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Design and Development of Herbal Delivery System for the Treatment of Lips Hyper-pigmentation

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ABSTRACT

Hyperpigmentation of lips that is characterized by darkening of red portion of lips accompanied with dryness and bleeding is common disorder occurring in both men and women. It mostly affects age group of 25-40 years and has unpredictable course. The major causative factors include; smoking, sun exposure, post surgical treatments, medications, excessive caffeine intake. Hyper pigmented dry lips crack and bleed if left untreated. More complex symptoms include pain, swelling that disfigures external appearance and personality. Topical polyherbal medicated oil "Kumkumadi oil" Chapstick is formulated for treatment of lips hyperpigmentation. Formulated Chapstick is evaluated for evaluation tests like organoleptic evaluation physicochemical evaluation, spreadability, washability, stability. At last it was concluded that the Kumkumadi oil Chapstick shows potential depigmentation activity.

Keywords: Lips hyperpigmentation, Kumkumadi oil, Chapstick, lips depigmentation

I. INTRODUCTION

Hyperpigmentation of lips that is characterized by darkening of red portion of lips accompanied with dryness and bleeding is common disorder occurring in both men and women. It mostly affects age group of 25-40 years and has unpredictable course. About 1% of world's population is affected and smokers are more vulnerable than non-smokers, particularly the men. The major causative factors include; smoking, sun exposure, post surgical treatments, medications, excessive caffeine intake. Hyper pigmented dry lips crack and bleed if left untreated. More complex symptoms include pain, swelling that disfigures external appearance and personality. Use of polymedicated herbal oil is having maximum benefits with minimum side effects.

Chapstick:
Chapstick is medicated or non medicated small stick of cosmetic substance used to prevent chapping, cracking of lips.

Kumkumadi oil is polyherbal oil contain *Crocus sativus, Sesanum indicum Linn, Pterocarpus santalinus, Rubia Cardifolia, Curcuma longa, Berberis*

aristata, Santalum album. The main component of the oil is saffron which is reported for depigmentation activity of dermis. Saffron containing Crocin, Carotenoids which are responsible for suppression of melanin synthesis by inhibiting the activity of tyrosinase. There are drawbacks of using Kumkumadi oil directly for lips as it is sticky, messy, unpleasant smell to overcome this the topic herbal chapstick is formulated.

The chapstick additives are white bees wax, shea butter, mango butter, Sal fat which super moisturizing agents.

- ❖ The marketed available chapstick products Slow healing due to minimum moisturizing agents
- ❖ Application with fingertips
- ❖ Requires high frequency of application
- ❖ Presence of colors in some products are not useful for males.
- ❖ Extremely damaged lips requires high dosage regimen.
- ❖ Medicated dosage forms are costly.
- ❖ Alternatives for poly medicated formulations are very less.

Value addition to formulated chapstick:-

- ❖ Presence of super moisturizing agents gives rapid healing
- ❖ Convenience for storage and ease of Application
- ❖ Convenience for storage and ease of Application
- ❖ Claimed to have few/lesser side effects
- ❖ Enhanced thermal, physical, chemical stability and formulation flexibility Termination of therapy, when needed

II. METHODS AND MATERIAL

Sr. No.	Name of Equipment/ Instrument	Make	Model	Purpose in the experimental.
1.	Abbes's refractometer	Sunbin	-	Measurement of refractive index
2.	Brookfield Viscometer	Brookfield Engineering Labs, US.	LVDV -E	Measurement of viscosity of formulation.
3.	Colorimeter	Chemline Analytical Instrument	CL60	Determination of colorimetric characteristic of raw, in process material.
4.	Digital pH Meter	HANNA Instruments, Woonsocket, USA	-	Measurement of pHof PMO experimental formulation.
5.	UV-visible Spectrophotometer	Shimadzu (Double beam)	1800	Determination of λ max and construction of calibration curves, chromatophores from herbal actives.

Kumkumadi oil is evaluated for Organoleptic, phytoconstituents. physicochemical, solubility & presence of

Figure 1. Marketed Kumkumadi oil formulation

Formula For medicated Chapstick

Heating and Congealing Method

- Melting waxes according to their decreasing M.P (Phase A)
- Heating of Kumkumadi oil in porcelain dish at 85°C. Addition of preservative in the oil with continuous stirring (Phase B).
- Cool Phase A to 75°C and mix with Phase B with continuous stirring
- Pouring of mixture to chapstick mould at temperature 70°C.
- Allow to cool the mould .& remove the chapstick.

