IJISET - International Journal of Innovative Science, Engineering & Technology, Vol. 7 Issue 7, July 2020
ISSN (Online) 2348 – 7968 | Impact Factor (2020) – 6.72
www.ijiset.com

Pharmacosomes: A Novel Vesicular Drug Delivery System

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Abstract

Pharmacosomes are amphiphilic complex of medication bearing dynamic hydrogen molecule and phospholipid reinforced by the covalent linkage. Pharmacosomes bearing one of a kind bit of leeway over other ordinary vesicle and come up as an elective potential. Their embodiments of medication in vesicle, little size, amphiphilic nature delay presence of medication in fundamental dissemination, diminishes the poisonousness, improves cell divider move and solvency of ineffectively water-solvent atom. This audit portrays all parts of pharmacosomes including creation, technique for readiness, strategy for portrayal and their restorative application. Pharmacosomes have been set up for different non-steroidal calming drugs, proteins, cardiovascular and antineoplastic medications.

Keywords: Pharmacosomes, Vesicular, Amphiphilic, Phospholipid.

1.0 INTRODUCTION:

From the earliest starting point of mankind; the journey is continuing for more up to date and better other options, and if there should be an occurrence of medications it will proceed; proceed till we discover a medication with most extreme adequacy and no reactions. Numerous medications, especially chemotherapeutic operators, have a tight remedial window, and their clinical use is constrained and undermined by a portion restricting poisonous impact. Along these lines, the restorative viability of the current medications is improved by planning them in an ideal manner. In the previous not many decades, significant consideration has been centered around the advancement of Novel Drug Delivery System (NDDS).

At present, no accessible medication conveyance framework acts in a perfect world, yet earnest endeavors have been made to accomplish them through different novel methodologies in sedate conveyance [1]. Approaches are being adjusted to accomplish this objective, by giving extensive consideration either to control the conveyance of medication by joining it in a bearer framework, or by changing the structure of the medication at the atomic level or to control the contribution of the medication into the bio-condition to guarantee a proper profile of appropriation. Novel medication conveyance framework targets giving some control, regardless of whether this is of worldly or spatial nature, or both, of medication discharge in the body.

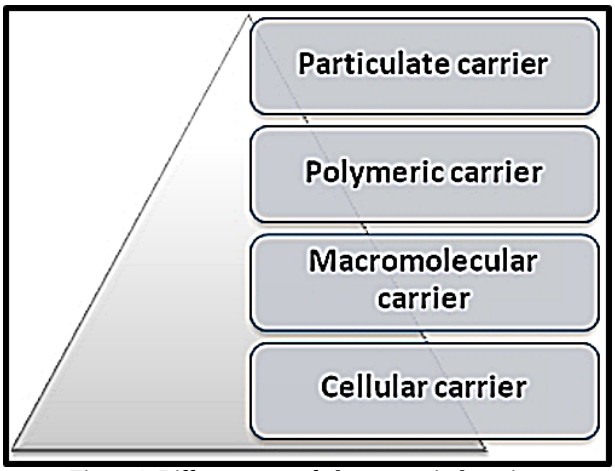

Figure 1: Different types of pharmaceutical carriers

Particulate type carrier is also known as a colloidal carrier system which includes:

- Lipid Particles (Low and High-Density Lipoprotein-LDL and HDL, respectively)
- Microspheres
- Nanoparticles
- Polymeric Micelles and vesicular Like Liposomes, Niosomes, Pharmacosomes, Virosomes etc. [2].

The novel medication delivery system is ever developing. As of late, vesicles have become the vehicle of decision in tranquilize conveyance. Lipid vesicles were seen as of an incentive in immunology, film science, demonstrative methods, and most as of late, hereditary designing. Vesicles can assume a significant job in displaying organic films, and in the vehicle and focusing of dynamic operators. Vesicular frameworks that have developed are Liposomes, Niosomes, Transfersomes, and Pharmacosomes.

