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## Review Article

# Phytoniosomes: A Bridge Between Traditional Herbal Medicine and Modern Drug Delivery

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### ABSTRACT

Phytoniosomes are a new and emerging category of vesicular drug-delivery systems, which aim to address the long-standing biopharmaceutical problems with herbal-therapeutics. The conventional phytoconstituents are not always highly soluble in water, do not pass readily across membranes, are readily metabolised, and their bioavailability is not always constant even though their potential as pharmacological entities is often huge. Phytoniosomes It is a non-ionic surfactant cholesterol phytoniosomes containing hydrophilic and lipophilic molecules of herbs surrounded by a stable bilayer structure which forms a protective layer and facilitates sustained and targeted delivery. This review considers the basics of phytoniosomal preparation, such as the choice of surfactants, the methods of vesicle formation, the entrapment efficiency, and vital characterization aspects, such as particle size, zeta potential, morphology, and stability. Literature evidence indicates a markedly better curative functioning of phytoniosome-conveyed phytoconstituents such as curcumin, quercetin, silymarin, berberine, neem extract, and resveratrol. Their multifaceted potential in varied therapy against antioxidant, anti-inflammatory, anticancer, hepatoprotective, and antimicrobial effects is exemplified. The aspects of safety, toxicity, and regulation are addressed and the necessity of the normalized manufacturing process, toxicological assessment on a comprehensive basis, and international regulatory measures on nano-herbal systems are highlighted. Phytoniosomes as a whole are an important breakthrough in incorporating traditional herbal medicine with modern nanotechnology, which serves as a solid scientific basis on which more effective and reliable herbal therapeutic agents can be founded. Further development of them can give the way to clinically acceptable next-generation phytopharmaceutical products.

### INTRODUCTION

Traditional herbal medicine has been a key component in the healthcare systems in the world

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over the centuries constituting the basis of the practice of therapy in Ayurveda, Traditional Chinese Medicine (TCM), Unani and various indigenous healing practices. Such formulations are usually based on crude plant extracts that are high in terpenoids, flavonoid, polyphenols and alkaloids. Conventional herbal preparations are often less aqueously soluble, have low membrane permeability, undergo rapid metabolism, and do not have optimal therapeutic efficacy despite having significant pharmacological potential [1,2]. These restrictions have in the past prevented the translation of herbal preparations into modern evidence-based medicine, particularly in comparison with synthetic drugs, which are subject to extensive optimization of the absorption, distribution, metabolism, and excretion (ADME) parameters.

Over the past twenty years, there has been tremendous research in the area of drug-delivery systems that are a technological feat of nanotechnology and this is what has revolutionized the face of contemporary therapy. Vesicular carriers, which include liposomes, niosomes and phytosomes, have extensively been researched on to improve drug stability, solubility and controlled release properties [3]. In this background, the phytoniosomes have become a new and promising platform that can help bridge traditional herbal pharmacotherapy with the current delivery technology. The phytoniosomes are vesicles in non-ionic surfactants that have phytoniosomes of plant-derived phytoconstituents. The close structural relatedness to niosomes, accompanied by the capability of accommodating hydrophilic as well as lipophilic herbs, is a beneficial solution when compared to traditional systems [4].

The need to come up with phytoniosomes is explained by the nature of the issue of using herbal

bioactives. There are numerous strong plant extracts, including curcumin, quercetin, berberine, silymarin, among others, with vast therapeutic potential but that are not well clinically exploited because they are hydrophobic and cannot stand physiological changes [5]. The enclosure of phytoniosomal vesicles is considerably effective to increase the rates of drug entrapment, prevent the decomposition of phytochemicals by enzymes, and enhance the permeability of drugs through the skin as well as the gastrointestinal tract. Also, the cholesterol and non-ionic surfactants stabilize the vesicular membrane, thus providing the active release of herbals at the target site of action in a sustained and target-specific manner [6]. This has the effect of enhancing the efficacy of the therapeutic agent, decreasing the dosing rate and making the patient more adherent.

The compatibility of phytoniosomes with a wide variety of herbal constituents is another factor that creates interest in phytoniosomes. Medicinal plants are chemically complicated, and their pharmacological activity is normally brought about by the interactive relationship of a combination of various classes of chemicals. Phytoniosomes can encapsulate such complex mixtures which fulfill the synergistic phytochemical interaction and alleviates the degradation or excessive clearance. This is in line with holistic traditional-medicine philosophies, which focus on the whole-plant efficacy, and not the individual compounds [7].

In addition, phytoniosomes are a technology, and a conceptual bridge uniting the traditional herbal systems and modern pharmaceuticals. They maintain the curative nature of the traditional remedies but in the forms of dosage that are scientifically optimized, stable and scalable, thus making it easy to integrate them in the conventional healthcare. They have various



possible uses in different therapeutic fields that include anti-inflammatory, antioxidant, anticancer, hepatoprotective, dermatological, and antimicrobial therapy. It was shown that preclinical practices have shown improved pharmacodynamic reactions with the administration of herbal bioactives via vesicular systems as opposed to crude extracts indicating the translational worth of the practice [8].

