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A REVIEW ON PHARMACOSOMES - VESICULAR DRUG DELIVERY SYSTEM

Aman Kumar[1], Ritika Gupta[2*], Kapil Kumar Verma[3]

[1]Department of Pharmacy, Minerva College of Pharmacy, Indora, India (H.P)

[2*]Department of Quality Assurance, Minerva College of Pharmacy, Indora, India (H.P)

[3]Department of Pharmacology, Minerva College of Pharmacy, Indora, India (H.P).

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***Corresponding Author**

Ritika Gupta

Department of Quality Assurance, Minerva College of Pharmacy, Indora, India (H.P)

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ABSTRACT

Pharmacosomes are an emerging class of vesicular drug delivery systems developed to enhance the therapeutic performance of pharmaceutical compounds. These systems are formed through the covalent linkage of drug molecules with phospholipids, resulting in amphiphilic complexes that can spontaneously organize into vesicular structures. This characteristic enables efficient delivery of both hydrophilic and lipophilic drugs. Compared to conventional delivery approaches, pharmacosomes offer improved drug stability, higher loading efficiency, and reduced risk of drug leakage. The phospholipid component plays a crucial role in protecting the drug from degradation and promoting cellular uptake, thereby supporting targeted delivery. In addition, these systems can be engineered to provide controlled and sustained drug release, which contributes to reduced side effects and enhanced patient compliance. However, certain limitations, including formulation complexity, stability issues during storage, and possible immunological responses, need to be addressed. Continuous research efforts aimed at optimizing formulation strategies and improving scalability are expected to expand the application of pharmacosomes in advanced drug delivery.

KEYWORDS: Pharmacosomes, vesicular systems, drug targeting, phospholipids, controlled release, bioavailability.

INTRODUCTION

The development of Novel Drug Delivery Systems (NDDS) has significantly transformed the field of pharmaceutics by enabling precise and efficient delivery of drugs to the desired site of action. Unlike traditional dosage forms, these systems are designed to optimize therapeutic outcomes while minimizing adverse effects.

An effective NDDS should ensure controlled release of the drug over a specified duration and facilitate its delivery to targeted tissues. These systems are particularly useful in overcoming challenges such as poor solubility, rapid drug degradation, and non-specific distribution.

The primary goals of NDDS include improving bioavailability, enhancing therapeutic efficacy, reducing toxicity, and maintaining consistent drug levels in the body. As a result, they play a vital role in modern drug therapy and patient care.[1]

➢ Aim of novel drug delivery systems

The major aim during the development of nanoparticles as delivery devices are:

a) To track particle size
b) To track surface quality
c) To the delivery of active pharmaceuticals to offer site-specific action quickly.
d) To set a medication dosing schedule
e) To reduce unwanted interactions

➢ Characteristics of novel drug delivery system are

1. Boost bioavailability.
2. Deliver medication in a controlled way.
3. Maintain stability and delivery under various physiological conditions.
4. Safe, reliable, easy to administer, and economical.[2]

➢ Basic modes of novel drug delivery are

a) Targeted drug delivery system.
b) Controlled drug delivery system.
c) Modulated drug delivery system.[3]

Table 1: The list of characteristics, description, example and their application of novel drug delivery system.[4]

Characteristic	Description	Example	Application
Controlled release	Drug is released at a predetermined rate over an extended period of time.	Transdermal patches, Implants, Oral extended-release tablets	Chronic diseases (e.g. hypertension, diabetes), Pain management, Vaccines
Targeted delivery	Drug is directed to a specific site in the body, reducing side effects and increasing efficacy.	Liposomes, Nanoparticles, Antibody-drug conjugates	Cancer therapy, Gene therapy, Infectious diseases
Mucosal delivery	Drug is absorbed through the mucosal membranes of the nose, mouth, or lungs.	Nasal sprays, Inhalers, Buccal patches	Allergies, Asthma Pain relief
Transdermal delivery	Drug is absorbed through the skin.	Patches, Gels, Creams	Pain relief hormone replacement therapy, Smoking cessation
Implantable delivery	Drug is released from a device implanted in the body.	Biodegradable implants, Pumps	Cancer therapy, Chronic pain management, Contraception
Responsive delivery	Drug release is triggered by a specific stimulus, such as changes in pH, temperature, or enzymes.	Glucose-responsive insulin delivery systems, Tumor-activated drug delivery systems	Diabetes, Cancer therapy

VESICULAR DRUG DELIVERY SYSTEM

Vesicular drug delivery systems are specialized carriers that improve the therapeutic effectiveness of drugs by encapsulating them within lipid-based structures. These carriers, such as liposomes, niosomes, and pharmacosomes, are capable of delivering drugs to specific sites in the body, thereby reducing systemic toxicity.[5]

One of the key advantages of these systems is their ability to carry both water-soluble and lipid-soluble drugs. Additionally, they protect drugs from degradation, extend their circulation time, and enhance their absorption into cells.

