



# “Formulation and Evaluation of Topical Delivery System of Herbal Active for the Management of *Striae Gravidarum*.”

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Research Article

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## ABSTRACT

Stretch marks (*Striae distensae*) are visible lines on the outer skin located usually on abdomen, breasts, thighs. Stretch marks which develop on pregnant women known as *striae gravidarum*. Almost 50-90% of pregnant women may develop *striae distensae*. It is caused due to sudden increase in weight during pregnancy, due to rapid weight gain the collagen fibres present between dermis and epidermis layer of skin gets break down and stretch marks appears. Because of various side effects of synthetic medications, the use of herbal medications has increased. To avoid side effects, oil obtained from the leaves of *Centella asiatica linn* i.e. *Gotukola (GKO)* was incorporated into the formulation stimulates collagen synthesis by energizing dermal fibroblast. The main active ingredient found in gotukola is triterpenoids (saponins) which includes asiaticosides, it increases collagen production in the body this may help to prevent new stretch marks from forming as well as help to heal any existing marks. The objective of the present study was to formulate and evaluate derma stick for the management of *striae gravidarum*. Derma stick which are rarely available in the market for the treatment of stretch marks, it avoids the use of fingertip. Derma stick was prepared by heating and congealing method by changing the concentration of butters. Total 7 formulations were prepared among these F7 batch, i.e., SBMBCB (shea butter, mango butter and cocoa butter) was selected as an optimized batch, in this (4.6%) concentration of oil was added. The final formulation batch GKOSBMBCB shows pH (6.4), Breaking point (120 gm), No skin irritancy, better spreadability and consistency, hence this batch containing gotukola oil can be used as an appropriate formulation to treat *striae gravidarum*.

Keywords: *Striae distensae*, *Centella asiatica linn*, *Gotukola*, *Striae gravidarum*.

**INTRODUCTION:** *Striae* (skin stretch marks) were first recognized by Roederer in 1773, and were later histologically described by Troisier and Ménétrier in 1889. In 1936, Nardelli made the first morphologically correct descriptions about stretch marks.<sup>1</sup> Ayurved describes stretch marks as *kikissa* with meaning closer to the description of *striae gravidarum*; Acharaya Charak was the founder of *kikissa* and describe about formation and condition of foetus advised the Antenatal Care of Garbhini (pregnant women) and proper diet regimen with or without medication in 7th month of pregnancy and a disease called *Kikkisa* develops during this period. Stretch marks (*Striae distensae*) are visible streaks on the outer skin located usually on abdomen, breasts, thighs and usually fade or disappear naturally over a period of 6-12 months. Almost 50-90% of pregnant women may develop *striae distensae*.<sup>3</sup> Stretch marks which appear during pregnancy produce due to rapid weight gain, and stretching between dermis and epidermis layer of skin. due to this stretching collagen fibres present between this two layers gets break down and

stretch marks formed.<sup>1,2</sup> Gotukola oil is one of the most important herbal drug considered to treat stretch marks. It is essential oil obtained from the leaves of *Centella asiatica* Linn, belonging to family Apiaceae. It was selected as an active ingredient because it contains triterpenoids (asiaticosides) which increases the synthesis of collagen fibres and regenerate the skin cells.<sup>4,5,6</sup> Many creams, lotions, ointments are available for the treatment of stretch marks but derma sticks are rarely available. It has several advantages over other dosage forms: it is easy to carry and apply, avoids use of fingertip and contamination is avoided. Hence, the objective of the present study was to formulate and evaluate derma stick for the management of striae gravidarum.

## Materials And Methods:

**Materials:** Gift sample (Gotukola oil) was collected from Moksha lifestyle products, and other ingredients like shea butter, mango butter, cocoa butter, bees wax, propylene glycol used were of analytical grade.

