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FORMULATION AND EVALUATION OF *HIBISCUS SABDARIFFA* [ROOT EXTRACT] BASED EMULGEL

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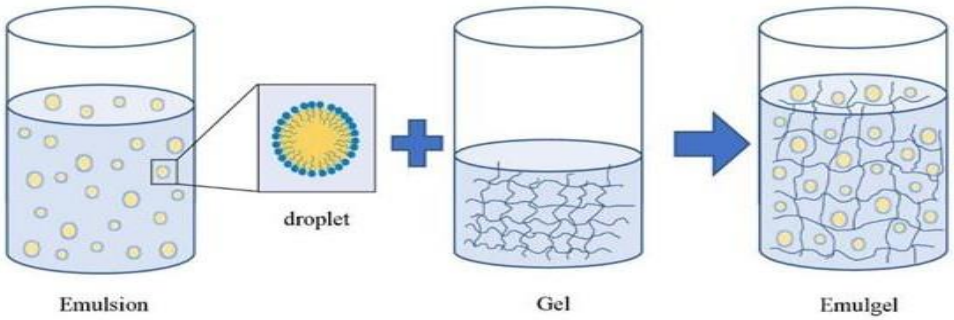
ABSTRACT
The search for new antimicrobial drugs has become intense due to the growing global challenge of antibiotic resistance. Topical drug delivery systems allow for the antibacterial activity of a medication to be delivered to any part of the body. The primary goal is to create a topical systemby making an emulsion based on plant extract and adding it to gel. Emulgel is a topical medication delivery device with antibacterial properties. The formulation of an emulgel basedon plant extract (Hibiscus sabdariffa) was assessed for its physical characteristics, homogeneity, pH, spreadability, viscosity, drug content, and antibacterial activity.

KEYWORDS: *Hibiscus sabdariffa* extraction, Emulgel formulation, Evaluation, anti- bacterial activity.

INTRODUCTION
An emulsion that has been gelled with the aid of a gelling agent is referred to as emulgel. Theycan be produced in w/o or o/w types. Poor water-soluble medication can be incorporated into Emulgel, a stable and improved system. Emulgel, to put it briefly, is emulsion mixed with gel. Gels have several benefits, but one major drawback is how hydrophobic medicines aredelivered. Therefore, this restriction is being addressed by using an emulsion-based solution, which enables even hydrophobic medicinal moieties to profit from the special qualities of the gel.

Emulgel's ability to distribute medicines in both hydrophilic and lipophilic forms is attributed to its dual aqueous and non-aqueous phases. They have been employed as a control release formulation in recent years. These are biphasic systems with improved stability and drug loading capacity.[1,2] Compared to traditional topical formulations, emulgel has a number of advantageous qualities, including better spreadability, greaselessness, thixotropy, high shelf life, odorlessness, and a pleasing look. Emulgel is a dual control release device that possessesboth gel and emulsion qualities.[3]



ADVANTAGES OF EMULGEL
- It is possible to incorporate hydrophobic medications into the gel basis rapidly by using water/oil/water type of emulsion.
- Increased load capacity and stability.
- Simple to produce and an inexpensive method.
- Steer clear of sonication.
- The first metabolism is circumvented.
- Steer clear of gastric incongrui
- Higher levels of patient adherence.

- Increased applicability and acceptance for self-medication among patient.[4]

DISADVANTAGES OF EMULGEL

- In patients with contact dermatitis, the medication and/or excipients may cause skin irritation.
- Some drugs don't pass easily through the skin.
- The potential for allergic responses.
- It is difficult for medications with larger particle sizes to penetrate the skin.[5]

THE RATIONALE OF EMULGEL FOR DRUG DELIVERY

There are numerous semisolids and other preparations on the market that can be used to change an operation to the underlying tissue pharmacologically or to restore the basic function of the skin.[6] Lotions, ointments, and creams are examples of formulations with a number of disadvantages, such as being sticky, having a low spreading coefficient, and experiencing stability problems.

Due to general restrictions within the semisolid preparations, only translucent gels are used in medicinal and cosmetic preparations.[7] To overcome this restriction, an emulsion-based approach is employed. Gels should therefore be used to integrate and provide the drug's hydrophobic moiety.

