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Review Article

A Review: Recent Trend on Novel Drug Delivery System

Srushti Mali*, Divya Malviya, Gaurav Marathe, Meenaz Sayyed, Ravindra Patil

Jijamata Education Society's College of Pharmacy, Nandurbar (425412), Maharashtra (India).

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ABSTRACT

Advanced methods of drug delivery that focus on understanding the pharmacokinetic and pharmacodynamic properties of pharmaceuticals are known as novel drug delivery systems or NDDS. The goals of these systems are to enhance drug bioavailability, reduce drug loss, and avoid negative effects. They may be predicated on biochemical or physical processes like electro-transport, osmosis, diffusion, erosion, or dissolution. Drug stability, controlled release, targeted dispersion, and increased bioavailability are all improved by NDDS, which integrate polymer science, pharmaceutics, bioconjugate chemistry, and molecular biology—this patient satisfaction in addition to improving therapy outcomes. The drug molecule can provide new life through a novel drug delivery system. One of the main Advantages for Handling issues associated with the drug's release A novel drug delivery system might be effectively designed at the site with a controlled rate." However, as technology advances, Novel drug delivery systems (NDDS) pave the way for the ongoing advancement of natural drug delivery methods. This article will cover the fundamental principles of a novel drug delivery system.

INTRODUCTION

Novel drug delivery systems are the ones that provide a more rational approach to developing the ideal drug delivery system by offering novel insight into the pharmacokinetic and pharmacodynamic behaviour of the drug. (1) There exist A variety of delivery methods have been created, and others are now being researched, with the goals of reducing prescription loss, minimizing adverse reactions, and increasing drug bioavailability. (1) aid in the drug's accumulation in the necessary bio-zone (site). (1) It's critical to assess the different kinds of terminologies applied within the many overarching categories of novel drug delivery systems. (1) the creation of novel drug forms with enhanced properties such as selective site binding, increased permeability parameters, and reduced particle sizes. (1)

Novel drug delivery systems:

Definition: A new strategy involving innovative formulations, innovative approaches, and safe delivery of pharmaceutical chemical substances to

***Corresponding Author:** Srushti Mali
Address: Jijamata Education Society's College of Pharmacy, Nandurbar (425412), Maharashtra (India).
Email ✉: malisrushti0@gmail.com

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the body as required to produce their intended pharmacological effects is known as a Novel Drug Delivery System, or NDDS. (2) When NDDS is a sort of traditional drug delivery method, the plasma drug level oscillates (2) innovative drug delivery strategy to reduce side effects and boost therapeutic effect (2) innovative drug delivery strategy to reduce side effects and boost therapeutic effect (2) Many medications, including vaccines, peptides, proteins, antibodies, and gene-based pharmaceuticals, should generally be administered via a traditional drug delivery route due to the possibility of enzymatic degradation, low bioavailability, and reduced intestinal mucosal penetration. (2) It is possible to distinguish between two main strategies for targeting the targeted areas for medication release: Active targeting and (i) passive targeting. To accomplish the desired therapeutic effect and reduce adverse or toxic effects, NDDS medications are made to target the location of the site. A novel approach to medicine distribution aims to eliminate every drawback associated with traditional drug administration systems. There exist multiple methods that can be employed to accomplish innovative medication administration. (2) Generally, the pharmaceutical drug delivery system consists of: Localized drug delivery devices provide drug action through rate-limiting drug release in the vicinity of the target. (2) which controls the molecular diffusion of drug molecules in systemic circulation. (2) a suitable dosage form (pharmaceutical formulations) that carries the drug into the body the release mechanism of a drug from the dosage form to the organ/cells of targeting after administration an optimum medical device/pharmaceutical technique used for manufacturing the dosage form.

Advantages of Novel Drug Delivery System:

- Decreased rate of increase in blood drug concentration.
- Blood level that is constant and sustained within the therapeutic window.
- Minimizing exposure to toxic.
- ability to achieve a particular drug release.
- Make tissue macrophages become more widely spread.

Disadvantages of Novel Drug Delivery System:

- Dose dumping.
- Reduced potential for accurate dose adjustment.
- Need for additional patient education.

Importance of novel drug delivery system:

Enhanced drug efficacy: By delivering treatments to the target site in a controlled and sustained manner, novel drug delivery systems may improve the therapeutic effect of medication. Less side effects: By targeting drug delivery, these systems can reduce the quantity of duration the the medicament in contact with healthy tissues and decrease side effects. Patient adherence to treatment plans can be improved by systems that simplify drug administration or reduce its frequency. Improving drug stability: Some methods of delivery may protect drugs from degradation, improving their shelf life and stability. Targeted drug delivery: These systems can deliver drugs specifically to the site of action, increasing their concentration at the target and reducing systemic exposure. Controlled drug release: Novel delivery systems can provide controlled release of drugs, maintaining therapeutic levels over an extended period and reducing the need for frequent dosing. Improved bioavailability: Some delivery systems can improve the bioavailability of poorly soluble drugs, increasing their absorption and effectiveness. Potential for combination therapies: Novel delivery systems can enable the delivery of multiple drugs simultaneously or sequentially, allowing for synergistic effects and improved treatment outcomes.

