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Review Article

Microspheres: Key Players in Targeted Drug Delivery and Controlled Release

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ABSTRACT

Over the past years, advanced drug delivery systems have become more prominent and crucial in pharmaceutical formulations. Traditional or conventional drug delivery systems have several drawbacks, such as the need for frequent dosing for certain drugs with short half-lives to maintain the desired therapeutic drug concentration in the bloodstream. This frequent dosing requirement leads to poor patient compliance and fluctuations in the drug's developing controlled drug delivery systems. Several methods exist for controlled drug delivery, including liposomes, niosomes, ethosomes, phytosomes, microemulsion, and microspheres. Of these, microspheres are the most practical, as the drug is gradually released from the polymer matrix and the polymers used are generally biodegradable and have no adverse effects. Microspheres not only enhance the availability of drugs in the body, but also offer a way to deliver them to specific locations, thereby reducing unwanted effects and increasing the accuracy of treatment. This breakthrough has greatly advanced the development of innovative drug delivery methods, paving the way for more effective and efficient medical treatments. This review attempts to bring information on various types of microspheres, different methods of preparation, and its applications, various parameters to evaluate their efficiency and also current trends and future perspectives.

INTRODUCTION

Controlled drug delivery systems that provide sustained and controlled release of medications to targeted areas have been attained great appeal for nearly half a century. Nevertheless, the practical application of controlled release started with the development of time-release coatings for pills or solid drug particles, which aimed to mask their unpleasant taste or make them more palatable. Microencapsulation technology emerged in the 1940s-1960s as a new way to deliver drugs. In the 1980s, polymer and membrane technologies became prominent in this field. Targeting and delivering drugs to specific sites with high accuracy can be achieved by attaching bioactive molecules to liposomes, biodegradable polymers, implants, monoclonal antibodies, and various particle-based carriers like nanoparticles and microspheres.

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Microspheres also known as microparticles. Microspheres are characterized as spherical microparticulate and free-flowing powders consisting of biodegradable polymers. They are typically between 1 and 1000 micrometers in size and can be used to carry and deliver drugs to specific target areas. By loading drugs into these polymeric microspheres, the therapeutic effects are focused on the targeted tissue, which can enhance the drug's effectiveness and improve its bioavailability while reducing toxicity and side effects.[1] There are two types :

1. Reservoir type
2. Matrix type

1. Reservoir type : In this system, the medication is trapped within a water insoluble polymer, which regulates the rate at which the drug is released. The commonly used polymers in such devices are ethylcellulose or polyvinyl acetate. This type is also referred as microcapsules.

2. Matrix type : In this type, the drug is evenly distributed in a polymer-based matrix, which regulates the rate of drug release. The commonly used polymers for this matrix-based type are sodium alginate or hydroxypropyl methylcellulose (HPMC). This type is also called micromatrices. [2]

Advantages

- Reduced gastric irritation.
- They reduced concentration of drug at site other than the tissue or the target organ.
- Decreases dose and toxicity
- Improve bioavailability
- Enhanced biological half-life
- They provide protection before after administration for the unstable drug.
- Provide Constant and Prolonged therapeutic effect.
- Particle size reduction for enhancing solubility of poorly soluble drugs.

Disadvantages

- Controlled release medications typically have a higher concentration of the active drug. If the release mechanism of the medication is compromised, it could lead to an unintended rapid release of the full dose, potentially causing the treatment to fail and posing a risk of toxicity.
- This type of medication should not be broken into pieces or chewed.
- A controlled release parenteral formulation can only accommodate a limited amount of drug, typically up to 50% of the total composition.
- The amount released from one dose may vary compared to another dose.
- Parental delivery of microspheres may interact or create complexes with blood components.[3]