Hydrophobic medications can be included into emulgel using drug/oil/water emulsions. The majority of medications cannot be directly injected into gel bases due to solubility acting as a barrier, which might cause issues with drug release.[8]

EMULSION

When two or more typically incompatible liquids are combined, an emulsion is created. Using an emulsifying agent, the oil phase and the aqueous phase in this system are miscible. Emulsion stabilization is achieved through the application of emulsifying agents. They penetrate nicely and are simple to remove.[9]

GEL

The term "gel" describes a method of increasing a liquid preparation's viscosity without affecting its other characteristics. Gels can be added to a formulation to thicken it and to help with uniformity and homogeneity. Using this chemical, a gel base is produced, which is subsequently combined with emulsion to produce emulgel.[10]

PHYSIOLOGICAL FACTORS

Lipid Content: Skin is an important water barrier; when the lipid weight in the stratum corneum of skin is minimal, percutaneous penetration increases.

Skin Thickness: The thickness of the skin varies from the epidermal layer to the subcutaneous layer.

Density of Sweat Glands: The epidermal layer is thick, measuring 100–150m

Hair Follicle Density: The infundibulum of a hair follicle has ten times the storage capacity of the stratum corneum.

THE pH Of SKIN: Skin pH increases due to an increase in the secretion of fatty acids and sweat at the surface of the skin.

Skin Permeation: As the temperature increases, the rate of skin permeation increases.

Skin Inflammation: As the stratum corneum is disrupted, the permeability increases.[11,12]

MEDICINAL APPLICATIONS OF EMULGELS

- Emulgels are used for topical delivery of drugs includes analgesics, anti-inflammatory, anti-fungal and anti-acne drugs.
- They show generally favorable formulation of hydrophobic drugs over gel formulation
- It shows control and better release of drugs incorporated in gel base to obtain gel filled emulsions.
- Emulgels have certain advantageous over gels and gels with thixotropic, highly spreadable, easily removable and greaseless emollient.

PLANT PROFILE

Hibiscus Sabdariffa

Roselle (Hibiscus sabdariffa) it is called roselle ‘hemp’ rosella and java jute Hibiscus sabdariffa L. family Malvaceae (HS) is a perennial herbaceous shrub grown widely in India, west and east Africa. It is now widely grown in both tropical and subtropical countries for its leaf, fleshy calyx, seed and Fiber. It is an annual, perennial herb or woody sub shrub meant for delicacy and medicinal properties. Tender young leaves, stems, roots and flowers having wide therapeutic applications as anti-inflammatory agent, antiseptic, antiscorbutic, astringent, antioxidant and anti-microbial properties. This plant has huge Phyto constituents such as alkaloids, terpenoids, flavonoids, phenolic compounds.[13,14]

Table 1: Taxonomical Description of *Hibiscus Sabdariffa.*[15]

Kingdom	Plantae
Phylum	Magnoliophyte
Class	Magnoliopsida
Order	Malvales
Family	Malvaceae
Genus	Hibiscus.L
Species	sabdariffa
Botanical name	*Hibiscus sabdariffa*

MATERIALS

Sodium CMC, liquid paraffin, beeswax, sodium alginate, propylene glycol, triethanolamine, methyl paraben.

PLANT MATERIAL AND PREPARATION OF EXTRACT

Hibiscus sabdariffa was purchased from local market and dried in the shade for 4 days and authenticated from botanical survey of India, Deccan regional center.

Dried portions of plant were powdered and weighed. 80 grams of powdered plant is extracted with 70% ethanol with ratio of 1:5 and the container with its contents were sealed in tight container with occasional shaking for 24 hrs. and further it was filtered and collected filtrate is evaporated and residue is collected.

PHYTO CHEMICAL ANALYSISFLAVANOIDS

Shinoda test: To the extract solution 1ml, 5ml of alcohol and few drops of HCL added and 1pinch of Mg turnings results in light pink color indicates presence of flavonoids.

SAPONINS

Foam test: Dilute 1ml of alcoholic extracts with distilled water to 20ml and shake in graduated cylinder for 15 min once foam is formed indicates presence of saponins.

TANNINS

Gelation test: To the 1ml of extract add 10% of gelatin indicates the formation of gelatin precipitate at the bottom indicates the presence of tannins.

GLYCOSIDES

NAOH Test: To the 1ml of extract 1ml of distilled water is added, add 3 drops of NAOH after heat it for 2min slight yellow ppt formation indicates presence of glycosides.

CARBOHYDRATES

Molisch test: To 1ml of extract add 2 drops of Molisch reagent and 2ml of violet ring formed indicates presence of carbohydrates.

