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Review Paper

Microspheres As Targeted Drug Delivery Systems: A Review

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ABSTRACT

Microspheres have emerged as a versatile and effective platform for targeted drug delivery, offering improved therapeutic efficacy and reduced systemic side effects. Typically ranging from 1 to 1000 µm in size, microspheres are composed of biodegradable or non-biodegradable polymers that enable controlled and sustained drug release. Their surface can be engineered to achieve site-specific targeting through ligand–receptor interactions, magnetic guidance, or pH- and enzyme-responsive mechanisms. Microsphere-based delivery systems have been extensively investigated for applications in cancer therapy, vaccines, gene delivery, and treatment of chronic diseases. Advantages such as enhanced drug stability, protection of labile drugs, improved bioavailability, and the ability to modulate release kinetics make microspheres superior to conventional dosage forms. Various preparation techniques, including solvent evaporation, spray drying, and emulsion polymerization, influence particle size, encapsulation efficiency, and release behavior. Despite their promising potential, challenges related to large-scale production, reproducibility, and regulatory approval remain. This review highlights the types of microspheres, materials used, drug loading and targeting strategies, therapeutic applications, and current challenges, providing an overview of recent advances and future prospects in microsphere-based targeted drug delivery systems.

INTRODUCTION

Microspheres can be characterized as solid, approximately spherical particles with a diameter having between 1–1000µm, including dispersed drugs in certain solution or microcrystalline shape. Both the terms microcapsules and microspheres are often used as synonyms.[1] Micromatrices are those in which the entrapped substance is dispersed within the microsphere's matrix and microcapsules are those in which the entrapped substance is clearly enclosed by the distinct

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capsule wall. Micromatrices are those in which the trapped material is dispersed within the microsphere matrix, and microcapsules are those in which the trapped substance is clearly enclosed by a discrete capsule wall. The solid biodegradable microspheres incorporated the drug dispersed or dissolved through the particle- matrix, and they have the potential to allow for regulated drug release. They are biodegradable, spherical, free flowing particles made up of proteins or synthetic polymers.[2]

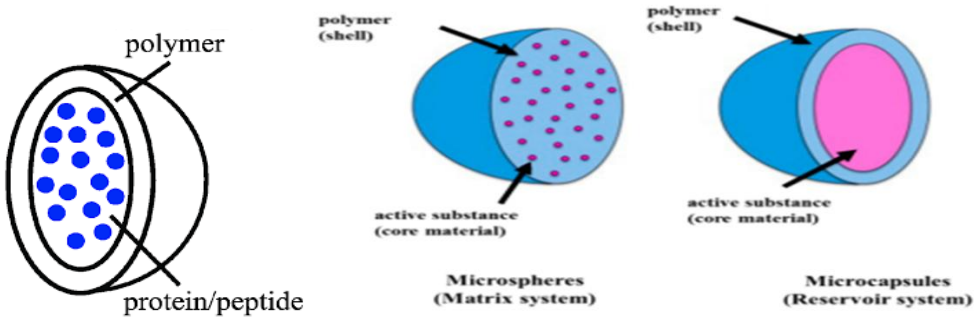
There are two types of microspheres;

- Microcapsules
- Micromatrices

Microcapsules have a distinct capsule wall around the entrapped material, while micromatrices have the entrapped substance dispersed within the microsphere's matrix. Controlled release of a drug can be accomplished by using solid biodegradable microspheres with a drug dispersed or dissolved via a particle matrix. They are made of biodegradable synthetic polymers and modified natural products, as well as polymeric, waxy, or other protective materials.[3]

Microspheres for oral use have been employed to sustain the drug release, gastrointestinal and tract to reduce or eliminate irritation. In addition, multiparticulate delivery systems spread out more uniformly in the gastrointestinal tract. This results in more reproducible drug absorption and reduces local irritation when compared to single-unit dosage forms such as no disintegrating, polymeric matrix tablets. Unwanted intestinal retention of the polymeric material, which may occur with matrix tablets on chronic dosing, can also be avoided.[4]

Microparticles used in skin applications required to benefit the release of the medication into the skin ensure that now the drug remains localized at the application site and does not enter the systemic circulation unnecessarily.[5]



ADVANTAGES OF MICROSPHERES[6]:

- Microspheres have a consistent and long-lasting therapeutic impact.
- Reduces the frequency of dosing and thereby improves patient compliance.
- Along with their spherical form and smaller size, they may be inserted into the body.
- Improved drug utilization will improve bioavailability while lowering the risk of side effects.
- The morphology of microspheres allows for controlled variability in drug release and degradation.
- Oils and other liquids are converted to solids to make them easier to handle.

