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Research Article

Formulation And Evaluation of Emulgel from Pongamia Oil

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ABSTRACT

Topical administration of therapeutic agents offers numerous advantages over oral and intravenous methods, allowing for targeted drug delivery to specific anatomical sites within the body. Emulgel, innovative dual-controlled release systems formed by blending emulsions and gels, represent a promising approach in topical drug delivery. Emulsions, such as oil-in-water and water-in-oil formulations, and gels each possess unique properties conducive to drug delivery. Emulgel combine the benefits of both, providing enhanced skin permeation, easy removal, and adjustable viscosity and appearance. Incorporating hydrophobic drugs, Emulgel offer advantages in dermatology, including compatibility with various excipients, cost-effectiveness, and improved patient acceptability. Pongamia pinnata, commonly known as the Pongam tree, is a versatile plant with significant medicinal properties. Found abundantly in India and other regions, its various parts have been utilized in traditional medicine for treating diverse ailments such as cancer, skin disorders, and diarrhoea. Phytochemical analysis reveals the presence of several bioactive compounds, including flavonoids and fatty acids. Pharmacological studies demonstrate its anti-inflammatory, anti-diarrheal, anti-plasmodial, and antioxidant activities, indicating its potential in therapeutic applications. A novel Emulgel formulation containing karanjin was prepared using a method involving the dispersion of polymers in water, adjustment of pH, and the creation of aqueous and oil phases, followed by blending and evaluation. Evaluation parameters included patch tests for sensitivity, viscosity analysis, Spreadability assessment, pH testing, and inspection of physical appearance. The results demonstrate the feasibility and potential of the Emulgel formulation for topical drug delivery, offering enhanced properties.


INTRODUCTION

The topical administration of therapeutic agents confers numerous advantages over oral and

intravenous administration modalities. This method encompasses not only the direct application of drugs onto the skin but also

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facilitates targeted drug delivery to various anatomical sites within the body via ophthalmic, rectal, and vaginal routes. Its utilization extends across a wide array of formulations, encompassing both cosmetic and dermatological applications,

catering to the needs of healthy and diseased skin alike.^[1] A drug carrier system is defined as a platform with the capacity to encapsulate a precise quantity of molecules.

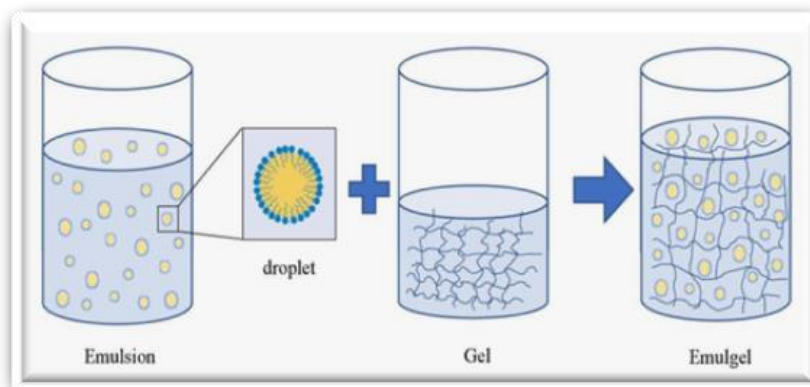


Figure 1. Emulgel and It's preparation

There by augmenting their selectivity, bioavailability, and efficacy. The efficacy of drug delivery via a carrier system relies heavily on the presence of a robust protective barrier. This barrier plays a crucial role in impeding mass transfer and diffusion from the inner core to the surrounding environment. Furthermore, the physicochemical properties of the carrier's bulk phase, which may consist of aqueous or gel matrices, or even mimic blood-like media, significantly contribute to its overall performance.^[2] Emulgels represent innovative drug delivery systems formed by blending emulsions and gels, thereby exhibiting properties characteristic of both. As a result, emulgels manifest as dual-controlled release systems endowed with multiple desirable attributes, alongside garnering high patient acceptability.^[3]

Pongamia pinnata:

The "Pongam tree," scientifically referred to as "Pongamia pinnata," is recognized as one of the most abundant and luminous trees in India. Its nomenclature, "Pongamia," originates from the Tamil term "pinnata," denoting "pinnate leaves." This tree belongs to the family "Fabaceae," with its subfamily identified as "Papilionoideae." In

