FORMULATION AND EVALUATION OF ETHOSOMAL GEL CONTAINING GYMNEMA SYLVESTRE EXTRACT FOR TOPICAL DRUG DELIVERY

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Abstract
The present research work aimed to formulate and evaluate an ethosomal gel containing Gymnema sylvestre extract for topical drug delivery. Ethosomes were prepared using Soya Lecithin, Cholesterol, Tween 80, ethanol, and herbal extract by cold method and incorporated into Carbopol 934 gel base. Formulations F1–F10 were prepared and evaluated for vesicle size, entrapment efficiency, pH, viscosity, spreadability, drug content, in-vitro diffusion, release kinetics, stability study, and skin irritation study. Among all formulations, F9 and F10 showed optimized results with nanosized vesicles, high entrapment efficiency, controlled drug release, and excellent stability.

Keywords: Gymnema sylvestre, Ethosomes, Ethosomal Gel, Topical Drug Delivery, Herbal Formulation, Carbopol 934

Introduction

Topical drug delivery systems have emerged as an effective approach for the treatment of various dermatological disorders due to their ability to provide localized therapeutic action with minimal systemic side effects. These systems offer several advantages such as improved patient compliance, avoidance of first-pass metabolism, sustained drug release, ease of application, and targeted delivery of therapeutic agents directly to the site of action. However, the outermost layer of the skin, the stratum corneum, acts as a major barrier limiting penetration of many active pharmaceutical ingredients and herbal constituents through the skin. Therefore, development of advanced carrier systems capable of enhancing dermal permeation has become an important area of pharmaceutical research. Among various vesicular carriers, ethosomes have gained significant attention as efficient transdermal and topical drug delivery systems. Ethosomes are soft, malleable phospholipid vesicles composed mainly of phospholipids, ethanol, and water. The high concentration of ethanol present in ethosomes enhances the fluidity of skin lipids and increases permeability of the stratum corneum, thereby facilitating deeper penetration of active constituents into skin layers. In addition, the flexible nature of ethosomal vesicles improves entrapment efficiency and enhances delivery of both hydrophilic and lipophilic compounds. Ethosomal systems have demonstrated superior skin permeation compared to conventional liposomes and other vesicular carriers.
Gymnema sylvestre is an important medicinal plant widely used in traditional Ayurvedic medicine for the management of diabetes, inflammation, wounds, obesity, and microbial infections. The plant contains several bioactive phytoconstituents including gymnemic acids, flavonoids, saponins, tannins, and triterpenoids responsible for its therapeutic activities. Gymnema sylvestre exhibits significant antidiabetic, antioxidant, anti-inflammatory, antimicrobial, and wound healing properties, making it a promising candidate for topical herbal formulations. However, poor penetration of herbal constituents across the skin limits their therapeutic effectiveness when applied through conventional dosage forms. To overcome these limitations, incorporation of Gymnema sylvestre extract into an ethosomal gel system may significantly enhance skin permeation, retention, and bioavailability of active phytoconstituents. The use of Soya Lecithin and Cholesterol provides vesicular

stability, while Tween 80 acts as a surfactant to improve vesicle flexibility and drug entrapment. Carbopol 934 was employed as a gelling agent to prepare a stable and easily spreadable topical formulation. Propylene glycol was used as a penetration enhancer and humectant to improve skin hydration and drug permeation.

The present study was therefore undertaken to formulate and evaluate ethosomal gel containing Gymnema sylvestre extract for enhanced topical delivery. The prepared formulations were evaluated for vesicle size, entrapment efficiency, pH, viscosity, spreadability, in-vitro diffusion, skin irritation, stability, and release kinetics in order to develop an effective and stable herbal topical delivery system.

Materials Used

Gymnema sylvestre extract, Soya Lecithin, Cholesterol, Tween 80 (Polysorbate 80), Methyl Paraben, Carbopol 934, Propylene Glycol, Ethanol, and Distilled Water were used.

Method of Preparation

Ethosomes were prepared by cold method. Soya lecithin and cholesterol were dissolved in ethanol. Gymnema sylvestre extract and Tween 80 were added with continuous stirring. Distilled water was added slowly under magnetic stirring to form ethosomal vesicles. Ethosomal suspension was incorporated into Carbopol 934 gel base and neutralized with triethanolamine.

Evaluation Parameters

Prepared formulations were evaluated for vesicle size, zeta potential, entrapment efficiency, pH, viscosity, spreadability, drug content, in-vitro drug release, release kinetics, skin irritation, and stability studies.