**Method:** Derma stick of gotukola oil were prepared by using heating and congealing method. All the ingredients were weighed separately. All the waxes and butters melted according to their decreasing melting point and mixed well to obtain base melt. The temperature of water bath was maintained at 70-75 °C. Then added almond oil in previously prepared base melt with continuous stirring. Then the gotukola oil and flavor oil were added at 35° C with continuous stirring. The hot mixture was poured into the glass mould and cooled to get the desired shape of sticks. The stick was removed from the mould after 24 h with the help of plunger and inserted into the placebo stick container. Total 7 batches were prepared of non medicated derma sticks using different concentration of natural butters. Among these SBMBCB batch was selected as an optimized batch because it shows good result with spreadability, washability, pH, breaking point. After this medicated derma stick was prepared by incorporating Gotukola oil into the optimized formulation batch.<sup>7,8</sup>

**Table No.2: Formula of derma stick GKOSBMBCB**

Sr.No	API/Additives	Concentration of Ingredients(% w/w)
1	Gotukola oil	4.6
2	Cetyl alcohol	15
3	Propylene glycol	25
4	Shea butter	5
5	Mango butter	5
6	Cocoa butter	2.5
7	Bees wax	15
8	Fragrance oil	2-4 drops
9	Almond oil	qs to make 100

**PREFORMULATION EVALUATION:** Solubility, boiling point determination, phytochemical testing was done for drug gotukola oil to test its purity and the values were found within the range, then Fourier transform infrared Spectroscopy (FT-IR) was conducted to test the compatibility of drug with the excipients.

## EVALUATION OF DERMASTICKS:

**Physical appearance:** The formulated sticks were visually inspected for colour, odour, solubility and appearance ,texture,shape are reported.<sup>10,11</sup>

**Weight variation:** Three sticks were selected randomly and weighed individually. The individual weights were compared with the average weight for determination of weight variation. As the shape of the stick is cylindrical the thickness and length was determined with the help of screw gauge and vernier calipers respectively. The average thickness was measured, by observing thickness at three different parts of the stick.<sup>10,11</sup>

**Melting point:** The melting point of formulated stick was determined by capillary tube method, the capillary tube was filled and keep in the capillary apparatus and firstly observed that the product was slowly melted. After sometimes observed product was completely melted. The above procedure was done in 3 times and the melting point ratio was observed in all formulations.<sup>10,11</sup>

**Breaking point:** Breaking point was done to determine the strength of the Medicated stick. The stick was held horizontally in a socket inch away from the edge of support. The weight was gradually increased by a specific value (10 gm) at specific interval of 30 second and the weight at which the stick breaks was considered as the breaking point.<sup>9,10,11</sup>

**pH measurement:** The small amount of sample was placed on a glass slide and the pH of the formulation was measured using a ph paper at room temperature and the results were reported.<sup>10,11</sup>

**Spread ability:** Spread ability is a term expressed to denote the extent of area to which the topical application spreads on application to skin on the affected parts. The therapeutic efficiency of the formulation also depends upon its spreading value. Hence, determination of spread ability is very important in evaluating topical application characteristics. For the determination of spread ability, the sticks was evaluated and ranked according to this grading: No spread ability (0), low spread ability (+), average spread ability (++), high spread ability (+++).<sup>10,11</sup>

**Surface anomalies:** This was studied for the surface defects, such as no formation crystals on surfaces,i.e sweating,blooming,catering.<sup>10,11</sup>

**Skin irritation potential:** Skin irritation study was carried out by HET-CAM (hen's egg chorioallantoic membrane) test. Using 0.9 % Nacl solution as negative control & 0.1 % SLS solution as positive control.<sup>12</sup>