Criteria for Microsphere Preparation

- The micro encapsulation technique allows for the incorporation of liquid, solid, or gaseous substances into one or more polymeric coatings.
- The regulated size of the particles and dispersability in the aqueous vehicle for injection.
- The preparation of microspheres should satisfy certain criteria:
  - ✓ It should be able to accommodate extremely high concentration of drugs.
  - ✓ The gradual and controlled release of an active substance over an extended period, under strict monitoring.
  - ✓ It should be capable of resisting chemical changes.
  - ✓ Biodegradability and controllable biocompatibility.
  - ✓ After synthesis, the formulation should have a consistency that ensures a clinically appropriate shelf life.
- The various techniques for producing various microspheres depend on factors such as the administration route, particle size, duration of drug release, rpm, cross-linking process, type of drug used for cross-linking, co-precipitation, evaporation time, and other factors.[4]

Polymer used for formulation of microspheres

Synthetic Polymers: There are two types

1. Biodegradable Polymer :

- Polyanhydrides
- Lactides glycosides & their co polymers

2. Non-biodegradable Polymer :

- Acrolein
- Glycidyl methacrylate
- Epoxy polymers

Natural Polymers: They are obtained from different sources like

- Carbohydrate (starch, agarose, carrageenan)
- Chemically modified carbohydrates [poly (acryl dextran), Poly (acryl starch)]
- Proteins (albumin, gelatin, collagen)[5]

Types of Microspheres

1. Bioadhesive microspheres
2. Magnetic microspheres
3. Radioactive microspheres
4. Mucoadhesive microspheres
5. Floating microspheres
6. Polymeric microspheres

1. **Bioadhesive microspheres** :

Bioadhesion describes the ability of a medication delivery device to stick to a mucosal membrane, including those in the buccal, ocular, rectal, or nasal areas. Materials that adhere to biological surfaces, such as these mucosal membranes, are known as "bioadhesive." This property allows bioadhesive drug delivery devices to form close and lasting contact at the site of administration by adhering to mucosal tissue. A longer residence time can enhance absorption, and when paired with a controlled release of the medication, it can improve patient compliance by lowering administration frequency. Carrier technology is an advanced approach to drug delivery that involves linking the medication to a carrier particle, like microspheres, which controls the release and absorption of the drug. Due to their small size and significant carrying capacity, microspheres play an essential role in these particulate drug delivery systems.

2. **Magnetic microspheres**

Magnetic microspheres are produced using substances like chitosan, dextran, and others. Different types of therapeutic magnetic microspheres are employed to deliver chemotherapy drugs specifically to liver tumors. This technique can also be used to target other drugs, including proteins and peptides. This delivery method is essential as it enables the medication to be directed to the specific site of the illness. A larger quantity of freely circulating medication can be substituted with a smaller amount of magnetically focused drug in this situation.

3. **Radioactive microspheres :**

These radioactive microspheres deliver a high dose of radiation to specific areas while minimizing damage to nearby tissues. Unlike a traditional medication delivery system, where substances are released from the microspheres, the radioactivity interacts from within a typical distance of the radioisotope and there are various types of radioactive microspheres that emit radiation.

4. Mucoadhesive microspheres :

Mucoadhesive microspheres can be customized to stick to various mucosal tissues, such as those in the eyes, nasal cavity, urinary tract, and gastrointestinal tract. This capability allows for both localized and systematic controlled drug release. Mucoadhesive microspheres, ranging from 1 to 1000 micrometers in diameter, can be composed either entirely of a mucoadhesive polymer or feature an outer layer made of such a polymer. This incorporation of mucoadhesive characteristics into the microspheres offers further benefits. Additionally, targeted delivery of the drug to the absorption site can be enhanced by attaching plant lectins, bacterial adhesins, antibodies, and other substances to the surface of the microspheres.[6]

