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## REVIEW ON MICROSPHERE BASED ORODISPERSING TABLET

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### ABSTRACT:

Tablets based on microspheres (ODT) represent a category of orally dispersible tablets that deliver active pharmaceutical ingredients. These solid dosage forms dissolve in the mouth when exposed to saliva. They are becoming increasingly significant as an innovative oral drug delivery mechanism due to their enhancement of patient compliance and ability to mask the taste of unpleasant medications, making them suitable for patients who face challenges in swallowing, including children, the elderly, and bedridden individuals. This review article addresses the applications, identification and characterization, preparation technique, and assessment of microsphere-based ODTs.

**KEYWORDS:** Orodispersible, solvent evaporation, microsphere matrix, drug entrapment

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### INTRODUCTION :

MICROSPHERES <sup>[1]</sup> : Microspheres are solid, nearly spherical entities, with sizes that range from 1 to 1000  $\mu\text{m}$ . They are composed of polymeric materials, wherein the drug is represented in the microsphere matrix. The components utilized in the formulation consist of biodegradable synthetic polymers and natural substances. The natural polymers selected are albumin and gelatin, while the synthetic polymers include polylactic acid and polyglycolic acid.

#### *ADVANTAGES OF MICROSPHERES*

- Microspheres offer a constant and extended therapeutic effect.
- They ensure safe and proper handling of hazardous materials.
- They effectively mask unpleasant odors or tastes.
- They enable controlled and targeted drug delivery.
- They contribute to enhanced bioavailability and stability.
- They decrease the frequency of dosing, therefore enhancing patient adherence to treatment.

#### *DISADVANTAGES OF MICROSPHERES*

- The expenses associated with materials and processing are relatively elevated.
- The rate of release for controlled-release dosage forms may differ based on various factors, including diet and intestinal transit speed. Variations in release rate from one dose to another.
- Alterations in processing variables - temperature, pH, solvent addition, and evaporation - may influence the stability of the core particles. Dosage forms of this nature should not be crushed or chewed. The reproducibility is comparatively lower.

#### *APPLICATIONS OF MICROSPHERES:*

1. Ophthalmic Drug Delivery
2. Oral Drug Delivery
3. Nasal Drug Delivery

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### ORO-DISPERSING TABLETS (ODTs)

Orally-dispersible tablets (ODTs) represent an innovative dosage form that dissolves swiftly in the mouth (1 to 3 minutes) without chewing when ingested and without requiring water. These tablets dissolve or break apart upon touching saliva to release the active medication.

**ADVANTAGES OF IMMEDIATE RELEASE TABLETS** Ease of administration in individuals who are unable to swallow. Improved compatibility. No necessity to chew. Suitable for controlled/sustained release active ingredients.

**DISADVANTAGES OF DISPERSIBLE TABLETS** Occasionally a higher frequency of administration may be needed. For optimal stabilization and safety of the stable product, ODTs require special packaging. Overall, they display insufficient mechanical durability. Therefore, appropriate handling is essential. Leaves an undesirable taste and/or a gritty texture in the mouth.

**IDEAL PROPERTIES OF ODTs** Rapidly dissolves or disperses in saliva within seconds. Pleasant taste. After administration, does not leave any residue in the mouth. Can be manufactured in a straightforward and conventional manner at a low cost. Should be less prone to environmental factors such as temperature, humidity, etc.

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## PREFORMULATION STUDIES <sup>[4]</sup>

It encompasses the examination of the physicochemical characteristics of the active pharmaceutical ingredient alongside the excipient prior to the creation of dosage forms. Preformulation needs: The aim of preformulation is to offer and comprehend information on: Degradation process Bioavailability. Pharmacokinetics and formulation of associated compounds. Toxicity. It establishes a physicochemically stable and convenient biopharmaceutical dosage form.

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## METHODS OF DRUG IDENTIFICATION AND CHARACTERIZATION.

1. Particle size and shape The procedures that are most frequently utilized for the visualization of microparticles are traditional optical microscopy (L. M) and scanning electron microscopy (SEM). Both methods can be applied to assess the outer shape and composition of microparticles. LM permits the regulation of coating parameters for double-walled microspheres. The configurations of the microspheres can be observed before and after the coating process, and the alteration can be quantified through microscopy, while SEM facilitates exploration of the microspheres' surfaces.

2. Swelling index The analysis of the microspheres is conducted utilizing the swelling index technique. Multiple solutions (100 ml) are collected, including (distilled water, pH solutions pH (1. 2, 4. 5, 7. 4), and alginate microspheres (100 mg) should be housed in a metal basket and positioned above the aforementioned solution, permitting them to swell at 37 ° C; weight changes between the initial mass of the microspheres and the mass caused by swelling were recorded by periodically weighing and blotting with filter paper Swelling index = Initial weight - Final weight / Initial weight 100.

3. Solubility Study The solubility of the drug was assessed by placing a specific amount of drug (approximately 1-2 mg) in a test tube individually and introducing 5 ml of solvent (water, ethanol, methanol, 0. 1 N HCl, 0. 1 N NaOH, and phosphate buffer). pH 6. 8). Shake forcefully and allow it to sit for a while. The solubility of the drug in various solvents was evaluated (at room temperature).

