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FORMULATION AND EVALUATION OF NATURAL PALM OIL BASED VANISHING CREAM

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ABSTRACT: In present work, a new vanishing cream using a natural base from palm oil and palm kernel oil and standard vanishing cream using stearic acid were prepared. The creams were o/w emulsions containing suitable combination of oil phase and aqueous phase along with preservatives. Both creams were white, non-greasy and smooth on application. They were subjected to various parameters such as; pH, viscosity, spreadability and tube extrudability. Stability studies of the prepared creams were determined at different temperatures for a period of 3 months as per ICH guidelines and the results revealed that both formulations were with good stability except the standard vanishing cream which was slightly hardened at 5^{o}C. The pH was found to be 6.7 and 6.98, and spreadability was found to be 11.30g. cm/sec and 13.33g.cm/sec for natural base and stearic acid based creams respectively. The tube extrudability was found to be good and fair for natural base and stearic acid based cream respectively. Furthermore, the formulations were studied for primary skin irritation test on rabbits and observed for skin rashes, inflammation, itching or redness on applied portions. Results revealed no adverse skin reactions with all the formulations. It was observed that vanishing cream containing natural base was pleasant, effective, easily washable and completely safe for human use. In contrast with ointments, which are greasy and messy in nature and may cause staining of clothes, the prepared Natural palm oil based vanishing cream was pleasant, easily washable thereby increasing patient compliance.

INTRODUCTION: Localized drug delivery by semisolid dosage forms continues to be a major area of research. Advances in formulation approaches have led to increased drug stability as well as improvement in the aesthetic appeal of semisolid dosage forms.

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Creams are semisolid dosage forms that contain one or more drug substances dissolved or dispersed in a suitable base, usually an oil in-water emulsion or aqueous microcrystalline dispersion of long-chain fatty acids or alcohols that are water-washable and are cosmetically and aesthetically acceptable. Semisolid dosage forms for dermatological drug therapy are intended to produce desired therapeutic action at specific sites in the epidermal tissue. A drug's ability to penetrate the epidermis, dermis, and subcutaneous fat layers of skin depends on the properties of drug and the carrier base. Although some drugs are meant primarily for surface action on the skin, the target area for most dermatological disorders lies in the viable epidermis or upper dermis.

The diffusive penetration of a drug on skin is through percutaneous absorption and hence it is an important aspect of drug therapy. The main portals of drug entry into the skin are the follicular region, the sweat ducts, or the unbroken stratum corneum between these appendages. A route of administration for a particular drug mainly depends on the physicochemical properties of the drug and the condition of the skin. Pharmaceutical preparations for treatment of conditions such as rashes, skin irritation, stings, fungal infections are normally supplied in the form of a cream as this provides an effective means of delivering the active ingredient directly to the required area. Products can be either a water in oil (w/o) or oil in water (o/w) emulsion, consisting of waxes, emollients and lubricants dispersed in an oil phase, and a water phase containing emulsifying, stabilizing and thickening agents, preservatives and in some cases, colorant.

Active ingredients are dispersed in either phase or added when the emulsion has been formed and allowed to cool. Unlike oral and parenteral dosage forms, topical dermatological formulations often require many excipients. Each excipient should be justified by function and need. If a novel excipient is used, it is probable that FDA will require additional safety data, which will increase the nonclinical study burden (time and cost). In the study excipients such as solvents, preservatives, antioxidants, surfactants and other agents are used to overcome solubility, stability, or skin penetration challenges [1].

Cosmetic elegance is necessary for patient acceptance and compliance may require additional excipients. With so many excipients, interactions may occur with each other or with the API, ultimately resulting in odor, discoloration, loss of viscosity, or loss of potency. In addition, it is also important to select well-characterized excipients whenever possible, in order to avoid future issues with variability [2].

Cream base from natural palm oil: The present study relates to pharmaceutical bases for drug delivery. More particularly to a thermostable pharmaceutical base formed from the mixture of palm oil from the fibrous mesocarp and lauric oil from the palm kernel. A base in which the pharmaceutical active ingredient is incorporated should be stable, non- irritating to the body, chemically and physiologically inert, compatible with a variety of drugs, stable during storage, without pharmacological activity or interfere with the release of drug substance and be able to provide products of esthetical value and easy to process during manufacturing.

