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A REVIEW ARTICLE ON FORMULATION AND EVALUATION TECHNIQUES OF MOUTH DISSOLVING TABLET INCORPORATING LIPOSOMES AND NIOSOMES ENHANCED DRUG DELIVERY

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ABSTRACT

The goal of this study is to create oral mouth dissolving tablets (MDTs) that include liposomes and niosomes as vesicular drug delivery systems in order to increase drug bioavailability and therapeutic effectiveness. Liposomes, which are made of phospholipids, and niosomes, which are made of non-ionic surfactants, are carriers that increase medication solubility and permeability while also shielding the drug from enzymatic and acidic breakdown when taken orally. Oral cavity disintegrating tablets offer quick disintegration and dissolution, which helps enhance patient adherence, especially for medications with low water solubility and first-pass metabolism. The goal of these vesicular systems in the designed MDTs is to enhance drug absorption by extending drug release, increasing drug stability, and bypassing the hepatic first-pass effect, all of which lead to greater bioavailability. Evaluation criteria often include drug entrapment efficacy, particle size, in vitro drug release, disintegration time, and in vivo pharmacokinetic studies that show enhanced systemic bioavailability when compared to traditional dosage forms. These formulations have promise for improved therapeutic effectiveness with drugs that are not very soluble and those that need a rapid onset of action. This strategy combines the benefits of oral disintegrating tablets

with the targeted and sustained release capabilities of liposomes and niosomes, demonstrating promise for improving the effectiveness of oral drug delivery.

KEYWORDS: Pediatric, Geriatric, Bioavailability, Mouth dissolving tablet, Liposome, Niosomes.

INTRODUCTION

In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms. Considering quality of life, most of these efforts have been focused on ease of medication. Among the various dosage forms developed to improve the ease of administration, The mouth dissolving tablet (MDT) is the most widely preferred commercial products. The oral cavity is an attractive site for the administration of drugs because of ease of administration. Various dosage forms like Tablets, Capsules, Liquid preparations are administered by oral route. During the last decade, mouth dissolving tablet (MDT) technologies that make tablets disintegrate in the mouth without chewing and additional water intake have drawn a great deal of attention. The MDT is also known as fast melting, fast dispersing, rapid dissolve, rapid melt, and or quick disintegrating tablet. The disintegration time for good MDTs varies from several seconds to about a minute. Orally Disintegrating tablets provide an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. Additionally, pediatrics patients may suffer from ingestion problems as a result of underdeveloped muscular and nervous control. MDTs disintegrate and/or dissolve rapidly in saliva; therefore, water is not required during administration. Some tablets are designed to dissolve in saliva within few seconds, and are true fast-dissolving tablets. Others contain agents to enhance the rate of tablet Disintegration in the oral cavity and are more appropriately termed as fast-disintegrating Tablets, as they may take about one minute to disintegrate completely. Many elderly individuals struggle with swallowing tablet, capsule or powder. This category of formulation is specifically designed for patient who experience difficulty swallowing, including geriatric, pediatric patient‟s. Liposomes, recognized as adaptable lipid-based nanoparticles, have gained significant attention as effective drug delivery systems in recent years. This extensive review seeks to offer a thorough examination of the progress, obstacles, and prospective uses of liposomes in the realm of drug delivery. It addresses multiple facets of liposomebased drug delivery, encompassing their structural characteristics, formulation techniques Niosomes are small vesicles or sac, used as a drug delivery systems, they are

made up of non- ionic surfactant and cholesterol and are similar to liposome but offer more stability and are easier to prepare . Niosomes are beneficial because they are encapsulate both hydrophobic and hydrophilic drug. Additionally, we explore the wide variety of drugs and therapeutic agents that can be encapsulated within liposomes and Niosomes along with their clinical applications aimed at targeting specific diseases. Liposomes are spherical vesicles composed of phospholipids, while Niosomes are surfactantbased vesicles. Both carriers enhance solubility, stability, and targeted delivery of drugs. Combining these vesicular systems with MDF technology improves drug disintegration in a few seconds absorption and bioavailability, making it a highly patient-friendly approaches.