4. Determination of shear angle and apparent density. Angle of repose The angle of repose was established using the fixed funnel approach. Physical mixtures of the drug with several excipients were created, and the drug powder or its physical mixture, precisely measured, was fed into a funnel. The height of the funnel was modified so that the tip of the funnel rested on the peak of the drug powder pile. The powder was permitted to flow freely through the funnel onto the surface. The angle of repose was computed with the following equations.  $\tan \theta = h/r$ ,  $\theta = \tan^{-1}(h/r)$ , where  $\theta$  is the angle of repose,  $h$  is the height,  $r$  is the radius. Bulk Density and Compressed Density The bulk density (LBD) and compressed density (TBD) were calculated. An accurately weighed sample of pellets, taken from a 50 ml graduated cylinder, was tapped 100 times on a flat wooden surface, and LBD and TBD were determined, computed using the following formulas.  $LBD = \text{Powder Weight} / \text{Bulk Volume}$ .  $TBD = \text{Powder Weight} / \text{Affected Volume}$ .

5. Void Volume The volume occupied by voids is referred to as the void volume "v" and is defined by the formula  $V = V_b - V_t$ , where  $V_b$  represents Bulk volume (volume before tapping)  $V_t$  represents Actual volume (volume after tapping) 6. Porosity Porosity and powder density are characterized as the ratio of void volume to the volume of the package. Porosity is often articulated as a percentage and is represented as  $\%E = (1 - V/V_b) \times 100$ .

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## METHOD OF PREPARATION <sup>[2][4][5]</sup>

1. Spray drying :- In spray drying, the polymer is initially dissolved in an appropriate volatile organic solvent like dichloromethane, acetone, etc. The drug in solid state is subsequently dispersed in the polymer solution under high-speed homogenization. This dispersion is then atomized in a stream of heated air. Atomization results in the creation of small droplets or a fine mist from which the solvent evaporates rapidly, resulting in the formation of microspheres measuring between 1 and 100  $\mu\text{m}$ . The microparticles are extracted from the hot air using a cyclone separator while remnants of solvent are eliminated through vacuum drying. A primary benefit of this method is the potential to operate under aseptic conditions; this process is quick, leading to the production of the porous microparticles illustrated.

2. Solvent evaporation :- The processes are performed in a liquid production apparatus. The microcapsule coating is dissolved in a volatile solvent that does not mix with the liquid phase of the manufacturing vehicle. A base material intended for microencapsulation is dispersed in the coating polymer solution. With stirring, the combination of base materials is dispersed in the liquid phase of the manufacturing vehicle to achieve microcapsules of the desired size. The mixture is then heated as needed to evaporate the polymer solvent from the base material dispersed in the polymer solution, causing the polymer to shrink around the core. If the base material is dissolved in the coating polymer solution, matrix-like microcapsules are produced. The base materials can be either water-soluble or water-insoluble substances. Solvent evaporation entails the creation of an emulsion between the polymer solution and an immiscible continuous phase, either aqueous (o/w) or non-aqueous. Mucoadhesive microspheres of hyaluronic acid, chitosan glutamate, and a mix of the two preparations via solvent evaporation with hyaluronic acid, along with gel microcapsules prepared through complex coacervation, were evaluated.

3. Freeze / freeze drying :- Freeze drying signifies drying at low temperatures under conditions that involve the removal of water through sublimation. Drug in a water-soluble matrix is then lyophilized to yield a highly porous structure. Lyophilized tablets break down rapidly in under 5 seconds because

of the swift penetration of saliva into the pores when introduced into the oral cavity. Freezing is beneficial for heat-sensitive drugs, meaning heat-stable substances.

4. Sublimation method :- The gradual dissolution of the compressed tablet, which also contains water-soluble components, is a result of the low porosity of the tablets. This volatile material is eliminated by sublimation separation, creating a highly porous matrix. Tablets manufactured using this approach usually disintegrate within 10 to 20 seconds. Solvents like cyclohexane and benzene may also serve as pore-forming agents.

5. Direct compression :- This is the easiest and most efficient method for manufacturing tablets for ODTs since they can be created using standard tablet manufacturing and packaging equipment, as well as due to the presence of compression excipients that possess enhanced flow characteristics, compressibility, and disintegration, particularly including tablet disintegrants, foaming agents, and sugar-based excipients. Several elements influence dissolution, including particle size distribution, contact angle, particle size distribution, and tablet firmness. Orodispersible tablets were manufactured through the direct compression process. The tablets were produced with super disintegrants (sodium starch glycolate, avicel), mannitol serving as a diluent, lactose functioning as a sweetener, and talc combined with magnesium stearate to aid in flow promotion. The optimized microspheres along with additional components were blended thoroughly, subsequently mixed in a cylindrical blender with talc and magnesium stearate, and then compressed into tablets.

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## MICROSPHERE EVALUATION

Micron Properties (particle size and shape): The most frequently utilized methods to visualize microparticles include conventional optical microscopy (LM), particle size analyzers, and scanning electron microscopy (SEM). Electron Spectroscopy for Chemical Analysis: The surface chemistry of microspheres can be assessed through electron spectroscopy for chemical analysis (ESCA). Drug Entrapment Efficiency: The aim is to ascertain the total drug entrapment within the microspheres. It can be computed using the subsequent formula,  $\text{Aggregation} = \text{Actual Content} / \text{Theoretical Content}$  X100 Density Determination: The density of microspheres can be gauged using a multi-volume cyclometer. Isoelectric Point: Microelectrophoresis is employed to evaluate the electrophoretic mobility of microspheres, from which the isoelectric point can be inferred. Contact angle: The contact angle is assessed to determine the wetting characteristics of a microparticle support. In Vitro Methods: Release studies for various kinds of microspheres are conducted utilizing different dissolution media compatible with the dissolution apparatus employed in IP/USP/BP.

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