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A REVIEW ON NOVEL DRUG DELIVERY SYSTEM: A RECENT TREND

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ABSTRACT

Plants have been used since ancient times as natural remedies for food and medicine. Today, there is a global interest in discovering herbal medicines from plants and developing suitable drug delivery systems for them. The basic idea is that nature holds a cure for every disease.

However, herbal drugs need improved delivery methods to achieve sustained release and better patient compliance. In the past, scientists faced difficulties in modifying herbal drugs due to problems with processing, standardization, extraction, and identification. But with modern technological advancements, **Novel Drug Delivery Systems (NDDS)** have opened new possibilities for developing **herbal formulations**.

Using advanced techniques helps in protecting drugs from toxicity, improving stability, enhancing bioavailability, and preventing physical or chemical degradation. NDDS improve the therapeutic value of herbal medicines while reducing side effects.

The main goals of these systems are to:

- Minimize drug degradation and loss
- Prevent harmful side effects
- Increase bioavailability
- Deliver drugs directly to the target site

Drug targeting can be achieved in two ways:

1. **Passive targeting**
2. **Active targeting**

Different drug carriers used include soluble polymers, microparticles, microcapsules, cells, liposomes, lipoproteins, and micelles. Controlled drug carrier systems such as micellar solutions, vesicles, liquid crystal dispersions, and nanoparticles (10–400 nm) show great potential for effective drug delivery. **Hydrogels**, which are 3D polymer networks capable of absorbing large amounts of water, are also promising carriers.

Keywords: New Drug Delivery System, Phytosome, Nanoparticles, Microsphere, Transdermal Drug Delivery System Carriers, Colloidal Drug Carriers.

1. INTRODUCTION

Herbal formulation means a dosage form consisting of one or more herbs or processed herbs in specified quantities to provide specific nutritional, cosmetic benefits, and/or other benefits. Herbal preparations are obtained by subjecting whole plant, fragmented or cut plants, plants parts to treatments such as distillation, extraction, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates [1]. Herbal drug itself is complex structure of many active constituents; As all of them provide synergistic action and enhance the therapeutic value [2]. Herbal drugs have lesser side effects [3,4].

Novel drug delivery systems can include those based on physical mechanisms and those based on biochemical mechanisms. Physical mechanisms also referred as controlled drug delivery systems include osmosis, diffusion, erosion, dissolution and electro transport. Biochemical mechanisms include monoclonal antibodies, gene therapy, and vector systems, polymer drug adducts and liposomes. Targeting is the ability to direct the drug-loaded system to the site of interest. Two major mechanisms can be distinguished for addressing the desired sites for drug release: (i) Passive and (ii) Active targeting.

Therapeutic benefits of some new drug delivery systems include optimization of duration of action of drug, decreasing dosage frequency, controlling the site of release and maintaining constant drug levels [5,6,7]

Advantages of novel drug delivery system:

1. Protection from physical and chemical degradation.

2. Sustained delivery.
3. Improved tissue macrophages distribution.
4. Enhancement of stability.
5. Enhancement of pharmacological activity.
6. Protection from toxicity.
7. Increased bioavailability.
8. Enhancement of solubility [8].

Recent developments in novel drug delivery system of herbals:

1. Phytosome
2. Liposome
3. Nanoparticles
4. Emulsions
5. Microsphere
6. Ethosome
7. Solid lipid nanopartical
8. Niosomes
9. Proniosomes
10. Transdermal Drug Delivery System
11. Dendrimers
12. Liquid Crystals
13. Hydrogels [9]

Phytosome:

Phytosomes are lipid compatible molecular complex which are composed of "phyto" which means plant and "some" meaning cell-like [10]. Complexing the polyphenolic phytoconstituents in the molar ratio with phosphatidyl choline results in a new herbal drug delivery system, known as "Phytosome". Phytosomes are advanced forms of herbal products that are better absorbed, utilized to produce better results than those produced by conventional herbal extracts. Phytosomes show better pharmacokinetic and therapeutic profiles than conventional herbal extracts [11].