Tamil, it is commonly known as "Ponga," "Dalkaramacha," "Pongam," and "Punku." In Hindi and Bengali, it is referred to as "Karanj," "Papar," or "Kanji." In English, it is dubbed the "Karum Tree" or "Poonga Oil Tree." Originating from the Indo-Malaysian region, it is a medium-sized tree thriving in alluvial and coastal regions from India to Fiji, reaching altitudes of up to 1200 m above sea level. Presently, it is distributed across Australia, Florida, Hawaii, India, Malaysia, Oceania, the Philippines, and Seychelles.^[4] Historically, aquamarine has been employed as a medicinal herb within folk medicine traditions, notably in the Ayurvedic and Siddha systems of Indian medicine.^[5] All components of the plant are utilized for their therapeutic effects against various ailments such as cancer, hemorrhoids, skin disorders, pruritus, abscesses, rheumatic conditions, wounds, ulcers, diarrhea, among others. It is employed as a raw material in the treatment of various diseases.^[6]

Geographical Distribution: It exhibits a wide distribution across Asia, including Seychelles, Southeast Asia, Australia, and India, particularly along the Maharashtra river. It is prolific in

intertidal and coastal forests adjacent to the Konkan coast, as well as along the Deccan River.

Table 1. Taxonomical Classification ^[7]

Kingdom	Plantae
Subkingdom	Tracheobionta
Division	Magnoliophyta
Superdivision	Spermatophyta

Superdivision	Magnoliopsida
Family	Fabaceae
Order	Order Fabales
Genus	Pongamia
Species	Pinnata



Figure 2: The Pongam Tree

Phytochemistry:

The proportions of saturated and unsaturated fatty acids, including two monoenoic acids, one dienoic acid, and two trienoic acids, are consistent. Oleic acid exhibits the highest content at 41.44%, followed by stearic acid and palmitic acid. From the seeds, karangin, pongamol, pongagalabrone, pongapin, pinnatin, and kanjone have been isolated. Immature seeds contain a flavone derivative named ‘pongol’. Other flavonoids isolated from the seeds include glabrachalcone and isopongachromene. The leaves and stems of the plant harbor various flavonoids and chalcone

derivatives, such as pongone, galbone, pongalabol, pongagallone A and B. Chemical investigations on the stems of the mangrove plant *Pongamia pinnata* have led to the isolation and characterization of five structurally distinct flavonoids. The structures of these metabolites were determined through spectral analysis and comparison with literature-reported compounds. Pongamones A-E were evaluated in vitro against DHBV RC DNAP and HIV-1 RT, and potential biogenesis pathways for drug isolation have also been proposed. ^[8]

MATERIALS AND METHODOLOGY:

Table 2: Materials used in formulation

Sr. No.	Name	Used As
1.	Carbopol934	Gelling Agent
2.	Triethylamine, Triethanolamine	Buffer
3.	Liquidparaffin	Emulsifierstabilizer
4.	Ethanol	Emulsifier
5.	Tween20	HydrophilicPhase
6.	Span20	LipophilicPhase

Table 3: Instruments used in formulation

Sr. No.	Instrumentation & Equipments	Make
1	Digital Balance	Modelno.91499IND/09/08/499PGB600
2	Heating Mantle	Modelno.BTI-19BIOTECHNICSINDIA
3	Magnetic Stirrer	Modelno.EQ-771
4	Mechanical Stirrer	National scientifically apparatus works
5	pH Meter	Systronics
6	Homogenizers	Remi

METHODOLOGY:**1. Aqueous Material:**

This forms the aqueous phase of the emulsion. Sometimes instead of water as vehicle, alcohols can also be used.

2. Oils:

This constitutes the oil phase of the emulsion. They may also act as permeation enhancers

3. Emulsifiers:

Emulsifying agents are used both to promote emulsification at the time of manufacture and to control stability during a shelf life; that can vary from days for extemporaneously prepared

emulsions to months or years for commercial preparations.

4. Gelling Agent:

These are the agents used to increase the consistency of any dosage form can also be used as thickening agent.

5. Co-surfactants:

In most cases, single-chain surfactants alone are unable to reduce the o/w interfacial tension sufficiently. Therefore, to enable an emulsification co-surfactant is used.

6. Preservative:

Part of formulation in order to prevent the growth of microorganisms in formulation.^[9]

Table 4: Formulation optimization Batches^[16]

Ingredients	F1	F2	F3	F4*
Pongamia pinnata seed oil	20ml	20ml	10ml	10ml
Carbopol934	1g	0.5	1g	0.5
Triethylamine	5ml	5ml	-	-
Triethanolamine	-	-	5ml	5ml
Liquid paraffin	5ml	5ml	5ml	5ml
Tween20	2.5ml	2.5ml	2.5ml	2.5ml
Span20	1.5ml	1.5ml	1.5ml	1.5ml
Ethanol	2.5ml	2.5ml	2.5ml	2.5ml
Distilled Water	Q.S.	Q.S.	Q.S.	Q.S.