Despite these benefits, traditional vesicular systems may face challenges such as instability, drug leakage, and limited loading capacity. These drawbacks have led to the development of advanced systems like pharmacosomes, which aim to overcome these limitations.[6]

➢ **Benefits of the vesicular drug delivery system**

1. Drugs that are both hydrophilic and hydrophobic can be easily encapsulated.
2. Drugs can stay in the body longer.
3. Problems with the stability of unstable medicines can be addressed.
4. Toxicity issues with some medications can often be fixed.
5. This method effectively lowers drug toxicity and targets it to the active site.
6. It helps reduce treatment costs.
7. It improved the bioavailability of poorly soluble medicines.
8. It lengthened the time between medication clearance and release by delaying the removal of rapidly metabolized drugs.
9. It addresses issues of drug stability, solubility, and degradation.
10. It serves as a drug reservoir by encapsulating the medication and solving the problems linked to traditional dosage forms.
11. These carriers are biocompatible and biodegradable as they match the structure and function of biomolecules, also it is effective in permeation of drugs into cells.[7]

➢ **Disadvantages of vesicular drug delivery system**

1. Drugs passively, which may lead to low drug loading efficiency and drug leakage in preparation, preservation and transport in vivo.
2. Need of intensive sonication, leads to leakages of drug during storage.[8]

➢ **Type of vesicular drug delivery system**

1. Lipoidal Biocarriers

a) Pharmacosomes
b) Liposomes
c) Emulosomes

2. Non-Lipoidal Biocarriers

a) Niosomes
b) Bilosomes
c) Aquasomes.[9]

PHARMACOSOMES

Pharmacosomes are part of a new drug delivery system. They were first introduced by Vaizoglu and Speriser in 1968. Pharmacosomes are defined as colloidal dispersions where

drugs are covalently bound to lipids. They can exist as ultra-fine vesicles, micelles, or hexagonal aggregates, depending on the chemical structure of the drug-lipid complex. The system works by linking a drug (pharmakon) to a carrier (soma), which is why they are called "Pharmacosomes." After absorption, how quickly they break down into the active drug depends largely on the size and functional groups of the drug molecule, the chain length of the lipids, and the spacer.[10]

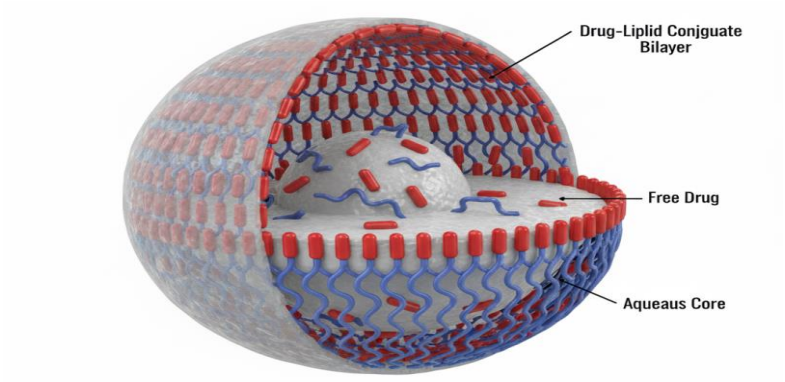

FIGURE 1: Pharmacosomes.

