ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

A Comprehensive Review on Microspheres as Promising Drug Delivery Systems

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Publication Date: 2026/07/14

Abstract: Microspheres are free-flowing, spherical particulate carriers, ranging from 1 µm to 1000 µm in size, constructed from biodegradable proteins or synthetic polymers. As multiparticulate drug delivery platforms, they are engineered to facilitate sustained or controlled therapeutic release, thereby enhancing drug stability and bioavailability while enabling targeted delivery with predefined kinetics. These systems offer a superior therapeutic alternative to conventional immediate-release dosage forms and provide versatile administration options, including encapsulation in hard gelatin capsules or integration into other delivery platforms. Microspheres encompass a broad spectrum of types—including bioadhesive, magnetic, floating, radioactive, and various polymeric variants—each fabricated through specific, optimized methodologies. Rigorous analytical evaluation is essential to confirm the quality of these systems. This review comprehensively examines the microsphere landscape, detailing their classifications, polymeric constituents, fabrication techniques, characterization, and clinical applications.

Keywords: *Microspheres, Types of Microspheres, Microspheres Polymers, Method of Preparation, Characterization, Applications.*

How to Cite: Madhuri Sahdev Keskar; Avinash Vasudev Dhobale; Tushar Balasaheb Shinde; Pradip Pralhad Dole; Dhanashree Sharadchandra Kherade; Nita Atamaram Tidke (2026) A Comprehensive Review on Microspheres as Promising Drug Delivery Systems. *International Journal of Innovative Science and Research Technology*, 11(6), 3324-3331. https://doi.org/10.38124/ijisrt/26jun1969

I. INTRODUCTION

Targeted drug delivery aims to maximize therapeutic efficacy while mitigating systemic toxicity and adverse effects. Several pharmacological strategies have been developed to achieve site-specific administration [1]. Microspheres, also known as microparticles, represent a prominent drug delivery platform in this field. These free-flowing, spherical, and biodegradable systems are constructed from proteins or synthetic polymers and generally maintain a diameter of less than 200 µm. Microspheres are categorized into two primary types: microcapsules, in which the active agent is enclosed within a distinct wall, and micromatrices, in which the active agent is uniformly dispersed throughout the polymeric matrix [2]. These carriers can be synthesized from a variety of natural and synthetic materials.

The evolution of controlled drug delivery systems has largely addressed the limitations associated with conventional dosing regimens. Microspheres facilitate the precise delivery of potent drugs, minimizing accumulation at non-target sites and protecting labile compounds from premature degradation throughout the administration process.

To achieve maximum therapeutic efficacy and minimize side effects, it is necessary to deliver the agent to the target tissue in the optimal amount. Some of the issues with conventional drug delivery systems have been solved by the development of controlled drug delivery systems that enhance the therapeutic efficacy of a given drug. The use of a microsphere to carry a drug in sustained-release drug delivery is one such method that enables exact delivery of minute quantities of a powerful drug, a diminution in drug levels at any location that is not the site of action, a

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

stabilization of the labile drug molecules during the administration and after administration, and also the controlled delivery to the site of action [3]

➢ *Ideal Characteristics of Microspheres:*

- The capacity to adopt relatively high drug concentrations.
- S• Stability of the formulation following synthesis with a shelf life that is clinically acceptable.
- Controlled particle size and injectable dispensability in aqueous media
- Controlled release of an active substance over a broad time period.
- With controllable biodegradability and biocompatibility.
- The capability to undergo chemical change.

➢ *Advantages of Microspheres:*

- Reduction of particle size to improve the solubility of poorly soluble drugs.
- It helps to deliver proteins and enzymes to a targeted site.
- Drug targeting is possible.
- It provides a consistent and longer therapeutic effect.
- It keeps the drug concentration in the blood consistent.
- It reduces toxicity and increases bioavailability.
- It reduces dosing frequency and improves patient compliance and stability.
- It can easily mask the unpleasant taste and prevent GIT irritation.
- Controllable variability in degradation and drug release.
- Protects the drug from enzymatic and photolytic cleavage, hence found to be best for the delivery of proteins.
- Biodegradable microspheres provide the benefit over big polymer implants in that they can be implanted and removed without surgery.

✓ *Limitations:*

- Poor reproducibility and poor entrapment efficiency are reported.
- The stability of the particles that are encapsulated may be affected by process variables such as temperature change, pH change, solvent addition, and evaporation.
- The changes in release from the formulations.
- The rate of drug release from microspheres varies with a variety of factors, such as diet and passage through the GIT.
- These dosage forms must not be eaten or broken.

