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A COMPREHENSIVE REVIEW ON PHYTOSOMES

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ABSTRACT

The effectiveness of any formulation depends on the delivery of the effective level of the therapeutically active compound. The term "Phyto" means plant and "some" means cell It is also mentioned as herbosomes this is a new patented technology, where standardized plant extracts or water soluble phytoconstituents are complexed with phospholipids to produce lipid compatible molecular complexes, there by greatly increasing absorption and bioavailability.

Phytosomes are complexes of phospholipids and naturally active phytochemicals that have been widely used in medicine since ancient times. This system allows a phytoconstituent to enter the bloodstream through the inner membrane of the intestine.

The improved absorption and pharmacological properties of phytosomes can be used to treat various diseases. Phytosomes are superior to conventional drug delivery systems due to their pharmacokinetic and pharmacodynamic properties. Most of the bioactive compounds in phytomedicines are soluble in water. They include flavonoids, terpenoids, and glycosides in which flavonoids perform broad therapeutic activities.

The phytoconstituents, especially polyphenolic and flavonoids, have various pharmacological activities such as anticancer, antidiabetic, hepatoprotective, anti-inflammatory, anti-obesity as well as cardioprotective.

The bioavailability of polyphenolic compounds can be improved by integrating them into the phospholipid-based self-assembled delivery systems, which are referred to as phytosomes or herbosomes. Phytosomes are vesicles in which the phospholipids bond with the hydrogen in the polyphenolic components to deliver the drugs to the targeted site without their metabolism.

Keywords: Phytosomes, Phyto-phospholipid complex, Phospholipids, Herbal Extract, Phytoconstituents

1. INTRODUCTION:

Chemical compounds with biological activity derived from herbal extracts, traditionally employed in home cures, are increasingly being incorporated into contemporary medicine.

Although most of the physiologically active components of plants are polar or water soluble, their limited absorption hinders their use and thus reduces their bioavailability. In order to enhance bioavailability, herbal products need to maintain effective equilibrium between hydrophilicity (for absorption into the fluid of the gastrointestinal system) and lipophilicity (for crossing lipid biomembrane) **[1]**.

While some key components of herbal medicine, such as glycosides and flavonoids, are readily soluble in water, their effectiveness is limited due to their partial solubility or hydrophobic nature. Consequently, when given topically, these components exhibit reduced therapeutic efficiency. Considerable attempts have been made to improve the bioavailability of these drugs by developing them for targeted drug delivery systems, such as phytosomes and liposomes, which are considered promising alternatives. Employing these methods in the formulation creation process can result in superior bioavailability of herbal medicines compared to traditional herbal extracts **[2]**.

In the Nano form, phytosomes refer to herbal drugs that are encapsulated within vesicles. Phytosomes form a protective layer around the active component of a medicine, rendering the primary component of a herbal extract resistant to breakdown by digestive secretions and bacteria. A phytosome is capable of efficiently absorbing substances from a water-repellent environment into the lipid-rich environment of the cell membrane and ultimately reaching the bloodstream. The present analysis focuses on the future potential and developing technologies in the domain of Neural Drug Delivery Systems (NDDS) for the advancement of herbal and traditional medicines derived from plants **[3]**. The term "Phyto" refers to a plant, whereas "some" denotes a cell-like structure. It is alternatively referred to as herbosomes. This is a novel intellectual property technology in which standardized plant extracts or water soluble phytoconstituents are combined with phospholipids to form lipid compatible molecular complexes, therefore significantly enhancing absorption and bioavailability. Phosphatidylcholine, phosphatidylserine, phosphatidylethanolamine, and phosphatidylinositol are phospholipids commonly employed for their targeted therapeutic effects in liver disorders, alcoholic steatosis, drug-induced liver damage, and hepatitis. Furthermore,

phospholipids serve as natural digestive aids and as carriers for nutrients that are both fat miscible and water miscible. Both the enterohepatic cell membranes and the stratum corneum layer of the epidermis can be readily traversed by phytosomes along their lipophilic pathway **[4]**.

2. ADVANTAGES OF PHYTOSOME VESICLES [5]

1. The drug's bioavailability has shown a significant rise.

2. Phytosomes provide herbal medications with an extended duration of action.

3. Phytosomes enhance the bioavailability of hydrophilic polar phytoconstituents by promoting their absorption through nasal, topical, and other administration routes.

4. Phytosomes are small cells that retain the essential constituents of herbal extracts by preventing their breakdown by digestive fluids and intestinal microorganisms.

