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Thermoresponsive In-Situ Gel for Scalp Drug Delivery: An Overview of Natural Polymer- Based Approaches

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Abstract: Thermoresponsive in-situ gels are a way to get medicine to the scalp. This is especially important for conditions like seborrheic dermatitis and dandruff. These conditions need medicine to stay on the scalp for a time to work well. Conventional topical formulations of ketoconazole do not stay on the scalp for long. They need to be applied, and people do not always use them as they should. Natural polymer-based systems are an alternative. They are safe and good for the environment. This review is about in-situ gel systems. It focuses on systems that use okra mucilage as a polymeric matrix. Okra mucilage is good for making gels because it swells well and is sticky. When okra mucilage is combined with poloxamer 407 and hydroxypropyl methylcellulose it makes a gel. Poloxamer 407 changes from a liquid to a gel at body temperature. The cold method is used to make poloxamer-based formulations. This method helps keep the polymer intact and makes sure the medicine is spread evenly. This review talks about how thermoresponsive in-situ gels work. It discusses the properties of gels. How they are made. Thermoresponsive, in-situ gels are a way to deliver medicine to the scalp. They help the medicine stay on the scalp and do not let it get into the rest of the body. Overall natural polymer-based thermogelling systems are a way to deliver medicine to the scalp. They are easy to use and work well.

Keywords: Thermoresponsive in-situ gel; Scalp drug delivery; Ketoconazole; Okra mucilage; Poloxamer 407

1. INTRODUCTION

Scalp disorders, such as dandruff and seborrheic dermatitis, are often associated with chronic illness caused by the overgrowth of *Malassezia* species or by altered sebaceous gland activity [21], [23]. The broad-spectrum antifungal activity of ketoconazole, a derivative of imidazoles, makes it primarily effective against dermatophytes and yeasts, as well as in mitigating inflammation associated with fungal colonization [25], [4]. Nevertheless, conventional topical preparations such as shampoos and creams tend to show limited time contact with the scalp surface, which in turn leads to reduced drug retention and less need for repeated use [15], [41]. Increasing interest in site-specific and retention-enhancing drug delivery systems for scalp therapy has been spurred by these limitations [14], [41].

Recently, in-situ gel systems that are thermoresponsive and can deliver drugs through topical or localized applications have received more attention [7], [36]. By forming low-viscosity liquids at room temperature and transitioning to sol-gel solutions at physiological temperature, the systems have been developed for increased residence time at the application site [37], [10]. Poloxamer 407, a thermosensitive polymer, has been extensively studied for its ability to undergo thermal gelation by micellar aggregation and packing at high temperatures [38], [17]. Additional polymers, such as HPMC, are commonly used in

the formulation matrix to enhance viscosity, mechanical strength, and drug release properties [18], [10]. Other known examples [31], [50].

The use of natural polymers in pharmaceutical formulations has gained popularity due to their sustainability, low toxicity, biodegradability, and biocompatibility [5], [30]. This is seen in recent years [26], [27]. A natural polymer that is rich in polysaccharides and has been shown to improve swelling, mucoadhesive behavior, and viscosity, okra mucilage can be used in both oral and controlled drug delivery systems [3], [8]. The combination of okra mucilage and thermosensitive polymers presents an attractive hybrid that enables both natural bioadhesion and temperature-triggered gelation [34], [35]. This is intriguing [36], [46].

The thermoresponsive systems are typically prepared using cold methods, particularly for poloxamer-based formulations, to ensure even distribution of polymers and prevent premature gelation during processing [1], [38].

