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Review Article

A Brief Review on Nanoparticulate Drug Delivery Systems for Bioavailability Enhancement of Drugs

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ABSTRACT

Nanomedicine and nano delivery systems are a relatively new but rapidly developing science where materials in the nanoscale range are employed to serve as means of diagnostic tools or to deliver therapeutic agents to specifc targeted sites in a controlled manner. The present review highlights the importance and superiority of unique nanoparticulate formulations which tends to ehance bioavailability. All the important literature along with online sources were searched and analysed. So, to achieve the desired therapeutic objective, the drug product must deliver the active drug at an optimal rate and amount. By proper biopharmaceutic design, the rate and extent of drug absorption (also called as bioavailability) or the systemic delivery of drugs to the body can be varied from rapid and complete absorption to slow and sustained absorption depending upon the desired therapeutic objective. . Due to numerous drawbacks of conventional DDSs, nanocarriers have gained immense interest. Nanocarriers like polymeric nanoparticles, mesoporous nanoparticles, nanomaterials, carbon nanotubes, dendrimers, liposomes, metallic nanoparticles, nanomedicine, and engineered nanomaterials are used as carriage systems for targeted delivery at specific sites of affected areas in the body, which also enhances bioavailability of drugs.

INTRODUCTION

Most of the drugs which are recently discovered are hydrophobic, and they show low bioavailability when administered through oral route.[1] Also, the newly discovered drugs are not suitable for oral delivery[2] because the new chemical entities discovered are having high molecular weight and increasing lipophilicity.[3-6]

Recently, advances in pharmaceutical research is focused on new delivery systems utilizing new devices to achieve modification of delivery time, targeting, as well as improve the in vivo solubility

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and hence bioavailability of poorly soluble drugs. Nanoparticulate drug delivery systems consists of diverse group of formulations, each consisting of varying functional and structural properties that are amenable to modifications achieved by varying the composition of lipid excipients and other additives. Nanoparticulate drug delivery systems has evolved, overtime to nano-scale enhancing the efficacy and therapeutic application of these systems.[7]

The novel carriers should ideally fulfill two prerequisites. Firstly, it should deliver the drug at a rate directed by the needs of the body, over the period of treatment. Secondly, it should channel the active drug to the site of action. Conventional dosage forms including prolonged-release dosage forms are unable to meet none of these. Hence there is a strong need to develop the novel drug delivery systems for the effective pharmacotherapy.[8] Development of drug delivery novel systems has proven their importance in case of drugs of synthetic origin. Similarly, they can play a crucial role in enhancing bioavailability, stability and effectiveness at large in the field of phyto-formulation research. Nanoparticulate based drug delivery systems such as polymeric nanoparticles and nanocapsules, liposomes, solid lipid nanoparticles, phytosomes and nanoemulsion etc. offer a number of advantages including enhancement of bioavailability though solubility improvement and thus better pharmacological activity, enhancement of stability, improving tissue macrophages distribution, sustained delivery, protection from physical and chemical degradation etc.[9-10]

Nanoparticulate drug delivery systems with biodegradable and essentially non-toxic vehicles, can encapsulate both hydrophilic and hydrophobic materials and which offer the potential to enhance the therapeutic index of anti-cancer agents, either by increasing the drug concentration in tumor cells and/or by decreasing the exposure in normal tissues exploiting enhanced permeability and retention effect phenomenon and by utilizing targeting strategies. There are many approaches for enhancing bioavailability of the drugs facing poor permeability.[11-13]

Nanotechnology is a combination of manufacturing science which is advanced and engineering where nanometer scaled material is being used. There is an advantage of more surface to volume ratio for a nanosized particles compared to bulk material. Nanoparticles also proved to have wide applications in various fields like agriculture to medicine.

Nano-sized inorganic particles of either simple or complex nature, display unique, physical and chemical properties and represent an increasingly important material in the development of novel nanodevices which can be used in numerous physical, biological, biomedical and pharmaceutical applications.[14-16]