5. Phytosomes facilitate the targeted delivery of drugs to the required tissues.

6. Chemical linkages established between the phosphatidylcholine molecule and elements derived from plants.

7. Phytosomes exhibit a robust stability profile.

8. Phytosomes effectively improve the transdermal absorption of phytoconstituents and are widely employed in cosmetics because of their enhanced skin penetration and high lipid profile.

3. PROPERTIES OF PHYTOSOMES

3.1 Physicochemical properties

Phytosomes are synthetic compounds that are chemically bonded with phospholipids. The formation of this complex involves the combination of phospholipids and the substrate in stoichiometric amounts inside an appropriate solvent. Spectroscopic findings indicate that the primary interaction between phospholipids and substrates is the establishment of hydrogen bonds between the polar head of phospholipids (namely the phosphate and ammonium groups) and the polar functionality of the substrate. Phytosomes adopt a micellar morphology upon contact with water, therefore forming a liposomal architectural arrangement. This may be deduced by comparing the NMR of the complex with that of the pure precursors. The fatty chain's orientations remain nearly unaltered. These findings indicate that the two elongated aliphatic chains wrap around the active material, creating a lipophilic protective layer that safeguards the polar head and active components of the phospholipid **[6]**.

3.2 Biological properties

Phytosomes are sophisticated herbal chemicals that give more efficient absorption, utilization, and thereby produce superior results compared to conventional herbal extracts. Numerous pharmacokinetic studies and pharmacodynamic investigations conducted on laboratory animals and human subjects have

demonstrated that phytosomes have superior bioavailability compared to non-complexed plant derivatives **[7]**.

4. Comparative Evaluation of Phytosome, Liposome, Niosome, Ethosome, and Transfersome in Nano-Delivery systems

Characteristics	Phytosome	Liposome	Niosome	Ethosome	Transfersome
Composition	Phospholipids &polyphenolic phytoconstituents	Phospholipids and Cholesterol	Non-ionic surfactant and cholesterol	Phospholipid, alcohol, polyglycol and water	Phospholipids and surfactant mixture
Flexibility	Rigid	Rigid	Rigid	Elasticity	Ultra-deformable
Main application	Phyto-delivery	Drug and gene delivery	Drug delivery & cosmetics	Skin delivery	Skin delivery
Administration	Oral, parenteral topical, transdermal	Oral, parenteral topical, transdermal	Oral, parenteral topical, transdermal	Topical and transdermal	Topical and transdermal
Key features	High entrapment efficiency along with a depot formation which releases the contents slowly	Bio-compatibility capacity for self assembly, ability to carry large drug payloads	Improved dispersion of with solubility issues,high stability, low-cost materials	Enhance permeation of drugs across/through the skin in an efficient manner	High deforming Ability which ensures deeper penetration in skin layers
Limitations	Leaching of the phytoconstituents which reduces the desired drug concentration indicating their unstable nature	Low skin penetratio , low tability	Low skin penetration and toxicity of surfactant	Poor yield, coalescence and fall apart on transfer into water, Loss of product During Transfer form organic to water media	Toxic effect of surfactant
Marketed Product	Leucoselect, Greenselect, Panax ginseng, Sabalselect, etc.	Doxil, Abelcet, Visudyne, DepoDur,etc.	Lancome and L'Oreal	MaccabiCARE, Nanominox, Trima, etc.	Daktarin

5. METHODS OF PREPARATION

Phytosomes are often formed by combining precise quantities of phospholipid, specifically Soya lecithin, with herbal concentrates in an aprotic solvent. The primary component of soy lecithin is Phosphatidylcholine, which has a dual purpose. This compound is lipophilic in its phosphatidyl group and hydrophilic in its choline group. The choline component is saturated with hydrophilic primary active components, while the phosphatidyl component is a lipid-soluble molecule coupled to a choline complex. This process leads to the creation of lipid complexes that exhibit enhanced stability and bioavailability **[8]**.

5.1 Anti-solvent precipitation technique

A mixture of plant extract and phospholipid in a 100 mL round bottom flask was combined with 20 mL of dichloromethane and subjected to reflux for 2 hours at a temperature less than or equal to 60°C. Concentrate the mixture to 5-10 mL. Following the cautious application of hexane (20 mL) with continuous stirring, the precipitate was filtered, collected, and stored in desiccators overnight. The pulverized desiccated solid is sifted between #100 mesh screens in a mortar. The powdered complex

was kept at room temperature in an amber-colored glass container **[9]**.

