



Original Article

Ghee-based all-purpose herbal cream of medicinal use

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ABSTRACT

The ethenopharmacological use of ghee and turmeric mixture on cut and burn wounds has extensively been practiced. However, their mixture found unstable in long-term use due to the rancidity of ghee and oxidation of turmeric. Therefore, developing its stable cream formulation could solve the purpose best as it could replace the mineral oils based all-purpose creams present in the market. The cream was developed by the phase inversion temperature method. It was found to be consistent, elegant, and smooth in feel. The pH, viscosity, firmness, spreadability, and extrudability of the developed cream were found to be 5.9 ± 0.32 , 4910 ± 70 cps, 38.33 ± 0.73 g, 67.76 ± 8.13 mJ, and 661.67 ± 8.28 mJ, respectively. It has shown excellent stability at 25°C. The ghee-based cream was prepared and stabilized successfully. It was found to be an excellent alternative to the other mineral oil-based all-purpose creams running in the market. It can be used in all types of wounds, foot and hand cracks, and to maintain the skin healthy with the medicinal value of ghee, curcumin, and lavender oil.

Keywords: Ghee, curcumin, lavender oil, all-purpose cream, anti-inflammatory, wound healing

INTRODUCTION

Ghee is an integral part of the Ayurvedic system of medicine. It has been used as a primordial vehicle for herbal medicines. Some of the investigations demonstrate it as an antioxidant and antiatherogenic agent.^[1] Due to immense lipidic nature, it has the potential to kill various microorganisms. It is applied to the skin to get the health benefits. People use it as massage oil in Asian countries. Ghee is composed of fatty acids which nourish and moisturize the skin to provide a healthy look, Vitamin A and E which have antioxidant properties and lipids which maintain moisture balance in the skin.^[2,3] Ghee has many beneficial effects on the skin such as soft elbows and knees, topical salves, as hair treatment, on hands and cuticles, silky heels, and for removing diaper rash.^[3]

Conventionally, the mixture of ghee and turmeric has been used over the skin for numerous benefits.^[4] Curcumin, i.e., obtained from the

rhizomes of *Curcuma longa* has also been used from thousands of years to treat a variety of ailments. It tends to stimulate the endogenous development of transforming growth factor-1 in the wound, which may play an important role in improving wound repair.^[5] Curcumin has traditionally been used as an ancient medicinal treatment in herbalism for skin inflammation.^[6] Curcumin has many advantages such as wound healing, antimicrobial property, antioxidant, and many more.^[6] However, the mixture of ghee and curcumin oxidizes upon storage and ghee rancidity leads to the breakage of lipid chains present in it. At the same time, ghee solidifies below room temperature. Therefore, delivering them in a suitable dosage form (cream or ointment) is still a target to achieve.

Creams are biphasic system containing aqueous and oily phase and are widely used for the topical applications.^[7] Several mineral oils such as light liquid paraffins and paraffin soft white are deliberately used to make a stable cream formulation.^[8] However, some of the reports cite their toxicity into the biological systems.^[9] Therefore, making ghee-based cream could solve the purpose best if it could replace these mineral oils up to some or large extent. However, the key factors that restrict the shelf life of ghee-based product are oxidative degradation which results in decline in market acceptability by modifying their

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organoleptic properties, losing essential nutrients, and creating toxic free radicals.^[10,11]

Therefore, we aimed to develop ghee, curcumin, and lavender oil based an all-purpose cream which can be used by all age group of people, applied to all skin types and can be used as a regular moisturizing cream to protect the skin from dryness, wounds infections, cracks, and inflammation. Development of stable and elegant cream of the said composition has immense potential to replace the current pharmaceutical market flooding with several mineral oil-based creams.

MATERIALS AND METHODS

Materials

All the materials used in this investigation were purchased in India only. Light liquid paraffin, glyceryl monostearate, sodium lauryl sulfate, glycerin, methyl paraben, and propyl paraben were purchased from HiMedia Pvt. Ltd., Paraffin soft white, stearyl alcohol, cetyl alcohol, and paraffin wax; tocopherol, curcumin, and oleic acid were purchased from Sigma Aldrich. Glycerin was purchased from CDH Lab. Ghee was purchased from local market of Moga, Punjab. Lavender oil was isolated by steam distillation process in ISF College of Pharmacy, Moga, Punjab.