Nanoparticulate drug delivery system

A nano-targeted preparation, also known as a targeted nanodrug delivery system, refers to a drug delivery system that concentrates explicitly a drug on a specific tissue or organ by using a particular drug carrier or drug delivery technique. It has the characteristics of specificity, targeting, long duration of drug action, small side effects, and wide drug loading range. It also provides some benefits over conventional preparations, including increasing the solubility of hydrophobic drugs, enhancing the stability of the drug in vivo, and improving its epithelial permeability. Compared with traditional preparations, the most prominent characteristic of targeted preparations is that drugs can be delivered to the target site to the maximum extent, the bioavailability of drugs can be

improved, and the therapeutic effect can be maximized. In the continuous development of nanotechnology, the targeted preparations of nanoparticles, liposomes, polymer micelles, dendrimers and microspheres have become more and more prominent in cancer treatment. It has received extensive attention and research.[17]

Necessity for nanoparticle-based drug formulations

There are various reasons why using nanoparticles for therapeutic and diagnostic agents, as well as advancement of drug delivery, is important and much needed. One of them is that, traditional drugs available now for oral or injectable administration are not always manufactured as the optimal formulation for each product. Products containing proteins or nucleic acids require a more innovative type of carrier system to enhance their efficacy and protect them from unwanted degradation. It is notable that the efficiency of most drug delivery systems is directly related to particle size (excluding intravenous and solution). Due to their small size and large surface area, drug nanoparticles show increase solubility and thus enhanced bioavailability, additional ability to cross the blood brain barrier (BBB), enter the pulmonary system and be absorbed through the tight junctions of endothelial cells of the skin. Specifically, nanoparticles made from natural and synthetic polymers (biodegradable and nonbiodegradable) have received more attention because they can be customized for targeted delivery of drugs, improve bioavailability, and provide a controlled release of medication from a single dose; through adaptation the system can prevent endogenous enzymes from degrading the drug. Secondly, the development of new drug delivery systems is providing another advantage for pharmaceutical sales to branch out. Innovative drug delivery is driving the pharmaceutical companies to develop new formulations of existing drugs. While these new formulations will be beneficial to the patients, it will also create a powerful market force, driving the development of even more effective delivery methods. The benefit of pharmaceutical companies taking advantage of this new technology is that nanotechnology gives new life to those drugs those were previously considered unmarketable due to low solubility and bioavailability, and high toxicity and marked side effects.[18-20]

Different types of Nanoparticles:

Liposomes:

Liposomes are the first ones to be investigated as drug carriers. Liposomes are of 80 to 300 nm size. They are spherical vesicles contained of phospholipids and steroids. Liposomes are proven to have increased the solubility of drugs and also improve pharmacokinetic properties like therapeutic index of chemotherapeutic agents, rapid metabolism, lower side effects and also increased in vivo and in vitro anticancer activity[21]. For liposomes with size greater than 100 nm, as the size increases clearance rate by mononuclear phagocytic system increased. Liposomes that are multifunctional and containing specific antigens, proteins, biological substances could be used to design drugs that act at specific tissue. For targeted drug delivery therapy, it is most promising type of drug delivery.

Encapsulation process is used to incorporate drug into liposomes. pH, composition of liposome, osmotic gradient, and environmental conditions regulate the release of drug from liposomes. Lipid transfer, fusion, adsorption realize the interaction of liposomes with cells. Anticancer drugs[21], antibiotics, anti-inflammatory and anti-rheumatic drugs are the drugs with liposomal formulations. Even with long history of investigation liposomes

haven't made a significant impact yet. They are being extensively used in cosmetic products.

Polymeric nanoparticles:

Nanoparticle structures with diameter ranging from 10 to 100 nm are polymeric nanomaterials. Synthetic polymers like poly e-caprolactone, polyacrylamide, or natural polymers like Chitosan, gelatin are used to obtain Polymeric nanoparticles. Polymeric nanoparticles are further classified as biodegradable and nonbiodegradable. In order to lower immunological and intramolecular reactions between surface chemical groups polymeric nanoparticles are usually coated with nonionic surfactants.[22-24]

Food and drug administration of US has approved biodegradable polymeric nanoparticles like PLA and PLGA. They are formulated in a way that they are able to encapsulate several low molecular weight compounds. Polymeric nanoparticles are more useful in regard to biocompatibility and biodegradation profiles, when chronic dosing is needed in formulations. One downside of polymeric nanoparticles is that large scale manufacturing and production is an issue. By using a double emulsion solvent evaporation system using oil and water with vinyl alcohol PLGA nanoparticles are formulated as an emulsifier. [25, 26]

Solid Lipid Nanoparticles:

Solid lipid nanoparticles are first designed in 1990s and are utilized as an alternative for emulsions and liposomes. In biological systems Solid Lipid nanoparticles are more stable than liposomes because of their rigid core that consists of hydrophobic lipids which are solid at room temperature. By including high level of surfactants these aggregates are further stabilized. Solid lipid nanoparticles are less toxic as they are biodegradable. They can be designed with 3 types of hydrophobic designs, and they have pharmacokinetic parameters which can be controllable. These three designs are a drug enriched shell, a drug enriched core and a homogenous matrix. SLNPs could be used to deliver drugs by inhaling, topically and orally. Particles of SLN are made of solid lipids that are like highly purified triglycerides, complex glyceride mixtures or waxes stabilized by various surfactants[27]. Nanostructured lipid carriers and Lipid drug conjugates are modifications of lipid based nanoparticles that have been developed to overcome limitations of conventional SLN. By combining liquid lipids with solid lipids nanostructured lipid carriers are formed and as a result special nanostructured lipids are formed for which payload and prevented drug expulsion have increased. There are 3 types of NLCs, imperfect type, multiple type, and amorphous type NLCs.

Dendrimer nanocarriers:

Dendrimer nanoparticles are unique polymers which has well defined structure and size. Some of the dendrimer nanocarriers are glycogen, amylopectin etc., Dendrimer can do multiple jobs like solubility enhancement, drug targeting. Dendrimers can be used using different routes of drug delivery oral, parenteral, nasal and intra ocular. Dendrimers can also behave like vectors in gene therapy. These 3D tree like branched molecules contain some good characteristics like narrow molecular weight distribution, and 3D structure tuned by dendrimer generation and dendron structure, and flexibility for tailored functional groups with high density on the periphery.

Carbon nanotubes:

Carbon nanotubes are first discovered in 1991.Multi walled nanotubes are prepared by

pyrolysis of metallocene's like ferrocene, cobaltocene, and nickelocene under reducing conditions. Single-walled carbon nanotubes (SWNT) were prepared in a related approach using dilute hydrocarbon–organometallic mixtures. Interestingly, pyrolysis of nickelocene in the presence of benzene at 1100 "C yields primarily MWNT. In contrast, pyrolysis of nickelocene in the presence of acetylene yields primarily SWNT, presumably due to the smaller number of carbon atoms per molecule.[28]

Silica nanoparticles: Sol-gel methods are used to prepare silica nanoparticles. Researcher had demonstrated an efficient co condensation process to monodisperse silica nanoparticles. Apart from this several other methods are described and proved to prepare silica nanoparticles like organic aqueous biphasic system described by Tan group. MCM-41 is a mesoporous silica nanoparticle, which is usually synthesized using sol-gel processes with the presence of surfactant like C12-trimethylammonium bromide versus C16-trimethylammonium bromide, to control pore sizes.[29]

Characteristics of Nanoparticles, and their effects on Drug Delivery:

Particle size: Particle size is an important factor in deciding nanoparticle characteristics. They decide toxicity, fate biologically and ability of targeting in nanoparticle systems. Along with that they could also affect drug loading, release rate of drug and stability of nanoparticles. Many research studies have proved that nanoparticles of sub micron sized have more uses than microparticles[30.] Intracellular uptake is more in nanoparticles than microparticles and is available to wide range of targets as they are relatively smaller in size and more mobile. It was found in the research that nanoparticles of 100nm had an uptake which is 2.5 times greater than 1µm microparticles. And the uptake is 6 times greater than 10µm microparticles. In another study it was proved that nanoparticles penetrated through submucosal layers in rate in situ intestinal loop model, while microparticles are local to epithelial lining.[31] Nanoparticles that are tween 80 coated have crossed the blood brain barrier. Compared to microparticles some cell line submicron nano particles can be consumed efficiently.

Particle size will have affect on drug delivery. Particles of small size will have large surface area, and major part of the drug associated would be at or near the particle surface, which leads to fast drug release. On the other hand, particles of large size will have large cores which allow drug to be encapsulated and leads to slow diffusion of drug.[32] During the nanoparticle dispersion, transportation and storage smaller particles have greater risk of aggregation. It is difficult to formulate nanoparticles in small size but with good stability. The most commonly used routine method used to determine particle size is photon correlation spectroscopy or dynamic scattering. Viscosity of the medium is necessary to be known in order to determine the diameter of particle.