5.2 Rotary evaporation technique

In a rotary circular bottom flask, the specific volume of plant material and phospholipid were dissolved in 30 mL of tetrahydrofuran, then stirred for 3 hours at a temperature not exceeding 40oC. A thin film of the sample was collected, to which n-hexane was applied and a magnetic stirrer was used to constantly stir the mixture. The precipitate was extracted and deposited at room temperature in an amber-colored glass bottle **[10]**.

5.3 Solvent evaporation technique

The precise volume of plant content and phospholipids is combined with 20 mL of acetone in a 100 mL circular bottom flask and subjected to reflux for 2 hours at a temperature range of 50-60°C. Following the condensation of the mixture to a volume of 5-10 mL, the precipitate was filtered and extracted. In an amber-colored glass container, the dry precipitate phytosome complex was stored at room temperature **[11]**.

5.4 Ether-injection technique

A pharmaceutical lipid complex is dissolved in an organic solvent during this procedure. The resulting mixture is subsequently introduced gradually into a heated aqueous solution, hence inducing the formation of vesicles. The state of amphiphiles is defined by their selective focus. At low concentrations, amphiphiles exist in a monomer state. However, when the concentration increases, they can form various configurations including circular, cylindrical, disc, cubic, or hexagonal structures **[12]**.

6. PREPARATION TECHNIQUES FOR PHYTOSOMES

6.1 Vesicles containing phytosomes were synthesised using the thin layer rotary evaporator vacuum technique. In a 250 ml round bottom flask, the phytosomal complex was combined with anhydrous ethanol. The flask was connected to a rotating evaporator (RHE). The solvent will undergo evaporation at roughly 60°C, resulting in the formation of a thin layer coating surrounding the flask. The film undergoes hydration using a phosphate buffer with a pH of 7.4. In this process, the lipid layer of the film will detach and produce a suspension of vesicles. The suspension containing phytosomes underwent probe sonication at an amplitude of 60%. Prior to characterisation, the phytosomal suspension will be refrigerated for 24 hours **[13]**.

6.2 In an equal proportion with 5 mL of dichloromethane (DCM), phospholipid, namely soya lecithin, was reacted with polyphenolic extract while stirring until it evaporated. Following the vaporization of DCM, 5 mL of n-hexane was introduced to the thin film while stirring and then placed

in a fume hood to ensure full elimination of the solvent. Upon full elimination of n-hexane, the thin film was hydrated and subjected to sonication to achieve the required phytosomal complex **[14]**.

6.3 Accurately measure the quantity of phospholipid and polyphenolic extract. The solution was transferred into a 100 ml round bottom flask and subjected to reflux with 30 mL of DCM at 60°C for 3 hours. It was then reduced to 5-10 mL and 30 mL of n-hexane was added while continuously stirring to avoid precipitation. The precipitate should be collected and thereafter kept in a vacuum desiccator overnight. Next, the desiccated solid is sifted through a #100 mesh screen and kept in a tightly sealed ambered colored container **[15]**.

6.4 Phytosomes can be synthesised using the reflux technique. The polyphenolic extract and phospholipid were combined in a 100 mL round bottom flask and subjected to reflux in DCM for 1 hour, with a maximum temperature of 40°C. The clear solution was evaporated and then 15 mL of n-hexane was added until a solid precipitate was formed. The precipitate was collected and deposited in a desiccator **[16]**.

6.5 Accurately, weight the quantity of phospholipid and cholesterol in a round bottom flask and dissolve it in 10 mL of chloroform. Then, subject the mixture to sonication for 10 minutes using a bath sonicator. The elimination of organic solvents can be achieved by exposing them to reduced pressure in a rotating evaporator set at 40°C. Complete solvent removal results in the formation of a thin layer that is hydrated with the polyphenolic extract of the medication using a rotary evaporator. The phospholipids mixture was subjected to sonication in an ice bath to facilitate heat dissipation. Prepared phytosome were stored in an amber colored bottle **[17]**.

7. CHARACTERIZATION TECHNIQUES [18]

7.1 Differential scanning calorimetry

A drug polyphenolic extract, phosphatidylcholine, a physical mixture of drug extract and phosphatidylcholine, and a drugphospholipid complex were subjected to heating in an aluminum cell using a nitrogen environment at a rate of 50-250°C/minutes from 0 to 400°C.