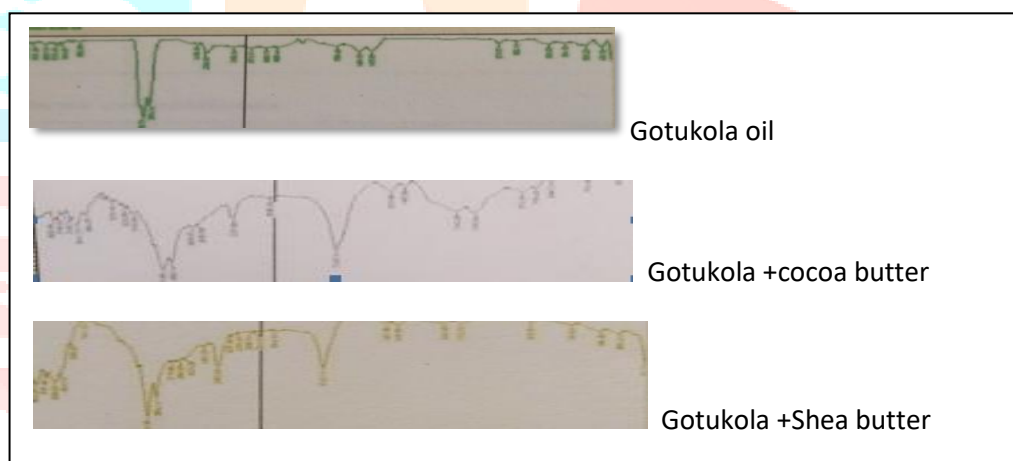
**Stability Studies:** Short-term stability studies for all the formulations prepared were carried out by storing at 27±2°C for a period of three weeks. At intervals of one week the sticks were visually examined for drug content uniformity and any physical change.<sup>10,11</sup>

## RESULTS AND DISCUSSIONS:

The results of phytochemical screening of gotukola oil revealed presence of alkaloids, flavonoids(quarcetin,kaempeferol,phenols(sitosterol,stigmasterol),terpenoids(Asiaticoside,asiatica cid,medacassic acid),glycosides(ursane,oleanane) etc.<sup>13</sup>

**Table No.3:Evaluation of final Derma stick GKOSBMBCB:**

Sr.No	Characteristics	Experimental findings of derma stick
<b>General description and organoleptic properties</b>		
1.	Appearance	Glossy homogenous
2.	Colour	Yellowish white
3.	Odour	Characteristic
4.	Texture	Smooth
5.	Shape	Cylindrical
<b>Physicochemical properties</b>		
6.	pH	6.3
7.	Melting point(°C)	72
8.	Breaking point (cm)	100
9.	Surface anomalies	No defects
10.	Spreadability	+++
11.	Washability	Good
12.	Skin irritation potential	No positive reaction

**COMPATIBILITY STUDY BY FTIR SPECTRA:**

The spectrum confirmed that there is no significant change in absorption band, hence no interaction between them. They are compatible with each other.

**Skin irritation potential (*in vivo*) of selected derma stick GKOSBMBCB**

The experimental derma stick formulation of GKO(4.6% w/w) with cocoa butter (2.5 % w/w), Mango butter (5 % w/w) and Shea butter (5 % w/w) was found to be devoid of any irritation potential.

**Table No.5 : Skin irritation potential of derma stick releved by HET CAM test****(Hen'sEgg Test on The Chrioallantoic Membrane)**

Sr. No	Test solution	Score	Inference
1.	NaCl 0.9 % (negative control)	0	Non irritant
2.	1 % SLS Solution (positive control)	3	Non irritant
3.	Test formulation LCMBSSBCB	0	Non irritant

**Stability study:**

The stability study of selected derma sticks GKO did not indicate any gross changes in physicochemical properties (**Table No. 6**)

**Table No.6: stability studies of medicated derma stick**

Duration	Temperature	Physical appearance	pH	Melting point
After 8 days	27±2 °C	No change	6.3	70
After 15 days	27±2 °C	No change	6.1	68
After 30 days	27±2 °C	No change	6.2	67

At the end of 30 days, the stability sample of the experimental derma stick GKO indicate no any changes in its physical as well as functional characteristics and exhibited that the formulations were safe to use in topical application



**Fig.1:** Photographs of non medicated derma stick(SBMBCB) and medicated (GKOSBMCB) derma stick

**CONCLUSION:** The present work formulation and evaluation of derma sticks was aimed to formulate a derma stick using herbal ingredients with a hope to minimize the side effects as produced by the available synthetic ones. The prepared derma stick shows better strength, spreadability, and no surface defects. The prepared medicated derma stick shows better stability after 30 days. From the above study it was concluded that derma sticks are easy to use and give a better moisturizing effect on stretch marks due to the use of different butters in formulations.

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