2. LITERATURE REVIEW:

1. In 1972, Schmolka studied the impact of temperature on Poloxamer 407 and its ability to transition from a liquid to a gel when it reaches physiological temperature. This transition occurs due to the packing of molecules leading to loss of water, allowing for the possibility of using Poloxamer 407 as a means of drug delivery.
2. Ricci et al (2005) created a gel formulation containing the antifungal drug, Ketoconazole, in conjunction with Poloxamer 407. Using a modification of an existing procedure, they were able to create an effective antifungal agent, with results indicating that the Poloxamer 407 gel formulation provided prolonged retention of the active ingredient in skin, compared to conventional cream formulations.
3. Koffi et al (2015) also conducted an investigation into the mucilage obtained from *Abelmoschus esculentus* for its potential use as a vehicle for drug delivery. The researchers found that *Abelmoschus esculentus* mucilage has excellent water-holding capacity and adhesive properties, making it an effective mucilage.
4. Baloglu & coworkers did an experiment with the polymer Poloxamer 407 in 2011. They combined it with another type of polymer to see if it would create something stronger than Poloxamer 407. They learned that it created a stronger bond and was more stable than Poloxamer 407 alone. They were able to show that their combination of polymers would allow for slow release of the drug.
5. In 2013, Singh & Chauhan published an article on the use of polymers as drug delivery vehicles through topical application. They stated that biodegradable and adhesive polymers are suitable technologies to deliver drugs to the skin. They reported finding that natural materials are also effective in retaining drugs delivered via topical preparation and that they do not irritate the skin.
6. In 2014, Pandey & coworkers produced a gel containing Poloxamer 407 (a commonly used polymer for drug delivery) and Ketoconazole (an antifungal drug). They evaluated the ability of the gel to release the drug over time. Their conclusion was that this gel had a greater ability than other antifungal drug preparations for delivering the drug through the skin.
7. In 2004, Ruel-Gariépy and Leroux wrote about gelatinous substances that turn into a soluble form when heated. These materials have applications for drug delivery into the body. In their investigation, researchers discovered that gel-like substances could deliver drugs over extended periods. These gel-based systems were shown to have the greatest value for skin application and ocular (nasal or ophthalmic) drug delivery.
8. Kumar and his collaborators conducted an investigation in 2017 to evaluate whether okra mucilage is suitable for use in the development of gel formulations. They found that mucilage could thicken gels and enhance their viscosity. Mucilage may also assist in retaining drugs in the skin for prolonged periods.
9. Ibrahim and collaborators conducted an investigation in 2012 to identify the optimal transportation medium for the delivery of Ketoconazole. They found that a gel-based delivery system was more effective at transporting this drug to the upper layers of the skin than either cream or lotion. In addition, gels increased drug retention at the upper dermis for prolonged periods.
10. Sharma et al. (2019) created an experimental gel containing poloxamer 407 and polysaccharides, which were tested in vitro for their adhesive properties to skin as well as the ability to deliver medication over extended periods of time. Their results indicated that this formulation exhibited

excellent adhesive properties and provided prolonged drug release. The researchers' belief is that this type of gel would have potential applications for topical use on the skin.

3. TOPICAL DRUG DELIVERY SYSTEM:

Topical Drug Delivery Systems (TDDS) are systems that convey the drug, used for topical purposes [15], [41]. In this type of system, an active agent enters the skin, in an attempt to achieve a local effect, rather than having the active agent absorbed systemically [12], [13]. The outer layer of the skin (the stratum corneum) is the main impediment to drug or active agent delivery via the skin [11], [14]. The stratum corneum is comprised of corneocytes in a lipid matrix and primarily serves to restrict permeation through the skin of drugs/active agents that have little molecular weight and moderate lipophilicity [11], [13]. Accordingly, successful topical therapeutic efficacy is dependent upon the characteristics of both the drug and the formulation(s) used to either penetrate this barrier, or alter it, without damaging the skin [12], [41].

Delivering medication topically can be very helpful when treating skin problems [15], [41]. By applying the medicine directly onto the skin where it works best (the area that hurts) you can get as much of that medicine onto the skin as possible while minimizing how much is absorbed into the blood and causing unwanted side effects [12], [45]. Topical dosage forms include lotions, creams, ointments, gels, lotions, creams, and ointment formulations are the most common topical form available as they are convenient to use and easy to create [15], [18]. The type of vehicle used (e.g. ointment, cream) is very important because it will determine how quickly the medicine slows down to be released, how well it moistens and dries your skin, how well it will spread out, and how much your patients will like the way the medicine feels [18], [20].