Advantages of phytosome:

1. Phytosome increases the absorption of active constituents, so its dose size required is small.
2. There is appreciable drug entrapment and improvement in the solubility of bile to herbal constituents, and it can target the liver.
3. In Phytosome, chemical bonds are formed between phosphatidylcholine molecules, so it shows good stability [12].
4. Phytosome improves the percutaneous absorption of herbal phytoconstituents [13]

Liposomes:

Tiny pouches made of lipids, or fat molecules surrounding a water core widely used for clinical cancer treatment. Several different kinds of liposomes are widely employed against infectious diseases and can deliver certain vaccines. During cancer treatment they encapsule drugs, shielding healthy cells from their toxicity, and prevent their concentration in vulnerable tissues such as those of patient kidneys and liver. Liposomes can also reduce or eliminate certain common side effects of cancer treatment such as nausea and hair loss.

They are form of vesicles that consist either of many, few or just one phospholipid bilayers. The polar character of liposomal core enables polar drug molecules to be encapsulated. Amphiphilic and lipophilic molecules are solubilized within phospholipid bilayer according to their affinity towards phospholipids.[14]

Advantages of liposomes:

1. The high biocompatibility.
2. The easiness of preparation.
3. The chemical versatility that allows the loading of hydrophilic, amphiphilic, and lipophilic compounds.

The simple modulation of their pharmacokinetic properties by changing the chemical composition of the bilayer components [15].

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Use of Liposomes:

Another major and important advancement in the novel drug delivery systems is the use of liposomes for carrying the drugs to the site of action. Liposomes in both modified and unmodified forms are able to change the course of pharmacokinetic parameters of the drugs. These are widely used in delivering the cytotoxic agents to the tumour tissue and preventing side effects like myelosuppression. These are also used in targeting through receptor-mediated endocytosis. Modified liposomes also have huge applications in targeting various drugs to the organs like heart, liver, kidney, lungs and bones [16].

Nanoparticles:

Nanoparticles (including nanospheres and nanocapsules of size 10-200 nm) are in the solid state and are either amorphous or crystalline. They are able to adsorb and/or encapsulate a drug, thus protecting it against chemical and enzymatic degradation. In recent years, biodegradable polymeric nanoparticles have attracted considerable attention as potential drug delivery devices in view of their applications in the controlled release of drugs, in targeting particular organs / tissues, as carriers of DNA in gene therapy, and in their ability to deliver proteins, peptides and genes through the peroralroute [17,18]

Advantages of herbal nanoparticle delivery system

1. Nanoparticulate system delivers the herbal formulation directly to the site of action.
2. Increased efficacy and therapeutic index.
3. Increased stability via encapsulation.
4. Improved pharmacokinetic effect.
5. Producible with various sizes, compound surface properties [19].

Emulsions:

Emulsion is a biphasic system in which one phase is intimately disperse in the other phase in the form of minute droplets in ranging in diameter from 0.1μm to 100 μm. In emulsion, one phase is always water or aqueous phase, and the other phase is oily liquid, i.e. non aqueous. Among them, the microemulsion is also called nanoemulsion, and the sub-micro-emulsion is called liquid emulsion [20]. Microemulsion is a clear, thermodyanamically stable, frequently in combination with a co-surfactant [21].

Advantages of emulsion-based formulations:

1. It can release the drug for a long time because it is packed in the inner phase and makes direct.
2. Contact with the body and other tissues.
3. As a result of the lipophilic drugs being made into o/w/o emulsion, the droplets of oil are phagocytosised by macrophages and increase its concentration in liver, spleen and kidney.
4. As the emulsion contains herbal formulation, it will increase the stability of hydrolyzed formulated material and improve the penetrability of drug into skin and mucous.
5. The new type, viz., Elemenum emulsion, is used as an anti-cancer drug and causes no harm to the heart and liver [22].

