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(Review Article)

Formulation and Development of Organogel Containing Dexamethasone and Diclofenac: A Review

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Abstract

Organogels have emerged as promising semi-solid delivery systems for topical drug administration due to their unique viscoelastic properties, biocompatibility, and ability to incorporate both hydrophilic and lipophilic drugs. This review focuses on the formulation and development of organogels containing dexamethasone and diclofenac for the effective management of inflammatory conditions such as arthritis. Dexamethasone, a potent corticosteroid, provides anti-inflammatory and immunosuppressive effects, while diclofenac, a non-steroidal anti-inflammatory drug (NSAID), offers analgesic and anti-inflammatory benefits. The synergistic combination enhances therapeutic efficacy while minimizing systemic side effects. The review discusses organogel composition, preparation methods, evaluation parameters, drug release mechanisms, and recent advancements. Organogels demonstrate controlled drug release, improved skin penetration, and patient compliance, making them a viable alternative to conventional topical formulations.

Keywords: Organogel, Dexamethasone, Diclofenac, Topical drug delivery, Drug release kinetics.

INTRODUCTION

Topical drug delivery systems have emerged as an important and rapidly advancing area in pharmaceutical research due to their ability to deliver therapeutic agents directly to the site of action. This localized delivery approach offers several advantages over conventional routes such as oral and parenteral administration. One of the most significant benefits is the reduction of systemic side effects, as the drug is primarily confined to the targeted area, thereby minimizing systemic exposure. Additionally, topical systems bypass first-pass metabolism in the liver, which can otherwise reduce drug bioavailability and necessitate higher doses. These features make topical drug delivery particularly attractive for the management of dermatological and musculoskeletal disorders, where localized treatment is both feasible and desirable. The skin, being the largest organ of the human body, serves as an effective barrier against environmental factors, but it also presents challenges for drug delivery due to its complex structure. The outermost layer, the stratum corneum, is highly resistant to the penetration of most substances, particularly hydrophilic drugs. Therefore, the development of efficient topical delivery systems requires innovative approaches to enhance drug permeation while maintaining safety and stability. Various formulations such as creams, ointments, gels, and transdermal patches have been explored for this purpose. Among these, gel-based systems have gained popularity due to their ease of application, non-greasy nature, and patient acceptability.

In recent years, organogels have attracted considerable attention as promising carriers for topical and transdermal drug delivery. Organogels are semi-solid systems in which an organic liquid phase is immobilized within a three-dimensional network formed by gelators, also known as organogelators. These gelators can be low molecular weight compounds or polymeric substances capable of self-assembly, leading to the formation of a structured network that entraps the liquid phase. Unlike conventional hydrogels, which are aqueous in nature, organogels are non-aqueous systems, making them particularly suitable for the delivery of lipophilic drugs. Their unique structural and physicochemical properties, including viscoelasticity, thermoreversibility, and stability, make them highly versatile for pharmaceutical applications. One of the key advantages of organogels is their ability to provide sustained and controlled drug release. The three-dimensional network within the gel acts as a barrier to drug diffusion, allowing for gradual release over an extended period. This not only improves therapeutic efficacy but also reduces the frequency of application, thereby enhancing patient compliance. Furthermore, organogels can improve the solubility and stability of poorly water-soluble drugs by incorporating them into the oil phase. The presence of certain excipients, such as penetration enhancers and surfactants, further facilitates the transport of drugs across the skin barrier, thereby increasing bioavailability.

Inflammatory disorders, such as arthritis, represent a major global health burden and often require long-term pharmacological management. Arthritis is characterized by pain, swelling, stiffness, and reduced mobility of joints, significantly affecting the quality of life of patients. The conventional treatment of such conditions typically involves the use of non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids, administered either orally or via injection. While these drugs are effective in reducing inflammation and pain, their long-term systemic use is associated with a range of adverse effects. NSAIDs, for example, are known to cause gastrointestinal irritation, ulceration, and even bleeding, while corticosteroids can lead to immunosuppression, osteoporosis, and metabolic disturbances when used chronically. To overcome these limitations, there has been a growing interest in the development of topical formulations that can deliver these drugs directly to the affected site. Topical delivery not only reduces systemic exposure but also allows for higher local drug concentrations, which can enhance therapeutic outcomes. In this context, the combination of dexamethasone and diclofenac in a single topical formulation presents a rational and effective strategy. Dexamethasone is a potent corticosteroid with strong anti-inflammatory and immunosuppressive properties, while diclofenac is a widely used NSAID known for its analgesic and anti-inflammatory effects. The combination of these two drugs offers a synergistic effect, targeting multiple pathways involved in inflammation and pain.