DISADVANTAGES OF MICROSPHERES[7]:

- The modified release from the formulations.
- The release rate of the controlled release dosage form may vary from a variety of factors like food and the rate of transit though gut.
- Differences in the release rate from one dose to another.
- Controlled release formulations generally contain a higher drug load and thus any loss

of integrity of the release characteristics of the dosage form may lead to potential toxicity.

- Dosage forms of this kind should not be crushed or chewed.

CHARACTERISTICS[8]:

1. Microsphere size may be critical to the proper function of an assay, or it may be secondary to other characteristics. Considering traditional diagnostic methods, the test or assay format commonly dictates particle size, such as the use of very small spheres (~0.1- 0.4µm) to ensure satisfactory wicking in lateral flow tests, or the use of larger, cell-sized spheres (~4-10µm) for bead-based flow cytometric assays.
2. Common microsphere compositions include polystyrene (PS), poly(methyl methacrylate) (PMMA), and silica. These materials possess different physical and optical properties, which may present advantages or limitations for different applications. Polymer beads are generally hydrophobic, and as such, have high protein binding abilities. However, they often require the use of some surfactant (e.g. 0.01-0.1% Tween® 20 or SDS) in the storage buffer to ensure ease of handling. During synthesis, functional monomers may be co-polymerized with styrene or methyl methacrylate to develop beads with surface reactive groups. Functional groups may be used in covalent binding reactions, and also aid in stabilizing the suspension. Silica microspheres are inherently hydrophilic charged. Consequently, and negatively aqueous silica suspensions rarely require use of surfactants or other stabilizers. Carboxyl- and amine functionalized silica spheres are available for use in common covalent coating protocols, and plain silica microspheres may be modified using a variety of silanes to generate functional groups or alter surface properties.
3. Microspheres may be coated with capture molecules, such as antibodies, oligonucleotides, peptides, etc. for use in diagnostic or separation applications. Microsphere coatings are typically optimized to achieve desired specific activity, while minimizing nonspecific interactions. Consideration should also be given to the required stability, development time frame and budget, and the specific biomolecule to be coated. These factors will aid in determining the most fitting coating strategy for both short- and long-term objectives. Standard microsphere products support three basic coating strategies: adsorption, coupling, and affinity binding.
4. Many applications in the life sciences demand added properties, such as fluorescence or a visible color, or iron oxide inclusions for magnetic separations. Polymer spheres (and polymer based magnetic spheres) are often internally dyed via organic solvent swelling, and many standard products are available. Dye concentrations can be adjusted to produce beads with different intensities to meet special needs, such as QuantumPlex™ for multiplexed flow cytometric assays, or our Dragon Green or Flash Red Intensity Standards, which support imaging applications and associated instrument QC. Many surface- or internally labeled fluorescent beads are also available as specialized flow cytometry standards.

Sl. No.	Property	Consideration
1	Size diameter	Uniformity/distribution
2	Composition	Density, refractive index, hydrophobicity/hydrophilicity Non specific binding Autofluorescence

3	Surface chemistry	Reactive groups Level of functionalization Charge
4	Special properties	Visible dye/fluorophore Superparamagnetic

CLASSIFICATION OF POLYMER:

Synthetic polymers:

- Non-biodegradable: Acrolein, Glycidyl methacrylate, Epoxy polymers, etc.[9]
- Biodegradable: Polyanhydrides, Polyalkylcyano- acryalates Lactides glycosides, and their copolymers.[10,11]

Natural materials: They are obtained from different sources like[12,13]

- Proteins (albumin, gelatin, collagen)
- Carbohydrate (starch, agarose, carrageenan)
- Chemically modified carbohydrates [poly (acryl dextran), Poly (acryl starch)]

TYPES OF MICROSPHERES:

Bioadhesive microspheres [14]:

Adhesion is the process of attaching a drug to a membrane by using the adhesive properties of water-soluble polymers. Bio adhesion is described as the adhesion of a drug delivery system to a mucosal membrane such as the buccal, ocular, rectal, nasal, and other mucosal membranes. These microspheres have a longer residence period at the application site, resulting in close interaction with the absorption site and improved therapeutic action.