Even after this promise, phytoniosom studies are at a very early stage of research progress and there is a shortage of clinical evidence and standardisation requirements. Issues like preparation of vesicles that can be reproduced, stability of vesicle preparation during long storage, regulatory approval, and scalable production continue to be a problem of concern. However, the continued development of nanotechnology, materials science, and herbal pharmacology have been continuously enhancing the scientific basis of phytoniosomes, making the phytoniosomes a new generation approach towards the delivery of herbal drugs.

To conclude, phytoniosomes are a promising and multifunctional instrument which is aimed at the solution of the problems that have persisted since the antiquity of the use of herbal medicines. Phytoniosomes can play an important role in expediting the movement of herbal therapeutics to the contemporary clinical setting by increasing the solubility, stability and bioavailability of phytochemicals whilst maintaining the natural pharmacological potential of herbal preparations in promoting modern clinical use. These are their formulation, characterization, applications, and an outlook in the future, which will be discussed below.

## 2. FUNDAMENTALS OF PHYTONIOSOMES

Phytoniosomes are recent non-ionic phytoconstituent-specific surfactant-based vesicular carriers that were developed to improve the delivery, stability, and bioavailability of phytoconstituents of herbs. They are a structural and functional improvement of traditional herbal preparations through linking the amphiphilic properties of niosomes to the therapeutic activity of the bioactives found in plants. Their structure is generally cholesterol, non-ionic surfactants (Span or Tween) and encapsulated phytochemicals and consists of a bilayered vesicle that is able to entrap hydrophilic and lipophilic molecules [9,10].

The minimal benefit with phytoniosomes is that they have the capacity to surmount pharmacokinetic constraints that are normally linked with herbal drugs. Numerous potent phytochemicals, including curcumin, quercetin and silymarin, are characterized by low solubility (in aqueous conditions), high first-pass metabolism and low membrane permeability resulting in low therapeutic activity with crude extracts. The phytoniosomes have the ability of improving solubility, enzymatic degradation, and enhanced transdermal and gastrointestinal absorption through encapsulation [11,12]. The surfactant also regulates the fluidity of membranes, enhancing the vesicle deformability and penetrability in biological tissues.

The phytoniosomes are often prepared by thin-film hydration, ether injection, sonication, or reverse-phase evaporation in which case surfactants and cholesterol spontaneously produces bilayers around the herbal active [13]. Surfactant ratios, medium of hydrating, pH, and temperature can be used to optimize the physicochemical properties of the system, which include particle size, zeta potential, lamellarity and entrapment efficiency. All of these parameters determine the stability of



vesicles, their release kinetics, and biological interaction profile [14].

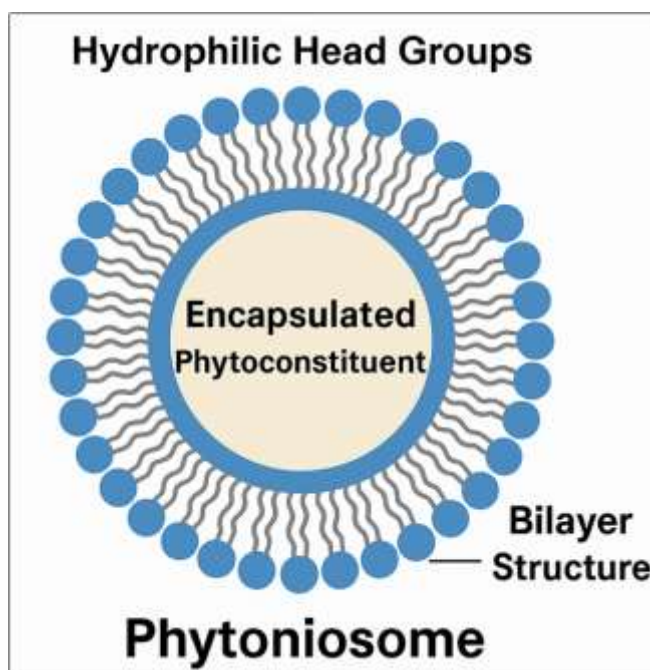
Phytoniosomes have a number of benefits over other nano-herbal system like phytosomes and liposomes and they include low cost, increased stability, simple to prepare, and can be easily scaled to an industrial scale [15,16]. Their capacity to package complicated mixtures of herbs places them into special use in traditional medicine in

which treatment already depends on synergistic actions among phytochemicals [17].

Phytoniosomes show improved antioxidant as well as anti-inflammatory and hepatoprotective and antimicrobial action as monitored in several preclinical research [18,19]. Current studies are being done to use them in both systemic and topical delivery systems with good prospects of their use in both targeted therapy and controlled release of multi-component herbal actives [20].

**Table 1. Key Components and Functions of Phytoniosomes**

Component	Function in Vesicle	Relevance to Herbal Delivery
Non-ionic surfactants (Span/Tween)	Form bilayer, enhance flexibility	Improve permeability of phytoconstituents
Cholesterol	Stabilizes membrane structure	Prevents leakage, enhances vesicle rigidity
Phytochemicals	Therapeutic agents	Provides pharmacological activity
Hydration medium (buffer)	Facilitates vesicle formation	Influences size and entrapment efficiency



**Figure 1. Schematic Representation of a Phytoniosome**

### 3. TRADITIONAL HERBAL MEDICINE & CHALLENGES IN DELIVERY

Conventional herbal medicine conventional medicine has been the foundation of the health care system since millennia, and it was the foundation of Ayurvedic, Chinese, Persian and

other native herbal systems of health care. The herbal preparations have various phytochemicals, such as flavonoids, alkaloids, terpenes, glycosides among others, which emerge with antioxidant, anti-inflammatory, antimicrobial, hepatoprotective, and immune-enhancing properties. This extensive therapeutic potential is

not without significant opposition to their current pharmaceutical assimilation practice with the large part being the poor biopharmaceutical performance of numerous herbal constituents. Many plant-based products have low aqueous solubility, low permeability, unstable in gastrointestinal environments, and broken down hepatically, have a highly constrained systemic exposure, and are relatively ineffective as a therapeutic modality [21,22].

