

HOLISTIC REVIEW OF NOVEL DELIVERY SYSTEM FROM CLASSICAL LIPOSOMES TO MODERN NANOCARRIERS AND RAPIDLY DISSOLVING PLATFORMS

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ABSTRACT

Improvements in delivery methods have revolutionized pharmaceutical sciences as we know, providing greater effectiveness, precision of delivery, and adherence rates of treated patients. This review discusses both established and innovative delivery methods and technologies, beginning with liposome: a versatile vesicular carrier for both hydrophilic and hydrophobic medicaments. The structural categorization of liposomal in relation to preparation techniques and clinical implications establishes the applicability of liposomes for controlled and targeted release of a medicament. In addition to discussing traditional vesicular carriers, the review provides insights on lipid-based nanocarriers (Solid Lipid Nanoparticle (SLNs) and Nanostructured Lipid-carriers (NLCs)) which could deliver products at higher drug stability and bioavailability, and site-specific distribution potential, although there are still

challenges associated with formulation. Proniosomes provide a long-term stable alternative for storage of niosomes. Proniosomes will allow a niosome precursor to alleviate storage problems, enhance drug entrapment and allow sustained drug release. We will also discuss microencapsulation procedures, since they can protect drugs that are sensitive to oxygen, light or humidity, allow controlled or pulsatile release, or allow delivery of therapeutic agents to a target. Targeted delivery of therapeutic agents is an increasingly hot topic in precision medicine! With regard to advancements in oral dosage forms that meet the need of patient

centricity, we are reaching special populations that may otherwise not be accessible to them. Examples may include: mouth-dissolving tablets, mouth-dissolving films, effervescent tablets, and chewable tablets - all enhancing patient therapeutic outcomes through improved administration and consequently blunted onset of action. Each one of these different technologies (including pro-nisomes and mouth-dissolving tablets) demonstrates the paradigm shift towards precision, personalized and patient centric therapy in the field of pharmaceutical sciences. Continued advances in nanotechnology, engineering of material science, and planning to optimize formulations will further accelerate therapeutic benefit and improvements to a patient's quality of life.

KEYWORDS: Liposomes, Solid lipid nanoparticles (SLNs), Proniosomes, Microencapsulation, Patient-centric dosage forms.

1. INTRODUCTION

The area of drug delivery has advanced substantially over the last several decades from classical systems, (such as liposomes) to advanced nanocarriers and patient-compliant platforms. This transition is based on the perpetual search for better bioavailability, site-specific targeting and better patient compliance. Liposomes are round structures containing concentric spheres of vesicles.^[1]

Liposomes are round vesicles composed of phospholipids and cholesterol and were first described by Alec Bangham in the early 1960's while investigating phospholipids under an electron microscope.^{[2],[9]} These vesicles mimic biological membranes and can consist of hydrophilic and lipophilic drugs, making them useful candidates for target-directed drug delivery.^{[3],[4]} Their amphipathic nature enables them to encapsulate a range of molecules which allows them to provide protection of agents from enzymatic degradation as well as limit in vivo systemic toxicity.^[5]

The potential of Liposomes is broad and has been applied in chemotherapy, gene therapy, and the delivery of vaccines. Novel liposomal formulations have demonstrated an increase in residence time in the systemic circulation as a result of evading the reticuloendothelial system (RES) and enhancing tissue uptake.^[6,7] In addition, existing liposomal products have been approved for topical clinical use such as liposomal amphotericin B and liposomal doxorubicin,^[7] which demonstrates the significance of this drug delivery technique as a therapeutic tool.

Furthermore, development has proceeded to functional modifications, such as PEGylation and ligand tagging systems to provide active targeting.^[10] Although traditional liposomes have many strengths, they also have some weaknesses, such as poor encapsulation efficiencies of certain drugs and poor stability under physiological conditions. These weaknesses have contributed to several new lipid-based systems and new nano formulations.^{[8],[11]}

In this review, the purpose is to provide a comprehensive account of modern drug delivery, starting with the role of liposomes, and concluding with modern nanocarriers and patient-friendly oral dosage forms. Each step is a step closer to personalized, improved and safer therapeutics.