ALKALIODS

Tannic acid test: To 1ml of extract add few drops of tannic acid allow it for heat then yellowppt is formed.

FORMULATION DEVELOPMENT

Preparation of Plant Extract

The obtained extract (1gm) is dissolved in 95% ethanol(2ml) with continuous stirring.

Formulation of Gel Base

- To create the gel bases, sodium CMC and sodium alginate were uniformly dispersed using a magnetic stirrer in the necessary hot purified water (800C) at varying concentrations (1%, 1.5%, and 2% w/v). Subsequently, triethanolamine (TEA) was added and the PH was continuously stirred.
- The plant extract is added to gel which ithad prepared previously and whole was adjustedto 50gm by using purified water.

PREPARATION OF EMULSION

- Bees wax was dissolved in liquid paraffin to create the oil phase of the emulsion, and Tween 80 was dissolved in purified water to create the aqueous phase. Propylene glycol was used to dissolve methyl paraben, and both solutions were combined to create the aforementioned aqueous phase.
- The oil and aqueous phases were heated independently to temperatures between 700 and 800 degrees Celsius. Then, the oily phase was introduced to the aqueous phase and continuously stirred with a magnetic stirrer until the mixture cooled to room temperature.

FORMULATION OF EMULGEL

The prepared emulsion was mixed to the gel base of sodium CMC and sodium alginate of different concentrations (1%, 1.5%, 2% w/v) in 1:1 ratio with gentle stirring to obtain emulgel.

DIFFERENT FORMULATIONS OF EMULGEL

Table 2: Composition of Herbal Emulgel Formulation Containing *Hibiscus Sabdariffa* Root Extract.

INGREDIENTS	FORMULATION					
	F1	F2	F3	F4	F5	F6
Plant extract	1gm	1gm	1gm	1gm	1gm	1gm
Sodium CMC	1%	1.5%	2%	-	-	-
Sodium alginate	-	-	-	1%	1.5%	2%
Beeswax	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm
Tween 80	1.5ml	1.5ml	1.5ml	1.5ml	1.5ml	1.5ml
Liquid paraffin	3ml	3ml	3ml	3ml	3ml	3ml
Propylene glycol	2ml	2ml	2ml	2ml	2ml	2ml
Methyl paraben	1ml	1ml	1ml	1ml	1ml	1ml
Ethanol	2ml	2ml	2ml	2ml	2ml	2ml
Water	q.s	q.s	q.s	q.s	q.s	q.s

EVALUATION OF PLANT EXTRACT

The obtained plant extract undergoes various physico chemical tests to identify color, odor, solubility and p^H

EVALUATION OF EMULSION TYPE OF EMULSION

Little amount of water is mixed with emulsion. If water distributes uniformly, it is O/W type of emulsion and if water separates out as layer than it is W/O type of emulsion.

EVALUATION OF *HIBISCUS SABDARIFFA* EMULGELPHYSICAL APPEARANCE

All the formulations were evaluated for their color, appearance, and homogeneity etc. color was noted by visual observation. Homogeneity of emulgel was checked by rubbing between fingers. The appearance of emulgel was checked by visual observation. Emulgel was applied on the skin to check its consistency.

SPREADABILITY

The term "spreadability" refers to the region that the emulgel easily covers when applied to the skin or the affected portion. The spreading value of an emulgel formulation also affects its bioavailability efficiency. Standard-sized glass slides were taken in two sets. Over one of the slides was the formulation for the herbal emulgel. The emulgel was sandwiched between the two slides in an area that took up 7.5 cm along the slide when the second slide was positioned on top of it. To create a thin layer of emulgel between the two slides, a 100g weight was positioned on top of the slides.

After removing the weight, the extra emulgel that had stuck to the slides was scraped off. The top slide was the only one that could slip off freely due to the weight attached to it because the other two slides were securely fastened to a platform without any agitation. A 10-gram weight was cautiously fastened to the upper slide. It was recorded how long it took the upper slide to move 6.8 cm and split off from the lower slide as a result of the weight. Three repetitions of the experiment were conducted, and the mean time was recorded for computation.

Spreadability was determined using the following formula: S= M.L/T.

VISCOSITY

The viscosity of emulgel was estimated using Brookfield viscometer. 1gm of emulgel sample was taken. The spindle was rotated at the speed of 50 rpm. Readings were obtained three timesand the average of the three readings was calculated.