Moreover, herbal extracts are multicomponent mixtures of complex types whose physicochemical characteristics also depend on the geography, harvesting, and cultivation as well as on extraction. This non-standardization leads to non-uniform therapeutic response, which makes it difficult to determine the dosage, as well as achieve clinical reproducibility [23]. Lots of phytoconstituents have big molecular masses or lipophilic arrangement that deter treatment of the membrane and some are easy to disintegrate under light, pH fluctuations, or enzymatic schemes [24]. These difficulties emphasize that efficient delivery systems that would help in maintaining phytochemical stability as well as improving absorption are required.

The other aspect of concern is that, traditional oral or topical preparations of herbs tend to provide inadequate levels of active components to the tissues of interest. Quick first-pass metabolism, enzyme degradation and lack of cellular uptake decrease drug efficacy and cause higher dose levels which might lead to toxicity or gastrointestinal side effects [25]. Moreover, a number of the herbal molecules experience the effect of multidrug-efflux mediated clearance which reduces intracellular retention and pharmacological efficacy [26].

The new opportunities in nanotechnology have offered new ways of overcoming these constraints.

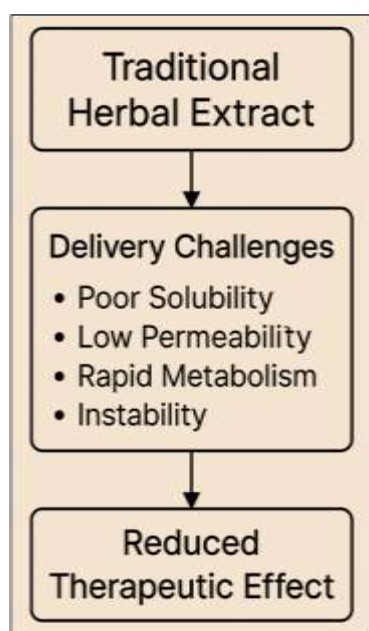
Liposomes, phytosomes, niosomes and more recently, phytoniosomes vesicular drug delivery systems provide protective encapsulation of sensitive herbal molecules, enhance solubility, permeability, and release progression [27]. These systems enable simultaneous delivery of interactive phytochemicals, are capable of maintaining multi-component integrity, and are improved when it comes to targeting tissues.

Although this has become increasingly popular, hybridization of the traditional herbal knowledge and the current pharmaceutical technologies needs to be scientifically verified. Problems related to scalability in formulations, quality control and regulatory approval should be addressed before nanotechnology-enhanced herbal products can be used widely in clinical setting [28,29]. The awareness of the problems leads to the critical role of refined delivery system like phytoniosomes that seek to reconcile the gaps between the traditional herbal knowledge and contemporary treatment criteria.

**Table 2. Key Challenges in Delivering Traditional Herbal Medicines**

Challenge	Description	Impact on Therapy
Poor solubility	Many phytochemicals are hydrophobic	Low absorption and bioavailability
Instability	Degradation by pH, enzymes, or light	Reduced potency
Rapid metabolism	First-pass hepatic elimination	Short half-life
Poor permeability	Large or polar molecules	Limited tissue penetration
Lack of standardization	Variability in extracts	Inconsistent therapeutic outcomes





**Figure 2.** *Conceptual Illustration of Challenges in Herbal Drug Delivery*

#### 4. PHYTONIOSOMES AS A MODERN DELIVERY TOOL

Phytoniosomes have become a much-needed workable vesicular delivery platform, which unites the therapeutic efficacy of herbal phytoconstituents with the architectural benefit of non-ionic surfactant-based nanocarriers. Their basic mechanism is due to the centralization of bilayer vesicles formed of cholesterol and surfactants that surround herbal actives either in the aqueous center or lipid bilayer as per their solubility characteristics. The design will help enhance stability of the drugs and phytochemicals, reduce degradation and increase release control kinetics [30].

Poor solubility, lack of sufficient membrane permeability, rapid metabolism, and poor bioavailability are some of the major constraints of traditional herbal formulations. These problems are overcome by phytoniosomes that enhance vesicle deformability, mucosal adhesion, and deep penetration into biological membrane thereby guaranteeing the improved absorption and

bioavailability of herbal compounds [31]. They can be useful at vesicular delivery by efficiently encapsulating hydrophilic and lipophilic molecules due to their flexible architecture and extend the range of herbal extracts that can be delivered by vesicles.

