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REVIEW ARTICLE ON NOVEL DRUG DELIVERY SYSTEMS

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INTRODUCTION

Based on the recently reported data, more than 70% of new drugs formulated are showing poor water solubility, which becomes the limiting factor in the absorption drug after oral admission.[1]

In this respect, developed novel drug delivery system and carriers for herbal drugs should ideally accomplish some prerequisites such as proper delivering of the drug at a rate oriented by the needs of the body, over the period of treatment and it should pass the active entity of herbal drug to the site of action.[2] Many approaches have been adopted to increase drug solubility, sustainability, bioavailability and gastrointestinal permeability.[3] Nanocarrier has gained tremendous attention in the development of new pharmaceutical carrier and delivery systems. One of the strategies to thwart this problem is to encapsulate natural plant metabolites into the biodegradable and biocompatible nanoparticle.[4]

Employment of innovative drug delivery systems including utilization of nanocarrier delivery to overcome the physicochemical and pharmacokinetic limitation of phytochemicals enhanced the controlled release and even efficacy of the bioactivities. This innovation shows the promising future of nanomedicine as a potential solution for impressive hindrance and handling of various chronic diseases.[5]

Micro encapsulation is the process in which small droplets or particles of liquid or solid material are surrounded or coated by a continues film if polymeric material.[6]

More reliable dosage forms, such as tablets and capsules During the last decades of the 20th century, a sub stantial effort was made to move from sustained, but essentially uncontrolled,

release systems (e.g., waxes and other polymeric matrices) to controlled-release systems such transdermal patches, improved oral-inhalation formulations, and erodible implants. In the 1990s, the appearance of new drugs with larger molecular sizes, higher dose sensitivities, and often poorer stabilities in biological environments led to a stronger push towards the development of efficient encapsula tion and controlled-release technologies. In addition to better clinical efficacy and patient compliance, economic considera-tions such as a decrease in both frequency and cost of admin-istering the drug, as well as extension of product life by the use of controlled-release formulation are driving the demand for versatile, high-performance controlled-release systems. This makes drug delivery one of the fastest-growing segments of the pharmaceuticals market, with approximately 10% an-nual growth and an estimated value in 2007 of usa $82 billion for the US market alone.[7,8]

NOVEL DRUG DELIVERY SYSTEMS

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

1. Passive and
2. Active targeting)[9,10,11]

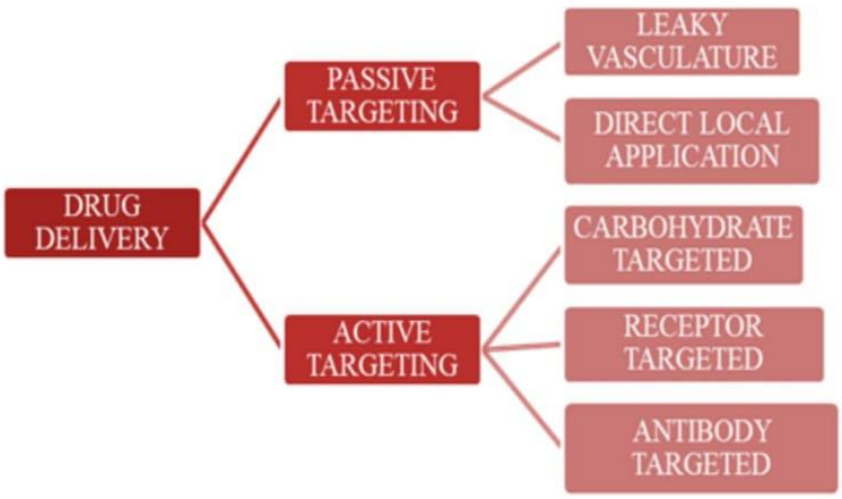

FIGURE 1: TYPES OF DRUG DELIVERY

Any drug delivery system may be defined as a system comprising of:

a) Drug formulation

b) Medical device or dosage form/technology to carry the drug inside the body

c) Mechanism for the release

The therapeutic benefits of these new systems include:

- Increased efficacy of the drug
- Site specific delivery
- Decreased toxicity/side effects
- Increased convenience
- Viable treatments for previously incurable diseases
- Potential for prophylactic applications
- Better patient compliance.

