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Review Article

Review on Microspheres

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ABSTRACT

In the current scenario of delivering therapeutic agents to the target site requires an efficient drug delivery carrier which can deliver the drug only on the site of action in a sustained and controlled manner among many such carriers microspheres fulfill all the parameters for a potent drug carrier. Microspheres are free flowing powders consists of proteins or synthetic polymers that are biodegradable in nature ranging between 1–1000-micron size. A well-designed controlled drug delivery system can overcome some of the problems of conventional therapy an enhanced the therapeutic efficacy of given drug.

INTRODUCTION

Many issues with traditional therapy can be resolved by a precisely planned controlled medication delivery system, which can also improve the therapeutic effectiveness of a certain medication. The new drug delivery system goal is to deliver drugs at a rate that is appropriate to the body's needs during treatment and to get the active ingredient to the site of action as quickly as possible. Drug delivery systems (DDS) with the ability to precisely monitor drug release rates or target drugs to particularly body sites have had a profound effect on the health-care system. Over the course of treatment, the best drug delivery device delivers drugs at a set pace determined by the body's needs and delivers the active ingredient to the site of action. By binding the drug to a carrier particle such as microspheres, nanoparticles, or lipids, drug carrier technology offers an intelligent approach to drug delivery.

Microspheres as drug carriers are one of the most effective novel approaches in sustaining and controlling the action of drug to a specific site (e.g. tissue). They are characteristically free flowing

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powders of spherical shape, consisting of proteins or synthetic polymers, which are either biodegradable or non-biodegradable in nature. There are two types of microspheres: microcapsules and micromatrices, which are described as, microcapsules are those in which entrapped Substances is distinctly surrounded by distinct capsule wall whereas in micromatrices the entrapped substance is dispersed or dissolved through the particle matrix, having the potential for the controlled release of drug. They are made up of polymeric, waxy, or other protective materials i.e. biodegradable synthetic polymers and modified natural products.[1]

Advantages [2]

1. The therapeutic action of microspheres is continuous and lasting.
2. It decreases the frequency of doses, which enhances patient compliance.
3. They were sufficient in size to be inserted into the body and had a spherical form.
4. The microspheres' configuration allows for predictable fluctuations in medication release and breakdown.
5. Reduced size results in an increase in surface area, which can improve a drug's poor solubility.
6. Drug distribution is greatest when the drug is coated with polymers to prevent enzymatic cleavage.
7. Become less reactive to the environment outside in relation to the core.
8. Reduced size increases surface area and can boost the effectiveness of the ingredient that isn't easily soluble.
9. Effective pharmaceutical use can increase bioavailability and decrease the likelihood or severity of negative side effects.

Disadvantages [3]

1. The release rate of the regulated dose process of release, which differs from several factors like diet and transfer levels through the gut.
2. Variations in the rate of discharge between doses.
3. These dosage forms must not be chewed.
4. Lowered reproducibility
5. The effectiveness of the polymer matrix and its effects on the environment.
6. Products of polymer matrix degradation that are detrimental to the environment might be produced by sunlight, heat, hydrolysis, oxidation, or biological processes.
7. Occasionally, during preparation, the drug content could not be uniform.

TYPES OF MICROSPHERES [4]

1. Magnetic microspheres

This type of delivery system is very important which localizes the drug to the diseased site. In this, by smaller amount of magnetically targeted drug the larger amount of freely circulating drug can be replaced. The magnetic carriers receive the magnetic responses to the magnetic field from the incorporated materials that are used for the magnetic microspheres are dextran, chitosan etc. To deliver the chemotherapeutic agent to the liver tumour the different type of therapeutic magnetic microspheres is used. Through this system the drugs like peptides & proteins can also be targeted.

Advantages of Magnetic Microsphere:

1. Increased duration of action.
2. First pass effect can be avoided.
3. Good patient compliance.
4. Improved protein and peptide drug delivery.
5. Therapeutic responses in target organs at only one tenth of the free drug dose.
6. Controlled drug release within target tissues for intervals of 30 min to 30 hours, as desired.