7.2 Scanning electron microscopy (SEM)

Structural dimensions and visual characteristics of the particle were determined using SEM. A dry sample was deposited onto a brass stub prepared with gold using an ion sputter technique on an electron microscope. Random scanning of the complex at 100.

7.3 Transition electron microscopy (TEM)

TEM was used to characterize the size of phytosomal vesicles with 1000 magnification

7.4. Particle size and zeta potential

Dynamic light scattering (DLS) with a computerized inspection method and photon similarity spectroscopy can be used to assess particle size and zeta potential.

7.5. Drug entrapment and loading capacity

Drug phytosomes complex was centrifuged at 10000 rpm for 90 minutes at 4°C to separate phytosome from the untrapped drug. The concentration of free drug can be measured by doing ultraviolet spectroscopy. The percentage drug entrapment can be calculated as given formula:

$$\text{Entrapment efficiency \%} = \frac{\text{Weight of total drug} - \text{Weight of free drug}}{\text{Weight of total drug}} \times 100$$

7.6 Transition temperature

A drug polyphenolic extract, phosphatidylcholine, a physical mixture of drug extract and phosphatidylcholine, and a drugphospholipid complex were subjected to heating in an aluminum cell using a nitrogen environment at a rate of 50-250°C/minutes from 0 to 400°C.

7.7 Surface tension activity measurement

The ring procedure in a Du Nouy ring tensiometer can be used to calculate the drug's surface tension response in an aqueous solution.

7.8Vesicle stability

The scale and shape of vesicles can be measured over time to assess their stability. DLS determines the average scale, while TEM monitors structural shifts.

7.9 Drug content

An updated high-performance liquid chromatographic process or an appropriate spectroscopic method may be used to evaluate the volume of drug current.

7.10 Proton-Nuclear Magnetic Resonance (1H-NMR)

Spectroscopic investigations are frequently employed to confirm the formation of complexes between phytoconstituents and the phospholipids component, as well as to examine the resulting interaction. This methodology can be employed to estimate the intricate interaction between active phytoconstituents and the phosphatidylcholine molecule.

7.11 Carbon-Nuclear Magnetic Resonance (13C-NMR)

Upon registration, the 13C-NMR of the phytoconstituents and the stoichiometric combination with phosphatidylcholine did not reveal the presence of the carbons themselves. Although the signals corresponding to the glycerol and choline components have been expanded and relocated, the resonance of most of the fatty acid chains has maintained its original clear line form.

7.12. Fourier-Transformed Infra-Red (FT-IR) Spectroscopy

One can validate the development of a complex using FT-IR spectroscopy by comparing the spectrum of the complex with the spectra of the individual components and

their mechanical mixes. Finite-temperature infrared (FT-IR) spectroscopy is a useful technique for regulating the stability of phytosomes whether they are disseminated in water or added to soapy cosmetic gels. Practically, the stability of the complex can be assessed by comparing the spectra of the complex in its solid state (phytosomes) with the spectrum of its small-scale distribution in water, after repeated lyophilization at different time intervals.

7.13 *In-vitro* and *in-vivo* evaluations

The predicted therapeutic action of the biologically active phytoconstituents found in the plants. Phytosomes are used to pick *in-vitro* and *in-vivo* evaluation models.

8. COMMERCIALLY AVAILABLE PHYTOSOMAL PRODUCT [19]

Sr. No.	Trade name	Chief constituents	Source	Dose	Use
1	Centella phytosomes	Triterpine	*Centella asiatica*	-	Cicatrizing, trophodermic
2	Ginselect phytosomes	Ginsenosides	*Gingko biloba*	120 mg	Adaptogenic
3	Greenselect phytosomes	Polyphenols	*Camellia sinensis*	-	Free radical scavenging activity
4	Leucoselect	Polyphenols	*Vitis vinifera*	300 mg	Antioxidant
5	Meriva	Curcuminoids	*Curcuma longa*	200-300 mg	Anti-inflammatory
6	Silymarin	Silymarin	*Silybum marianum*	-	Antihepatotoxic
7	Oleaselect TM phytosome	Polyphenols of olive oil	*Olea europaea*	-	Anti-inflammatory, antioxidant
8	Crataegus phytosomes	Vitexin-2'-O-rhamonoside	*Crataegus Mexicana*	-	Antioxidant
9	Visnadine	Visnadine	*Ammi visnaga*	-	Circulation improver
10	Bilberry	Triterpine	*Vaccinium myritillus*	-	Potent antioxidant
11	Ruscogenin phytosomes	Steroid saponin	*Ruscus aculeatus*	-	Anti-inflammatory
12	PA2 phytosomes	Proanthocynidin	*Horse chestnut bark*	-	Antiwrinkles UV protectant
13	Zanthalene phytosomes	Zanthalene	*Zanthoxylum bungeanum*	-	Soothing, anti-itching
14	Lymphaselect phytosomes	Triterpenes	*Melilotus officinalis*	-	Indicated in insomnia
15	Sabalselect phytosome	Fatty acid, sterols	*Serenoa repens*	-	Beningn prostate hyperplasia