Sr. No.	Name of ingredients	F1 (gm)	F2 (gm)	F3 (gm)	F4 (gm)
1	**Kumkumadi Oil**	1.0	1.0	1.1	**1.2**
2	**white Bees Wax**	0.5	0.8	2	**1.5**
3	**Shea Butter**	1	2	3	2
4	**Mango Butter**	1.30	1.70	2	**2.1**
5	**Sal Fat**	1.56	1.56	1.80	**1.95**
6	**Sodium Lauryl Sulfate** (gm)	0.2	0.2	0.2	**0.2**
7	**Polysorbate 80** (**Tween80**)(ml)	1	1	1	**1**
8	**Methyl paraben** (gm)	0.5	0.5	0.5	**0.5**

Evaluation of Kumkumadi Oil

Organoleptic characteristics:

Colour: Reddish yellow

Odour: Characteristic

Texture :Smooth

- Phytoconstituents analysis
- Presence of terpenoids
- Compatibility test
- TLC

Kumkumadi oil

Presence of Terpenoids in Kumkumadi oil

For this, method described by Dr Sheel. R was followed,

i) **Preparation of standard curve:** About 1ml of Polyherbal medicated oil was transferred in test tube. To this 2ml of chloroform was added followed by 3ml of sulphuric acid. The mixture was scanned over the range of 400-800nm and the λmax was noted. Blank was prepared by following the same procedure except oil. Terpenoids content in PHMO was determined as linalool equivalent.

❖ Compatibility Test

Compatibility of API & formulation additives are checked by keeping 1;1 ratio for 30days. Analyzed for change in color, physical reaction/ chemical reaction.

❖ TLC

The TLC helps in determining the number of components in PHMO & identity of Compound

Evaluation of Chapstick

Organoleptic characteristics:

Colour: Cream

Odour: Pleasant

Texture :Smooth

- Melting Point
- Surface anamolies
- Spreadability
- Washability
- Force of application
- Stability Study

Chapstick

❖ Melting point

The melting point apparatus (VEEGO mode-VMP-D, India) used to determine melting point of lip balm. To determine the melting point, sample of Chapstick was taken in a glass capillary whose one end was sealed by flame. The capillary containing PHMO was dipped in liquid paraffin inside the melting point apparatus.

❖ **Surface anomalies**

This was studied for the surface defects, such as no formation crystals on surfaces, no contamination by moulds, fungi etc.

❖ **Test of spreadability**

The test of spreadability consisted of applying the Chapstick(at room temperature) repeatedly onto a glass slide to visually observe. he following criteria were established:

G - Good: uniform, no fragmentation, without deformation of the Chapstick.

I - Intermediate: uniform; leaves few fragments.

B - Bad: not uniform; leaves many fragments.

❖ **Force of application**

A piece of paper kept on a shadow graph balance and chapstick was applied at 45º angle to cover a 1 sq. Inch area until fully covered. The pressure reading is an indication of force of application.

❖ **Skin irritation test**

It is carried out by applying product on the skin for 10 min.

❖ **Stability study**

Stability study is done by keeping the Chapstick at room temperature, refrigeration and oven temperature.

III. RESULTS AND DISCUSSION

➢ **Evaluation of Kumkumadi Oil**

Sr. No.	Parameter/test	Experimental observations	Reported values
General description and organoleptic			
1	Appearance	Clear viscous reddish liquid	Reddish liquid
2	Color	Pale reddish	Pale reddish
3	Odour	Characteristic	Characteristic
4	Texture	Smooth	Soft
5	Specific gravity	0.92	0.92
6	Refractive index	1.47	1.50
7	pH	5-6	4-5

Solubility in different solvents

I.	Distilled water	Immiscible	Immiscible
II.	Acetone	Immiscible	Immiscible
III.	Ethanol(95%v/v)	Immiscible	Immiscible
Iv.	n- hexane	Miscible	Miscible
V.	Chloroform	Completely miscible	miscible

Phytoconstituents present in PHMO

Sr. No	Type of phytoconstituents	observations	Reported	Inference
I.	**Carbohydrate test(Molisch's test)**	**+ve**	**+ve**	complies
II.	**Test for reducing sugar (benedicts test)**	**-ve**	**-ve**	complies
III.	**Proteins (Biuret test)**	**+ve**	**+ve**	complies
IV.	**Fats/ oils**	**+ve**	**+ve**	complies
V.	**Alkaloids (Dragendorff's Test)**	**+ve**	**+ve**	complies
VI.	**Flavonoids (Sodium hydroxide test)**	**+ve**	**+ve**	complies
VII.	**Tannins (Ferric chloride test)**	**+ve**	**+ve**	complies

Compatibility of neat samples of PHMO and selected formulation additives.