Tailored treatments: These systems can be designed to deliver drugs according to individual patient needs, allowing for personalized medicine approaches.

Facilitation of drug development: Novel drug delivery systems can facilitate the development of new drugs by improving their delivery and efficacy, potentially leading to the development of new treatments for Multiple diseases. (1)

Types of Novel Drug Delivery Systems:

1. Nanoparticles-based systems:

Liposomes: A Liposome is a small artificial vesicle spherical in shape, having at least one lipid bilayer. Due to their hydrophobicity & or hydrophilicity biocompatibility, particle size, and many other properties liposomes can be used as drug delivery vehicles for the administration of pharmaceutical drugs and nutrients, such as lipid nanoparticles in mRNA Vaccines & DNA Vaccines. Liposomes can be prepared by disrupting biological membranes is also called sonication. (3)

Advantages:

- Increase the stability of entrapped drugs
- Reduce the drug toxicity
- Possibility of ligand attachment
- Reduce the number of administrations. (3)

Disadvantages:

- Liposomal drug delivery systems are expensive to produce.
- Phospholipids may undergo oxidation and hydrolysis reactions
- May undergo leakage during their transit to the site of action.
- Difficult in large-scale manufacturing and sterilization. (3)

Drug delivery mechanism by liposome:

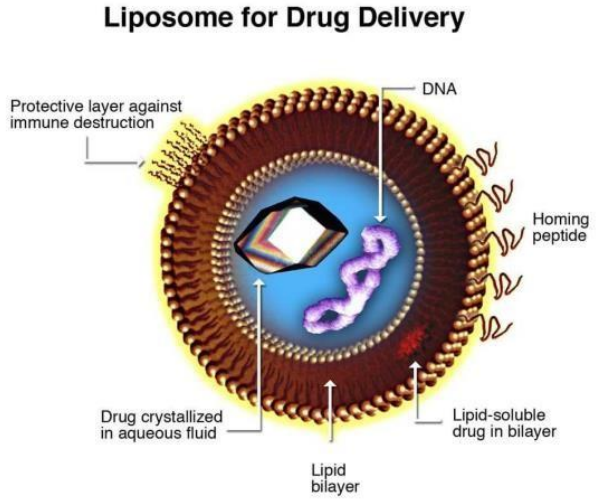

Fig. Liposome

Mechanism:

Liposomes are small lipoidal vesicles enclosing an aqueous solution inside a hydrophobic membrane, to deliver the molecules to the targeted site, the lipid bilayer can fuse with other bilayers such as the cell membrane, thus liposomes act as drug carriers for drug delivery. There are various clinically approved liposomal drugs like liposomal daunorubicin, doxorubicin, Liposomal amphotericin B, and Liposomal cytarabine. (3)

Application of liposomes:

- Liposomes as drug delivery vehicle
- Liposomes as vaccine carriers.
- Liposomes in tumor therapy.
- Liposomes in gene delivery.
- Liposomes of artificial, blood surrogates. (3)

2. Micelles:

Micelles formed in aqueous solutions due to the self-assembly of amphiphilic block copolymers

(5–50 nm) are extremely attractive for drug delivery applications. It can be achieved to be carried at concentrations greater than their inherent water solubility by physically trapping within the core of block copolymer micelles. Further, a tight shell can be created around the micellar core So, the hydrophobic core's contents have been effectively protected by degradation by enzymes and hydrolysis. In addition, the corona can block the reticuloendothelial system's detection and thus, the micelles' first removal from blood flow. (12)

A final feature that makes amphiphilic block copolymers attractive for drug delivery applications is The ease with which the micelles' shape and size can be manipulated by changing their chemical makeup, total molecular weight, and block length ratios. By functionalizing block copolymers with cross-linkable groups, their resulting micelles' stability and temporal control can be increased A novel approach to a wider range of sites of activity with greatly enhanced selectivity is the substitution of block copolymer micelles for specific ligands. (12)

Advantages:

- High drug encapsulation & loading capacity.
- High cellular uptake because of their nanosized range.
- Reduced drug toxicity
- Disease site targeting of several drugs.

Disadvantages:

- The poor solubility of small-sized micelles.
- Poor loading capacity.
- Poor physical stability in vivo.

Applications:

- Gene delivery.
- Diagnostic imaging & drugs.
- Micelles act as emulsifiers & surfactant.
- As it allows for targeted delivery of chemotherapy drugs to tumor sites.

Mechanism:

When the clusters of molecules are formed then the hydrophilic tail comes at the interior of the cluster and the ionic and comes at the surface of the cluster. Micelles are effectively utilized as drug delivery systems specifically for lipophilic drugs. With various advantages such as small size (10-100 nm), shell-core structure, prolonged circulation time, and enhanced drug accumulation at the tumor site.