One of the greatest advantages of phytoniosomes is that they improve the treatment effect of phytochemicals and their natural shape is not changed. Better pharmacokinetic properties which include a longer circulation duration, prolonged release of drugs and lowering the number of doses are commonly seen in phytoniosomal formulations over conventional herbal extracts [32]. They are particularly beneficial to such herbal constituents as curcumin, quercetin, and silymamarin, which otherwise show low systemic exposure when taken orally.

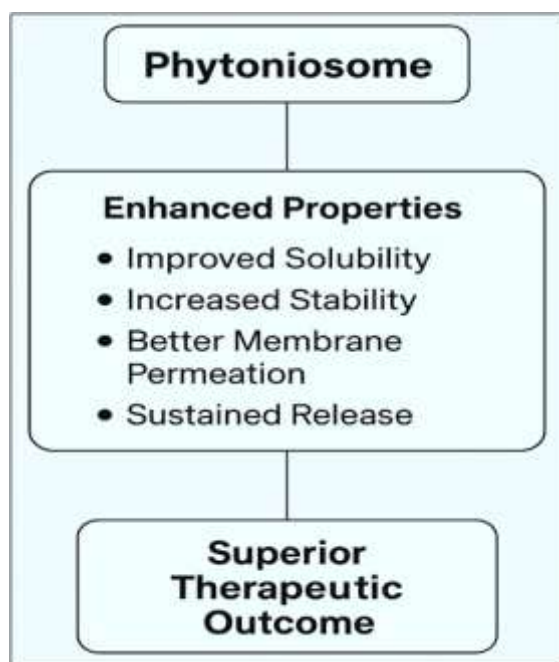
There is also good potential in phytoniosomes in topical and transdermal herbal delivery. They are appropriate in dermal applications that need the localized or systemic absorption because of their small sizes, improved deformability, and penetration in the presence of a surfactant [33]. Research has presented enhanced skin permeation and skin retention of phytoniosomal herbal encapsulating molecules, and there are legitimate applications in supporting skin antimicrobial, anti-inflammatory and wound-healing studies [34].

On the manufacturing side, the advantages of phytoniosomes include low cost of production, scalability, and comparatively easy preparation techniques in comparison with liposomes and other nanoparticles [35]. Their stability characteristics are also better because the non-ionic surfactants are inherently more robust and this lowers aggregation and oxidation problems that tend to afflict phospholipid-based systems.

In general, phytoniosomes can be considered a novel, effective, and universal herbal drug-delivery system, which can fill the gap existing between traditional phytotherapy and modern pharmaceutical technology. Their capacity to enhance solubility, augment permeability, augment stability, and maximize therapeutic effect makes them a promising drug product in terms of next-generation natural-product-based therapeutic products [36].

**Table 3. Advantages of Phytoniosomes Over Traditional Herbal Formulations**

Parameter	Traditional Herbal Extracts	Phytoniosomes
Solubility	Often poor	Significantly enhanced
Stability	Vulnerable to degradation	Protected via vesicle encapsulation
Permeability	Limited tissue penetration	Higher membrane transport
Bioavailability	Low to moderate	Substantially improved
Release Profile	Uncontrolled	Sustained and targeted



**Figure 3. Schematic Representation of Phytoniosomes as a Modern Herbal Delivery Tool**

## 5. FORMULATION ASPECTS OF PHYTONIOSOMES

Phytoniosomes design Phytoniosomes design entails a reasonably ordered combination of non-ionic surfactants, cholesterol, and phytoconstituents that form stable bilayer vesicles that can be utilized to improve the delivery of herbal drugs. The surfactant selection is at the center of vesicle size, rigidity, entrapment efficiency and permeability. Sulfate surfactants, including Span 20, Span 60, Tween 20, Tween 80, etc. vary in terms of their HLB values, which affect the formulation of the vesicles and the encasement of the phytochemicals [37]. Vesicles can be formed by using the surfactants with the right HLB value that stabilizes the vesicles as much as possible.

Phytoniosomal preparations have cholesterol parameters as an essential stabilizer. Its inclusion into the bilayer increases the rigidity of the membrane, decreases leakage of the herbal compounds trapped by it, and increases the stability of the vesicles in storage [38]. Surfactant-to-cholesterol ratio has a pronounced influence on the vesicles morphology whereby increasing the cholesterol concentration tended to stabilize the vesicles but it decreased the deformability. It is therefore important to have the best ratio in order to balance rigidity, flexibility and entrapment efficiency.

Phytoniosome formation is usually done using several methods which include thin-film hydration, ether injection, reverse-phase evaporation and sonication. The most common technique has been the thin-film hydration method because of ease and the capability of synthesizing homogeneous vesicles with a large encapsulation ability [39]. Hydration temperature, duration, pH of the medium, agitation speed, and hydration time are process variables that affect vesicle

characteristics and have to be optimized as closely as possible to facilitate stable performance.

Another parameter of importance is the degree of entrapment efficiency which is the degree to which the herbal active has been entrapped into the vesicular structure. The choices of surfactant, cholesterol and phytochemical solubility, as well as hydration are all direct factors in encapsulation [40]. The entrapment efficiency is high thereby boosting bioavailability and protecting herbal molecules of sensitive nature.

