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A Review : Recent Updates In Novel Drug Delivery System (NDDS)

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ABSTRACT
Novel drug delivery systems (DDSs) hold great promise for the treatment of oral cavity diseases. The main objective of this article was to provide a detailed overview regarding recent advances in the use of novel and nanostructured DDSs in alleviating and treating unpleasant conditions of the oral cavity. Strategies to maximize the benefits of these systems in the treatment of oral conditions and future directions to overcome these issues are also discussed.Localized drug delivery devices provide drug action through spatial or temporal control of drug release (usually rate- limiting) in the vicinity of the target. Rate- pre-programmed drug delivery systems provide drug action by manipulating the release of drug molecules by system design which control the molecular diffusion of drug molecules.Targeteddrug delivery provides drug action by using carries either for passive or active targeting or one base or self programmed approach, usually anchored with suitable sensory devices, which recognize their receptor at the target.

Keywords: Novel drug delivery system, Transdermal drug delivery system, Penetration Enhancer.

I. INTRODUCTION

Novel drug delivery systems is the new system Recent advances in the understanding of pharmacokinetic & pharmacodynamic behaviour of drug have offer a more rational approac to the development of optimal drug delivery system. the novel drug delivery systems (NDDS) are carriers which maintain the drug concentration in therapeutic range for longer period of time[9]. The method by which a drug is delivered can have a significant effect on its efficacy. Some drugs have an optimum concentration range within which maximum benefit is derived, sand concentrations above or below this range can be toxic or produce no therapeutic benefit at all. In the novel drug delivery systems (NDDS), there are various novel carriers which have advantage over conventional dosage forms. Conventional dosage forms show high dose and low availability, in-stability, first pass effect, plasma drug level fluctuations and rapid release of the drug. NDDS is one of the important tool expanding drug markets in pharmaceutical industry. NDDS can minimize problems by enhancing efficacy, safety, patient compliance and product shelf life[1].

Novel drug delivery systems

Various drug delivery systems have been developed and some of them under development with an aim to minimize drug degradation or loss, to prevent harmful side effects and to improve drug bioavailability and also to favour and facilitate the accumulation of the drug in the required bio-zone (site). There are no. Of novel carries which have been established and documented to be useful for controlled and targeted drug delivery. It is important to critically evaluate different terms used under the different broad categories of novel drug delivery system. Sustained- or controlled- drug delivery systems provide drug action at a pre determined rate by providing a prolonged or constant (Zero-order) release respectively, at the therapeutically effective levels in the circulation. Localized drug delivery devices provide drug action through spatial or temporal control of drug release (usually rate- limiting) in the vicinity of the target. Rate- pre-programmed drug delivery systems provide drug action by manipulating the release of drug molecules by system design which control the molecular diffusion of drug molecules.Targeteddrug delivery provides drug action by using carries either for passive or active targeting or one base or self programmed approach, usually anchored with suitable sensory devices, which recognize their receptor at the target[2].

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Table No. 1: List of various marketed formulations based on novel drug delivery systems

DRUG	INDICATION	MANUFACTURER
Dexorubicin	Kaposi's sarcoma	SEQUUs
Daunorubicin	Advanced kaposi' sarcoma	NeXstar
Amphotericin B	Systemic fungal infection	NeXstar
Amphotericin B	Systemic fungal infection	SEQUUS
Leuprolide acetate	Prostate cancer	Takeda-Abott
Triptorelin	LHRH agonst	Novartis

TYPES OF NOVEL DRUG DELIVERY SYSTEM

By Route of Administration

- Oral Drug Delivery Systems
- Injectable Drug Delivery Systems
- Pulmonary Drug Delivery Systems
- Transdermal Drug Delivery Systems
- Others

By Mode of NDDS

- Targeted Drug Delivery Systems
- Controlled Drug Delivery Systems
- Modulated Drug Delivery Systems

ADVANTAGES OF NOVEL DRUG DELIVERY SYSTEM

- Protection from physical and chemical degradation.
- Sustained delivery.
- Improved tissue macrophages distribution.
- Enhancement of stability.
- Enhancement of pharmacological activity.
- Protection from toxicity.
- Increased bioavailability.
- .Enhancement of solubility.