The current trends in developing topical drug delivery systems center around increasing penetration efficacy, increasing residence time on the skin, and delaying drug release [41], [48]. Some examples of these advancements are the use of polymer-based gels, emulsions, liposomes, nanoemulsions, and systems that respond to certain stimuli [42], [49]. Bioadhesive polymers are being added to many formulations to provide a means for prolonged retention at the site of application, and thermoresponsive systems are capable of changing phase when exposed to body temperature thereby increasing the length of time the drug is in contact with the body [7], [36]. These types of innovations are especially pertinent with regards to treating the scalp since hair thickness and sebum production are both factors that hinder the ability of usual topical formulations to deliver drug effectively [21], [23].

Topically applied medications that use a hydrophilic vehicle help the medicine pass through the outer layer of the skin by increasing moisture within the stratum corneum, while lipophilic delivery systems allow the lipophilic vehicle components (e.g. oils) to interact with the outer layer of the skin (stratum corneum) [12], [13].

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Physicochemical characterization (pH, viscosity, spreadability), in vitro drug release evaluations, permeation tests using diffusion cells, rheological analysis, and stability testing under controlled conditions are all part of the evaluation process for topical drug delivery systems [6], [43]. Skin irritation and compatibility studies are also necessary to evaluate the safety profile of the topical drug delivery system to ensure the system is appropriate for use on a repeated basis when deemed necessary [41], [45].

In conclusion, topical drug delivery systems are a logical and patient-friendly method of treating localized skin disorders [15], [41]. Continued advances in polymer science, coupled with improvements in formulation technology, will further improve performance and result in enhanced therapeutic benefits, increased patient compliance, and increased bioavailability of drugs delivered at the site of action [34], [39].

4. IN-SITU GELLING SYSTEM:

Systems that form in situ gels are current alternatives for drug delivery and can form a gel after administration of a drug (phase change from a liquid to a gel) [7], [36]. Thermoresponsive systems are

specifically suited for use as drugs applied topically or to the scalp, as they are free-flowing liquids at room temperature so that they can be easily applied and uniformly spread, but convert to a semi-solid gel after contact with skin [10], [47]. This phase change (from sol to gel) induced by temperature aids in maintaining the gel at the site of application and reduces the amount of gel spilled or washed away (the traditional problem with topical formulations) [37], [41].

Temperature-induced changes in polymer structure and the interaction between polymers determine the thermogelling behaviour of a poloxamer-based system [38], [17]. A Mid-Temperature Effect (MTE) occurs when micelles begin to pack closely together and form gel-like structures as the temperature increases [38], [31]. The hydrophilic portion of each poloxamer will remain hydrated and in solution at colder temperatures, while the heating process will promote the physical removal of water from the hydrophobic portion of the poloxamer chain through evaporation [17], [38]. This dehydration creates a water phase surrounding the hydrophilic parts of the poloxamer which form micelles, thus producing a gel-like solution through phase separation due to temperature changes (dehybridisation) or solute-induced dehybridisation [31], [37]. Reversible thermoresponsive systems offer a unique and reliable modality of drug delivery to applications on dermal and scalp areas, where the need for localized gel formation is met without necessitating a chemical cross-linking reaction [36], [40].

One major benefit of thermoresponsive in situ gels is that they can extend the time period that drugs remain on the skin's surface [7], [47]. In the treatment of the scalp, increased hair density, sweating and sebum production can shorten the time that traditional creams or lotions are able to remain in contact with the scalp [21], [23]. A thermogelling system can overcome this problem by forming a gel matrix after application that will provide a stable environment for sustained release of the drug and, thus, enhanced efficacy of treatment [37], [50]. This is particularly true for antifungal therapies, since prolonged exposure of the fungal pathogen to the active ingredient will improve the efficacy of treatment [25], [4].

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The selection of a polymer is an extremely important factor in determining the temperature at which gelation occurs, as well as the mechanical strength, behavior of drug release, and level of comfort experienced by the patient [38], [39]. Poloxamer 407 is a common polymer used extensively because of its well-known thermoreversible properties and pleasing safety profile [38], [31]. Poloxamer 407 alone will typically have low gel strength and will erode rapidly when used without the addition of another supportive polymer such as hydroxypropyl methylcellulose (HPMC), which enhances viscosity, increases structure and stability, and modulates diffusion of the drug [18], [10]. The inclusion of natural biopolymers, including mucilages from plants, will improve bioadhesion/biocompatibility, as well as complement the current trends toward the use of sustainable/naturally derived excipients [5], [29].