2. Liposomal Drug Delivery Systems

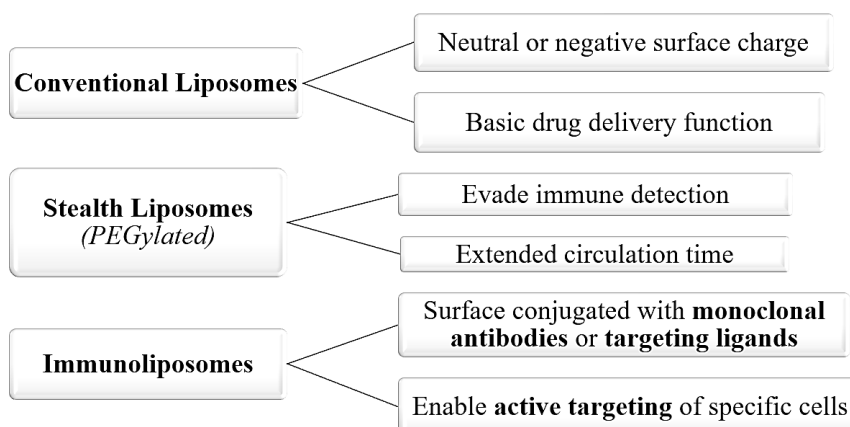
Liposomes are variable and biocompatible nanocarriers that have revolutionized drug delivery systems. Liposomes are spherical vesicles with either single- or multi-phospholipid bilayers and a beneficial aqueous core. The structural characteristics of liposomes can deliver both hydrophilic and hydrophobic drugs. Liposomes have the capability to enhance therapeutic effects, minimize systemic toxicity, and provide targeted delivery, which led to a wide of variations of liposomal formulations being reported in the clinical setting.^[12]

2.1 Classification of Liposomes^{[12],[13],[16]}

2.1.1. Based on Lamellarity & Size

| Type | Structure | Size Range |
|-----------------------------------|------------------------------|-------------|
| Small Unilamellar Vesicles (SUVs) | Single bilayer | 20–100 nm |
| Large Unilamellar Vesicles (LUVs) | Single bilayer | 100–1000 nm |
| Multilamellar Vesicles (MLVs) | Multiple concentric bilayers | 500–5000 nm |

2.1.2. Based on Surface Modification



2.2 Methods of Preparation

The preparation of liposomes requires the optimization of encapsulation efficiency, stability, and potential for scale. The method or technique used provides for the varying size and composition of liposomes or lipid particles. The methods most commonly employed include:

2.2.1. Thin-Film Hydration Method

The standard method consists of dissolving the lipids in an organic solvent, evaporating the solvent to natural thin film and hydrating the lipids into an aqueous drug solution. The standard method generally results in multilamellar vesicles (MLVs), which can be sonicated or extruded to give small unilamellar vesicles (SUVs).^{[12],[14],[15]}

2.2.2 Reverse-Phase Evaporation Method (REV)

REV is a method that was designed to better encapsulate hydrophilic drugs. The technique is to prepare a water-in-oil emulsion, ejecting the lipids and water and evaporating the solvent to get a large unilamellar vesicle with a distinct aqueous core.^{[14],[15]}

2.2.3 Ethanol and Ether Injection

These methods allow for spontaneous liposome formation when lipids dissolved in colonized into ethanol/ether are accidentally injected into aqueous media. This method is more favorable for generating relatively uniform vesicles at laboratory scale.^{[14],[15]}

2.2.4 Microfluidics and Supercritical Fluid Techniques

These methods provide a better control of the liposomes in terms of size and polydispersity in terms of controlling the liposome production methods and reproducibility and scalability.^{[13],[17]}

Each of these approaches has its pros and cons and each one is selected depending on application, drug profile or drug properties, and/or any scalability considerations.

2.3 Applications in Drug Delivery

Liposomes are flexible and advantageous delivery systems for various therapeutic applications because they are non-toxic, flexible in structure, and capable of encapsulating a wide variety of compounds.

