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Formulation And Evaluation Of Nano-Emugel Containing *Musa Paradiasica*

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Abstract: The skin is the largest organ in the body and carries out numerous vital tasks that are necessary for good health and wellbeing. Its main function is to serve as a barrier of defense, keeping the body safe from outside dangers like infections, UV rays, and toxins from the surroundings. Skin cells are damaged by UV radiation, which raises the possibility of mutations and skin cancer. Tannin is produced when melanin production rises and acts as a natural barrier against UV ray damage. Nevertheless, overexposure to UV radiation can override this defense mechanism, resulting in sunburn and hastening the skin's aging process. Prolonged exposure to UV radiation also raises the risk of melanoma and other skin cancers. The skin is also vulnerable to numerous microbial infections because it is the organ that comes into direct contact with the outside world first. Numerous factors may contribute to these infections. As a solution to this skin issue, Preapared a unique emulgel formulation that successfully addresses issues with microbial infection, and sun protection. The combination of the qualities of an emulsion and a gel is known as emulgel in pharmaceutical formulas. Particularly for topical applications, this special combination offers multiple benefits in drug delivery. The natural ingredients used in the herbal emulgel formulation, such as essential oils and plant extracts, make it a strong substitute for synthetic products. They are safe to the skin and suitable for those with sensitivity or allergy issues because their formulation is frequently devoid of harsh chemicals and artificial additives. The formulation is designed to protect the skin from UV radiations and it also has anti-inflammatory as well as anti-microbial property. To obtain herbal and natural solution to this condition our formulation consists of plant extract. Later on, while evaluating the formulation we have estimated it on the basis of color, consistency, spreadability, pH, SPF studies, thermodynamic stability studies and anti-microbial study. On achieving satisfactory results, we can assure you that the banana plant extract can be widely used for sun protection.

Key Words: Nano-Emugel, Olive oil, Sun Protection factor, extrudability, *Musa Paradiasica*

I. INTRODUCTION

As the largest organ in the body, the skin carries out numerous essential tasks that are critical to overall health and wellbeing. Its main function is to serve as an external barrier, keeping the body safe from harmful substances like infections, UV rays, and pollutants found in the environment. The skin also helps to maintain internal homeostasis by controlling blood flow and sweat production.

The skin, which is the outermost layer of our body, is a complex organ made up of several layers that cooperate to carry out different tasks that are vital to our overall health and wellbeing. The epidermis, which is the outermost layer, acts as a barrier to keep out pathogens, UV rays, and environmental pollutants. The dermal layer, a thicker layer with blood vessels, nerve endings, hair follicles, and glands, is located beneath the epidermis. The skin's structural support system, the dermis, is home to vital substances like collagen and elastin that keep the skin firm, supple, and strong. Subcutaneous tissue is located deep within the skin and is made up of fat cells that act as insulation and cushioning, as well as blood vessels and nerves that supply the skin above with nutrients and feeling.

It is made up of active ingredients such as banana extract. This formulation is a w/o emulsion and gel formulation. All the ingredients used are safe for topical use. Banana extract has many more benefits in the field of cosmetic science. Apart from sun protecting properties, it also possesses anti-inflammatory and anti-microbial properties.

II. MATERIALS AND METHODS:

Drugs and chemicals:

Sr No.	Reagents
1.	*Musa paradisiaca* extract
2.	Olive oil
3.	Span 20
4.	Tween 20
5.	Ethanol
6.	Triethanolamine
7.	Carbopol 934
8.	Distilled water

III. PROCEDURE

The gel phase in the formulations was prepared by dispersing Carbopol 934 in purified water with constant stirring at a moderate speed using mechanical shaker, then the pH was adjusted to 6-6.5 using triethanolamine (TEA).

The oil phase of the emulsion was prepared by dissolving span 20 in olive oil in beaker A.

The aqueous phase was prepared by dissolving Tween 20 in purified water in beaker B.

Whereas drug was dissolved in ethanol. And added to beaker B, solutions were mixed with the aqueous phase.

Then the oily phase was added to the aqueous phase with continuous stirring 1500-1600 rpm for 25-30 minute, until it got cooled to room temperature.

The obtained emulsion was mixed with the gel in 1:1 ratio with gentle stirring to obtain the emulgel.

IV. FORMULATION TRIALS

Table:

Ingredients	**Quantity (%)**			**Category**
	Trial 1	**Trial 2**	**Trial 3**	
Musa paradisiaca	5 mg	2.5 mg	1 mg	Active ingredient
Olive oil	33 gm	16.5 gm	7.5 gm	Oil phase
Tween 80	16.5 mg	7.5 mg	3.75 mg	Solubilizer
Span 20	16.5 mg	7.5 mg	3.75 mg	Solubilizer
Distilled water	33 mg	16.5 mg	7.5 mg	Solvent
Carbopol	0.88 mg	0.44 mg	0.22 mg	Gel formation
Ethanol	Q.S mg	Q.S mg	Q.S mg	Solvent

V.OPTIMISED TRIALS

Table:

Ingredients	**Quantity (%)**			**Category**
	Trial 1	**Trial 2**	**Trial 3**	
Musa paradisiaca	6 mg	3 mg	1.5 mg	Active ingredient
Olive oil	35 gm	17.5 gm	8 gm	Oil phase
Tween 80	17 mg	8 mg	4.5 mg	Solubilizer
Span 20	17 mg	8 mg	4.5 mg	Solubilizer
Distilled water	35 mg	16 mg	7.5 mg	Solvent
Carbopol	0.90 mg	0.48 mg	0.23 mg	Gel formation
Ethanol	Q.S mg	Q.S mg	Q.S mg	Solvent

V. EVALUATION PARAMETERS

- Physical examination

The prepared emulgel formulations were inspected visually for their color, appearance and consistency. [5,6]

- pH measurement

A digital pH meter is used to determine the pHof all prepared emulgel. Calibration of the pH meter is performed before using a standard buffer solution. 1 gm of the formulation is dispersed in distilled water until a uniform dispersion is formed and is kept aside for 2 hours. After 2 hours the glass electrode is dipped in the suspension and the pH is measured. [5]

- Centrifuge test

6 g of Emulgel was taken in 10 ml graduated centrifuge tubes and were subjected to spin at 4000 RPM for 10 min. The sample was observed for any phase separation occurrence.

- Swelling Index

Swelling index is determined by taking 1g of emulgel in a porous aluminium foil and mixed with0.1N NaOH kept in a 50ml beaker. Then samples are withdrawn at different time intervals and kept for drying and it is reweighed. Swelling index is calculated as follows:

Swelling Index = {Wi - Wo/Wo} 100

Where, (SW) % = Equilibrium percent swelling, Wt = Weight of swollen emulgel after time t Wo = weight of emulgel at zero time.

- Drug Content determination

A spectrophotometer is used to determine the drug concentration in the emulsion. The drug content of an emulsion is determined by sonicating a known amount of emulsion in a solvent (methanol). In UV/VIS spectrophotometer, absorbance is measured after absorbing measured after appropriate dilution. [5]

- Determination of emulsion type

Emulsion type was determined through utilization of dilution test based on solubility of the emulsion's external phase in water or oil. Briefly a few drops of prepared emulsion were added to the test tube containing a small amount of water. If the outer phase of the emulsion distributed evenly in water, it would be determined as O/W type and if it was separated as a layer, it would be determined as W/O type. [5]

- Stability studies

The prepared emulgels were packed in aluminum collapsible tubes (5 g) and subjected to stability studies at 5°C, 25°C / 60% RH, 30°C /65% RH, and 40 °C /75% RH for a period of 3 months.Samples were withdrawn at 15-day time intervals and evaluated for physical appearance, pH, rheological properties and drug content (Harmonized Tripartite Guidelines, 2003). [6]

- Zeta potential

The zeta potential of the emulgel formulation is determined using the Zetasizer (Malvern Zetasizer). The result is computed when the formulation is placed in a transparent, disposable zeta cell. Cuvettes are soaked in methanol before being filled with the experiment's sample

- Rheological studies

A Brookfield viscometer with spindle no.18 at 100 rpm is used to determine the rheological properties of the various emulgel compositions at 25℃. [5,6]

- Spreadibility:

Spreadibility was determined by the apparatus which consists of a wooden black, which was provided by a pulley at an end. By this method spreadibility was nearest on the basis of slip and drag characteristics of gel. An excess of gel (about 2g) under study was placed on the ground slide.The gel was then sandwiched between this slide and another glass side having the dimension of fixed ground slide and provided with the hook. A one kg weighted was placed on the top of the two sides for 5 minutes to expel air and to provide a uniform film of the gel between the slides.Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 gm. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5cm is noted. A shorter interval Indicate better spreadibilty.

Spreadibility was calculated using the following formula:

S=M x L/T

Where, S=Spreadability, M-Weight in the pan (tied in the upper slide) 1-Length moved by the glass side T=Time (in sec) takes to separate the slides completely from each other. [6]

- Extrudability Study [tube test]

It is calculated by the force required to extrude the emulgel from the tube. The method applied for determination of applied shear in the region of the rheogram corresponding to a shear rate exceeding the yield value and exhibiting consequent plug flow. In this study, an emulgel extruded from lacquered aluminium collapsible tube on application of weight in grams required to extrude at least 0.5cm ribbon of emulgel in 10 seconds. For better extrudability, more quantity is extruded. For the measurement of extrudability, it is done in triplicate and the average values are calculated. The extrudability is then calculated by using the following formula.

Extrudability = weight applied to extrude emulgel from tube(in gm) / Area (in cm2). [8]

- Particle size and polydispersity index (PDI)

The globule size of emulgel is measured at 25℃ by using a zetasizer (Malvern zetasizer instrument,). The sample is diluted before the experiment. [7]

- Solubility

Solubility of drug was seen in water, ethanol, It was partially soluble in water and soluble in ethanol. [5]

- Anti-oxidant activity

The anti-oxidant activity was measured by employing Marsden S. Blois method using DPPH (1, 1-diphenil-2-pieryhydrazyl) which is a stable free radical. Equal volume of diluted extract was mixed with DPPH 0.5 µl in analytical grade ethanol, and the final mixture was kept at room temperature for 30 minutes.After that, absorption of the mixtures at 517 nm was taken, in comparison with the control solution (maximum absorption). Vitamin-C was used as a standard. Action of free radical was calculated in percentage inhibition according to the following equation [3,4]

% Inhibition =[(A control - A test)/A control] × 100.