[Note: Above Formulation (*) was selected on basis of Evaluation parameter discussed below.]

Procedure*:

To prepare the gel, various concentrations of polymers were dispersed individually in distilled water with continuous stirring at a moderate speed using a mechanical shaker. The pH of each formulation was then adjusted to from range 6 to 7



using triethanolamine (TEA). Specifically, for our project, to prepare gel phase we

utilized 0.5g of Carbopol 934 and dissolved it in 60ml of distilled water.



Figure 3. Gel formation

To prepare the emulsion, first, the aqueous phase was created by dissolving 2.5ml of Tween 80 in 47.5ml of purified water. Subsequently, a mixture of 2.5ml of ethanol for every 10 ml of seed oil (the main chemical constituent) was prepared. This



Figure 4. pH balanced

seed oil and ethanol mixture was then dissolved into the aqueous phase with continuous stirring, and the whole mixture is going to be used as Aqueous Phase for further experiment.



Figure 5. Aqueous Phase

Following that, the oil phase was prepared by dissolving 1.5 ml of Span 80 in 5 ml of liquid paraffin. The oil phase was then added drop wise into the aqueous phase while maintaining a constant temperature of 70°C and a stirring speed of 500rpm for at least 30minutes using a Hot Plate

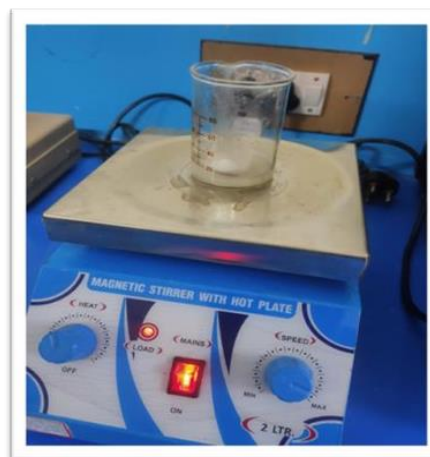


Figure 6. Oil Phase

magnetic stirrer, or at 3000 rpm for 15minutes using a Homogenizer.

Preparation of Emulgel: The emulsion obtained was blended with the gel under continuous stirring to produce the Emulgel.



Figure 7: Emulsion and Gel

[Note: It is essential to ensure that both the oil phase and the aqueous phase are maintained at a temperature of 70°C throughout the mixing process.]

Evaluation Parameters

Patch Test/Sensitivity Test:

For the patch test, three human volunteers were chosen. A formulation of 1g was applied to the fore arms of the volunteers in the form of a bandage disc and covered with surgical dressing. After 24 hours, the patches were removed, and the areas were rinsed with saline solution. The volunteers were questioned regarding any irritation, and the application sites were examined for the presence or absence of edema and erythema (redness of the skin).^[10]

Gel Viscosity Analysis:

The viscosities of the gels were assessed using the Brookfield Viscometer RV. Measurements were conducted at a temperature of 25°C.^[11]

Spreadability:

Spreadability was assessed using a spreadability apparatus comprising two slides. One slide was firmly fixed in a wooden frame, while the other slide could glide over the surface of the fixed one. An excess of gel was placed between the two

slides, and a 1kg weight was applied to the slide for 5 minutes to form a uniform gel film and expel air between the slides. Careful removal of excess gel from the slide edges ensued. The bottom slide was anchored properly, and the top slide was subjected to an 80g weight pull. The time (20 in seconds) taken by the top slide to cover a distance of 7.5cm was recorded. A shorter interval indicates better spreadability. Spreadability was then calculated using the formula: $S = M \times L / T$, where S represents spreadability, M stands for the weight in the pan (tied to the upper slide), L indicates the length moved by the glass slide, and T denotes the time taken to completely separate the slide.^[12]

pH Testing:

A precise weight of 2.5g of gel was dispersed in 25ml of distilled water. The pH of the resulting dispersion was measured using a digital pH meter.^[13]



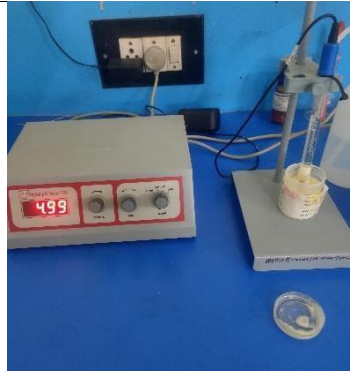

Physical Appearance:

The prepared Emulgel formulation in fused with Pongamia pinnata seed oil underwent inspection for its physical appearance, including color, consistency, and homogeneity.^[14]

RESULTS & DISCUSSION

Table 5 Observation for all accepted and rejected batches

S.N.	Formulations	Observation	Appearance
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1.	1	This batch of formulation is rejected due to gel coagulation and clot formation	 <p>Figure. 8 Rejected</p>
2.	F2	This batch of formulation is rejected due to Phase separation	 <p>Figure. 9 Rejected</p>
3.	F3	This batch of formulation is rejected due to imbalance in pH	 <p>Figure. 10: Rejected</p>
4.	F4*	The following batch accepted due to it passes through all evaluation parameters.	 <p>Figure.11: Accepted</p>

Based on the evaluation criteria, Batch F4 has been approved as it meets the required standards and

demonstrates satisfactory performance compared to other batches (F1,F2, and F3). All the

observation data for physical and chemical evaluations of F4 batch of Emulgel is presented as follows:*

Table 6. Comparison of evaluation parameters for prepared formulation and marketed formulation.^[15]

Sr. No.	Batch	Results(F4*)	Specifications [44][45]
1.	Washability	✓✓	✓✓
2.	Ph	6.54	6 to 7
3.	Spreadability [GCM/SEC]	30	25.00–31.82
4.	Viscosity[cps]	4582	4600
5.	Appearance of Emulgel	Yellowish white, viscous, And creamy.	Yellowish white Viscous creamy
6.	Odour	Characteristic	Characteristic
7.	Irritancy	No	No
8.	Texture	Smooth	Smooth

Washability: All batches (F1, F2, F3, and F4) exhibit excellent washability, denoted by the presence of double checkmarks (✓✓). This indicates that the Emulgel formulations can be easily removed from the skin upon washing.

pH: Batch F4 has a pH of 6.54, which falls within the acceptable range alongside batches F1, F2, and F3. The pH level is crucial for ensuring compatibility with the skin and maintaining optimal conditions for drug delivery.

Spreadability: While batch F4 has a spreadability value of 8.2gcm/sec, which is slightly lower compared to other batches, it still meets the required standard for ease of application and uniform coverage.

Viscosity: Batch F4 exhibits a viscosity of 4582 cps, which is within the acceptable range alongside other batches (F1, F2, and F3). This indicates the appropriate consistency of the Emulgel formulation.

Appearance of Karanjin Oil: The karanjin oil in all batches appears as clear-brownish red transparent liquid, indicating consistency in the quality of the oil used across formulations.

Appearance of Emulgel: Batch F4 displays a yellowish-white, viscous, and creamy appearance,

which is consistent with the desired characteristics of the Emulgel formulation.

Odor: The characteristic odor is observed in all batches, including batch F4, indicating the presence of the intended ingredients without any undesirable smell.

CONCLUSION

In conclusion, topical drug administration offers a versatile approach with advantages over oral and intravenous methods, enabling targeted delivery to specific anatomical sites. Emulgel, combining properties of both emulsions and gels, present innovative dual-controlled release systems with high patient acceptability. Emulsions and gels individually offer unique advantages in drug delivery, including skin permeation, easy removal, and adjustable viscosity. The combination of these systems in Emulgel enhances their utility in dermatology, catering to various skin conditions with improved efficacy and patient compliance. Pongamia pinnata, a versatile medicinal plant abundant in India and other regions, holds promise for therapeutic applications due to its diverse pharmacological activities. With its anti-inflammatory, anti-diarrheal, anti-plasmodial, antioxidant, and anti-hyperammonaemia properties, P. pinnata presents a valuable resource

for drug development. Phytochemical analysis reveals the presence of bioactive compounds, further supporting its medicinal potential. The development of novel formulations such as Emulgel incorporating *P. pinnata* extracts signifies a step forward in harnessing the plant's therapeutic benefits for dermatological applications. The preparation and evaluation of Emulgel involve meticulous procedures ensuring safety, efficacy, and stability. Evaluation parameters such as patch tests, viscosity analysis, Spreadability assessment, stability testing, pH testing, and inspection of physical appearance provide comprehensive insights into formulation characteristics. The successful formulation and evaluation of Emulgel containing *P. pinnata* extracts underscore their potential as effective topical drug delivery systems. Future research should focus on optimizing formulations, exploring additional pharmacological activities, and conducting clinical trials to validate their therapeutic efficacy in dermatological disorders. Overall, the integration of traditional medicinal plants like *P. pinnata* into modern drug delivery systems holds promise for advancing dermatological therapy and addressing unmet medical needs.

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