2.3.1 Drug Encapsulation and Delivery

Liposomes can encapsulate hydrophilic drugs in the aqueous core of a liposome and hydrophobic drugs into the lipid bilayer. In each case, the presence of the aqueous core or lipid bilayer can improve the solubility and/or bioavailability of poorly water-soluble drugs. The lipid bilayer can also achieve direct delivery of drugs to the cytosol by fusing with biological membranes.^[12,16]

2.3.2 Targeted Delivery and Reduced Toxicity

When the liposome is functionalized with PEG or another ligand, the circulation time is increased for passive delivery or the liposome can achieve active targeting, respectively. For example, Doxil®, a PEGylated liposomal formulation of doxorubicin was designed to preferentially accumulate in tumor tissues (effect of enhanced permeability and retention [EPR]) and for which the clinical data suggested lower cardiotoxicity than free doxorubicin.^[16,17]

2.3.3 Gene Delivery and Lipofection

In gene therapy, liposomes were developed to deliver DNA and RNA, yet were well suited to transfection applications due to their ability to protect the genetic material from enzymatic degradation, and to facilitate entry into cells. In gene therapy, the process of transfection is referred to as lipofection.^[13]

2.3.4 pH-Responsive and Endocytosis-Targeted Systems

Liposomes are also being developed to identify changes in the surrounding pH. Some of the side effects of Doxorubicin can be attributed to an acidic environment, which can facilitate drug delivery, such as in tumor tissues or intracellular compartments. Various ranges of liposome sizes may also be recognized by macrophages, which perform phagocytosis, and this may be an excellent possibility for delivering drugs solely in pathological conditions related to the immune system.^[13,16]

2.3.5 Non-Pharmaceutical Applications

Liposomes have had non-pharmaceutical uses as well, and many businesses have used liposomes to encapsulate and deliver enzymes in food technology, dyes and agents in textile applications, and active ingredients in cosmetics. In the application of nano-cosmetology, liposomes improve penetration of active ingredients into the dermis, allow a slow or controlled release of agents, stabilize active agents and minimize irritant effects.^[13]

There appears to be an expanding range of promising uses for liposomes, in medical and in industry, given the advances we are now seeing in nanotechnology and new surface engineering strategies.^[12,13]

3. Lipid-Based Nanocarriers and Polymeric Nanoparticles

With the advances in nanotechnology, novel possibilities for drug delivery are being investigated, widely, it seems, on lipid-based nanocarriers and polymer-based nanoparticles. Such devices are also common in the pharmaceutical industry where they may be used to increase the solubility, stability, delivery, and release characteristics of active agents. Combining the biocompatibility and designed structures, the drug delivery systems and the polymer nanoparticles are perfect candidates for encapsulating many drugs, even for those having poor water solubility and bioavailability. Lipid Based Carrier for EGCG - Solid lipid nanoparticles (SLNs)^{[6],[16]} and Nanostructured Lipid Carriers (NLCs) In the recent times, lipid based carrier is being used as a potential alternative of conventional delivery systems and has advanced the delivery systems per se, by addressing the solubility issues.^{[18],[19]}

3.1 Solid Lipid Nanoparticles (SLNs)

SLNs are submicron colloidal drug carriers based on a combination of the advantages of polymeric nanoparticles and lipid emulsions. In contrast to emulsions, the lipids in SLNs are solid at storage and physiological temperatures, thus providing a matrix for active drug molecules to reside and enhance the protection of the drug and allow for controlled release purposes.^[20] SLNs can be created using several methods including high-pressure homogenization, solvent evaporation, or microemulsion processes. The lipids and surfactants should be selected based on their ability to develop favorable performance characteristics relative to particle size, entrapment efficiency, and release characteristics.^[20]

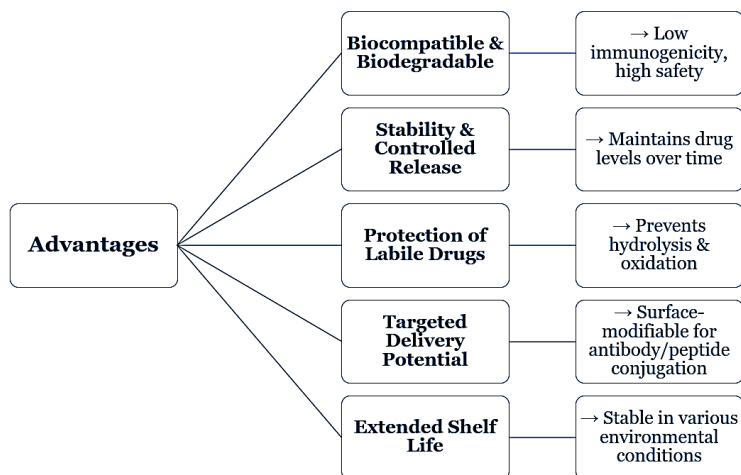
The solid lipids of SLNs can confer the key performance advantage of protecting the fragile drugs by shielding the molecules from enzymatic degradation/oxidation. Additionally, in comparison with emulsions, and by choosing the lipids and manufacturing process it is possible to either fabricate SLNs to target lipophilic or hydrophilic drugs. SLNs are also considered biodegradable, exhibit low toxicity, and therefore have great applicability within the pharmaceutical market space.^[19] The down side with SLNs may be their potentially low drug loading capacity due to size limitations, and possibility of drug expulsion or lipid resaturation may limit their applicability depending on the selected lipids during storage due to lipid polymorphism.^[20]