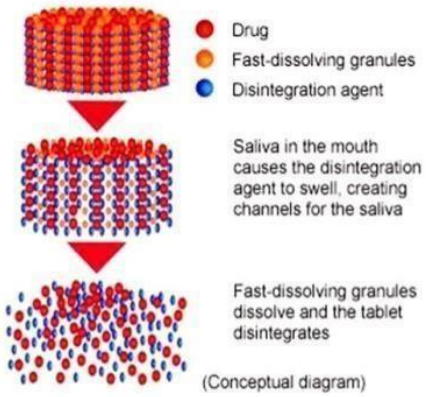

Fig. 1: Mechanism of Action of Mouth dissolving tablet.

Mouth dissolving tablet (MDT)

It is a tablet that disintegrates and dissolves rapidly in the saliva, within a few seconds without the need of drinking water or chewing. A mouth dissolving tablet usually dissolves in the oral cavity within 15 s to 3min. Most of the MDTs include certain super disintegrates and taste masking agents.

Ideal properties of Mouth Dissolving Tablets

- Require no water for oral administration, yet dissolve / disperse/ disintegrate in mouth in a matter of seconds.
- It should have pleasant mouth feel.
- It Should have an acceptable taste masking property.
- It should have sufficient hardness to withstand rigors during manufacturing processes And post manufacturing handling.
- It should allow high drug loading.

- Should leave minimal or no residue in mouth after disintegration.
- Should exhibit low sensitivity to environmental conditions (temperature and humidity).

• ADVANTAGES

1. The drug is absorbed and dissolves rapidly.
2. Preventing first-pass metabolism.
3. Water is not necessary for the dose to be taken
4. No water is necessary.
5. No need to chew.
6. Improved stability.

Liposome

Liposomes are spherical concentric vesicles that are formed by combining the Greek words Lipos,‟ which means fat, and „Soma,‟ which means body. Liposomes are spherical, vesicle like structures made of phospholipid molecules that enclose a water droplet, especially when they are artificially created to aid in the delivery of drugs into tissue membranes. The size of a liposome, which is about 100 nm, makes it a nanoparticle. Bangham first proposed the idea of liposomes in 1961, as a result of an accidental find that occurred when he dissolved phosphatidylcholine molecules in water. He found during this procedure that the molecules created a closed bilayer arrangement, with an aqueous compartment surrounded by a lipid bilayer. Liposomes are beneficial since they act as carriers for a wide range of medications and have possible medicinal uses. Drugs can be targeted to particular locations using a variety of carriers, such as liposomes, lectins, polysaccharides, micro particles, and nanoparticles. Liposomal drug delivery is becoming more popular because of its use in medication delivery systems, cosmetics, and the makeup of biological membranes. A liposome is a tiny vesicle with a membrane made of a phospholipid bilayer. Phospholipids, such phosphatidylethanolamine and phosphatidylcholine, are commonly the main components of these membranes. Phospholipids have ampiphilic properties, meaning they have a hydrophilic polar head and a hydrophobic hydrocarbon tail.

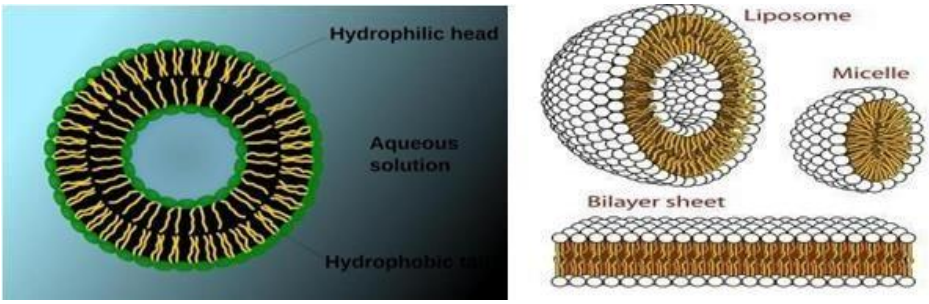

Fig. 2: Structure of Liposome.

Advantage of Liposome

Some of the advantages of liposome are as follows:

- Provides selective passive targeting to tumour tissues (Liposomal doxorubicin).
- Increased efficacy and therapeutic index.
- Increased stability via encapsulation.
- Reduction in toxicity of the encapsulated agents.
- Site avoidance effect.
- Improved pharmacokinetic effects (reduced elimination, increased circulation life times).
- Flexibility to couple with site specific ligands to achieve active targeting

Disadvantages

- Short half-life. Low solubility.
- Leakage and fusion of encapsulated drug/ molecules.
- Production cost is high.
- Fewer stables.
- Sometimes phospholipids undergo oxidation and hydrolysis-like reaction.