3. Solid lipid nanoparticles:

Solid lipid Nanoparticles:

It is a technique developed in the 1990s. It is a colloidal carrier used especially for the delivery of lipophilic compounds. The average mean size of solid lipid nanoparticles ranges from 50 nm to 1000 nm. Solid lipid nanoparticles are composed of a lipid matrix, which becomes solid at room temperature and body temperature. The main features of solid lipid nanoparticles (SLNs) regarding parenteral application are the excellent physical stability/ and protection of incorporated labile drugs from degradation. To cross the blood-brain barrier, it should be made for selection of lipids and surfactants. The SLNs are prepared by different methods such as homogenization warm micro-emulsion high-speed stirring ultrasonication and solvent-diffusion method. Lipids show compatibility with lipophilic drugs and increase the entrapment efficiency and drug-loading into the SLN. (1)

Advantages:

- It provides controlled release and site-specific drug Targeting
- Large-scale production can be done.
- In this formulation, both lipophilic and hydrophilic drugs can be loaded.
- Another advantage is that it is made of lipid matrix (physiological lipids),
- which decreases the danger of chronic and acute toxicity. (7)

Disadvantages:

- Liquid dispersion has water content.

- Limited transdermal medication delivery.
- Hydrophilic drug loading capacity is constrained.
- The toxicity of lipid nanoparticles on retinal cells has not yet been thoroughly investigated.

Applications:

- SLN is a potential new adjuvant for vaccines.
- SLNs in cancer chemotherapy.
- SLN is a targeted carrier for anticancer drugs to solid tumours.
- SLNs for delivering brain drug delivery.
- SLN in cosmetic and dermatological preparations.

Mechanism:

The enhanced permeability and retention effect allows tumor targeting due to the tumor microenvironment characteristics. In normal conditions, nanoparticle extravasation does not occur; however, the discontinuity of the vascular epithelium in the tumor region and the improper functioning of the lymphatic drainage system facilitate enhanced extravasation. Angiogenesis stimulates the formation of irregular blood vessels with discontinuous epithelium in tumor sites. The increased permeability is due to the discontinuities between epithelial cells, nanoparticles in the size range from 100 to 800 nm can flow across the interstitial space. Tumor tissues have a dysfunctional lymphatic system and insufficient lymphatic outflow, resulting in nanoparticle accumulation in the tumor tissue. The EPR effect influences molecular distribution through three related mechanisms: nanoparticle extravasation from blood arteries, nanoparticle diffusion into cancer tissue, and nanoparticle interaction with intracellular or extracellular targets in the tumor microenvironment.

4. Nanoparticles:

Definition: The drug is known as a dissolved, trapped, encapsulated, or nanoparticle-attached nanoparticle matrix as a particulate dislocation or a solid particulate with sizes between 10 and 1000NM. NPs are classified into several categories of nanomaterials with different configurations such as nanocapsules, nanospheres, nanopores, and Nanoshells. (3) as nanoparticles with a diameter between 10 and 100 nm. Nanoparticles are in solid form and are either amorphous or crystalline-like nanospheres and nanocapsules of the size 10-200 nm. Their pharmacodynamics and pharmacokinetic properties are modified as a targeted supply mechanism for the distribution of small and large molecules. (3)

Advantages:

- The nanoparticulate system delivers the herbal formulation directly to the site of action. (3)
- Producible with various sizes, compound surface properties. (3)

Disadvantages:

- Presents biocompatibility restrictions.
- Difficult to manufacture on a large scale.
- Their small particle size and large surface area can lead to particle-particle aggregation, making the physical handling of nanoparticles difficult in liquid and dry forms.
- Small particle size and large surface area readily result in limited drug loading and burst release. These practical problems must be overcome before nanoparticles can be used clinically or commercially available.
- The present work is a step towards the development of nanoparticulate drug delivery systems, surface modification issues, drug loading strategies, release control, and potential applications of nanoparticles. (3)

Mechanism:

Nanoparticles deliver the drug onsite by preventing the reticuloendothelial system, using improved permeability, retention effect, and targeting. Dogs with nanoparticles as carriers apply two forms of approaches

Surface bound: The drug molecules are connected to the nanoparticle's surface

Core bound: The drug particles are concentrated in such a technique into the nano pharma matrix and transported into the body to the target. Drugs can be loaded onto nanoparticles by adding or adding to the reaction mixture during polymerization to a solution that includes previously prepared nanoparticles. Chemistry, superficial adsorption, or any binding or contact may be the essence of the interaction of nanoparticles with drug products. The number Relies on the chemical structure of the drug and polymer and the conditions for drug loading, the binding drug, and the form of interaction between the drug and nanoparticles. (3)

Fig. Nanoparticle

5. Microparticle-based system

I. Microspheres:

The microsphere comprises 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 made of albumin, modified starch, gelatin, polypropylene dextran, polylactic acid, and the like are typical biodegradable microspheres. The only polymer that is presently approved for use by people in nonbiodegradable microspheres, according to recent literature reports, is polylactic acid, which serves as a controlled-release agent. Solid and hollow microspheres vary widely in density and therefore are used for different applications. (3)

Advantages:

- Administration of medication via a micro-particulate system is advantageous because microspheres can be ingested or injected, and they can be tailored for desired release profiles and used for site-specific delivery of drugs and in some cases can even provide organ-targeted release.
- Drugs can be easily released from the formulation.
- It can protect the specific function of drugs and can release the drugs into an outer phase for a long period. (3)

Disadvantages:

- Microspheres tend to migrate away from the injection site.
- Lead to potential risk.
- Embolism and further organ damage.

