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Novel Drug Delivery Systems: A Paradigm Shift in Pharmaceutical Technology

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ABSTRACT

Drug delivery systems are conventional, and they have many shortcomings, such as low bioavailability, instability, and side effects. In order to deal with such problems, a series of novel drug delivery systems (NDDS) have been developed. Thus, NDDS like nanoparticles, liposomes, microspheres and nanotubes are more potent having a better bioavailability, targeted delivery and the controlled-release of active therapeutics.

This review highlights the recent development of NDDS, and their applications and advantages. NDDS for sustained/controlled release, targeting, and gene delivery are covered in this relevance. NDDS is a revolutionary concept in pharmaceutical industry which can improve patients outcomes. The recent advancements of NDDS as well as inherent limitations and future outlook of NDDS are also being discussed.

Thus different NDDS generally have the future scope of treating many diseases which includes cancer, diabetes and infectious diseases. Nanomedicine aims to develop Nano drug delivery systems (NDDS) with the intention to provide controlled and site-specific delivery of therapeutic agents, thereby eventually increasing efficiency, lowering side effects as well as improving patient compliance.

This review ought to provide an overview of NDDS and why they must reform the pharmaceutical, and to do so is paramount in helping reduce the burden in healthcare systems.

1] INTRODUCTION

Traditional drug delivery systems have several limitations such as high dosage requirement to achieve the most desirable pharmacologic effect, decreased bioavailability causing a negative impact on therapeutic results, poor stability of the drug, first pass effect causing the drug to be metabolized before reaching its target area, and variable plasma drug concentration causing undesired therapeutic outcomes7-9.

These drawbacks have led to the development of Novel Drug Delivery Systems (NDDS). The advantages of NDDS are better performance by improving bioavailability and efficacy, protection of therapeutic agent from degradation or inactivation, increased patient compliance due to lower administration frequency or improved formulation, reduced product expiry which leads to increased wastage and providing effectiveness in supply chain management.

The NDDS usually comprises nanoparticles with a diameter between 10 and 100 nm. These microscopic particles possess unique characteristics that make them preferable for the selective delivery of medications. Nanoparticles were shown to modify the properties of pharmacodynamics and pharmacokinetics, and to enhance therapeutic effects, which was applied in NDDS [5]. Active agents can be encapsulated or adsorbed on particles to protect them from degradation or inactivation in the bloodstream, while the localized administration of the medications01 can limit side effects and enhance the efficacy.

In addition, NDDS employing nanoparticles has the potential to revolutionize the evolution of drug delivery systems to date. Undeniably, NDDS is an excellent concept; it can be used for improving public health by giving better therapeutic outcomes, improved patient compliance, and economical healthcare. [1]

It enables more consistent and regulated drug release, and maintaining the therapeutic concentration of the drug in the blood for longer durations[5]. It could offer a new means to reduce the risk of adverse side effects, which in drug therapy come in the form of wildly varying doses and plasma concentrations. By providing constant and predictable drug release, these systems improve patient compliance, decrease frequent dosing, and reduce total dosage administered. Moreover, constant effective release features in a single delivery mechanism can significantly improve the therapeutic impact due to better treatment yield and efficient disease management. [2]

1.1] TYPES OF NDDS

A] [NANOPARTICLES

The advent of drug delivery through Nanoparticles has played a key role in making medicine selective and efficient, which would pave the way for newer drug delivery mechanisms in the pharmaceutical industry. Nanotechnology the new frontier; the impact of these rapid advances are expected to be felt across the drug delivery industry, affecting everything from oral medications to injectables, leading to more effective and targeted treatment delivery. Nanoparticles are increasingly being used for drug delivery because of their many advantages, such as decreased toxicity, lower treatment cost, improved bioavailability, and increased patent duration of drugs. This will greatly enhance the power of drug treatments, reduce [3] In addition, nanoparticles are being explored as the basis for new molecular contrast agents, creating a bridge from poorly soluble and labile biological materials to potent therapeutics. With one of the largest design spaces to explore; not only due to their unique properties of improved intracellular penetration, bioavailability across multidrug resistant biological targets and circumvention of biological barriers make nanoparticles a promising prospect for targeted drug delivery but also heralding a new era of drug discovery by development of pharmacokinetics. [4]

