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Development of Liposomal Drug Delivery System for Improved Bioavailability of Poorly Soluble Drugs : A Review

Amit Maity[1] and **Sanjib Kumar Nayak**[2]
Department of Pharmaceutics, Debi College of Pharmacy, Tilakpur, Nadia, West Bengal, India[1]
Department of Pharmaceutics, Anurag University, Hyderabad[2]
Corresponding Author: Amit Maity
amitmaity946@gmail.com
sanjibnayak2830@gmail.com

Abstract: *Poor aqueous solubility remains one of the primary obstacles in contemporary drug development. A significant proportion of newly discovered therapeutic agents exhibit low water solubility, resulting in poor dissolution, limited absorption, and reduced oral bioavailability. Liposomal drug delivery systems have emerged as a promising approach to address these challenges. Liposomes are phospholipid-based vesicular carriers capable of encapsulating both hydrophilic and lipophilic drugs, thereby enhancing solubility, stability, and therapeutic performance. This review discusses the structural characteristics of liposomes, mechanisms involved in bioavailability enhancement, preparation techniques, characterization parameters, applications in poorly soluble drugs, advantages, limitations, and recent advancements. Liposomal technology continues to play a critical role in improving the pharmacokinetic and pharmacodynamic profiles of poorly soluble therapeutic agents.*

Keywords: Liposomes, Bioavailability, Poorly soluble drugs, Nanocarriers, Phospholipid vesicles, Drug delivery

I. INTRODUCTION

The pharmaceutical industry increasingly faces the challenge of formulating poorly water-soluble drug molecules. It is estimated that nearly 40–70% of newly developed drugs exhibit poor aqueous solubility, limiting their clinical effectiveness. According to the Biopharmaceutics Classification System (BCS), Class II and Class IV drugs suffer from solubility-limited absorption.

Low solubility often leads to:

- Reduced dissolution rate
- Incomplete gastrointestinal absorption
- High inter-patient variability
- Low and inconsistent bioavailability

Various formulation strategies such as micronization, solid dispersion, salt formation, complexation, and nanoparticulate systems have been explored. Among these, liposomal drug delivery systems provide a versatile and biologically compatible solution for enhancing drug solubility and systemic availability.

II. LIPOSOMES: STRUCTURE AND COMPOSITION

Liposomes are spherical vesicles composed of one or more phospholipid bilayers surrounding an aqueous core. They were first described in the 1960s and have since been widely investigated for drug delivery applications.

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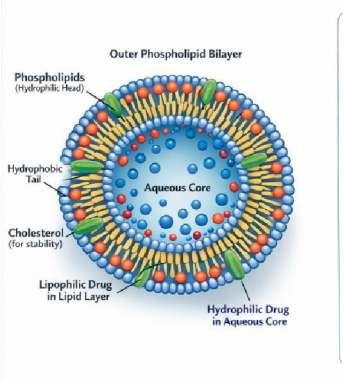
2.1 Structural Components

Liposomes generally consist of:

- **Phospholipids**: Form the bilayer structure
- **Cholesterol**: Enhances membrane rigidity and stability
- **Aqueous core**: Encapsulates hydrophilic drugs
- **Lipid bilayer region**: Incorporates lipophilic drugs

The amphiphilic nature of phospholipids allows liposomes to encapsulate both water-soluble and lipid-soluble compounds, making them suitable for diverse drug molecules.



Structure Of Liposomes

2.2 Classification of Liposomes

Liposomes may be classified based on size and lamellarity:

- Small Unilamellar Vesicles (SUVs)
- Large Unilamellar Vesicles (LUVs)
- Multilamellar Vesicles (MLVs)

They may also be classified based on surface modification:

- Conventional liposomes
- PEGylated liposomes
- Targeted liposomes
- Stimuli-responsive liposomes

III. MECHANISMS OF BIOAVAILABILITY ENHANCEMENT

Liposomes improve bioavailability through multiple complementary mechanisms.

3.1 Enhancement of Apparent Solubility

Poorly soluble drugs can be incorporated into the lipid bilayer, increasing their apparent solubility in biological fluids.

3.2 Improved Dissolution Rate

By dispersing drug molecules at the nanoscale level, liposomes increase the effective surface area, resulting in faster dissolution.

3.3 Protection from Degradation

Encapsulation protects drugs from:

- Acidic gastric conditions
- Enzymatic degradation
- Oxidative stress

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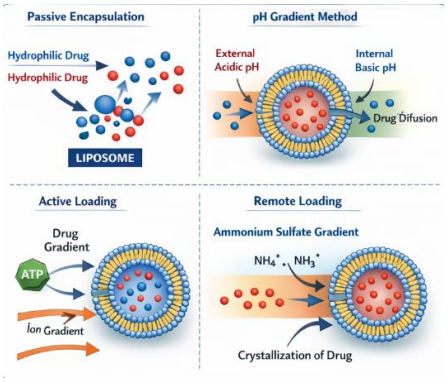
3.4 Enhanced Absorption

Liposomes can:

- Fuse with biological membranes
- Be internalized via endocytosis
- Promote lymphatic uptake

Lymphatic transport may reduce hepatic first-pass metabolism, increasing systemic availability.



