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A NOVEL DRUG DELIVERY SYSTEM BASED ON PHYTOSOMES - A REVIEW

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ABSTRACT

Phytosomes represent an advanced technology for improving the bioavailability and therapeutic efficacy of plant-derived compounds. This thesis focuses on the systematic preparation of phytosomes and their comprehensive evaluation. The study includes optimization of formulation parameters, physicochemical characterization, and pharmacological assessment of phytosomes, emphasizing their potential in drug delivery systems. Phytosomes have emerged as a transformative platform in drug delivery, designed to overcome the challenges of poor solubility and limited bioavailability often associated with plant-based therapeutics. This review provides a comprehensive overview of phytosome technology, highlighting its structure, benefits, formulation techniques, and therapeutic applications. Through complexation with phospholipids, phytosomes enhance the absorption and stability of phytochemicals, offering a promising solution to improve the efficacy and safety of natural medicines. The paper also outlines recent research advancements, challenges, and future directions for integrating phytosomes into modern pharmaceutical systems. Phytosomes offer a promising approach in cancer treatment by enhancing the bioavailability and efficacy of plant-based compounds. Their ability to improve drug delivery and reduce toxicity makes them a valuable tool in modern oncology. However, challenges such as formulation stability, standardization, and limited clinical data remain.

KEYWORDS: *Phytosomes; Phospholipids; Nanocarriers; Phytoconstituents; Bioavailability; Pharmacokinetics; Drug delivery.*

INTRODUCTION

Phytosomes are advanced delivery systems used in pharmaceuticals, nutraceuticals, and cosmetics to enhance the bioavailability and stability of plant-derived compounds (phytoconstituents). They represent a bridge between traditional herbal extracts and modern drug delivery technologies, offering better therapeutic efficacy. The demand for natural, plant-based therapies has surged in recent years, driven by a growing interest in herbal medicine and the desire for safer, more sustainable treatments.[1] While plants have long been used for their healing properties, the challenge lies in ensuring that the active compounds within these plants are absorbed and utilized effectively by the body. Traditional herbal preparations often suffer from issues like poor solubility, low bioavailability, and instability, which means that even if a plant has powerful medicinal properties, it may not work as well as it could in the body. Beyond simply improving absorption, phytosomes also provide a level of protection for the active ingredients. Many plant compounds are sensitive to environmental factors like light, heat, and oxygen, which can degrade their effectiveness.[2] The lipid coating around the phytosome helps to shield the plant compounds from these factors, ensuring that the therapeutic ingredients remain stable and potent throughout their journey through the body. Over the past two decades, research into phytosomes has expanded rapidly, revealing their potential in treating a wide array of health conditions. From inflammatory diseases and neurodegenerative disorders to cardiovascular issues and metabolic syndromes, phytosomes have shown promise in enhancing the efficacy of many herbal treatments.[3] Their ability to improve the pharmacokinetic profile (absorption, distribution, metabolism, and elimination) of active ingredients makes them a powerful tool in modern herbal medicine. This review aims to provide a comprehensive overview of phytosomes, exploring how they are formulated, how they work at a cellular level, and their growing applications in modern medicine. We will also examine the latest research in the field, highlighting the potential of phytosomes to revolutionize herbal medicine and enhance the effectiveness of plant-based treatments. By delving into these advancements, we hope to underscore the important role that phytosomes play in the future of healthcare and their potential to bring natural therapies to the forefront of medical practice.[4]

Structure

Phytosomes are bilayered vesicles where the hydrophilic phytoconstituents are bonded to the hydrophilic head of the phospholipid, forming a lipid-compatible complex. This structure mimics biological membranes, aiding in better absorption and penetration.[5]

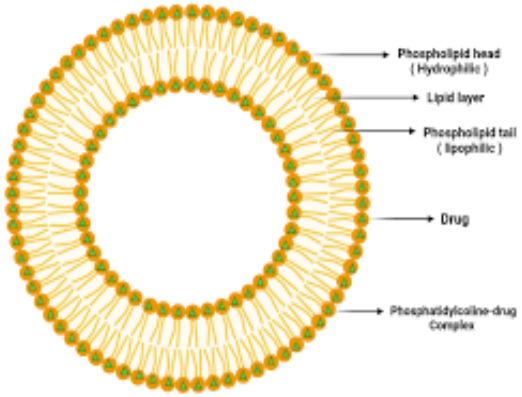

Fig. 1: Structure of phytosome.