1.1 Liposomes:

Liposomes are basic tiny vesicles in which lipid bilayer structures are available with a fluid volume totally encased by a film, made out of lipid atom. There are a few segments present in liposomes, with phospholipid and cholesterol being the fundamental fixings. The kind of phospholipids incorporates phosphoglycerides and sphingolipids, and along with their hydrolysis items. All techniques for arrangement of liposomes include the disintegration of cholesterol, lecithin, and charge in a natural dissolvable, trailed by drying it to a slim film, and afterward scattering of film in a fluid medium to acquire liposome suspension at a basic hydrating temperature. The techniques for arrangement have been grouped to the two essential methods of scatterings:

- Physical dispersion
- Solvent dispersion [3]

The liposomes are characterized for their physical attributes i.e. size, shape, and size distribution [4] surface charge per cent capture entrapped volume lamellarity through freeze-fracture microscopy and P-NMR [5].

Application of Liposomes:
1. Topical ocular drug delivery.
2. Oral administration of insulin.
3. Photodynamic therapy.

1.2 Niosomes:

A vesicular delivery system comprising of unilamellar or multilamellar vesicles called Niosomes. For this situation, a fluid arrangement is encased in an exceptionally requested bilayer comprised of non-ionic surfactant, with or without cholesterol and dicetyl phosphate, and display a conduct like liposomes in vivo. Niosomes have extraordinary favorable circumstances over liposomes. Niosomes are very steady structures, even in the emulsified structure [6]. They require no extraordinary conditions, for example, low temperature or dormant climate for insurance or capacity and are artificially steady. Moderately minimal effort of materials makes it appropriate for modern production.

Methods of preparation of Niosomes:

- Lipid layer hydration method
- Reverse phase evaporation method
- Transmembrane pH gradient uptake process (Remote loading)
- Hand Shaking method
- Ether Injection
- Sonication.

Types of Niosomes:

- Multilamellar Vesicles (MLV, Size >0.05 µm),
- Small Unilamellar Vesicles (SUV, Size -0.025-0.05 µm),
- Large Unilamellar Vesicles (LUV, Size >0.10 µm).

Niosomes are portrayed for various characteristics, for example, vesicle width utilizing a light magnifying instrument, photon relationship microscopy, freeze catch microscopy, ensnarement productivity, and in vitro discharge rate. Different perspectives contemplated are medicate steadiness, drug spillage in saline and plasma on capacity, pharmacokinetic angle, toxicity, and so forth.

Applications of Niosomes:

- Highest protection of insulin against proteolytic enzymes.
- Stable carriers for tretinoin.
- Enhanced anti-inflammatory activity of Nimesulide drug.
- An Antileishmanial property of Bacopasaponin C was maximal without any side effects.
- Carriers for iobitridol, a diagnostic agent used for X-ray imaging

1.3 Transfersomes:

Liposomal just as niosomal frameworks, are not appropriate for transdermal conveyance, on account of their helpless skin porousness, breaking of vesicles, spillage of medication, conglomeration, and combination of vesicles. To beat these issues, another kind of bearer framework called "Transfersome", has as of late been presented, which is fit for transdermal conveyance of low just as high atomic weight drugs. Transfersomes are extraordinarily advanced, ultra-deformable (ultra-adaptable) lipid supramolecular totals, which can infiltrate the mammalian skin unblemished. Each transfersome comprises of at any rate one internal fluid compartment, which is encircled by a lipid bilayer with exceptionally custom fitted properties, because of the consolidation of "edge activators" into the vesicular film [8]. Because of their deformability, transfersomes are acceptable contender for the noninvasive conveyance of little, medium, and huge measured medication.

Transfersomes are prepared in two steps:

- Thin film, comprising phospholipid and surfactant is prepared, hydrated with buffer (pH 6.5) by rotation, and then brought to the desired size by sonication. The concentration of surfactant is very crucial in the formulation of transfersomes because, at sublytic concentration, these agents provide flexibility to vesicles membrane, and at higher concentration, cause destruction of vesicles.
- Sonicated vesicles are homogenized by extrusion through a polycarbonate membrane.

Transfersomes are portrayed for various physical properties, for example, vesicle distance across, capture proficiency, vesicle measurement level of deformability or porousness, in vitro medicate discharge, confocal scanning laser microscopy (CSLM) study, in vivo pharmacokinetic viewpoints [9], for example, toxicity studies and so on.

Applications of Transfersomes:

- Carrier for protein and peptides like insulin, bovine serum albumin, vaccines, etc.
- Transfersomes provides a very successful means for the noninvasive therapeutic use of such large molecular weight drugs on the skin.
- It improves the site-specificity, overall drug safety, and lower the doses Transfersomes.
- Enhanced passive estradiol penetration
- Improve the therapeutic efficacy of cyclosporine and the site-specificity and safety of corticosteroids.