DISADVANTAGES OF NOVEL DRUG DELIVERY SYSTEM

While these advantages can be significant, the potential disadvantages cannot be ignored like the possible toxicity or non-biocompatibility of the materials used, undesirable by-products of degradation, any surgery required to implant or remove the system, the chance of patient discomfort from the delivery device.

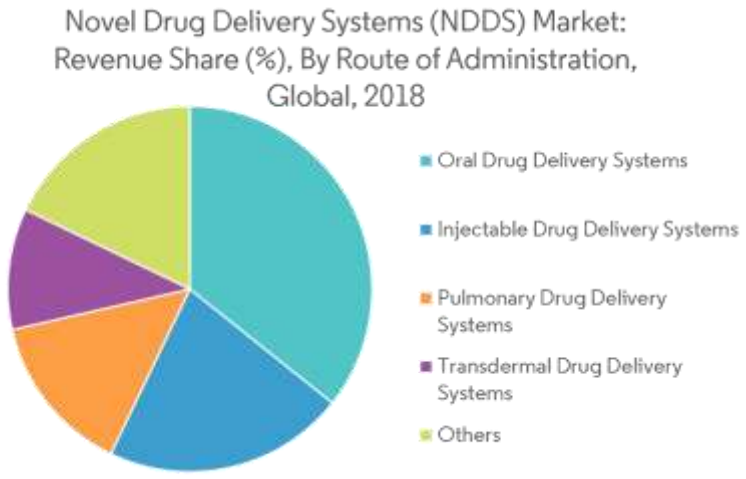

Figure 1 Novel Drug Delivery System Market

TYPES OF NOVEL DRUG DELIVERY SYSTEM

1. **TRANSDERMAL DRUG DELIVERY SYSTEM**

The transdermal drug delivery system (TDDS), commonly known as "patches," is a dosage form that is designed to distribute a therapeutically effective amount of drug over the skin of a patient. The overall morphological, biophysical, and physiochemical aspects of the skin must be studied in order to transfer medicinal agents via the human skin for systemic action.[3]

Transdermal delivery not only allows for controlled, consistent drug administration, but it

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also allows for continuous input of medications with short biological half-lives and prevents pulsed entry into systemic circulation, which can result in undesirable side effects. systems are expected to improve adherence because of being safe for patients with impaired swallowing or those at risk of aspiration and also allow caregivers to confirm that a drug is being used (reducing missed doses or overdose). Transdermal patches provide continuous drug delivery, which might be favorable for sustaining efficacy with fewer adverse reactions by maintaining a stable plasma concentration.

Transdermal drug delivery system basic components-
1. The drug.
2. Polymer matrix.
3. Permeation enhancers.
4. Adhesive.
5. Backing layer.
6. Release linear.

1. Drug

Properties

- The drug's molecular weight should be less than 500 daltons.
- The drug's affinity for both lipophilic and hydrophilic phases should be high.
- The drug's melting point should be low.
- The medicine should be effective with a daily dose of a few milligrames.
- The drug's half-life (t1/2) should be short.
- The drug must not cause skin irritation or an adverse reaction.
- Drugs that breakdown in the gastrointestinal tract and are inactivated by the hepatic firstpass effect are good candidates for transdermal administration.
- Tolerance to the drug must not develop due to transdermal delivery's near zero-order
- release profile.
- Drugs that must be administered for an extended length of time or that have side effects in
- non-target tissues can be prepared for transdermal delivery.7. Other excipients such as plasticizers and solventore quickly.