There is no uniform and established definition of drug delivery systems. It is assumed to be based on two basic parameters: Route of entry (A) and Dosage form (B). Any member of the cartesian product of (A X B) is defined as a drug delivery system. Such a definition implies that there are a vast number of members in this group.[12]

Novel drug delivery system is a novel approach to drug delivery that addresses the limitations of the traditional drug delivery systems. Modern medicine cures a particular disease by targeting exactly the affected zone inside a patient's body and transporting the drug to that area. Drug delivery system is the method by which an optimum amount of the concerned drug is administered to the patient in such a way that it reaches exactly the 'site of action' and starts working then and there. Novel drug delivery system attempts to eliminate all the disadvantages associated with conventional drug delivery systems. There are various approaches by which novel drug delivery can be achieved.[13,14]

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, and concentrations above or below this range can be toxic or produce no therapeutic benefit at all. On the other hand, the very slow progress in the efficacy of the treatment of severe diseases has suggested a growing need for a multidisciplinary approach to the delivery of therapeutics to targets in tissues. From this, new ideas on controlling the pharmacokinetics, pharmacodynamics, non-specific toxicity, immunogenicity, bio-recognition and efficacy of

drugs were generated. These new strategies, often called drug delivery systems (DDS), are based on interdisciplinary approaches that combine polymer science, pharmaceutics, bioconjugate chemistry and molecular biology.[15]

A Novel Drug Delivery System (NDDS) represents an innovative approach integrating advanced development, formulations, and cutting-edge technologies to efficiently deliver pharmaceutical compounds within the body to achieve desired pharmacological effects safely.[16]

Characteristics of Novel Drug Delivery System:

Increase the bioavailability

Provide controlled delivery of drug

Transport the drug intact to the site of action avoiding the non-diseased tissue.

Stable and delivery be maintained under various physiological variables.

Easy to administer, safe and reliable.

Cost-effective.[16]

The three main goals of novel drug delivery system (NDDS) is by providing sustained drug release, selected targeting to the site of action and increased patient compliance [Figure 1]. NDDS not only reduce the frequency of administration but also reduce the Peak and valley fluctuations which lead to enhanced bioavailability. The applications of NDDS in phytopharmaceuticals have been widely investigated, and various commercial formulations of phytoconstituents are available in the global market which people will consume and take benefit from it. In Phytoformulation research, various drug delivery vehicles, such as liposomes, polymeric nanoparticles, microemulsion, microspheres, solid lipid nanoparticles (SLNs), are used in which phytoconstituent is solubilized and release the drug in a sustained manner.[17-22]

Figure 2: Types Of Drug Delivery Systems.[23]

Carrier based Drug Delivery System

A) Liposomes

B) Nanoparticles

C) Microspheres

D) Monoclonal antibodies

E) Niosomes

F) Resealed erythrocytes as drug carriers12

G. Emuslions

H. Ethosomes

I. Solid lipid nano particle

J. proniosomes

K, Transdermal drug delivery system

L. Dentimers

M. Liquid crystals

N. Hydrogels[24]

Novel Nano-Drug Delivery System (NDDS) refers to a novel approach in the pharmaceutical field, harnessing the potential of nanotechnology for drug delivery. Depending on the carrier materials and structures used, NDDS fall into distinct categories, including nanosuspensions, nanoliposomes, micelle, microemulsions/self-microemulsions, nanocapsules, and solid lipid nanoparticles. These NDDS, typically ranging from 1 to 100 nanometers in size, effectively address conventional limitations such as poor solubility and instability, thereby improving the stability, solubility, and absorption of natural products.[25] Furthermore, NDDS enables precise delivery of natural products to specific sites in vivo, enhancing their therapeutic efficacy while minimizing side effects.[26] Additionally, co-encapsulating different natural products provides synergistic therapeutic effects, where the combined action is greater than the sum of individual effects.[27] For patients, higher delivery efficiency reduces the dosages and the frequency of administration, contributing to better medication adherence, and making treatment more convenient and effective.[28]

Advantages of novel drug delivery system

- Protection from toxicity.
- Enhancement of pharmacological activity.
- Enhancement of stability.
- Improving tissue macrophages distribution.
- Sustained delivery.
- Protection from physical and chemical degradation.
- Reduce side effect.
- Rapid onset of action.
- Increased bioavailability.[29,30]
- Make medication more user- friendly
- Improved results
- Reduced side effects
- Avoidance of costly health care services
- Tweaking the duration of action of drugs
- Decrease in dosing frequency
- We can decide where the drug would be released
- Constant drug levels maintenance
- Reducing the number of emergency visits
- Direct delivery of drugs to Central Nerves System