Application:

- Microspheres in terms of drug release.

- Thus, improves the therapeutic performance of drugs.
- Including isolation of nucleic acids, cell separation, and immuno- and DNA-base says.

II. Microcapsules:

The process of microencapsulation involves covering or encapsulating tiny droplets or particles of a liquid or solid with a continuous layer of polymer material. First, the microencapsulation process was discovered in 1931 by Bunge Burg de Jon and Kan. This included the production of gelatin spheres and the use of an aging process. Controlled drug delivery systems have been used to alleviate problems associated with conventional treatment and improve the therapeutic effect of a given drug. Maximum therapeutic effects can be achieved by delivering the drug to the target tissue at the optimal rate, with low toxicity and minimal side effects. The micro-encapsulation process helps convert liquids to solids, alter colloidal and surface properties, provide environmental protection, and control the release properties of various coated materials. Some of these properties can be achieved by macro packaging techniques, but in microencapsulation, small, coated particles were used to make a wide variety of dosage forms, which was impractical. A new drug delivery system was initiated in the process of optimizing bioavailability by changing the bioavailability of drug levels in the blood. (13) A recent finding in pharmaceutical research is that the rate of drug absorption can be controlled by controlling the rate of release from the dosage form. Sustained release dosage forms are designed and formulated to include sustained release, sustained release, sustained release, sustained release, and sustained release agents. This was achieved through the development of new drugs, and the discovery of new polymeric materials suitable for prolonging drug release, increasing safety, and improving therapeutic efficacy. (13)

Advantages:

- Formulation of sustained release and controlled release dosage forms.
- Masking of bitter taste of the drugs.
- Reduced hygroscopic nature of the substance.
- Reduction of vaporization of volatile drugs.

Disadvantages:

- Cross-reaction between core and shell material is possible.
- Expensive techniques.
- The fate of polymer additives such as plasticizers, stabilizers, Antioxidants, and fillers.

Applications:

- Mask the taste of bitter drugs.
- To overcome problems inherent in producing tablets from otherwise tacky granulations.
- Prolonged release dosage forms.
- Prepare enteric-coated dosage forms.
- To reduce gastric irritation.

6. Matrix systems:

I. 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.

Advantages:

- Biocompatible, biodegradable, and can be injected
- Hydrogels possess a wide degree of flexibility like natural tissue.
- Have good transport properties and are easy to modify. (11)

Disadvantages:

Hydrogel is a lack of strength.

- The main disadvantage is the high cost.
- Difficulty in loading.
- Difficult to be sterilized.

Applications:

Colon-specific drug delivery

- topical drug delivery
- ocular drug delivery
- wound healing, and industrial applicability
- Tissue engineering

II. Patches:

The launch of the first transdermal patch "scopolamine hydrobromide adhesive patches" In 1979. For therapy to be effective with conventional oral dosage forms, many doses must be administered in precise amounts and at certain intervals. There are several drawbacks to multiple delivery of drugs, including unease during administration, the possibility of overdosing if delivered faster than the scheduled time, low patient compliance, patients missing doses, and variability in drug plasma levels. Transdermal medication delivery systems were created to prevent these issues. A transdermal patch is a discrete, self-contained medicine patch that gives an easy way to deliver medication for a variety of body and skin issues. By better understanding the mechanisms by which substances pass through the skin, researchers will be able to create technologies aimed at increasing the delivery of medication through the skin. The drugs are delivered using the transdermal drug delivery system to maintain the desired drug level for an extended period(9).

Advantages:

- Patches are non-invasive, painless, and simple to apply.
- A medication can be taken over a long duration of time.
- Dosage frequency reduces because a single patch delivers the drug continuously for a longer amount of time.
- There are no adverse reactions between drugs, food, beverages, enzymes in them, or other GI organisms.
- Effective for medications that lessen negative effects and are unpleasant when taken orally. (9)

Disadvantages:

- Large doses (more than 10 mg/day) are difficult to administer.
- Transdermal delivery systems for drugs have difficulties with offering ionic drugs.
- Medicine that has a molecular weight of over 500 Dalton is not appropriate for the transdermal drug delivery method.
- Both very high and very low partition coefficients make it hard for drugs to reach circulation. (9)

Application:

- The patient should clean and disinfect the area where they will apply the patch with clear water, patting the area until it is scored.
- They should avoid using any soaps, alcohols, lotions, or oils immediately before applying the patch.
- These patches use diffusion processes to deliver these active ingredients directly into the systematic circulation.

