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Review Article

Design And Characterization Of In Situ Gel Formulations

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ABSTRACT

The development of in situ gel formulations has gained prominence in pharmaceutical science due to their potential benefits in drug delivery and patient compliance. These formulations, which transition from a liquid to a gel or semi-solid state upon administration, offer enhanced bioavailability and controlled release profiles. This review examines the key aspects of designing in situ oral syrup formulations, including the selection of appropriate gelling agents, characterization techniques, and recent advancements in the field.

INTRODUCTION

In situ gel formulations represent a significant innovation in drug delivery systems. Unlike conventional syrups, which remain in liquid form until they are consumed, in situ gel are designed to undergo a gelation process once ingested. This transition is triggered by physiological conditions such as pH, temperature, or the presence of specific ions. The primary advantages of these systems include improved bioavailability, enhanced stability, and prolonged drug release [1]. The drug development with new dosage forms has always been done to provide effective and easy to use by patients. In addition, the presence of new drug preparations may increase bioavailability and reduce side effects. One of the discoveries is a breakthrough of oral syrup preparations with unique characteristics, such as in situ gel. Over the last decades, an impressive number of novel temperatures, pH and ion induced in situ forming solutions have been described in the literature. Each system has its own advantages and drawbacks. The choice of particular hydrogels depends on its intrinsic properties and investigated therapeutic use. In situ gel is a new drug delivery system. When applied, the system is carried out in contact with the body, in situ gel will undergo phase change to gel due to conditions of pH,

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electrolytes and temperature [2]. In situ gel produces a constant plasma drug profile in the body by sustaining the release of drug so it is attached and absorbed in gel form and is known to prolong the life of the drug in mucose [3]. Another advantage of in situ gel is easy to use, simple manufacturing at the factory, and improve both adherence and patient comfort by minimizing the frequency of its use [4].

Classification of in situ gelling polymers

Based on their origin, polymers can be classified or the mechanism of gelation. According to a source in situ, gelling systems are classified into two types [5].

i. Natural polymers (e. g., Alginic acid, carrageenan, chitosan, guar gum, gellan gum, pectin, sodium hyaluronate, xanthan gum, xyloglucan, etc.)
ii. Synthetic or semi-synthetic polymers (e. g., CAP, HPMC, MC, PAA, PLGA, poloxamers)

Sol-gel technique

Typically, the "sol" or starting ingredients are either organic compounds like metal alkoxides or inorganic metal salts. The precursor in the traditional "sol-gel" process undergoes hydrolysis, polymerization, or condensation processes to create a colloidal suspension or solution. Conversion from the "sol" (liquid phase) to the "gel" (solid phase) is directed by complete polymerization and the ensuing loss of solvent [6].

Preparation of in situ gel

Based on the advancement of in situ gelling technologies, the polymer might change. Using a magnetic stirrer, the necessary amounts of copolymers and polymers were dissolved until the polymers were entirely dissolved, resulting in the polymeric solution. Following the manufacture of an aqueous drug solution, the drug is transferred to a polymeric solution that has been made principally. Stirring continuously is needed to get a homogenous solution. Excipients are then added according to the delivery system. Lastly, use distilled water to equalize the volume [7].

Approaches of in situ gels

A. Physiological stimuli

Thermally triggered systems or temperature-induced in situ gelling systems

In these situations, gelation can occur without the need for any external heat source beyond body temperature. The most popular systems are these ones [8].

pH-triggered apparatuses

This method uses pH-sensitive or pH-responsive polymers to create a gel. All pH-sensitive polymers have ionizable functional groups, either acidic or alkaline, that can absorb or release protons in response to pH changes. Poly-electrolytes are a vast class of ionizable groups [8]. Some of the anionic groups utilized as pH triggered systems create in situ gels as a result of the swelling of hydrogels brought on by these poly-electrolytes' increase in external pH. For example, polyethylene glycol (PEG), carbomer and its derivatives, pseudo latexes, cellulose acetate phthalate (CAP), poly-methacrylic acid (PMC), mixtures of PMA and PEG, etc., have also been employed as a pH-sensitive system to accomplish gelation. The majority of anionic pH-sensitive polymers are derivatives of PAA (carbopol, carbomer) [9, 10].

B. Physical stimuli

When a material absorbs water from the surrounding environment, in situ formation may also occur and expand to the desired space [11].

Solvent exchange or diffusion

This process solvent diffuses from the polymer solution into surrounding tissue and results in precipitation or solidification of the polymer matrix. The most commonly used polymer for this approach is N-methyl pyrrolidone (NMP) [12].

Swelling

The polar lipid or polymer swells from inside to outside and slowly releases the drug (i.e., to form

lyotropic crystalline phase structures). It has some bio-adhesive properties and degraded in vivo enzymatic action [13].