Microsphere:

Microsphere comprises of small spherical particles, with diameters in the micrometer range, typically 1 μm to 1000 μm (1 mm). Microspheres are sometimes referred to as micro-particles. Microspheres can be manufactured from various natural and synthetic materials. Glass microspheres, polymer microspheres and ceramic microspheres are commercially available. Microspheres are classified as biodegradable or non-biodegradable. Biodegradable microspheres include albumin microspheres, modified starch microspheres, gelatin microspheres, polypropylene dextranmicrospheres, polylactic acid microspheres, etc. According to the current literature reports on non-biodegradable microspheres, polylactic acid is the only polymer approved to be used by people, and it is used as a controlled-release agent. Solid and hollow microspheres vary widely in density and therefore are used for different applications [23].

Ethosomes:

Ethosomes are developed by mixture of phospholipids and high concentration of ethanol. This carrier can penetrate through the skin deeply lead to improve drug delivery into deeper layer of skin and in blood circulation. These formulations are useful for topical delivery of alkaloids in form of gel and cream for patients comfort. They show increase in their permeability through the skin by fluidizing the lipid domain of the skin. Unstable nature and poor skin penetration are limits for Ethanosomes tropical delivery. The Ethosomes was developed and examined for their ability

the topical absorption of Tetrandine through dermal delivery, and the relation of formulations to the pharmacological activity of Tetrandrine loaded in the formulation was also accessed. Result of the drug levels in rat plasma showed that when Tetrandrineloded Ethosomes were topically administered in rats the drug level was low to be detected in rat plasmaIn conclusion, Ethosomes were demonstrated to be promising carrier for improving topical delivery of Tentrandrine via skin [24].

Advantages of ethosomal drug delivery:

1. Ethosomes enhance transdermal permeation of drug through skin.
2. Ethosomes are a platform for the delivery of large amounts of diverse groups of drugs.
3. Ethosomaldrud is administered in semisolid form resulting in improvement in patients compliance [25].

Solid lipid nanoparticles:

(SLNs) are a new pharmaceutical delivery system or pharmaceutical formulation.

The conventional approaches such as use of permeation enhancers, surface modification, prodrug synthesis, complex formation and colloidal lipid carrier based strategies have been developed for the delivery of drugs to intestinal lymphatics. In addition, polymeric nanoparticles, self-emulsifying delivery systems, liposomes, microemulsions, micellar solutions and recently solid lipid nanoparticles *(SLN)* have been exploited as probable possibilities as carriers for oral intestinal lymphatic delivery.[25]

A solid lipid nanoparticle is typically spherical with an average diameter between 10 and 1000 nanometers. Solid lipid nanoparticles possess a solid lipid core matrix that can solubilize lipophilic molecules. The lipid core is stabilized by surfactants (emulsifiers). The term lipid is used here in a broader sense and includes triglycerides (e.g. tristearin), diglycerides (e.g.glycerolbahenate), monoglycerides (e.g. glycerol monostearate), fatty acids (e.g. stearic acid), steroids (e.g. cholesterol), and waxes (e.g. cetyl palmitate). All classes of emulsifiers (with respect to charge and molecular weight) have been used to stabilize the lipid dispersion. It has been found that the combination of emulsifiers might prevent particle agglomeration more efficiently.[26,27]

Niosomes:

Niosomes are multilamellar vesicles formed from non-ionic surfactants of the alkyl or dialkyl polyglycerol ether class and cholesterol. Earlier studies, in association with L'Oreal have shown that, in general, niosomes have properties as potential drug carriers similar to liposomes. Niosomes are different from liposomes in that they offer certain advantages over liposomes [28].

Proniosomes:

Proniosomes gel system is step forward to niosome, which can be utilized for various applications in delivery of actives at desire site. Proniosomal gels are the formulations, which on in situ hydration with water from the skin are converted into niosomes [29].