- Sun Protection Factor (SPF) study

Sample preparation Weigh about 1.0g of the sample in a 100mL volumetric flask and add ethanol about 3/4th volume of the flask. Sonicate the contents for about 10 minutes and make up to the mark using ethanol. Filter the solution through Whatman Nol filter paper and collect the filtrate by rejecting the first few mL of the filtrate. Take 5mL of the aliquot in a 50mL volumetric flask and make up to the mark using ethanol. Then take 5mL of the diluted solution in to the 25mL volumetric flask and make up to the mark using ethanol. The absorption spectra of sample solution were obtained in the range of 250 to 400 nm using 1 cm quartz cell, and ethanol as blank. The absorption data were obtained in the range of 290 to 320, every 5 nm, and 3 determinations were made for each samples. The SPF of the samples were calculated using the below equation (a mathematical expression derived by Mansur) and the relationship between erythemogenic effect and radiation intensity at each wavelength, (EE X I) was determined as described by Sayre

SPF = CF × E130 EE (2) * I (1) * Abs(2)

Where: EE - erythemal effect spectrum; I - solar intensity spectrum; Abs - absorbance of sunscreen product; CF - correction factor (= 10). The values of EE x I are constants. [9]

VI. RESULTS AND DISCUSSION

Consumers concerned with the environment are willing to spend more on “environment friendly” products, favoring the growth of the market for organic cosmetics. Following this trend, cosmetic manufacturers have invested in research and development of this product category. However, the development of organic cosmetics has major technical challenges, besides requiring the experience and skill of the formulator, there is restriction on use of raw materials since 95% of the formulation must be of organic origin.

Talking about our formulation’s overall results we conclude the following:

- ORGANOLEPTIC CHARACTERISTICS:

The prepared formulation of emulgel was white in color with characteristic odour. All the results are shown in the table below:

PARAMETERS	**OBSERVATIONS**
Colour	Whitish
Odour	Characteristic
Appearance	Excellent
Consistency	Smooth And light to spread

- SPF studies:

The SPF of the emulgel formulation was found to be 3.5%.

- Zeta Potential:

The zeta potential of the formulation was found to be (±) -3.13

- Anti-microbial activity:

The anti-microbial activity of the nano-emulgel formulation inhibited the *Staphylococcus aureus.*

- EVALUATION TABLE:

SR NO	TEST	RESULT
1.	Physical examination	
2.	Colour	Whitish
3.	Odour	Characteristic
4.	Appearance	Emulgel
5.	Greesseness	Non greasy
6.	Washability	Washable
7.	Consistency	Very good
8.	Homogenicity	Very good
9.	Particle size	135.6 d.nm
10.	Physical compatibility	Compatibility
11.	Ph measurement	7.1
12.	Centrifuge test	No phase separation
13.	Determination of emulsion type	Oil in water
14.	Stability studies	Stable
15.	Rheological studies	15120 cp

SWELLING INDEX

Batch no	Time (min)	Initial weight of emulgel (gm)	Final weight of emulgel (gm)	Average weight	Swelling index (%)
F1	10	1.36	2.12	1.99	32.75±1.26
	20	1.36	1.98		
	30	1.36	1.88		
	40	1.54	1.54		
F2	10	1.54	1.94	2.01	30.5±11.74
	20	1.54	2.56		
	30	1.16	1.67		
F3	20	1.16	1.52	1.54	46.32±0.76
	30	1.16	1.44		

EXTRUDABILITY STUDY (TUBE TEST)

Formulation	Colour	Appeareance	Extrudability
F1	Whitish	Clear and transparent	Good
F2	Whitish	Clear and transparent	Excellent
F3	Whitish	Clear and transparent	Excellent

SPREADABILITY

Formulation	Average spreadability value(mean+SD)
F1	31.33±2.63
F2	29.33±0.94
F3	26.33±1.24

CONCLUSION:

Acne breakouts and inflammation as well as tanning is an aesthetic concern as it masks the overall appearance of the individual. Today's society gives immense credentials to smart pleasant looks and an internal craving to meet the demanding standards of society plays a pivotal role in propelling the the patients to undergo such aesthetic corrections externally. Treating the inflammation and protecting our skin enhances the personality of patients.

The formulation provides a natural and genuine approach to treat inflammation of the skin. It also provides sun protecting properties. Including the product in one's AM and PM skincare routine helps to achieve the good results.

In conclusion, herbal nano-emulgel formulation can be beneficial to your skincare routine, providing hydration, nourishment and reducing the inflammation caused by acne or sunburns. However, it is essential to remember that overall skincare, along with proper hydration and balanced diet, is crucial for maintaining healthy and beautiful skin.

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