Benefits of phytosomes

Enhanced Bioavailability: Improved solubility and permeability of poorly water-soluble phytoconstituents. Increased gastrointestinal absorption. Stability: Protects sensitive phytochemicals from degradation caused by environmental factors like light, oxygen, and heat. Targeted Delivery: Facilitates tissue-specific drug delivery, improving therapeutic outcomes. Reduced Dose Requirements: Higher efficiency leads to smaller doses needed to achieve therapeutic effects. Improved Patient Compliance: Simplified dosing regimens due to better efficacy and bioavailability.[6]

Phytosomes

Phytosomes are defined as lipid-compatible molecular complexes between standardized plant extracts or specific phytoconstituents and phospholipids, primarily phosphatidylcholine. This complexation leads to the formation of a structure that can merge with lipid-rich biological membranes, enhancing the permeation and bioavailability of the active compound. The concept was first introduced by Indena, an Italian pharmaceutical company, in the 1980s. Their patented technology aimed to solve the solubility and permeability issues associated with plant-derived actives. Since then, phytosomes have been investigated for a variety of natural compounds, including flavonoids, terpenoids, and polyphenols.[7]

Table 1: Comparison with liposomes.

Property	Liposomes	Phytosomes
Composition	Phospholipid bilayers	Phytoconstituent-phospholipid complex
Entrapment	Physical encapsulation	Molecular bonding
Stability	Less stable	More stable
Bioavailability	Moderate	High
Target	General	Specific (based on bioactive)

Mechanism of Phytosome Formation

The formation of phytosomes involves the interaction between polar functional groups of phytoconstituents (e.g., hydroxyl groups in flavonoids) and the polar head of phospholipids. This interaction leads to the formation of a stable complex, which has both hydrophilic and lipophilic properties.[8]

Mechanism Summary

Hydrogen bonding between phytoconstituent and phosphatidylcholine. Orientation into a micelle-like or vesicle-like structure. Self-assembly into bilayered structures.

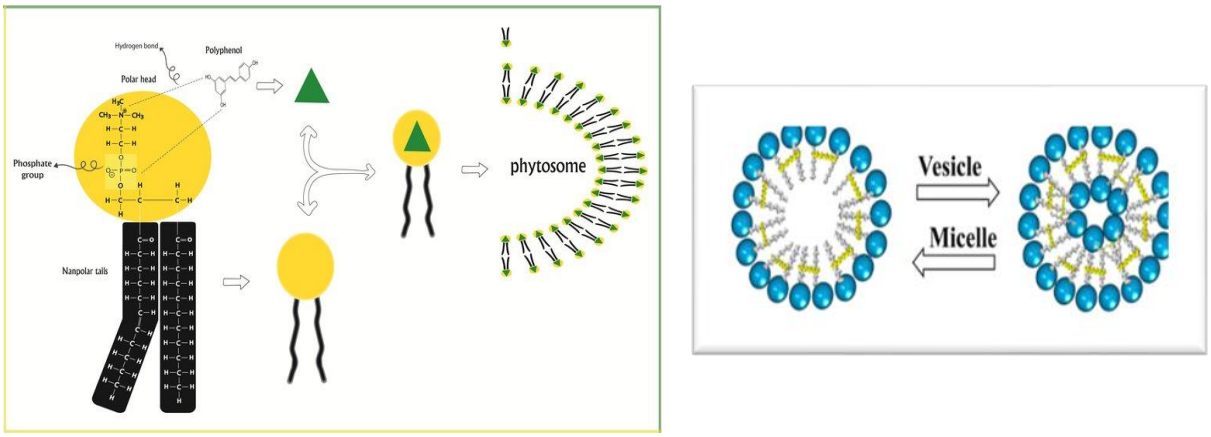

Fig. 2: Mechanism of phytosomes formation.