2. Polymer matrix or matrices-

- The polymer regulates the drug release from the device. For a polymer to be utilised in
- transdermal patches, it must meet the following requirements.
- The polymer's weight and chemical activity should be such that the specific drug
- Molecular diffuses and is released appropriately through it.
- The polymer should be long-lasting.
- The polymer must not be harmful.
- The polymer should be simple to produce.
- The polymer should be low-cost.

3. Penetration enhancers-

By modifying the barrier characteristics of the stratum corneum, penetration enhancers aid drug absorption. Non-toxic, non-allergic, pharmacologically inert, tasteless, affordable, and compatible with drug and excipients are all requirements for a penetration enhancer.Intercellular lipid interactions can increase skin permeability by disrupting cellular structure and thereby Increasing permiablity.

4. Adhesives-

All transdermal devices are attached to the skin with a pressure sensitive adhesive that can be placed on the device's face or in the rear and extends peripherally. Both adhesive systems must meet the following requirements:

- It should aggressively attach to the skin and be easily removed.
- Shouldn't leave a sticky residue on the skin that can't be washed off.
- Skin should not be irritated or sensitised., for example, Silicones, and polyisobutylene.
- Backing membrane

5. Backing membranes- are flexible and offer a good binding to the drug reservoir, as well as preventing the drug from escaping through the top of the dosage form and allowing printing For example, Metallic plastic, is an impermeable substance that protects the product while it is being used on the skin. For example, cellulose derivatives and polypropylene silicone[4].

TYPES OF TRANSDERMAL PATCHES

1. Single layer drug-in-adhesive

The drug is also contained in the adhesive layer of this system. The adhesive layer of this kind of patch not only serves to adhere the numerous layers together, as well as the entire system to the skin, but it also serves to release the drug. To the outer side of adhesive layer there is lining of temporary liner and a backing.

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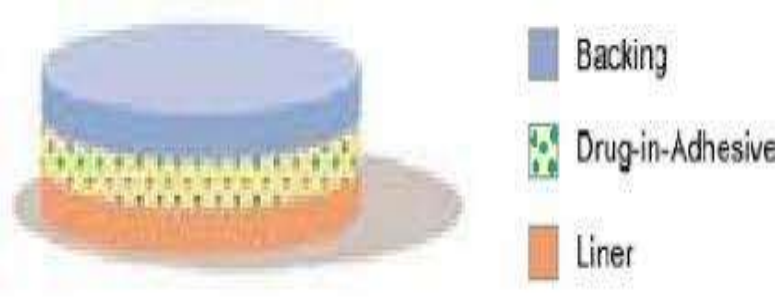

Figure 2: Single-Layer Drug In-adhesive

2. Multi-layer Drug-in-adhesive

In the same way that both adhesive layers are responsible for drug release, it's identical to the single layer system. The multilayer system, on the other hand, adds a second layer of drug-in adhesive material, usually separated by a membrane (but not in all cases). A temporary liner layer and a permanent backing surround this patch.