Selection of the key ingredients of cream

The selection of the key ingredients of the cream was done on the basis of safety and potential uses. Ghee is well known for its anti-inflammatory properties.^[12] At the same time, it also provides a vehicle base for other mixed ingredients. It has also been used in wound healing purposes.^[13,14] Curcumin is a known anti-inflammatory^[14] and wound healing agent.^[15] The ghee and turmeric mixture is a known remedy of wound created by cuts or burn.^[16] In addition, lavender oil has anti-inflammatory and anti-infective properties.^[17]

OPTIMIZATION OF CREAM FORMULATION

Optimization of the ghee-based cream base was done based on cream stability, homogeneity in cream texture, and presence, or absence of grittiness in the cream. For this purpose, we have used a well-established cream base formula. This cream base was stabilized first using mineral oils. However, most of the end users do not rely on mineral oil-based creams because of the safety issues. Therefore, we planned to replace the mineral oils with ghee. The cream base was optimized based on process variables such as homogenization speed and time, whereas emulsification temperature was kept constant. After optimization of the mineral oil-based cream base on process variables, ghee-based cream base was optimized on ghee and mineral oil concentrations. The effect of change of these parameters was checked using one variable at a time approach. Each version of the prototype was inspected for their stability, smoothness, and elegance. If any prototype found unstable (phase separation and creaming), an improved version was prepared based on the heuristics and experiences. This iterative process continued until a satisfactory prototype was produced.

Method of preparation of cream formulation

Phase inversion temperature method was used to prepare the cream formulation.^[18] About 100 g cream was prepared to get a sufficient quantity for performing various evaluation tests. The ingredients were separated in two groups, i.e., oil and aqueous soluble. The oil phase encompassed oil soluble ingredients; however, the water phase comprised the aqueous soluble ingredients. Oil phase was prepared by mixing light liquid paraffin, propyl paraben, paraffin soft white, ghee, oleic acid, stearyl alcohol, paraffin wax, cetyl alcohol, tocopherol, and sunflower oil in a beaker. The aqueous phase was prepared by mixing glyceryl monostearate, methyl paraben, sodium lauryl sulfate, glycerine, curcumin, and distilled water in another beaker. Both the phases were kept separately on a heating plate maintained at 65°C and 800 rpm. After the assurance of the complete mixing of the ingredients in each phase, the aqueous phase was poured slowly into the oil phase by beaker wall with continuous stirring at 300 rpm. Once the whole content of the aqueous phase was added to the oil phase, the emulsified content was closed with an aluminum foil and homogenized (REMI equipment) for 60 min at 65°C. Lavender oil was mixed into the final emulsion. After 5 min homogenization, the emulsified mixture was left for natural cooling. For better filling in a tube, the cream was poured into the empty tubes when its temperature reaches to 45°C and kept as such for 45 min at room temperature for further cooling. At last, the tubes were sealed with the help of manual tube sealing machine. The color and fragrance were added once the temperature of the emulsion reaches to 40°C. The cream was kept at a bath sonicator for 5 min if any trapped bubbles were observed. To scale up the ghee-based cream formulation, we prepared 2 kg batch with the help of mechanical homogenizer (IKA Eurostar WERKE Laboratory Reactor [Power Control-Visc P7]).

Some of the suitable author's recommendations with the method of preparation may give better elegance and stability to the formulation. The practical experience says, the stirring speed should be maintained near to 300 rpm to avoid foaming of the cream and temperature should be maintained in the range of 60–70°C. After mixing of two phases, the emulsion should at least be homogenized for 45 min to make smooth and elegant cream formulation. Ultrasonication (using bath sonicator) is recommended in the case of air entrapment. Volatile and organoleptic ingredients should be added after proper emulsification of both phases. The whole process should be done in well closed container because curcumin can be oxidized and lavender oil can be evaporated in presence of light and heat, respectively.

Evaluation of the cream characteristics

Organoleptic properties

Organoleptic properties of the optimized cream were evaluated in terms of elegance, color, sensorial feel, phase separation, fragrance, and homogeneity. These parameters were evaluated by sensorial observation. Elegance, color, phase separation, and homogeneity were checked by visual observation; however, fragrance and sensorial feel were checked by smell, and finger touch, respectively.^[18]

pH determination

A definite amount of the optimized cream (100 mg) was dissolved in 10 mL distilled water and mixed well with the help of magnetic stirrer (REMI equipment). The pH of the cream was recorded using Digital pH Meter (Arvind Industries SV4). pH evaluation was carried out in triplicate at 25°C.^[19]

Viscosity measurement

The viscosity of the optimized batch was measured using Brookfield R/S Plus Rheometer. The measurement was carried out at 25 ± 2°C and 10 rpm speed using spindle no. C75-1 in triplicate.