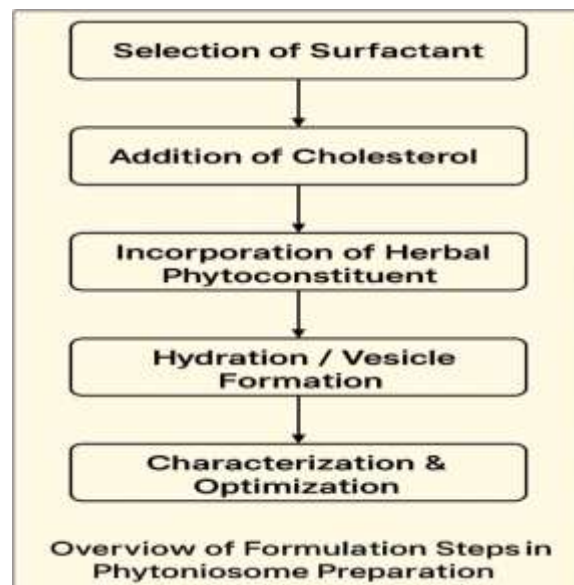
Such methods of characterization as particle-size distribution analysis, zeta potential measurement, scanning electron microscopy (SEM), transmission electron microscopy (TEM), and differential scanning calorimetry (DSC) are needed to evaluate the quality of the formulation [41,42]. Additional stability research has also been performed under different temperature and humidity and this determines the shelf-life and the applicability of the phytoniosomes in as a pharmaceutical [43].

The general trends are that the phytoniosomes have to be formalized so that the choice of surfactant, the proportion of cholesterol, the method of preparation, and the parameters of the process are optimally selected, which enables the formation of a stable and effective vesicular delivery system of herbal phytochemicals.

**Table 4. Key Formulation Components and Their Functional Roles**

Component	Role in Formulation	Impact on Final Vesicle
Surfactant (Span/ Tween)	Bilayer formation	Affects size, flexibility, entrapment
Cholesterol	Membrane stabilizer	Enhances rigidity, reduces leakage

Hydration Medium	Activates vesicle formation	Influences size and encapsulation
Phytoconstituent	Therapeutic agent	Determines vesicle loading capacity



**Figure 4. Overview of Formulation Steps in Phytoniosome Preparation**

## 6. PHYTONIOSOME-BASED DELIVERY OF MAJOR HERBAL PHYTOCONSTITUENTS

Phytoniosomes have been under scrutiny in order to improve the therapeutic efficacies of a number of herbal phytoconstituents that have limited bioavailability, poor instability, and solubility. The encapsulation of phytochemicals in phytoniosomal vesicles significantly enhances or alters the pharmacokinetic and pharmacodynamic properties of phytochemicals by allowing phytoniosomal vesicles better permeability over the membrane, prolonged release, and inhibition against degradation by enzymes [44]. This has culminated in a couple of phytoniosomes herbal compounds formulations which have been tested to have improved biological activity.

Curcumin is a strong anti-inflammatory and anti-oxidant compound that has been shown to have much better solubility and absorption in

phytoniosomal form. Research indicates that it exhibits a more cytotoxic and enhanced wound-healing properties in comparison with the conventional preparation of curcumin [45]. Likewise, quercetin is a flavonoid that has a strong antioxidant and cardioprotective effect, which is better absorbed using phytoniosomes, it increases its entrapment satisfaction, and its therapeutic results [46].

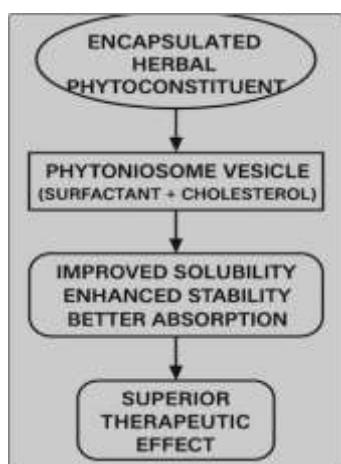
Silymarin, which finds wide application as a hepatoprotective agent, is poorly bioavailable orally; this is owing to poor aqueous solubility. Phytoniosomal encapsulation increases its dissolution and liver-targeting ability leading to improved hepatoprotective effects in preclinical research [47]. Berberine is another antimicrobial and antidiabetic agent, which has the advantage of phytoniosomal delivery with improved intestinal permeability and reduced P-glycoprotein efflux, which in combination have improved systemic exposure [48].

The neem (*Azadirachta indica*) extract that contains many limonoids, and flavonoids was formulated in phytoniosomes to enhance its antimicrobial and anti-inflammatory activity. The vesicular system allows control of release and penetration of the tissues, which applies in both topical and systemic applications [49]. Resveratrol is yet another bioactive in this category showing better stability and antioxidant properties when encapsulated by phytoniosomes with an increased bioavailability and uptake by cells [50].

In general, phytoniosomal transfer of herbal phytoconstituents overcomes significant biopharmaceutical obstacles, and provides a mechanism of enhanced therapeutic adoption in various disease sectors. These results support the prospect of phytoniosomes as a replacement delivery system of herbal medicines in the future.