C. Chemical reactions

Chemical polymerization of ionic cross-linking

Ion sensitive polymers induce gelation in the presence of ions like Na+, K+, Ca+2, and Mg+2. These ionic polymers undergo a phase transition to form a gel. Some of the polysaccharides fall into this class [14,15].

Enzymatic polymerization or enzymatic cross-linking

In this approach, the gel was formed by cross-linking with the enzymes that are present in the body fluids and have some advantages over chemical and photochemical methods, and mechanism showed in fig. 3 [16,17].

Photo-initiated polymerization

It is the most convenient and commonly used approach in the formation of in situ gels. Monomers or reactive micromere solutions and the initiators injected into a tissue site, and the application of electromagnetic radiation used to form a gel. Usually, long wavelength ultraviolet (i.e., ketones) and visible (camphor-quinone and ethyl eosin) wavelength polymers were used (i.e., acrylates or other polymers) short-wavelength polymers not used because they are biologically harmful [18].

Novel approaches of in situ gels

A variety of unique systems are used to extend the drug delivery by in situ gelling systems. These systems delay the elimination of active ingredients from the eye and also improved corneal penetration of a drug molecule [19].

Nanoparticles incorporated in situ gel

Recently, nanoparticles were employed to address issues related to topical formulations. These represent promising drug carriers for targeting ocular tissues by remaining at the site of application and providing prolonged release by particle degradation or erosion drug diffusion or a combination of both [20].

Liposome incorporated in situ gel

It is also a tool for prolonged controlled delivery of a drug; in lipid vesicles, active ingredients were encapsulated and transport drug through the cornea [21].

In situ gelling ocular films or inserts

Ocular inserts or films are semisolid or solid consistency, usually composed of a polymeric vehicle containing the drug, whose size and shape are designed for ophthalmic application [22].

Nanoemulsified in situ gels

Nanoemulsions are widely using due to its intrinsic advantages such as the higher penetration into the deeper layers, sustained release of drugs to the cornea, and ease of sterilization [23].

Evaluation of in situ gels

Physical evaluation

Compatibility studies Compatibility studies carried out for a physical mixture of interaction between drug and excipients by a suitable method such as Fourier Transform Infra-Red Spectroscopy (FTIR) or Differential Scanning Calorimetry (DSC) [24].

Appearance

Preferably, the gels should be transparent. The formulations were observed for a general appearance by the naked eye, such as color, odor, and the presence of suspended particulate matter [25].

Clarity test

The clarity of the product checked using a black and white background [26].

pH

The pH was checked by using a calibrated digital pH meter immediately after preparation. In the case of ocular preparations, the pH preferably near to ocular pH to avoid eye irritation and enhance patient compatibility and tolerance [27].

Homogeneity

By placing the preparation between two glasses, then observe particle roughness under the light [28].

Isotonicity

The formulation is mixed with few drops of blood, observe under a microscope, and compare with standard ophthalmic preparations. For all ophthalmic preparations, maintenance of isotonicity must need to prevent tissue damage and irritation to the eye [29].

Sol-gel transition temperature

The temperature of the phase transition of 'sol' meniscus was noted first and then heated at a specified rate. 'Gel' formation is indicated by a lack of movement of the meniscus on tilting the tube and note down the temperature [22, 83].

Gelling time

Gelling time is the time required for the first detection of gelation, as defined in sol-gel transition temperature [31,32].

Texture analysis

The cohesiveness, consistency, firmness of in situ gels assessed using a texture profile analyzer, which mainly indicates the syringe ability of 'sol' so the formulation can be quickly administration via in vivo [33].

Spreading coefficient

The apparatus consists of a wooden block with a ground glass slide placed on it. On this ground slide, every formulation weighing roughly two grams was positioned and examined. After that, a second slide with dimensions similar to the fixed glass slide was sandwiched between it and the gel preparation. An attached hook was given to the second slide. To create a homogenous gel coating between the two slides and release any trapped air, a one-gram weight was placed on top of each slide for five minutes. The measured weight is set on a pan that is hooked onto the pulley. It was noted how long it took for the top slide to split off from a ground slide. A better spreading coefficient (S) is indicated by a shorter interval [34, 35].

$$S = \frac{M \times L}{T}$$

M = Weight tied to upper slide

L = Length of glass slides

T = time taken to separate the slides

Gelling strength

The gelling strength was measured using a rheometer and is dependent on the gelling agent's method, which involves preparing a specific amount of "gel" from the "sol" form in a beaker. Pushing a probe slowly into the "gel" and measuring the load on the probe by measuring the depth of immersion of the "gel" surface allows this "gel" containing beaker to be elevated at a precise rate [36].

Procedures 1

This method is used to determine the appropriate polymer concentrations or gelling agent to form in situ gelling systems. It involves placing a drop of a freshly prepared formulation into a vial containing 2 ml of stimulated tear fluid (STF) and noting how long it takes for the "gel" to form or dissolve in 7.4 pH phosphate buffer [37].