7. Simple Method of preparation.
8. Avoidance of acute drug toxicity.[5]

Disadvantages of Magnetic Microspheres:

1. It is an expensive technical approach, requiring specialized manufacturing and quality control systems.
2. Specialized magnets are needed for targeting and monitoring, along with trained personnel for performing procedures.
3. Magnets must have relatively constant gradients to prevent focal over-dosing with toxic drugs.
4. A significant portion of the entrapped magnetite is permanently deposited in tissues.
5. Controlled release formulations typically have a higher drug load, and any loss of integrity in release characteristics may lead to potential toxicity. [6]

2. Floating microspheres

The bulk density is less than the gastric fluid in floating types & without affecting gastric emptying rate it remains buoyant in the stomach. At the desired rate the drug is released slowly, if the system is floating on gastric content, it increases the gastric residence & fluctuation in the plasma concentration. Also, it reduces the chances of striking & dose dumping & produces the prolonged therapeutic effect.

Advantages of Floating microspheres:

1. Improved bioavailability
2. Improvements in first-pass biotransformation
3. decreased variations in medication concentration
4. Site-specific medication delivery
5. Increased receptor activation selectivity
6. Reduces the body's natural defence mechanisms, increasing medication effectiveness.
7. It can be accomplished by giving the medicine a controlled release more than a long period of time.
8. Site-specific medication delivery to the stomach is possible.
9. Gastrointestinal diseases, including gastro-oesophageal reflux disease, are treated.[7]

Disadvantages of Floating Microspheres:

1. These systems require a high level of fluid in the stomach for drug delivery to float and work efficiently.
2. Not suitable for drugs that have solubility or stability problem in GIT.
3. Drugs such as nifedipine which is well absorbed along the entire GIT, and which undergoes first pass metabolism, may not be desirable.
4. Drugs which are irritant to gastric mucosa are also not suitable.
5. The drug substances that are unstable in the acidic environment of the stomach is not suitable candidates to be incorporated in the systems.
6. The dosage form should be administered with a full glass of water (200-250 ml).[8]

3. Polymeric microspheres

The polymeric microspheres can be classified as:

Synthetic polymeric microspheres:

The synthetic polymeric microspheres are widely used in the clinical application, moreover that also used as the embolic particles, bulking agent, drug delivery vehicles, fillers etc & proved to be the safe & biocompatible. But the main drawback of these kinds of microspheres is that they tend to

migrate away from the injection site & lead to the potential risk, embolism and further damage of organ.

Biodegradable polymeric microspheres:

With the concept that they are bioadhesive, biodegradable & biocompatible in nature the natural polymers such as starch are used. The biodegradable polymers prolong the residence time when they come in contact with the mucous membrane due to its high degree of swelling property with the aqueous medium thus results in gel formation. By the concentration of polymer & the release pattern in the sustained manner, the rate & extent of the drug release is controlled. The main disadvantage is that in clinical use the drug loading efficiency of the biodegradable microspheres is complex & it is difficult to control the release of drug.

Advantages of Polymeric Microspheres:

1. Provide a slow and steady release of the drug over a long period, reducing dosing frequency.
2. Protects drugs from degradation (e.g., enzymatic or hydrolytic) and improves absorption.
3. Can be designed to release drugs at specific sites (e.g., tumor, intestine).
4. By maintaining steady drug levels, side effects from fluctuating concentrations are minimized.
5. Many polymers (like PLGA, PLA, chitosan) are safe and naturally degrade into non-toxic byproducts.
6. Fewer doses and better therapeutic effects improve patient adherence.
7. Suitable for various routes of administration — oral, injectable, nasal, ocular, etc.
8. Encapsulated drugs are protected from light, moisture, and oxidation.[9]

Disadvantages of Polymeric Microspheres:

1. Preparation methods (e.g., solvent evaporation, spray drying) require precise control and can be costly.
2. Sometimes difficult to entrap a high amount of drug inside microspheres.
3. A rapid release of the drug may occur initially, leading to potential toxicity.
4. Sensitive to temperature, humidity, and light — may require special storage conditions.
5. Laboratory methods are often hard to reproduce on an industrial scale.
6. Organic solvents used in preparation (like dichloromethane) may leave residues that can be harmful.
7. Biodegradable polymers (e.g., PLGA) and specialized equipment are expensive.
8. Small changes in formulation can alter drug release behavior unpredictably.

4. Bioadhesive microspheres

The sticking of drug to the membrane by using the sticking property of the polymers that are water soluble is defined as adhesion. The bioadhesion can be termed as the adhesion of the drug delivery device to the mucosal membrane such as rectal, buccal, nasal, ocular etc. The term bioadhesion describes the materials that bind to the biological substrates such as the mucosal members. The adhesion of the bioadhesive drug delivery devices to the mucosal tissue offers the possibility of creating an intimate & prolonged contact at the site of administration. This residence time which is prolonged can result in the enhanced absorption & in combination with the controlled release of the drug by reducing the frequency of administration it also improves the patient compliance. For the drug delivery the carrier technology offers an intelligent approach by coupling the drug to the carrier particles such as nanoparticles, microspheres, liposomes, nanospheres etc which

modulates the absorption & release of the drug. The microspheres constitute an important part of these particulate drug delivery systems by virtue of their small size & efficient carrier capacity.

