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Review Paper

Novel Drug Delivery System

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ABSTRACT

The advancement of pharmaceutical sciences has led to the development of various novel drug delivery systems (NDDS) that improve the efficacy, safety, and patient compliance of therapeutic agents. Traditional drug administration methods often encounter challenges such as poor bioavailability, non-specific distribution, and the need for frequent dosing. To overcome these limitations, several innovative approaches have been explored. Transdermal drug delivery systems (TDDS) allow for sustained drug release through the skin, bypassing first-pass metabolism. Vesicular drug delivery systems (VDDS), including liposomes and niosomes, enhance drug solubility, protect active ingredients, and enable targeted delivery. Floating drug delivery systems (FDDS), are designed to prolong gastric residence time, improving absorption of drugs with narrow absorption windows. Microencapsulation techniques protect drugs from degradation and control release profiles. Mucosal and nasal administration routes offer non-invasive alternatives with rapid onset of action, bypassing hepatic metabolism and providing direct access to systemic circulation or the central nervous system. These systems collectively represent a significant shift towards more precise, effective, and patient-friendly drug therapies.

INTRODUCTION

The creation of innovative drug delivery systems (NDDS) for herbal medications has received a lot of interest in recent decades. Two needs should preferably be met by the innovative carriers.(1) In the past, practically all medications were made from plants, which for centuries were the only source of chemistry for humans. A herbal "renaissance" is taking place all over the world, and a growing number of people are using herbal remedies instead of conventional medicine to cure a variety of illnesses.(2) In the past several decades, diabetes mellitus, or DM, has become a global epidemic and is now the fifth leading cause of mortality in the majority of both developed and developing nations. Globally, diabetes has affected 382 million people (5.1 million deaths and 21 million live births due to diabetes during

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pregnancy), and by 2035, that number is predicted to rise to 592 million, according to the International Diabetes Federation's (IDF) most recent atlas (Misra et al., Citation2011; Internationally Diabetes Federation, Citation2013).(3) Researchers and academicians generally agree that the idea of integrating the medicine into a noisome improves drug targeting to the right tissue destination. Niosomes can be used for targeted, ophthalmic, topical, parental, and other drug delivery methods.(4) Additionally, there is mounting evidence that a large number of current medication interventions neglect the underlying disease mechanisms in favor of merely suppressing symptoms. On the other hand, a lot of natural products seem to treat the root cause of a lot of illnesses and produce better clinical outcomes. Regretfully, the majority of doctors and patients are unaware of the existence of these natural alternatives. However, the process of conducting research in this area never ends.(5) Proteins or synthetic polymers make up microspheres, which are free-flowing powders that are biodegradable and preferably have a particle size of less than β00μm. This is the key strategy for delivering a medicinal chemical in a regulated and sustained release manner to the Intendedspot.(6) They make it easier to precisely distribute tiny amounts of powerful medication and lower drug concentrations to locations other than the intended organ or tissue. Before they are available at the site of action, they offer protection for unstable drugs both before and after administration. They offer the capacity to control the drug's pharmacokinetic profile, tissue distribution, cellular contact, and in vivo action. They allow for regulated medication release. Examples include steroid hormones, antagonists, and narcotics.(7)

Transdermal Drug Delivery System :-

Introduction :-

Compared to the previous two decades, advancements in the field of medication delivery are occurring far more quickly. New drug delivery technologies are inherently linked to increased patient compliance and efficacy.(8) A permanent medication patch that is applied over the skin to administer a precise dosage of medication through the skin and into the bloodstream at a predetermined rate of release is known as a transdermal patch. The most widely used transdermal technology on the market today is primarily based on semi-permeable membranes known as patches. A therapeutically effective dosage of medication is intended to be delivered through a patient's skin and into their bloodstream by transdermal drug delivery devices (TDDS), sometimes referred to as "transdermal patches" or "skin patches.(9) Transdermal medication delivery refers to self-contained, distinct dosage forms that, when applied to undamaged skin, allow the drug to enter the bloodstream at a regulated pace. A crucial component of innovative drug delivery systems is the transdermal drug delivery system (TDDS).(10) Delivery mechanisms through the mucosa, etc., appeared. Limiting hepatic first pass metabolism, improving therapeutic efficacy, and preserving a constant medication plasma level are some significant benefits of transdermal drug administration. In 1979, the FDA approved Transdermal Scoop, the first transdermal device, to prevent ravel-related nausea and vomiting, especially by sea. Measurable drug levels in the blood, detectable drug and metabolite excretion in the urine, and the patient's clinical reaction to the prescribed medication therapy can all be used as indicators of percutaneous drug absorption.(11)

Advantage[12] :-

Avoid intestinal metabolism, salivary metabolism, and hepatic first pass metabolism.

