REVIEW PAPER

Phospholipid-Drug complex tagged SNEDDS: Lipid based approach for oral bioavailability enhancement

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ABSTRACT
Despite having high therapeutic potential, many of synthetic as well as herbal molecules are hindered to show their potential due to challenges like low solubility and oral bioavailability. Although phospholipid-drug complex (PL-D complex) have emerged as an effective strategy for enhancing the dissolution rate and oral bioavailability of poorly soluble drugs, due to their limited aqueous solubility and relatively high viscosity PL-D complex faces the hindrance in dispersion and dissolution in gastrointestinal tract thereby restricting their biopharmaceutical performance. Aforementioned problems can be overcome by formulating them in Phospholipid-drug complex followed by the incorporation in SNEDDS. Phospholipids are biologically compatible and make hydrogen bonds with the active drug constituent which enable phospholipid complex as integral part. The combined effect of Phospholipid-drug complex embedded SNEDDS has been shown to enhance Intestinal permeability in vivo studied as well as Caco2 cells and permeability seems to enhance 2-3 folds. This review is packed with the general preparation methods of phospholipid drug complex, optimization and characterization. Some of the previous work has been done in this interest is also included in this review with their findings.
Keywords: Phospholipid-drug complex, Bioavailability enhancement, Intestinal permeability, biologically compatible
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INTRODUCTION

A number of synthetic as well as herbal drugs have been synthesised during past years having wide range of pharmacological potential. Solubility and oral bioavailability of these molecules
cause hindrance in their uses which arises the need of overcoming these issues. Various approaches are being used to subside the issues of solubility and bioavailability such as size reduction, solid dispersions, salt formation, co-solvency, hydrotrophy, etc.
Phospholipid-drug complexes are being successfully used to enhance dissolution rate and oral bioavailability of poorly soluble drugs. Poor water solubility and high viscosity limit the dispersion and dissolution of Phospholipid-drug complexes in GI fluid. In accordance to overcome this hurdle, a number of approaches have been developed including incorporation of Phospholipid-drug complex in lipid nanoparticles, nanocarriers, into oil solution and so on. Due to thermodynamic stability, self nanoemulsion drug delivery systems (SNEDDS) have been a subject of interest for researchers and multiple researches have been done in past decades. 1
Phospholipids are basically lipid molecules containing phosphate group in itself and various plant seeds and egg yolks are the rich sources of phospholipids. Industrially produced phospholipids are also available in market nowadays.2On the basis of backbone structure of phospholipids, they are divided in sphingomyelins and glycerophospholipids. On addition, phosphatidylcholine (PC), phosphatidylethanolamine (PE), phosphatidylserine (PS), phosphatidic acid (PA), phosphatidylinositol (PI), and phosphatidyl- glycerol (PG) are different phospholipids that can be included in glycerophospholipids.3The most widely used phospholipids in preparation of phospholipid complex are phosphatidylcholine, phosphatidylserine and phosphatidyl ethanolamine due to their composition having hydrophilic head and hydrophobic hydrocarbon chains. Phosphatidylcholine is the most frequently used in the preparation of phospholipid drug complex due to its amphipathic properties which enables the moderation of solubility in water and lipid phase. Also, PC is the one of the key components of cell membranes exhibiting low toxicity as well as good biocompatibility. More over PC has been reported to possess hepatoprotective activity in previous research against clinical manifestations of hepatitis, fatty liver diseases and liver cirrhosis. (4,5)
The lipid component of the majority of biological membranes contains the highest concentrations of phosphatidylcholine and phosphatidylethanolamine, which primarily make up the membrane matrix. Saturated fatty acids, like stearic or palmitic acid, are found in position 1 of naturally occurring phospholipids, whereas unsaturated ones, like oleic, linoleic, or arachidonic acids, are found in position 2.6 Phospholipids that are commonly used are derived from soyabean having larger proportions i.e. 76% of phosphatidylcholine which contains high content (about 70%) of polyunsaturated fatty acids such as oleic acid and linoleic acid.(2,7)

1.1 Physiological properties of phospholipids

The highest plasma concentration of soy phospholipids, attained after oral administration was found to be 90% of the given dose.8 Phospholipids, particularly those containing phosphatidylcholine, have been demonstrated to be integrated into the cell membrane to take the role

of cellular phospholipids, which alters the membrane fluidity.