Dendrimers:

Dendrimers are precisely defined, synthetic nanoparticles that are approximately 5–10 nm in diameter. They are made up of layers of polymer surrounding a control core. The dendrimers surface contains many different sites to which drugs may be attach and also attachment sites for materials such as PEG which can be used to modified the way of dendrimer which interacts with body. PEG can be attached to dendrimer to ‘disguise’ it and prevent the body’s defense mechanism for detecting it, there by slowing the process of break down. This fascinating particle holds significant promise for cancer treatment. Its many branches allow other molecules to easily attach to its surface. Researchers have fashioned dendrimers into sophisticated anticancer machines carrying five chemical tools–a molecule designed to bind to cancer cells, a second that fluorescence upon locating genetic mutations, a third to assist in imaging tumor shape using x–rays, a fourth carrying drugs released on demand, and a fifth that would send a signal when cancerous cells are finally dead. The creators of these dendrimers had successful tests with cancer cells in culture and plan to try them in living animals soon [30,31]

Liquid Crystals:

Liquid Crystals combine the properties of both liquid and solid states. They can be made to from different geometries, with alternative polar and non-polar layers (i.e., a lamellar phase) where aqueous drug solutions can be included [32].

Hydrogels:

Hydrogels are three-dimensional, hydrophilic, polymeric networks capable of imbibing large amounts of water or biological fluids. They are used to regulate drug release in reservoir-based, controlled release systems or as carriers in swellable and swelling-controlled release devices [33].

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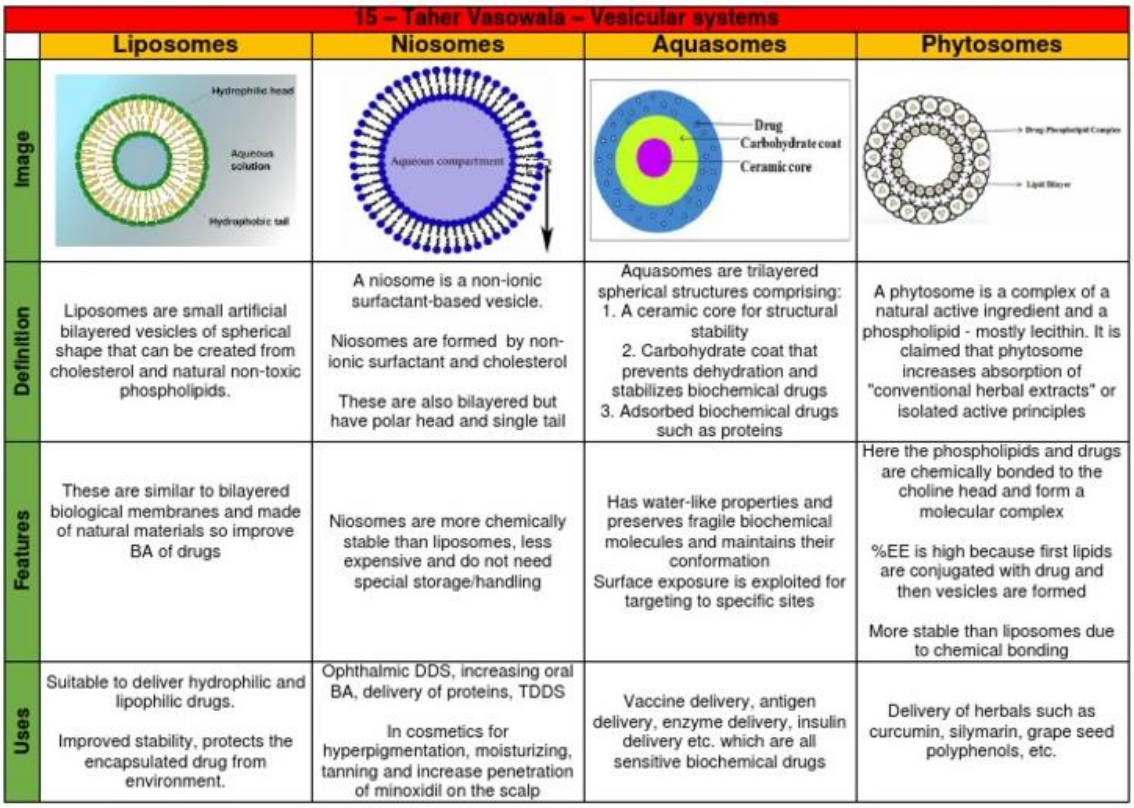