P^H

Evaluation of pH is a crucial factor, particularly for topical formulations. To match the skin's pH, the emulgel's should be between 5-7. Patient discomfort may result from an acidic or basic pH in the manufactured emulgel. A digital pH meter was used to measure the emulgel's pH. After dissolving 1g of gel in 100ml of distilled water, the mixture was left for 2 hours. Afterwards, the glass electrode was dipped into an emulgel. Each formulation's pH was measured three times, and the average results were determined.

SKIN IRRITATION TEST

Sample application was done on the left dorsal surface of human participants, marking an area of one square centimeter, and time was recorded. After a 24-hour observation, the erythema, edema, and irritation were recorded.

ANTI-MICROBIAL STUDY

Bacterial strains selected for susceptibility Assay: Gram-positive Staphylococcus aureus and gram-negative Pseudomonas aeruginosa were the two microorganisms that were chosen for the current investigation. The bacteria cultures were kept at 37°C in nutrient agar slants. Before doing a sensitivity test, each bacteria was individually reenergized by being placed in a differenttest tube with nutrient broth and kept heated at 37°C for the entire night.

ANTI -BACTERIAL TEST

The best-proven formulation's antibacterial properties were investigated using the conventional agar well diffusion assay. Agar (nutrient agar medium for Pseudomonas aeruginosa and nutritional agar for Staphylococcus aureus) was used to produce Petri dishes, which were thenseeded with a bacterial strain inoculum. After allowing the media to solidify, distinct petri dishes were labeled for every type of bacteria. Using a sterile

cup-borer, 6mm wide holes were scratched in firm agar medium. After adding a little amount of the formulation to each well, the plates were incubated for 24 hours at 37°C. We assessed the zone of inhibition.

RESULTS AND DISCUSSION

The plant extract which was obtained undergoes various preformulating studies those are as follows:

Table 2: Physico Chemical Test of *H. SABDARIFFA EXTRACT.*

S.NO	PARAMETER	OBSERVATION
1	Colour	brown
2	Odour	Characteristic
3	Taste	Characteristic
4	Solubility	Water and alcohol
5	pH	6.5-7

Phyto Chemical Screening of Plant Extract

The ethanolic extract of Hibiscius sabdariffa demonstrates the presence of tannins, alkaloids, and flavonoids. The resulting extract was then taken through a series of phytochemical analyses to determine the presence of alkaloids, tannins, flavonoids, and other phenolic compounds forgood anti-bacterial action.

Table 3: Phytochemical Screening of *H. Sabdariffa* Extract.

Test	Ethanolic Extract	Observation
Alkaloids	(+) tannic acid test	Yellow ppt is formed
Tannins	(+) gelatin test	Gelatin ppt is formed
Flavonoids	(+) Shinoda test	Light pink formed
Carbohydrates	(+) Molisch test	Violet ring is formed
Saponins	(+) froth test	Froth is formed
Glycosides	(+) NoaH test	Yellow ppt is formed

(+) ve indicates presence of Phyto constituents

EVALUATION OF EMULSION

No phase separation was seen for any of the formulation and when a little drop of water is added to the emulsion water is uniformly distributed.

Table 4: Determination of Type of Emulsion.

Formulation	F1	F2	F3	F4	F5	F6
Emulsion type	o/w	o/w	o/w	o/w	o/w	o/w

EVALUATION OF EMULGEL

All the formulations were evaluated for color, consistency, homogeneity, greasiness, appearance and washability. All the formulations were shown slight yellow creamy color. All formulations are shown good homogeneity and consistency where F2, F5, F6 are shown very good consistency and homogeneity.

Table 5: Characterisation of *H. SABDARIFFA* Emulgel Formulations.

Characterisation	F1	F2	F3	F4	F5	F6
Color	creamy	creamy	creamy	creamy	creamy	Creamy
Appearance	Semi-solid	Semi-solid	Semi-solid	Semi-solid	Semi-solid	Semi-solid
Consistency	Good	Very good	Good	Good	Good	Very good
Homogeneity	good	Very good	good	good	good	Very good
Greasiness	Non greasy	Non greasy	Non greasy	Non greasy	Non greasy	Non greasy
Washability	Washable	Washable	Washable	washable	washable	washable

DETERMINATION OF P^H AND SPREADABILITY

The spreadability and pH of each formulation were examined. All formulations were found tohave pH values between 6.56 and 6.85; those that did not fall within this range were corrected with triethanolamine to bring them back into the intended range. The spreadability of an emulgel reveals how much of it will spread when applied to skin. Better spreadability is indicated by a shorter spread time. All of the formulations fell within the 6.40cm–6.85cm spreadability range. F2 had a pH of 6.85 and a spreadability of 6.74cm, whileF5 had a pH of 6.80 and a spreadability of 6.70cm.