Soy phospholipids have been reported for not showing any kind of acute and chronic toxicity in experimental laboratory animals at higher dose then recommended doses and also non immunogenic.3 Phosphatidylcholine and choline both are obtained from phospholipids and both are able to liquefy the fat accumulated in liver cells in hepatic steatosis and show hepatoprotective activity.5 Phospholipids are also reported to facilitate enhance circulation of HDL in plasma by helping serum cholesterol clearance and reduction in coronary heart disease.9 They also possess antiatherogenic and anti-lipidemic activity by obstructing boost increased level of total lipids in hypercholesterolemia.10

In past few decades, complexation of herbal drug as well as synthetic drugs with phospholipid has emerged as a most successful approach to improved bioavailability and therapeutic efficacy of substance. This method uses phospholipid molecules with phosphatidylcholine in their structure to create complexes with standardized herbal extracts and/or the particular active pharmaceutical ingredient of plants. This increases the water-oil partition coefficient, membrane permeability, and ultimately the systemic bioavailability of these medications.11

Water-soluble drugs have significantly improved their bioavailability by increasing their penetration through the lipoidal plasma membrane when incorporated with phospholipids, while poorly water-soluble drugs have improved their bioavailability by becoming more soluble in gastric fluids when their phospholipid complexes are formed. (12,13)

The administration of highly effective plant actives with an enhanced biological profile has been made possible in recent years by the Phyto phospholipid complexation approach. Using phospholipids as special carriers Although there are numerous methods for enhancing the bioavailability and, consequently, the therapeutic effectiveness of herbal medications, complexation with naturally occurring phospholipid molecules has emerged as a viable carrier.14 system for enhancing the bioavailability of plant extracts or active ingredients that are poorly absorbed. They are quite compatible with the human physiological system because of their distinct structural elements, which resemble the lipid composition of the mammalian cell membrane. 15

In 1989, drug phospholipid technique was first discovered by chemically reacting polyphenolic with phospholipids containing phosphatidylcholine. On comparison between the bioavailability of pure extract and complex, bioavailability of polyphenolic extract-phosphatidylcholine complex was found markedly increased.16 The first Commercially available Phytosome®4 containing silybin, significantly increased systemic absorption in humans on oral administration.4 Small-size micelles are able to penetrate lipoidal membrane without using energy and also do not damage cellular lipid bilayer which makes the transport nontoxic to the cells.17 Cell internalization oaf phytosome vesicles suggested due to interactions between dietary phospholipids with plasma membrane which results in piloting complexed drug into circulation system.18

2. Preparation method of Phospholipid complex

A number of methods are used to prepare phospholipid complex like salting out- anti solvent precipitation method, solvent evaporation, mechanical dispersion method.

2.1 Solvent evaporation method

This method involves preparation of reaction mixture of phytoconstituent and PC in a flask full of required amount of organic solvent afterward keeping this mixture at a temperature 40 o C for a time period of 1 hour to facilitate drug entrapment to maximum extent as possible. After that evaporate organic solvent with the help of rotary evaporator following sieving of phytosome and storage in desiccator for overnight and flushed with nitrogen at room temperature.(19-21)

2.2 Salting out anti solvent precipitation method

In this method drug, PC and organic solvent are taken and this mixture refluxed at required temperature for sufficient period of time on a magnetic stirrer followed by addition of n hexane to concentrate solvent.22 A precipitate will be formed which further filtered and stored in air tight container glass.

2.3 Mechanical dispersion

Mechanical dispersion method involves the lipid solubilisation in organic solvent and introduced to aqueous phase carrying drug in it.23 Subsequently organic solvent evaporates under reduced pressure which results in formation of Phyto-phospholipid complex. Super critical fluids (SCF), Gas anti-solvent technique (GAS), compressed anti solvent process and supercritical anti solvent method (SAS) are some novel techniques used to prepare phospholipid-drug complex. (24,25)

3. Optimization and Characterization of PL-Drug complex

3.1 Morphology

Morphology and other characters of formulations are depended on various variables such as ratio of drug to phospholipid, temperature, solvent selection, solvent evaporation time, experimental duration, rotation per minute and type of drying method.(26-29) In general morphology of PL-DRUG COMPLEX determined by using SEM and TEM. Both techniques produced high resolution images by using electron as the source light.(30,31 SEM involves the bombardment of electrons which leads to analysis of elemental composition of the sample while TEM employs transmission of elector across particle which gives the information about surface and internal structure of particle as well.32