In the past decade, palm oil has become internationally well known as being the most versatile oil of various products. Its price competiveness and readily available production from crude palm oil and evaluation of supply is able to serve the needs of oils and fats [3]. Palm oil has a balanced ratio of saturated and unsaturated fatty acids while palm kernel oil has mainly saturated fatty acids which are broadly similar to the composition of coconut oil. Compared to soy oil, palm oil has a higher amount of saturated fatty acids but this makes it more stable and less prone to oxidation at high temperatures. Recently the natural palm oil base was used successfully to formulate and evaluate sustained release suppositories of diclofenac sodium [4].

MATERIALS AND METHODS: Natural palm oil base – Obtained as a gift sample from University Malaya, Malaysia. Glycerol, Stearic acid, Potassium hydroxide, Sodium hydroxide, Methyl Paraben, Propyl Paraben were supplied by AP Lab Scientific., Malaysia. Triethanolamine, Citric acid and rose oil were supplied by Kofa Chemical Ltd., Malaysia.

Preparation of Vanishing Cream Formulation: Vanishing creams are o/w emulsion based preparations containing aqueous phase and oil phase.

Ingredients: The oil phase (A) was mixed together by melting in a china dish on constant stirring. Components of aqueous phase (B) were mixed together in a separate container and warmed to about same temperature of oil phase. Aqueous phase was added to oil phase drop by drop on constant stirring. Perfume was incorporated when the formulation begins to solidification. The preservatives propyl paraben and methyl paraben were added after cooling. **Table 1 and Table 2** represents the formulae. **Physical appearance:** The physical appearance was virtually checked for the color, consistency texture and greasiness of formulations and observations are shown in **Table 3**.

TABLE 1: INGREDIENTS FOR NATURAL PALM OIL BASED VANISHING CREAM

Sr. No.	Ingredients	Quantity (g)
A) 1.	Natural palm oil base	12.5
2.	Triethanolamine	1
3.	Glycerol	6
B) 4.	Citric acid	0.2
5.	Propyl Paraben	0.025
6.	Methyl Paraben	0.05
7.	Rose oil	Qs
8.	Purified water	30.1

TABLE 2: INGREDIENTS FOR STEARIC ACID BASED VANISHING CREAM

Sr. No.	Ingredients	Quantity (g)
A) 1.	Stearic Acid	12.5
2.	Cetyl alcohol	1
3.	Glycerol	6
B) 4.	Potassium hydroxide	1
5.	Propyl Paraben	0.025
6.	Methyl Paraben	0.05
7.	Rose oil	Qs
8.	Purified water	29.34

TABLE 3: COMPARISON OF PHYSICAL PARAMETERS OF PREPARED CREAMS

Formulations	Color	Consistency texture	Greasiness
Natural palm oil based vanishing cream	White and pearl like appearance semisolid cream	Smooth and glossy	Not greasy on application
Stearic acid based vanishing cream	White semisolid cream	Smooth	Not greasy on application

The creams were evaluated for pH, drug content, viscosity, spreadability, tube extrudability, stability studies and primary skin irritation tests were conducted on experimental animals (Rabbits).

Determination of pH: Accurately weighed 5g of the cream was dispersed in 45 ml. of water to determine the pH of the suspension at 27°C using digital pH meter [9].

Viscosity: Rheological measurements can be regarded as sensitive tools for detecting structural changes in pharmaceutical creams and should be regarded as an integral part of the quality evaluation of pharmaceutical creams [5]. The viscosities of formulated vanishing creams were measured by Brook field Viscometer (DV-II) at room temperature [6].

Spreadability [7]: Spreadability 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 spreadability is very important in evaluating topical application characteristics. For the determination of spreadability, excess of sample (3g) was applied in between two glass plates and was compressed to uniform thickness by placing 1000 g weight for 5 minutes. Thereafter weight (50g) was added to the pan and the top plate was subjected to pull with the help of string attached to the hook. The time in which the upper glass slide moves the lower plate to cover a distance of 10 cm is noted.