Liposome drug loading mechanism

IV. METHODS OF PREPARATION

Several techniques are used for liposome preparation.

4.1 Thin Film Hydration Method

This classical method involves dissolving lipids in an organic solvent, evaporating the solvent to form a thin lipid film, and hydrating the film with aqueous solution under agitation. Size reduction is achieved using sonication or extrusion.

4.2 Reverse Phase Evaporation Method

A water-in-oil emulsion is formed, followed by removal of organic solvent under reduced pressure to yield liposomes with high encapsulation efficiency.

4.3 Ethanol Injection Method

Lipids dissolved in ethanol are injected into an aqueous phase, leading to spontaneous formation of vesicles.

4.4 High-Pressure Homogenization and Microfluidization

These techniques produce uniform nanosized liposomes suitable for large-scale production.

V. CHARACTERIZATION OF LIPOSOMES

Proper evaluation ensures quality, reproducibility, and performance.

5.1 Particle Size and Polydispersity

Measured using Dynamic Light Scattering (DLS). Particle size influences biodistribution and cellular uptake.

5.2 Zeta Potential

Surface charge indicates physical stability. Higher absolute zeta potential values generally enhance colloidal stability.

5.3 Encapsulation Efficiency

Encapsulation efficiency (%) = (Amount of entrapped drug / Total drug added) × 100

5.4 In Vitro Drug Release

Release studies are conducted using dialysis methods or diffusion cells to evaluate sustained-release behavior.

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5.5 Stability Studies

Stability assessment includes monitoring leakage, aggregation, oxidation, and size changes during storage.

VI. APPLICATIONS IN POORLY SOLUBLE DRUGS

6.1 Anticancer Agents

Many chemotherapeutic drugs exhibit poor solubility and systemic toxicity. Liposomal encapsulation enhances therapeutic index and reduces adverse effects.

6.2 Antifungal Drugs

Liposomal formulations improve solubility and reduce organ toxicity.

6.3 Anti-inflammatory Drugs

Improved solubilization enhances systemic absorption and therapeutic efficacy.

6.4 Phytoconstituents

Plant-derived bioactive compounds with poor water solubility benefit significantly from liposomal encapsulation.

VII. ADVANTAGES

1. Biocompatible and Biodegradable

Liposomes are primarily composed of natural or synthetic phospholipids, which are structurally similar to the phospholipids present in biological cell membranes. Because of this similarity, liposomes are generally well tolerated by the body and exhibit minimal immunogenicity. After performing their drug delivery function, liposomal components are metabolized through normal lipid pathways, reducing the risk of long-term toxicity. Their biodegradable nature makes them safer compared to many synthetic polymer-based nanocarriers.

2. Suitable for Both Hydrophilic and Lipophilic Drugs

One of the most significant advantages of liposomes is their ability to encapsulate drugs with different physicochemical properties.

Hydrophilic drugs can be incorporated into the aqueous core of the liposome.

Lipophilic drugs can be embedded within the phospholipid bilayer.

This dual-loading capacity makes liposomes a versatile delivery platform suitable for a wide range of therapeutic agents, including small molecules, peptides, proteins, and even nucleic acids.

3. Reduced Systemic Toxicity

Liposomal encapsulation helps in reducing the exposure of healthy tissues to the drug. By entrapping the drug within vesicles, the distribution pattern can be modified, thereby minimizing unwanted accumulation in non-target organs.

For example, liposomal formulations of anticancer drugs have demonstrated reduced cardiotoxicity and nephrotoxicity compared to their conventional counterparts. Controlled distribution leads to fewer adverse effects and better patient compliance.

4. Targeted Delivery Capability

Liposomes can be engineered for both passive and active targeting:

Passive targeting occurs due to the enhanced permeability and retention (EPR) effect, especially in tumor tissues.

Active targeting can be achieved by attaching specific ligands, antibodies, or peptides to the liposome surface, allowing selective binding to target cells.

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This targeted delivery improves therapeutic efficiency while reducing off-target toxicity. It is particularly beneficial in cancer therapy and inflammatory diseases.

5. Controlled and Sustained Drug Release

Liposomal systems can be designed to provide controlled or prolonged drug release. The release rate depends on lipid composition, vesicle size, surface modification, and environmental conditions.