**Table 5. Examples of Herbal Phytoconstituents Delivered Through Phytoniosomes**

Phytoconstituent	Therapeutic Use	Benefit of Phytoniosomal Delivery
Curcumin	Anti-inflammatory, anticancer	Improved solubility & bioavailability
Quercetin	Antioxidant, cardioprotective	Enhanced permeability & efficacy
Silymarin	Hepatoprotective	Better dissolution & liver targeting
Berberine	Antidiabetic, antimicrobial	Reduced efflux & increased absorption
Neem extract	Antimicrobial, anti-inflammatory	Controlled release & deeper penetration
Resveratrol	Antioxidant	Improved stability & cellular uptake



**Figure 5. Conceptual Illustration of Phytoniosomal Delivery of Herbal Actives**

## 7. CHARACTERIZATION TECHNIQUES

To comprehend physicochemical characteristics, stability, and applicability of phytoniosomes as herbal drug-delivery vehicles, characterization of phytoniosomes is required. The appropriate evaluation will guarantee uniformity in vesicle creation, filling, liberation, and drug action. Parameters evaluated by different methods of analysis let include the size of the particles, their zeta potentials, morphology, entrapment efficiency, and thermal stability [51].

### Particle Size and Distribution:

DLS is extensively employed to determine the size of vesicles and polydispersity index (PDI). The size of particles affects strongly cellular endocytosis, pharmacokinetics of release and biodistribution. Smaller sized vesicles tend to be more permeable and stable whilst large sizes tend to release slower [52].

### Zeta Potential:

Surface charge is calculated by Zeta potential analysis and colloidal stability is anticipated. Large values of abs zeta potential are associated with a high degree of electrostatic repulsion between vesicles hence minimizes aggregation and enhances long-term storing stability [53].

### Morphological Examination:

The surface topology, shape and lamellarity of phytoniosomes are demonstrated with the aid of Transmission Electron Microscopy (TEM), Scanning Electron Microscopy (SEM) and Atomic Force Microscopy (AFM) [54]. TEM is perfect to identify vesicle bilayers whereas SEM offers morphology of the surface. AFM can be used to image nanoscale in wet conditions, which is why it is applicable to soft vesicles [55].

### Entrapment Efficiency (EE%):

The efficiency of the entrapment is indicated as a percentage of the phytoconstituent that is effectively delivered into the vesicles. It is usually assessed by centrifugation and spectrophotometric or chromatographic analysis of drug that is not

entrapped. EE% is sensitive to the concentration of the surfactant, cholesterol ratio and phytochemical solubility [56].

### Fourier Transform Infrared Spectroscopy (FTIR) & Differentiating Scanning Calorimetry (DSC):

FTIR assists in the identification of interaction between surfactants, cholesterol, and phytoconstituents through identification of functional group shifts. DSC can give a deeper understanding of the behavior of thermal analysis, melting, and changes in crystallinity, which prove the formation of vesicles and drug entrapment [57].

### In Vitro Release Studies:

The release patterns of herbal actives of phytoniosomes are assessed through dialysis techniques. Such tests can be used to identify sustained-release properties and in vivo behavior [58].

### Stability Studies:

Stability is also tested using different temperatures, humidity, and under light conditions to determine the capability of vesicles to survive. The size, zeta potential and entrapment efficiency are observed parameters influencing integrity of formulation [59].

All of these methods provide in-depth understanding of the phytoniosomes functioning and allow the optimization of the therapeutic effect.

**Table 6. Key Characterization Techniques and Their Purpose**

Technique	Parameter Assessed	Purpose
DLS	Particle size, PDI	Predicts stability & uptake
Zeta Potential	Surface charge	Indicates colloidal stability
TEM / SEM / AFM	Morphology	Confirms vesicle structure
EE% Analysis	Drug loading	Measures entrapment efficiency



FTIR / DSC	Molecular interactions, thermal behavior	Verifies encapsulation & compatibility
In Vitro Release	Release kinetics	Evaluates sustained delivery
Stability Testing	Physical & chemical stability	Determines shelf-life



Figure 6. Conceptual Flow of Phytoniosome Characterization Techniques

## 8. THERAPEUTIC APPLICATIONS OF PHYTONIOSOMES

Phytoniosomes have also been a promising nanocarrier that has great contributions to improve the therapeutic performance of herbal phytoconstituents in various areas of clinical application. Phytoniosomes allow the delivery of herbal actives, which have poor biopharmaceutical properties, to be effectively delivered through better solubility, stability and membrane permeability. It has led to significant gains in the anti-inflammatory, antioxidant, anticancer, antimicrobial, hepatoprotective, dermatology and cardioprotective uses [60].

### Anti-inflammatory and Antioxidant Therapy:

The use of herbal compounds e.g. curcumin, quercetin and resveratrol has poor bioavailability as free form. Phytoniosomal encapsulation increases their dissolution, allows more penetration into deep tissues and extends the

period of circulation and therefore yields life force anti-inflammatory and antioxidant effects than traditional formulation [61].

### Anticancer Applications:

A number of phytochemicals have strong anticancer effects, yet little therapeutic effects because of rapid metabolism and low absorption into cells. Phytoniosomes can circumvent such obstacles with increased efficacy, increased cytotoxicity of the drug being directed to cancer cells and decreased systemic toxicity through the increased drug delivery via intracellular pathways and extending the release of the drug [62].

### Hepatoprotective Uses:

There has been a greater liver-targeting efficiency of phytoniosome delivery of silymarin, andrographolide and other hepatoprotective herbs. Increased bioavailability translates to increased antioxidant protection, inhibition of lipid peroxidation, and defence against chemologically-induced hepatic injury [63].