Texture analysis

Texture analysis is done to measure the physical properties of the semisolid formulation such as hardness/firmness, spreadability, and extensibility. Texture analysis of the optimized cream was done using CT3 texture analyzer. TexturePro CT software was used to measure the texture. Firmness was evaluated using TA-25 probe and fixture TA-RT-KIT set up. For spreadability determination, male and female cone probe was used. Extrudability of the developed cream was measured by TA DEC dual extrusion cell. Target value was fixed at 10 mm and holding time was 2 s.^[20]

Stability studies

International Conference on Harmonization guidelines were followed for the investigation of the accelerated stability studies of the optimized formulation. Opaque, tube filled cream formulation was stored at 25

± 2°C/60 ± 5 %RH and 40 ± 2°C/75 ± 5% RH for a period of 30 days in a stability chamber. At predetermined intervals, 0, 10, 20, and 30 days, samples were withdrawn and their physicochemical evaluation parameters such as color, consistency, smoothness-related problem, altered smoothness, viscosity, spreadability, and pH were evaluated.^[18]

RESULTS AND DISCUSSION

Optimization of the cream base

After selecting the oil and aqueous soluble ingredients, total 15 batches were prepared. First optimization was done on the basis of process parameters such as homogenization speed and time. Changes in each group variables are highlighted with gray color in Table 1. Optimum parameters such as stability, elegance, and smoothness were evaluated on the different levels of intensity. Sign (+) depicts average, (++) depicts good, and (+++) depicts excellent intensity of the parameter. Best process parameters were observed to be 300 rpm homogenization speed and 60 min homogenization time at which a stable (no phase separation) cream was prepared with smooth and elegant appearance. Further, as per our need, we started replacing mineral oils such as light liquid paraffin and paraffin soft white with ghee. F4 depicts the first ghee-based formula which was found to be stable and elegant. Therefore, the concentration of ghee increased and concentrations of mineral oils decreased until stable and elegant formulation was developed. We fixed all the variables and changed only one at a time. We found F8 batch with good elegance and stability. Further increase

Table 1: Optimization of ghee based herbal cream formulation

Ingredients	Batches (ingredients used in weight percentage)														
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15
Oil phase															
Light liquid paraffin	9	9	9	9	9	9	9	7	7	7	7	8	8	8	7
Paraffin soft white	13	13	13	9	9	7	7	7	7	6	5	6	6	5	5
Ghee	-	-	-	4	6	6	8	8	10	10	10	10	12	12	12
Oleic acid	-	-	-	1	1	1	1	1	1	1	1	1	1	1	1
Lavender oil	-	-	-	1	1	1	1	1	1	1	1	1	1	1	1
Stearyl alcohol	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Paraffin wax	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Cetyl alcohol	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Sunflower oil	-	-	-	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Propyl paraben	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Tocopherol	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS
Aqueous phase															
Glyceryl monostearate	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15	3.15
Methyl paraben	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sodium lauryl sulfate	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85	0.85
Glycerin	-	-	-	4	4	4	4	4	4	4	4	4	4	4	4
Curcumin	-	-	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Distilled water	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS
Process variables															
Homogenization speed (rpm)	500	300	300	300	300	300	300	300	300	300	300	300	300	300	300
Homogenization time (min)	30	30	60	60	60	60	60	60	60	60	60	60	60	60	60
Homogenization temp (°C)	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65
Critical quality attributes															
Stability	++	+++	+++	+++	+++	+++	+++	+++	+++	++	+++	+++	+++	++	+
Smoothness	++	++	+++	+++	+++	+++	+++	+++	+++	++	++	+++	++	+	+
Elegancy	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++

Changes in each group are highlighted with gray color. (+) average, (++) good, (+++) excellent. F12 batch is the optimum batch

Table 2: Data for accelerated stability of ghee-based cream

Parameters	Stability at 25±2°C				Stability at 40±2°C			
	0 th day	10 th day	20 th day	30 th day	0 th day	10 th day	20 th day	30 th day
pH	5.90±0.37	5.92±0.31	5.91±0.35	5.97±0.76	5.90±0.37	5.90±0.16	5.72±0.85	5.45±0.38
Viscosity (Pa/s)	4910±70	4923±77	4911±84	4949±88	4910±70	4892±67	4741±89	4532±108
Spreadability (g)	67.76±8.13	67.29±12.35	67.71±8.44	67.33±9.17	67.76±8.13	67.93±8.15	62.16±9.17	54.66±5.15
Fungal growth	No	No	No	No	No	No	No	No
Visual changes								
Color	+++	+++	+++	+++	+++	++	++	+
Consistency	+++	+++	+++	+++	+++	+++	++	+
Smoothness	+++	+++	+++	+++	+++	+++	+++	++

Data presented as average ± SD, n=3. (+) average, (++) good, (+++) excellent

in ghee concentration in F9 offered slight grittiness in the cream. Best result was observed at 8% light liquid paraffin, 6% paraffin soft white, and 10% ghee in F12 batch (optimized). Further increase in ghee concentration led to the development of grittiness. We were not able to stabilize the batches with 12% ghee; hence, we considered F12 as the best batch out of all. The optimized cream formulation was evaluated on the basis of pH, viscosity, organoleptic properties, texture analysis, and accelerated stability studies.