The use of cold methods is typically used to create thermoresponsive in situ gels during preparation [1], [38]. In the cold preparation process, the thermogelling polymer is dissolved in a chilled aqueous medium to avoid premature gelation and allow for uniform hydration of the polymer before adding drug and other excipients under controlled temperature conditions to ensure that the mixture remains clear and stable [1], [31]. By using this method, the functional integrity of the components sensitive to temperature will remain intact and gelation characteristics can be reproduced consistently [38], [47].

Thermoresponsive hydrogels that form in situ are a combination of the ease of using a liquid pharmaceutical formulation and the retention benefits of a semi-solid internal formulation [7], [40]. Thermoresponsive hydrogels are beneficial in chronic dermatological diseases like seborrheic dermatitis, as they allow for controlled drug delivery, decreased frequency of dosing, and improved adherence to therapy by utilizing both natural polymers and known thermogelling agents [21], [22]. By combining these polymers, these systems allow for a more complete approach to localized drug therapy while providing safety and comfort for patients [39], [41].

5. DESEASE PROFILE- SEBORRHEIC DERMATITIS:

Seborrheic dermatitis is a long-lasting (chronic), recurring (relapsing) skin disorder that's characterized by red, flaky skin with greasy black patch detaches on it; itchy skin in the affected ae a; and red (irritated) skin

[21], [22]. It primarily occurs in areas that have a lot of oil-producing glands (sebaceous glands); such as your scalp, face, and the upper part of your body (trunk) [21], [24].

Seborrheic dermatitis is very common all over the world, and is likely one of the most frequently diagnosed skin conditions associated with the scalp (dandruff) and other forms of scalp inflammation [23], [24]. The initiation of seborrheic dermatitis is typically associated with some form of a skin irritant, however, it can also appear regardless of the presence of a skin irritant [22], [23]. Seborrheic dermatitis can develop at any age; however, it is generally also seen in newborns as cradle cap, and in adults when they are in their early 20's or later [21], [24].

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Although the complete pathogenesis of this condition is multifactorial, it is currently not fully learned; however, many recent studies indicate a strong link between *Malassezia* ("lipophilic" or "Oleaginous Yeast") and seborrhea, which indicates greater likelihood for development from excessive amounts of *Malassezia* being present as part of the normal skin flora of normal human beings [22], [23]. The metabolism of the triglyceride lipids can lead to the production of free fatty acids that are irritating to the skin and subsequently cause inflammatory reactions in susceptible individuals [21], [22]. Alterations in the normal activity of the sebaceous glands, abnormal barrier function of the epidermis and/or immune dysregulation in the individual may also lead to the progression of the disease process [21], [23]. There have been elevated levels of inflammatory cytokines including interleukins and TNF- α as well as other known proinflammatory mediators found in the skin lesions associated with seborrheic dermatitis [22], [23]. This has lead researchers to indicate that dysregulation of the immune system is an important feature of the disease process [22], [23].

Clinically, involvement of the scalp typically occurs as diffuse or patchy scales together with mild erythema and pruritus [21], [24]. In the case of more severe disease, crusts may form on the scalp, and secondary infections may develop [23], [24]. The disease has a chronic and recurrent nature, thus significantly diminishing the quality of life, causing discomfort, cosmetically embarrassing, and leading to psychological distress [21], [22]. There have been numerous reports of environmental factors such as stress, cold weather, and neurological disorders exacerbating symptoms [22], [23].

Management of seborrheic dermatitis consists of managing fungus growth, controlling redness/inflammation and repairing the skin barrier [21], [25]. Topical antifungals (most commonly ketoconazole) are the first line treatment to hit ergosterol right at the membrane wall of the fungus (*Malassezia*) and reduce production of that fungus [25], [4]. Patients usually require other medications for anti-inflammatory effects (and keratolytics) to manage this condition [22], [25]. Exposure to medicine through conventional dosage forms (shampoo, cream) only allows for the patient to have temporary contact with the skin; therefore, decreasing the ability of those medicines to be effective [15], [41].