Fig 1: Structure of Liposome &Phytosome

Comparison of liposome and phytosome structures

Feature	Liposome	Phytosome
Basic Structure	A spherical vesicle composed of one or more concentric lipid bilayers that enclose an inner aqueous volume.	A complex formed by a stoichiometric reaction between a natural herbal extract and a phospholipid, most commonly phosphatidylcholine. When placed in water, these complexes can form liposome-like, micellar structures.
Active Ingredient Interaction	The active ingredient is physically encapsulated within the aqueous core of the vesicle (if hydrophilic) or embedded within the lipid bilayer (if hydrophobic). No chemical bonds are formed between the drug and the phospholipids.	The active ingredient is chemically bonded to the polar head of the phospholipid molecule. This means the active compound is an integral part of the phytosome's membrane, rather than simply being trapped.
Key Components	Composed primarily of phospholipids, such as phosphatidylcholine, and often includes cholesterol to enhance stability and fluidity.	Formed from a plant-based bioactive compound (e.g., flavonoids, terpenoids, polyphenols) and phospholipids (usually soy lecithin) in a 1:1 or 2:1 molecular ratio.
Bonding	No chemical bonds exist between the active ingredient and the phospholipids. The drug is simply enclosed.	Covalent and hydrogen bonds anchor the active constituent to the phospholipid's polar head.

Bioavailability	Provides enhanced bioavailability compared to conventional methods, but generally less than phytosomes, especially for poorly soluble drugs.	Significantly improves the bioavailability and absorption of active herbal ingredients due to the formation of a lipid-compatible complex.
Drug Delivery	Versatile for delivering both water-soluble (hydrophilic) drugs in the core and fat-soluble (hydrophobic) drugs in the bilayer membrane.	Particularly effective at delivering polar, water-soluble plant extracts (like flavonoids and polyphenols) across lipid-rich biological membranes by making them lipid-compatible.
Stability	Stability can be a challenge due to potential leakage or fusion of the lipid membranes. Surface modifications, such as PEGylation, can be used to increase stability and circulation time.	Increased stability is observed due to the formation of strong chemical bonds between the active constituent and the phospholipid.

Future Prospects and Opportunities in India:

India is one of the most strategic regions for the pharmaceutical market. Therefore many multinational giants have been keen to invest and grow preferentially in this sector. Developments in the new and advanced techniques in the field of NDDS will create huge demand for variety of excipients usage and development. India is well known for its quick adaptability to new excipients and associated technologies. So market for excipients in India will grow on two aspects; one is in the form of exporting new organic excipients and the second one in the form of employing new excipients in various advanced delivery technologies. Majority of the pharmaceutical companies in the country have been applying and receiving new patents in the field of the Novel drug delivery systems. This eventually, in the near future derives huge demand for the products and services offered by pharmaceutical and allied businesses. Nanotechnology offers various modern applications in novel drug delivery systems that potentially improve the diagnosis, treatment and help monitoring of post-administration transformation of drug composition within the body systems. Another important milestone to be mentioned here is Computer aided Drug Design, which offers a lot of scope for the development of this kind of novel and advanced systems. Computer aided Drug Design helps in designing and developing the drugs and delivery systems consuming less time and resources with more accuracy and quality compared to traditional methods [34,35].