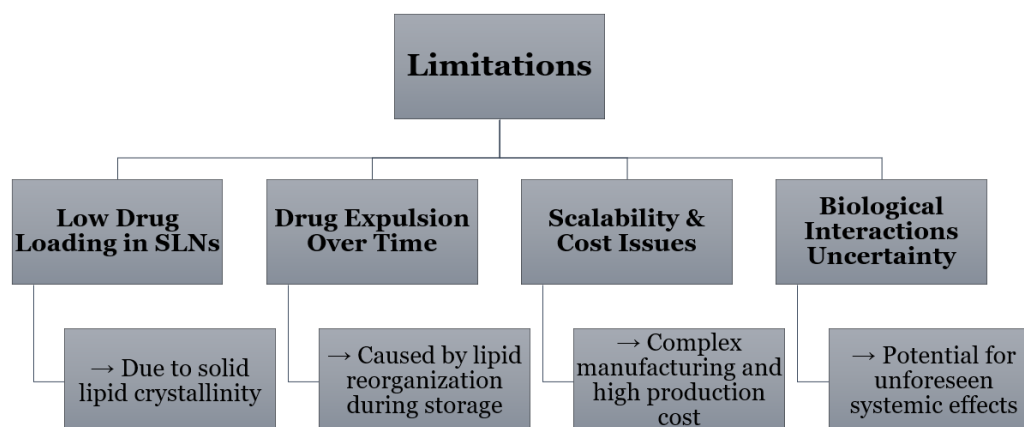
3.2 Nanostructured Lipid Carriers (NLCs)

Nanostructured Lipid Carriers (NLCs) have been developed as a second-generation lipid nanoparticle system to overcome some of the limitations associated with SLNs. NLCs are prepared with both solid and liquid lipids which create a less ordered lipid matrix relative to SLNs. This allowed to accommodate more pharmaceutical agents, resulted in increased drug loading and pharmacological agents being lost during very long-term storage.^[20] NLCs have exhibited improved entrapment efficiency and stability compared to SLNs and can encapsulate a wider variety of drugs including poorly soluble and unstable molecules.^[18]

These carriers showed greater flexibility in any administration routes, and have been effectively used in oral, topical, ocular, and pulmonary drug delivery systems. NLCs can effectively traverse a biological membrane and they have been shown to have a longer mucosal residence time which is advantageous for chronic disease therapy. The capacity for NLCs to be surface-modified to attach targeting ligands enables targeted based drug delivery and minimization of systemic synthesis side effects from a variety of routes of administration.^{[18],[22]}

3.3 Advantages and Limitations^{[18],[19],[20],[21],[22]}





4. Proniosomes and Microencapsulation Approaches^[23-25]

4.1 Structure and Mechanism of Proniosomes

Proniosomes are in dry granular or powder form that can be hydrated to form niosomes (a viscous liquid that contains vesicles made up of non-ionic surfactants). Proniosomes are semi-solid gels that formed from a combination of different liquid crystalline phases (lamellar, cubic and hexagonal). The lamellar structures are microscopic structures that typically contain non-ionic surfactants in combination with cholesterol. In the bilayer arrangement, the hydrophobic tails of the non-ionic surfactants orientate inwards, while the hydrophilic heads orientate outwards creating a sufficiently stable bilayer. During drug loading, hydrophilic drugs are entrapped into the aqueous core of the vesicles. Hydrophobic drugs are incorporated into the lipid bilayer of the proniosomes.^[27] Proniosomes have been researched as alternatives to liposomes and other carrier systems for both polar and non-polar (hydrophilic and hydrophobic) drug encapsulation. Proniosomes have a number of advantages, notably low toxicity due to the non-ionic nature of the surfactants, which means minimal aerosolized surfactant is present in the pharmaceutically useful form of the proniosome, and special environment or condition when formulating or preparing the proniosome product is not necessary. Proniosomes can also be made simply, safely, rapidly, and on a large scale without toxic solvents. In the development of any drug delivery system, stability is a critical component. In terms of stability, proniosomes have better chemical stability compared to liposomes and are inexpensive to produce, also proniosomes have a reduced risk of instability in the sense of common physical stability such as fusion, leakage, sedimentation, and aggregation during storage.^[28]