5. Radioactive microspheres

The radio emobilisation therapy microspheres of sized 10 to 30 nm are of larger than the capillaries & it gets tapped in the first capillary bed when they come across. Into the arteries, they are injected that lead to the tumour of interest. Without damaging the normal surrounding tissues, these radioactive microspheres deliver the high radiation dose to the targeted areas. from the drug delivery system, it differs, as the radio activity is not released from the microspheres but acts from within the radioisotope typical distance & the different kinds of the radioactive microspheres are γ emitters, α emitters & β emitters.

6. Diagnostic microspheres

The magnetic drug transport technique is based on the fact that the drug can be either encapsulated into the magnetic microsphere, or it can be conjugated on the surface of the microsphere. The accumulation of the carrier at the site of target allows them to deliver the drug locally.

7. Mucoadhesive microspheres

The mucoadhesive microspheres which are of 1 to 1000mm in diameter & consisting either the entirely of the mucoadhesive polymer or having the outer coating of it & coupling of the mucoadhesive properties to the microspheres has the additional advantages. For e.g.: The enhanced bioavailability & the efficient absorption of the drugs due to the high surface to volume ratio, the much more intimate contact with a mucus layer, the specific targeting of the drug to the absorption site which is achieved by anchoring the plant lectins, antibodies & bacterial adhesions, etc. on the surface of microspheres. To adhere to any mucosal tissue the mucoadhesive microspheres can be tailored which includes those found in the GIT [gastrointestinal tract], nasal cavity, eye & urinary tract, thus offering the possibilities of the localized as well as the systemic controlled release of the drugs.

Advantages of Mucoadhesive microspheres:

1. The use of specific bioadhesive molecules allows for possible targeting of particular sites or tissues, for example the gastrointestinal (GI) tract.
2. Offers an excellent route, for the systemic delivery of drugs with high first-pass metabolism, there by offering a greater bioavailability.
3. Better patient compliance and convenience due to less frequent drug administration.
4. Uniform and wide distribution of drug throughout the gastrointestinal tract which improves the drug absorption.
5. Prolonged and sustained release of drug.
6. Maintenance of therapeutic plasma drug concentration.
7. Better processability (improving solubility, dispersibility, flowability).
8. Increased safety margin of high potency drugs due to better control of plasma levels.

Disadvantages of Mucoadhesive Microspheres:

1. The release from the formulations may get modified.
2. The release rate may vary from a variety of factors like food and the rate of transit though gut, mucin turnover rate etc.
3. Differences in the release rate can be found from one dose to another.
4. Any loss of integrity in release pattern of the dosage form may lead to potential toxicity.

5. These kinds of dosage forms cannot be crushed or chewed.

Ideal Characteristics of Microspheres:

- Ability to control the release rate for a predefined period.
- Higher concentrations of the drug can be given to serve as a depot.
- Non-toxic.
- Relative stability.
- Bioresorbability.
- Increase therapeutic efficiency.
- Control of content release.
- Stability of the preparation after synthesis with a clinically acceptable shelf life.
- Biocompatibility with controllable biodegradability.
- Controlled particle size and dispersion of the drug in aqueous solvent for parenteral.
- Longer duration of action.
- Protect drug.
- Serializability.
- Water solubility or dispersibility.[10]

Method of Preparation:[11]

1. Solvent evaporation method:

i) Single emulsion technique:

The microparticulate carriers of natural polymers which are proteins and carbohydrates are prepared by a single emulsion technique. The natural polymers are dissolved/dispersed in an aqueous medium followed by dispersion in the non-aqueous medium e.g., oil. In the next step, cross-linking of the dispersed globule is carried out either using heat or by using chemical cross-linkers. The chemical cross-linking agents used lauraldehyde, formaldehyde, terephthalate chloride, diacid chloride. Crosslinking by heat is affected by adding the dispersion to previously heated oil. Heat denaturation is not suitable for the thermolabile drugs while the chemical cross-linking suffers the disadvantage of excessive exposure of active ingredient to chemicals if added at the time of preparation and then subjected to centrifugation, washing, and separation.