Limitations of Transfersomes:

- Chemically unstable because of their predisposition to oxidative degradation.
- Lack of purity of the natural phospholipids.
- Expensive.

2.0 PHARMACOSOMES:

Pharmacosomes bearing special favorable circumstances over liposome and baneful vesicles have come up as a possible option in contrast to ordinary vesicles. They are the colloidal scatterings of medications covalently bound to lipids. Contingent on the compound structure of the medication lipid complex they may exist as ultrafine vesicular, Micellar, or hexagonal totals. As the framework is shaped by connecting a medication (pharmakon) to a transporter (soma), they are named as "pharmacosomes". They are a successful instrument to accomplish wanted restorative objectives, for example,

sedate focusing on and controlled discharge. The standard for the advancement of the vesicular pharmacosome is reliant on surface and mass collaborations of lipids with the medication. Any medication having a functioning hydrogen iota (- COOH, - OH, - NH2, and so forth.) can be esterified to the lipid, with or without spacer chain that emphatically brings about an amphiphilic compound, which will encourage film, tissue, or cell divider move, in the life form.

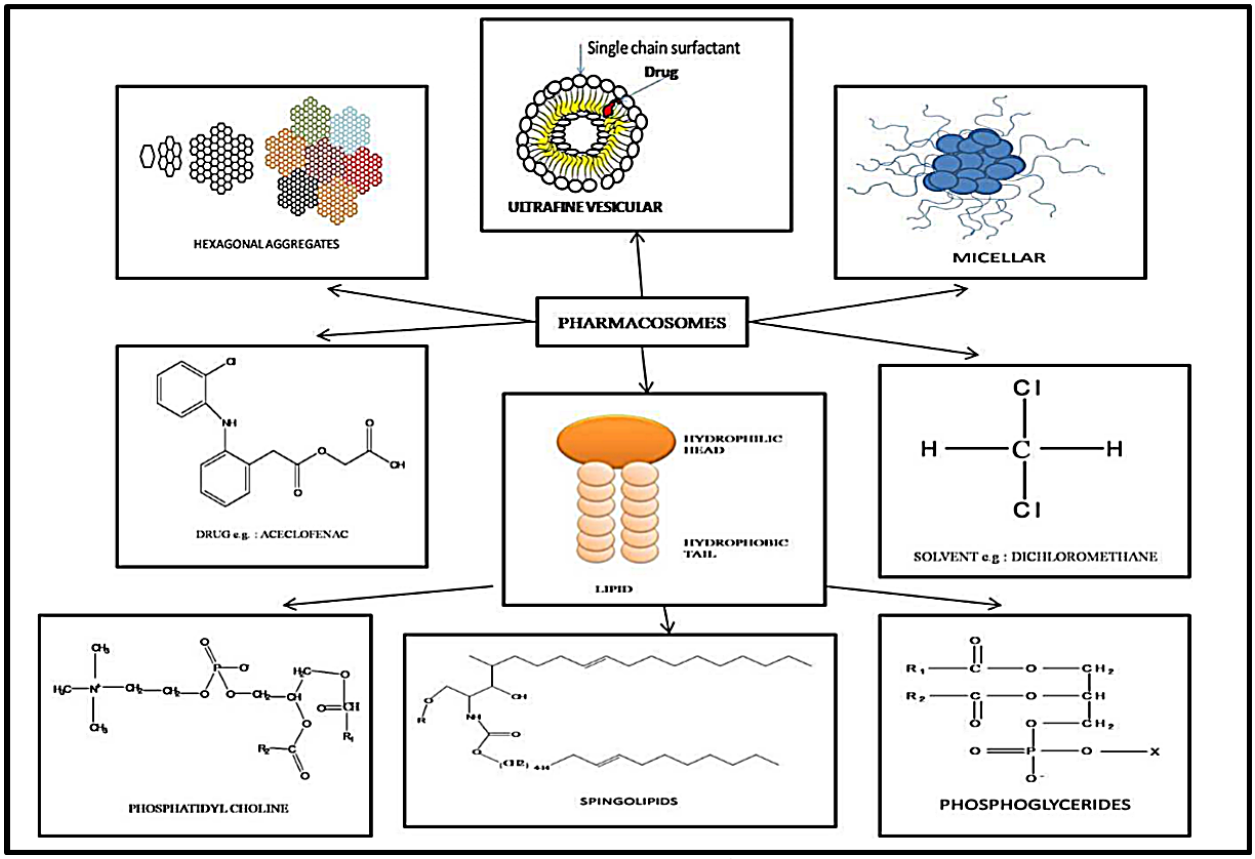

Figure 2: Form & Component of Pharmacosomes

2.1 Principle:

It depends on the rule that the medication ties covalently to a lipid where the subsequent compound is the transporter and the dynamic compound simultaneously. The physicochemical properties rely upon sedate just as the lipid. This framework shows low ensnarement productivity and medication spillage during capacity for hydrophilic medications. Pharmacosomes have some significance in getting away from the monotonous strides of expelling the free from ensnared tranquilize. Like other vesicular framework pharmacosomes give a productive strategy to conveyance of medication straightforwardly to the site of disease, prompting decrease of medication harmfulness with no unfriendly impacts likewise lessens the expense of treatment by improved bioavailability of prescription, particularly if there should be an occurrence of inadequately solvent medications. Pharmacosomes are reasonable for joining both hydrophilic and lipophilic medications. The prodrug conjoins hydrophilic and lipophilic properties, and subsequently obtains amphiphilic characters, and like other vesicle shaping parts, was found to decrease interfacial strain, and at higher focuses displays mesomorphic conduct [10] Many imperatives of different traditional vesicular medication conveyance frameworks, for example, issues of medication joining, spillage from the bearer, or inadequate time span of usability, can be dodged by the pharmacosome approach. The thought for the advancement of the vesicular pharmacosome depends on surface and mass collaborations of lipids with sedate. Any medication having a functioning hydrogen particle (- COOH, - OH, NH2, and so forth.) can be esterified to the lipid, with or without spacer chain. Amalgamation of such a compound might be guided so that emphatically bring about an amphiphilic compound, which will encourage layer, tissue, or cell divider move, in the creature [11]. At low fixation the amphiphiles exists in the Monomer State. Further