3.2 Structural analysis by NMR

Molecular interaction and complexation confirmation are studied by using Spectrophotometric analytical methods such as 1H-NMR, 31P-NMR, IR and 13C NMR. Identification of interaction signify by the changes shown in chemical shift in case of NMR while in IR, new bands appear when there is any molecular interaction occurs.33

3.3 Physical state characterization (XRD, DSC)

Crystalline and polymorphic structure analysis of PL-DRUG complex is determined by using X-ray diffraction and Differential scanning calorimetry (DSC). XRD involves the absence or disappearance or reduction in the intensity of diffraction peaks corresponding to crystalline structure of PL-Drug complex.34 Besides in DSC show

the appearance of new peaks, changes in peaks and onset, relative peak area or changes in enthalpy.34,35

3.4 Drug loading and entrapment efficiency

Drug loading and entrapment efficiency is determined by using most widely used technique, centrifugation

$$\% \text{ Drug Entrapment efficiency} = \frac{\text{W initial Drug-W free Drug}}{\text{W initial Drug}} \times 100$$

$$\text{Loading efficiency} = \frac{\text{Amount of drug in pellet}}{\text{Total weight of pellet}} \times 100$$

3.5 Particle size and stability

Stability of PL-Drug complex defined by the particle size, zetapotential and polydispersity index of formulation. All three parameters can be determined by using particle size and zeta potential analyser. PDI represents size distribution while zeta potential refers the measurement of surface potential. In general, particle size may vary from 50 to few hundred micrometre and greater value of zeta potential than ±30 mV is considered more stable.37

Self-nanoemulsifying drug delivery system have been a subject of interest since last few decades due to their high thermodynamic stability and most efficient absorption.38 Many researchers used SNEDDS to entrap phospholipid- drug complex so as to provide stability to the drug and enhanced bioavailability as well.

4. Oral Bioavailability enhancement by phospholipid-drug complex containing SNEDDS

Jinghuan et al. developed phospholipid drug complex incorporated SNEDDS to enhance oral bioavailability of matrine. PL and Drug was weighed in the ratio 1:1 and 20 ml of DCM was refluxed at 35o C followed by collection of dried residues (prepared pc-drug complex). The prepared phospholipid complex was the incorporated into SNEDDS prepared by using lauroglycol FCC: Transcutol HP: Cremophore El in the ratio of 6:1:4. Matrine phopspholipid complexation was investigated by physicochemical methods and liposolubility was found to be significantly enhanced when compared to physical mixture of matrine and phospholipids. Intestinal permeability of matrine was reported as the cause of low oral bioavailability. In this work, an improvement in membrane permeability and biocompatibility were essentially found to be improved due to complex formation which leads permeation through intestinal epithelial cells. Although extent of absorption was increased in Matrine- phospholipid drug complex when compared to free matrine. Oral delivery of SNEDDS in rats observed investigated and found to be increase in Cmax from 4.12 from 6.52 and 7.95 µg/ml in matrine, PL-Drug complex and PL-Drug complex-SNEDDS respectively. A drastic increment in absolute bioavailability from 25% to 84.6% of matrine.39

Another research was conducted in 2015 by Amelia et al to develop Phospholipid drug complex based SNEDDS containing ellagic acid. Phospholipid drug complex was prepared by anti-solvent method by taking ellagic acid and soy lecithin in molar ratio of 1:1 followed by incorporation in SNEDDS prepared by using captex 500: Cremophor RH: PEG 400. The drug release of ellagic acid from ellagic acid complex SNEDDS were found to mention in previous research.36 The principal of method is associated with the centrifugation of formulation in order to separate free drug and estimation by UV spectrophotometry.

be increased. This results in the higher absorption of ellagic acid hence an increment in bioavailability was observed. The purpose of enhancing oral bioavailability and enhanced solubility was served by served properly by this system.40

SNEDDS containing PL-Drug complex also promise the delivery of anticancer drug like paclitaxel. Paclitaxel phospholipid complex and SNEDDS facilitate the great colloidal stability which is indicated by particle size, PDI and zeta potential. Oral bioavailability of paclitaxel increased by this dual approach which investigated in rats and compared with Paclitaxel and paclitaxel-PL complex. Cremophor EL35, Labrafil M and glycerine results in smaller particle size which affect stability of paclitaxel and alleviated absorption. Absolute oral bioavailability of Paclitaxel-PL complex SNEDDS found to be 2.14 times and 3.42 times than paclitaxel solution and paclitaxel PL complex also Cmax value of drug-PL complex and drug-PL complex-SNEDDS when compared with the Cmax value of paclitaxel solution. These results concluded this strategy as an efficient approach to facilitate oral bioavailability approx. 2 times higher than usual and can be promising approach for delivery of hydrophobic drugs.41