➢ *Materials Used in the Preparation of Microspheres:*

Microspheres are prepared by using natural or synthetic polymers. They are classified as follows:

- Natural polymers
- Synthetic polymers

✓ *Natural Polymers:*

Natural polymers can be produced from a variety of materials, including proteins, carbohydrates, and chemically modified carbohydrates.

- Proteins: Albumin, Gelatin, Collagen.
- Carbohydrates: Starch, Carrageenan, Agarose, and Chitosan.
- Chemically Modified Carbohydrates: Polystarch, Polydextran.
- Polysaccharides: Sodium Alginates
- Natural Gums: Xanthan Gum, Gur Gum, Gum Karaya

✓ *Synthetic Polymers:*

- *Biodegradable Polymers-*

Example. Polyalkyl cyanoacrylates, lactides, glycolides, and their copolymers, as well as polyanhydrides.

- *Non-Biodegradable Polymers-*

Example. Acrylonitrile, Glycidyl Methacrylate, and Epoxy Polymers are examples of polymethylmethacrylate (PMMA).

The use of polyalkyl cyanoacrylates as a drug carrier could be advantageous for ophthalmic, oral, and parenteral formulations. Anticancer medications like cisplatin, cyclophosphamide, and doxorubicin, as well as narcotic antagonists, can be effectively transported via polylactic acid. The sustained-release formulation of the anti-malarial medicine uses a copolymer of polyglycolic acid and polylactic acid. Timolol maleate is administered intraocularly in polyadipic anhydride capsules. A valuable type of microsphere is polyacrolein.

➢ *Criteria for Microspheres:*

- The dosage of the medication should be moderately high. After synthesis, the preparation must be stable and have a respectable shelf life.
- Compatibility with controlled biodegradability.
- There is a chance of chemical modification.
- In aqueous injection vehicles, particle size and solubility should be controlled.
- Should give prolonged, controlled release of the active pharmaceutical reagents.

➢ *Techniques of Drug Loading in Microspheres:*

The drug can be loaded in microspheres by using the following two methods:

- During the microsphere preparation
- After the preparation of the microspheres, they were incubated with the drug solution.

There are several methods for loading the active pharmaceutical ingredient, including surface absorption, chemical coupling, and physical trapping. The presence of additives, the preparation method, the heat of polymerization, the intensity of mixing, and all other parameters can all affect

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

the maximum drug loading in microspheres when the drug is incorporated during the preparation process. Drug loading is done once the microspheres have been successfully manufactured by adding them to a suitable solvent that has a high concentration of the drug. Both absorption and penetration through the microspheres' perforations can be used to include drugs.

➢ *Types of Microspheres:*

- *Bioadhesive Microspheres:*

By using the adhesion ability of water-soluble polymers, adhesion is defined as the sticking of a medication to a membrane. The adsorption of the dosage form to mucosal membranes, such as those in the mouth, eyes, nose, and other body cavities, is known as bio-attachment. These types of delivery systems have a longer contact time at the targeted site, which improves the therapeutic effect of the drug [4].

- *Magnetic Microspheres*

Are a delivery system enabling selective access of a drug to the pathological site. A smaller dose of a drug magnetically targeted can, in such a case, replace the additional dose of the drug circulationally released. These materials are often made of a combination of the magnetic carriers (magnetite and dextran) and natural polymers (chitosan and dextran). that respond magnetically to a magnetic field. Different types of microspheres are employed to deliver chemotherapeutic drugs to liver tumors. Through this method, peptides and natural proteins can be targeted [5].

- *Floating Microspheres:*

The gastric fluid has a higher density than floating microspheres, so they float freely on gastric content without slowing down the emptying rate of the stomach. The medicine is released at the targeted speed, and it is discovered that the system floats on gastric content, increasing stomach residence and causing plasma concentration fluctuations. It decreases the possibility of dose dumping. As a result, dose frequencies are reduced, and a prolonged therapeutic impact is produced. The medication is administered as floating microspheres. Through this approach, it can be targeted [6].

- *Radioactive Microspheres:*

These microspheres, which are larger than capillaries and are tapped into the first capillary bed upon contact, are employed in radio-immobilization therapy. Their sizes range from 10 to 30 nm. They are injected straight into the arteries that supply the tumor of interest. As a result, these radioactive microspheres shield the tissues while delivering high radiation doses at the targeted location. It differs from drug delivery systems in that radiation acts from a distance typical of radioisotopes rather than being released from the microspheres [7].