4.1.1 How proniosome systems work

a drug delivery system can be proniosome by utilizing the process of niosome formation. The function will be described in the following steps:

4.1.1.1 Hydration of the niosomes formation

Proniosomes which are dry and/or gel formulations are made up of non-ionic surfactants, cholesterol and possibly lecithin, are turned into niosomes (vesicular structures) through hydration with an aqueous phase. When the proniosomes are hydrated they will swell, the bilayers will swell, and spontaneous formation of around closed vesicles occur.

4.1.1.2 Formation of bilayers with niosomes

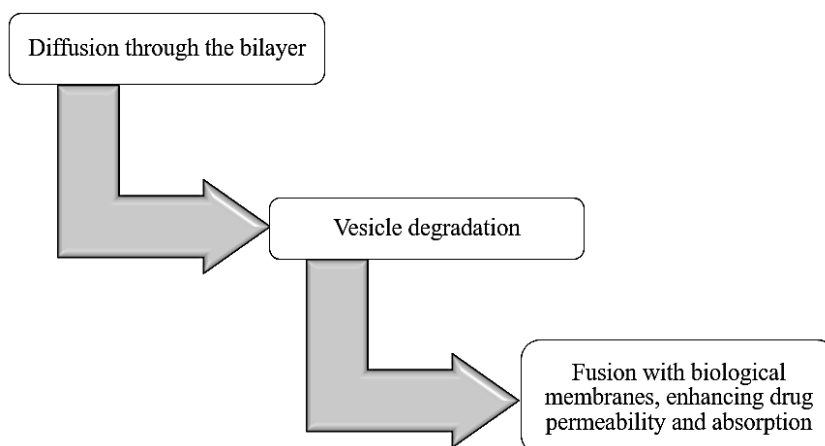
The surfactant molecules arrange themselves to that hydrophobic tails form adjacent bilayers. The water soluble (hydrophilic) heads of the surfactant molecules point outside the bilayer. The cholesterol separates the bilayers while contributing to the rigidity and stability of the membrane.

4.1.1.3 Drug encapsulation

When hydrophilic drugs are incorporated into the niosomes and become entrapped in the aqueous core or between bilayers. Hydrophobic drugs are contained within the lipids depending upon their characteristics.