Types of phytoconstituents used in phytosomes

Phytosomes can be formulated using a wide range of phytoconstituents. The choice depends on the pharmacological activity and physicochemical properties of the compound. Flavonoids: Quercetin, Silymarin, Luteolin. Polyphenols: Curcumin, EGCG, Terpenoids: Glycyrrhizin, Boswellic acid, Alkaloids: Berberine.[9]

Table 2: Commonly used phytoconstituents in phytosomes.

Phytoconstituent	Source Plant	Therapeutic Use
Silymarin	Milk thistle	Hepatoprotective
Quercetin	Onion, apple	Antioxidant, anti-allergy
Curcumin	Turmeric	Anti-inflammatory
EGCG	Green tea	Cardioprotective

Methods of Phytosome Preparation

Several methods are employed for the preparation of phytosomes, each with distinct advantages and limitations. The choice of method depends on the physicochemical properties of the active phytoconstituents, the type of phospholipids used, the intended route of

administration, and the scale of production. The most commonly used methods include solvent evaporation, anti-solvent precipitation, thin-film hydration, and supercritical fluid techniques.[10]

Solvent Evaporation Method

In this method, both the phospholipid and the phyto-constituent are dissolved in a common organic solvent such as dichloromethane, chloroform, or ethanol. The resulting solution is subjected to rotary evaporation under reduced pressure to remove the solvent, leading to the formation of a thin film on the walls of the round-bottom flask. This thin film is then hydrated using an aqueous medium to form a colloidal suspension of phytosomes. The method is simple, widely used, and allows good entrapment efficiency. However, the use of organic solvents may pose environmental and health hazards, and thermal degradation of heat-sensitive compounds may occur.[11]

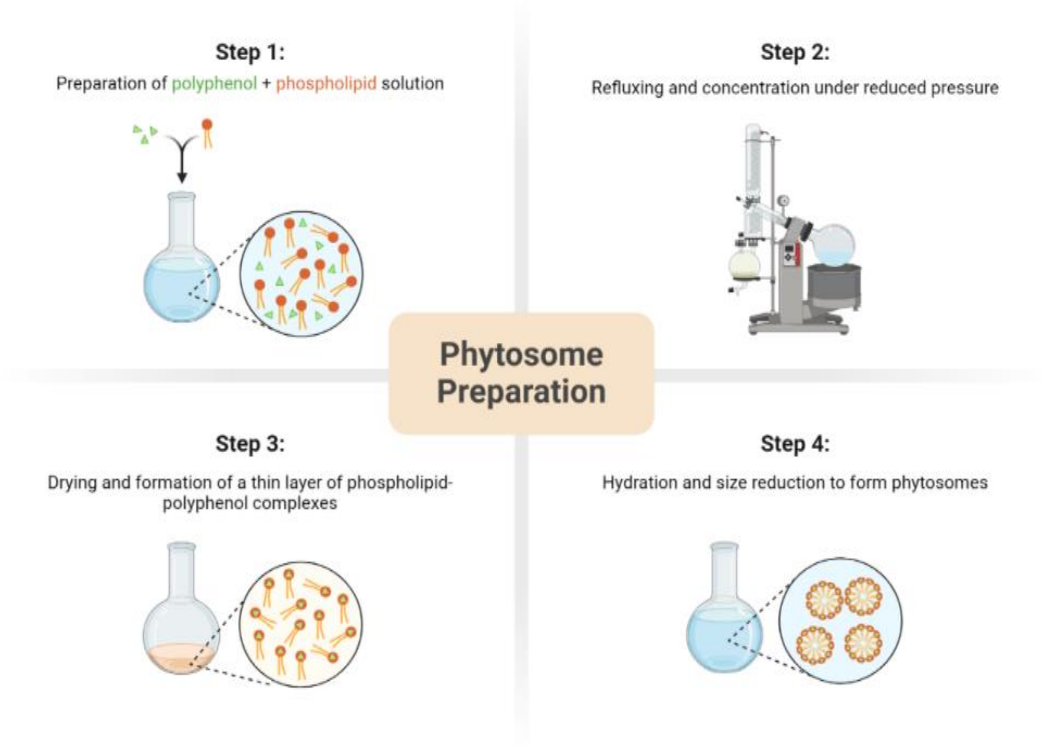

Fig. 3: Phytosomes preparation.