- **Advantages of Pharmacosomes**

a) Drug can be delivered to the active site of infection.
b) It improves bioavailability, especially for hydrophobic drugs.
c) There is a reduction in side effects and toxicity.
d) Drug carriers, like liposomes, nanoparticles, and micro emulsions, can lead to problems like low physical stability and low drug-loading efficiency. Issues such as sedimentation, aggregation, and drug leakage during preparation are not found in pharmacosomes.
e) Entrapment efficiency is high and predefined because the medication and carrier are covalently bonded, forming a defined unit.
f) The drug can be easily incorporated.[11]
g) Reduce the GIT Toxicity.
h) Avoid first pass metabolism.[12]

Table 2: Advantages of Pharmacosomes over other conventional vesicular system.[13]

Vesicular system	Feature	Problem	Pharmacosomes
Liposomes	One or more lipid bilayers, separated by water or an aqueous buffer compartment in	Preparation costs are high, and the drug is degraded by oxidation, sedimentation, and	Entrapment efficiency is self-determining and is not dependent on inclusion volume

	a microscopic vesicle (25nm to 100m).	leaching. Also, there is a lack of purity in natural phospholipids.	and drug bilayer interactions, covalent bonding prevents drug leakage, oxidation resistance, and the use of pure and natural phospholipids is not required.
Transferosomes	Suitable for both low and high molecular weight drugs, as well as lipophilic and hydrophilic drugs.	Expensive, susceptible to oxidative degradation, and lacking of natural phospholipids purity.	Phospholipids that are less expensive, more resistant to oxidation can be used and use of pure and natural phospholipids is not required.
Niosomes	They are non-ionic surfactant vesicle	Time consuming, drug leaching, and poor mechanical properties	More robust and efficient

- **Disadvantages of Pharmacosomes**

1. Pharmacosomes can only encapsulate the water insoluble drugs in relatively small hydrophobic regions within membrane bilayer rather than relatively large surface.
2. Pharmacosomes on storage undergo fusion and aggregation as well as chemical hydrolysis.
3. Synthesis of a compound depends upon its amphiphilic nature.[14]

- **Principle of Pharmacosomes**

It depends on the rule that the medication binds tightly to a lipid, with the resulting compound acting as both the transporter and the dynamic compound. The properties of this system depend on the sedative and the lipid. This setup shows low entrapment efficiency and medication leakage during storage for hydrophilic drugs. Pharmacosomes play a crucial role in avoiding the complex steps of removing the free drug from the trapped substance. Like other vesicular systems, pharmacosomes offer an efficient way to deliver medication directly to the disease site. This approach reduces drug toxicity without side effects and also lowers treatment costs by improving the bioavailability of the drug, especially for poorly soluble medications. Pharmacosomes are suitable for incorporating both hydrophilic and lipophilic drugs.[15]

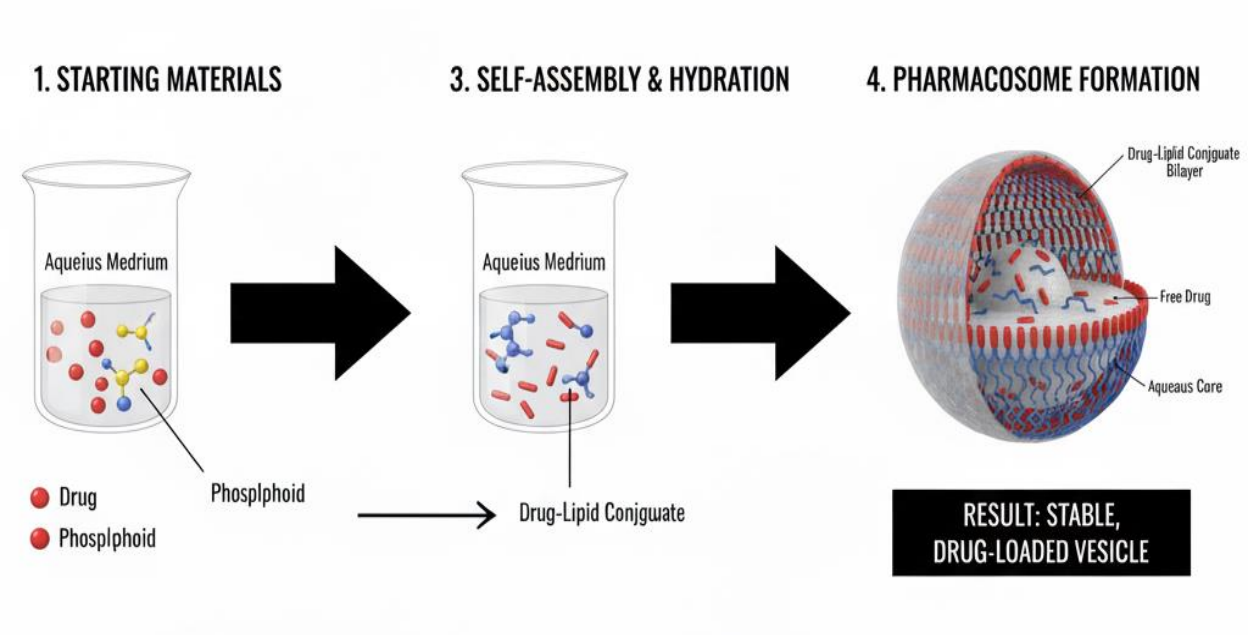

FIGURE 2: Principle of Pharmacosomes.

