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Recent advances in lipid based formulations

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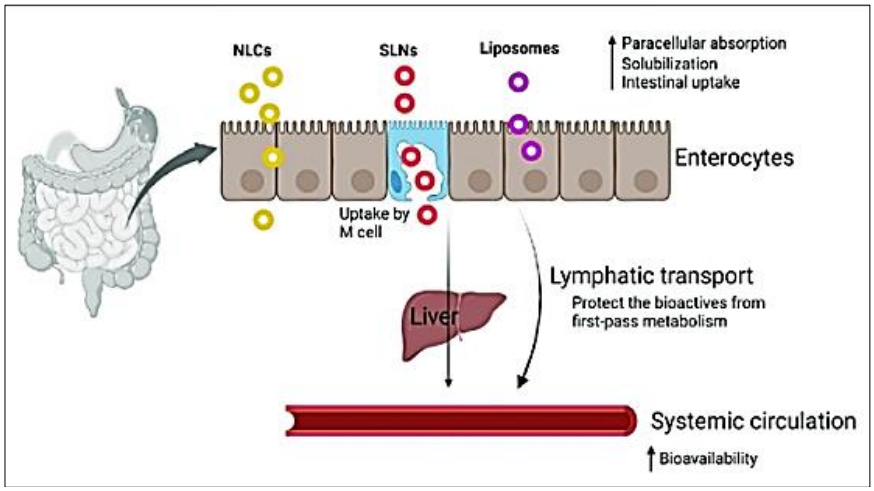
Abstract
Lipid based drug delivery system {LBDDS} are an emerging technology designed to address challenges like the solubility and bioavailability of poorly water soluble drugs. This review article focuses on novel lipid based formulations, including emulsions, vesicular systems, and lipid particulate systems, as well as their applications in pharmaceutical drug delivery.
The paper discusses the principle objectives of formulating lipid based drugs, which is to enhance their bioavailability. It covers various aspects of LBDDS, including formulations approaches, characterisation methods, stability considerations, and regulatory aspects.
The lipid based for formulations can be tailored to meet a wide range of product requirements and are commercially viable for formulating pharmaceuticals for topical, oral, pulmonary, or parenteral delivery. The review also notes that lipid based formulations have shown the ability to reduce toxicity of various drugs by changing their biodistribution away from sensitive organs.

Keywords: Lipid-based drug delivery systems, bioavailability enhancement, poorly water-soluble drugs

Introduction
Lipid based formulations are designed to address the challenges of poor solubility by enhancing the drug stability in lipids, making it more bioavailable.
Lipids can protect drugs from degradation in the acidic stomach environment.
Lipid based formulations are a powerful tool to increase oral bioavailability of poorly water soluble or poorly permeable drugs.
To overcome the limitations lipid based formulations have emerged as a promising approach to enhance the delivery of such drugs.
Several investigations demonstrated that the lipid based formulations in capsules significantly improved the solubility and dissolution rate of poorly water soluble drugs compared to the non-lipid formulations.
Oral administration constrained by decreased oral bioavailability due to problems with drugs physicochemical properties. Numerous molecule with potential therapeutic properties have been developed because of advances in drug design. However bulk of recently discovered chemical entities have higher molecular weights are categorised as Biopharmaceutical Classification System (BCS II). Some of the drugs like halofantrine and danazol have a greater bioavailability. Recently, lipids have received a lot of attention as delivery methods for drugs with limited water solubility. LBDD systems have gained a lot of attention in recent years because of their ability to improve the solubility and bioavailability of dugs with low water solubility.

Lipid-Based Drug Delivery Systems [LBDDS] Via Oral Route
Medicines that are weekly water soluble, such as BCS class II and IV medicines, have been administered. LBDDS are a desirable option for oral delivery because of their inherent biocompatibility, versability in particle size ease of scaleup and cost. It has recently has been shown that oils increases the absorption of lipid soluble vitamins, including lipid soluble vitamins A, D,E, and K. In recent study, diabetic rats were used to examine oral bioavailability of solid lipid nanoparticles [SLNs] carrying insulin. This LBDDS kept the insulin from entering the gastro-intestinal environment, also had a 5 fold better bioavailability than insulin solution.