Magnetic microspheres [15]:

This kind of delivery system is very much important which localizes the drug to the disease site. In this larger amount of freely circulating drug can be replaced by smaller amount of magnetically targeted drug. Magnetic carriers receive magnetic responses to a magnetic field from incorporated materials that are used for magnetic microspheres are chitosan, dextran etc. The different types are therapeutic magnetic microspheres and diagnostic microsphere:

i. Therapeutic Magnetic Microspheres: It is used to deliver chemotherapeutic agent to liver tumor. Drugs like proteins and peptides can also be targeted through this system.

ii. Diagnostic Microspheres: It can be used for imaging liver metastases and also can be used to distinguish bowel loops from other abdominal structures by forming nano size particles supramagnetic iron oxides.

Radioactive microspheres [16,17]:

Therapy with Radioembolization Microspheres 10-30 nm in size are larger than capillary microspheres and are tapped in the first capillary bed as they pass through, they are inserted into the arteries that cause a tumor of interest. Thus, under all these cases, radioactive microspheres provide a high dose of radiation to the target areas without affecting normal surrounding tissues. It differs from the drug delivery system, as radioactivity is not released from microspheres but acts from within a radioisotope typical distance and the different kinds of radioactive microspheres are α emitters, β emitters, γ emitters.

Polymeric microspheres:

The different types of polymeric microspheres can be classified as:

Biodegradable polymeric microspheres [18]:

Natural polymers like starch are used because they are biodegradable, biocompatible, and bioadhesive. Due to its excellent degree of swelling in an aqueous medium, biodegradable polymer extend the residence time when in contact with mucous membranes, resulting in the formation of gels. The concentration of polymer and the release pattern in a sustained manner regulate the rate and degree of drug release. The main disadvantage is that drug loading performance of biodegradable microspheres in

clinical use is complicated, making drug release difficult to manage. However, in microsphere-based therapy, they have a wide variety of applications.

Synthetic polymeric microspheres:

Synthetic polymeric microspheres are widely used in clinical applications, as well as bulking agents, fillers, embolic particles, drug delivery vehicles, and other applications, and have been shown to be safe and biocompatible.[19] However, the main downside of these microspheres is that they have a tendency to move away from the injection site, posing a risk of embolism and further organ damage.

MECHANISM OF MICROSPHERES [20]:

The majority of drug delivery via microparticles prevents the formation of a matrix-like internal solid dispersion morphology structure. The drug may be insoluble in the polymeric matrix, and it is released by erosion. First, water diffuses into the matrix, dissolving the resulting near the device's surface. The resulting osmotic pressure is alleviated by forming a channel to the surface and releasing a predetermined amount of drug in the initial drug burst.

METHOD OF PREPARATION:

Single emulsion technique [21]:

This method can be used to prepare a variety of proteins and carbohydrates. The natural polymers are first dissolved in an aqueous medium, then dispersed in an oil phase, which is a non-aqueous medium. That is the initial phase in the process.

Two methods are used to cross-link the next step as:

- **Cross-linking by heat :**By adding the dispersion into heated oil, but it is unsuitable for the thermolabile drugs.
- **Chemical cross-linking agents:** By using agents i.e. Formaldehyde, diacid chloride, glutaraldehyde, etc. However, it is detrimental to the undue exposure of active ingredients to chemicals when applied at the time of preparation and then subjected to centrifugation, washing and separation. Chitosan solution (in acetic acid) by applying w/o emulsion to the liquid paraffin containing a surfactant. Microsphere is prepared using a 25 percent solution of glutaraldehyde as a cross-linking agent. [22]