➢ **Limitation of Pharmacosomes**

1. Synthesis of a compound depends on its amphiphilic nature
2. It requires surface and bulk interaction of lipids with drugs.
3. It requires covalent bonding to prevent the leakage of drugs.
4. During storage, there is fusion and aggregation, along with chemical hydrolysis.[16]

➢ **Salient features of Pharmacosomes**

a) Pharmacosomes can incorporate both water-loving and fat-loving drugs.
b) The physical and chemical bonding characteristics of the complex control the overall stability of the formulation.
c) They can penetrate the cell membrane, cell wall, and tissues.
d) Drug leakage can be prevented because of the covalent bond between the drug and phospholipids.
e) It can be given through several routes, including topical, oral, rectal, extra vascular, or intravascular.
f) It has a set of entrapment efficiency.
g) Membrane fluidity relies on the phase transition temperature of the drug-lipid complex.
h) When administered, the speed of degradation into an active drug molecule depends on the size and functional group of the drug molecule, as well as the fatty acid chain length in the lipid.[17]

➢ **Importance of Pharmacosomes**

1. Pharmacosomes help avoid the repetitive steps involved in extracting free uninterrupted material.
2. Pharmacosomes serve as an effective delivery system for medication directly targeting the infection site. This approach reduces drug toxicity without adverse effects and lowers therapy costs by improving drug availability, especially for poorly soluble drugs.
3. Pharmacosomes work well for both lipophilic and hydrophilic drug incorporation.
4. The efficiency of entrapment is not only high but also predictable because the drug itself forms vesicles with lipids.
5. There is no need to follow the tedious, time-consuming step of removing the free, uninterrupted drug from the formulation.
6. Since the drug is covalently linked, there is no loss from drug leakage.
7. There are no issues with drug incorporation.
8. The volume captured and the drug-bilayer interaction in pharmacosomes does not impact the efficiency of entrapment.
9. The stability of pharmacosomes depends on the properties of the drug-fat complex.[18]

MATERIAL REQUIRED FOR FORMULATION

1. **Drugs:** Compounds that contain an active H2 atom can form amphiphilic complexes by esterifying to the lipid. This can happen with or without a spacer chain. The strong amphiphilic compound that results from this process can help the organism transfer membranes, tissues, or cell walls.[19]

2. **Solvents:** For preparing pharmacosomes, the solvents need to be pure and volatile. A solvent with moderate polarity is chosen for making pharmacosomes.

3. **Lipids:** Lipids are the building blocks of the cell membrane.[20] Phospholipids are the main structural elements of biological membranes. Two types of phospholipids, phosphoglycerides and sphingolipids, are commonly used. The most prevalent phospholipids is the phosphatidylcholine moiety. Phosphatidylcholine is an amphiphilic molecule, with a glycerol bridge connecting two hydrophobic acyl hydrocarbon chains and a hydrophilic polar head group made of phosphocholine.[21]

