionectomy (surgical removal of the external lip)  
Laser ablation

The treatments like chemotherapy and radiotherapy have many side-effects such as skin irritation, blistering, change in skin colour, acne, increased sensitivity to sun, hair loss etc. In case of oral chemotherapy, the side-effects like fatigue, nausea, increased risk of infection are common. The natural remedies are considered to avoid these side-effects and to improve the effect of treatment for skin cancer [6].

The word herbal is a symbol of safety in contrast to the synthetic one which has adverse effects on human health.

Lip balms are formulations applied onto the lips to prevent drying and protect against adverse environmental factors. To formulate lip balms, it is

necessary to balance the concentration of the main ingredients including butters, oils, waxes and other excipients. The presented work showed the formulation of natural lip balm used to treat actinic chilitis.

In these concern there are many herbs used to treat cancer of lip

**Turmeric** is a good candidate for the natural remedy of skin cancer. Turmeric is also known as Indian saffron, jiang huang, haridra and haldi. It is a spice grown in many Asian countries. It belongs to the ginger family and is a main ingredient of curry powder. The main active ingredient in turmeric is curcumin or diferuloyl methane [7]. Curcumin is a component of turmeric, the yellow spice derived from the rhizome of *Curcuma longa*. It has been demonstrated to modulate multiple cell signaling pathways, including apoptosis, proliferation, angiogenesis and inflammation and affect both the types of skin cancer, i.e. non-melanoma and melanoma [8].

In case of human basal cell carcinoma (a non-melanoma skin cancer), curcumin induces apoptosis by increasing levels of p53 protein (a pro-apoptotic protein).

In case of melanoma cells, curcumin induced cell death by increasing the expressions of various pro-apoptotic factors like Bax, p38 and p53. It also inhibited the activation of anti-apoptotic factors like Bcl-2 and Mcl-1. Curcumin is also known to

modulate microRNAs which are involved in cell cycle regulation and apoptosis [9].

**Olive oil** acts as an antioxidant, which is a substance that prevents oxidation. Oxidation is a process that can produce free radicals, which are chemicals that can potentially damage cells and may contribute to cancer development.

In the study, scientists applied the oil to the skin of mice that had been exposed to potentially harmful ultraviolet (UV) rays. Tumor growth was significantly lower in the mice that had olive oil on their skin compared with those who did not [10].

**Almond oil** can be used to treat acne. Its concentration of vitamin E can also help to heal sun damage, reduce the signs of aging, and fade scars [11].

#### FORMULATION:

The herbal lipbalm was formulated as per general method of lipbalm formulation. In this formulation, vegetable oil, butter and ghee were melted porcelain dish on water bath with decreasing order of their melting point. Then add all the oils and turmeric powder. Rose essence and lemon juice were added at 35°C. Then mixture was poured into lipbalm mould in excess amount and mould was kept on ice bath. After solidification surplus amount was scrapped with blade. Lipbalms were removed from mould and flamed.

**Table 1 Ingredients with their prescribed quantity in the formulation of natural lipbalm**

S. No.	Ingredients	F1	F2	F3	F4
1	Almond Oil	2ml	2ml	2ml	2ml
2	Lemon Juice	1ml	1ml	1ml	1ml
3	Saffron	1mg	1mg	1mg	1mg
4	Coconut oil	2ml	2ml	2ml	2ml
5	Olive oil	2ml	2ml	2ml	2ml
6	Turmeric	0.7 gm	0.7 gm	0.7 gm	0.7 gm
7	Vegetable Oil	20gm	10gm	13gm	10gm
8	Butter	-	4gm	1gm	7gm
9	Desi Ghee	-	6gm	6gm	3gm
10	Rose oil	1ml	1ml	1ml	1ml



**Figure 4: Herbal Lipbalm**

**EVALUATION PARAMETERS:**

It is very essential to maintain a uniform standard for herbal Lip balm, keeping this view in mind the formulated natural Lip balms was evaluated on the parameters such as melting point, Breaking point force of application, surface anomalies etc. Both The lip balms shown the result in the specific limits for the Respective evaluation parameter and were found nearly same as Reported in table

**1. pH parameter:**

The pH of formulated herbal lipbalm was determined using pH meter

**2. Melting point :**

The melting point of lip balms was determined by capillary tube method. Approximate temperature of melting was noted.

**3. Breaking point:**

Breaking point was determined to access the strength of the lip balms. The lip balms were separately held horizontally in a socket about half inch away from the edge of support. Gradual increasing weights (10 gm every time successively) at specific interval of 30 sec was loaded until the lip balms broke. The final weight at which the lip balm broke was considered as the breaking point.

**4. Surface anomalies:**

A surface anomaly was observed from the surface defects if any, such as absence of crystal formation on the surfaces or contamination by moulds fungi etc.

**5. Aging stability/Droop Point Test:**

The temperature at which the lipbalm started oozing out oil or flatten from within the case is known as droop point. In this test the lip balm was stored at 40 °C.

**6. Skin irritation test:**

The lip balms were applied to the skin surface and allowed to remain for 10 min.

**7. Perfume stability:**

The formulated herbal lipbalm stored in oven at 40 °C by making periodic comparison of perfume with fresh lipbalm [11].

**8. Force of Application:**

It is test for comparative measurement of the force to be applied for application. A piece of coarse brown paper kept on a shadow graph balance and lip balm was applied at 45° angle to cover a 1 sq. Inch area until fully covered. The pressure leading is an indication of force of application.

**9. Microbiological test:**

The test is carried out in order to determine the extent of contamination either from the raw materials or mould. The test involves the plating of known mass of sample on two different culture media for the growth of microorganism and incubating them for a specific period of time. The extent of contamination can be estimated by counting the number of colonies [12,13].

**Table-2 Evaluation of formulated natural lipbalm**

S. No.	Evaluation Parameters	Inference			
		F1	F2	F3	F4
1	Color	Yellow	Yellow	Yellow	Yellow
2	pH	6.43	6.7	6.8	6.7
3	Melting Point	60°C	58°C	57°C	49°C
4	Breaking Point	20gm	35gm	40gm	23gm
5	Surface Anomalies	No	No	No	No
6	Aging Stability	Smooth	Smooth	Smooth	Smooth
7	Skin Irritation Test	No	No	No	No
8	Perfume Stability Test	+++	+++	+++	+++
9	Force of Application	Poor	Good	Good	Very Easy
10	Microbiological test	No Growth	No Growth	No Growth	No Growth

**RESULT & DISCUSSION:**

Four different lip balm formulations (F1, F-2, F-3 and F-4) were prepared using varying proportions of the selected ingredients. The proportion of different ingredients used is presented in Table 1.

The formulated lipbalm were evaluated for colour, breaking point, melting point, surface anomalies, Force of application, aging stability, solubility and skin irritation test using recommended procedures. The results of the study are presented in Table 2.

Among all the prepared formulations, it was observed that the formulations F2 was good enough to meet the general characteristics for ideal lip balms. However formulation F1 was very brittle due to use of excess vegetable oil. In formulation F3 & F4, butter was added instead of half of vegetable oil and prepared lipbalm became very soft.

### CONCLUSION:

The present study offers new prototype of lip balm formulation containing natural ingredients used to treat **actinic cheilitis** and also serves as a guideline to use natural products in lip balm formulations so as to avoid toxic effects of harmful chemicals used to treat. The prepared lip balm formulation F2 showed ideal properties like shining, spreading and smoothness of lips after application.

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