Role of Liposomes in MDTs

1. Liposomes are vesicular carriers made from phospholipids, capable of encapsulating both hydrophilic and lipophilic drugs, providing protection from degradation in the gastrointestinal tract and supporting controlled or sustained drug release.
2. Protecting labile drugs such as peptides and proteins from degradation by gastric acid and digestive enzymes.
3. Enhancing bioavailability by improving absorption across mucosal membranes.
4. Allowing for both immediate and sustained release depending on lipid composition and coating.

Niosomes

Niosomes are vesicles composed of non-ionic surfaceactive agent bilayers, which serve as novel drug delivery systems. Niosomes are microscopic in size and their size lies in the nanometric scale on the outside and inside of the vesicle while the hydrophobic chains face each other within the bilayer Hence, the vesicle holds hydrophilic drugs within the space enclosed in the vesicle while the hydrophobic drugs are embedded within the bilayer itself. The application of niosomal technology is widely varied and can be used to treat a number of diseases. One of the most useful aspects of niosomes is their ability to target vaccines and drugs to the Reticulo-endothelial system. Niosomes are beneficial because they are encapsulate both hydrophobic and hydrophilic drug. Additionally, we explore the wide variety of drugs and therapeutic agents.

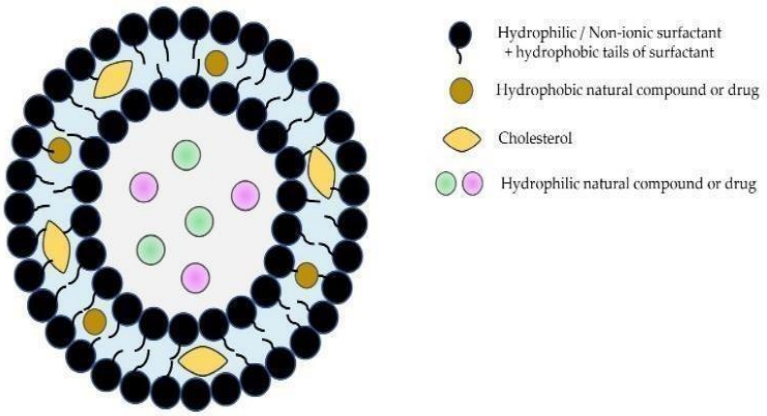

Fig. 3: Composition of Niosomes.

Role of Niosomes in MDTs

1. Niosomes are non-ionic surfactant vesicles with a structure similar to liposomes, but made using surfactants and cholesterol, leading to greater stability and costeffectiveness.
2. In MDT formulations, niosomes offer: Enhanced drug stability and protection against enzymatic chemical degradation.
3. Improved encapsulation efficiency for various drugs, especially peptides and macromolecules.
4. Targeted and controlled release, allowing for localized drug action in the oral cavity, important in the treatment of oral infections or conditions requiring rapid onset of action.

Material used in formulation of Mouth dissolving tablet 1. API

Active pharmaceutical ingredient

2. Superdisintegrants

These are crucial for the rapid breakdown of the tablet into smaller particles upon contact with saliva.

Examples Synthetic/Cross-linked Polymers

Croscarmellose Sodium (CCS or Ac-Di-Sol): Cross-linked carboxymethyl cellulose; works by swelling and wicking (capillary action), Sodium Starch Glycolate (SSG or Primogel/Explotab): Cross-linked starch; works primarily by rapid swelling (7-12 folds). Crospovidone (CP or Polyplasdone XL-10): Cross-linked polyvinylpyrrolidone (PVP); works mainly by wicking/capillary action, with minimal swelling, which prevents gelling

Diluents/Bulking Agents (Fillers)

These make up the bulk of the tablet, improve compressibility, and often contribute to the rapid dissolution and good mouthfeel. Saccharides (Sugars and Sugar Alcohols): These are commonly used because they are highly water-soluble, which is essential for fast dissolution and provides a pleasant taste/cooling.

Example

Mannitol (a very common choice), Lactose, Xylitol, Sorbitol, Dextrose

• **Cellulose Derivatives**

Microcrystalline Cellulose (MCC or Avicel): Often used in combination with sugars.

• **Co-processed Excipients:** These are blends of excipients manufactured together to offer superior properties like flowability, compressibility, and rapid disintegration. Examples include commercial products like F-Melt, Pharmaburst, and ProSolv ODT.