- *Mucoadhesive Microspheres:*

Additional advantages of adding mucoadhesive microspheres include more effective drug absorption and increased bioavailability due to a high surface-to-volume ratio, much closer exposure to the mucus layer, and precise targeting of the drug to the absorption site achieved by anchoring plant lectins, bacteria, or other molecules. Microspheres made completely of mucoadhesive polymer range in diameter from 1 to 1000 mm. Mucoadhesive microspheres can target any type of mucosal tissue for adhesion, including those in the mouth, nose, urinary tract, and gastrointestinal tract [8].

- *Polymeric Microspheres:*

They can be subdivided into two types: synthetic microspheres and biodegradable polymeric microspheres [9].

✓ *Biodegradable Microspheres:*

The concept behind the use of naturally obtained polymers is that they are biodegradable in nature, like starch. Due to their high swelling capacity in aqueous conditions, biodegradable polymers extend the residence time when interacting with biological membranes, leading to the formation of a gel.

✓ *Synthetic Polymeric Microspheres:*

The primary drawback with synthetic microspheres is that they have the ability to move out of the area of injection, which raises the possibility of embolism and subsequent organ damage. Synthetic microspheres are commonly used as additives for bulking, fillers, delivery vehicles, etc. [10].

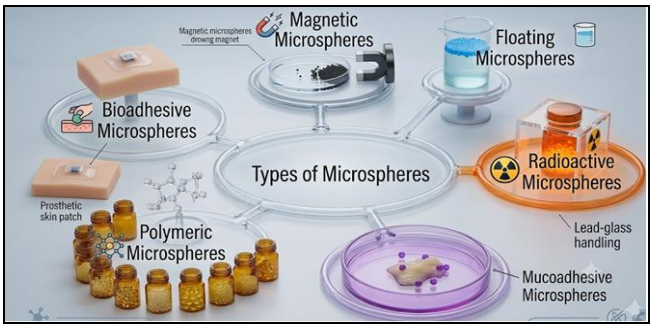

Fig 1 Types of Microspheres

➢ *Method of Preparation:*

The technique utilized for the development of microspheres depends on the type of polymer, either natural or synthetic and the duration of treatment. Microsphere preparation methods[11]:

- Simple emulsion method
- Double emulsion techniques
- Coacervation method
- Spray drying
- Solvent evaporation
- Solvent extraction
- Ionic gelation method
- Polymerization

✓ Normal polymerization
✓ Interfacial polymerization

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

➢ *Simple Emulsion Method:*

The formulation of a variety of microspheres is done using a simple emulsion process. In this method, first, all-natural polymers are dissolved in an aqueous solution and then added in an oily phase to form an emulsion. Cross-linking can be carried out either by using temperature or synthetic cross-linkers. Cross-linking by heat: by mixing the dispersion into hot oil, even though it is inappropriate for thermolabile drugs. The main drawback of chemical cross-linking is that if applied during preparation and subsequently put through centrifugation, washing, and separation, the active components are exposed to excessive amounts of chemicals[12].

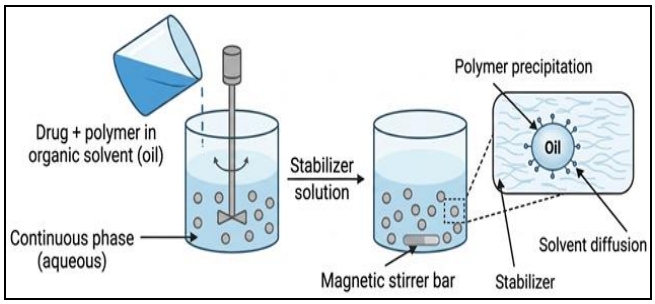

Fig 2 Simple Emulsion Method

➢ *Double Emulsion Technique:*

This approach works better with aqueous-soluble medications, peptides, proteins, and vaccines and can be applied to both natural and manmade polymers. Double emulsions of the w/o/w kind are prepared using this technique. This method involves adding the aqueous active ingredient solution to the continuous phase. A polymer that encloses proteins scattered throughout the water phase typically makes up the continuous phase. The emulsion is then blended before being added to the aqueous solution, which results in the creation of an emulsion. Following that, the solvent is eliminated using either the solvent extraction method or solvent evaporation.[13].