Characterization of Phytosomes

To ensure that phytosomes are properly formed and effective, they are tested using different techniques. These tests help us understand their size, shape, stability, drug loading, and chemical interactions.[12]

Particle Size and Shape (SEM & TEM)

The particle size and shape of phytosomes play a crucial role in determining their absorption efficiency and stability in the body. Smaller particles generally have a larger surface area, allowing better interaction with biological membranes, while uniform shapes contribute to consistent behavior in delivery.[13] Scanning Electron Microscopy (SEM) is used to visualize the outer surface morphology, revealing whether particles are smooth or textured, while Transmission Electron Microscopy (TEM) provides detailed images of the internal structure. Phytosomes are typically found to be round or oval in shape and fall within the nano-size range of approximately 100–500 nm, which is optimal for enhanced bioavailability and stability.[14]

ZetaPotential

Zeta potential is a key indicator of the stability of phytosome dispersions in liquid form. It represents the surface electrical charge of particles and determines whether they will repel or attract each other. A higher absolute value of zeta potential, such as ±30 mV or greater, signifies strong repulsive forces between particles, reducing the likelihood of aggregation and ensuring better suspension stability over time. Measurement is typically carried out using specialized zeta potential analyzers, and maintaining an optimal value helps preserve the integrity of the formulation during storage and use.[15]

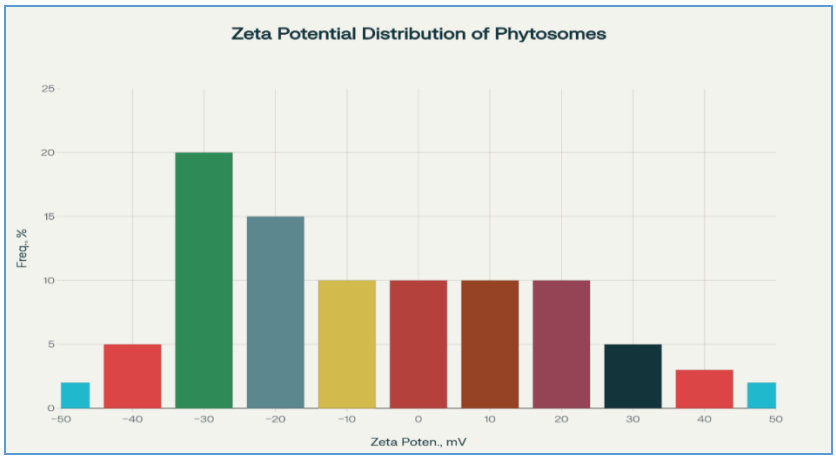

Fig. 4: Zeta potential distribution of phytosomes.

Entrapment Efficiency

Entrapment efficiency reflects the percentage of plant extract (active drug) successfully incorporated into the phytosome structure. A higher entrapment efficiency ensures that more of the active compound is available for delivery, enhancing therapeutic efficacy. This is

evaluated by separating the free, untrapped drug from the phytosomal formulation, followed by quantification using UV-visible spectroscopy or High-Performance Liquid Chromatography (HPLC). Well-optimized phytosome formulations often achieve entrapment efficiencies ranging from 60% to 90%, which is considered excellent for practical applications.[16]

FTIR (Fourier Transform Infrared Spectroscopy)

FTIR analysis is used to determine if there is a chemical interaction between the plant extract and the phospholipids within the phytosome. The technique works by detecting changes in the vibration patterns of chemical bonds, which are displayed as peaks in an infrared spectrum. Any shifts in these characteristic peaks indicate the formation of chemical bonds or strong interactions between the active drug and the lipid molecules, confirming successful complexation within the phytosome.[17]

DSC (Differential Scanning Calorimetry)