addition in monomers may prompt assortment of structures for example micelles of round or bar like or circle formed sort or cubic or hexagonal shape. Mantelli et al., looked at the impact of diglyceride prodrug on interfacial pressure, with the impact created by a standard cleanser dodecyl amine hydrochloride, and watched comparable impact on bringing down of surface strain. Over the critical micelle concentration (CMC), the prodrug displays mesomorphic lyotropic conduct, and gathers in supramolecular structures. The readied prodrugs are by and large portrayed for their structure conformation (by IR, NMR

spectrophotometry, thin layer chromatography (TLC), liquefying point assurance), partition coefficient, surface pressure, and prodrug hydrolysis.

2.2 Salient Features of Pharmacosomes:

- Entrapment efficiency is not only high but predetermined. Because drug itself in conjugation with lipids forms vesicles.
- Unlike liposomes, there is no need of following the tedious, time-consuming step for removing the free, unentrapped drug from the formulation.
- Since the drug is covalently linked, loss due to leakage of the drug does not take place. However, a loss may occur by hydrolysis.
- There is no problem of drug incorporation in the body of the patient.
- Encaptured volume and drug-bilayer interactions do not influence entrapment efficiency, in case of pharmacosome. These factors, on the other hand, have a great influence on entrapment efficiency in case of liposomes.
- The lipid piece in liposomes chooses its film smoothness, which thusly impacts the pace of medication discharge, and physical strength of the framework. Be that as it may, in pharmacosomes, film smoothness relies on the stage progress temperature of the medication lipid complex, however it doesn't influence the discharge rate since the medication is covalently bound.
- The drug is released from pharmacosome by hydrolysis (including enzymatic).
- Phospholipid transfer/exchange is reduced, and solubilization by HDL is low. The physicochemical stability of the pharmacosome depends upon the physicochemical properties of the drug-lipid complex.
- Due to their amphiphilic behaviour, such systems allow, after medication, multiple transfers through the lipophilic membrane system or tissue, through cellular walls piggyback endocytosis and exocytosis.
- Following retention, their debasement speed into a functioning medication atom relies generally upon the size and useful gatherings of the medication particle, the chain length of the lipids, and the spacer. These can be changed moderately decisively for advanced in vivo pharmacokinetics.
- They can be given orally, topically, extra-or intravascularly.
- Mantelli et al [9] analyzed the impact of diglyceride prodrug on interfacial pressure, with the impact delivered by a standard cleanser dodecyl amine hydrochloride, and watched a comparable impact on bringing down of surface strain over the critical micelle concentration (CMC), the prodrug shows mesomorphic lyotropic conduct and amasses in supramolecular structures. The readied prodrugs are by and large described for their structure conformation (by IR, NMR spectrophotometry, thin layer chromatography (TLC), liquefying point assurance), partition coefficient, surface pressure and prodrug hydrolysis.