3. Binders (Adhesives)

These impart cohesive qualities to the powder material, giving the tablet the necessary mechanical strength to withstand handling and packaging, without interfering with the quick disintegration. Low-viscosity and quick-dissolving binders are preferred.

Common Examples

Low concentration of high-solubility polymers like Polyvinylpyrrolidone (PVP or Povidone).
Low-substituted Hydroxypropyl Cellulose (L-HPC).
Hydroxypropyl Methylcellulose (HPMC) (often low viscosity grade).

Gelatin.

4. Taste-Masking Agents, Sweeteners, and Flavors

MDTs dissolve on the tongue, so taste is a critical factor.

- **Sweeteners**: Aspartame, Saccharin, Sucralose, Stevia. Mannitol and xylitol also serve as bulk sweeteners.
- **Flavors**: Menthol, mint, cherry, orange, etc.
- **Taste Masking:** Methods like microencapsulation, use of cyclodextrins, or ionexchange resins are used to prevent the patient from tasting the often bitter Active Pharmaceutical Ingredient (API)

3. Other Excipients

- **Lubricants and Glidants:** To improve powder flow and prevent sticking to the tablet press. Examples include Magnesium Stearate, Talc, and Colloidal Silicon Dioxide (Aerosil).
- **Subliming Agents:** For sublimation techniques, volatile materials like Camphor, Menthol, or Ammonium Bicarbonate are compressed into the tablet and then removed by vacuum, creating a highly porous, fast-dissolving structure.
- **Effervescent Agents:** Forn effervescent methods, a combination of a carbonate/bicarbonate (like Sodium Bicarbonate) and an organic acid (like Citric Acid or Tartaric Acid) is used.

Steps Involved In Preparation Of Mouth Dissolving

1. Preparation of Liposomes
2. Preparation of Niosomes
3. Preparation of MDTs

1. Preparation of Liposomes The following factors determine the appropriate liposome production method

1. The liposome‟s physicochemical properties and those of the substance being trapped components.
2. The lipid vesicles are dispersed in the medium, which is determined by its nature.
3. The concentration of the trapped substance that is effective, as well as its possible toxicity.
4. Additional procedures that occur throughout the vesicle application/delivery process;

5. The vesicles should have the ideal size, polydispersity, and shelf life for the intended purpose, as well as
6. Batch-to-batch replication and the potential for large-scale manufacturing of safe and effective liposomal good.

3. Preparation of Niosomes

1. Hand shaking method (Thin film hydration technique)
2. Sonication method
3. Ether Injection method
4. Reverse Phase Evaporation (REV)
5. Multiple membrane extrusion method
6. Microfluidization method
7. Bubble method
8. Transmembrane PH gradient drug uptake.

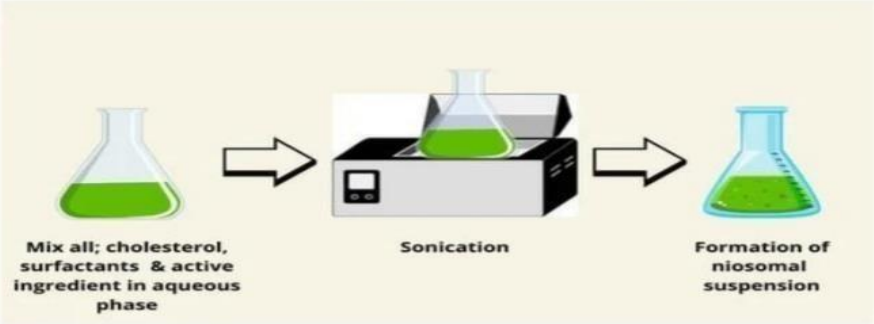

Fig. 4: Sonication method.

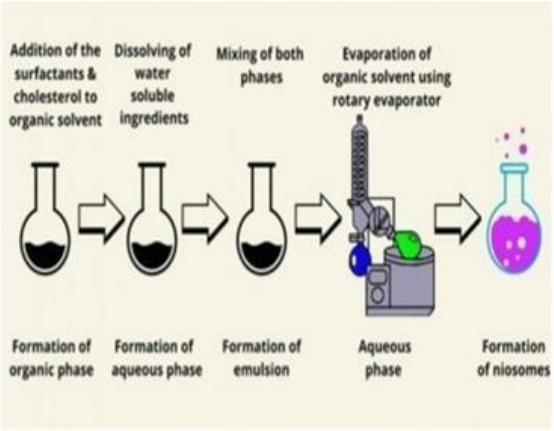

Fig. 5: Ether injection method.