Since seborrheic dermatitis is an ongoing problem requiring long-term localized delivery, cutting-edge topical delivery systems (e.g., thermoresponsive in situ gels) may provide possible benefits (e.g., increasing drug retention, providing a sustained antifungal release and increasing patient compliance) [7], [47]. Thus, a good understanding of the pathological basis of seborrheic dermatitis allows for the creation of improved scalp-targeted formulations [21], [41].

6. DRUG PROFILE-ANTIFUNGAL CATEGORY:

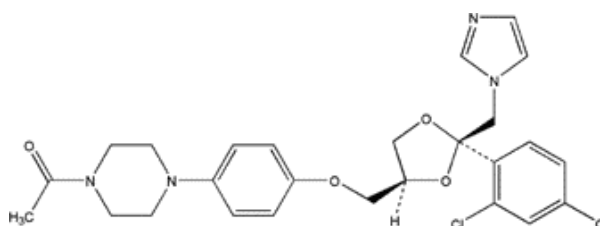
Overgrowth of *Malassezia* (also called *Pityrosporum*), a type of fungus, is responsible for the vast majority of Seborrheic Dermatitis (SebD) cases on the scalp [22], [23]. Symptoms of SebD include scaling, inflammation, flaking, and excessive itchiness [21], [24]. Conventional shampoos and lotions typically don't stay on an individual's scalp long enough to provide any kind of therapeutic effect [15], [41].

To address this challenge, researchers are examining the use of thermoresponsive in situ gel systems [7], [36]. These formulations will stay in a liquid form at room temperature; the gels will be formed upon reaching the scalp temperature [10], [47]. This change from liquid to gel will help improve drug retention and provide a sustained drug release [37], [50].

Parameter	Content
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Drug name	Ketoconazole
Category	Antifungal (Imidazole derivative)
Chemical Name	cis-1-acetyl-4-[4-[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl] methoxy] phenyl] piperazine
Molecular Formula	C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄
Mechanism of Action	Inhibits ergosterol synthesis in fungal cell membrane, causing fungal cell death
Route of Administration	Topical scalp application
Dose in Topical Formulation	Commonly 1–2% w/w
Role in Thermoresponsi ve Gel	Provides prolonged antifungal activity through sustained scalp retention

6.1 Chemical structure:



Ketoconazole has an antifungal effect, and its complex structure contains an imidazole ring, dichlorophenyl groups, a dioxolane ring, and a piperazine moiety [25], [4]. These four elements work together to have a strong antifungal effect on the *Malassezia* fungus, which is one of the causes of s Benefits of Ketoconazole in Thermosensitive in Situ Gel [25], [4].

6.2 Advantages of Ketoconazole in Thermoresponsive in Situ Gel:

- Effective in treating fungus-induced seborrheic dermatitis.
- Longer duration of therapy on the scalp.
- Decreases itching, flaking, and inflammation from the scalp.
- Improved drug delivery by continued drug release increases therapeutic effectiveness.
- Decreases need frequent applications of therapeutic shampoo versus other therapeutic methods.
- Greater convenience and adherence for patients.
- Can be used for incorporation into gels made from natural polymers. seborrheic dermatitis.

7. SMART APPROACH: THERMORESPONSIVE IN-SITU GEL FOR TARGETED MANAGEMENT OF SEBORRHEIC DERMATITIS:

Thermoreversible gel formulations that form an in-situ gel on the scalp will be an appropriate and rational solution for the management of scalp disorders like seborrheic dermatitis [7], [47]. While traditional dosage forms such as shampoos, creams or lotions are still used to treat scalp fungus, their efficacy is limited because they are only applied to the scalp for short periods of time [15], [41]. Daily activities, such as washing hair, sweating on the scalp, and having long/thick hair, can shorten the amount of time that antifungal medications remain on a patient's scalp, thereby interfering with their ability to provide complete eradication of all fungal organisms or prevent the recurrence of symptoms [21], [23]. Consequently, to obtain an adequate therapeutic response from these preparations; patients may need to utilize these products in multiple doses; this will negatively impact the patients' motivation to continue to use the products, as well as the overall success of their treatment [15], [41].