5. Floating microspheres :

Floating microspheres are a type of gastro-retentive drug delivery system that rely on a non-effervescent method. Hollow microspheres are spherical particles without core. These microspheres are free-flowing powders consist of proteins or synthetic polymers, with a size of less

than 200 micrometers. Solid biodegradable microspheres can incorporate a drug either dispersed or dissolved throughout their matrix, allowing for controlled drug release. Gastro-retentive floating microspheres are designed as low-density systems, which provide enough buoyancy to float over gastric contents and remain in the stomach for an extended duration. As these systems float, they release the drug gradually at a consistent rate, leading to improved gastric retention and minimized fluctuations in plasma drug concentration. [7]

6. Polymeric microspheres:

polymeric microspheres can be classified as:
i) Synthetic polymeric microspheres : Synthetic polymeric microspheres are commonly used not only as bulking agents, fillers, embolic particles, and drug delivery vehicles, but also in various clinical applications where they have demonstrated safety and biocompatibility. However, a significant disadvantage of these microspheres is their tendency to migrate from the injection site, which raises the possibility of embolism and subsequent organ damage.
ii) Biodegradable polymeric microspheres : The concept of using natural polymers such as starch is based on their biodegradable, biocompatible, and bioadhesive properties. Their ability to swell significantly in aqueous media enhances their residence time when interacting with mucous membranes, leading to gel formation. The concentration of the polymer, along with the sustained release mechanism, determines the rate and extent of drug release. However, a major drawback is that in clinical applications, achieving effective drug loading efficiency with biodegradable microspheres is complicated, which poses difficulties in controlling the release of the medication.[8]

Mechanism of drug release from the microspheres

The mechanism of drug release from microsphere can occur in the following ways:

1. Diffusion: When the particle comes into contact with aqueous fluid in the gastrointestinal tract (GIT), water penetrates into its core. This leads to the dissolution of the drug, which then diffuses through the release coating to the outside.

2. Erosion: Certain coatings can be designed to erode gradually over time, thereby releasing the drug contained within the particle.

3. Osmosis: When water is allowed to enter under appropriate conditions, it creates osmotic pressure inside the particle. This pressure pushes the drug out of the particle and into the surrounding environment through the coating. [9]

Method of Preparation:

The choice of method largely depends on the characteristics of the polymer being used, the drug itself, and various formulation and technological factors. This includes the required particle size, ensuring that the drug or protein is not adversely affected by the process, achieving a consistent release profile, and the method used. Additionally, there should be no stability issues concerning the final product. The various methods employed to create microspheres involve the use of both hydrophobic and hydrophilic polymers as the matrix materials.

- The stability of the formulations after synthesis is maintained, ensuring they have an acceptable shelf life for clinical use.
- The processes allow for precise control over particle size and dispersibility, facilitating injection into aqueous solutions.
- Ensure effective release of the active ingredients while providing robust control over the release duration.
- The microspheres are designed to be biocompatible, with the ability to manage biodegradability and respond to chemical modifications.
- Enable the incorporation of relatively small medication doses. [10]

Methods used for the preparation of microspheres are:

1. Single emulsion technique: This technique is primarily used to prepare various carbohydrates and proteins. The process involves dissolving natural polymers in an aqueous solution, then dispersing them in a non-aqueous (oil) medium. The next step is to crosslink the dispersed globules, which can be done using two different methods.

- **By Heat:** Addition of dispersion into heated oil, but this is not an appropriate technique for drugs that are sensitive to heat.
- **By Chemical Cross-linking Agent:** Using cross-linking agents like glutaraldehyde, formaldehyde, and acid chlorides can lead to the drawback of excessive exposure in chemical cross-linking processes.

2. Double emulsion technique: The double emulsion method for preparing microspheres entails creating multiple emulsions, specifically a water-in-oil-in-water (w/o/w) type. This technique is particularly effective for incorporating water-soluble drugs, peptides, proteins, and vaccines. It can be applied using both natural and synthetic polymers. An aqueous protein solution is mixed into a lipophilic organic continuous phase, which may include the active ingredients. This continuous phase typically consists of a polymer solution that encapsulates the proteins from the dispersed aqueous phase. The primary emulsion is then treated through homogenization or sonication before being combined with a polyvinyl alcohol (PVA) aqueous solution. This process leads to the creation of a double emulsion. Subsequently, the emulsion undergoes solvent removal, which can be achieved through either solvent evaporation or solvent extraction.