Double emulsion technique [23,24]:

It is the creation of several emulsions, i.e. W/O/W is prepared by pouring the primary w/o emulsion into an aqueous polyvinyl alcohol solution. This w/o/w emulsion shall be put at constant stirring for 30 min. Slowly add some water to the emulsion for a duration of 30 min. Collection of microcapsules by filtration and dry under vacuum. It is ideally suited for water-soluble medicines, peptides, proteins and vaccines. Natural as well as synthetic polymers can be used for this process. The aqueous protein solution is distributed in a continuous organic lipophilic phase. This protein solution will contain active ingredients. Disperse in oil/organic phase homogenization/vigorous i.e. the formulation of the first emulsion then the addition of the aqueous solution of PVA (Poly Vinyl Alcohol) i.e. the multiple emulsion now produced by the addition of the broad aqueous phase denaturation/hardening after this separation, the washing, drying and collection of the microspheres is prepared using the o/w/o multiple emulsion process.

Phase separation coacervation technique [25,26]:

This method is based on the idea of decreasing the solubility of the polymer in the organic phase in order to influence the formation of a polymer-rich phase called coacervates. In this process, the drug particles are dispersed into a polymer solution and an incompatible polymer is added to the device,

which separates the first polymer phase and engulfs the drug particles. Adding the non-solvent results to the solidification of the polymer. This process has been used to prepare polylactic acid (PLA) microspheres by using butadiene as an incompatible polymer. Process variables are very significant as the rate of achievement of the coacervates determines the distribution of the polymer film. The size of the particles and the agglomeration of the formed particles. Agglomeration must be avoided by stirring the suspension using an appropriate speed stirrer, because as the process of microsphere forming starts, the formed polymerized globules begin to adhere and form agglomerates. Process variables are therefore important as they govern the kinetics of the formed particles, since there is no given state of equilibrium attainment.

Polymerization techniques [26]:

Two techniques are mainly used for the formulation of microspheres are as follow;

- **Normal polymerization:**

In bulk polymerization, a monomer or a mixture of a number of monomers along with the initiator or catalyst is usually heated to initiate polymerization. The polymer so obtained
may be molded as microspheres. Drug may be done by adding the drug during the process of polymerization. It is a pure polymer formation technique but it is very difficult to dissipate the heat of the reaction which affects the thermolabile the active ingredients.

Suspension polymerization is carried out at a lower temperature and also refer to as pearl polymerization in which heating the monomer mixture with the active drug as droplets
dispersion in the continuous aqueous phase.

- **Interfacial polymerization:**

The reaction of various monomers at the interface between the two immiscible liquid phases forms a film of polymer that essentially envelops the dispersed phase. In this
technique two reacting monomers are employed; one is dissolved in the continuous phase while the other is dispersed in continuous phase (aqueous in nature) throughout which the second monomer is emulsified.

Spray drying [27]:

The polymer is first dissolved in a suitable volatile organic solvent, such as dichloromethane or acetone, before being spray dried. Thereafter, the compound is dispersed in a polymer solution using high-speed homogenization. This dispersion is then atomized in a hot air current. The atomization results in the formation of tiny droplets or fine mist from which the solvent evaporates instantaneously leading to the formation of microspheres in the 1-100µm range. Microparticles are separated from hot air using a cyclone separator, and the solvent residue is removed using vacuum drying. One of the main benefits of the procedure is the viability of action under aseptic conditions. This process is rapid, leading to the formation of porous microparticles.

Solvent evaporation [28]:

Solvent evaporation method is used for the preparation of microparticles, involves removal of the organic phase by extraction of the organic solvent. The method involves water miscible organic solvents such as isopropanol. Organic phase is removed by extraction with water. This process decreases the hardening time for then microspheres. One variation of the process involve direct addition of the drug or protein to polymer organic solution. The rate of solvent removal by extraction method depends on the temperature of water, ratio of emulsion volume to the water and the solubility profile of the polymer.