The combined effects of PC and SMEDDS in enhancing the bioavailability of Baicalein (BA), a BCS Class IV compound, have been systematically evaluated through in vitro physicochemical models, a Caco-2 cell transport model. In theory, the phospholipid complex (PC) could enhance the membrane permeability of BA due to its high log P. Yet, the reduced Q of BA–PC compared to free BA. Specifically, PC increased the solubility of BA in water only 1.7-fold, while it improved solubility in octanol by 48-fold at a 1:1 molar ratio. This excessive lipophilicity impaired the uniform dispersion of BA–PC in buffer, likely due to the unique structure of PP. When polar groups in PP—such as the positively charged choline or negatively charged phosphate—form hydrogen bonds with polar groups on the drug, the PC becomes electrically neutral and is more easily trapped by the two lipophilic tails of PP.

The comparison of Papp values between BA and BA–PC indicates that a proper balance between lipophilicity and hydrophilicity is critical for efficient membrane transport. The limitation of PC was addressed through the use of SMEDDS, which improved the dispersion of BA–PC–SMEDDS in buffer. Both Q and Papp values for BA–PC–SMEDDS were significantly higher than those of free BA, with increases correlating to higher BA-to-PP molar ratios after 90 minutes.

Moreover, since SMEDDS alone can enhance drug permeability, the results suggest a synergistic effect between PC and SMEDDS in promoting BA transport across bio membranes.42 Other study also reported improved intestinal perfusion of phytoconstituent Silybin which is obtained from Silybum marianum. Intestinal perfusion noted to be increased by 2-fold and 3.5 folds which indicates increased transport of drug by

PL-Drug complex and PL-Drug incorporated SNEDDS. The relative bioavailability of SB-PC and SB-PC-SNEDDS seems to increase by 1265.9% and 1802.5% in lymph duct canulated rats and showed alleviation in water solubility. The inhibition of P-GP efflux, enhanced membrane fluidity also indicates improved bioavailability.43

5. Conclusion

In conclusion, the formulation of drug-phospholipid complexes, particularly using phosphatidylcholine-rich phospholipids, has emerged as a highly promising strategy to overcome the challenges of poor solubility and low bioavailability associated with both synthetic and herbal drugs. Among the various techniques developed to address these issues, phospholipid complexation stands out due to its ability to enhance membrane permeability, improve the water-oil partition coefficient, and facilitate better absorption through the gastrointestinal tract. Phosphatidylcholine, being amphipathic, biocompatible, and hepatoprotective, plays a central role in forming these complexes. Soy-based phospholipids, due to their high PC content and safety profile, are widely used in these applications. The successful integration of drugs into phospholipid complexes has led to significant improvements in systemic bioavailability, particularly in phytopharmaceuticals, as evidenced by the development of commercially available formulations like Phytosome®. Furthermore, the compatibility of phospholipids with human cell membranes and their physiological benefits, including lipid regulation and liver protection, add value to their role as carriers. Overall, the use of phospholipid-based drug delivery systems not only enhances the therapeutic potential of drugs but also supports safe and efficient drug administration, making them a valuable tool in modern pharmaceutical development. SNEDDS formulated with phospholipid-drug complexes have also shown potential in delivering anticancer agents such as paclitaxel. The combination of paclitaxel with a phospholipid complex within a SNEDDS system enhances colloidal stability, as demonstrated by favourable measurements of particle size, polydispersity index (PDI), and zeta potential. he future scope of SNEDDS containing phospholipid-drug complexes, especially for delivering anticancer agents like paclitaxel, is highly promising. With ongoing advancements in nanotechnology and drug delivery systems, this approach offers the potential to further improve the therapeutic index of poorly soluble chemotherapeutic drugs while minimizing their systemic toxicity. Research may focus on optimizing formulation parameters to achieve even better stability, targeted delivery, and controlled release. Additionally, combining SNEDDS with surface modifications or ligands could open pathways for tumor-specific drug delivery, enhancing efficacy while reducing side effects. The versatility of this system also paves the way for its application in delivering a broader range of drugs, including combination therapies, gene delivery, and personalized medicine.

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