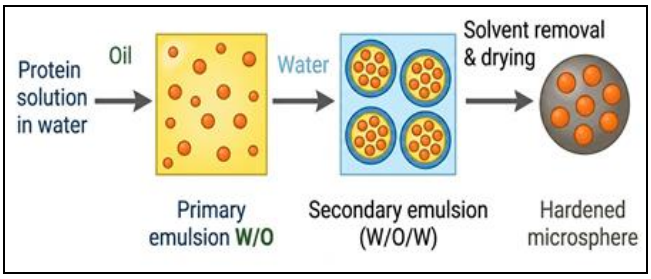

Fig 3 Double Emulsion Technique

➢ *Coacervation Method:*

A thick coacervate layer, which is relatively condensed in large molecules, and two immiscible types of material that are separated into two by this approach from the macromolecular fluid. When there is only one macromolecule present, this process is known as basic coacervation. These processes are referred to as complicated coacervations if there are more oppositely charged macromolecules present. The former occurs by specific factors, such as changes in temperature, the use of non-solvents, or micro-ions that contribute to the dehydration of macromolecules because they promote contacts between polymers and interactions between polymer and solvent. This can be developed by producing microspheres with different qualities[14].

➢ *Spray Drying:*

This procedure involves precisely weighing the polymer and dissolving it in an appropriate solvent, such as acetone, dichloromethane, or chloroform. The polymer solution is then constantly stirred with the medication. A hot air jet is then used to atomize the drug-polymer dispersion. Microspheres with a size range of 1-100 µm are created by the atomization process as small droplets or a thin mist, where the solvent rapidly evaporates. The residual solvent is vacuum-dried after tiny particles are extracted from the air using a cyclone separator. One of the process's primary advantages is that it may be used in aseptic environments.

➢ *Solvent Evaporation:*

This method involves dissolving the drug in a polymer that has been previously distributed in chloroform. After that, an aqueous phase containing 0.2% sodium PVP as an emulsifying agent is mixed with the resultant solution. Stirring the aforementioned liquid at 500 rpm produced small droplets. As the solvent evaporated, these droplets solidified into microspheres, which were then filtered, washed with demineralized water, and left to dry at room temperature for an entire day. Aceclofenac microspheres were produced using this technique.[15].

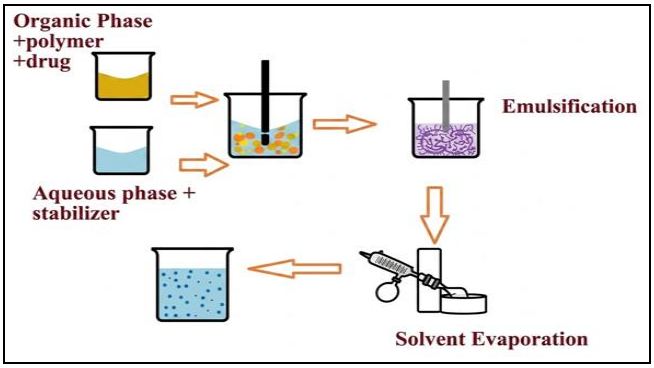

Fig 4 Solvent Evaporation Method

➢ *Solvent Extraction:*

The solvent extraction used for manufacturing microparticles and involves elimination of the organic solvent by extraction of the non-aqueous solvent. It uses water-soluble organic solvents, such as isopropanol. Water extraction used to get rid of the organic phase. The microspheres' hardening time is slashed by this procedure. Direct protein or drug integration into an organic polymer solution is one form of the procedure. Solvent removal from particles using the extraction process is affected by the water's temperature and polymer solubility[16].

➢ *Ionic Gelation Method:*

In this technique, highly viscous gel particles are produced by complexing a hydrophilic polymer with a multivalent cation (such as calcium chloride) or polyanionic (such as sodium tripolyphosphate), which

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

produces an opalescent suspension. To obtain microspheres, the suspension is centrifuged afterward. Microspheres are lyophilized for 24 hours after being freeze-dried. Positively charged groups and negatively charged anions interact electrostatically to generate the resultant microspheres. By employing this technique, acyclovir-loaded chitosan microspheres were created, allowing for sustained drug release in the treatment of ocular viral infections. The medication was released from microspheres via non-fiction diffusion and first-order kinetics[17].

➢ *Polymerization Technique:*

Usually, microspheres are produced using the polymerization process[18].

