Pharmacognostic Relevance of Calendula officinalis-based organic lip Balm in Managing Human Lip Infections

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Abstract: Recently, there has been rising global demand for organic products which is environmentally friendly. This is the most attractive attribute of organic products. Lip balm is a cosmetic product whose sole purpose is to prevent dryness of lips, relieve chapped lips, maintain the durability of its moisturizing effect and protect against adverse environmental conditions. Calendula officinalis (Pot marigold), is a species in the daisy family Asteraceae. It is an age-long antibiotic, wound-healing, anti-fungal, anti-bacterial, antiviral and anti-inflammatory agent which directly acts against identified human lip infections. This study aimed at developing an organic lip balm formulated with C. officinalis as a basal ingredient and the execution of physicochemical tests. After the Preliminary Stability Test, the selected formulation was submitted to the Normal Stability Test under the following storage temperature: Room Temperature (22.0 \pm 3.0 °C), Oven (40.0 \pm 2.0 °C) and Refrigerator (5.0 \pm 1.0 °C), for 60 days. The results indicated a successful formulation that met the requirements for lip balm production. It had normal organoleptic characteristics and acceptable stability and spreadability being uniform; without fragments or particles; Perfect application without deformation of the balm. All samples met necessary requirements during the chosen periods at different temperatures. The odor remained stable under all conditions as did the melting point, throughout the course of stability testing (60 days). In this regards, Calendula based organic lip balm is recommended for users as assurance for healthy human lips.

Keywords—Calendula officinalis, Organic Lip balm, Spreadability, Stability, Human Lip infection

1. INTRODUCTION

The human lips are the visible part of the mouth, with upper and lower regions. They are soft, movable and serve for food intakes, articulation of sound and speech [1, 2]. The lips are also used as organs of suction and in human intimacy [3]. The skin of the lips consist of 3-5 cellular layers and thinner

than the skin of the face which consist of 15-16 cellular layers.

The lip skin lack melanocytes, hence the blood vessels appear clearly visible through the lip skin with notable reddish colour [4,5]. The lips do not have hairs and sweat glands, as such they do not have equal and the usual protection by the gland and oils that keep the skin smooth, moistened to inhibit invasion of pathogens and regulate warmth [6]. For these reasons, the lips often loose moisture, smoothness, easily dry out faster and get chapped; the condition which can predispose the lips to bacterial or fungal infection; often referred to as lip disorder [7,8].

The human lips could be infected or face disorders of different kinds depending on what may be causative agents; these include: swellings, sun damage, inflammation, discoloration and sores. Lip inflammation or chalets occurs when the corners of the mouth become broken, chapped and painful. The cracked or broken points could become entry points for bacteria or fungi. In the other hand, some people believe that inflamed cracked lips are symptoms for fever and drug reactions [9, 10, 11].

Lip swellings results due to allergic reactions resulting from sensitivity to certain foods, beverages, drugs, lipsticks or air-

borne irritants. It is not usually constant because if the source of allergy is removed, the swellings may give way. However, if hereditary angieedema is involved, the swelling may reoccur [12,13,14,15].

Freckles and irregular-shaped brown areas known as melanotic macules common around the lips are indications of lip discoloration and it may last longer. However, multiple, small scattered brownish-black spots may signal a hereditary disease known as Peutz-jeghers syndrome in which Polyps form in the stomach and intestines [16.17,18,19,20].

Sores are raised areas with hard edges on the lips which may result to cancer of the lip skin. Sores may also develop as symptoms of other medical conditions, such as oral herpes simple viral infection/syphilis or as a sign of drug reactions [3,7,21,22].

Lip Print have conventionally been developed using substances such as Lysochrome, fluorescent, or indigo dyes, aluminium and silver metallic powders; however, like every synthetic product; they may not be totally free from certain negative impacts on the health of users. So, the strategy of using organic products in the formulation of lip balm may help to reduce or eliminate identified lip disorders to make an alternative to the synthetic lip products [23,24].