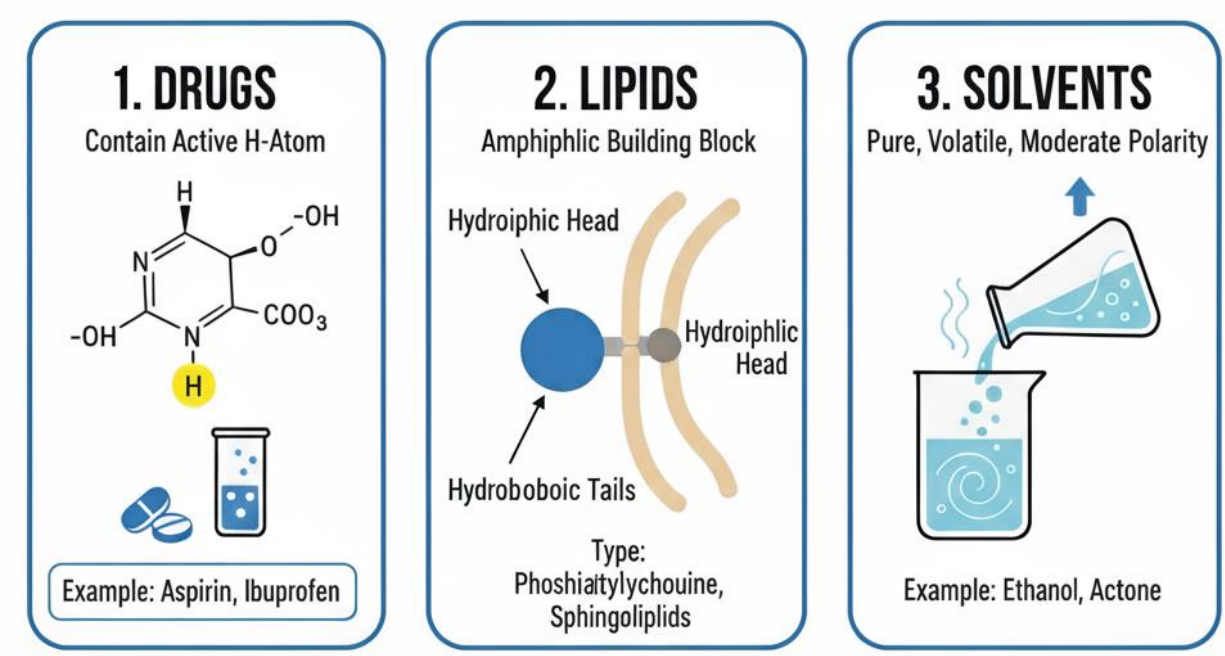

FIGURE 3: Material Required for Pharmacosomes.

METHOD OF PREPARATION OF PHARMACOSOMES

1) Hand shaking method

- Firstly, a mixture of drug and lipid are dissolved in a volatile organic solvent such as dichloromethane Thereafter solvent is evaporate using rotatory evaporator in round bottom flask which leaves a thin film of solid mixture deposited on the walls of flask.
- Then dried film hydrated with aqueous medium & readily gives a vesicular suspension.

2) Anhydrous co-solvent lyophilization technique

- The Drug and phospholipids are dissolved in a dimethyl sulfoxide solution mixed with glacial acetic acid.
- The mixture is then shaken to get a clear liquid. It is freeze-dried overnight at condenser temperature.
- After obtaining the complex, it is flushed with nitrogen and stored at 4˚C.[22]

3) Ether injection method

- The drug-lipid complex is dissolved in a set amount of ether. The resulting mixture is gradually injected into a heated buffer solution to create the vesicles.
- The concentration affects the vesicle's characteristics, especially its shape.
- Depending on the amphiphilic condition, various shapes can form, including spherical, cylindrical, disc, cubic, and hexagonal types.

4) Solvent evaporation method

- The drug is first acidified during the solvent evaporation process for making pharmacosomes. This step helps release active hydrogen for forming complexes.
- A 100 ml round-bottom flask contains exactly weighed amounts of phosphatidylcholine (PC) and drug acid, which are then dissolved in dichloromethane. The mixture is refluxed for one hour. After that, the solvent is removed under vacuum at 40 °C using a rotating vacuum evaporator. Once the mixture is completely dry, the remaining material is collected and placed in vacuum desiccators.

5) Supercritical fluid process

- This method is also called complicated supercritical fluid enhanced dispersion by solution. First, the drug and lipid complex mixture is mixed with carbon dioxide supercritical fluid.
- A high super saturation is then reached by passing the mixture through a nozzle. Right now, the turbulent flow of carbon dioxide and solvent causes quick mixing of the dispersion, which leads to the creation of a pharmacosomes.[23]

➢ For e.g. The Mefenamic Acid loaded Pharmacosomes was prepared by hand shaking method by using these formulation

➢ The Mefenamic Acid loaded Pharmacosomes were prepared and mentioned as f1, f2, f3, f4, f5 and f6.

Table 3: Composition table of The Mefenamic Acid loaded Pharmacosomes.[24]

Formulation code	Mefenamic acid (mg)	Methanol (ml)	Soya lecithin (gm)	Mannitol	Polyvinyl pyrrolidone (mg)	Cholesterol	HPMC (mg)
F1	50	1	1	3	-	2%	20
F2	50	1	2	3	-	5%	-
F3	50	1	3	3	0.5	3%	-
F4	50	1	4	3	-	6%	10
F5	50	1	5	3	10	4%	-
F6	50	1	6	3	10	7%	10

Table 4: Outcomes of Various Drugs after Incorporation in Pharmacosomes.[25]

Drugs	Outcomes
Etodolac	Increased solubility, entrapment efficiency and sustained release
Aceclofenac	Enhancement of solubility, dissolution profile and improved bioavailability
Diclofenac	Improved solubility and drug loading.
Ketoprofen	Improved solubility, dissolution profile
Cytrabin	Biological activity was enhanced.