The incorporation of dexamethasone and diclofenac into an organogel formulation further enhances their therapeutic potential. The non-aqueous nature of organogels allows for better solubilization of these drugs, particularly diclofenac, which has limited water solubility. Moreover, the structured network of the organogel facilitates controlled drug release, ensuring a sustained therapeutic effect over time. The inclusion of suitable excipients, such as penetration enhancers, can further improve drug permeation through the skin, enabling effective delivery to deeper tissues, including joints and muscles. Another important aspect of organogel-based formulations is their improved patient acceptability. Unlike ointments, which are often greasy and difficult to wash off, organogels are typically non-greasy, transparent or translucent, and easy to apply. They spread easily over the skin and are quickly absorbed, leaving minimal residue. This enhances patient compliance, particularly in chronic conditions such as arthritis, where long-term treatment is required.

In addition to their therapeutic advantages, organogels also offer formulation flexibility. By varying the type and concentration of gelators, oils, and other excipients, it is possible to tailor the properties of the organogel to meet specific requirements, such as viscosity, spreadability, and drug release rate. This adaptability makes organogels a versatile platform for the development of customized drug delivery systems. Despite these promising features, certain challenges remain in the development and commercialization of organogel-based formulations. These include issues related to stability, scalability, and regulatory approval. However, ongoing research and technological advancements are expected to address these limitations and further expand the applications of organogels in pharmaceutical science.1-6

Classification of Gels:

Gels may be classified supported colloidal phases, nature of solvent used, physical nature and rheological properties.

1. Based on nature of solvent

Hydro gels (water based)

Here they contain water as their continuous liquid phase E.g. bentonite, derivatives of cellulose, carpooler, and synthetic poloxamer gel. Example-plastibase (low molecular wt. polyethylene dissolved in oil) Olag (aerosol) gel and dispersion of metallic stearate in oils.

Hydrogel

A Hydrogel, is a semisolid formulation of gel dosage forms, which has an immobilized external apolar phase. The apolar phase is immobilized within spaces of the 3D network structure formed due to the physical interactions amongst all polymers the self-assembling structures of compounds regarded as gelators.7

Xerogels

Solid gels with low solvent concentration are called xerogels. These are produced by evaporation of solvent or freeze drying, leaving the gel framework behind on contact with fresh fluid, they swells and may be reconstituted. E.g. Tragacanth ribbons, acacia tear β1-cyclodextrin, dry cellulose and polystyrene.8

2. Based on colloidal phases:

They're classified into Inorganic (two phase system) kind of force that's accountable for the linkages determine the structure of the network and therefore the properties of the gel.8

Single-phase system these contain large organic molecules existing on the twisted strands dissolved during a continuous phase.

3. Based on rheological properties:

Usually the gels show non-Newtonian flow properties. They're classified into, a) Plastic gels b) Pseudo plastic gels c) Thixotropic gels. (a) Plastic gels E.g. - Bingham bodies, flocculated suspensions of aluminium hydroxide exhibit a plastic flow and also the plot of rheogram gives the yield value of the gels above which the elastic gel distorts and begins to flow. (b) Pseudo-plastic gels E.g. - Liquid tragacanth dispersion, sodium alginate, Na Carboxy methyl cellulose etc. exhibits pseudo-plastic flow.9

4. Based on physical nature:

(a) Elastic gels Gels of agar, pectin, guar gum and alginates exhibit an elastic behavior. The fibrous molecules being linked at the purpose of junction by

relatively weak bonds like hydrogen bonds and dipole attraction. E.g.: Alginate and Carbapol. (b) Rigid gels this may be formed from macromolecule within which the framework linked by primary valance bond. E.g.: In colloid, silic acid molecules are held by Si-O-Si-O bond to provide a polymer structure possessing a network of pores.