Organic lip balms are formulations applied to the lips to prevent drying, chapping and provide protection against adverse environmental factors [3,25]. Numerous lip balms originate from synthetic chemicals, and there is dearth of

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information on organic lip balm formulations, although references related to lip stick formulations apply because, it is a cosmetic form similar to organic lip balms [20,25,26]. The similarity extends to include organoleptic and stability requirements such as resistance to temperature variations, pleasant taste, innocuousness, smoothness, drug application, adherence, spreadability and easy intentional removal [27,28].

Organic lip balm is not equivalent to lip gloss with the former being a product intended for unisex [27]. Organic lip balms are antimicrobial, anti-inflammatory and analgesic especially when formulated with *C. officinalis*. They are anti- obscident; anti-fungal, anti bacterial and anti-viral. Organic lip balm with calendula has wound-healing effects, analgesic, nephroprotective and hepato- protective potentials [29,30,31].

There are some recently identified plant species which serve the purpose for organic lip balm formulation and these include *Melissa officinalis*, *Menthra* x *Piperita*, *Rosmarius officinalis*; *Thymus vulgaris*; *C. officinalis* [24,32].

[7] had reported that protection of human lip from health disorders is possible, using *C. officinalis* as a legal ingredient in the formulation of organic lip balm.

C. officinalis is commonly known as 'pot marigold'. It is a century-old antifungal and anti-septic; a wound-healing plant in the family Asteraceae. It is reported that methonoic floral

2. MATERIALS AND METHODS

2.1 Plant Sample

Calendula plant sample was purchased from horticultural Centres in Rivers State in November, 2019. The sample was washed under running tap water to remove all residues and impurities. The clean sample was dried using cloth paper for further use.

2.2 Calendula Oil Extraction

Calendula Oil was extracted from the flower florets. Each of the compoundment had the oil as basic ingredient. The calendula oil contains flavonoids, Palulitrin and Palaletin, saponin, faradiol-3-0 palmitate, myristate, calendaladiol -3-0

Table I: Organic lip balm prescription samples

Prescription number	Ingredients	Amount
1.	Bees Wax	30.0
	Shea butter	20.0
	Peach oil	30.0
	Calendula oil extract	20.0
2.	Bees Wax	25.0
	Palm oil	15.0
	Peach oil	30.0
	Calendula oil extract	20.0

The final formulation is as shown in Table 2 below:

extracts of *C. officinalis* has potential against extracellular (Promastigate) and intracellular (amastigate) forms of *Leishmania major* in controlling cutaneous leishmania [6].

[29] also reported that the floral extracts of *C. officinalis* has the potential to control inflammation of the lips; hence the floral extract contains carrageenin (histidine and kinnins). It has also been reported that the bioactive chemicals in the plant lowers the IFN-1 level and reduces expression of cyclo-oxygenase 2 (cox-2) which contributes to anti-flammatory potency.

It has been reported that the bioactive constituents of the plant differs according to the parts used. [3,29]. They reported that the leaves of *C.officinalis* contain quinones; the roots contain terpenoids and in the flowers are volatile oils, flavonoids Coumarins and terpenoids.

Generally, *C. officinalis* contians carotene, pigments, free and esterised triterpenic acids, calenduline, oleanolic acid glycosides, amyrin, calenduladiol, coflodiol. Additionally, the plant also contains saponins, flavonoids, carotenes, mucilage, resins and steroidal chemicals [1,33-35]. Based on the available information, this work was aimed to formulate organic lip balm with plant -based material as an antedote to check the infections of the lip of human beings.

palmitate and about 8 other bioactive, triterpenoids mono esters [36]. These are the potential constituents for protection, healing and prevention of human lip infections/disorder.

All prescriptions were considered according to the rule of homogenous ointment and drug technology such as Preparation procedures, measuring of ingredients, melting of ingredients accordingly by heating in water bath in descending temperature order and pouring out in appropriate bottle or packings.

2.3 Formulation of lip balm

Four prescription samples were formulated as shown in Table I.

3.	Bees wax	20.0
	Coconut oil butter	15.0
	Peach oil	30.0
	Calendula oil	20.0
	extracts.	
4.	Bees Wax	15.0
	Shea butter	15.0
	Coconut oil butter	20.0
	Peach oil	30.0
	Calendula oil extract	20.0

Table 2: Final Prescription for Organic Lip Balm Formulation.