B] LIPOSOMES

Small vesicular structures which are multilamellar (Figure no. 1), consisting of phospholipids arranged in layers, which separates an internal compartment from an external medium, are called liposomes. These regions have differential affinities for various drug molecules which facilitate their selective and effective encapsulation. Hydrophilic drugs, which have strong solubility in water, are easily entrapped within the internal zone, or core, of the liposome, while hydrophobic drugs, or those that cannot be dissolved in water, are taken into the peripheral zone within the phospholipid-lipid layers [5]. Different types of liposomal formulations have also been developed, such as niosomes, phytosomes, ethosomes, and transfersomes, which have different types of features. The construction of these structures requires the use of nonionic surfactants with little or no phospholipid that favor the formation of niosomes that exhibit excellent aqueous dispersibility and stability, which are highly applicable in pharmaceuticals and cosmetics. [6,7]

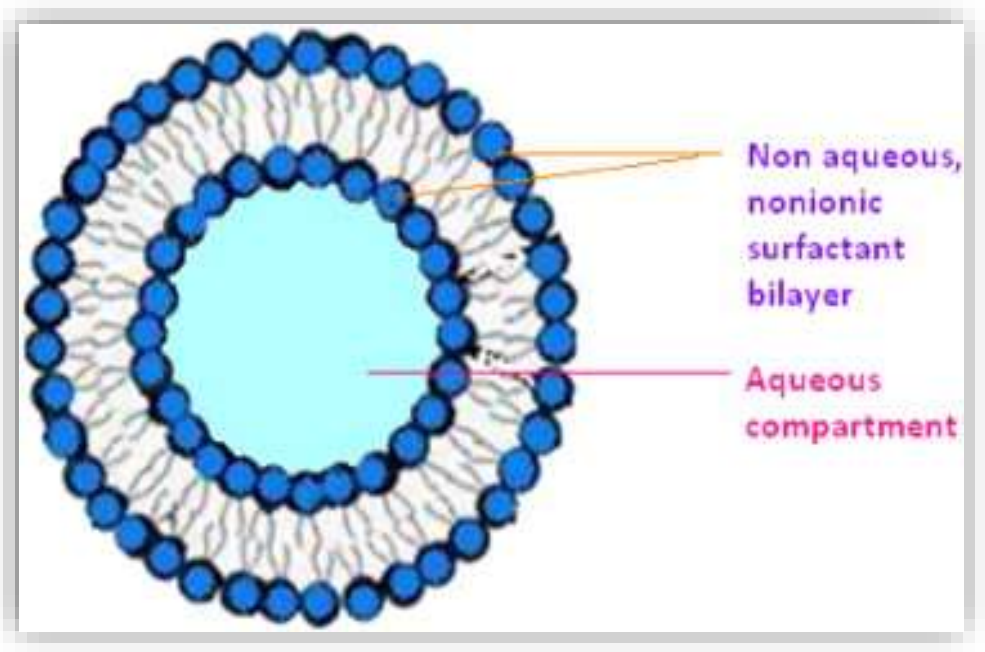

Fig no. 1: Structure of Liposomes

C]TRANSFEROMES

Transferosomes are a type of liposome that exhibits exceptional flexibility and elasticity due to the presence of single-chain surfactants, which act as edge activators. In contrast, ethosomes are a variant of liposomes that are prepared using ethanol as a primary component. Phytosomes, on the other hand, refer to liposomes that are specifically designed to encapsulate active ingredients of herbal or plant origin. The unique vesicular structure of liposomes has made them an attractive option for encapsulating a wide range of biotherapeutic agents, which vary in terms of their physicochemical properties and three-dimensional structures. This versatility has enabled liposomes to be tailored to meet the specific needs of different therapeutic agents, making them a valuable tool in the development of novel drug delivery systems.[8]

D]MICROSPHERE:

Microspheres are incredibly small, spherical particles that range in diameter from 1 micrometer to 1 millimeter, and are also referred to as micro-particles. These tiny particles can be fabricated from a diverse array of natural and synthetic materials, including glass, polymers, and ceramics, each with its own unique properties. Microspheres can be broadly classified into two categories: biodegradable and non-biodegradable. Biodegradable microspheres, such

as those derived from albumin, starch, gelatin, and polylactic acid, are designed to break down naturally in the body, making them ideal for applications where biocompatibility is crucial. In contrast, non-biodegradable microspheres are more durable and can be used for controlled-release applications, where the release of a therapeutic agent is carefully regulated over time. Notably, polylactic acid is the only polymer approved for human use, and it is utilized as a controlled-release agent due to its unique properties. The density of microspheres can vary significantly, with solid and hollow microspheres exhibiting different properties, making them suitable for a wide range of applications, from pharmaceuticals to cosmetics.[9]

1.2] Role Of Drug Delivery System

Sustained/Controlled Release

The novel drug delivery system has revolutionized the pharmaceutical industry by enabling the prolonged release of therapeutic agents from their dosage forms, thereby reducing the frequency of dosing and improving patient compliance. This approach is particularly beneficial for drugs with short half-lives, as it allows for the development of sustained-release formulations that maintain optimal drug concentrations in the body for an extended period. By converting therapeutic substances into novel forms, researchers can significantly improve oral bioavailability, enhance the efficacy of treatments, and minimize side effects. For instance, the antidiabetes agent miglitol, which has a half-life of approximately 2 hours, was incorporated into poly-e-caprolactone microspheres to create a sustained-release delivery system for managing type-2 diabetes mellitus. The resulting microspheres demonstrated a slowed release rate over 10 hours, with significant models for drug release, highlighting the potential of this approach to improve glycemic control. Similarly, researchers developed microspheres of metformin hydrochloride using low-cost agar, which exhibited sustained-release action for 12 hours, providing a promising alternative for the management of diabetes. These innovative formulations showcase the potential of novel drug delivery systems to transform the treatment of various diseases, offering improved therapeutic outcomes, enhanced patient compliance, and reduced healthcare costs.[10]

Targeting Using Carriers

New carriers li (niosomes, nanoparticles, liposomes, and resealed erythrocytes) are considered a new generation tool for target drugs transporting drugs to the targeted tissue at a predetermined time. Targeted drug delivery aims at localizing the therapeutic agent at the tissue level leading to extensive therapeutic actions with the least side effects. A drug's therapeutic efficacy depends on its specific interaction with its target receptor, and a targeted drug delivery system can improve the therapeutic efficacy of a drug administered to the systemic circulation. Using these innovative carriers, researchers are able to design drug paradigms that can maximize those therapeutic benefits and minimize cytotoxicity with enhanced patient compliance. [11]

NDDS as Delivery Vehicles

Nanocarriers such as nanoparticles, resealed erythrocytes, and niosomes have recently been developed as innovative carriers for targeted drug delivery, thereby providing a localized and prolonged pharmacological action than that of conventional dosage forms. These nanocarriers can be employed judiciously to precisely deliver therapeutic agents, like anticancer drugs, to specific sites of action, like tumors, where they are most effective. This paved the way for, among many others, the development of polymeric micelle nanoparticles for targeted drug delivery to tumors, as well as polymeric-coated iron oxide nanoparticles capable of breaking down aggregates of bacteria for improved therapy of chronic bacterial infections. Also, biomolecule nanoparticles are potential carriers for biomolecules such as DNA, RNA, and proteins, and protect the biomolecules from degradation and facilitate their transport across the membranes of cells. In addition, nanoparticles can also be used to deliver anticancer drugs due to their potent anticancer effects relative to standard drug formulations – making a safe and efficient platform for cancer therapy. [12]

Gene Delivery

Nanocarrier-based systems have also been reported for gene delivery, and they hold great promise in cancer gene therapy. In particular, nanotubes have been used to shuttle DNA delivery past cell membranes, which is essential for gene therapy. They do this by either attaching DNA to the tips of nanotubes or encasing it in the tubes themselves. In addition, the application of plasmid DNA targeted delivery to specific organs using ultrasound and nanobubbles has been studied. Under ultrasound, nanobubbles cavitate, which helps in transporting plasmid DNA across cell membranes. Learn about this novel method by which genetic material can be effectively delivered to your cells and tissues, paving the way for next-generation vectors for gene therapy. [13,14]

2]EVALUATION OF NOVEL DRUGS

2.1] Theorem on Drug Stability]]

Temperature: Changes in temperature may lead to chemical reactions and degradation. Higher temperatures increase the hydrolysis rate which has an impact on drug stability.