Organogels: Overview, Drug Profile and Formulation Aspects

Organogels Overview: Organogels are semi-solid, thermoreversible systems composed of an organic solvent (oil phase) immobilized within a three-dimensional network of gelators, which may be low molecular weight or polymeric agents. These systems are non-aqueous in nature, making them highly suitable for lipophilic drugs, and they exhibit important characteristics such as thermal stability, biocompatibility, and the ability to provide sustained drug release. The major advantages of organogels include improved drug stability by preventing hydrolysis, enhanced skin permeation, reduced dosing frequency due to controlled release, and improved patient compliance because of ease of application and non-greasy nature.

Drug Profile: Dexamethasone is a corticosteroid that acts by inhibiting inflammatory mediators and cytokines, and is widely used in conditions such as arthritis, dermatitis, and allergic disorders; however, prolonged systemic use may lead to adverse effects. Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) that works by inhibiting cyclooxygenase (COX) enzymes, thereby reducing prostaglandin synthesis responsible for pain and inflammation, but its oral use is associated with gastric irritation. The combination of dexamethasone and diclofenac provides synergistic anti-inflammatory action, allows dose reduction of individual drugs, enhances therapeutic efficacy, and minimizes systemic side effects, making it highly suitable for topical delivery via organogels.

Components of Organogel Formulation: The formulation of organogels includes several essential components such as the oil phase, gelators, surfactants, and additives. The oil phase, including isopropyl myristate, liquid paraffin, and soybean oil, plays a crucial role in drug solubilization and permeation. Gelators like sorbitan monostearate, lecithin, and pluronic polymers form the structural network responsible for gel formation. Surfactants such as Span 60 and Tween 80 stabilize the formulation and improve consistency, while additives like penetration enhancers (menthol, oleic acid), preservatives, and stabilizers enhance drug permeation, prevent microbial growth, and improve formulation stability.

Methods of Preparation: Organogels can be prepared using different techniques depending on formulation requirements. In the direct method, the gelator is dissolved in the oil phase at an elevated temperature and forms a gel upon cooling. In the emulsion-based method, either water-in-oil or oil-in-water emulsions are prepared and then converted into gels using suitable gelators. The fluid-filled fiber method involves the formation of a fibrous network that entraps the liquid phase, resulting in a stable gel system.

Evaluation Parameters: Evaluation of organogels involves several parameters to ensure quality and performance. Physical evaluation includes assessment of color, homogeneity, and absence of phase separation. Rheological properties such as viscosity and spreadability determine the ease of application. Drug content uniformity ensures even distribution of active ingredients throughout the gel. In-vitro drug release studies are conducted using Franz diffusion cells to determine release kinetics, while skin permeation studies evaluate drug penetration through the skin. Stability studies are performed under different environmental conditions to assess shelf-life and formulation integrity.

Drug Release Mechanism and Applications: Drug release from organogels primarily follows a diffusion-controlled mechanism and often fits the Higuchi model. Factors such as gelator concentration, oil viscosity, and drug solubility significantly influence the release profile. Organogels have wide applications in topical and transdermal drug delivery, cosmetic formulations, and anti-inflammatory therapies. Recent advancements include nano-organogels, natural gelators, and stimuli-responsive systems for targeted delivery. However, challenges such as stability issues, scale-up difficulties, limited clinical data, and higher costs exist. Despite these limitations, organogels hold significant future potential due to improved therapeutic outcomes, scope in personalized medicine, and integration with nanotechnology.

Future Prospects

Organogels are increasingly recognized as a promising platform in the field of advanced drug delivery systems due to their unique physicochemical properties and versatility. With continuous advancements in pharmaceutical technology, organogels are expected to play a significant role in improving therapeutic outcomes. Their ability to provide controlled and sustained drug release ensures that drugs are delivered at a consistent rate over an extended period, thereby maintaining optimal drug concentration at the target site. This not only enhances efficacy but also reduces the frequency of administration, which is particularly beneficial in the management of chronic conditions. Moreover, the non-aqueous nature of organogels allows for improved solubilization of lipophilic drugs, thereby enhancing their bioavailability and therapeutic performance.