Sr. No.	Name of the sample and characteristic assessed.	Stability at ambient temperature			
		Day 01	**Day 8**	**Day 15**	**observations**
1.	**Appearance**	Homogeneous clear liquid			No change

2.	**Colour**	reddish			No change
3.	**Odour**	Characteristic			No change
4.	**Sp.gravity g/ml**	0.92	0.92	0.92	No change
5.	**Boiling range (^{0}C)**	176°C	176°C	176°C	No change

Rfvalue of PHMOin EA: n-hexane (1:9):

The given sample of PHMO indicated presence of yellow band (Rf 0.47) in the selected mobile phase

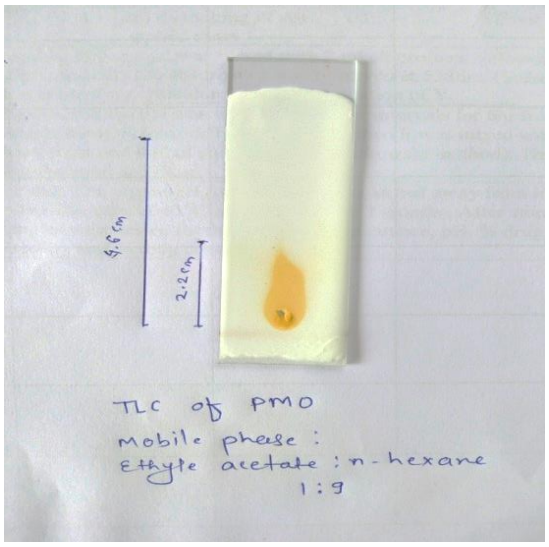


Fig 1 : TLC of PHMO

- **Presence of Terpenoids in Kumkumadi oil**

The KO: CHCl3: H_2SO_4 (1:2:3) wavelength of maxima at **465nm**. Presence of terpenoids in the ***Sesamum indicum, Crocus Sativus, Pterocapus Santalinus, Rubia cardifolia, Curcuma longa, Berberis aristata in*** **Kumkumadi oil.**

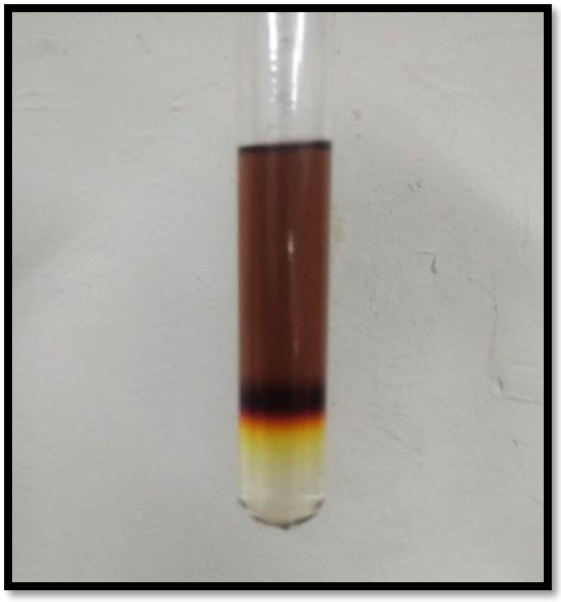
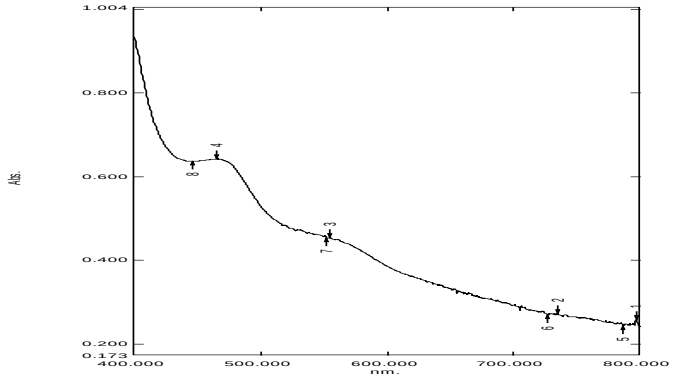


Photo No.: Salkowaski reaction giving reddish brown colour, indicative of presence of terpenoids in the Kumkumadi oil.

α Termerone, β Termerone from turmeric, picrocrosin from saffron,Santalene from sandalwood are responsible for Photoprotective, antioxidant, anti-inflammatory activity.