A shorter interval indicates better spreadability. The spreadability (S) was calculated using the formula;

$$'S' = m.l/t$$

Where, S is spreadability, m is weight tied to upper glass slide. l is length moved on glass slide and t is time.

Tube extrudability [8]: The method adopted for evaluating vanishing cream formulation for extrudability was based upon the quantity in percentage of cream extruded from tube on application of certain load. More the quantity extruded better was its extrudability. The formulations were filled into a clean, lacquered aluminium collapsible one- ounce tube with a 5 mm opening. It was then placed in between two glass slides and was clamped. Extrudability was determined by weighing the amount of creams extruded through the tip when a constant load of 1kg was placed on the slides and creams extruded was collected and weighed. The percentage of cream extruded was calculated and grades were allotted (++ good; + fair). The comparative extrudability of the formulations is noted.

Primary Skin Irritation test [9]: The study was conducted upon the approval of University Animal Ethics Committee. The animals selected were albino rabbits. The animals selected were albino rabbits. These animals were kept in different cages and supplied with fresh food and water during the test period, 24 hours prior to test, the hair from the neck and thigh region was shaved to expose sufficiently large test area.

The test site was cleaned with surgical spirit briefly. Then vanishing cream was applied to the test area. The test site was observed for erythema and edema for 24 h; 48 h; and 72 h after application. This test was conducted to evaluate the irritation caused by the prepared cream on the intact skin of animals. The prepared cream does not show any erythema or edema, indicating that the prepared formulation was non-irritant on the skin of animals [4].

Stability studies [10]: Formulated cream preparations were kept at different temperature condition like ambient temperature 5±3°C (refrigerator temperature), 25±2°C (room temperature) and 45±5°C (condition of accelerated stability testing) for a period of three months and the observations are shown in Table **4 and 5**.

TABLE 4: EFFECT OF STORAGE CONDITION ON THE STABILITY OF NATURAL PALM OIL BASED VANISHING CREAM

Parameter	Monitoring Phases	Storage temperature		
		5°C	25°C	45°C
Visual appearance	Initial	Pearly white and non-greasy on application		
	Final	Same	Same	Same
pH	Initial	6.70	6.70	6.70
	Final	6.70	6.70	6.70
Extrudability	Initial	+++	+++	+++
	Final	+++	+++	+++
Spreadability	Initial	11.30	11.30	11.30
	Final	11.35	11.30	11.30
Phase separation	Initial	-	-	-
	Final	-	-	-
Nature	Initial	Smooth		
	Final	Same	Same	Same

TABLE 5: EFFECT OF STORAGE CONDITION ON THE STABILITY OF STEARIC ACID BASED VANISHING CREAM

Parameter	Monitoring phases	Storage temperature		
		5°C	25°C	45°C
Visual appearance	Initial	white and non-greasy on application		
	Final	Same	Same	Same
pH	Initial	6.98	6.98	6.98
	Final	7.00	6.98	6.95
Extrudability	Initial	++	++	++
	Final	+	++	++
Spreadability	Initial	13.33	13.33	13.33
	Final	13.38	13.33	13.30
Phase separation	Initial	-	-	-
	Final	-	-	-
Nature	Initial	Smooth and glossy		
	Final	Slightly hardened	Same	Same

RESULTS & DISCUSSION: The formulations shown good stability except the standard base vanishing cream was slightly hardened at 5°C. pH was 6.70 and 6.98, spreadability was found to be 11.30g.cm/sec and 13.33 g.cm/sec. The tube extrudability of the formulations was found to be good and fair for the natural palm oil based and standard creams respectively. Furthermore, the prepared natural palm oil based vanishing cream was studied for primary skin irritation test in rabbit and observed for skin rashes, inflammation, itching or redness on applied portions. Results revealed no adverse skin reactions, erythema or sensation with the formulations even after 72 hours of applications. Physicochemical properties of the prepared formulations of natural palm oil based vanishing cream shown good spreadability and tube extrudability with proper viscosity which is needed for vanishing cream formulations, **Fig. 1-2** represent the comparative graphical data and **Fig. 3**

represent the pictures of animal study. The prepared formulations of the new base was a found to be free from skin irritation on application to rabbit skin and stable for three months.