EVALUATION PARAMETERS OF MICROSPHERES:

Characterization:

The characterization of the microparticulate carrier is a significant phenomenon that aids in the development of a suitable carrier for the delivery of proteins, drugs, or antigens. The microstructures of these microspheres vary. The release and stability of the carrier are determined by these microstructures.[29]

Particle size and shape:

The most well-known used procedures to visualize microparticles are conventional light microscopy (LM) and scanning electron microscopy (SEM). Both can be used to analyze the shape and outer structure of microparticles. LM provides control over coating parameters in the case of double-walled microspheres. The microspheres structures can be seen before and after coating and the change can be measured microscopically. SEM provides a higher resolution in contrast to the LM. SEM enables the investigation of the surfaces of the microspheres, and when the particles are cross-sectioned, it can also be used for the investigation of double-walled structures.[29]

Electron spectroscopy for chemical analysis:

The surface chemistry of the microspheres can be determined using electron spectroscopy for chemical analysis (ESCA).[30]

Density determination:

The density of the microspheres can be calculated by using a multi-volume pycnometer.[31]

Isoelectric point:

Micro-electrophoresis is used to calculate the electrophoretic mobility of microspheres from which the isoelectric point can be calculated.[32]

Angle of contact:

The contact angle is determined to determine the wetting properties of the microparticle carrier.[33]

In vitro methods:

Release studies for a specific type of microsphere are executed using a different suitable dissolution medium, often by rotating paddle apparatus (USP/BP).[34]

Drug entrapment efficiency:

The entrapment efficiency of the microspheres or the percent entrapment can be determined by holding the microspheres in the buffer solution and allowing lysing. The lysate obtained is filtered or centrifuged and then subjected to monograph requirements for the determination of active constituents. Drug entrapment efficiency can be calculated using the following equation,

% Entrapment = Actual content / Theoretical content x 100 [35]

Percentage yield:

It is calculated as the weight of microspheres obtained from each batch divided by the total weight of drug and polymer used to prepare that batch multiplied by 100. [35]

Flow properties [35,36]:

Density:

- **Bulk density:** It is measured by pouring a sample of microspheres of known weight into a measuring cylinder without tapping and measuring its length, and then dividing the weight by the volume. Bulk density = wt. of microspheres/bulk volume
- **Tapped density:** It is determined by pouring a sample of microspheres of known weight into a measuring cylinder & thoroughly tapping it & measuring its volume, then dividing the weight by the volume. Tapped density = wt. of the microspheres/volume after tapping
- **Hausner's ratio:** Hausner's ratio is the ratio of the tapped density to the bulk density of microspheres & can be used to predict

microspheres flow. A Low Hausner's ratio of < 1.2 indicates a free-flowing microsphere. Hausner's ratio = bulk density – tapped density

- **Angle of repose:** It is defined as the maximum angle to the horizontal that is attainable by a heap of microspheres. The fixed height cone and the fixed base cone are among the methods available for calculating the angle of repose. Angle of Reposeθ= tan−1 h/r r = the radius of the base of the heap of microsphere ;h = height of the heap of microsphere

Zeta potential: The polyelectrolyte shell is set up by consolidating chitosan of various atomic load into the W2 stage and the subsequent particles are dictated by zeta potential estimation.[37]

Attenuated total reflectance Fourier Transform Infrared Spectroscopy:
FT-IR is used to determine the deterioration of the carrier device polymer matrix. The surface of the microspheres shall be examined by calculating the alternative cumulative reflectance (ATR). The ATR-FTIR shall include details on the surface composition of the microspheres, depending on the manufacturing processes and conditions.[38,39]

In-vitro release study:
Standard IP/BP/USP disintegration mechanical assembly is used to think about the in-vitro discharge profile in the disintegrating media which is the liquid present at the ingestion site according to the monograph, the use of a pivoting bin or an oar form disintegration contraption.