Procedures 2

They were utilizing water-soluble colors, like indigo blue, amaranth, and Congo red, which they blended with the in-situ gel after dissolving 1 g in distilled water. The gelling capabilities of the formulations were measured in vitro by keeping the temperature at 37±0.5 °C while adding 5 ml of gelation solution (STF) to a glass test tube. It changed instantly to a hard, gel-like look. Gelling capacities in vitro are assessed based on the gel's stiffness. Additionally, the amount of time the thick gel stays thick. Additionally, the color was added to give the gel a visual appeal. The gelling capacity period was computed using the three in vitro categories [38].

+ 'gel' forms after a few minutes disperse rapidly

++ immediately gelation occurs, remains for a few hours

+++ immediately gelation occurs, remains for an extended period of time

Viscosity and rheology

Using a Brookfield viscometer, measure the viscosity at room temperature (25 °C) and body temperature (37±0.5 °C). The gel's thixotropic nature allowed for the observation of rheology. Before and after the gelation process, in situ gel preparations should exhibit pseudo-plastic and Newtonian flow. It should be 5-1000 m Pas ('sol') before gelling and 50-50,000 m Pas ('gel') after gelling, respectively. In situ gel formulation needs to be well-formulated to provide appropriate patient administration, particularly for ocular administration. Nevertheless, the drawbacks of these agents include obscured vision and deposit on the eyelids; their high viscosity might also make screening challenging [39, 40].

stability analyses

According to the International Conference on Harmonization, stability testing sought to determine the material's use and storage period (ICH). For about a month, place the sample in a climate chamber with a temperature of 40±2 °C and a relative humidity of 75±5%. A few months later, the sample was examined for related issues with rheology, in vitro dissolution, pH, viscosity, and drug content. The chosen study duration and storage conditions should provide for the necessary time for storage, transportation, and eventual usage [41, 42].

Drug release studies

In vitro drug release

In vitro release study of in situ gelling systems can be carried out by using Franz diffusion cell to check the duration [43].

In vivo drug release

Evaluation of drug preparation is one drug release in the body (in vivo). By knowing the time devastated and the polymer components used, we can design the drug as per the needs of pharmacotherapy [44].

Microbiological evaluation

Sterility testing

This testing is done with the aseptic transfer technique to avoid contamination of the environment. Sterility testing is an essential parameter for all ophthalmic preparation, and it must perform for aerobic, anaerobic bacteria and fungi by using suitable media under aseptic conditions. As per Indian Pharmacopoeia (IP) and British Pharmacopoeia (BP), mostly direct inoculation method used to test sterility. Initially, inoculate the sample into liquid media (thioglycollate medium and soybean digest medium). After that, incubate for 7-14 d at different temperatures; for thioglycollate medium (30-35 °C) and soybean digest medium (20-25 °C), then identify microbial growth [45, 46].

Irritation studies

Albino rabbits are using for the Draize irritation test, a single drop of 0.04 ml formulation instilled into rabbit eyes (the lower conjunctive cul-de-sac). The test eye and by the eyelids can be held together for several seconds after installation. Rabbit eyes were observed periodically at 1, 24, 48, 72 h, one week after exposure. Ocular changes were graded by a scoring system that includes rate any alterations to eyelids, conjunctiva, cornea, redness, swelling, watering, and iris [47, 48].

Antifungal studies

Initially, sabouraud dextrose dissolves in hot water (i.e., media), after 15-20 min. of autoclaving transfer, the organisms such as Candida albicans, Aspergillus fumigatus, etc., in media in order and put a sample test with a micropipette and let set aside for 30 min. After 24 h incubation at 25 °C, the diameter of the zone of inhibition or zones was measured, finally compared with positive and negative controls [49].

Antibacterial studies

This test was conducted to find out the effectiveness of antibacterial of active antibiotic substances, the concentrations that are referred to

as antibacterial. Finally, the results of the growth of bacteria samples could compare with standard antibiotics [50].

Challenges and Future Directions

Ensuring compliance with regulatory standards for safety and efficacy remains a challenge. Comprehensive testing and validation are required to meet regulatory requirements. While in situ oral syrups offer many benefits, patient acceptance and compliance must be continually assessed. Formulations must be palatable and easy to use. Future research should focus on integrating emerging technologies to further improve the design and performance of in situ oral syrups. This includes exploring novel materials and advanced characterization techniques.

CONCLUSION

In situ gel technology offers a number of benefits over traditional dosing forms. outstanding and outstanding drug delivery systems can be created by using water-soluble, biocompatible, and biodegradable polymers in the in-situ gel formulation. There is potential to offer an enhanced medication delivery technology, and researchers have shown interest in recent years. These systems can be enhanced and enhanced by including a novel carrier to achieve prolonged medication delivery. Because these systems can be administered as solutions, they gel at the site of action. And lastly, gels provide patient comfort and compliance while being simple to apply in situ.

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