Another important aspect contributing to the future potential of organogels is their compatibility with personalized medicine approaches. Personalized medicine focuses on tailoring treatment based on

individual patient characteristics such as genetic makeup, disease condition, and response to therapy. Organogels offer formulation flexibility, allowing modification of composition, viscosity, drug concentration, and release characteristics according to specific patient needs. This adaptability makes them suitable for designing customized therapeutic systems that can deliver precise doses in a controlled manner. For instance, organogels can be engineered to release drugs in response to specific physiological conditions, such as pH or temperature changes, thereby ensuring targeted and efficient drug delivery. The integration of nanotechnology further enhances the potential of organogels in modern drug delivery. The incorporation of nanoparticles, liposomes, or nanoemulsions into organogel systems leads to the development of nano-organogels, which combine the advantages of both nanocarriers and gel systems. These hybrid systems offer improved drug loading capacity, enhanced skin permeation, and better targeting of drugs to specific tissues or cells. Nanotechnology also enables the delivery of poorly soluble drugs and biomolecules, which are otherwise difficult to administer effectively. Furthermore, nano-organogels can provide protection to sensitive drugs from degradation, thereby improving stability and shelf-life. In addition to these advancements, organogels are being explored for their potential in transdermal and targeted drug delivery applications. Their ability to enhance skin penetration through the inclusion of suitable permeation enhancers makes them ideal for delivering drugs to deeper tissues, including joints and muscles. This is particularly advantageous in the treatment of conditions such as arthritis, where localized drug delivery is required for effective management. Organogels also exhibit favorable rheological properties, such as appropriate viscosity and spreadability, which contribute to ease of application and patient acceptability.

Despite these promising features, certain challenges need to be addressed to fully realize the potential of organogels. These include issues related to large-scale production, long-term stability, and regulatory approval. However, ongoing research and technological advancements are expected to overcome these limitations. The development of novel gelators, biocompatible excipients, and advanced formulation techniques will further enhance the performance and applicability of organogels. In the coming years, organogels are likely to become an integral part of advanced pharmaceutical formulations, offering innovative solutions for effective and targeted drug delivery.

CONCLUSION

Organogels represent a promising and innovative drug delivery system, particularly for the topical administration of anti-inflammatory drugs such as dexamethasone and diclofenac. Their unique structure, consisting of an organic liquid phase immobilized within a three-dimensional network, provides several advantages over conventional formulations. One of the key benefits of organogels is their ability to deliver drugs directly to the site of action, thereby minimizing systemic exposure and reducing the risk of adverse effects. This is especially important in the treatment of chronic inflammatory conditions such as arthritis, where long-term drug therapy is required. The combination of dexamethasone and diclofenac in an organogel formulation offers a synergistic therapeutic effect by targeting multiple pathways involved in inflammation and pain. Dexamethasone, being a potent corticosteroid, effectively suppresses inflammatory responses, while diclofenac, as a non-steroidal anti-inflammatory drug, provides analgesic and anti-inflammatory effects by inhibiting cyclooxygenase enzymes. The use of these drugs in combination allows for dose reduction and enhances overall therapeutic efficacy, while the topical delivery system ensures localized action with minimal systemic side effects.

In addition to their therapeutic advantages, organogels exhibit desirable physicochemical properties such as good stability, ease of application, and excellent patient acceptability. Their non-greasy nature, smooth texture, and ability to spread easily over the skin make them more user-friendly compared to traditional ointments and creams. Furthermore, organogels can be formulated to provide controlled and sustained drug release, which helps maintain consistent drug levels at the site of application and reduces the need for frequent dosing. The formulation of organogels can be tailored by selecting appropriate components such as oil phase, gelators, surfactants, and additives, allowing optimization of properties such as viscosity, spreadability, and drug release profile. The inclusion of penetration enhancers further improves drug permeation through the skin, enabling effective delivery to deeper tissues. Advances in formulation technology, including the use of nano-organogels and stimuli-responsive systems, are expected to further enhance the performance and applicability of organogel-based drug delivery systems.

Despite some challenges related to stability, scalability, and cost, the overall potential of organogels in pharmaceutical applications is significant. With continued research and development, these systems are expected to overcome existing limitations and gain wider acceptance in clinical practice. In conclusion, organogels offer a highly effective and versatile platform for topical drug delivery, particularly for the management of inflammatory conditions.

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