- Patients can self-administer these systems due to their ease of use.
- In an emergency, drug input can be immediately discontinued by taking off the patch at any moment during treatment.
- There is little variation between and within patients because practically all individuals have the same structural and biochemical makeup of skin.
- It is possible to appropriately deliver medications through the skin that exhibit gastric discomfort and absorption.
- For medications with a short biological half-life that would ordinarily need frequent administration, continuous, non-invasive infusion is possible.
- Patient compliance is improved as a result of less frequent doses.
- It is possible to prevent therapeutic failures linked to dose inconsistencies with traditional medicines.
- A consistent and ideal blood concentration time profile reduces adverse effects.

Disadvantage[13,14]:-

- When one or more system components cause contact dermatitis at the application site, certain patients must stop using the product.
- Due to the skin's inherent limitations on drug entry, only strong medications make good candidates for transdermal patches.
- Certain medications, like scopolamine transdermal patches, are painful when applied behind the ear.
- Long-term adhesion is challenging.
- For the medicine to penetrate the stratum corneum, it must possess certain desirable physicochemical qualities. Additionally, transdermal distribution will be extremely challenging if the drug dose needed for therapeutic benefit exceeds 10 mg/day.
- Because the skin's impermeability naturally limits drug entry, only reasonably powerful medicines are appropriate candidates for TDDS.
- Some patients get contact dermatitis at the application site for one or more system components, which requires stopping the medication.
- Another aspect that must be thoroughly considered before deciding to create a transdermal medicine is clinical need.
- The skin's barrier function varies with age, from person to person, and within the same individual.

Preparation of TDDS:-

Polymer Matrix:-

Transdermal medication delivery systems are based on polymers. Transdermal delivery systems are made as multilayered polymeric laminates with a drug reservoir or drug–polymer matrix positioned between two polymeric layers: an inner

polymeric layer that acts as an adhesive and/or rate-controlling membrane and an outer impervious backing layer that stops drug loss through the backing surface.(15) In order to create transdermal delivery systems that work, it is important to take into account the design and selection of polymers. Designing a polymer matrix is the primary challenge, which is followed by optimizing the drug-loaded matrix in terms of release characteristics, adhesion cohesion balance, physicochemical properties, compatibility and stability with skin and other system components, and more.(16)

Drug :-

A better and more ideal option for medications with the right pharmacology and physical chemistry is the transdermal route. For medications that require considerable first-pass metabolism, have a limited therapeutic window, or have a short half-life, transdermal patches are a very appealing choice.(17) The transdermal route is a very alluring choice for medications with the right physical chemistry and pharmacology. Transdermal patches are very beneficial for medications having a short half-life, a small therapeutic window, or substantial first pass metabolism. such as nitroglycerine, fenatyl, etc. (18)

Permeation enhancers :- Also known as absorption promoters, accelerators, or penetration enhancers, these substances facilitate the penetration of medications administered topically. (19)

Pressure sensitive adhesive (PSA):- A substance known as a Pressure Sensitive Adhesive (PSA) aids in preserving close contact between the skin's surface and the transdermal system.

Backing laminate :-

The backing laminate's main purpose is to offer support. They ought should be able to stop the medication from escaping through the top of the dosage form. They must be impervious to permeability enhancers and medicines. For instance, foam pads, vinyl, polyethylene, and polyester films, metallic plastic laminate, and aluminum foil. (20)

Release liner :- Before the patch is applied to the skin, the protective liner covering it is taken off and thrown away during storage. It keeps the patch safe while being stored. Teflon or silicon make comprise a release coating layer.(21)

Vesicular drug delivery :-

Introduction:- During the course of treatment, novel vesicular drug delivery systems seek to route the active ingredient to the site of action and administer the medicine at a rate determined by the body's needs. When ÂBinghamÊ initially described the biological genesis of these vesicles in 1965, they were dubbed ÂBingham bodiesÊ. To accomplish targeted and regulated medication delivery, several innovative vesicular drug delivery systems that cover a range of administration routes have been developed.(22) The creation of innovative drug delivery systems has received a lot of attention in recent decades. The innovative drug delivery systems are designed to meet two requirements: they carry the medicine directly to the inflammatory tissues and/or organs and distribute it at a rate determined by the body's needs during the course of treatment.(23) The most preferred method of drug delivery is by far oral because it is simple to administer, therapy is inexpensive, patients comply, formulations may be changed, and more. There are several restrictions associated with the gastric emptying time for oral continuous drug delivery formulations. Both variable and An excessively quick gastrointestinal transit may cause the drug to