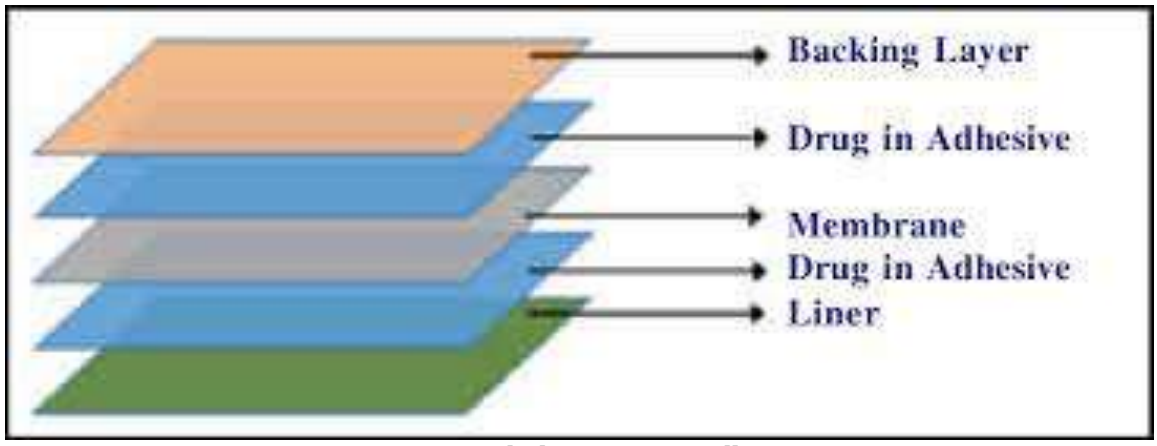

Figure 3: Multi-layer Drug-in-adhesive

ORAL DRUG DELIVERY SYSTEM

Modified oral release drug delivery system has been developed to extend the drug release for several hours (by combining drug with release-retardant material to form matrix core or by applying release modifying film coat over the core drug material). The MR system offers reduction in dosing frequency. Low incidence of side effects and better therapeutic effect and enhancement of bioavailability.[4]

Factor influencing performance of modified drugs formulation

Food: The influence of food on the bioavailability of drug must be investigated for safety and efficacy. If any food effects are found then a justified dose with respect to the product intake in relation to meals is given4.

Gastro- Intestinal function: By the modified release formulation is co- administrated with drug affecting GI tract physiology then investigation related to MR dosage form must be done.

Diurnal Rhythms: Plasma concentration profile measured for 24 hrs at steady state of any difference occurs in view of Day/ night. Site of application: The absorption of drug at different site must be investigated of the application site in not limited to one body area.

Dose dumping : The chances of unexpected release of drug resulting in unacceptable higher exposure occur when the MR formulation contains higher compared to immediate release product

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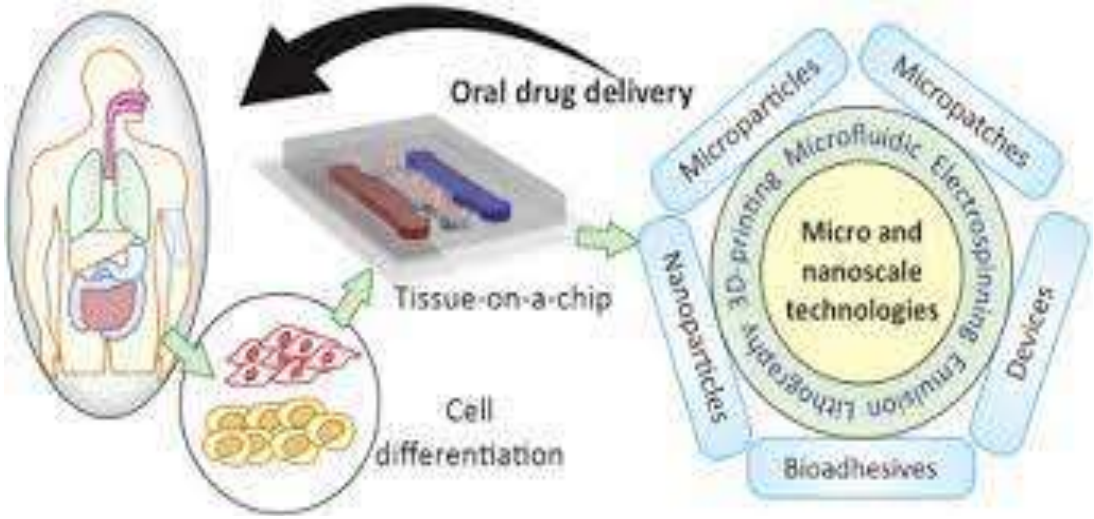

Figure 4: Oral Drug Delivery System

The oral route is by far the most common route for drug administration in the gastrointestinal tract (GI tract) and can be used for both systemic drug delivery and for treating local gastrointestinal diseases. It is the most preferred route by patients, due to its advantages, such as ease of use, non-invasiveness, and convenience for self-administration**.**