Ingredients	Mass share
	(g)
Bees Wax	15.0
Shea butter	15.0
Coconut butter	20.0
Peach oil	30.0
Calendula oil	20.0
extracts	q.s (quantum
Orange essential	satis)
oil	

2.4 Preliminary Stability Study

The formulation developed was evaluated on Preliminary Stability Tests which included organoleptic characteristics (color, odor and appearance) and spreadability, over at least three days at room temperature (22.0 \pm 3.0 °C) and oven temperature (40.0 \pm 2.0 °C). As this type of cosmetic form undergoes softening and deformation at temperatures over 50 °C, the oven condition was chosen as the highest temperature of the stability study [37,38]. As this formulation exhibited no organoleptic or spreadability changes, it was submitted to Normal Stability Study.

2.5 Normal Stability Study

The Stability Test of a lip balm usually begins 24 or 48 hours after preparation, a time described in the literature as sufficient to stabilize the formulation [37,39].

A quantity of 350 g of the formulation was prepared for the Normal Stability Test, in which the organoleptic characteristics (color, odor, appearance), spreadability and melting point were evaluated for 60 days under the conditions of Room Temperature (RT, 22.0 ± 3.0 °C) and Oven (O, 40.0 ± 2.0 °C) [38]. The samples were stored in duplicates.

The formulation was stored at room temperature (22.0 \pm 3.0 °C) for 48 hours and then evaluated at baseline (t_0) [41]. It was then stored under different conditions, according to the Normal Stability Study, and characteristics assessed on the 3^{rd} , 7^{th} , 15^{th} , 30^{th} and 60^{th} days. Assessments at t_0 were considered as a reference for comparing the results.

2.6 Preparation of Organic Lip Balm

All the butters were melted in a heating water bath at 45-50°c in a controlled manner with an indirect flame until complete melting and homogenization to a maximum temperature of 90.0 °C. The calendula oil was obtained by maceration. The flower florets of *calendula officinalis* were mixed in 10ml of 90% ethanol and boiled for 3 hours together with the waxes to facilitate easy removal of the balm [7,25,29,40,41,42]. After homogenizing, the mixture was maintained at 87.0 °C to allow

molding of the lip balm at a temperature of at least 1.0 °C above the melting temperature of the component with the highest melting point, in this case, carnauba wax of approximately 86.0 °C [40]. The lip balm was poured into lip stick packaging, a round plastic case with an elevator system, and the product was then refrigerated (5.0 \pm 1.0 °C) for at least one hour and stored at room temperature for 48 hours to stabilize the preparation.

2.7 Testing for Melting Point

To determine the melting point, the material is made molten to full capillaries (duplicate). The cappilaries are coupled to a system with a thermometer and immersed in a vial with water at a controlled temperature. The temperature of which melting point of the lip balm sample is observed is considered to melting point [37,41].

2.8 Organoloptic characteristics

Organoleptic study included: colour and appearance, physical and chemical analysis evaluated.

Coconut oil contained the requirement for fatty acid composition profile of fatty acids as determined under fat and fixed oils. The butter contents fight and prevent aging and treat health issues. The initial colour of beeswax is white, but on heating it turns yellow with time in the process. The yellow colour originates from propolis and pollen colourants; the taste of beeswax is pleasant and it helps the product to last longer.

It Considers colour and appearance viewed usually with a loupe, lox magnification; while the odour is compared by an evaluator. The evaluation determines the organoleptic parameter by determining the formulation to be N, M or IM where N= normal; M= modified and IM=intensely modified.

2.9 Test for spreadability

This is tested by applying the product (at room temperature $22.0\pm 3.0c$) repeatedly on a glass slide to

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usually observe the uniformity in the formation of the protective layer and determine if the product is fragmented, deformed or broken during application. The criteria used for spreadability, G-Good: (uniform; does not leave fragment; perfect application; without deformation of the lip balm).

G - Good: uniform, does not leave fragments; perfect application, without deformation of the lip balm;

I - Intermediate: (uniform, leaves few fragments; appropriate application; little deformation of the balm)
 B- Bad: not uniform, (leaves many fragment; difficult or inappropriate application; intense deformation of the balm).