not release fully from the device into the window for absorption, which would reduce the effectiveness of the dose that is given. Recent studies and patent literature make it clear that there is a growing interest in new dosage forms that are kept in the stomach for a lengthy and consistent amount of time.(24) A medication delivery method having a delayed and/or prolonged release of the medicine is referred to as sustained delivery. The primary goal of creating these systems is to increase a product's safety and prolong its duration of action. These systems have a number of drawbacks, including increased bioavailability, dose dumping, a longer time to reach therapeutic blood levels, and an improved first pass impact.(25) The process of gastric emptying of dosage forms is highly variable, and the capacity to extend and regulate emptying time is a useful feature for dosage forms, which more time is spent in the stomach compared with traditional dose forms. The capacity to limit the dose form in the targeted region of the gastrointestinal tract is one of these challenges (Yie W.Chein et al., 1992; Sanjay Garg et al., 2003).(26)Lipid particles, micro- and nanoparticles, micro- and nanospheres, polymeric micelles, and vesicular systems such as liposomes, sphingosomes, niosomes, transfersomes, aquasomes, ufasomes, and so on are examples of particles type carriers, also referred to as aqueous carrier systems.(27)

Advantage[28,29] :-

Vesicular drug delivery systems are superior to both prolonged-release and traditional dose forms in a number of ways.

- The medications' ability to penetrate cells effectively.
- Prolong their presence in the systemic circulation.
- Decrease toxicity by selective absorption.
- Enhances bioavailability
- Lowers therapeutic costs.
- Drugs that are lipophilic
- Hydrophilic can be included.
- Delays the removal of medications that are rapidly digested;
- Addresses issues with drug instability, insolubility, and rapid degradations; Provides sustained-release system performance.

Disadvantage[30]:-

VDDS has several benefits, but it also has some s ignificant drawbacks that limit its applicati.medic ations passively, which could result in poor drug l oading effectiveness and drug leakage during in v ivo preparation, storage, and transportation.Intens e sonication is required, which can cause drug lea ks while being stored.As a result, their main stabil ity issue limits their utilization by acting as a barr ier.

Floating Drug Delivery :-

Introduction:- Because of its convenience of administration, cheap therapy costs, patient compliance, formulation flexibility, and other advantages, oral drug delivery is by far the most preferred method of drug delivery. Formulations for oral continuous medication administration have several drawbacks related to the time it takes for the stomach to empty. Incomplete drug release from the device into the absorption window due to variable and excessively quick gastrointestinal transit may reduce the effectiveness of the dose that is delivered. Recent studies and patent literature make it clear that there is a growing

interest in new dosage forms that are kept in the stomach for a lengthy and consistent amount of time.(31) A controlled or sustained delivery system has been developed as a result of these factors. A medication delivery method having a delayed and/or prolonged release of the medicine is referred to as sustained delivery.The primary goal of creating these systems is to increase a product's safety and prolong its duration of action. These systems have a number of drawbacks, including dose dumping, increased bioavailability, a longer time to reach therapeutic blood levels, and an improved first pass effect. (32) The incapacity to confine the dosage form in the desired region of the gastrointestinal tract is one of these challenges. Drug absorption from the gastrointestinal tract is a complicated process that depends on numerous factors, and it is generally accepted that the duration of contact with the small intestinal mucosa determines the extent of drug absorption from the gastrointestinal tract (Hirtz, 1985).(33)

Advantage[34]:-

1. For medications intended for local action in the stomach, the floating systems are beneficial. Example - Antacids,

2. When acidic compounds, such as aspirin, come into touch with the stomach wall, they create irritation. As a result, FDDS could be helpful for administering aspirin and other such medications.

3. Drugs absorbed through the stomach benefit from the floating systems. Example - An acid, ferrous salts.

4. The medicine will dissolve in the stomach fluid if prolong-release floating dosage forms, such as tablets or capsules, are administered.

5. When the stomach's contents are emptied, they dissolve in the gastric fluid and become accessible for absorption in the small intestine.

Disadvantage[35] :-

1. For medications that have stability or solubility issues in the gastrointestinal tract, a floating device is not practical.

2. For medication delivery to float and function well, these systems need a lot of fluid in the stomach, such as coat, water.

3. Candidates are medications that undergo substantial first pass metabolism and are highly absorbed through the gastrointestinal system.