Evaluation of Chapstick

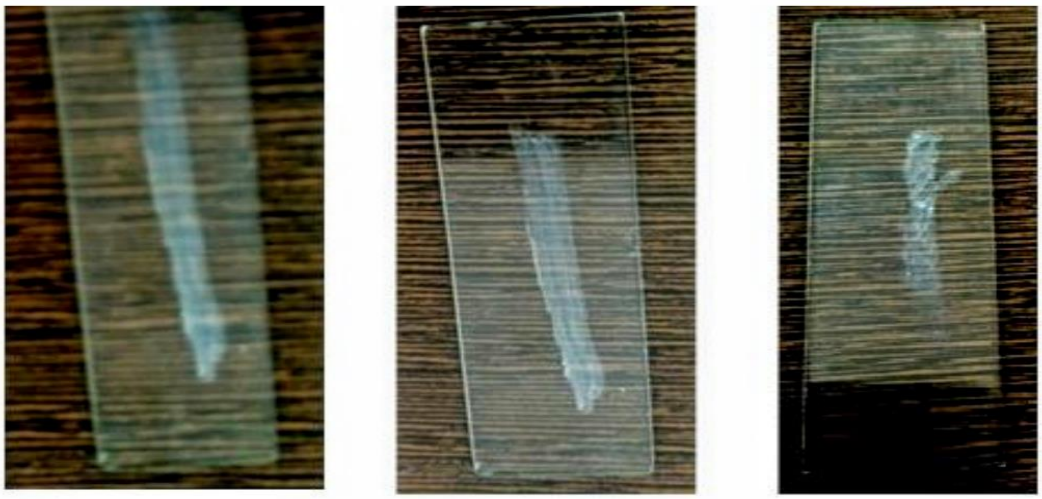
Sr. No.	Parameter/ Test	Experimental Observations	Reported values
A. General description & Organoleptic characteristics			
1	**Appearance**	Glossy, homogenous	Homogenous
2	**Colour**	Yellowish	yellowish
3	**Odour**	Characteristic	Characteristic
4	**Texture**	Smooth	Soft
C. Physicochemical characteristics			
5	**Ph**	5-6	4-5
6	**Solubility in different solvents**		
	Distilled water	**Immiscible**	
	Ethanol	**Miscible**	
	Ether	**Miscible**	
	Chloroform	**Immiscible**	
	Hexane	**Immiscible**	
7	**Surface anomalies**	No defect	Complies
9	Melting point	50-52℃	47℃

10	Breaking point	31	26
11	Force of application	Good	Good
11	Surface anomalies	No	No

Spreadability test

Criteria for analysis:-

G-Good I- Intermediate B- Bad



Spreadability of Lip balm A) at 25.0 ± 3.0 ºC, B) 4± 2.0 ºC, C) 40.0 ± 2.0 ºC

Inference: The Kumkumadi oil chapstick shows Good Spreadability at room temperature.

Washability test

Photo No.: Comparative washability of **F1 Kumkumadi oil chapstick** and reference topical Marketed Chapstick

Photo No.: Comparative washability of **F2 Kumkumadi oil chapstick** and reference topical Marketed Chapstick

Inference: - Kumkumadi oil Chapstick shows +++ for washability.

Stability studies were carried out for 1 month/ 30 days at

- room temperature (25.0 ± 3.0 ºC),
- refrigeration (4± 2.0 ºC) and

Parameters	**Temperature condition**		
	(25.0 ± 3.0 ºC),	{4± 2.0 ºC)	(40.0 ± 2.0 ºC).
Color	Cream	Cream	Cream
Odor	Pleasant	Pleasant	Pleasant
Melting point	47	47	45
Spreadability	G	G	I

Observation:

At **room temp** & **Refrigeration** gives **good** uniform, no fragmentation, no deformation.
At **Oven temp Intermediate** uniform, leaves few fragments, little deformation**.**

Figure 3- Organoleptic characteristics of Lip balm A) at 25.0 ± 3.0 ºC, B) 4± 2.0 ºC, C) 40 ±2.0 ºC.

IV. CONCLUSION

The experimental chapstick formulation possessed acceptable colour, odour, shape, appearance, spreadability, texture, pH values and was devoid of any gross surface anomalies. The formulation's analytical tests Dermal irritancy, spreadability, washability, force of application, short term stability studies are pending. All the experimental additives are non-irritant and possess good cosmetic and therapeutic potential. and greater functionality with retention of originally super moisturizing efficacy of the Ayurvedic product. Novelty of formulation is holding the Polyherbal Medicated oil with super moisturizing ingredients which emphasizes on speedy recovery with ease of application.

V. ACKNOWLEDGMENTS

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