Like other vesicular frameworks, pharmacosomes are portrayed for various traits, for example, size and size dispersion, atomic attractive reverberation (NMR) spectroscopy, capture effectiveness, in vitro discharge rate, soundness contemplates, and so forth. The methodology has effectively improved the remedial presentation of different medications for example pindolol maleate, bupranolol hydrochloride, Taxol, acyclovir, and so on.

Table 1: Some Vesicular System Associated Problems & benefit of Pharmacosomes over it

VESICULAR SYSTEM	PROBLEMS	PHARMACOSOMES
LIPOSOMES	• Degradation by oxidation sedimentation and leaching of the drug. • Lack of purity of natural phospholipids. • Expensive to prepare	• Less expensive to plan, entrapment effectiveness is free of consideration volume and medication bilayer communications, covalent linkage forestalls drug leakage, oxidation safe and unadulterated and common phospholipids not required.
TRANSFERSOMES	• Chemical Instability because of their predisposition to oxidative degradation.	• More stable, more efficient.

	• Lack of purity of natural phospholipids. • Expensive to prepare	
NIOSOMES	• The aqueous suspension may exhibit aggregation, fusion, leaching or hydrolysis of entrapped drugs thus limiting the shelf life • Time-consuming preparation requires specialized equipment and inefficient particularly if smaller quantities are required for a particular application or dose	• Cheaper, oxidation resistant, pure & natural phospholipids not needed.

2.3 Vesicular drug delivery system has some of the advantages like:

- Prolong the existence of the drug in the systemic circulation, and perhaps, reduces the toxicity if uptake can be achieved due to the delivery of the drug directly to the site of infection.
- Improves the bioavailability especially in the case of poorly soluble drugs.
- Both hydrophilic and lipophilic drugs can be incorporated.
- Delays elimination of rapidly metabolizable drugs and thus function as sustained-release systems.

2.3 Merits:

- Suitable for both hydrophilic and lipophilic drugs. The aqueous solution of these amphiphiles exhibits concentration-dependent aggregation.
- High and predetermined entrapment efficiency as drug and carrier form a stoichiometrically defined unit covalently linked together.
- The volume of inclusion doesn't influence entrapment efficiency.
- No need of removing the free, unentrapped drug from the formulation which is required in the case of liposomes.
- As the drug is covalently bound; membrane fluidity does not affect release rate, but in turn depends upon the phase-transition temperature of the drug-lipid complex.
- No leakage of the drug takes place as the drug is covalently linked to the carrier.
- The drug can be delivered directly to the site of infection.
- Drug release from pharmacosomes is by hydrolysis. (including enzymatic).
- Their degradation velocity into an active drug molecule, after absorption depends very much on the size and functional groups of the drug molecule, the chain length of the lipids, and the spacer.
- Improves bioavailability especially in the case of poorly soluble drugs.
- Reduction in adverse effects and toxicity.
- Reduced cost of therapy.

3.0 PREPARATION:

In general, five methods employed to prepare the pharmacosomes:

- **Solvent evaporation method / Hand-shaking method:** Firstly, a blend of medication and lipid are disintegrated in a volatile organic solvent, for example, dichloromethane. From that point solvent is vanished utilizing rotatory evaporator in a round base carafe which departs a meager film of strong blend stored on the dividers of the jar. At that point dried film hydrated with aqueous medium and promptly gives a vesicular suspension. [12, 13, 14]

- **Ether injection method:** In this technique solution containing drug-lipid complex is gradually infused into a hot watery medium through bandage needle and vesicle is framed promptly. [12, 13, 14]