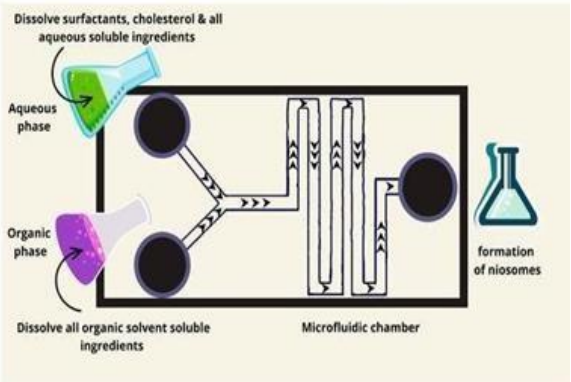

Fig. 6: Microfluidization method.

3. Preparation of MDTs

Various techniques used in the preparation of mouth

Disintegrating drug delivery systems

• Conventional technique

1. Sublimation
2. Freeze drying or Lyophilization
3. Moulding
4. Spry drying
5. Direct compression
6. Mass extrusion

1. Sublimation technique

The mixture is compressed into a tablet after combining inert solid ingredients like urea, urethane, camphor, ammonium carbonate, and naphthalene with additional tablet excipients. Through sublimation, volatile compounds are eliminated, leaving a porous structure. The tablet has adequate mechanical resistance and dissolves in 20 seconds. Highly water-soluble components in traditional compressed tablets frequently face challenges due to the matrix‟s low porosity. As a result, volatile components are used to make the matrix, which is then put through a sublimation process.

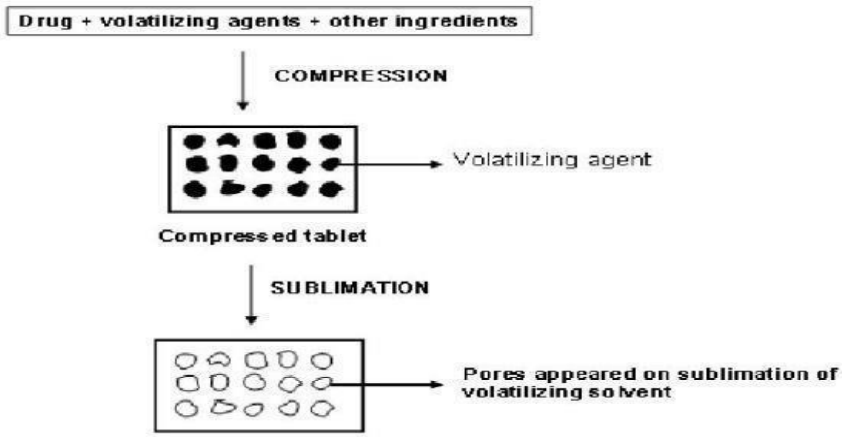

Fig. 7: Step involved in sublimation technique.

2. Freeze – drying (Lyophilization technologies)

Water is sublimated from the product in this process after it has been frozen. Lyophilization, a pharmaceutical technique, facilitates the drying of heat. – biologically and medicinally

sensitive materials at low temperatures under circumstances that allow for water removal via sublimation. Lyophilization is the process that produces the preparation. That have a very high specific surface area and are quite porous, facilitating quick dissolution and improving bioavailability and absorption.

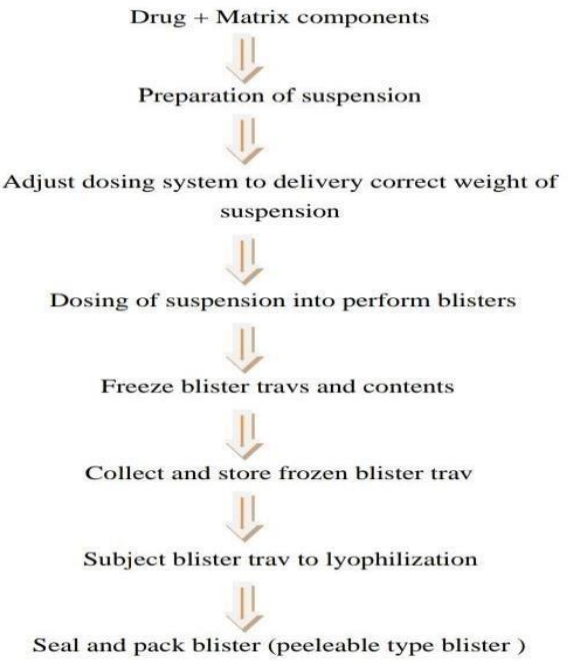

Fig. 8: Steps involved in freeze drying method.