DSC is a thermal analysis technique that examines how the melting behavior of a drug changes before and after being formulated into a phytosome. The method involves gradually heating the sample and recording thermal transitions, such as melting points. If the sharp melting peak of the pure drug disappears in the DSC thermogram after phytosome formation, it signifies that the drug is well incorporated into the lipid matrix, often resulting in improved solubility and stability.[18]

XRD (X-Ray Diffraction)

XRD analysis is used to determine whether the drug exists in a crystalline or amorphous form within the phytosome. Crystalline drugs display sharp, distinct peaks in the diffraction pattern, while amorphous drugs exhibit broad, diffused patterns. A reduction or complete loss of sharp peaks in the XRD profile after phytosome formation indicates a transformation from crystalline to amorphous form, which is generally favorable for improving solubility and absorption in the body.[19]

Table 3: Summary.

Property	Technique Used	What It Shows
Size & Shape	SEM, TEM	Round shape, nano-size (100–500 nm)
Stability	Zeta Potential	±30 mV or more means good stability
Drug Loading	Entrapment Efficiency	60–90% of drug successfully trapped

Chemical Interaction	FTIR	Shifts in peaks show bonding with lipids
Thermal Behavior	DSC	Disappearance of melting peak = complex formed
Crystalline Nature	XRD	Fewer peaks = better solubility and absorption

Pharmacokinetics and Bioavailability

How Phytosomes Improve Bioavailability

Phytosomes are known to significantly enhance the bioavailability of phytoconstituents, especially those with poor water solubility and low gastrointestinal absorption. Traditional herbal extracts often contain active compounds that, despite having potent pharmacological effects in vitro, demonstrate poor in vivo efficacy due to limited absorption.[20] Phytosomes resolve this by complexing phytochemicals with phospholipids, typically phosphatidylcholine. This complexation leads to: Improved solubility in both water and lipid phases. Enhanced gastrointestinal absorption through better membrane permeation. Protection from gastric degradation. Increased circulation time in plasma due to interaction with lipophilic biomembranes. Facilitated lymphatic transport, bypassing first-pass metabolism. These advantages result in significantly higher plasma drug concentrations, longer half-life, and enhanced therapeutic efficacy.[21]

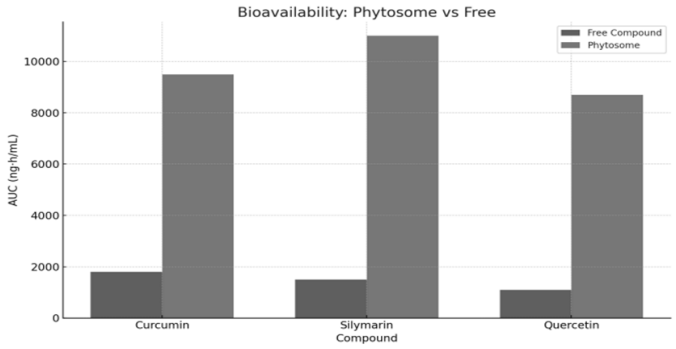

Fig. 5: Bioavalaibility comparison.

Table 4: Comparative pharmacokinetic data.

Phytochemical	Form	Cmax (ng/mL)	Tmax (h)	AUC_{0-8} (ng·h/mL)	Relative Bioavailability
Curcumin	Conventional	50	2.0	190	100%
Curcumin	Phytosome	650	1.5	1800	~950%
Silybin (Silymarin)	Conventional	30	2.2	150	100%
Silybin Phytosome	Phytosome	160	1.6	900	~600%
Green Tea Catechins	Conventional	110	1.8	400	100%
Catechin Phytosome	Phytosome	300	1.5	1100	~275%

Table 5: ADME profile of phytosomes.