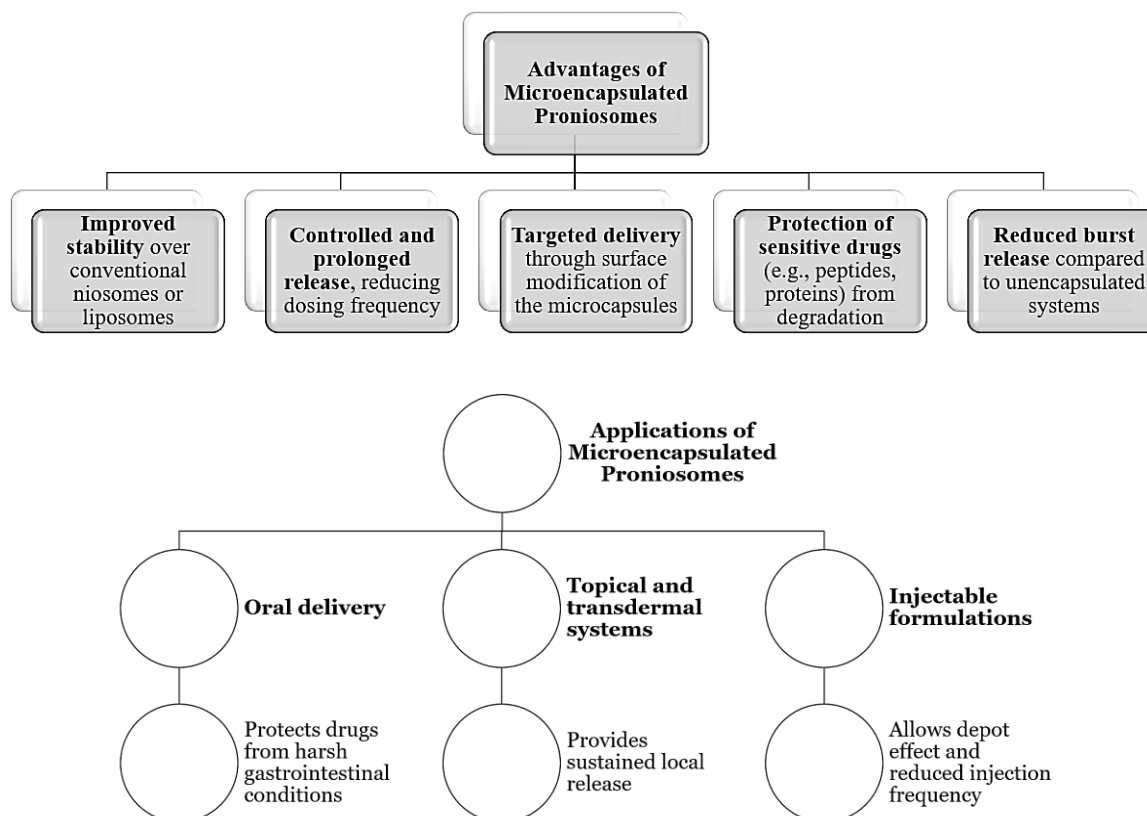
4.1.1.4 Drug release

Once niosomes formed from the proniosomes are applied (topical, orally or parenteral), they will act as a sustained-release instead of burst release system. the drugs will be released by:



4.2 Controlled Drug Delivery via Microencapsulation

Microencapsulation is a technique used to encase active pharmaceutical ingredients within a protective coating or matrix, often at the microscopic level. When applied to proniosomes, this technique enhances their ability to deliver drugs in a controlled and sustained manner.^[29]



Microencapsulation is a familiar technology that is used to encapsulate solid, liquid, or gaseous materials in a thin, protective, polymeric or lipid shell. It allows for modifying the rate of drug release, protects drugs from environmental degradation, and masks undesirable tastes or smells.^[21] There are many ways to microencapsulate a drug including coacervation, spray-drying, solvent evaporation, and interfacial polymerization. Each method is based on the physicochemical properties of the core material and encapsulating polymer.^[21]

Microencapsulation's great benefit is the ability for controlled or pulsatile drug delivery, which can be designed for a specific therapeutic requirement such as chronotherapy. For example, low density multiparticulate systems, which are a type of microencapsulation that are designed to float or remain at a specific part of the gastrointestinal tract to prolong the gastric residence time and time drug release with the diurnal rhythm.^[30] These drug delivery

systems are beneficial for treating diseases in which therapeutic timing is critical as in the case of hypertension, arthritis and asthma.^[30]

Moreover, microencapsulation can increase adherence through the decreased frequency of dosing and decreased side effects associated with peak drug concentrations. Also, the technology may have applications for targeted drug delivery, local action, and decreased systemic exposure, which is extremely useful for potent drugs with narrow therapeutic indices.^[21]

Overall, proniosomes and microencapsulation are important drug delivery innovations and provide flexible real-world solutions for the shortcomings of classic dosage forms. Further studies into proniosomes and microencapsulation are hopeful for a more intelligent, patient-centered therapy with improved therapeutic outcomes.^[15,21,30]

5. Rapidly Dissolving and Patient-Centric Oral Dosage Forms

5.1 Mouth-Dissolving Tablets and Films

Mouth dissolving tablets (MDTs) are formulated with the ability to disintegrate or dissolve in saliva rapidly within seconds to one minute without the ingestion of water. The use of MDTs will benefit patients that have dysphagia or dislike swallowing solid dosage forms of medications.^[31] These formulations typically use superdisintegrants, effervescent agents, or porous structures to enable rapid disintegration. Patel and Patel (2007) formulated mouth dissolving tablets of cinnarizine using superdisintegrants (crospovidone) and achieved disintegration times ≤ 26 seconds and better bioavailability.^[31] Kamboj et al. (2013) noted the importance of MDTs in the case of antihypertensive medication indicating that they formulated mouth dissolving tablets for amlodipine besylate. Their study illustrates the use of taste-masking agents and additionally optimize disintegration for use.^[32] The trend also seems to have progressed into mouth-dissolving films (MDFs), thin flexible films placed on the tongue. Sengar et al. (2024) developed MDFs of propranolol hydrochloride, and the authors reported rapid dissolution (within 30 seconds) and effective drug release, and thus may serve as an alternative for patients who prefer not to swallow or cannot tolerate tablets.^[33] Not only do these technologies not only offer greater therapeutic efficacy with faster onset of action but they also promote satisfaction and compliance.^[31,32,33]