Surface properties of nanoparticles: Nanoparticles are determined easily by immune system of body when they are administered and are cleared by phagocytes for the circulation. The amounts of proteins adsorbed are determined by size of nanoparticles and their surface hydrophobicity, and in vivo fate of nanoparticles is influenced by this.[33] The process of binding opsonin to nanoparticles surface is called opsonization and it acts as bridge between phagocytes and nanoparticles.

In order to increase the success rate of nanoparticle-based drug targeting, it is important to lower the opsonization and to extend the

nanoparticle circulation in vivo. This process can be achieved by:

- Nanoparticles surface coating using hydrophilic polymers and surfactants.
- Formulation of nanoparticles with biodegradable copolymers with PEG, poloxamer, poloxamine and polysorbate 80.

Drug Loading:

Drug loading capacity is one of the important factors of a successful nanoparticle drug delivery system. Drug loading capacity needs to be high, and that helps reduce the amount of matrix materials needed for administration. Drug loading can be achieved by two methods:

- One method is incorporation method in which drug is incorporated at the time of nanoparticle production
- Drug absorption after nanoparticles are formed by incubating the carrier with a concentrated drug solution, which is called absorption technique.

Drug loading and entrapment efficiency depend on solid state drug solubility in polymer which in turn relates to the drug polymer interactions and molecular weight.

Drug Release:

Drug release is an important factor for a successful nanoparticulate drug delivery system. Usually drug release depends on two factors

- Solubility of drug
- Desorption of the surface drug
- Diffusion of drug through nanoparticle matrix
- Combination of erosion/ diffusion process

When it comes to nanospheres drug will be uniformly distributed and the release happens by erosion of the matrix under sink conditions. If the matrix erosion is slower than drug diffusion, release mechanism is controlled by a diffusion process.

Nanoparticulate Drug delivery system applications:

Recently several articles have been published both research and review on nano vehicular intracellular drug delivery systems. This article includes several aspects of nanodrug delivery systems and their use in biological systems at cellular levels. Various nano systems and their applications has been reviewed. Nanoparticles based drug delivery systems and their treatment towards chronic pulmonary disease has been explained in[34]. With all these research studies it was proved that nanoparticulate drug delivery systems show a promising approach to achieve desired drug delivery properties by modifying pharmacokinetic properties. To overcome diseases that are cause through genes, it is good to combat the root cause rather than treating the disease, and gene therapy for it is a promising strategy.[35]

Liposomes offer good option for delivering chemotherapeutic agents. In addition to that micelles are also great to make insoluble drugs soluble as they have hydrophobic core. Several different forms of nanoparticles have shown good progress in treating cancer, and one of them was carbon nanotubes. It is carbon in allotropic form with framework in cylindrical framework. They are classified into single walled carbon nanotubes and multiwalled depending on the number of sheets in concentric cylinders. Drug can be loaded easily into carbon nanotubes as they have hollow interiors. Use of nanoparticles in diagnostic testing

has been explored widely in the recent years, as the current technology that has been use for this is hindered by inadequacies of fluorescent markers like fluorescence fading after single use, dyes and restricted usage. Nanoparticles provide good use to overcome these problems. Recently theranostic nanoparticles have gained lot of attention for diagnostic reasons. The primary reasons of stokes are vascular diseases like atherosclerosis and hypertension. For the diagnosis and detection nanoparticles have been used for atherosclerotic plaques. Same kind of targeting strategies are used to deliver therapeutic agents to this plaque. Identifying the disease at early stages and intervening it may prevent the worst outcomes that may lead to plaque rupture and thrombosis. [36-40]

CONCLUSION AND FUTURE PROSPECTS

As the many drugsespecially from BCS class-II undoubtedly have the issues with the less bioavailability, due to their poor lipid solubility or improper molecular size or many such reasons, which limits the absorption as well as oral bioavailability. So such formulations are challenging task for formulation scientist to enhance oral bioavailability. Nanoparticulte drug delivery system is considered as the most promising and novel technology to enhance drug bioavailability by using various polymers in the formulation. This review is focused on different formulation aspects of such formulations. Although the nanoparticulte drug delivery system is the most accepted technique for bioavailability enhancement there are few limitations regarding stability, manufacturing methods, and official database regarding the solubility of drugs in lipids. Further research work promptly has to be carried out to correlate between in-vitro and in-vivo studies. The present review summarized that the nanoparticulate drug delivery system definitely improves the absorption and ultimately bioavailability of the drugs and which would be enormously helpful for the advancement of sophisticated technology to obtain safe and efficacious formulations.

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