Microencapsulation

Introduction:-

The technique of microencapsulation involves the creation of thin wall material coverings around solids, liquids, or even gases, enclosing them in minute particles. The method was developed in the late 1930s in response to the business machinery industry's need for a cleaner alternative to carbon paper and carbon ribbons. A variety of microencapsulated materials, including medications, were developed as a result of the 1950s breakthrough of reproduction paper and ribbons that contained dyes in tiny gelatin capsules that were released upon impact by a typewriter key or the pressure of a pen or pencil. [36] Micro particulate formulations are occasionally described using conflicting language. and perplexing to those who are not knowledgeable in the area. In general, a "micro particle" is any particle having a diameter between 1 and 1000 µm, regardless of its exact internal or external structure. The subcategory of "microcapsules" pertains to microparticles with a

core encased in a substance that is significantly different from the core, whereas "microspheres" specifically refers to spherical micro particles within the larger category of microparticles. The core might be a gas, liquid, or solid. [37]mA medicinal drug can be delivered to the target location in a prolonged controlled release form using a variety of techniques. Using microspheres as medication carriers is one such strategy. Typically, microspheres are free-flowing powders made of synthetic polymers or proteins that are biodegradable and preferably have a particle size of less than 200 μm. The process of microencapsulation involves coating or enclosing minuscule droplets or particles of liquid or solid substance with a continuous layer of polymeric material. Bioencapsulation, which is more limited to encasing a biologically active material (such as DNA in a whole cell or group of cells) in order to increase its performance and/or lengthen its shelf life, is a subset of microencapsulation. [38]

Advantage :-

1. **Protection of Core Material:** By shielding delicate substances (such as vitamins, probiotics, medications, or flavors) from light, oxygen, heat, and moisture, microencapsulation extends the stability and shelf life of these products.[39]

2. **Restricted Release:**The ability to time or trigger the release of the core material (by pH, temperature, or enzymes) is very helpful in the food, pharmaceutical, and agricultural industries.[40]

3. **Masking of Taste or Odor**: It is possible to successfully disguise unpleasant or bitter tastes and scents, such as those found in certain medications or fish oils.[41]

4. **Improved Handling and Flow**:-It is possible to turn sticky or liquid materials into free-flowing powders, which facilitates processing and transportation.[42]

5. **Specific Delivery** :- Microencapsulation aids in directing active substances to certain bodily locations, especially in medicine delivery.[43]

6. **Decrease in Volatility**:-Essential oils and other volatile chemicals can be less likely to evaporate or degrade when encapsulated.[44]

Mucosal Administration :-

Introduction :- In an adult, the mucous membrane epithelium covers several hundred square meters. The gastrointestinal, respiratory, and urogenital tracts are the primary mucosal surfaces, making them susceptible to infection by harmful microbes. Physicochemical defense mechanisms and innate and adaptive mucosal immune systems, which are made to differentiate between antigens that enter the body through mucosal surfaces and those that are put straight into the circulation, shield mucosal surfaces from external threats. The mucosal immune system can essentially be separated into inductive and effector sites. Either by working with expert antigen-presenting dendritic cells (APCs) or by generating the M cell, a specialized epithelial phenotype, antigens are extracted from mucosal surfaces and then excite corresponding naive T and B lymphocytes. [45] The mucosae of the genitourinary, respiratory, digestive, and oral canals make up the largest exposed area of the human and animal body. Because of their critical roles in physiologic processes, these mucosae are essential to the basic life-supporting systems. While mucosa-associated lymphoid tissues (MALTs) are essential organs for eliciting effective protective immune responses, mucus serves as the initial barrier against the entry of microbes on these mucosal surfaces. The mucosa

is a prime candidate for vaccination because of its highly developed immune system. Both pathogen-specific mucosal immunity and systemic immune protection, including antibody production and immune cell-mediated responses, can be advantageously induced by mucosal vaccination.[46]

Advantage :-

Non-invasive: When compared to injections or other techniques, mucosal administration is usually non-invasive, which lessens patient discomfort and anxiety.[47]

Rapid Absorption: Due to the abundance of blood vessels in the mucosal membranes, chemicals can be absorbed quickly. This may cause some drugs to start working more quickly.[48]

Preventing First-Pass Metabolism: When medications are taken orally, they must first pass through the liver, which may cause them to degrade or lose some of their potency (first-pass metabolism). Drug distribution can be more effectively achieved by avoiding this procedure by mucosal administration.[49]

Targeted Delivery: By focusing on certain locations of action, such as the gastrointestinal tract or respiratory system (for respiratory infections), mucosal methods like nasal or oral delivery can increase the accuracy of treatment.[50]