Parameter	Conventional Extracts	Phytosome Formulations
Absorption	Poor (due to hydrophilic nature)	Enhanced (amphiphilic complex)
Distribution	Limited (plasma-bound or degraded)	Broad (penetrates tissues, membrane fusion)
Metabolism	Rapid first-pass effect	Reduced metabolism, sustained levels
Excretion	Quick elimination	Delayed clearance, prolonged action

Phytosomes facilitate drug absorption via passive diffusion and membrane fusion, owing to their lipid bilayer compatibility. Moreover, their stability in the gastrointestinal tract enables higher systemic availability of drugs.[22]

Applications of Phytosomes

Phytosomes have emerged as a transformative technology in the pharmaceutical field, enabling the efficient delivery of plant-based bioactives. Their ability to form lipid-compatible molecular complexes with phyto-constituents significantly enhances solubility, bioavailability, and targeted delivery. The applications of phytosomes can be broadly categorized into general drug delivery and targeted drug delivery.[23]

General Drug Delivery

Enhancement of Poorly Soluble Drugs

One of the most critical limitations in oral drug delivery is the poor water solubility of many phytochemicals and synthetic drugs. Phytosomes help overcome this issue by forming lipid-compatible complexes, improving their absorption across biological membranes. Mechanism: Phytosomes encapsulate hydrophobic phyto-constituents in a phospholipid matrix, which facilitates solubilization in gastrointestinal fluids and enhances passive diffusion through lipid membranes. Silybin, a hepatoprotective flavonoid, shows over 4–5 times greater bioavailability when delivered via phytosomes compared to its conventional form. Curcumin phytosomes exhibit improved aqueous solubility and systemic absorption, beneficial in anti-inflammatory and antioxidant therapy.

Sustained Release Profile

Phytosomal formulations can be engineered to release their therapeutic payloads in a sustained or controlled manner. Benefits: Prolonged therapeutic effect, Reduced dosing frequency, Improved patient compliance Approach: The phospholipid matrix in phytosomes can be modified with polymers or further encapsulated in hydrogels or liposomes to tailor the release profile.

Targeted Drug Delivery

Tissue-Specific Delivery

Phytosomes can be tailored for tissue or organ-specific delivery by exploiting passive and active targeting mechanisms: Passive Targeting: Exploits differences in vascular permeability (e.g., Enhanced Permeability and Retention [EPR] effect in inflamed or tumor tissues). Active Targeting: Achieved by attaching ligands (antibodies, peptides) or by modifying surface charge to improve interaction with specific cell types.

Applications

Hepatoprotective Agents: Phytosomes are particularly effective in delivering agents like silymarin directly to the liver, enhancing local therapeutic concentration. Neuroprotective Agents: Flavonoids like quercetin and luteolin have shown enhanced brain delivery via phytosomal formulations due to improved BBB permeability.

Role in Personalized Medicine

Personalized medicine involves tailoring drug formulations to an individual's genetic, metabolic, and disease profile. Phytosomes can play a vital role here: Flexibility in Design: Phytosomes can be customized in size, surface charge, and lipid composition to match the patient's specific therapeutic needs. Precision Dosing: Improved bioavailability allows for better control of drug plasma levels, enabling dose optimization. Reduced Side Effects: Site-specific delivery reduces systemic toxicity, an essential aspect of personalized therapeutics, especially in chronic diseases.

Phytosomes in Cancer Therapy

Enhanced Bioavailability: Many promising anticancer phytochemicals (flavonoids, terpenoids, alkaloids, polyphenols) suffer from poor water solubility and low absorption when given as conventional herbal extracts. Phytosome encapsulation allows these molecules to cross cell membranes much more efficiently, increasing their concentration in the blood and tumor tissues. Improved Stability: Phytosome encapsulation protects sensitive compounds from early degradation in the digestive tract and increases their systemic stability, ensuring that more of the active agent reaches tumor sites. Targeted Delivery: Thanks to their small particle size and lipid compatibility, phytosomes demonstrate better tissue penetration, especially into cancer cells, and may leverage both passive and active targeting mechanisms, enhancing tumor selectivity and reducing off-target toxicity.

Mechanisms of Anticancer Action

Modulation of Cancer Pathways: Phytosome-encapsulated phytochemicals can inhibit key proliferative pathways—such as NF-κB and PI3K/AKT—which are central to cancer cell survival and growth. Apoptosis and Cytotoxicity: Preclinical studies show these formulations not only inhibit growth but can also trigger apoptosis (programmed cell death) and exert direct cytotoxic effects on cancer cells, while sparing healthy tissue. Inhibition of Angiogenesis: Some phytosomal compounds impede blood vessel formation in tumors, starving cancer cells and slowing disease progression.