- Normal polymerization
- Interfacial polymerization

➢ *Normal Polymerization:*

Micellar polymerization occurs in bulk, suspension, or precipitation. To begin polymerization, a mixture of monomers in combination with the initiators or catalysts is typically heated in bulk. The resulting polymer can be shaped into microspheres. During the polymerization process, drug incorporation is carried out. Granular polymerization is another name for suspension polymerization. A mixture of monomers is used to carry it out as droplets disperse in an ongoing aqueous phase. Dispersion of droplets in an ongoing aqueous phase Dispersion of drops in an ongoing aqueous phase. A catalyst and other chemicals may also be present in droplets. Suspension polymerization is different from emulsion polymerization because an initiator is present in the aqueous phase that diffuses at the surface of particles during emulsion polymerization.

➢ *Interfacial Polymerization:*

The polymerization of monomers at the boundary between the two liquids to form a thin film of polymer which encloses the dispersed phase.

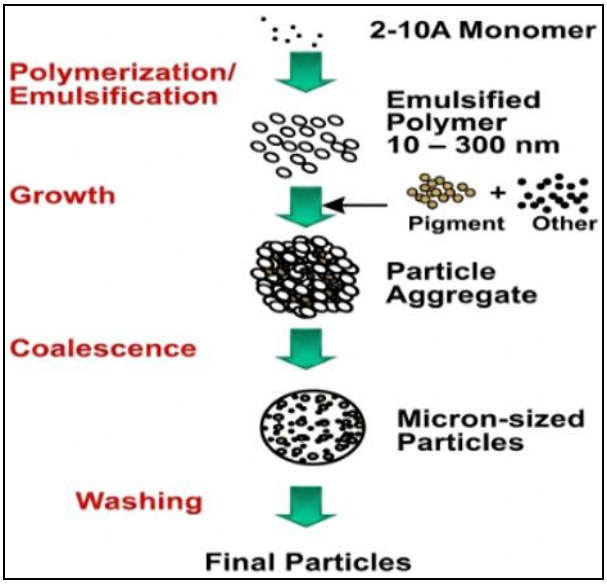

Fig 5 Polymerization Method

II. EVALUATION PARAMETERS

➢ *Particle Size and Shape:*

Conventional scanning electron microscopy (SEM) is widely used for the determination of the shape and outer structure of microspheres. Other than instrumental methods, laser light scattering and a multi-size Coulter counter are utilized for observation of size, shape, and morphology of microspheres.

➢ *Determination of Density:*

Microsphere density is mostly determined using a multi-volume pycnometer.

A cup containing a precisely weighted sample is inserted in the pycnometer with different volumes. Helium is used to fill the chamber and allowed to expand under steady pressure. Two continuous readings of pressure reduction at distinct initial pressures are noted as an outcome of this development in the chamber. Micellar polymerization may occur in suspension, bulk, or as precipitation.

➢ *Percentage Yield:*

The percentage yield is calculated by the total amount of microspheres in grams divided by the total weight of drug and polymer used to prepare that batch of microspheres, multiplied by 100.

➢ *Flow Properties:*

The flow properties can be examined using Hausner's ratio, angle of repose, and Carr's compressibility index. To determine the bulk and tapped density of the sample, the volumetric cylinder was used.

➢ *Optical Microscopy:*

The particle size of microspheres is determined by optical microscopy using a stage micrometer. About 100 microspheres particle size is determined under 450x (10x eyepiece and 45x objective).

➢ *Infrared Spectroscopy:*

The drug-polymer interaction and degradation of microspheres can be evaluated by FTIR.

➢ *Scanning Electron Microscopy:*

SEM can be used to determine the surface morphology of microspheres. The sample of microspheres can be scanned with a high-energy beam of electrons that gives topographical images of microspheres.

➢ *The Isoelectric Point*

The isoelectric point can be ascertained by measuring the electrophoretic mobility of microspheres using a device called microelectrophoresis. Surface-contained charge, ionizable behavior, or the microspheres' ability to absorb ions can all be connected to electrophoretic mobility.

➢ *Surface Carboxylic Acid Residue:*

The surface carboxylic acid residue is measured using radioactive glycine. The radioactive glycine conjugates are

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

created when the microspheres react with C14-glycine ethyl ester hydrochloride. The radioactivity of the conjugate is then measured using a liquid scintillation counter. Consequently, the carboxylic acid residue can be compared and correlated.