- Good penetration
- Enhancement of solubility[31]

Disadvantages of novel drug delivery systems

- The immune reactions can be occurred against intravenous administered carrier systems
- Requires highly sophisticated technology for the formulation of NDDS drugs
- Requires skilled man power for manufacturing, storage and administration
- Difficult to maintain stability of dosage forms
- Drug loading can be slow
- Dose dumping can occure.[32]
- High research and development costs
- Regulatory approval for novel drug delivery systems can be more challenging due to the need for comprehensive safety and efficacy assessments.
- Some novel materials used in drug delivery systems may raise concerns about biocompatibility and long-term safety.
- Some advanced drug delivery technologies may not be easily accessible in resource-limited or developing regions.
- Certain novel drug delivery systems may involve the use of materials that pose environmental challenges, especially if they are not biodegradable.
- Disposal of devices or carriers may contribute to environmental pollution.[31]

Approaches of novel drug delivery systems

Novel systems represent advanced approaches that focus on overcoming the limitations of conventional methods. They employ technologies like nanocarriers, controlled-release formulations, and transdermal patches to ensure targeted delivery, sustained release, and reduced side effects.[33]

1. Controlled Drug Delivery Systems/ Sustained release drug delivery system

This is the drug delivery system in which a constant level of a drug is maintained in blood and tissue for an extended period. The controlled delivery system, shows zero-order PK with just a single dose of controlled drug delivery from a specific formulation or device. The drug levels are maintained constantly within the therapeutic window.[34]

Sustained release tablets are generally taken once or twice a day during a course of treatment whereas in conventional dosage forms there is need to take 3-4 times dosage in a day to achieve the same therapeutics action. The key role behind administering a single dose of a drug is sustained release dosage forms is that it can be released over an extended period of time to maintain uniform concentration of a drug in a blood this may lead to better patient compliance and provide enhanced clinical output of the drug.[35]

eg., Covera-HS® (verapamil), a controlled release system for the management of hypertension and angina pectoris;[36,37]

2. Delayed release drug delivery system

Delayed-release formulations continue to be a highly relevant formulation approach. Traditionally, the main focuses have been to protect acid-sensitive drugs against gastric fluid and to safeguard gastric mucosa against aggressive actives. In the future, however, targeted drug delivery will be the major motivator for formulating drugs with delayed-release characteristics.

The potential of delayed-release formulations to improve therapeutic effects is reflected in the number of market authorisations in this area, as listed by the US FDA. Although immediate-release (IR) dosage forms strongly dominate the pharmaceutical market, manufacturers increasingly select modified-release approaches to improve their products. New modified-release products, either as extended or delayed release, can lead to better patient compliance or to improved treatment of diseases with specific therapeutic needs.

“New modified-release products, either as extended or delayed release, can lead to better patient compliance or to improved treatment of diseases with specific therapeutic needs…”

e.g., rheumatic arthritis (RA) is associated with high cytokines levels, especially in the early morning.1 Patients with RA can be treated with the glucocorticoid prednisone. This therapy is highly efficient if the drug plasma concentration matches the circadian rhythm of RA patients.[38,39]