3. Solvent evaporation technique : This is one of the initial techniques for producing microspheres. Both the polymer and the drug need to be soluble in an organic solvent, commonly methylene chloride. The mixture of polymer and drug can be dispersed in an aqueous phase to create droplets. Continuous stirring and higher temperatures may be used to evaporate the more volatile organic solvent, resulting in solid polymer-drug particles suspended in an aqueous medium. Ultimately, the particles are filtered out from the suspension.

4. Solvent extraction : The solvent extraction method is utilized in the production of microparticles and involves the elimination of the organic phase through the extraction of an aqueous or non-aqueous solvent. This technique employs water-miscible organic solvents like isopropanol. The organic phase can be extracted using water, which shortens the hardening time for the microspheres. A variation of this method includes the direct incorporation of the drug or protein into the polymer's organic solution. The rate of solvent removal via the extraction method is depend on the water temperature, the ratio of emulsion volume to water, and the solubility characteristics of the polymer.

5. Phase separation co-acervation technique : The phase separation method is primarily intended for the preparation of reservoir-type systems. The process involves reducing the solubility of the polymer in the organic phase to promote the development of a polymer-rich phase known as coacervates. This coacervation occurs when a third component is introduced to the system, leading to the creation of two distinct phases: one that is rich in polymer and another that is the supernatant, which is low in polymer content. Several effective methods are used to facilitate the phase separation of coacervates. The methods are based on the salt addition, on-solvent addition, addition of the incompatible polymer.[11]

6. Polymerization : Polymerization techniques are conventionally used for the preparation of the microspheres. They are mainly classified as

Normal polymerization : This is achieved through various methods such as bulk, suspension, precipitation, emulsion, and micellar polymerization. To initiate polymerization, a monomer or a blend of monomers is usually heated with an initiator or catalyst in bulk. The resultant polymer can then be shaped into microspheres. The polymerization process can involve the incorporation of drugs. Another term for suspension polymerization is bead or pearl

polymerization. This method involves heating the monomer or a combination of monomers while they are dispersed as droplets within a continuous aqueous phase. The droplets may contain an initiator and other chemicals. In contrast, emulsion polymerization differs from suspension polymerization because the initiator is located in the aqueous phase and subsequently diffuses to the surface of the micelles. One of the key benefits of bulk polymerization is the production of pure polymers.

Interfacial polymerization : The process involves the reaction of different monomers at the interface between two immiscible liquid phases, resulting in the formation of a polymer film that surrounds the dispersed phase. To achieve this enveloping polymer film, two reacting monomers are utilized; one is dispersed in the continuous phase, while the other is dissolved within it. [12]

7. Spray Drying: The concept of the spray drying technique involves two different processes based on how the solvent is removed or the solution is cooled: spray drying and spray congealing. Spray drying commonly utilized industrial technique for particle formation and drying them. As such, it is an optimal method when the final product needs to meet specific quality criteria related to particle size distribution, moisture content, bulk density, and particle shape.

Principle: Three steps involved in spray drying:
a) Atomization: of a liquid feed change into fine droplets.
b) Mixing: it involves the passing of hot gas stream through spray droplets which result in evaporation of liquids and leaving behind dried particles.
c) Dry: Dried powder is separated from the gas stream and collected.
In this method, the polymer is initially dissolved in a suitable volatile organic solvent like dichloromethane or acetone. The drug, in its solid state, is then mixed into the polymer solution using high-speed homogenization spray congealing. Very rapid solvent evaporation results in the creation of porous micro particles.[13]

Evaluation of Microspheres:

1. **Particle size analysis** : The dried microspheres were examined using a calibrated optical micrometer, a standard microscopy technique commonly used to visualize microparticles, such as standard light microscopy (LM).
2. **Flow properties :** The flow characteristics can be examined by calculating the Carr's compressibility index, Hausner ratio, and angle of repose. A volumetric cylinder was utilized to evaluate the bulk and tapped densities.
3. **Thermal analysis** : Thermal analysis techniques regularly examine these changes by implementing planned temperature adjustments for both heating and cooling, along with specified atmospheric conditions and pressures.[10]
4. **Percent yield of microsphere:** The completely dried microspheres were collected and accurately weighed. The given formula used to calculate the percentage yield.
   %Yield = (mass of microsphere / total weight of medication)*100
5. **Optical microscopy :** This technique and an optical microscope were employed to determine particle size. (Meizer OPTIK). The measurement was conducted on 100 particles under 450x magnification (10x eyepiece and 45x objective).
6. **Scanning electron microscopy** : The surface morphology was examined using SEM. The microcapsules were directly placed on a sample of the SEM stub using double-sided tape, and then coated with a thin layer of gold while operating under low pressure.
7. **Swelling index :** Swelling index of the microsphere was calculated using the following formula.
   Swelling index = (mass of swollen microspheres – mass of dry microspheres / mass of dried microspheres) 100. [14]
8. **Density determination:** A multivolume pycnometer is used to measure the density of microspheres. In this process, a sample of a specific weight is placed in a cup within the pycnometer. The chamber is then filled with helium gas at a constant pressure, which is

allowed to expand. Two separate pressure readings are taken at different initial pressures. These readings are then utilized to calculate the volume, which in turn allows for the determination of the density of the microsphere carriers.

9. **Drug entrapment efficiency:** A specific amount of microspheres is extracted and then fragmented. Pieces are dissolved in a buffer solution with the help of a stirrer and subsequently filtered. The resulting filtrate is analyzed at a particular wavelength using a UV spectrophotometer, referencing a calibration curve for accurate measurement.

   Drug Entrapment efficiency = Actual weight of microspheres /Theoretical wt. of drug and polymer× 100
10. **In vitro methods**: This method evaluates membrane permeability and its release characteristics. The in vitro method is applied in product development, pharmaceutical manufacturing, and various fields as a quality control measure. It is essential to obtain reasonable and consistent release data generated from environments that are well-defined in terms of chemical, physical, and hydrodynamic properties.
11. **In vivo method:** The permeability of intact mucosa is assessed through methods that offer biological responses either locally or systemically, along with direct evaluations of drug absorption or accumulation on the surface. A common approach for in vivo studies involves using animal models and conducting buccal absorption tests.[15]

Application of Microspheres

1. **Nasal and pulmonary drug delivery :** Nasal and pulmonary microspheres have advantage of the natural mucosal lining of the respiratory system. Medications that are inhaled and then exhaled can enhanced their bioavailability by the use of mucus-adhering polymers. Chitosan is one of the most commonly used polymers in nasal drug delivery systems. Using chitosan microspheres in nasal and pulmonary medications can increase the drug residence in the nose, which can enhance the local and overall effects of the treatment. Mucoadhesive polymers include alginate, gellan gum, polylactic-co-glycolic acid, pectin, and hypromellose.
2. **Parenteral drug delivery :** Microspheres act as a storage system that allows for regulated delivery of medications through parenteral formulations. Poly (lactic-co-glycolic acid) is the most common polymer used in microsphere formulations for parenteral administration. Parenteral microsphere preparations are often administered subcutaneously and intramuscularly, with the muscle tissue serving as a mechanism for releasing and storing energy.
3. **Topical drug delivery :** Drugs can be delivered to specific areas on the skin using microspheres as carriers. Medication contained in microspheres can release gradually, providing a prolonged and controlled therapeutic effect. The controlled release of drugs from the microspheres can enhance the effectiveness of topical treatments and maintain the desired medication levels in the skin. By improving drug penetration into the skin and increasing the availability of the drug, these microspheres can improve the therapeutic efficacy of topical therapies. [16]
4. **Oral drug delivery:** Polymer-containing microspheres can form films, allowing their use in film-based drug formulations as an alternative to tablets. The pH-sensitivity and reactivity of the primary amine groups make microspheres more suitable for oral drug delivery applications. Examples include chitosan and gelatin.
5. **Gastrointestinal drug delivery:** Polymer granules with internal spaces created by de acidification can float when added to acidic and neutral media and they can gradually release the drug. Examples include Eudragit, a combination of Ethyl cellulose and Carbopol, and Gelatin. [17]
6. **Gene delivery :** Gene delivery systems include viral vectors, cationic liposomes and microencapsulated systems. Viral vectors are beneficial for gene transfer because they are