General routes- Parenteral, Ocular, Intranasal, and Vaginal routes



Parenteral Route: Medications including peptides and proteins, cannot be taken orally because of an enzymatic breakdown. Solid lipid nanoparticles (SLNs) is a promising drug delivery systems for long term controlled release parenteral administration are a LBF. SLNs easily circulate in microvascular system.

Tropical Route: LB products used to deliver drugs when applied tropically because they have different properties such a small particle size, makes as easier for medications to penetrate skin.

Ocular route: LBDDS cure different severe optical conditions such as glaucoma infections, ocular irritation, diseases that impact the structures of posterior eye.

Mechanism of action drug release from LBDDS in oral route: Depends on 2 primary principles:

1. Digestion
2. Absorption

Absorption stimulate the lymphatic transport. Medicine is given through gut environment and found when API is dissolved in LBDDS. The drug absorption was superior to that of traditional solid dosage forms. LBDDS enhances drug absorption, solubility, and stability by encapsulating drugs within lipid matrices, thus protecting them from degradation [1].

- Popular administration routes include oral, parenteral, topical, ocular, and pulmonary, each offering distinct advantages for controlled release and biocompatibility [1].
- Encountered obstacles: enzymatic breakdown, stability concerns, and ongoing clinical trials to verify oral efficacy [1].

Classification

Table 1: Lipid excipients used in lipid based formulations

Formulation type	Excipients	Features	Advantages	Disadvantages
TYPE-I	oils	Requires digestion	Increase compatibility with capsule	More lipophilic drug causes poor solvent capacity
TYPE-II	Required water soluble surfactants and oils	Without water soluble SEDDS formed	Holding solvent capacity often dispersion	
TYPE-III a)Fine emulsion b)Micro-emulsion	Both water soluble and insoluble	W-S-C produce SEDDS and SMEDDS	Without digestion drugs are absorbed	
TYPE-IV	Water soluble surfactants and co-solvents	Micellar solution formed by dispersing formulation	Suitable for many drugs as a solvent	

Common lipid excipients include glyceryl dibehenate, stearate, caprylate, triglycerides, and surfactants like polysorbates and PEG derivatives. These excipients influence solubility, dispersion, digestion, and absorption characteristics.

Formulation Techniques

Various methods are employed to prepare LBDDS, including:

- Spray drying and spray congealing to convert liquid lipid formulations into powders or solid particles.
- Adsorption onto solid carriers to improve flow and handling.
- Melt granulation for preparing solid lipid granules.
- Supercritical fluid methods for coating drugs with lipids.
- Ultrasonication, solvent emulsification, and high-pressure homogenization to produce nano-sized lipid carriers.

Fundamental Aspects of Poorly Water-Soluble Drugs

Many therapeutic agents discovered in recent years have high molecular weights and poor solubility (Biopharmaceutical Classification System, BCS-II), leading to reduced dissolution and absorption [2].

Variability in oral bioavailability stems from issues such as poor solubility, low permeability, instability, and rapid metabolism [1].

Strategies to improve solubility include surfactants, solid dispersions, micronization, complexation, and notably, lipid-based systems [3].

Lipid-Based Drug Delivery Systems (LBDDS)

Mechanisms and Routes: LBDDS enhances drug absorption, solubility, and stability by encapsulating drugs within lipid matrices, thus protecting them from degradation [1].

Popular administration routes include oral, parenteral, topical, ocular, and pulmonary, each offering distinct advantages for controlled release and biocompatibility [4].

Encountered obstacles: enzymatic breakdown, stability concerns, and ongoing clinical trials to verify oral efficacy [1].

Digestion and Absorption: Upon oral administration, lipid-based products undergo digestion via gastric and pancreatic lipases, forming emulsified colloidal systems and facilitating absorption of lipophilic compounds through intestinal mechanisms [2].