Other systems:

I. Oral Drug Drug Delivery:

a. Effervescent tablet:

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been employed for the systemic delivery of drugs via various pharmaceutical products of different dosage forms. The oral sustained drug delivery system is complicated by limited gastric residence times (GRTs). Rapid GI transit can prevent complete drug release in the absorption zone and reduce the efficacy of the administered dose. Effervescent tablets are becoming increasingly popular in a variety of sectors including supplements and pharmaceutical use due to the ease with which they can be consumed. Effervescent tablets are designed to break in contact with liquid such as

water or juice, often causing the tablet to dissolve into a solution. These buoyant delivery systems utilize matrices prepared with swellable polymers such as Methocel or poly-saccharides, e.g., chitosan, and effervescent components, e.g., sodium bicarbonate and citric or tartaric acid. Recently a multiple-unit type of floating pill, which generates carbon dioxide gas, has been developed. The system consisted of sustained-release pills as seeds surrounded by double layers. The inner layer was an effervescent layer containing both sodium bicarbonate and tartaric acid. (10)

Advantages:

- Fast onset of action.
- No need to swallow tablets.
- Good stomach and intestinal tolerance.
- Incorporation of large amounts of active ingredients.
- Improved Therapeutic Effect. (10)

Disadvantages:

- The unpleasant taste of some active ingredients.
- Larger tablets require special packaging materials.
- Relatively expensive to produce due to large amounts of more or less expensive excipients and special production facilities. (10).

Application:

- Effervescent tablets are tablets when added to water release carbon dioxide.
- The effervescent technique can be used as an alternative to developing a dosage form that can accelerate drug disintegration and dissolution.
- Effervescent tablets are used to simplify the handling of doses, provide optimal compatibility, promote superior & rapid absorption, increase the patient's liquid intake, and circumvent the difficulty of swallowing large pills.

II. Sublingual delivery:

Sublingual spray:

For many years, medications have been topically applied to the mucosa. Despite the epithelium's generally poor permeability properties, this administration method offers several advantages. An alternative to injectable and enteral techniques of systemic medication delivery, sublingual drug delivery has several benefits. Unlike intravenous delivery, medications absorbed through the oral mucosa enter the systemic circulation directly after passing through the gastrointestinal tract and first undergoing metabolism in the liver due to the oral mucosa's high vascularization Sublingual sprays, which are intended to be applied beneath the tongue, allow the medication to enter the body directly through the mucosal lining of the mouth beneath the tongue and have an instant systemic effect. The medication is absorbed three to ten times through the sublingual route. (14)

Advantages:

- When compared to sublingual tablets, the sublingual spray formulation has a quicker onset, a longer duration, and fewer side effects. Simplicity in administering a tablet to people who are unable to swallow it.
- The spray formulation may be a better option for people with dry mouth because it doesn't require drug disintegration and doesn't rely on patient saliva for dissolution.
- As saliva flows down into the stomach, some medications are absorbed from the mouth, pharynx, and esophagus; under these situations, the drugs' bioavailability is enhanced. (14)

Disadvantages:

- This site is not well suited to sustained delivery systems.
- Generally, not applicable for drugs that require high blood levels or large Doses
- Drugs that are not absorbed by passive diffusion or irritating to the oral mucosa

- also, not applicable to this drug delivery system.
- Taste masking is the main problem associated with this formulation. (14)

Mechanism:

The sublingual artery travels forward to the sublingual gland, it supplies the gland and branches to the neighboring muscles and the mucous membranes of the mouth, tongue, and gums. Two symmetrical branches travel behind the jawbone under the tongue to meet and join at its tip. Another branch meets and anastomoses with the submental branches of the facial artery. The sublingual artery system stems from the lingual artery – the body's main blood supply to the tongue and the floor of the mouth – which arises from the external carotid artery. The proximity to the internal carotid artery allows fast access to its route supplying the greater part of the cerebral hemisphere.

Mechanism of drug release:

Drugs directly go to the arterial circulation by sublingual vein and capillaries, then to the jugular vein, and then to the superior vena cava to blood vessels.

Sublingual sprays deliver drug-containing aqueous droplets to the mouth. The velocity and size of the droplets are monitored to ensure delivery to the oral cavity rather than to the lungs. Rapid Mist technology has also currently been evaluated for the buccal delivery of morphine and fentanyl. On actuation, the drug-containing mist is sprayed in the oral cavity and deposited in the buccal and sublingual mucosal membranes.

Application:

- The sublingual dosage form is to be placed under the tongue & produce an immediate systemic effect.
- The drug is absorbed directly through the mucosal lining of the mouth beneath the tongue which very reaches to vascular blood supply.
- The sublingual spray is to be spread for faster onset of action.
- Fentanyl sublingual spray is used to treat breakthrough pain.

III. Transdermal delivery:

In other words, DDS covers the routes of administration and drug formulations that efficiently deliver the drug to maximize therapeutic efficacy while minimizing any side effects. Depending on the delivery route, there are many types of administration modalities, such as oral administration, transdermal administration, lung inhalation, mucosal administration, and intravenous injection. Among them, the transdermal drug delivery system (TDDS) represents an attractive approach. TDDS has become one of the most widely investigated routes of noninvasive drug delivery into the body through the skin, unlike conventionally used direct administration routes that make use of needle-based injections. TDDS has significantly influenced the delivery of various therapeutic agents, especially in pain management, hormonal therapy, and treatment of diseases of the cardiovascular and central nervous systems' does not involve passage through the gastrointestinal tract; therefore, there is no loss due to first-pass metabolism, and drugs can be delivered without interference from pH, enzymes, and intestinal bacteria. In addition, TDDS can be used to control drug release according to usage restrictions, thereby contributing to the high persistence of this method. Most importantly, because TDDS is a noninvasive administration method and involves minimal pain and burden on the patient, drugs. (6)

Advantages:

- They can avoid gastrointestinal drug absorption difficulties caused by gastrointestinal pH, enzymatic activity, and drug interactions with food, drink, and other orally administered drugs.