A new type of gel formulation can change from liquid to gel state by using both liquid and gel methods to deliver medication [7], [36]. The medication is applied as a low viscosity liquid, which makes it easy to distribute across the surface of the scalp and between the hair follicles [10], [47]. When the formulation reaches skin temperature, the formulation undergoes a rapid change from liquid to gel and will stay on the scalp as a gel for much longer than if it had been removed by external factors [37], [50].

By incorporating antifungal agents (for example; Ketoconazole, Imidazole, Luliconazole, clotrimazole) into thermoresponsive carriers, prolonged and localized delivery of these agents can be achieved at the infected site [25], [41]. The antifungal agent will be encapsulated in a thermoresponsive polymer gel-forming network and will be released slowly over a long time period so that adequate antifungal levels can be maintained at the infected site [37], [50]. Anti-fungal drugs have been shown to have increased effectiveness against *Malassezia* species (the causative agent of seborrheic dermatitis) when exposed to therapeutic levels for long periods [22], [25]. The polyvinyl alcohol (PVA) gel with extended periods of delivery compared to other topical therapies will provide less frequent dosing and greater therapeutic response to treatment [41], [43].

Optimizing the selection of the polymeric system, as an added bonus, yields a system that is smart [38], [39]. The thermogelling polymers, such as Poloxamer 407, are temperature-dependent gel-creating polymers [38], [31]. The viscosity enhancing polymers, like Hydroxypropyl methyl cellulose, are used to build up the strength of the gel and control drug release rates through diffusion [18], [10]. There are additional benefits to using natural polymers, such as mucilage from *Abelmoschus esculentus*, to achieve increased bioadhesive properties for an effectively biocompatible matrix that can support sustained release of the drug formulation [3], [8]. The combination of these hybrid polymer systems provides the best conditions for obtaining optimal gelation temperatures, adequate mechanical strength and prolonged retention on the scalp [34], [35].

The added benefit of this method is that it has a higher degree of patient acceptance compared to heavy creams or greasy ointments which tend to be thick and sticky [15], [20]. Thermoresponsive gels are usually clear, non-sticky, and easy to apply and their thinness allows for uniform distribution over the scalp and will not leave a greasy residue behind [10], [47]. The fact that these products are aesthetically appealing is very important for long-term dermatology care because comfort and convenience tends to have a significant influence on a patient's ability to follow through on their treatment regimen [15], [41].

The use of antifungal medications incorporated into thermoresponsive in-situ gel formulation allows for an innovative way to deliver medications to the scalp [7], [47]. Utilizing the ability of these medications to stay on the scalp longer, provide prolonged release of medication and providing increased patient compliance are just a few of the advantages that this method addresses with many issues faced today with other topical products or cosmetic formulations [37], [50]. Therefore, thermoresponsive gels provide a great opportunity to help treat seborrheic dermatitis in a more effective manner and with greater comfort to patients [21], [41].

8. ADVANTAGES OF NATURAL POLYMER – BASED THERMORESPONSIVE SYSTEMS:

1. Natural polymers are biocompatible and safe.
2. They show low irritation and reduced toxicity.
3. Due to possessing good adhesive properties, the formulation remains longer on scalp surface.
4. Sustained and controlled drug release, make the activity of anti-fungal drug for extended period.
5. Natural polymers improve the viscosity and stability of thermoresponsive gel formulation.
6. Support gradual drug diffusion because of their swelling ability which forms a hydrated gel matrix.
7. They are biodegradable and eco-friendly, thus useful for modern pharmaceutical formulations.
8. Most natural polymers are readily available and at a low cost compared to synthetic polymers.
9. When combined with thermogelling polymers, they can improve gel strength and scalp retention of the formulation.
10. They can improve patient compliance and act as efficient topical drug delivery system.