➢ *Surface Amino Acid Residues:*

The amino acid residue connected to the surface is identified by the radioactive C14-acetic acid conjugate. Since a liquid scintillation counter is used to detect the carboxylic acid residue, it is possible to estimate the amino acid residue indirectly.

➢ *Swelling Index:*

The swelling ability of microspheres can be determined by using the following equation,

Swelling index = (Mass of swollen Microspheres – Mass of dried microspheres / Mass of dried microspheres) 100

➢ *Entrapment Efficiency:*

By allowing washed microspheres to lyse, it is possible to calculate the percent entrapment or the capture efficiency of the microspheres. The active ingredients of the lysate are then determined according to the requirements of the monograph. The following equation is used to calculate the percent encapsulation efficiency,

$$\% \text{ Drug Entapment} = \text{Actual content/Theoretical content X } 100$$

➢ *Floating Behavior:*

When floating microspheres are dispensed in stomach juice without enzymes, the polymer dissolves into solution, leading to matrix erosion that results in pores forming on the microspheres. This causes the microspheres to float. The percentage of the floating microspheres was calculated using the formula below.

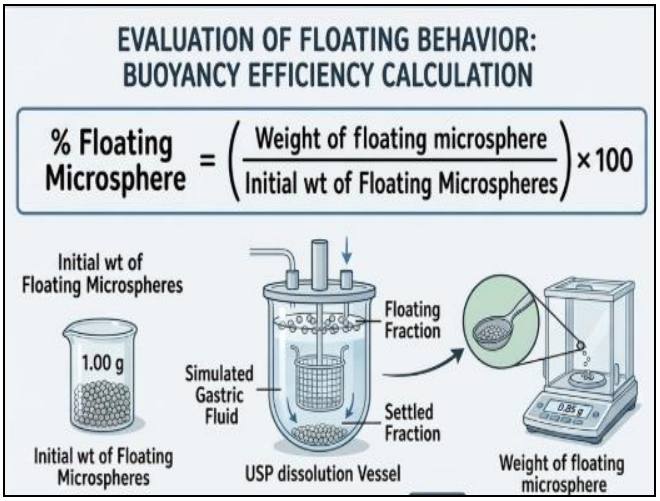

Fig 6 Floating Behavior

➢ *Drug Content:*

Drug content of microspheres can be determined by using the following procedure:

The mixture needs to be put aside so that the dust can settle before being washed away.1 mL of the filtrate was added to a volumetric flask, and the volume was then adjusted with 0.1 N NaOH, and further dilutions were prepared. UV spectrophotometer was used to determine drug content.

➢ *Dissolution Studies:*

Using standard USP or BP dissolution test apparatus, such as a rotating paddle or basket apparatus, in vitro drug release from microspheres can be determined. The dissolution medium used for the study ranged from 500-900 ml with a rotation speed of 50-100 rpm.

➢ *Stability Studies:*

In this study, the sample in a screw-capped glass container which is stored under the following conditions[19]:

- Relative humidity condition
- Room temperature (27±2ºC)
- Oven temperature (40±2 ºC)
- Refrigerator (5 ºC - 8 ºC)

The stability of microspheres can be tested for about 60 days with fixed time intervals, and after that, drug release and entrapment efficiency can be evaluated by UV spectroscopy.

III. APPLICATIONS

➢ *Delivery of Vaccines Using Microspheres:*

An ideal vaccination must fulfil the criteria for effectiveness, safety, ease of use, and cost. The drawbacks of conventional vaccines might be overcome via biodegradable parenteral vaccine delivery systems[20]. Parenteral (subcutaneous, intramuscular, and intradermal) carriers are popular because they provide greater benefits, including:

- Adjuvant effect increases antigenicity
- Modifying antigen release
- Preservation of the antigen

➢ *Microparticulate Carrier for Drug Targeting:*

The concept of site-specific drug delivery, or targeting, is well-established. The drug's ability to reach and engage specifically with its candidate receptors is essential to its therapeutic effectiveness. Drug action depends on the capacity to leave the pool in a repeatable, effective, and precise manner, and is mediated by the use of a carrier system[21].