- They can substitute for oral administration of medication when that route is unsuitable, as in the case of vomiting and diarrhea.
- They avoid the first-pass metabolism and avoid drug deactivation by liver enzymes.
- They are non-invasive so avoiding the inconvenience of parenteral therapy.
- They provide extended therapy with a single application, improving compliance over other dosage forms, and requiring more frequent dose administration.
- Drug therapy may be terminated rapidly by the removal of Transdermal drug delivery systems from the surface of the skin.
- They are easily and rapidly identified in emergencies (e.g. unresponsive, unconscious, or comatose patient) because of their physical presence, features, and identifying markings. They can be used for drugs with narrow therapeutic windows. (9)

Disadvantages:

- The limitations of transdermal drug delivery are mainly associated with The barrier function of skin, so it is limited to potent drug molecules.
- Skin irritation or contact dermatitis due to drugs, excipients, and enhancers is another limitation. (9)

Applications:

- TDDS is a painless method of delivering drugs systemically by applying a drug formulation onto intact and healthy skin.
- The drug initially penetrates through the stratum corneum and then passes through the deeper epidermis and dermis without drug accumulation in the dermal layer.
- Anti-inflammatory.
- For treatment of angina pectoris.

Mechanisms of Drug Release:

1) Diffusion Controlled Release System:

In this system, the rate-controlling step is not the dissolution rate but the diffusion of the dissolved drug through an insoluble polymer barrier. This diffusion process is described by the Fick's first law:

The movement of drug particles from higher concentration to the low is directly proportional to the particle's concentration gradient.

$J = -D. dc/dx$

where,

J= Flux

D= Diffusion Coefficient

DC/dX= rate of change in concentration across the membrane X.

A polymeric matrix or reservoir is porous and allows the diffusion of dissolved drugs.

2) Ion exchange release system:

It is based on the formation of a drug resin complex formed when the ionic solution is kept in contact with ionic resins. It provides the controlled release of an ionic or ionizable drug for intra-gastric delivery. The drug release characteristics rely only on the ionic environment of the resin-containing drug and therefore should be less susceptible to environmental conditions, such as enzyme content and pH at the site of absorption.

3) Dissolution controlled released system:

In this system, solid substances solubilize in a given solvent (dissolution) i.e. mass transfer from the solid surface to the liquid phase. The rate of drug release depends on how quickly the drug particles dissolve (dissolution rate), and the rate-limiting step in this process is the diffusion of the dissolved drug from the solid surface to the surrounding solution through the stagnant layer. This dissolution process at a steady state is described by the Noyes-Whitney equation:

The surface area of the drug particles (larger surface area = faster dissolution)

Concentration of dissolved drug (higher concentration = slower release)

The rate of dissolution is given by Noyes and Whitney:

$Dc/dt = k (Cs – Cb)$

Where,

Dc/dt = dissolution rate of the drug

K = dissolution rate constant

Cs = concentration of the drug in the stringent layer

Cb = concentration of drug in the bulk of the solution at time t.

Applications of NDDS:

There exist numerous potential applications for novel drug delivery strategies in the pharmaceutical and medical sectors. These systems serve to improve patient compliance, maximize treatment efficacy, and eliminate adverse consequences. Here are a few significant uses for novel medication delivery systems

Targeted Drug Delivery: One of the primary applications of novel drug delivery systems is targeted drug delivery. These systems can deliver drugs specifically to the site of action in the body, such as tumors or specific organs. This allows for localized treatment, minimizing systemic exposure and reducing side effects.

Controlled Release: Novel drug delivery systems enable the controlled release of drugs over a prolonged period. This ensures a consistent and optimal concentration of the drug at the target site, improving its effectiveness. Controlled release can also reduce the frequency of drug administration and improve patient compliance.

Personalized Medicine: delivery systems can be tailored to individual patients based on their specific needs and conditions. This allows for personalized medicine, where drugs are delivered in a manner that maximizes their therapeutic effects and minimizes side effects.

Chronic Disease Management: Many novel drug delivery systems are designed for the management of chronic diseases. These systems can provide long-acting formulations that deliver the drug over an extended period, reducing the need for frequent dosing. This improves patient compliance and simplifies the treatment regimen for chronic conditions.

Combination Therapies: Novel drug delivery systems can be used to deliver multiple drugs simultaneously or sequentially. This enables combination therapies, where different drugs with complementary mechanisms of action can be delivered together to enhance therapeutic outcomes. Combination therapies are particularly effective in treating complex diseases or drug-resistant infections.

Gene and Cell Therapies: Drug delivery systems play a crucial role in the field of gene and cell therapies. These systems can deliver genetic material or therapeutic cells to specific sites in the body, facilitating targeted and efficient treatment. They can protect the genetic material or cells from degradation and enhance their uptake by the target cells.