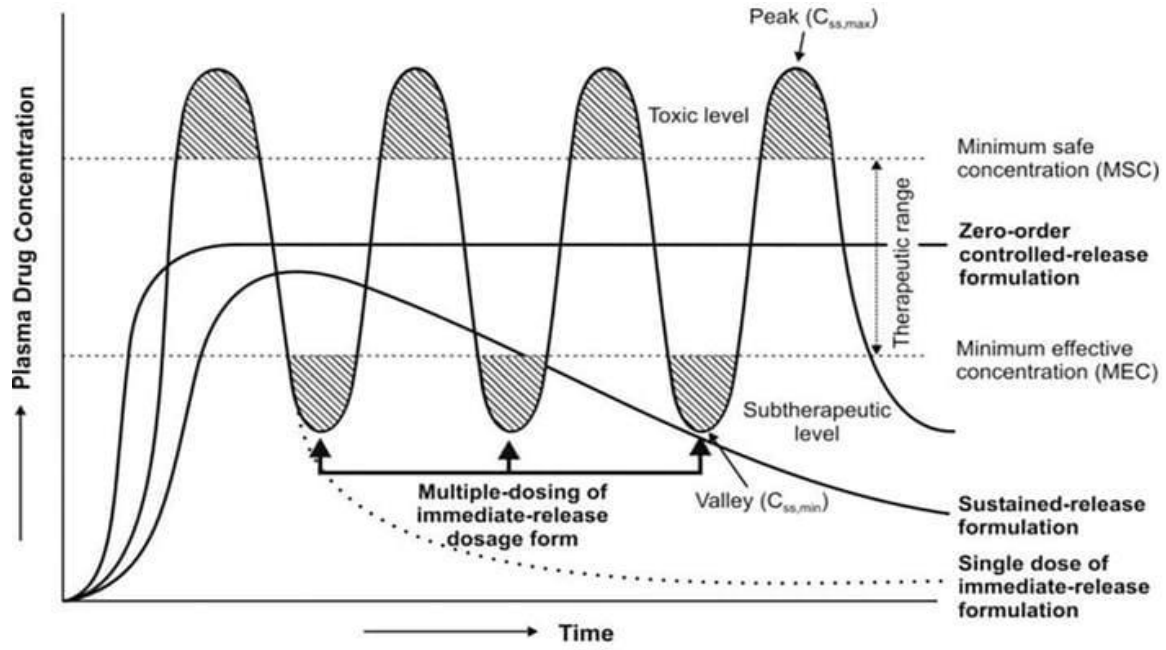

Figure 3: A hypothetical plasma concentration-time profile from conventional multiple dosing and an ideal controlled delivery formulation.[40]

3. Target drug delivery system

The targeted drug delivery system is the system of delivering a drug into the body which is characterised by the transportation of a particular drug selectively at a specified diseased site, to bring pharmacological effects to that particular site and minimize adverse effects on the whole body.[41] As discussed, a conjugating drug with a biologically compatible polymer would increase the ease of delivery of the drug by increasing the solubility, minimizing the toxic effects of the drug, and optimizing the duration of the drug effect.[42]

A main component of targeted drug delivery systems is the 'targeting fraction', which can specifically bind with certain moieties or receptors at the target site. Moreover, targeted drug delivery can achieve the goal of personalized therapy due to its low drug dosage, high efficacy, and few side effects.[43]

e.g., Applied dual-targeting for delivery of paclitaxel and curcumin for management of brain tumors.[44]

Applications of Novel Drug Delivery Systems (NDDS)

Here are many technological challenges to be met, in developing the following techniques:

a) Nano-drug delivery systems that deliver large but highly localized quantities of drugs to specific areas to be released in controlled ways;

b) Controllable release profiles, especially for sensitive drugs;

c) Materials for nanoparticles that are biocompatible and biodegradable;

d) Architectures / structures, such as biomimetic polymers, nanotubes;

e) Technologies for self-assembly;

f) Functions (active drug targeting, on-command delivery, intelligent drug release devices/ bioresponsive triggered systems, self-regulated delivery systems, systems interacting with the body, smart delivery);

g) Virus-like systems for intracellular delivery;

h) Nanoparticles to improve devices such as implantable devices/nanochips for nanoparticle release, or multi reservoir drug delivery-chips;

i) Nanoparticles for tissue engineering; e.g. for the delivery of cytokines to control cellular growth and differentiation, and stimulate regeneration; or for coating implants with -- nanoparticles in biodegradable polymer layers for sustained release;

j) Advanced polymeric carriers for the delivery of therapeutic peptide/proteins (biopharmaceutics), And also in the development of:

k) Combined therapy and medical imaging, for example, nanoparticles for diagnosis and manipulation during surgery (e.g. thermotherapy with magnetic particles);

l) Universal formulation schemes that can be used as intravenous, intramuscular or peroral drugs

m) Cell and gene targeting systems.

n) User-friendly lab-on-a-chip devices for point-of- care and disease prevention and control at home.

o) Devices for detecting changes in magnetic or physical properties after specific binding of ligands on paramagnetic nanoparticles that can correlate with the amount of ligand. -Better disease markers in terms of sensitivity and specificity.[45]