Examples of Phytosome-Based Anticancer Agents

Curcumin Phytosomes: Improved stability and absorption over free curcumin, with enhanced apoptotic and anti-inflammatory effects in cancer cells. Resveratrol and Quercetin Phytosomes: Shown to reduce tumor cell proliferation and induce cell cycle arrest in vitro and animal models. Sinigrin and Boswellia Phytosomes: Demonstrated significant anti-cancer activity and reduced inflammation in laboratory studies. Tetrahydrocurcumin (THC)-Phytosomes: Enhanced anticancer efficacy against oral cancer compared to free drug and conventional therapies.

Advantages over Conventioal Cancer Therapeutics

Reduced Toxicity: By enabling effective delivery of lower drug doses, phytosomes help minimize adverse effects commonly seen with high-dose conventional chemotherapy. Synergistic Potential: Phytosome formulations can be combined with existing chemotherapeutics (e.g., mitomycin, paclitaxel) for additive or synergistic anticancer effects. Versatility: Suitable for oral, injectable, topical, and even ocular/respiratory delivery routes, broadening therapeutic options and patient compliance.

Challenges and limitations of phytosomes in drug delivery

Despite the promising potential of phytosomes in enhancing the bioavailability and efficacy of phytoconstituents, several challenges and limitations continue to hinder their widespread adoption in clinical settings and commercial pharmaceutical formulations.

Scalability and Cost

One of the significant challenges associated with phytosome technology is scalability for industrial production. The preparation of phytosomes often involves sophisticated techniques such as thin-film hydration, solvent evaporation, or supercritical fluid methods, which are

difficult to scale up without compromising quality and reproducibility. These methods require specialized equipment and controlled conditions, contributing to higher production costs compared to conventional drug delivery systems. Moreover, sourcing high-purity phospholipids and plant extracts further adds to the economic burden, making it less viable for large-scale applications, especially in resource-constrained settings.

Stability Issues

Phytosomes are lipid-based complexes, and like most lipid carriers, they are susceptible to oxidation, hydrolysis, and aggregation over time, especially under fluctuating storage conditions. These stability concerns can result in reduced shelf life, altered entrapment efficiency, and inconsistent drug release profiles. Additionally, maintaining the integrity of the phospholipid-phytoactive complex during formulation, packaging, and storage requires optimized formulations and possibly the addition of antioxidants or preservatives, which may raise regulatory and safety concerns.

Lack of Clinical Validation

Although numerous in vitro and in vivo studies demonstrate the improved bioavailability and pharmacokinetic profiles of phytosomes, clinical data in human populations remain limited. Most studies are preclinical, with only a few small-scale clinical trials available. This lack of large-scale, randomized, controlled clinical trials makes it challenging to confirm efficacy, safety, and long-term outcomes in patients. Consequently, healthcare providers may hesitate to recommend phytosome-based therapies due to insufficient clinical evidence and the absence of standardized treatment protocols.

Need for Regulatory Guidelines

Currently, there is a lack of specific regulatory frameworks for phytosomes in many countries. Phytosomes often fall into a gray area between nutraceuticals, herbal products, and pharmaceuticals, leading to ambiguities in quality control, safety assessment, and labeling requirements**.** Regulatory bodies such as the FDA and EMA have not established standardized guidelines for the development, approval, and marketing of phytosome-based formulations. This hampers their smooth entry into the pharmaceutical market and raises concerns about batch-to-batch consistency, product claims, and consumer safety.

RESULTS AND DISCUSSION

Phytosomes represent a significant advancement in drug delivery science, offering a novel approach to improving the therapeutic potential of herbal bioactives. The results from various studies indicate that phytosomal formulations can overcome the inherent limitations of conventional plant extracts, particularly regarding poor solubility, low permeability, and rapid metabolism.