CHARACTERIZATION OF PHARMACOSOMES

1) **Stability of pharmacosomes:** Correlating the solid-state spectrum of complex at different times with the dispersion spectrum in water, which contains small particles, is used to assess the stability of the system after the product is lyophilized.
2) **Drug-lipid compatibility:** Differential scanning calorimetry is a thermo-analytical technique utilized to determine drug-lipid compatibility and their interactions, if any. The thermal response is studied using separate samples and heating them in a sample pan which is closed. The nitrogen gas is purged, and the temperature is maintained in a definite range with a specific heating rate.[26]
3) **Drug content:** To evaluate the drug content in the drug-pc combination, a drug-equivalent complex was weighed and put into a volumetric flask containing the appropriate solvent. The solution is blended using a magnetic stirrer. After 24 hours of appropriate dilution, drug concentration is evaluated UV spectrophotometrically.
4) **Dissolution studies:** Dissolution studies in vitro are done using several models available utilizing different buffers, and then the findings obtained are calculated depending on the drug's activity.
5) **Surface morphology:** Surface morphology can be seen using scanning electron microscopy (SEM) or transmission electron microscopy (TEM). Purity grades of phospholipids impact the form and size of pharmacosomes, as well as process factors such as speed of rotation, vacuum applied, or the technique utilized.[27]
6) **Melting Point:** The melting point is an important parameter that gives information regarding any structural changes in the organic compound. The pro drug formation is characterized by a change in melting point which is normally notably different from that of either pure drug or lipid. The incorporation of lipid moiety to the drug molecule has been reported to either increase or decrease the melting point of the original drug. A technique like differential scanning calorimetry (DSC) is widely used to determine the melting point of compounds.
7) **Complex Determination:** The formation of the complex can be determined by IR spectroscopy by comparing the spectrum of the complex or conjugate of a drug with the spectrum of each individual component and its mechanical mixture. Stability of pharmacosomes can is characterized by comparing the spectrum of its micro dispersion in water after lyophilization at different time intervals.[28]
8) **X-ray power diffraction:** It is performed to determine the degree of crystallanity by using the relative integrated intensity of reflection peaks. The integrated intensity is given

by the area under curves of the XRPD patterns and it represents the specimen characteristics.

9) **Solubility:** As this process leads to complexation, it is caused by the change in solubility that can be measured using the shake flask technique.

- In this process, two phases are used: one is octanol and the other is an aqueous phase.
- This occurs at a temperature of 37°C for one day, and constant shaking is required during this time. The concentration is determined using ultraviolet high-performance liquid chromatography by analyzing the liquid section separated by the solution.[29]

➢ **Approaches of Pharmacosomes**

1) Pharmacosomes provide a broader stability profile and a longer shelf life.
2) Many researchers have successfully used this approach to improve the therapeutic effectiveness of various drugs.
3) Pharmacosomes are more selective when targeting specific cells.
4) Raikhman et al. described pharmacosomes as building blocks that can carry physiologically active molecules, including proteins and nucleic acids.
5) In a study, Yi-Guang et al. created acyclovir pharmacosomes. They found that plasma proteins in the blood absorbed the pharmacosomes and affected how erythrocytes interacted, which reduced the amount of hemolysis.[30]

CONCLUSION

Pharmacosomes have emerged as a promising platform in the field of advanced drug delivery due to their ability to enhance drug solubility, stability, and targeting efficiency. Their unique structural design, involving drug–lipid conjugation, allows for improved drug loading and minimizes common issues such as leakage.

These systems are particularly beneficial for drugs with poor bioavailability or rapid metabolism. Although certain formulation and stability challenges remain, ongoing advancements in pharmaceutical technology are expected to overcome these limitations.

Future research focusing on targeted delivery approaches, surface modification techniques, and large-scale manufacturing will further strengthen the clinical relevance of pharmacosomes. Overall, they represent a versatile and effective approach for controlled and site-specific drug delivery.

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