3. Molding method

The water-soluble components of the molded tablet ensure that it breaks down or dissolves completely and quickly. Hydroalcoholic solvents are used to moisten the powder, which is then molded into tablets using less pressure than conventional techniques. These tablets have porous structures that make them easy to dissolve. The tablet‟s mechanical strength can be increased by including sucrose, acacia, or PVP k30, which will facilitate easier dissolution. Additionally, the mechanical strength of the tablet might be increased by the inclusion of sucrose, acacia, or PVP K30.

4. Spray drying technique

The method of spray drying produces very fine, extremely porous powders. Can be made. Spray-dryers are always utilized in the pharmaceutical industry to manufacture extremely porous powders. Using this method, Allen et al. have reported treating the Fast-dissolving tablet manufacturing.[10] The spray drying process can be used to create fast-dissolving tablets this method is used to make tablets that dissolve quickly. Based on a particulate support

matrix produced by watery mixture with support for spray drying. A matrix and other elements that combine to create a very porous and delicate structure powder. This is then combined with the active ingredient, and tablet compressed. Spray produces a tablet that dissolves quickly within 20 seconds, the drying method fell apart.

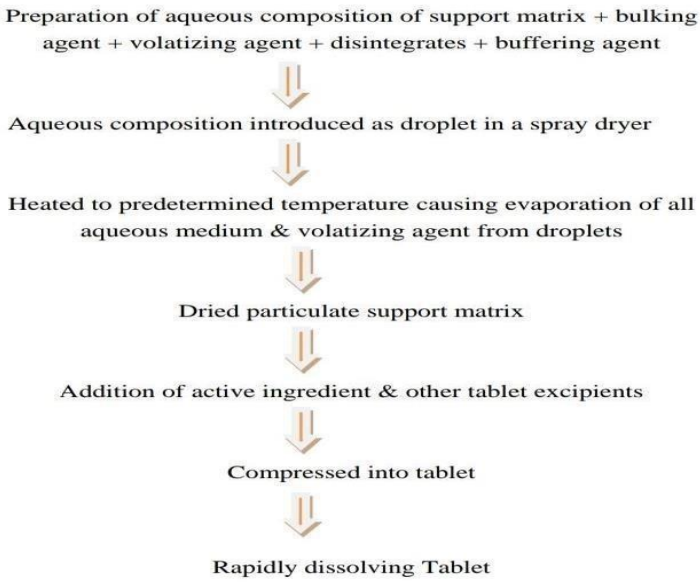

Fig. 9: Steps involved in spray drying technique.

5. Direct compression

Direct compression is a simple and cost-effective table manufacturing method requiring minimal processing. Tablet disintegration depends on excipients, disintegrants, and effervescent agents. Selecting the right type and concentration of disintegrant is crucial for rapid breakdown. Superdisintegrants, effective at low concentrations, improve disintegration efficiency, compressibility, and mechanical strength without adverse effects.

6. Mass Extrusion

In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and thereby masking their bitter taste.

Patented Technologies for Mouth Dissolving Tablets 1. Zydis Technology

The special freeze-dried tablet known as the Zydis formulation physically entraps the medicine or When Zydis units are introduced into the freeze-dried structure breaks down

immediately in the mouth and doesn‟t need water to help ingestion. The Zydis matrix is made up of a variety of materials that are intended to accomplish a variety of things goals. Polymers such as dextran and gelatin are used to give strength and resilience during handling. Or include alginates. These create a shiny, formless structure that gives it its streng.

2. Durasolv Technology

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of drug, filler and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packaged into conventional packaging system like blisters. Durasolv is an appropriate technology for product requiring low amounts of active ingredients.

3. Orasolv Technology

The Orasolv Technology was created at CIMA laboratories. This technology allows active medication to be taste masked. It also has a effervescent disintegrating agent. Tablets are manufactured by direct in order to reduce oral dissolution time, a low compression force compression technique is used. These pills are manufactured using a tablet machine 100 and a traditional blender. The pills the result is a product that is soft and breakable.