- **Supercritical fluid process (Solution enhanced dispersion by complex supercritical fluid):** Medication and lipid complex are broken down in a supercritical liquid of CO_2, at that point blend into spout blending chamber. [12]

- **Anhydrous co-solvent lyophilization method:** Drug powder and phospholipids broke down in 1 ml of Dimethyl sulfoxide (DMSO) containing 5% glacial acetic acid, after that shakes the blend to get a reasonable fluid. Freeze-dried for the time being at condenser temperature. At that point, resultant complex flushed with nitrogen and put away at 4o C. [12]

- **Another approach:** Another methodology for delivering pharmacosomes was as of late created in which a biodegradable micelle shaping medication conjunct was blended from the hydrophobic medication Adriamycin and a polymer made out of polyoxymethylene glycol and polyaspartic acid. This technique has the advantage that in spite of the fact that it might be conceivable to dilute out the micelle, the medication will likely not hasten as a result of the water dissolvability of the monomeric drug conjunct. Approaches have been done to connect medications to different glyceride-like gatherings, and the subsequent amphiphilic atoms have been suddenly scattered. They were marked pharmacosomes in view of their propensities to shape unilamellar vesicles. It was recommended that these atoms should improve lymph transport. [14]

3.0 EVALUATION TECHNIQUES:

Table 2: Various techniques used for the evaluation of the pharmacosomes

Parameters	Techniques and instrument
• Size and size distribution • Shape & surface morphology • Confirmation of complex formation • State of phospholipid complex • In vitro dissolution studies • Solubility study • Formation of the complex • Drug content	• For measurement of the drug lipid complex • Scanning electron microscopy (SEM) • Transmission electron microscopy (TEM) • Atomic Force Microscopy (AFM) • DSC differential scanning calorimetry • X-ray powder diffraction studies • Dissolution test apparatus • Shake-flask method • Infrared Spectroscopic Analysis • Nuclear magnetic resonance (NMR) spectroscopy 13 C-NMR • UV-Visible spectrophotometer

4.0 CHARACTERISATION:

Like other vesicular frameworks, pharmacosomes are described for various characteristics, for example, size and size distribution, nuclear magnetic resonance (NMR) spectroscopy, entrapment efficiency, in vitro release rate, stability examines, and so forth [9] thought about the impact of diglyceride prodrug on interfacial pressure, with the impact created by a standard cleanser dodecyl amine hydrochloride and watched a similar impact on bringing down of surface strain. The readied prodrugs are described for their Structural conformation (by IR, NMR spectrophotometry, thin layer chromatography (TLC), melting point assurance), surface pressure, partition coefficient and prodrug hydrolysis. The phase transition temperature of pharmacosomes in the vesicular and Micellar state could have huge effect on their association

with layers. Pharmacosomes can collaborate with bimembranes empowering a superior exchange of dynamic ingredients this association prompts change in stage progress temperature of bimembranes along these lines improving the film ease prompting upgrade permeations.

- **Complex Determination**: With the assistance of FTIR range, the development of the complex or the conjugate can be dictated by associating range observed in the complex sample with that of discrete constituents and furthermore with their blend.

- **Stability of Pharmacosomes**: Connecting the range of the complex at different purposes of time in the strong state with a range of a scattering in water comprising of little particles, when the item has been lyophilized, is utilized to assess the stability of the framework.

- **Scanning Electron Microscopy/Transmission Electron Microscopy**: These procedures can be used for considering the surface request of pharmacosomes. The immaculateness evaluations of the lipid being utilized and barely any factors observed during activity (technique for preparation, vacuum doled out, and rotational speed) modify the shape and size of pharmacosomes. Pharmacosomes are framed of oily nature whenever arranged utilizing lower immaculateness evaluations of lipids bringing about the enormous total development and those created utilizing lipids of over 90% purity grade demonstrate helplessness to corruption because of oxidation, which influences complex stability. In this way, 80% of immaculateness grade is the generally utilized phospholipid grade.

- **Solubility**: The adjustment in dissolvability brought about by complexation can be assessed utilizing the shake-jar strategy. In this strategy, the natural stage, that is, 1-octanol and watery stage, that is, cradle arrangement at suitable pH comprising of the medication phospholipid conjugate associate, and after steady shaking, harmony is kept up at a temperature of 37∘C for 1 day. The watery stage is isolated and afterward fixation is resolved utilizing UV or HPLC method.