- More interesting applications, like imaging of single cells or tumors, delivery of drugs or genes, local heating and separation of peptides, signalling molecules or organelles from a single living cell or from a living (human) body are still subjects of intensive research. superparamagnetic nanoparticles during the last decades lead to a broad field of novel applications for superparamagnetic nanoparticles.[46]

- One of the earliest nanomedicine applications was the use of nanocrystalline silver which is as an antimicrobial agent for the treatment of wounds,[47]

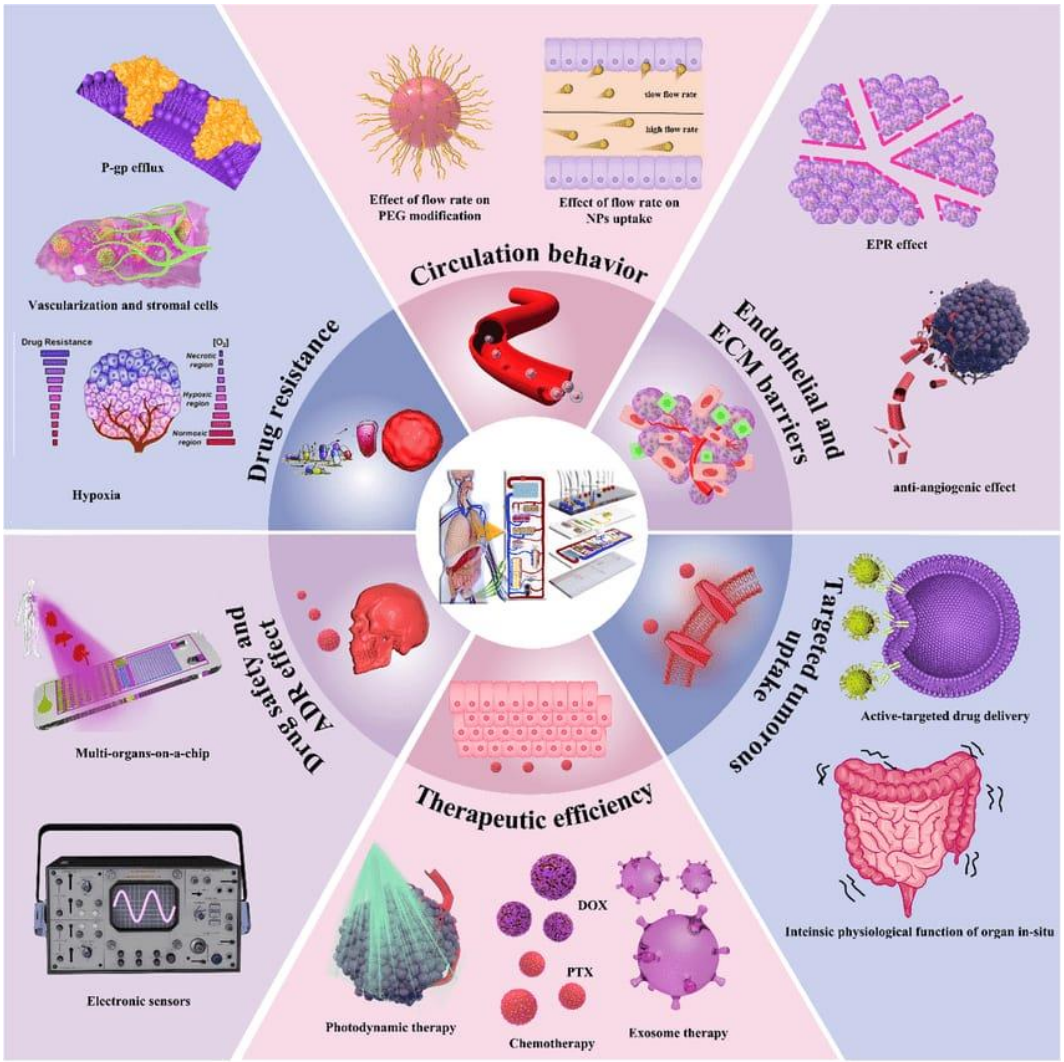

Figure 4: Application of TOC platforms in every important step of the NDDS delivery, including circulation behavior after infusion, endothelial and ECM barriers, tumorous uptake, therapeutic efficiency as well as evaluation of drug safety and resistance. Every step can be influenced by varied aspects.[48]

- Nanotechnology truly has the potential to be humanity's savior in the struggle against such a terrible disease, as well as the future of medical sciences.[49]

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