Organoleptic characteristics

The medicated creams always criticized for its elegance in terms of appealing appearance, fragrance, and smoothness. Despite the presence of turmeric-based mineral oil-based cream formulations, none of the formulations present in the market is claimed to have ghee and turmeric with excellent stability and elegance. The results of the organoleptic properties of this investigation showed the development of an elegant, stable and yellow color cream formulation with excellent sensorial feel, fragrance, and homogeneity. User's acceptability is more or less depending on various organoleptic properties. The excellent elegance, color, and fragrance of the developed cream assure its acceptability as an alternative to the other mineral oil-based cream formulations present in the market.

pH, viscosity, and texture of the cream

The pH of the optimized cream formulation was found to be 5.9 ± 0.32. The range of the skin pH (4.5–6) outlines the suitability of the developed cream for skin use. Therefore, it is expected to offer no/minimum safety concern following skin administration. Viscosity of the optimum cream was found to be 4910 ± 70 cps. It reveals the semisolid consistency of the cream formulation than can suitably be used for topical application.^[21] Hardness/firmness, spreadability, and extrudability of the cream were observed to be 38.33 ± 0.73 g, 67.76 ± 8.13 mJ, and 661.67 ± 8.28 mJ, respectively. Texture analysis data delineate the utility of texture analyzer in emulating the human sensorial perception in terms of firmness, spreadability, and extrudability. Firmness defines the force required to deform the sample by a finger. In comparison to the texture analysis results given reported by Yadav *et al.* 2014,^[18,19] our results seem to be in reasonable agreement as a firm cream base to apply for. The value of the spreadability should be minimum for better application over the skin surface. Data indicate the reasonable agreement with the published facts and hence lesser work done is expected to spread the developed cream over the skin surface. The work done required to extrude a cream from a tube is

also a very important parameter. It should be optimum so as to ensure the easy extrusion of the content from the tube. Very loose or hard cream shows leakage from the tube or blockage of the mouth of the tube, respectively. Technically, the amount of work done to extrude the developed cream without leakage should be as minimum as possible. Data depict the good extrudability of the developed cream.

Stability study

The developed cream was subjected to the accelerated stability study for 30 days. Results reveal that the evaluated parameters such as color, consistency, fungal growth, smoothness, viscosity, spreadability, and pH did not change considerably with time when kept at 25 ± 2°C; however, at 40 ± 2°C, considerable change in pH, viscosity, and spreadability of the cream was observed with slight change in color and consistency. We did not observe fungal growth or phase separation in any of the conditions. Data given in Table 2 depicts more than 5% change in pH, viscosity, and spreadability of the developed cream on 30th day of the study period. Drastic change in color and consistency of the cream was observed at higher temperature. This suggests the stability problem of the cream over 35°C; however, it will be stable around room temperature.

CONCLUSION

The present study highlights the immense potential of ghee, curcumin, and lavender oil-based cream for improved safety and better medicinal value in wounds and skin cracks. Ghee, curcumin, and lavender oil-based cream was developed successfully to replace the mineral oil-based all-purpose cream in the market meant specifically for wound healing and skin health. It is well characterized to have semisolid consistency, smooth texture, and excellent stability at 25°C. Ghee, curcumin, and lavender oil are well known for their medicinal values and ethenopharmacological uses as anti-inflammatory, anti-infective, wound healing, and anti-oxidative agents; therefore, cream base prepared mainly by ghee have immense utility in various skin ailments.

AUTHORS' CONTRIBUTIONS

Vineet Kumar Rai: Design and conceptualization of the work and manuscript writing

Sumel Ashique: Commencement of the experiments and manuscript writing

Amit Sharma: Preparation of the batches and manuscript editing

Ajmer Singh: Evaluation of the prepared batches

Sudhanshu Gupta: Evaluation of the prepared batches

Alok Sharma: Steam distillation of the lavender oil and analysis
Ghanshyam Das Gupta: Conceptualization and arrangement of the facilities required for the experimentations.

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