Molecular imprinting technology:

The molecular imprinting technology has an enormous potential for creating satisfactory drug dosage forms. Molecular imprinting involves forming a pre-polymerization complex between the template molecule and functional monomers or functional oligomers (or polymers) with specific chemical structures designed to interact with the template either by covalent, non-covalent chemistry (selfassembly) or both. Once the pre-polymerization complex is formed, the polymerization reaction occurs in the presence of a cross-linking monomer and an appropriate solvent, which controls the overall polymer morphology and macroporous structure. Once the template is removed, the product is a heteropolymermatrix with specific recognition elements for the template molecule.Examples of MIP-based drug delivery systems involve: (i) rate-programmed drug delivery, where drug diffusion from the system has to follow a specific rate profile, (ii) activation-modulated drug delivery, where the release is activated by some physical, chemical or biochemical processes and (iii) feedback-regulated drug delivery, where the rate of drug release is regulated by the concentration of a triggering agent, such as a biochemical Substance, the concentration of which is dependent on the drug concentration in the body. Despite the already developed interesting applications of MIPs, the incorporation of the molecular imprinting approach for the development of DDS is just at its incipient stage. Nevertheless, it can be foreseen that, in the next few years, significant progress will occur in this field, taking advantage of the improvements of this technology in other areas. Among the evolution lines that should contribute more to enhance the applicability of imprinting for drug delivery, the application of predictive tools for a rational design of imprinted systems and the development of molecular imprinting in water may be highlighted [36]

ADMINISTRATION ROUTES:

The choice of a delivery route is driven by patient acceptability, the properties of the drug (such as its solubility), access to a disease location, or effectiveness in dealing with the specific disease. The most important drug delivery route is the peroral route. An increasing number of drugs are protein and peptide based. They offer the greatest

potential for more effective therapeutics, but they do not easily cross mucosal surfaces and biological membranes; they are easily denatured or degraded, prone to rapid clearance in the liver and other body tissues and require precise dosing. At present, protein drugs are usually administered by injection, but this route is less pleasant and also poses problems of oscillating blood drug concentrations. So, despite the barriers to successful drug delivery that exist in the gastrointestinal tract (i.e., acid-induced hydrolysis in the stomach, enzymatic degradation throughout the gastrointestinal tract by several proteolytic enzymes, bacterial fermentation in the colon), the peroral route is still the most intensively investigated as it offers advantages of convenience and cheapness of administration, and potential manufacturing cost savings.

Pulmonary delivery is also important and is effected in a variety of ways - via aerosols, metered dose inhaler systems (MDIs), powders (dry powder inhalers, DPIs) and solutions (nebulizers), all of which may contain nanostructures such as liposomes, micelles, nanoparticles and dendrimers. Aerosol products for pulmonary delivery comprise more than 30% of the global drug delivery market. Research into lung delivery is driven by the potential for successful protein and peptide drug delivery, and by thepromise of an effective delivery mechanism for gene therapy (for example, in the treatment of cystic fibrosis), as well as the need to replace chlorofluorocarbon propellants in MDIs. Pulmonary drug delivery offers both local targeting for the treatment of respiratory diseases and increasingly appears to be a viable option for the delivery of drugs systemically. However, the pulmonary delivery of proteins suffers by proteases in the lung, which reduce the overall bioavailability, and by the barrier between capillary blood and alveolar air (air-blood barrier). Transdermal drug delivery avoids problems such as gastrointestinal irritation, metabolism, variations in delivery rates and interference due to the presence of food. It is also suitable for unconscious patients. The technique is generally non-invasive and aesthetically acceptable, and can be used to provide local delivery over several days. Limitations include slow penetration rates, lack of dosage flexibility and/or precision, and a restriction to relatively low dosage drugs [37].

2. CONCLUSION

Novel drug delivery system not only reduces the repeated administration to overcome non compliance, but also helps to increase the therapeutic value by reducing toxicity and increasing the bioavailability, and so on. Extensive research is going on for herbal drugs to incorporate them in novel drug delivery systems. Application of these novel techniques to natural medicines will led to enhanced bioavailability, reduced toxicity, sustained release action, protection from GI degradationwhich cannot be obtained through conventional drug delivery system due to large molecular size, poor solubility, degradation of herbal medicines in Gastrointestinal media.

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