Table 6: Determination of P^h and Spreadability.

Formulations	F1	F2	F3	F4	F5	F6	Onabet
P^H	6.78	6.85	6.62	6.70	6.80	6.56	6.90
Spreadability	6.85cm	6.74cm	6.50cm	6.90cm	6.70cm	6.40cm	6.76cm

DETERMINATION OF VISCOSITY AND SKIN IRRITATION TEST

Viscosity is a crucial metric to assess because it primarily determines the uniformity of dose forms and the release of medication content. The viscosities of each formulation were measured at 50 rpm using a Brookfield viscometer. The values are listed in the table. The F3& F6 formulation (12500 cp) was the most viscous. The high gelling agent level is to blame for this. The key to verifying topical treatments' safety is that when administered topically, they must not result in contact dermatitis. Patch tests were carried out in order to achieve this (Khan et al., 2016). Edema and erythema were checked in the skin areas that were applied to. On the applied locations, there was no evidence of erythema or edema.

Table 7: Determination of Viscosity and Skin Irritation Test.

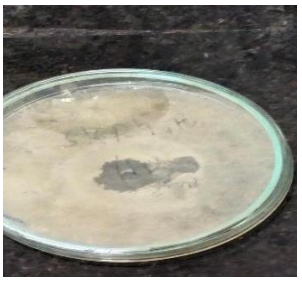
Formulations	F1	F2	F3	F4	F5	F6	Onabet
Viscosity	1800cp	1850cp	1985cp	1750cp	1820cp	1957cp	1875cp
Skin Irritationtest	Nill	Nill	Nill	Nill	Nill	Slight irritation	Nill

ANTI BACTERIAL ACTIVITY

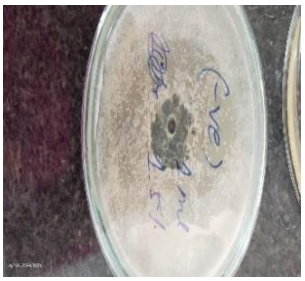
The Agar well-diffusion method was employed to look into the H. sabdariffa emulgels' antibacterial activity. Nutrient agar was the media employed. For antimicrobial investigations, the primary bacteria responsible for oral health issues have been identified as Gram-positive (S. aureus) and Gram-negative (P. aerogenosa) pathogens. Table 6 compares the antibacterial properties of hibiscus sabdariffa emulgel formulations with the commercial formulation (onabet emulgel) against several types of bacteria, including S. aureus and P. aeruginosa. It was shown that F2 and F5 had strong antibacterial activity.

F2gram+ve

F2 Gram-ve



F4gram +ve



F4 gram -ve

Standard (Marketed Emulgel)

Table 8: Determination of Anti-Bacterial Activity.

Formulations	F1	F2	F3	F4	F5	F6	onabet
Staphylococcusaureus	28.4mm	37mm	20.4mm	29mm	36.4mm	No activity	38.4mm
Pseudomonasaeriginosa	26.4mm	34.4mm	No activity	26.2mm	24.4mm	No activity	35.2mm

CONCLUSION

Herbal emulgels are also exhibiting increased activity, making emulgels a promising topical drug delivery method. These are applied to infections that are localized. Many plants are capable of exhibiting stronger antibacterial activity. One of the plants with stronger antibacterial properties is Hibiscus sabdariffa. The plant is more dispersible since it is water soluble.

An attempt was made to create a topical emulgel using Hibiscus sabdariffa extract. Sodium alginate and sodium CMC were used in six different concentrations to generate the formulations (F1, F2, F3, F4, F5, F6). Formulated emulgels were assessed based on a numberof factors. Every formulation has a creamy yellow color and a nice uniformity and look.

None of the formulations caused skin irritation. Every formulation was nearly neutral and fell within a pH range that is good for skin. 6.5-7. The spreadability of F2 and F4 was determined to be the highest. Additionally, the growth of bacteria is inhibited by F2 and F4. chosen for the test. Finally, it was determined that F2 and F4 were superior than the rest.

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