### Dermatological Applications:

The vesicles are deformed, which allows an increased permeation of the skin of the phytoniosomes. This is particularly useful in the treatment of inflammatory skin diseases, microbial and hyperpigmentation and in healing wounds. Topical herbal agents (encapsulated) have enhanced dermal retention and tissue penetration, relative to the topical creams/gels [64].

### Antimicrobial and Antiviral Uses:

Examples of neem, berberine, and tea tree oil herbal extracts have a higher antimicrobial activity

when administered in phytoniosomes. Improved membrane permeation and continuous release facilitates greater delivery of the microbial cell walls and biofilms [65].

### Cardioprotective and Metabolic Effects:

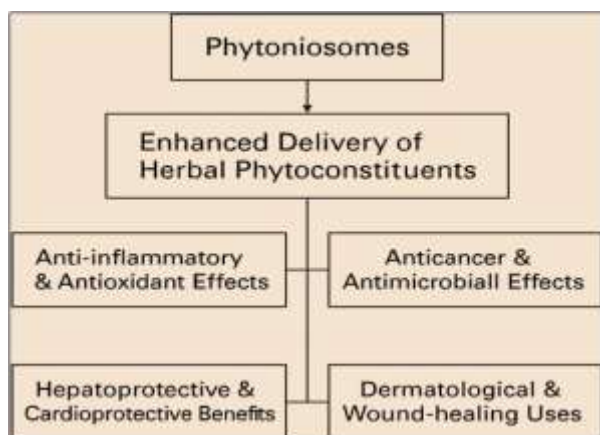
Phytoniosomal, formulations of flavonoids and polyphenols have demonstrated a greater cardiovascular protective effect, better antioxidant

effect, lipid regulation and endothelial performance [66]. Encapsulation enhances oxidative stress and glucose management in metabolic malfunctions [67].

Taken together, these results indicate the wide range of therapeutic applications of phytoniosomes as a new platform of herbal medicines with greater clinical effects.

**Table 7. Major Therapeutic Areas Benefiting from Phytoniosomal Delivery**

Therapeutic Area	Herbal Actives	Key Benefits of Phytoniosomes
Anti-inflammatory	Curcumin, Boswellia	Higher absorption, stronger response
Antioxidant	Resveratrol, Quercetin	Improved stability and bioavailability
Anticancer	Curcumin, Berberine	Enhanced uptake, sustained cytotoxicity
Hepatoprotective	Silymarin, Andrographolide	Better liver targeting, improved efficacy
Dermatological	Neem, Aloe vera	Enhanced permeation & dermal retention
Antimicrobial	Tea tree oil, Neem	Stronger activity via sustained release
Cardioprotective	Polyphenols, Flavonoids	Improved endothelial and antioxidant effects



**Figure 7. Conceptual Representation of Therapeutic Applications of Phytoniosomes**

## 9. SAFETY, TOXICITY AND REGULATORY PERSPECTIVES

Safety and regulatory assessment of phytoniosomes needs to be done before their clinical application since herbal nanoparticles should comply with the pharmaceutical standards of quality, safety, and effectiveness. Though the phytoniosomes are usually made using biocompatible ingredients, although these include non-ionic surfactants, cholesterol, and herbal actives, it is important to consider the toxicological

profile of these phytoniosomes so as to guarantee patient safety. Because of lack of irritation pathogenicity and minimum systemic toxicity, non-ionic surfactants are commonly used in drug-delivery systems, with Spans and Tweens being the most commonly used surfactants. Nevertheless, when used in excess amounts or over an extended period, they can cause disruption of membranes or even cytotoxicity and require regulated parameters of formulation [68].

Surface charge, composition and size of nanocarrier play a significant role that affects biodistribution and toxicity. Smaller vesicles can closely infiltrate cells and tissues, and therefore, it might cause unwanted accumulation. Thus, thorough in vitro and in vivo toxicological testing such as cytotoxicity, hemolysis investigations, oxidative stress detection and organ histopathology are necessary to achieve safety [69]. The other issue is how the phytoniosomes react with the immune cells. Though non-immunogenic most combinations of surfactants

can cause mild inflammation, which highlights the importance of immunocompatibility studies [70].

There is the added complication of herbal components. Even though phytochemicals are safe in their natural form, they may become toxic in dosage, have a herb-drug interaction, or cause metabolic up-setting. Encapsulation can lead to changes in the pharmacokinetics based on the possibility of a higher systemic exposure, thus, the toxicity measurements need to take into account the free and the nano-encapsulated counterparts [71].

Regulatively, herbal nanocarriers have special problems. Nano-herbal formulations do not have any dedicated global regulatory schemes which further leaves the classification ambiguity of whether it is a nano-medicine, herbal products, or combination products [72]. The FDA, EMA and WHO are agencies that propose strict characterization, safety data, and reproducibility criteria of formulations of nanotechnology. Problems of batch-to-batch consistency, long-term stability, scalability and phytochemical standardization should be taken to the extreme and these issues need to be fully met before the nod [73].

Regulatory authorities focus on Good Manufacturing Practices (GMP) of herbal material i.e. authentication, purity test and control of contaminants. Also, nanospecifics also have specific guidelines to be characterized in detail, including physicochemical-characterization, stability investigations, and risk-to-benefit assessment [74]. The significance of post-marketing surveillance is that herbal products can differ in their composition as they are produced by different plants, using different extraction and they may differ with seasonal changes [75].