9. PHYTOSOME FORMULATIONS DEVELOPMENT

Phytosome complexes can be transformed and integrated into several oral and topically administered pharmaceutical formulations. A range of products can be developed to optimize the benefits of this technological progress, including enhanced formulation control and improved bioavailability.

9.1 Soft gelatin capsules

In the preparation of phytosome complexes, soft gelatin capsules provide a very commendable alternative. The phytosome complex can be solubilized in oily vehicles and subsequently encapsulated within soft gelatin capsules. This may be accomplished using either vegetable or semi-synthetic oils. In order to manufacture accurate capsules, Indena advises utilizing a granulometry level of 100 percent. Based on Indena's

understanding, the effects of phytosome complexes vary when used in oily vehicles and when the oily solution is concentrated in soft gelatin capsules. Therefore, it is necessary to carry out initial feasibility studies to identify the most effective vehicle **[20]**.

9.2 Hard gelatin capsules

Phytosome complex can also be used to manufacturing hard gelatin capsules. Although the conspicuous low density of the phytosome complex limits the total powder capacity of a capsule, a direct volumetric filling method (without pre-compression) can be employed (often not exceeding 300 mg for a size 0 capsule). Maximizing the powder capacity of a capsule can be achieved by employing a piston tamp capsule filling technique. However, it is important to note that pre-compression can have an effect on the duration of disintegration. Indena recommends closely monitoring the pertinent parameters during the development of a product or procedure. The most optimal production technique is characterized by an initial dry granulation procedure **[21]**.

9.3 Tablets

The safest method for producing tablets with greater unitary dosages and adequate technical and biopharmaceutical characteristics is dry granulation technology. To compensate for the limited flow capacity, potential stickiness, and low apparent density of the phytosome complex, it is advisable to dilute the phytosome complex with 60-70 percent excipients when using a direct compression method. This will enhance its technical characteristics and ensure the production of tablets with adequate morphology. Nevertheless, wet granulation should be avoided because of the adverse impact of water and heat (granulation/drying) on the stability of the phospholipid complex [**22]**.

9.4 Topical dosage forms

The phytosome complex can also be administered by topical application. To incorporate the phytosome complex into an emulsion, it is necessary to disperse the phospholipidic complex within a restricted fraction of the lipid phase and then introduce it into an emulsion that has already been generated at low temperatures, namely below 40°C. The phytosome complexes freely dissolve in the lipid solvents commonly employed in topical preparations. Phytosome complexes in formulations with low lipid content should be dispersed in the aqueous process and thereafter added to the final formulation at a temperature below 40°C **[23]**.

10. APPLICATIONS [24]

1) Enhancing Bioavailability

2) Delivery of large and diverse drugs, eg. peptides and proteins

3) Safe composition

4) Hepato-Protective

5) Approved for cosmetic and pharmaceutical applications

6) Low-risk profile

7) Toxicological properties have been well documented

8) High market attraction

11. CONCLUSION

A comprehensive investigation was conducted to examine the present research on phytosomes and their applications, such as wound healing, antioxidant characteristics, anti-cancer benefits, and others. Empirical evidence has shown that phytosome technology is more effective than free medicines as a means of delivering medicine. The insights acquired in this study will be highly beneficial for researchers who are interested in studying a vesicular drug delivery system that ensures the targeted release of a potent medicine without enduring metabolic processes.

Additional exploration of phytosome technology is necessary for the therapeutic control of diverse neurological, cardiovascular, autoimmune diseases, and skin-related disorders.

Although many phytosome products are now available on the market, there are still many phytoconstituents with considerable potential to mitigate life-threatening diseases that have not yet been incorporated into the structure of phytosomes. Further research may be undertaken to develop phytosomes that exhibit high selectivity towards defined targets.

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