By controlling drug release:

- Plasma drug levels remain within the therapeutic window for a longer duration.
- Dosing frequency can be reduced.
- Patient adherence improves.
- Stimuli-responsive liposomes can also release drugs in response to pH, temperature, or enzymatic triggers.

6. Improved Therapeutic Index

The therapeutic index refers to the ratio between the toxic dose and the effective dose of a drug. Liposomal formulations enhance this index by:

- Increasing drug concentration at the target site
- Reducing exposure to healthy tissues
- Protecting the drug from premature degradation
- As a result, higher efficacy can be achieved with lower systemic toxicity, improving overall treatment outcomes

VIII. LIMITATIONS

Although liposomes offer significant therapeutic advantages, several formulation and practical challenges must be addressed before large-scale clinical application.

1. Physical Instability (Fusion, Aggregation, and Drug Leakage)

Liposomes are colloidal systems and therefore inherently prone to physical instability. Over time, vesicles may undergo:

- **Fusion**, where two or more liposomes combine to form a larger vesicle
- **Aggregation**, leading to increased particle size
- **Drug leakage**, resulting in reduced encapsulation efficiency

These changes can alter pharmacokinetics, reduce therapeutic efficacy, and compromise product consistency. Factors such as temperature fluctuations, pH changes, and ionic strength of the medium may accelerate instability.

2. Oxidation and Hydrolysis of Phospholipids

Phospholipids, especially those containing unsaturated fatty acids, are susceptible to oxidative degradation. Exposure to oxygen, light, or heat may lead to lipid peroxidation.

Additionally, hydrolysis of ester bonds in phospholipids can occur in the presence of moisture, leading to structural disruption of the bilayer. These degradation processes may:

- Affect vesicle integrity
- Reduce shelf stability
- Alter drug release characteristics

To minimize this issue, antioxidants and proper storage conditions are often required.

3. High Production Cost

The manufacturing of liposomal formulations involves:

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- High-purity phospholipids
- Specialized equipment (e.g., homogenizers, extruders)
- Strict quality control procedures

These factors significantly increase production costs compared to conventional dosage forms. Moreover, sterilization and aseptic processing add further economic burden, particularly for parenteral formulations.

4. Scale-Up and Manufacturing Complexity

While liposomes can be prepared easily at laboratory scale, large-scale production presents several challenges:

- Maintaining uniform particle size distribution
- Ensuring batch-to-batch reproducibility
- Preserving encapsulation efficiency
- Controlling sterility and contamination

Process parameters must be carefully optimized to maintain consistency during industrial manufacturing.

5. Limited Shelf Life

Liposomes generally have a shorter shelf life compared to solid dosage forms. Issues such as:

- Lipid degradation
- Vesicle aggregation
- Gradual drug leakage

can occur during storage. Most liposomal formulations require controlled storage conditions, such as refrigeration, which increases logistical complexity.

Strategies to Overcome Limitations

Recent technological advancements have helped address many of these challenges:

PEGylation improves circulation time and reduces immune recognition.

Lyophilization (freeze-drying) enhances stability and extends shelf life.

Use of antioxidants and cryoprotectants improves chemical stability.

Advanced manufacturing techniques such as microfluidics improve scalability and reproducibility.

Although limitations remain, ongoing research and formulation innovations continue to enhance the stability, efficiency, and commercial viability of liposomal drug delivery systems.

IX. RECENT ADVANCES AND FUTURE PERSPECTIVES

Liposomal drug delivery technology has evolved considerably over the past two decades. Modern research is focused not only on improving solubility and bioavailability but also on enhancing targeting efficiency, therapeutic precision, and large-scale manufacturability.

1. Ligand-Targeted Liposomes

Surface modification of liposomes with specific ligands has significantly improved targeted drug delivery. These ligands may include antibodies, peptides, aptamers, or small molecules that recognize receptors overexpressed on diseased cells.

Targeted liposomes offer several advantages:

- Selective binding to specific tissues or tumor cells
- Increased intracellular drug uptake
- Reduced exposure to healthy tissues
- Enhanced therapeutic efficiency

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This strategy is particularly beneficial in cancer therapy, where receptor-mediated targeting improves accumulation at tumor sites while minimizing systemic toxicity.

2. pH-Sensitive Liposomes

pH-sensitive liposomes are designed to release their drug payload in response to acidic environments. Many pathological sites, such as tumors and inflamed tissues, exhibit lower pH compared to normal physiological conditions. These systems:

- Remain stable at physiological pH (around 7.4)
- Undergo structural destabilization in acidic conditions
- Trigger rapid drug release at the target site

Such controlled release improves drug localization and enhances treatment outcomes.