Challenges Associated with Oral Delivery

Oral drugs are transported and absorbed in the GI tract, which is in the shape of a conduit. Some drugs have local effects in the gut, while most of them are sent to the bloodstream in the systemic circulation to act in other parts of the body. The GI tract can be divided into upper and lower parts. The upper GI tract includes the oral cavity, pharynx, esophagus, stomach and the initial part of the small intestine, known as the duodenum.[8]

PULMONARY DRUG DELIVERY SYSTEM

The pulmonary route has gained increasing importance in the recent times due to its unique properties such as a large absorptive area of up to 100m2; extremely thin 0.1 µm - 0.2 µm absorptive mucosal membrane and good blood supply. Devices used to deliver drug by pulmonary route area based on one of three platforms pressurized metered dose inhaler, nebulizer and dry powder. Pulmonary route possesses many advantages over other routes of administration for the treatment of specific disease states, particularly lung associated large protein molecules which degrade in the gastrointestinal conditions and are eliminated by the first pass metabolism in the liver can be delivered via the pulmonary route if deposited in the respiratory zone of the lungs.[17]

Pulmonary route have been used to treat various respiratory diseases for centuries. Ancient inhalation therapies included the use of leaves from plants, vapors from aromatic plants, balsams, and myrrh. In the 1920 s adrenaline was introduced as a nebulizer solution, in 1925 nebulizer porcine insulin was used in experimental studies in diabetes, and in 1945 pulmonary delivery of the recently discovered penicillin was investigated 2, 3. Steroids had been introduced in the mid 1950s for the treatment of asthma and nebulizers were enjoying widespread use. In 1956 the pressured metered dose inhaler (pMDI) was introduced, over the past 5 decades, helped by the advances in molecule design and drug discovery the pMDI has risen to become the main stay of asthma treatment[5]

Pulmonary drug delivery has attracted increasing attention in biomedicine, and porous particles can effectively enhance the aerosolization performance and bioavailability of drugs. However, the existing methods for preparing porous particles using porogens have several drawbacks, such as the inhomogeneous and uncontrollable pores, drug leakage, and high risk of fragmentation.

Advantages of drug delivery via the pulmonary route:

Pulmonary delivery is expanding a category of drugs called ‘‘inhalables,’’ defined as respiratory and systemic therapies administered simply by inhaling. Inhalables offer several advantages over injectables, transdermal or oral methods of delivery [4].Provide a non-invasive method of delivering drugs into the bloodstream for

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those molecules that currently can only be delivered by injection. These include peptides and proteins, such as insulin for diabetes or interferon beta for multiple sclerosis and most of the drugs developed in recent years by biotechnology companies. Enable effective drug targeting to the lungs for relatively common respiratory tract diseases such as asthma, emphysema, bronchiectasis and chronic bronchitis.Provide for very rapid onset of action similar to the i.v. Route and quicker than can be achieved with either oral delivery or subcutaneous injections.Inhaling helps avoid gastrointestinal tract problems such as poor solubility, low bioavailability, gut irritability, unwanted metabolites, food effects and dosing variability.[5]Reduction of dosage i.e. Drug content of one 4 mg tablet of salbutamol equals to 40 doses of meter doses.