Water: Absorption of moisture can change some of their physical and chemical properties, resulting in instability. Hydrolysis, oxidation, or other degradation reactions can occur when moisture is present.

pH: The pH of the environment affects the rate of hydrolysis. Buffers act as a regulatory system that keeps pH levels stable.

Excipients: Some excipients (starch and povidone) impact stability as they have inherent water content and can also interact chemically with drugs.

Oxygen: Some products can oxidise, leading to degradation. The replacement of oxygen by either carbon dioxide or nitrogen can help stabilize them.

Light: Some of these drugs are sensitive to light and degrade when exposed to it, which means they must be packaged and stored in special containers.

2.2] Types of Stability

Physical Stability: Critical for safety and effectiveness, impacting drug uniformity and release rate. These may refer to physicals, such as size, palatability, homogeneity, dissolution, and suspension.

Chemical stability: Guarantees that the chemical quality and actual strength of the active ingredients are within specified limits. Chemical stability is essential to ensure efficacy and safety.

Microbiological Stability: Antimicrobial agents keep working, and product is sterile or resistant to microbial growth.

Therapeutic Stability — Keeps the therapeutic effect stable Therapeutic stability is essential for reproducibly good efficacy and safety.

Stability in Toxicological Concerns: There is a responsible absence of excessive increase in toxicity. TOXICOLOGICAL STABILITY Safety can only be maintained if the formulations are stabilised.

2.3] Methods of Stability Testing

Stability testing is an essential part of product development: it helps ensure that a drug remains effective and safe for its intended shelf life. Stability testing can be of four types:

Long-term Stability Testing: In this test, the product is stored for a longer time period to induce significant degradation. Understanding Real-time Testing Real-time testing is the practice of getting real-world stability data.

For Humidity: Accelerated Stability Testing: Exposing products at higher temperature to predict stability and shorten development plans. Shortened tests give early indication of stability.

Stability Testing/Sample Retention: Testing products that have been retained in order to confirm their stability over time. Stability data from retained sample testing gives further evidence.

Cyclic Temperature Stress. Testing: Testing a product under varying temperature. conditions to assess stability. Thermal stability data is provided via cyclic temperature testing.

2.4] Essential Aspects of Stability Testing

Stability testing is essential in maintaining quality, safety and efficacy of any pharmaceutical products. It helps to:

Ensure Shelf -predicts the shelf life of a product, ensuring it remains effective and safe throughout its storage and use.

Identify Degradation Pathways — Stability testing identifies degradation pathways that, in turn, can be addressed by developing preventive or mitigative strategies.

STABILITY TESTING: They help in ensuring the stability of a product.

Compliance with Regulatory Requirements: Regulatory agencies require stability testing to demonstrate compliance with safety and efficacy requirements.

CONCLUSION

To sum up, NDDS has redefined the pharmaceutical industry by allowing for targeted, sustained, and controlled release of drugs. The advent of nanoparticles, liposomes, microspheres, and other nanocarriers has enabled a new era of drug and gene delivery systems as they have improved bioavailability, lower toxicity, and higher therapeutic efficacy. These cutting-edge systems have shown tremendous promise in numerous applications from cancer therapy and gene delivery to chronic diseases like diabetes and bacterial infections. In addition, NDDS have been suggested to help improve patient compliance, lead to lower healthcare costs, and improve quality of life of patients. NDDS are likely to become increasingly important in the practice of medicine, as researchers continue to push the boundaries of drug delivery technologies to provide innovative solutions for various health challenges, improve therapeutic outcomes, and enhance the quality of life of patients.

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