5.2 Effervescent Tablets

Effervescent tablets are the modern patient-specific dosage form that dissolves in water to create a bubbly solution that is easier (and tastier) to take. These dosage forms are composed of effervescent compounds along with medicament, like citric acid and sodium bicarbonate. They will generate carbon dioxide due to a chemical reaction that helps the tablet dissolve faster and can help mask taste.^[34] Gupta and Mishra (2011) highlighted some of the benefits associated with effervescent tablets, including they can be used in patients having difficulty swallowing, and being pre-dissolved may also aid in faster absorption.^[34]

Kumar and Singh (2012) created paracetamol effervescent tablets, and were able to show the tablets maintained good mechanical strength while dissolving quickly. Their paracetamol formulation was also helpful in providing immediate relief associated with pain, or fever.^[35] Sengar et al.(2024) discussed formulation design options of effervescent tablets in more detail and indicated they could be formulated for use beyond analgesics to vitamins, minerals, and other actives where rapidity of action and palatability are important properties.^[36] This dosage form allows an opportunity for patients to comply with prescribed treatment regimens better based on better taste and better and faster effects.^[34,35,36]

5.3 Chewable Tablets

Orally-disintegrating tablets disintegrate and dissolve in the mouth and offer a treatment option for patients who are unable or unwilling to swallow a solid tablet. These can be flavored & sweetened for taste and are suitable for paediatric as well as geriatric population.^[37] For water-dissolving technology, the drug loading is low, unlike in the SS Chewable, which can load the drug extensively and can work for the drugs that are stable in a buccal cavity.

Sengar et al. (2024) worked on designing chewable tablets and reported the patient acceptability, and benefits such as easy to carry, desired taste and potential for local drug targeting to the oral cavity. The force considerations were also underscored with regard to technical appearance regarding retention of astral force solution against bursts when chewing.^[37] Therefore, chewable tablets offer an alternative between the conventional solid dosage forms and patient liking applications, to increase compliance and therapeutic effects.^[37]

In general, fast-dissolving, patient-friendly oral dosage forms such as MDTs, oral films, ODTs, effervescent tablets, and chewable tablets represent the ultimate in pharmaceutical technology for increasing patient convenience, treatment efficacy, and compliance.^[31–37]

6. CONCLUSION

Drug delivery has evolved over decades of development from conventional carriers like liposomes to advanced nanocarriers and patient-friendly oral dosage forms. The liposomes are still in use due to their capability to encapsulate a variety of drug molecules for controlled release with reduced toxicity and they continue to evolve through their classification and preparation. Lipid-based nanocarriers such as solid lipid nanoparticles (SLNs) and nanostructured lipid carriers (NLCs) have potential in enhancing the stability, bioavailability, and even targeted therapy of drugs or active pharmaceutical ingredients (APIs), and there are still some remaining issues related to lipid polymorphism and scale-up. Proniosomes can be utilized as a viable alternative for conventional delivery systems due to their stability and versatility as it provides a mean of hydration when mixing with niosomes for the preparation of niosomes, they show improved storage stability and drug entrapment. The microencapsulation process is another way for the drugs or API to be delivered, since through microencapsulation not only the active ingredient is protected from elements in the environment that would degrade them such as light and oxygen but also can encapsulate bad tasting drugs, and allow the release of the drugs is tailored to the therapeutic need (controlled release, pulsatile release) of the API. During the course of development of other advanced carriers, these patient compliant dosage forms like mouth dissolving tablets and films, effervescent tablets and chewable tablets have addressed some of the practical problems related to drug delivery, particularly in patients with dysphagia who require immediate therapeutic effects, increased compliance and ease of use without diminishing therapeutic effectiveness.

Overall, these technologies and new systems represent a crucial achievement towards the precision medicine and personalized therapeutics, toward establishing a match up between drug delivery and patient demand in the context of modern patient-driven healthcare. Progress on the other hand, by pushing further adaptations to solid and/or micro- and nano-technologies and, of more developed technology, will further evolve safe, efficient, patient-friendly drug delivery systems into the subsequent higher level of pharmaceutical care.

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