Enhanced Bioavailability: Quantitative Evidence

Phytosomes improve pharmacokinetic behavior through their ability to form lipid-compatible complexes that enhance drug solubility and membrane permeability. Experimental data show remarkable enhancements: Silymarin phytosome increased oral bioavailability by 4.6 times over the conventional extract. Curcumin phytosome exhibited 5–10 times higher systemic exposure than free curcumin. Quercetin phytosome achieved a 3-fold increase in AUC and Cmax. These improvements are significant in formulation science as they directly correlate with higher therapeutic levels and better clinical efficacy at lower doses.

Improved ADME Characteristics

Phytosomal formulations exhibit a more favorable ADME profile compared to their non-phytosomal counterparts. The lipid component of phytosomes aids in rapid absorption, reduces enzymatic degradation, and prolongs systemic circulation. This allows for better bio-retention**,** targeted tissue accumulation, and reduced excretion rates. As a result, drugs delivered via phytosomes demonstrate more consistent pharmacological activity over time, making them especially useful for chronic therapy.

Clinical Relevance in Disease Management

Phytosomes have shown encouraging results across various therapeutic areas. In cancer, for example, phytosomes of curcumin and quercetin have demonstrated increased cytotoxic effects on tumor cells**,** improved drug uptake, and synergism with standard chemotherapeutics. In neurodegenerative diseases, phytosomal delivery enhances blood-brain barrier permeability of polyphenols, improving outcomes in preclinical models of Alzheimer’s and Parkinson’s disease. Additionally, liver disorders, cardiovascular diseases, and diabetes have shown positive responses to phytosome-based formulations of silymarin, resveratrol, and green tea polyphenols.

Phytosomes as a Versatile Drug Delivery System

What distinguishes phytosomes from other nanocarriers is their natural compatibility, ease of formulation, and ability to improve delivery without chemical modification of the active compound. This positions them as an ideal platform for plant-based therapeutics, especially in areas where synthetic drugs have limitations due to toxicity or resistance.

Limitations and Future Prospects

Despite promising results, phytosomes are not without limitations. Issues such as batch-to-batch consistency**,** storage stability**,** and limited clinical trial data restrict their widespread use in mainstream medicine. Future directions include: Standardization of production protocols, Integration with targeted delivery technologies, Conduct of large-scale clinical studies to validate efficacy and safety, Regulatory support for phytosome-based product approvals. With continued innovation, phytosomes have the potential to become a core platform in natural product-based drug development**.**

CONCLUSION

Phytosomes have emerged as a highly effective strategy for improving the delivery and efficacy of plant-derived bioactives, particularly those with poor solubility and limited bioavailability. By forming stable complexes between phytoconstituents and phospholipids, phytosomes enhance absorption across biological membranes and protect active compounds from premature degradation. This has been clearly demonstrated in pharmacokinetic studies, where silybin, curcumin, and quercetin phytosomes showed a 3- to 10-fold increase in bioavailability compared to their conventional forms. Such improvements are closely tied to enhanced ADME profiles—better absorption, targeted tissue distribution, reduced first-pass metabolism, and prolonged systemic retention. These benefits have significant implications in the field of drug formulation and development, especially for chronic conditions where long-term, low-toxicity, and effective therapies are required. In oncology, phytosomes have shown the potential to enhance anticancer efficacy, improve drug synergism, and minimize side effects through targeted delivery. Beyond cancer, their applications are expanding into the treatment of neurodegenerative diseases, cardiovascular conditions, and metabolic disorders. Furthermore, with advances in nanotechnology and personalized medicine, phytosomes could be tailored to individual patient profiles for optimized therapeutic outcomes. Overall, phytosomes offer a biocompatible, scalable, and clinically relevant drug delivery system that bridges the gap between traditional herbal medicine and modern pharmaceutical demands.

Their continued research and development hold strong potential for transforming the future of therapeutics across a wide range of diseases.

Conflict of Interest

The authors declare that there are no commercial or financial relationships that could be construed as a potential conflict of interest. This review was conducted independently and without any external influence or sponsorship. All opinions and interpretations presented are solely those of the authors.

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