3. Thermosensitive Liposomes

Thermosensitive liposomes are engineered to release drugs in response to mild hyperthermia. When exposed to slightly elevated temperatures (typically 40–42°C), the lipid bilayer undergoes phase transition, resulting in rapid drug release. This approach is useful in combination with localized heating techniques such as:

- Focused ultrasound
- Radiofrequency ablation
- External thermal therapy

Thermosensitive systems allow spatial and temporal control of drug release, increasing treatment precision.

4. Nanotechnology-Integrated Liposomal Systems

Integration of liposomes with advanced nanotechnology has led to hybrid systems that enhance stability, targeting capability, and controlled release. Examples include:

- Polymer-coated liposomes
- Magnetic liposomes
- Stimuli-responsive nanocarriers
- Lipid–polymer hybrid nanoparticles

These systems improve circulation time, protect encapsulated drugs, and enable multifunctional therapeutic strategies such as combined imaging and therapy (theranostics).

5. Advances in Personalized Medicine

The shift toward personalized medicine has influenced liposomal research significantly. Patient-specific treatment strategies require precise control over dosage, targeting, and pharmacokinetics.
Liposomal systems support this approach by:

- Enabling customized drug combinations
- Allowing surface modification for disease-specific targeting
- Reducing variability in drug distribution

As genomic and molecular diagnostics advance, liposomal carriers are expected to play a key role in individualized therapy.

6. Manufacturing Innovations and Scalability

One of the major historical challenges of liposomal formulations has been large-scale production. Recent advancements in manufacturing technologies aim to overcome these barriers:

- Microfluidic-based production for uniform particle size

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- Continuous manufacturing systems
- Improved sterilization techniques
- Automation and process analytical technology (PAT) integration

These innovations enhance reproducibility, reduce batch variability, and lower production costs, making commercial-scale manufacturing more feasible.

Future Perspectives

The future of liposomal drug delivery lies in multifunctional and smart delivery systems. Research is increasingly directed toward:

- Stimuli-responsive and environment-sensitive carriers
- Combination therapies incorporating multiple drugs
- Gene and nucleic acid delivery
- Long-acting injectable liposomal formulations
- Integration with artificial intelligence for formulation optimization

With continued technological refinement and regulatory advancement, liposomal drug delivery systems are expected to remain a cornerstone of modern pharmaceutical development, particularly for poorly soluble and high-potency therapeutic agents.

X. CONCLUSION

Poor aqueous solubility is a major limitation in pharmaceutical development and frequently affects the therapeutic efficiency of many drug molecules. A considerable number of newly discovered compounds exhibit low solubility in water, which can lead to slow dissolution, inadequate absorption, and ultimately poor bioavailability. These challenges may result in reduced clinical effectiveness and variability in patient response. Therefore, the development of advanced drug delivery strategies to enhance the solubility and bioavailability of poorly soluble drugs has become an important area of research in pharmaceutical sciences.

Liposomal drug delivery systems have gained considerable attention as an effective approach to address these limitations. Liposomes are nanoscale or microscale vesicular carriers composed of phospholipid bilayers that enclose an aqueous core. This structural organization enables liposomes to incorporate both hydrophilic and lipophilic drugs. Hydrophilic compounds can be entrapped within the aqueous interior, whereas poorly soluble or lipophilic drugs can be incorporated into the lipid bilayer. This dual loading capability allows liposomes to act as versatile carriers for a wide variety of therapeutic agents.

Encapsulation of poorly soluble drugs in liposomal structures can significantly improve their apparent solubility and dissolution behavior. In addition to improving solubility, liposomes provide protection against chemical and enzymatic degradation, which helps maintain the stability of the drug during circulation in the body. Liposomal carriers may also enhance drug absorption and distribution by facilitating interaction with biological membranes. Furthermore, these systems can modify the pharmacokinetic profile of drugs, allowing more controlled release and improved therapeutic performance.

Another important advantage of liposomal drug delivery is the potential reduction in drug-related toxicity. By encapsulating the drug within lipid vesicles, exposure of healthy tissues to high drug concentrations can be minimized. This targeted or controlled delivery approach is particularly beneficial for drugs that have narrow therapeutic indices or significant side effects, such as anticancer agents.

Recent progress in nanotechnology and lipid-based formulation techniques has further expanded the capabilities of liposomal systems. Advanced designs such as surface-modified liposomes, long-circulating liposomes, and stimulus-responsive liposomes have been developed to improve targeting efficiency and drug release control. These technological advancements continue to enhance the potential of liposomal formulations in modern drug delivery.

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Overall, liposomal drug delivery systems offer an effective and adaptable platform for improving the performance of poorly soluble drugs. Their ability to enhance solubility, protect drug molecules, and improve therapeutic outcomes highlights their importance in contemporary pharmaceutical research. Ongoing advancements in liposomal design and formulation are expected to further strengthen their role in future drug delivery and therapeutic innovation.

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