➢ *Microspheres in Antibody Targeting:*

Microspheres used in monoclonal antibody targeting are called immune microspheres. This type of targeting is used to achieve specific targeting to a particular site. The monoclonal antibodies can be direct binds covalently with microspheres by coupling. Mabs can be covalently coupled to the microspheres directly to form an attachment[22]. There are several methods; these are the following:

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

- Non-specific adsorption and specific adsorption
- Direct coupling
- Coupling via reagents

➢ *Sublingual Drug Delivery:*

The oral mucosa has low molecular weight, great potency, and a long biological half-life for peptide drug delivery. Venlafaxine mucoadhesive microspheres with linseed mucilage as a mucoadhesive agent were spray-dried for buccal administration to prevent hepatic first-pass metabolism by lengthening residence time in the buccal cavity.

➢ *Microspheres in Cancer Therapy:*

A catheter is surgically placed precisely into the subclavian artery or a portion of the subclavian artery to deliver cytotoxin-filled microspheres to treat breast cancer.

However, by exchanging out the angiographic catheters right inside the arteria mammaria interna, it is possible to do a second differentiation insertion into the first portion of the subclavian artery (thyrocervical trunk). These microspheres, when administered intra-arterially, are transported by blood flow to the area, where they carry the therapeutic chemical to the appropriate spot and result in embolization. Adriamycin-loaded albumin microspheres have been demonstrated in animal experiments to be extremely successful in preventing the growth of cancer-causing cells when delivered radiologically in arteries using a catheter, in addition to the free medicine [23].

➢ *Nasal Drug Delivery:*

It has been shown that polymer-based drug delivery systems, such as microspheres, liposomes, and gels, have high bioadhesive properties. It quickly expands when it comes in contact with the nasal mucosa, increasing the bioavailability and duration of the drug's residence time. Such as starch, dextran, and albumin.

➢ *Microspheres for Topical Use:*

Several active components, including emollients, perfumes, volatile oils, and others, are delivered through microspheres. In addition, these porous microspheres can be mixed with active medications to create dosage forms like creams and lotions.

➢ *Brain Tumor:*

To deliver the diagnostic agent to the brain tumor cells, a microsphere delivery device has been developed. Microspheres of 5-fluorouracil have been developed with the polymer polymethylidene malonate for controlled release. A sustained-release drug delivery system developed results in therapeutic substance being delivered for a longer period of time due to the rate of polymer degradation being carefully controlled.

➢ *Intratumoral and Local Drug Delivery:*

Local and intratumoral drug delivery systems have recently gained importance as a potential cancer treatment. To deliver paclitaxel to cancer in a therapeutically efficient concentration, polymer films were developed. 31% (w/w) of paclitaxel could be incorporated into transparent films. Using a casting technique with excellent loading efficiencies, the study claims that polymer films containing paclitaxel were manufactured, keeping the chemical properties of the molecules [24].

➢ *Other Applications:*

There are a few more applications. Fluorescent microspheres can be used in cell biology, microbiology, and membrane-based flow cytometer technologies. In microspheres, natural excipients are being used extensively.

IV. CONCLUSION

The present review shows that the microsphere delivery system is a suitable choice for delivering a drug to the targeted site to treat a particular disease. It reduces the dosing frequency and improves the stability, bioavailability, and dissolution rate. It also helps to deliver the drug to specific sites in the body. In the future, microspheres are predicted to have an important role in new drug delivery in combination with several other strategies, particularly in diagnosis, the most efficient and safe delivery of genes and genetic materials, and proteins. A large number of disorders in humans can be treated by using microspheres as a targeted drug system.

FUTURE SCOPE

The field of microspheres has shown immense potential and has a wide range of applications across various industries. Microspheres have already demonstrated their capabilities in drug delivery, but future research aims to improve their efficiency and expand their applications. This includes developing microspheres that can release drugs in response to specific triggers or stimuli within the body. Researchers are also exploring the use of microspheres to deliver a wider range of therapeutic agents, including proteins, peptides, and gene therapies. Microsphere technology may also enable the development of more complex and functional tissue constructs, including organoids and bioengineered organs. The future scope involves the development of innovative microspheres with enhanced functionalities, such as controlled release of active ingredients, improved sensory attributes, and targeted delivery of cosmetic actives.

➢ Conflict of Interest: None.

ACKNOWLEDGMENT

The author expresses sincere gratitude to Honorable Shri. Sangramdada Thopte, Smt. Swarupa S. Thopte, and the Principal of Rajgad Dnyanpeeth's College of Pharmacy, Bhor, for providing the necessary infrastructure and facilities to complete this review article. Additionally, heartfelt thanks go to the faculty and peers for their constant encouragement and support.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1969

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