Vaccines: Novel drug delivery systems can also be used in the development and delivery of vaccines. These systems can improve the stability and efficacy of vaccines, enhance antigen presentation, and provide sustained release of vaccine components, leading to better immune responses and protection against infectious diseases.

Transdermal Delivery: Transdermal drug delivery systems, such as patches, are widely used for the systemic delivery of drugs. They can provide a controlled release of the drug through the skin, bypassing the digestive system and the first-pass metabolism. Transdermal delivery is particularly useful for drugs with poor oral bio-availability

Benefits of NDDS:

- **Medical:** Optimum dose, at the right time and the light location.
- **Industrial:** Efficient use of expensive ingredients, reduction in production cost.

- **Social:** Beneficial to patients, better therapy, improved compliance, and standard of living. (3)

Novel Drug Delivery Approaches:

To reduce drug loss and degradation, avoid negative side effects, and boost drug bioavailability and the percentage of the drug accumulated in the needed zone, several drug delivery and targeting systems are presently being developed. Soluble polymers, microparticles composed of insoluble or biodegradable natural and synthetic polymers, microcapsules, cells, cell ghosts, lipoproteins, liposomes, and micelles are a few examples of drug carriers. The carriers can be designed to degrade gradually, respond to stimuli (such as changes in pH or temperature), or even be targeted (for example, by conjugating them with certain antibodies that target particular traits of the target area). The capacity to guide the drug-loaded system to the desired location is known as targeting. For addressing the targeted locations for drug release, two main strategies can be distinguished: (i) passive and (ii) active targeting. Because tumor tissues have higher vascular permeability than healthy tissue, chemotherapeutic drugs preferentially accumulate in solid tumors as an illustration of passive targeting. Drug carriers that have been surface functionalized with ligands that are specifically recognized by receptors on the surface of the target cells may be able to facilitate active targeting. A more accurate targeting of the site of interest may be possible due to the high selectivity of ligand-receptor interactions. Successful formulation development requires controlled drug release and subsequent biodegradation. Possible release pathways include: (i) drug desorption from surface-bound or adsorbed materials; (ii) diffusion via the carrier matrix; (iii) diffusion via the carrier wall (in the case of nanocapsules); (iv) attrition of the carrier matrix; and (v) a combination of erosion and diffusion. The development of effective formulations depends on controlled drug release and subsequent biodegradation. Potential methods of the release include: (i) drug desorption from surfaces bound to adsorbed materials; (ii) drug diffusion through the carrier matrix; (iii) drug diffusion through the carrier wall (in the case of Nanocapsules); (iv) carrier matrix erosion; and (v) a combination of erosion and diffusion process. Given that the way a medication is taken frequently influences the choice of drug, the mode of delivery can mean the difference between a drug's success and failure. Drugs that are released at a controlled rate from polymers through diffusion out of the polymer or polymer degradation over time are known as sustained (or continuous) releases. When it comes to drug distribution, pulsatile release is frequently the chosen option because it closely resembles the body's natural process of producing hormones like insulin. This is accomplished by employing polymers that contain drugs and react to stimuli, such as light exposure, pH changes, or temperature variations (6). Researchers have recognized for more than 20 years the potential advantages of nanotechnology in offering significant advancements in medication delivery and targeting. Patients stand to gain greatly from improved delivery methods that reduce toxicity and increase efficacy, and this also creates new opportunities for pharmaceutical and drug delivery businesses. Other methods of drug delivery concentrate on finding acceptable and alternate routes for the delivery of protein drugs other than via the gastrointestinal tract, where degradation can occur, or on overcoming specific physical barriers, such as the blood-brain barrier, to better target the drug and improve its effectiveness. Novel drug delivery technologies are now only commonly used for allopathic medications, but they have drawbacks of their own. Instead, it would be better to use tried-and-true Ayurvedic

herbal drug formulations that are safe, effective, and herbal. (6)

Future scope and challenges:

According to Dhanasekaran and Chopra (2016), a smart drug-targeted delivery system delivers the best therapeutic medicine for malignant and other diseases to the precisely targeted tumor site at the optimum dosage, minimizing the chance of modifications that could affect the efficacy of the methods being tested. Drug delivery technology, together with medical technology advancements, clarifies the molecular and cellular mechanisms behind disease (Kaur and Kumar, 2019) (19) Nanoparticle sponges: Large substances can be enclosed using a material of small particles with cavities that are only a few nanometers wide. This improves the solubility of the complexing, conjugating, and lipophilic nanoparticles. According to Yan and Li (2016), liposomes derived from vesicles within hydrophobic domains could selectively filter the passive diffusion of tiny solutes, ions, nutrients, and antimicrobial substances (4).

Erythrocytes: They are naturally occurring, biodegradable, and capable of entrapping drugs without the need for chemicals or altering eukaryotic cells through cell infusions, RBCs, and targeting the reticuloendothelial system (Kumar et al., 2017) (4).

Transdermal drug delivery: Self-contained, direct dosage, first-pass metabolism, gastrointestinal incompatibility, and self-administration improve physiological and pathological response; they are reliable, safe, and consistent (Jahangir Ian et al., 2017). (4).