very effective and can target many different cell types. Polymers have been used to carry DNA for gene delivery purposes. Additionally, polymers could be helpful for delivering genes orally due to their adhesive and transport abilities in the digestive system.

7. **Buccal drug delivery :** A polymer is suitable for buccal delivery because it has adhesive properties that allow it to stick to mucous membranes and can also enhance drug absorption. Buccal tablets made from chitosan microspheres containing the drug chlorhexidine diacetate provide extended release of the drug in the mouth, improving the drug's antimicrobial effectiveness. Even polymer microparticles without any drug have antimicrobial properties due to the polymer itself.
8. Other potential applications of microsphere include:

- Converting liquids to solids for easier handling
- Masking taste and odor
- Delaying volatilization
- Safe handling of toxic substances. [18]

Challenges and Future Prospective

Pharmaceutical microspheres have many benefits for drug administration, but there are also some issues that need to be resolved to maximize their capabilities. Some of the challenges are **:**

A. Size Control: Precise control of the size of microspheres is essential to achieve the intended drug release. Variations in the size of microspheres can result in unstability in the drug release**.**

B. **Drug Stability:** Certain drugs might diminish in effectiveness or degrade during the encapsulation process or while stored in microspheres over time.

C. Scale-Up and Manufacturing: Moving from laboratory-scale production to commercial-scale manufacturing can be challenging because of problems with reproducibility, consistency between batches, and cost efficiency.

D. **Controlled Release :** Attaining accurate regulation of drug release kinetics is a complex task, and customizing microspheres to meet specific therapeutic needs can be quite difficult.

E. **Biocompatibility and Toxicity:** The biocompatibility of materials utilized in microsphere formulations is crucial to avoid adverse reactions in the body. It is important to ensure that microspheres break down safely and do not trigger an immune response.

Future Prospective

A. **Precision Medicine:** Explore personalized medicine strategies that utilize microspheres to customize drug delivery according to the specific requirements of each patient.

B. **Combination Therapies:** Investigate the capabilities of microspheres for the simultaneous delivery of various medications to address complex diseases more effectively.

C. **Advanced Materials:** Exploring new biodegradable and biocompatible materials for microsphere formulation could enhance the variety of drugs that can be encapsulated while also improving safety profiles.

D. **In Vitro-In Vivo Correlations:** Create stronger correlations between in vitro drug release research and in vivo therapeutic results to enhance the development and regulatory approval processes for microsphere-based formulations.

E. **Continuous Manufacturing:** Explore continuous manufacturing methods to improve production efficiency and consistency.

Manage these challenges and exploring these research prospective will enable the full potential of pharmaceutical microspheres in drug delivery, resulting in more effective, patient-centered treatments for various medical conditions. [19]

CONCLUSION

Microspheres are being explored for targeting nearly all major organ systems in the body. They have demonstrated greater efficacy than traditional drug delivery systems, as they can overcome several significant physiological

barriers. Additionally, their versatility and the potential for structural modifications to meet specific needs provide them with a distinct advantage. The future of microspheres is full of potential, with advancements in materials science, biotechnology, and environmental sustainability paving the way for new applications. As technology evolves, microspheres will likely become even more integral to industries ranging from healthcare to manufacturing.

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