Immune System Activation: Mucosal surfaces, such as mucosa-associated lymphoid tissue, or MALT, are intimately linked to the body's immune system. Because mucosal administration can aid in promoting both local and systemic immune responses, it is especially beneficial for vaccinations and immunotherapies.[51]

Patient Compliance: Especially for chronic illnesses, mucosal delivery can result in greater patient compliance because it is less intrusive and more convenient than alternative methods (like injections).[52]

Decreased negative Effects: Compared to oral or injectable routes, some medications delivered through mucosal channels may have fewer negative effects because of lower systemic concentrations.[53]

Options for Sustained Release: Mucosal formulations with the potential for long-lasting therapeutic effects can be made for sustained release.[54]

Disadvantage[55] **:-**

- **Complex Formulation**: These systems might be technically difficult to design and formulate.
- **Stability Problems**: Because of pH or enzymatic activity, certain medications may become unstable in the mucosal environment.
- **Variable Absorption:** Individual variations in mucosal conditions may result in varying medication absorption.
- **Mucus Renewal**: For certain drug delivery systems, a prolonged mucus turnover may result in a shorter residence period.
- **Possible Irritation**: Mucosal tissues may become irritated by some formulations.

Nasal Administration:-

Introduction :- The tradition of nasal medicine delivery, which dates back thousands of years, has been revitalized.

For medications like proteins and peptides that are active at low dosages and do not have minimal oral bioavailability, it is a helpful delivery technique. Rapid displacement from the absorption site in the nasal cavity as a result of the mucociliary clearance mechanism is one of the causes of the low degree of peptide and protein absorption via the nasal route.[56] The nasal route avoids the hepatic first pass elimination and is dependable, easy, and easily accessible. Its highly vascularized epithelium and porous endothelium membrane allow for quick absorption of substances into the systemic circulation. Furthermore, dose reduction, a speedier initiation of pharmacological activity, a quicker attainment of therapeutic blood levels, and fewer side effects are all made possible by intranasal drug administration.
The nasal cavity's low metabolic environment may be able to replicate the advantages of intravenous delivery while overcoming the drawbacks of the oral route. Furthermore, nasal administration offers noninvasiveness, self-administration, patient comfort, and patient compliance—all of which are challenges in intravenous drug therapy—while reducing the lag time linked to oral drug delivery. [57] A viable substitute for systemic administration of medications that are not well absorbed by the oral route is nasal delivery. Only two cell layers divide the nasal lumen from the thick blood vessel network in the lamina propria, and the nasal epithelium has a comparatively high permeability. The nasal mucosa is susceptible to the negative effects of medications and excipients in nasal drug formulations because of these features, which also make nasal drug administration an appealing delivery method. Damage to the nasal mucociliary clearance system is especially likely. Because mucociliary clearance is crucial for respiratory system protection, this could have major repercussions. Ciliary movement carries noxious chemicals trapped in the nasal cavity's mucus layer towards the nasal cavity.[58]

Advantage[59] :-

1) There is no evidence of drug breakdown in the gastrointestinal tract.
2) First-pass metabolism in the liver is avoided.
3) It is possible to attain a rapid beginning of action and rapid medication absorption.
4) Absorption enhancers or other methods can be used to increase the bioavailability of bigger medication molecules.
5) For smaller pharmacological molecules, the nasal bioavailability is good.
6) Nasal drug delivery is a method of delivering drugs to the systemic circulation that are not taken orally.
7) Research to date suggests that the nasal route is a substitute for the parenteral route, particularly for medications containing proteins and peptides.
8) More convenient for patients than parenteral medication, particularly for those undergoing long-term therapy.
9) The nasal route is used to provide medications with poor stability in GI fluids.
10) Polar substances with low oral absorption might be especially well-suited for this delivery method.

Disadvantage[60]:-

- In the nasal cavity, the delivery volume is limited to 25–200 μL.

- This method cannot transport high molecular weight drugs (mass cut off ~1 kDa).
- Negatively impacted by medical disorders.
- This pathway exhibits significant interspecies diversity.
- The permeability of drugs is impacted by normal defensive systems such as ciliary beating and mucociliary clearance.
- Medications like Budesonide and Azilactine that irritate the nasal mucosa.
- At this point, models are less established and mechanisms are not fully understood.
- It is yet unknown whether absorption enhancers cause systemic toxicity.
- The absorption surface is smaller than that of GIT.
- Inconvenient when compared to the oral route due to the potential for nasal discomfort.
- The enzymatic barrier to drug permeability.

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