Market opportunities: The drug delivery system's global market value reached $50.9 billion in 2009, with a compound annual growth rate (CAGR) of 7.5% predicted for the next five years, or 45.8 billion dollars. This represents the second-largest market share (Mulla et al., 2017). (4).

Other drug treatments and their uses in other causes: For diabetes mellitus to be effectively managed, new medications must be developed (Anitha and Ashwini, 2017). These medications include radiofrequency ablation, cryosurgery, chemotherapy, targeted therapy using monoclonal antibodies, and angiogenesis inhibitors. Reducing toxicity and increasing the bioavailability of anticancer medications to the target tumor cells is the main goal of their anti-diabetic, anti-oxidant, astringent, anti-viral, cytotoxic, and anti-inflammatory activities (Lakshmi et al., 2015) (Sharma et al., 2019b) Using both in silico and in vitro techniques, prior research has demonstrated the anticancer efficacy of Bisco Marin (SSBC) against several humans in vitro cancer cell lines (Ezhilarasan, Lakshmi, Vijayaragavan, et al., 2017). SSBC is known to induce apoptosis and limit cancer proliferation. Perumal Samy and associates, 2018Drug delivery to specific targets is facilitated by nanoparticles (Mehta et al., 2019). Treatment of Bcl-2 gene expression was also significantly downregulated (Ezhilarasan, Lakshmi, Nagaich, et al., 2017). Reactive intermediates are thought to trigger the production of collagen, profibrogenic cytokines, and several inflammatory markers as hepatic fibrosis advances. (Ezhilarasan, 2018) shortly, proapoptotic drugs and senescence inducers with a strong affinity for activated HSCs might provide a unique therapeutic approach for the treatment of hepatic fibrosis (Ezhilarasan, Sokal, and Najimy, 2018). The hepatoprotective, anti-inflammatory, immunomodulatory, free radical scavenging/ and antioxidant properties of syringic acid (SA) have all been investigated.(Ezhilarasan and Ghenea, 2019b) Nowadays, due to their numerous advantages, selenium nanoparticles have become increasingly important in the field of medicine. (4)

Recent Novel Advancements and Drug Delivery Strategies:

The gene therapy approach involves identifying a specific functional gene or specific fragment and replacing it in place of a defective gene for the treatment of diseases originating due to genetic disorders. Mutation of the gene that codes the enzyme adenosine deaminase results in disorders of the normal gene sequence. Once the replacement gene is identified, the next step involved is inserting it into an appropriate site within the genome. The crucial step involved in this exercise is to ascertain the activity. Al-Raavi et al. in their study identified the role of N-JARID2, a fragment of JARID2, in maintaining the normal architecture of the skin. The group found that the protein N-JARID2 is responsible for maintaining skin cells in their normal state of differentiation and this can have potential application in the treatment of psoriasis. The Posttranscriptional gene silencing process by RNA interference involves the degradation of specific messenger RNA in the cell cytoplasm by small interfering RNA molecules. This strategy has attracted significant attention since the resultant reduction in protein expression applies to several classes of molecular targets, representing a great promise for silencing disease-promoting genes. Skin disorders related to inflammation (such as psoriasis, vitiligo, and atopic dermatitis), abnormal cell behavior (squamous cell carcinoma and melanoma), and damage (burn and wound) as well as monogenetic skin disorders (pachyonychia congenital) have been considered suitable for small interfering RNA therapy due to the existence of well-defined molecular targets that can be silenced, resulting in therapeutic benefits. Topical administration of small interfering RNA to the skin would be feasible due to the accessibility of the site, ease of administration, and possibility of overcoming the first-pass metabolism. However, the skin's outermost layer, the stratum corneum, represents an efficient barrier against the entry of substances into the skin. To overcome the limitations related to size, rapid enzymatic degradation, and strong anionic charge of the phosphate backbone of small interfering RNA molecules (with consequent electrostatic repulsion from the anionic cell membrane surface), novel delivery strategies are employed. Nonviral vectors, nanocarriers, small interfering RNA complexes with positively charged compounds (e.g., cationic polymers, lipids, dendrimers, and peptides or proteins), conjugates with small molecules (e.g., cholesterol), antibodies, polymers, and lipids have been shown promising results in small interfering RNA delivery to knock down specific targets in different cell lines and tissues (23).

CONCLUSION:

A Novel Drug Delivery System (NDDS) combines cutting-edge methods with recently created dosage forms that outperform traditional dosage forms by a significant margin. A novel medication delivery system serves to improve therapeutic value by lowering toxicity, raising bioavailability, and reducing the need for repeated administration to overcome non-compliance. Therefore, future research should focus on nanomedicine and the clinical implementation of these SMART nanocarrier-based drug delivery systems. Advantages of the Novel Drug Delivery System are: Optimum dose at the best time and proper location, affordable use of expensive drugs, excipients and discount in cost, useful to patients, better clinical aid, stepped forward consolation, and commonplace of living. Novel Drug delivery & drug targeting are new techniques that are used in pharmaceutical science. Like targeting drug delivery, vaccine delivery, Gene therapy, and commercial development of novel carriers.

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