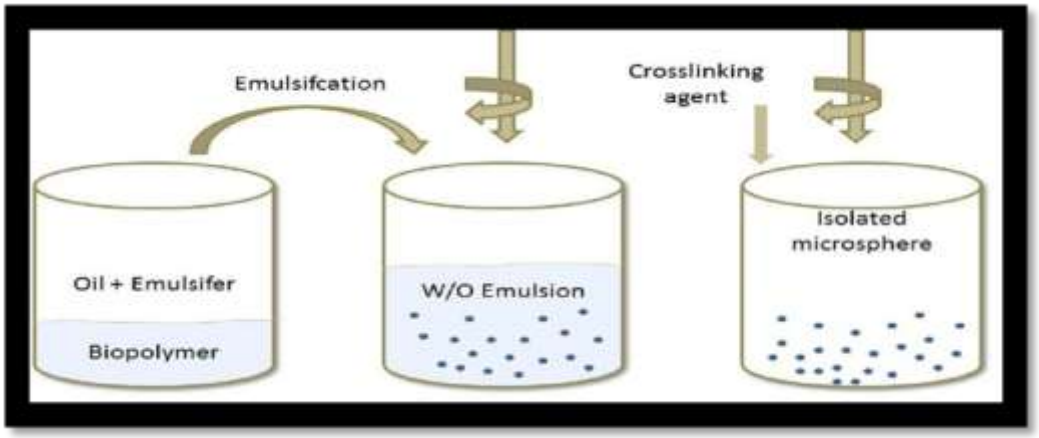

Fig No. 01: Single Emulsion Technique

ii) Double emulsion technique:

This process consumes the formation of the multiple emulsions or the double emulsion of type w/o/w and is best suited to the water-soluble drugs, peptides, proteins, and vaccines. The aqueous protein solution is dispersed in a lipophilic organic continuous phase which is generally consisted of a polymer solution that eventually encapsulates protein contained in the dispersed aqueous phase. The primary emulsion is then subjected to homogenization before addition to an aqueous

solution of PVA. This results in the formation of double emulsion which is then subjected to solvent removal by solvent evaporation maintaining the emulsion at reduced pressure or by stirring so that the organic phase evaporates out. Examples are hydrophilic drugs like LHRH agonists, vaccines, and proteins.

Fig No. 02: Double Emulsion Technique

2. Coacervation phase separation method:

This method is used to prepare the reservoir type of the system to encapsulate water-soluble drugs like peptides, proteins, matrix type particularly. When the drug is hydrophobic e.g., steroids. In a matrix-type device, the drug or the protein is soluble in the polymer phase. The process is based on the principle of decreasing the solubility of the polymer in the organic phase to affect the formation of the polymer-rich phase called the concordats. The coacervation can be brought about by the addition of the third component to the system which results in the formation of the two phases, one i.e., supernatant, depleted of the polymer. In this technique, the polymer is first dissolved in a suitable solvent and then the drug is dispersed by making its aqueous solution, if hydrophilic or dissolved in the polymer solution itself, if hydrophobic.

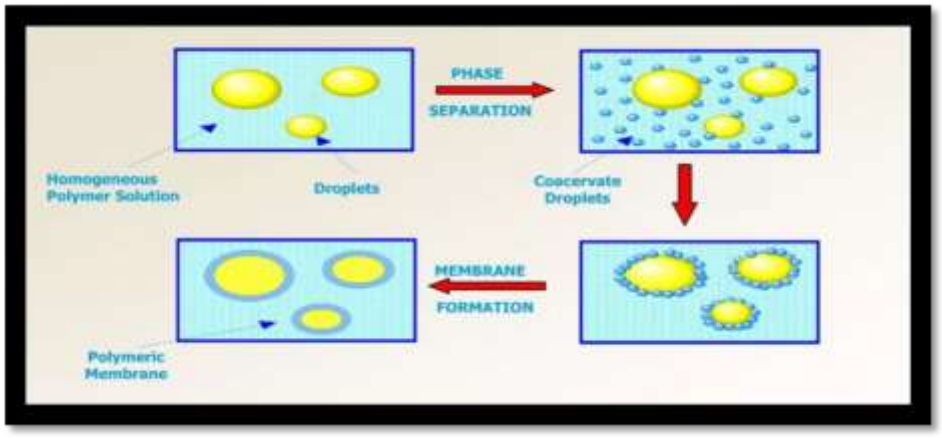

fig.No. 03: Coacervation phase separation method

3.Spray drying and spray congealing:

These methods are based on the drying of the mist of the polymer and drug in the air. Depending upon the removal of the solvent or cooling of the solution, two processes are named spray drying and spray congealing, respectively. The polymer is first dissolved in a suitable volatile organic solvent such as dichloromethane, acetone, etc. The drug in

the solid form is then dispersed in the polymer solution under high-speed homogenization. This dispersion is then atomized in a stream of hot air. The atomization leads to the formation of the small droplets or the fine mist from which the solvent evaporates instantaneously leading to the formation of the microspheres in a size range of 1-100 µm. Microparticles are separated from the hot air using the cyclone separator while the traces of solvent are removed by vacuum drying. One of the major advantages of the process is the feasibility of operation under aseptic conditions. The spray drying process is used to encapsulate various penicillin. Thiamine mononitrate and sylphethylthiadiazole are encapsulated in the mixture of mono and triglycerides of stearic acid and palmitic acid using spray congealing. Very rapid solvent evaporation, however, leads to the formation of porous microparticle.

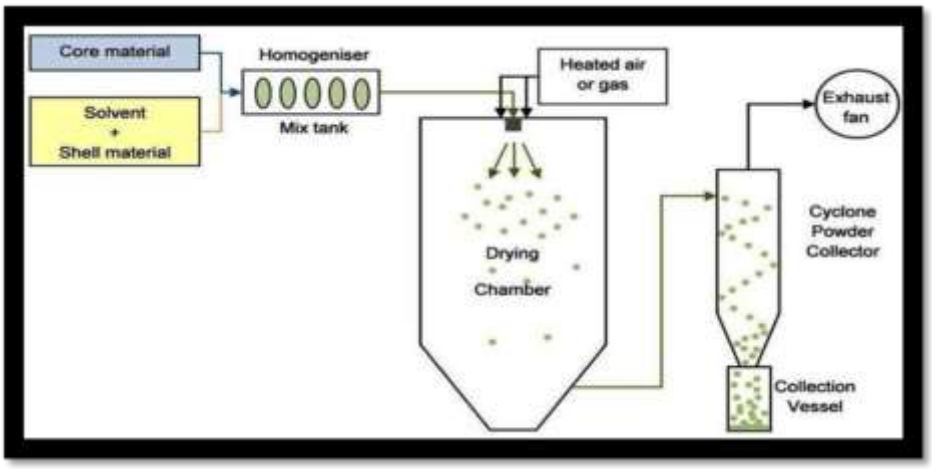

Fig No. 04: Spray drying and Spray congealing

4. Polymerization techniques:

The polymerization techniques conventionally used for the preparation of the microspheres are mainly classified as:

i) Normal polymerization:

- It is carried out using different techniques as bulk, suspension, precipitation, emulsion, and micellar polymerization processes.
- In bulk, a monomer or a mixture of monomers along with the initiator or catalyst is usually heated to initiate polymerization.
- Polymer so obtained may be molded as microspheres. Drug loading may be done during the process of polymerization.

Suspension polymerization is also referred to as bead or pearl polymerization. Here it is carried out by heating the monomer or mixture of monomers as droplets dispersion in a continuous aqueous phase. The droplets may also contain an initiator other additive. Emulsion polymerization differs from suspension polymerization due to the presence initiator in the aqueous phase, which later on diffuses to the surface of micelles. Bulk polymerization has the advantage of the formation of pure polymer.

ii) Interfacial polymerization:

It involves the reaction of various monomers at the interface between the two immiscible liquid phases to form a film of polymer that essentially envelops the dispersed phase.

Solvent extraction:

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

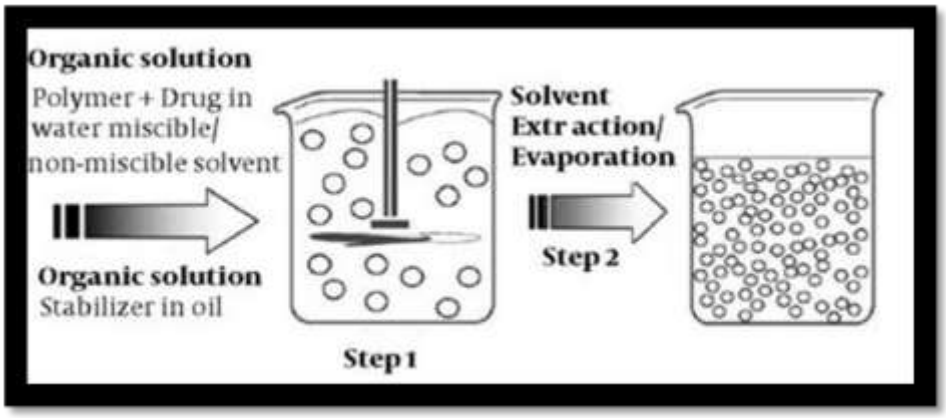

Fig No. 05: Solvent Extraction

Novel Applications of Microspheres: [12]