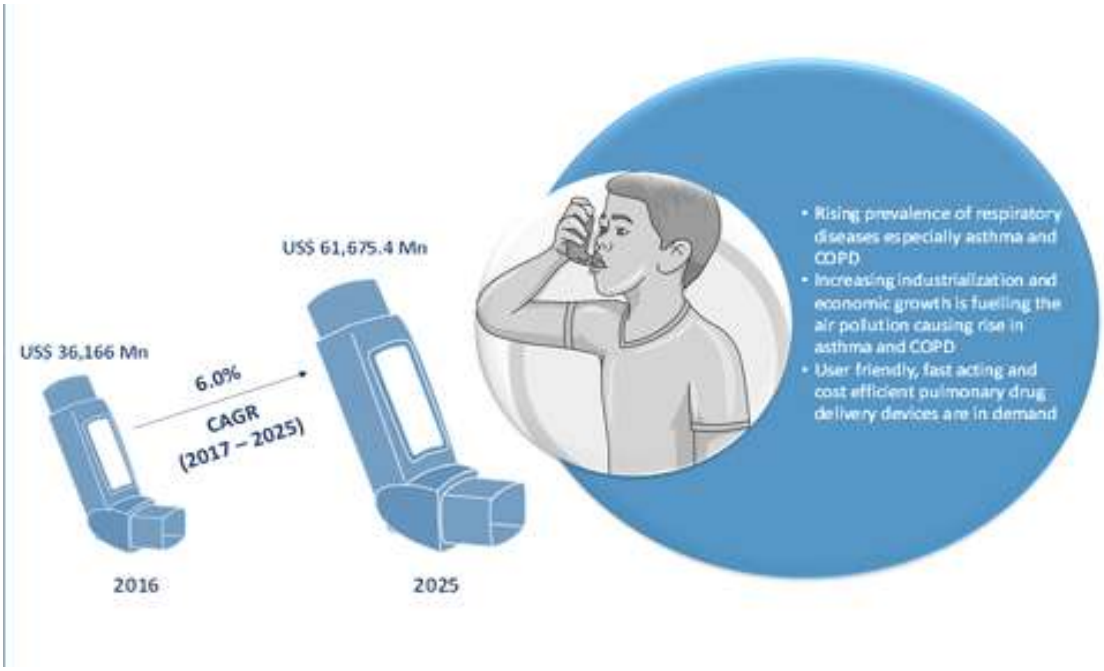

Figure 5: Global Pulmonary Drug Delivery Devices Market Segmentation

Injectable drug delivery system

Parenteral preparations are sterilepreparations which have one or moreactive ingredients administered byinfusion, injection, or implantation into thebody.Excipients such as solvents, bufferingagents, solubility enhancers, stabilizers orantimicrobial preservatives suspending agents,isotonic agents are added to the parenteralpreparations.Excipients are added to aminimum level. No incompatibility amongthe added substances of the dosage form.Water for injections is used as the vehiclefor aqueous injections. Many advanced drugdelivery systems are evolved over the yearsand parenteral drug delivery system being oneof them. In parenteral drug delivery systems injection is directly administered into the tissuefluid or blood instead of crossing intestinalmucosa. The conventional intravenousinjection may produce the high drug plasmaconcentration, near to the minimum toxicconcentration. Due to the short duration ofaction, sometimes it becomes essential toadminister the drug repetitively in traditional systems. To overcome the problems faced by conventional intravenous injections, the advanced parenteralcontrolled release drug delivery systems are developed,which give predictable, consistent, or desired drug releaseprofiles.[6]Injectable thermosensitive hydrogel has been regarded as attractive drug delivery system, which displays a sol-gel phase transition upon injection in response to temperature.[16]Liposomes, niosomes, suspensions, microparticles,emulsions, and implants are identified as parenteral controlledrelease drug delivery systems. This drug delivery systemis beneficial only if drugs have short half-lives and poorabsorption by other routes of administration. Two approachescan be used to obtain constant drug level in the blood.

ADVANTEGES

- It maintains a high drug concentration in the blood or
- prolongs the duration of drug action

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- Improved drug pharmacokinetics
- Improvement of physical stability
- Decrease in side effects by achieving a constant drug
- level via parenteral depot systems
- Reduction in systemic adverse effects and increase in
- specificity for targeted drug delivery
- A chance to control a specific rate of drug release
- Improved patient compliance
- More uniform effect.