APPLICATIONS OF MICROSPHERES:

Oral drug delivery:
The oral route is an easy and convenient route for administration of the drug with higher patient compliance. There are large numbers of pharmaceutical products administered through the oral route. The principal behind oral absorption totally depends on the solubility and permeability of the drug. Microsphere drug delivery offers a sustained and controlled manner drug release for a longer period of time leads to reduce dosing frequency and improve patient compliance.[40]

Transdermal and topical drug delivery:
Polymers having good film-forming ability used for delivery of drug through the skin, for example, Chitosan, Alginate, and PLGA loaded microspheres are used as Transdermal Drug Delivery. It also used for delivering the drug for topical application, for example, Asiaticoside loaded microspheres for wound healing showing an acceleration in reepithelization as well as promoting the angiogenesis.[41]

Gene therapy:
In this technique, microspheres are fabricated with viral vectors in gene-drug delivery. This technique offers ease of preparation, site targeting, and large scale production and shows low immunogenic response as compared to the direct viral vector drug delivery.[42]

Intranasal drug delivery:
This route is mainly preferred for the delivery of proteins and the peptides. Conventional formulations are easily get drained off from nasal mucosa. Bioadhesive microspheres provide better bioavailability by exerting its sustained/controlled mechanism.[43]

Buccal drug delivery:
Mucoadhesive microspheres serve as a reservoir for the drug; it releases the drug from the applied site for a longer period of time. Mucoadhesive polymers reside on the mucosa of the buccal cavity and act as a reservoir; it also improves the bioavailability of the drug by avoiding first-pass metabolism in the body.[44]

Intra-tumoral and local drug delivery:

Anticancer drugs should be delivered at the tumor site inappropriate concentration, for example, paclitaxel loaded microspheres. Film forming polymers are used to sustain the release at local site, that is, oral cavity.[45]

Vaccine delivery:

The precondition of a vaccine is safety toward the microbes and its harmful component. An ideal vaccine should satisfy this same necessity of effectiveness, protection, affordability in application and charge. The aspect of protection and avoidance of severe effects is a complicated. The aspect of safeness and the extent of the manufacturing of antibody responses are intently linked to mode of application. Biodegradable delivery technology for vaccines which are provided by intravenous path may resolve the shortcoming of this same conventional vaccines. The involvement in parenteral (subcutaneous, intramuscular, intradermal)carrier exists even though those who offer significant benefits.[46]

Colonic drug delivery:

Microspheres are used for delivering the drug at a specific site in intestine, that is, colon. Insulin loaded into chitosan microspheres targeted to release its drug at colon**.** [47]

Vaginal drug delivery:

Microspheres drug delivery used for treating vaginal infections such as mycotic infection of the genital tract. Chitosan, Gelatin, and PLGA polymers are used for fabricating the microspheres to treat vaginal infections.[48]

Targeting using microparticulate carriers:

The principle of trying to target is a well established dogma, that is trying to gain huge interest present a days. The response manufactured by drug depends itself on availability and ability to interact to binding site generally pellets technique is confirmed that can be formulated by utilizing extrusion / Spheronization innovation e.g. microcrystalline cellulose (MCC) and chitosan.[49]

Radioactive application:

It can be used for embolization of liver and spleen tumors. It is used for radio synvectomy of arthritis joints, local radiotherapy, interactivity treatment, Imaging of liver, spleen, bone marrow, lung and even imaging of thrombus in deep vein thrombosis can be done.[50]

Other applications:

Fluorescent microspheres can be used for membrane based technology for flow cytometry, cell biology, microbiology, Fluorescent Linked Immuno-Sorbent Assay.[51] Yttrium 90 can be used for primary treatment of hepatocellular carcinoma and also used for pre transplant management of HCC with promising results.[52]

CONCLUSION

Microsphere-based drug delivery systems represent a promising approach for achieving targeted and controlled therapeutic outcomes. Their ability to encapsulate a wide range of drugs, protect active agents from degradation, and provide sustained and site-specific release makes them highly advantageous over conventional dosage forms. Advances in polymer science and formulation techniques have enabled the development of microspheres with tailored physicochemical properties and targeting capabilities. Applications in cancer therapy, vaccine delivery, and treatment of chronic diseases highlight their broad therapeutic potential. However, challenges such as scale-up, batch-to-batch reproducibility, long-term safety, and regulatory complexities continue to limit their widespread clinical translation. Future research focused on multifunctional microspheres, improved targeting efficiency, and scalable

manufacturing processes is expected to further enhance their role in next-generation targeted drug delivery systems.

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