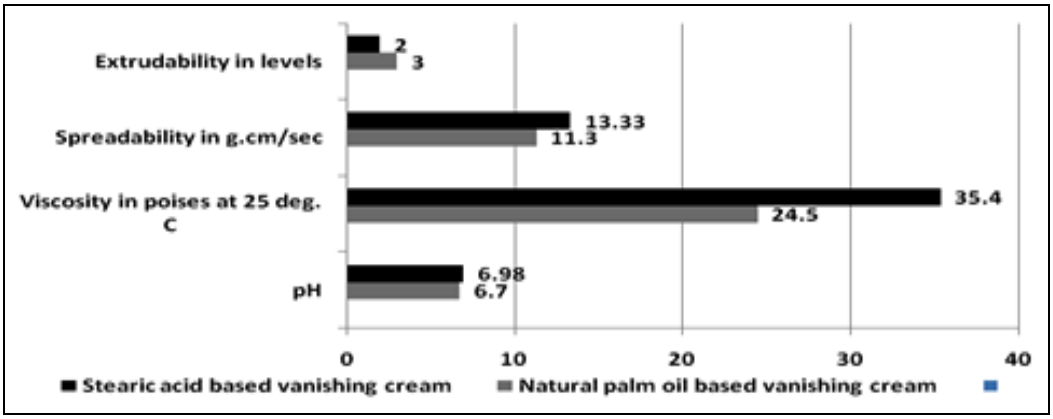

FIGURE 1: COMPARISON OF NATURAL PALM OIL BASED VANISHING CREAM PARAMETERS WITH THE PARAMETERS OF STEARIC ACID BASED VANISHING CREAM

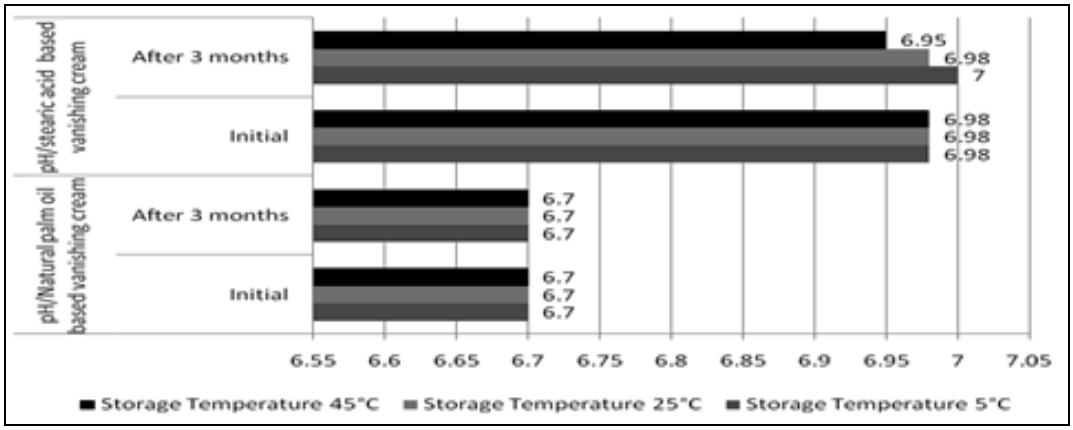

FIGURE 2: COMPARISON OF STABILITY STUDIES AND THE EFFECT OF STORAGE TEMPERATURE ON pH

FIGURE 3: RABBIT SKIN- ON APPLICATION WITH NATURAL PALM OIL BASED VANISHING CREAM

CONCLUSION: Our study concludes that the vanishing cream with natural palm oil base will be useful as skin moisturizer when compared with other preparations which are greasy and messy in nature and may cause staining of cloths. From the results it can be concluded that natural palm oil base can be used as a base for preparation of vanishing cream. The prepared vanishing cream with natural palm oil base was pleasant, easily washable with good spreadability and extrudability, thereby increase the patient compliance.

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