Types Of Parentral Release Injectables-

A. Injectables

- Solutions
- Dispersions
- Microspheres and microcapsules
- Nanoparticles and niosomes
- Liposomes and pharmacosomes
- Resealed erythrocytes
- In situ forming implants (ISFIs)

B. Implants

C. Infusion device

- Osmotic pumps (Alzet)
- Vapor pressure powered pumps (infusaid)
- Battery powered

Injectable solution

Both aqueous as well as oil solution may be used for parenteral controlled drug release. With the aqueous solutions, the drug release may be controlled by increasing the viscosity of vehicle by use of methylcellulose (MC), carboxy MC, and polyvinylpyrrolidone and thus decreasing the molecular diffusion and localizing the injected drug.

Injectable suspension

Injectable suspensions are heterogeneous and dispersed system having excipients and insoluble drug molecules which need to be redispersed or resuspended before administering to patient. Injectable suspensions are either being formulated as reconstitution before use or as ready to use injection. The formulation of stable suspension mainly involves use of high solid content and/or increased viscosity of thesystem. However, most parenteral suspensions are usuallydilute and have particles limitation for viscosity becauseof syringeability and injectability constraints. Lecithin,polysorbate 20, polysorbate 80, pluronic F-68, and sorbitantrioleate are used as surfactant in injectable suspension.

Injectable emulsion

They could be administered by intravenous, intra-arterial, intrathecal, intraperitoneal, intraocular, intramuscular, or subcutaneous injection. The development of parenteral emulsion continues to play an important role in formulation and delivery of many drugs.An emulsion formulation can avoid the use of conventional cosolvent systems and associated undesirable effects caused by precipitation of the drug at the injection site, as seen in case of anticancer drug taxol.Parenteral emulsions are the best known as a source of calories and essential fatty acids for the nonambulatory patients, but significantly their physical properties and low toxicity make them excellent vehicle for the formulation and delivery of drugs with a broad range of application. Investigators continue to study the various Types of spans and Tweens that are approved by the various pharmacopoeias for parenteral administration and have been included in the parenteral emulsion formulation. In recent years, the concept of tailored emulsion for delivery of oil-soluble lipophilic compound has gained significant attention in the field of parenteral drug delivery.Parenteral delivery of the hydrophobic drugs is a very challenging task. Microemulsions have evolved as a novel vehicle for parenteral delivery of the hydrophobic drugs. Parenteral emulsion is special o/w emulsion used to fee patients whose medical condition makes them unable to eat normally.

Figure 6: Injectable Emulsion

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Application of novel drug delivery system

Novel drug delivery system in breast cancer

Breast Cancer (BC) is a carcinoma of breast tissues, the major recurrent cancer in women and also the foremost cause of death with approximate 5 million annual deaths worldwide.Currently, cancer research focuses on improving BC treatment using various novel delivery systems of chemotherapeutic agents such as nanoformulations, liposomes, hydrogels, exosomes, dendrimers, microspheres, microbubbles, phytosomes, micelles, etc. The present review encloses existing assorted novel drug delivery systems and approaches intended for diagnosis and treatment of BC[14].

BY MODE OF NOVEL DRUG DELIVERY SYSTEM

Controlled Drug Delivery System

The primary objectives of controlled drug delivery system (CDDS) are to ensure safety and enhance efficacy of drug with improved patient compliance. An ideal CDDS is the one which delivers the drug at a predetermined rate, locally or systemically, for a specified period of time. An ideal targeted DDS as the one which delivers the drug only to its site of action and not to the non target organs or tissues. The goal of a sustained release (SR) dosage form is to maintain therapeutic blood or tissue level of the drug for an extended period. The main mechanisms to control drug release include complexation, matrix embedment and coated reservoir systems. Complexation may involve ion exchange resins or other adsorption agents. The use of long chain polymers or waxy lipids to embed drugs in is a popular option to design matrix-based controlled release products and is often presented as part of the multi-layered tablets or tablet-in-tablet designs.[18]