Lipid excipients stimulate lymphatic transport and affect gut environment, increasing drug solubility and absorption rates [1].

Classification and Formulation Approaches

Lipid Formulation Classification System (LFCS)

Table 2: Selection of Candidate Drugs

Type I Oils	Type Ii Seeds	Type IIIA And IIIB SEDDS/SMEDDS	Type Iv Lipid Free
Lipids, no surfactant	No water soluble component	Include lipid and water soluble surfactant and co-solvent	Comprises only water soluble surfactants and co-solvents
No limited dispersion	Emulsion	IIIA: fine emulsion IIIB: transparent dispersion	Micellar solution
Requires digestion	Will be digested	Digestion may not be necessary	Limited digestion

Focus on BCS-II/IV drugs, with consideration for "grease-ball" (high lipophilicity, low melting point) vs. "brick dust" compounds (rigid crystal, poor solubility) [1].

Grease-ball molecules may benefit from added surfactants/lipids, while brick-dust compounds improve solubility via co-solvents [3].

Additive and Excipient Selection

- Lipid excipients: triglycerides, surfactants, co-solvents, antioxidants [1].
- Hydrophilic-lipophilic balance (HLB) governs surfactant selection and efficiency in emulsification [4].
- Formulation Strategies
- Methods include high-pressure homogenization, micro-emulsion breaking, solvent emulsification-diffusion, ultrasonication, supercritical fluid techniques, and spray/freeze drying for solid lipid particles [3].
- Innovative carriers: liposomes, solid lipid nanoparticles (SLNs), nanostructured lipid carriers (NLCs), ISAsomes, lipid-coated mesoporous silica nanoparticles [1] Marketed Lipid-Based Capsule Formulations

Table 3: Characterization of Lipid-Based Formulations

Trade Name	Drug	Capsule Type	Uses
Neoral	Cyclosporin A	Soft gelatin	Immunosuppressant
Sandimmune	Cyclosporin A	Soft gelatin	Immunosuppressant
Gengraf	Cyclosporin A	Hard gelatin	Immunosuppressant
Convulex	Valproic acid	Soft gelatin	Antineoplastic
Targretin	Bexarotene	Soft gelatin	Antineoplatic
Rocaltraol	Calcitriol	Soft gelatin	Calcuim regulation
Norvir	Ritonavir	Soft gelatin	HIV antiviral
Fortovase	Saquinavir	Soft gelatin	HIV antiviral
Kaletra	Lopinavir Ritonavir	Soft gelatine	HIV-1 antiviral

Key parameters: appearance, homogeneity, pH, density, viscosity, droplet size, zeta potential, and dissolution profile [2].

Analytical methods include dynamic light scattering, viscometry, SEC, and *in vitro* dissolution models [1].

Challenges and Solutions

- Stability, drug loading efficiency, and scalability remain key concerns [4].
- Advances in solidified formulations (S-SEDDS), nanoemulsions, and engineered carriers offer solutions to poor stability and limited loading [1].

Future Perspectives

- Integration of lipid-based formulations with nanotechnology and targeted delivery can enable personalized medicine and new modalities for challenging drug molecules [3].
- Emerging carriers such as lipid nano capsules, ISAsomes, and mesoporous silica have shown promise for sustained release and enhanced bioavailability [1].
- Ongoing research on mechanism, clinical efficacy, and human trials is essential to translate laboratory success into therapeutic breakthroughs [1].

Conclusions

Lipid-based oral formulations in capsules represent a versatile and robust approach for addressing the challenges of poorly water-soluble drugs. Their continued innovation, supported by advances in excipients, carrier systems, and manufacturing techniques, is poised to enhance therapeutic outcomes and broaden the pharmaceutical toolkit for

clinicians, researchers, and formulators. The evidence and clinical applications reviewed herein underscore the future potential of lipid-based systems in pharmaceutical development [1].

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