1. Oral Drug Delivery: Microspheres are used in oral formulations to enhance the bioavailability of drugs, especially those that are poorly soluble in water. By encapsulating the drug, they can improve absorption in the gastrointestinal tract. They can also protect drugs from degradation in the acidic environment of the stomach, allowing for the release in the intestines.

2. Parenteral Delivery: Injectable microspheres are used for delivering drugs subcutaneously or intramuscularly, providing a depot effect where the drug is slowly released over time. This is often used for long-term treatments, such as hormone therapy or antipsychotic medications.

3. Parenteral Delivery: Injectable microspheres are used for delivering drugs subcutaneously or intramuscularly, providing a depot effect where the drug is slowly released over time. This is often used for long-term treatments, such as hormone therapy or antipsychotic medications.

4. Bone Repair and Regeneration: Microspheres made of bioactive ceramics, such as calcium phosphate or hydroxyapatite, are used for bone grafting and repair. They support the growth of bone cells and are gradually resorbed as new bone tissue forms. They are often used in orthopaedic surgery to fill bone defects and to support the healing of fractures.

5. Immunotherapy and Vaccine Delivery: Microspheres are used to deliver antigens in vaccine formulations, ensuring a controlled release and enhancing the immune response. They can also protect the antigens from degradation, allowing for a more effective vaccination. By presenting antigens in a sustained manner, microspheres can simulate a natural infection and stimulate both humoral and cellular immunity.

6. Controlled Release of Active Ingredients: In cosmetics, microspheres are used to deliver active ingredients like vitamins, retinoids, or moisturizing agents, allowing for a controlled

release over time, thus prolonging their effects on the skin. This technology is used in creams, serums, and lotions to provide a long-lasting benefit without the need for frequent application.

7. Encapsulation of Nutrients: In the food industry, microspheres are used to encapsulate vitamins, minerals, and other bioactive compounds to protect them from degradation and improve their stability. This allows for the controlled release of these nutrients in the digestive tract. Encapsulation can also mask the taste or odour of certain nutrients, making them more palatable in dietary supplements and fortified foods.

8. DNA and RNA Delivery: In gene therapy research, microspheres are used to deliver DNA, RNA, or other genetic materials into cells. They protect nucleic acids from enzymatic degradation and facilitate their entry into target cells

Drug	Commercial Name	Company	Technology
Risperidone	RISPERDAL® CONSTA®	Janssen®/Alkermes, Inc.	Double emulsion (oil in water)
Naltrexone	Vivitrol®	Alkermes	Double emulsion (oil in water)
Leuprolide	Lupron Depot® Enantone Depot® Trenantone® EnantoneGyn	TAP Takeda Takeda Takeda	Double emulsion (water in oil in water)
Octreotide	Sandostatin® LAR	Novartis	Phase separation
Somatropin	Nutropin® Depot®	Genentech/Alkermes	AlkermesProLease® Technology (Cryogenic spray-drying)
Triptorelin	Trelstar™ depot Decapeptyl® SR	Pfizer Ferring	Phase separation
Buserelin	Suprecur® MP	Sanofi-Aventis	N/A
Lanreotide	Somatuline® LA	Ipsen-Beafour	Phase separation
Bromocriptine	Parlodel LAR ™	Novartis	Spray dry
Minocycline	Arestin®	Orapharma	N/A

Fig No. 06: List of Marketed Microsphere Drug Product

CONCLUSION:

Compared to traditional drug delivery methods, the idea of microsphere drug delivery systems has several advantages, such regulated and sustained distribution. Additionally, drug targeting to several systems, including ocular, intranasal, oral, and IV routes, is made possible by microspheres. Compared to traditional technologies, novel technologies such as immunological microspheres and magnetic microspheres have several benefits and applications. Microspheres are a fantastic affinity for well- known marketing preparations like Protonix, Zilretta, Lumson, Definity, etc., since they increase their efficacy and improve their therapeutic impact.

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