3. RESULTS AND DISCUSSION

The results of the test; for the use of C. officinalis in the formation of organic lip balm are shown in Tables 3-6 and Figures 1-2

The result of quality control indicated that prescription numbers 1-3 which contained 30% beeswax had modified organoleptic properties and intermediate spreadability (ie, uniform, but left very few fragments; had appropriate application but very little deformation of the balm). The melting point was high (from 50-51°c).

The prescription no 4 with twice less concerntration of beeswax and combinaton of two different plant butters had necessary properties. Normal organoleptic characteristics (Pleasant odour, surface without fissures, yellow colour) and good spreadability (uniform, no fragments or particles; perfect application, and no deformation of the balm). Melting point was 41 + 0.6 (Figure 2; Tables 3).

Table 3: Organoleptic, physical and chemical analysis of C. officinalis based organic lip balm.

Prescription	Organoleptic	Test of	Melting
number	characteristics	spreadability	point
1	M	1	51 <u>+</u> 0.8
2	M	1	50 <u>+</u> 0.5
3	M	1	50 <u>+</u> 1,0
4	N	G	41 <u>+</u> 0.6

M = modified, N = Normal, I = Intermediate, G = Good



Fig. 1. Spreadability of lip balm at room temperature

3.1 Preliminary Stability Study

The compounded lip balm was evaluated with organoleptic characteristics (of colour, odour and apperance) and spreadabilty, over 3 days at room temperature (22.0 \pm 3.0C) and oven temperature (40.0 \pm 2.0C). It had 'N = normal' organoleptic characteristics and G = 'good' test of spreadability being uniform; without fragments or

particles; Perfect application without deformation of the balm.

3.2 Normal Stability Test

Normal stability study results in 60 days are indicated in **Table 4**. It was formulated into 15 balm samples (10g each) and divided into 3 groups (5 samples per group). The samples were stored in 3 different conditions and analysed with organoleptic and spreadability parameters (Figure 3).



Table 4: Quality control of lip balm at different storage conditions.

Periods/names of	Evaluated Parameters at different conditions			
Parameters	Room Temp 22.0 <u>+</u> 3.0°c	Oven temperature $40.0 \pm 2.0^{\circ}$ c	Refrigerator 5.0 ± 1.0^{0} c	
	1	3 rd day	-	
Organoleptic	N	N	N	
Test of spreadability	G	G	G	
		7 th day		
Organoleptic	N	N	N	
Test of spreadability	G	G	G	
		15 th day		
Organoleptic	N	N	N	
Test of spreadability	G	G	G	
		30 th day		
Organoleptic	N	N	N	
	G	G	G	

$60^{th} day$

Organoleptic	N	N	N
Test of spreadability	G	G	G

N = Normal, G = Good

All samples met necessary requirements during the chosen periods at different temperatures.