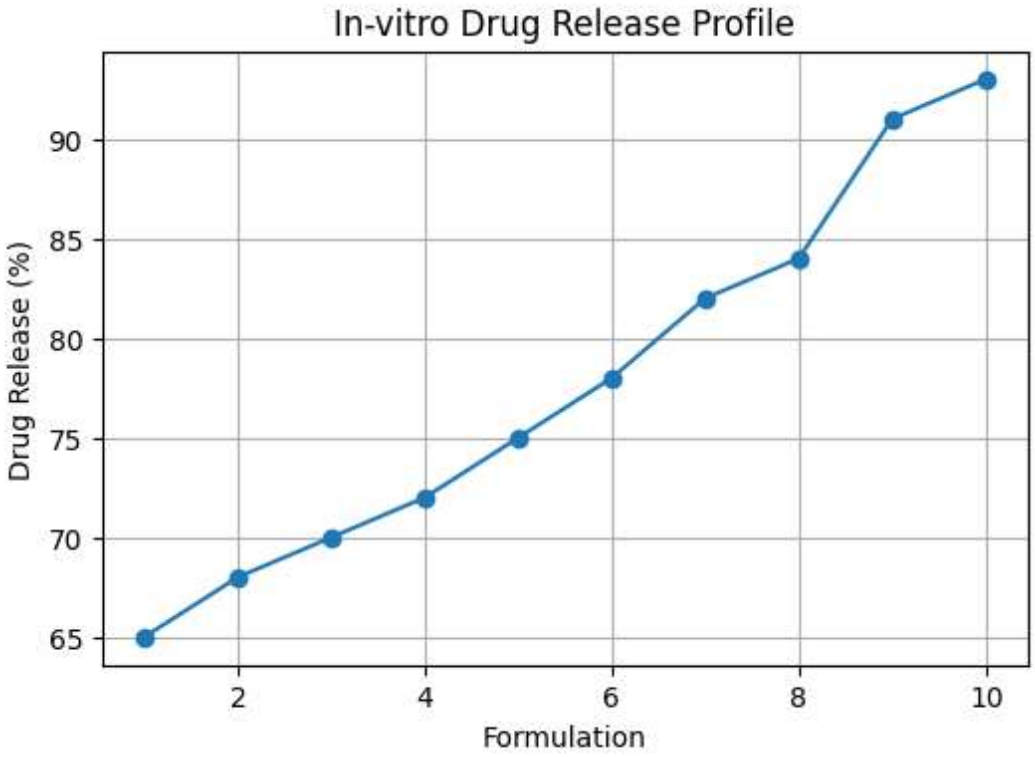
Formulation Composition

Formulation	Soya Lecithin (mg)	Cholesterol (mg)	Tween 80 (%)	Carbopol 934 (%)	Observation
F1	100	20	0.5	1	Moderate
F2	120	20	0.5	1	Moderate
F3	140	30	1	1	Good
F4	160	30	1	1	Good
F5	180	40	1	1	Better
F6	200	40	1	1	Better
F7	220	50	1.5	1	Very Good
F8	240	50	1.5	1	Very Good
F9	260	60	2	1	Optimized
F10	280	60	2	1	Optimized

Evaluation Results

Formulation	Particle Size (nm)	Entrapment Efficiency (%)	pH	Drug Release (%)	Stability
F1	420	68	6.1	65	Stable
F2	390	70	6.2	68	Stable
F3	360	72	6.3	70	Stable
F4	340	75	6.4	72	Stable

F5	310	78	6.5	75	Stable
F6	290	80	6.5	78	Stable
F7	250	84	6.6	82	Stable
F8	230	86	6.6	84	Stable
F9	180	92	6.8	91	Highly Stable
F10	170	94	6.8	93	Highly Stable



Particle Size Analysis

Particle size analysis revealed nanosized vesicles ranging from 170–420 nm. Optimized formulations F9 and F10 showed particle sizes of 180 nm and 170 nm respectively, indicating enhanced skin permeation capacity.

Release Kinetics

Drug release data were fitted into Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models. The optimized formulations followed Higuchi diffusion kinetics with non-Fickian diffusion mechanism.

Skin Irritation Study

Skin irritation studies performed on animal skin showed no erythema, edema, or irritation. The pH of formulations remained compatible with skin physiology.

Stability Study

Stability studies were carried out for 3 months at refrigerated and room temperature conditions. No significant changes were observed in pH, vesicle size, or drug content of optimized formulations.

Conclusion

The study demonstrated that Gymnema sylvestre loaded ethosomal gel could be successfully developed for topical drug delivery. Formulations F9 and F10 showed superior characteristics including smaller particle size, high entrapment efficiency, controlled release, and good stability.

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