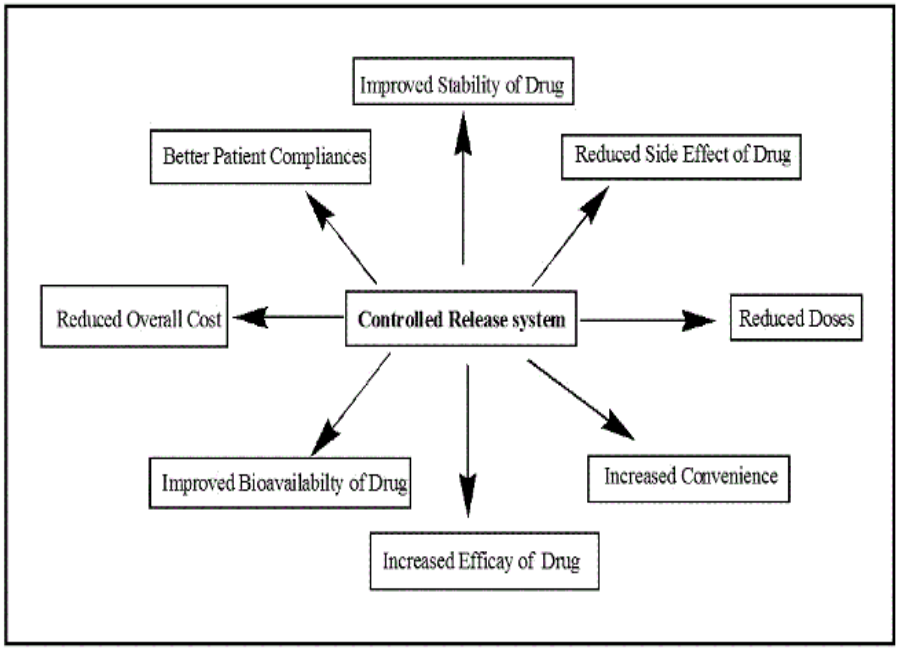

Figure 7: Controlled Release System

Targeted Drug Delivery System-

Targeted drug delivery is a system of specifying the drug moiety directly into its targeted body area (organ, cellular, and subcellular level of specific tissue) to overcome the aspecific toxic effect of conventional drug delivery, thereby reducing the amount of drug required for therapeutic efficacy.

Targeted drug delivery (TDD) is emerging as a powerful tool for the treatment of cancer because of enhanced delivery of drugs, as well as genes, to a tumor site with protection from the extracellular environment. Stimuli-responsive nanogels (NGs) are three-dimensional hydrophilic polymer networks that are formed via covalent linkages or self-assembly processes and are able to change their structural properties in the presence of external stimuli. These NGs have been widely examined as smart drug delivery carriers for a variety of anticancer drugs, as well as genes,

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because of stability, ease of synthesis, good control over particle size, and easy functionalization. They can control sizes from 5 to 400 nm, followed by different polymerization conditions[18].

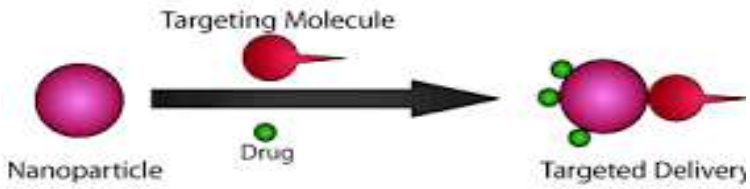

Fig No 8 .Targeted Delivery

II. CONCLUSION

Novel drug delivery systems (DDSs) hold great promise for the treatment of oral cavity diseases. The main objective of this article was to provide a detailed overview regarding recent advances in the use of novel and nanostructured DDSs in alleviating and treating unpleasant conditions of the oral cavity. Strategies to maximize the benefits of these systems in the treatment of oral conditions and future directions to overcome these issues are also discussed. In the present study we discuss novel drug delivery system, advantages, disadvantages of each method. It will be benificial for the researchers to understand the concept of novel drug delivery system.

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