4. Flash Dose Technology

Fuisz has received a patent for flash dose technology. A novel form of ibuprofen is the Nurofen melted. Biovail Corporation‟s initial commercial offering is flash dose technologybased melt-in-the-mouth tablets. The self-binding shear form matrix makes up the flash dose tablets. Referred to as “floss.” Flash heat processing is used to create shear form matrices.

5. Wow tab Technology

Wow tab technology is patented by Yamanouchi Pharmaceutical Co. WOW means “Without Water”. In this process, combination of low mouldability saccharides and high saccharides is used obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide (eg.lactose, glucose, and Mannitol), granulated with a high mouldability saccharide (e.g. Maltose, oligosaccharides) and then compressed into tablet.

6. Flash tab technology

The Flash tab technology has been patented by the Prographarm labs. This system is used to prepare tablets. Made up of tiny crystals of an active ingredient. The drug micro granules might by prepared employing the well-known methods of coacervation, microencapsulation, and extrusion spheronization. Conventional tableting technology was used for all processing.

Evaluation of Mouth Dissolving Tablet General Appearance

The general appearances of a tablet include Size, shape, colour, taste, odour, surface Texture.

Size, Shape, Thickness and diameter

The dimensions and form of the tablet can be Described, observed, and regulated. The thickness of tablets is a Crucial attribute for their appearance and also plays a role in counting When using filling equipment. Certain filling equipment employs The consistent thickness of the tablets as a method for counting. Ten tablets were Selected, and their thickness was measured using a vernier caliper.

Uniformity of weight

In the Indian Pharmacopoeia, the procedure for assessing uniformity of weight involved taking ten or twenty tablets, with their weights measured both individually and collectively using a digital weighing balance. The average weight of a single tablet was calculated based on the total weight. The weight variation test serves as an effective method for evaluating the uniformity of drug content.

Hardness of Tablets

Hardness of tablet is defined as the force Applied across the diameter of the tablet in The order to break the tablet. The resistance Of the tablet to chipping, abrasion or Breakage under condition of storage Transformation and handling before usage Depends on its hardness.

Hardness of the Tablet of each formulation was determined Using Monsanto Hardness tester.

Friability of tablets

The fribrater is composed of a plastic chamber that rotates at a speed of 25 revolutions per minute, releasing the tablets from a height of 6 inches with every rotation. The tablets were subjected to rotation in the fribrater for a minimum duration of 4 minutes.

$$\text{Friability (\%)} = \frac{\text{Initial Weight (W1)} - \text{Final Weight (W2)}}{\text{Initial Weight (W1)}} \times 100$$

Wetting time

Take five circular tissue papers of 10 cm diameter and placed them in a petridish with a 10 cm diameter. 10 millimeters of water containing Eosin, a Water-soluble dye, is required to add in petridish. Then place a tablet carefully on the surface of the tissue paper. The time required for water to reach upper surface of the Tablet is noted as a wetting time.

Disintegration time

As described in pharmacopoeia, tablets are placed in the disintegration tube and time is noted. According to the European pharmacopoeia the fast disintegration or dispersible tablets should disintegrate within 3 min without leaving any residue on the screen.

In-vitro dispersion time test

To determine dispersion time take a 10ml of measuring cylinder and pour a 6ml of distill water in it, then drop a tablet in the same. Finally the time required for complete dispersion was determined as a dispersion time.

Future perspective

The future of formulating and evaluating Mouth Dissolving Tablets (MDTs) incorporating liposomes and niosomes is promising and likely to play a major role in advanced drug delivery systems. Both liposomes and niosomes offer innovative solutions to overcome existing challenges in MDTs, such as enhancing drug solubility, stability, and patient compliance.

- Modified-release possible with vesicular systems
- Regulatory advances expected, focus on scalability and commercialization
- Use of nanotechnology, 3D printing, and continuous manufacturing
- Emphasis on advanced imaging and IVIVC

CONCLUSION

Liposomes and niosomes significantly enhance oral drug delivery by improving stability, targeted delivery, and controlled release. These vesicular carriers encapsulate drugs within bilayers, increasing therapeutic efficacy while reducing toxicity. Niosomes, compared to liposomes, offer greater stability, lower cost, and longer circulation time, making them ideal for large-scale MDT applications. Formulation methods like thin-film hydration ensure high drug entrapment, better permeation, and customizable release profiles. Overall, combining

liposomes and niosomes in MDTs provides an effective, safe, and advanced approach for delivering a wide range of therapeutic agents.

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