- **Drug-Lipid Compatibility**: Differential scanning calorimetry is a thermo-investigative strategy used to decide drug lipid similarity and their connections assuming any. The warm reaction is considered utilizing separate examples and warming them in an example pan which is shut. The nitrogen gas is cleansed, and the temperature is kept up in a positive range with a particular warming rate.

- **Crystalline State Measurement**: The crystalline idea of the medication can be resolved utilizing the X-beam diffraction procedure. The cylinder voltages and cylinder current can be managed in the X-beam generator. Copper lines might be utilized as the wellspring of radiation. The sweep point can be managed. The general joined power of all reflection tops is anticipated by the zone under the bend of the X-beam powder diffraction design that indicates the example properties.

- **Dissolution Studies**: Dissolution studies, in-vitro are finished utilizing different models accessible for the reason. The outcomes are surveyed dependent on the secured action of the dynamic constituents remedially.

Table 3: Drug effect after incorporation in pharmacosomes [10, 14, 15, 16, 17]

Drugs	The effect after incorporation in Pharmacosomes
• Pindolol diglyceride	• Three to fivefold increase in plasma concentration, Lower renal clearance
• Amoxicillin	• Improved cytoprotection and treatment of *H. pylori* infections in male rats
• Taxol	• Improved biological activity
• Cytarabine	• Improved biological activity
• Dermatan sulfate	• Improved biological activity
• Bupranolol hydrochloride	• Enhanced effect on intraocular pressure Enhance lymph transport

5.0 RESEARCH UPDATE ON PHARMACOSOMES:

A few investigations show that pharmacosomes can improve the dissolution capacity of the inadequately dissolvable non-steroidal anti-inflammatory drugs. The dissolvability of the diclofenac phosphatidylcholine (80 %) complex was improved to 22.1 mg mL–1 when contrasted with that of diclofenac [18] (10.5 mg mL–1). Additionally, the Aceclofenac [19] stacked pharmacosomes arranged through solvent evaporation strategy demonstrated a discharge pace of 79.78% toward the finish of 4hrs. Headache medicine [20] and Naringenin [21] stacked pharmacosomes additionally delineated comparable outcomes. Further investigations by Garcia et al., (1998) on dioleylphosphatidylcholine (DOPC) complex of ketoprofen (KP) indicated solubility improvement capacity of the pharmacosomes. The saturation of the medication over the skin was likewise upgraded in the mind boggling when tested by in vitro percutaneous ingestion by utilizing a flow-through diffusion cell. Muller-Goymann and Hamann [22].

JIN Yi-Guang et al. [23], defined the contrarily charged nanometer Acyclovir succinyl glyceryl monostearate pharmacosomes by the tetrahydrofuran infusion strategy. Transmission electron microscope and laser scattering technique were utilized for the investigation of the complex framed. Weak impact of centrifugation and warming were found on the dependability of the pharmacosomes while freezing and lyophilization upset the Pharmacosome structure. In vivo, pharmacosomes were discovered consumed by the plasma proteins in the blood along these lines diminishing the hemolytic response.

6.0 CONCLUSION:

The bioavailability of inadequately ingested medications can be improved by setting up their PL edifices, gave their retention is disintegration or penetration rate restricted. The PLs are a perfect characteristic transporter with their helpful qualities. Setting up the zwitterionic, amphiphilic mixes may improve the bioavailability of a wide range of medications, for example, insulin, salmon calcitonin, NSAIDs, etc. With the improvement of pharmacosomes of NSAIDs, their dissemination across lipid layers and into target cells is quickened. The pharmacosomes may even decrease GI toxicity of NSAIDs. In addition, comparative PL buildings can likewise improve the biopharmaceutical properties of organically dynamic phytoconstituents, for example, flavones, glycosides, xanthones, etc. Like other vesicular frameworks, pharmacosomes assume a significant job in the particular focusing on and the controlled delivery of different medications. With the approach of current procedures, for example, supercritical liquid and lyophilization techniques, far and away superior outcomes can be acquired by pharmacosomes.

It is commonly seen that bioavailability of a large portion of the herbal or engineered drugs is constrained by the poor biopharmaceutical properties as it were. Accordingly, the pharmacosomes can assume the job of straightforward, protected, effective and stable medication conveyance frameworks that can be set up by basic and reproducible techniques for better helpful execution.

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