9. PLAN OF WORK:

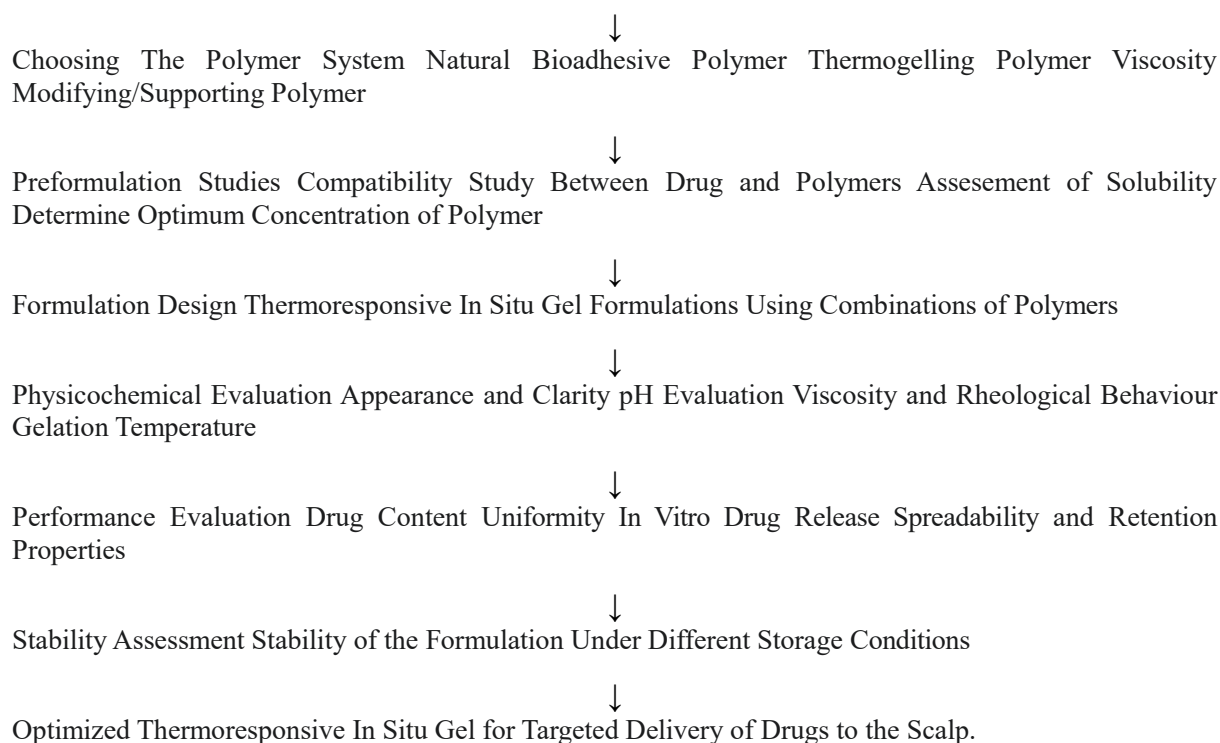
Identification of Need for Treatment Due to Fungal Conditions of the Scalp



Selecting The Appropriate Class of Drugs Topical Antifungal Agents



Selecting An Appropriate Delivery Method Thermoresponsive In Situ Gel System for Scalp Application



10. CONCLUSION:

The use of thermoresponsive in-situ gel systems in treating scalp conditions like seborrheic dermatitis provides a new way to increase the effectiveness of topical drug delivery. Traditional products such as shampoos, creams, and lotions have limited contact time with the scalp and so may not be very effective therapeutically. However, the thermoresponsive gel systems start off as liquids when applied to the scalp but convert to gels once they reach body temperature, allowing for improved retention at the site of application and an increase in the duration of drug activity at that site.

The effectiveness of a system is further enhanced by combining a natural polymer and a thermogel polymer to create a more effective bioadhesive system, increase compatibility with parts of the body (bio), and extend the time that the medicine will remain at an effective concentration on the scalp during antifungal treatment by enhancing and controlling the rate at which the drug is released after it is applied. In general, natural polymer-based thermoresponsive in situ gels are a more efficient and patient-friendly alternative to traditional topical formulations. Continued research and optimization of this delivery system appears to have significant capacity for improving the results of treatment for seborrheic dermatitis and other scalp conditions related to that disease, on the scalp or other target area of use.

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