In general, enhancing phytoniosomal formulations through ensuring safety and regulatory conformity is a requisite that provides translation into clinically viable therapeutic modalities. The combination of toxicological assessment and the sound standardization and international regulatory models will ease their placement in the mainstream medicine.

**Table 8. Safety and Regulatory Considerations for Phytoniosomes**

Aspect	Key Concerns	Requirements
Surfactant Safety	Cytotoxicity, irritation	Optimal concentrations, biocompatibility studies
Nano-toxicity	Cellular uptake, accumulation	In vitro & in vivo toxicity testing
Herbal Component Variability	Dose-dependent effects, impurities	Standardization, quality control
Stability & Scalability	Aggregation, reproducibility	GMP manufacturing, validated methods
Regulatory Compliance	Lack of clear nanomedicine rules	Detailed documentation, risk assessment

## 10. DISCUSSION

Phytoniosomes is an important breakthrough in herbal drug delivery as this is a technological gap bridging the traditional wisdom in healing with modern pharmaceutical science. Their capacity to entrap lipophilic and hydrophilic phytoconstituents position them at the top of nanovesicular delivery systems to enhance the herbal bioavailability as well as pharmacological efficacies. The literature persistently points out that phytoniosomal formulations have improved solubility, stability, and targeted delivery; this is exhibiting a wide potential usage with categories of therapeutics.

One of the most common themes of the studies is the enhancing effect on biopharmaceutical profiles



to a significant degree. Formulations of traditional herbs often have low solubility, high metabolism and low penetrance—a combination that significantly decreases clinical actions. Phytoniosomes can overcome these constraints by building up protective bilayers, which block degradation of phytochemicals and release them gradually and with control. They are able to intentionally penetrate the tissues and gain uptake by the cells because of their small size (nanoscale), thus improving therapeutic responses even when they penetrate tissues with low doses. Such improvements are most obvious with curcumin, silymarin, quercetin and berberine all which show significant advances in antioxidant, anti-inflammatory or anti-cancer activity in being provided using phytoniosomes.

The other notable finding is their versatility based on routes of administration. The advantages of oral formulations are enhanced dissolution and intestinal absorption whereas topical application has other advantages margins of dermal penetration and retention. This provides immense benefits in the treatment of dermatological diseases, localized inflammation and systemic metabolic diseases. Moreover, vesicular delivery maintaining interactions through multi-action in a complex of herbs- the property provides programs consonant with natural medicine cysticphilosophy of the whole-plant effectiveness.

Nevertheless, there still are restrictions despite its promise. The major challenge is standardization of natural materials; although the phytochemical composition is influenced by the source of the plant, cultivation, extraction, season, etc. This variability may impact on vesicle formation, entrapment efficiency and reproducibility. Also, the precise fine-tuning of the surfactant and cholesterol ratios is important to prevent the unwanted toxicity and instability. More complex

characterization methods can be used to overcome such concerns, although more comprehensive coordination of the protocols of analysis is needed to be wide-spread.

Rapid commercialization is not facilitated by regulatory barriers as well. The present-day international systems lack the capability to test nano-herbal products which poses a uncertainty in classification and process of approval. Safety issues, in specific the long term exposure to surfactants or nanoparticles, need to be tested carefully based on proven toxicological data. Another important necessity is to establish manufacturing procedures that are GMP compliant since to use them in clinics, the consistency in batches to batches is required.

To conclude, phytoniosomes have a bright future as a new system of delivering herbal drugs. This capability to surmount biological and physicochemical obstacles makes them a new instrument that can be used in converting clinically-failing herbal molecules into effective therapeutic agents. Combining the long-standing knowledge in botany together with the latest advancement in nanoscience can lead to new prospects in coming up with customized, efficient and safer natural-based medicines. The research in the future should concentrate on harmonizing the regulation, mass production, and clinical validation so that they could be introduced in the mainstream healthcare.

## 11. CONCLUSION

Phytoniosomes provide a radical approach to improving the clinical potential of herbal phytoconstituents to overcome the historical drawbacks due to the insolubility, lack of stability, and bioavailability observed with traditional herbal preparations. Phytoniosomes provide better protection, deliver over an extended release and



targeted delivery of hydrophilic and lipophilic herbal actives through the inclusion of non-ionic surfactants and cholesterol into a stable vesicular system. Such improvements greatly increase therapeutic performance in a wide range of applications- as anti-inflammatory, antioxidant, anticancer, hepatoprotective, and dermatological therapies, as well as cardioprotective therapies.

They are also compatible with more complex herbal mixtures, which also maintain the synergistic effects that traditional medicine is known to be highly conscious of. Although optimistic, the fact remains that to successfully put phytoniosomes into clinical use, intense safety evaluation, standard manufacturing and compliance with dynamic regulations are mandatory. Further investigation of optimization of the formulation parameters, long term toxicological studies and creating strong clinical evidence will be essential.

Altogether, phytoniosomes are a new and effective blend of an ancient wisdom of herbs and contemporary nanotechnology. They provide a way to more effective, reliable, and science-based herbal medicines that could satisfy the modern therapeutic needs.

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