Table 5: Flowchart of calendula oil extract manufacturing

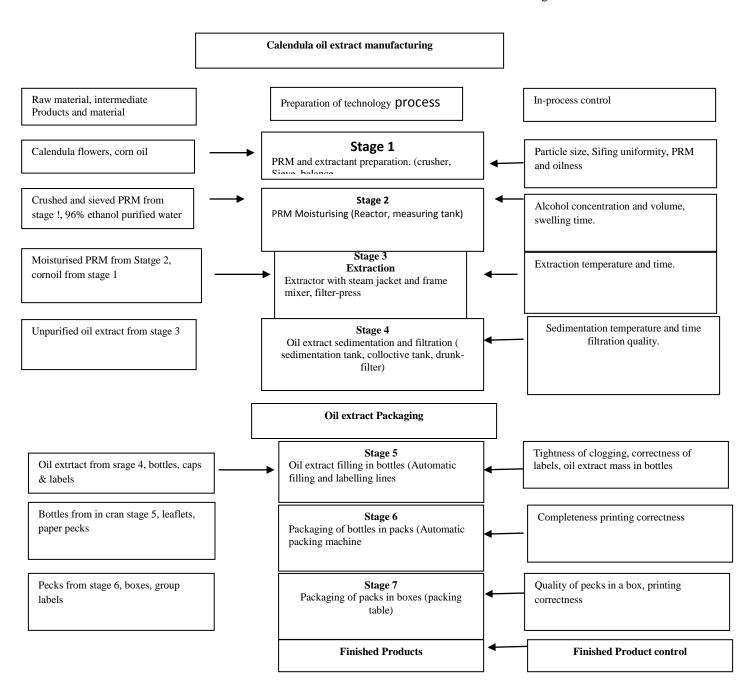
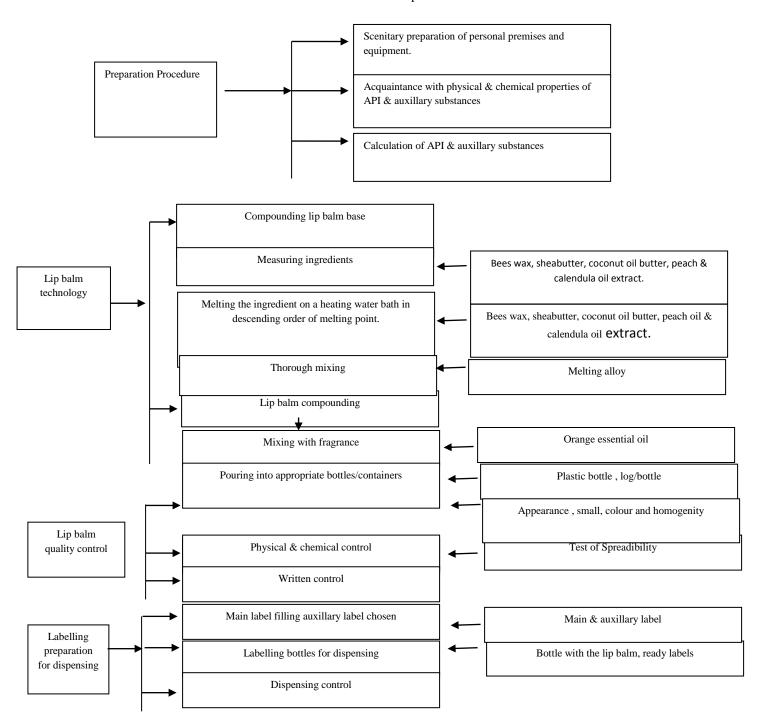


Table 6. Flow chart of the lip balm formulation.



4. DISCUSSION

The Calendula-based organic lip balm was formulated according to the requirements of lip balm properties. The test of its spreadability showed uniformity without fragments or particles; and perfect application without deformation. These showed stability which is an indication of clear manifestation of the quality of product. This is in-line with the successful

formulation of the organic lip balm; meeting the standard of operation guarantees the healing of sores and other wounds resulting from lip infection or disorder. This also agrees with the report of [43] on the wound healing potentials of Calendula. And Calendula being an age-long anti-biotic will fight against every form of germs against

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possible wounds on the lips. The lip balm will also prevent inflammation, as was reported by [43] who reported that the floral extracts of Calendula contain bio-active compounds which lower the IFN-1 level, thereby reducing the expression of cyclo-oxygenase -2 which contributes to anti-inflammation potency.

The successful formulation of Calendula – based organic lip balm (like the one in this study) is a guarantee against extracellular (promastigate) and intracelluler or amastigate

forms of leishmania in controlling cutaneous leishmania. This is clearly in line with the report of [6] on the use of the floral part of calendula as in this study.

The contents of carotone pigment, oleanolic acid, saponius, flavonoids,mucilege, resins, steriodal compounds in Calendula give the organic product lip balm an assurance of usage with no known negative impact on the users; in line with the reports of [33,34]. The detailed work of [7] was a good leading on the use of Calendula in the formulation of good organic lip balm

5. CONCLUSION

The stability test of this study indicated an appropriate melting point (mean $41 \pm 0.6^{\circ}$ c) irrespective of the storage condition, with normal spreadability and perfect application. Storage under these conditions was considered adequate, particularly because the functionality of the Gproduct was maintained. An

assurance that organic -based products will serve as an alternative to replace the synthetic lip sticks; owing to the fact that the identified lip infections or disorders can be well managed, to treated and prevented if attentions are shifted to the use of plant-based organic lip balms.

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