

Formulation and Evaluation of Mouth Dissolving Tablets of Telmisartan Using Guar Gum as a Natural Superdisintegrant

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ABSTRACT

Mouth dissolving tablets (MDTs) have emerged as an innovative oral drug delivery system designed to improve patient compliance and enhance therapeutic effectiveness, particularly in populations experiencing difficulty in swallowing conventional tablets. Telmisartan, an angiotensin II receptor blocker widely used in the management of hypertension, exhibits poor aqueous solubility and low bioavailability, which can limit its clinical performance. These challenges necessitate the development of alternative formulation strategies to enhance its dissolution and absorption characteristics.

The present review focuses on the formulation and evaluation of mouth dissolving tablets of Telmisartan using guar gum as a natural superdisintegrant. Guar gum, a biodegradable and biocompatible natural polymer, possesses excellent swelling and water absorption properties, which facilitate rapid tablet disintegration and improved drug release. The use of natural superdisintegrants has gained increasing attention due to their safety, cost-effectiveness, and eco-friendly nature compared to synthetic alternatives.

Various formulation techniques such as direct compression, wet granulation, freeze drying, and sublimation are discussed, with emphasis on their impact on tablet properties and performance. The evaluation of MDTs includes pre-compression parameters such as flow properties and compressibility, as well as post-compression parameters including hardness, friability, disintegration time, and drug content uniformity. In-vitro dissolution studies play a critical role in assessing the drug release profile and ensuring improved bioavailability of Telmisartan.

The incorporation of guar gum as a superdisintegrant significantly enhances the disintegration rate and dissolution profile of the tablets, resulting in faster onset of action and improved therapeutic outcomes. Additionally, MDTs offer advantages such as ease of

administration, improved patient compliance, and reduced risk of choking, making them a preferred dosage form in modern pharmaceutical practice.

In conclusion, the formulation of mouth dissolving tablets of Telmisartan using guar gum represents a promising approach to overcome the limitations of conventional dosage forms. This strategy not only improves drug delivery and bioavailability but also aligns with the growing demand for natural and patient-friendly pharmaceutical excipients. Future advancements in formulation techniques and excipient optimization are expected to further enhance the potential of MDTs in oral drug delivery systems.

Keywords: Mouth dissolving tablets; Telmisartan; Guar gum; Natural superdisintegrant; Rapid disintegration; Oral drug delivery; Bioavailability enhancement; Dissolution rate; Patient compliance; Tablet evaluation

I. INTRODUCTION

Oral drug delivery is the most widely accepted and convenient route of drug administration due to its ease of use, cost-effectiveness, and high patient compliance. However, conventional solid dosage forms such as tablets and capsules present certain limitations, especially for paediatric, geriatric, and dysphagic patients who experience difficulty in swallowing. These challenges often lead to poor compliance and reduced therapeutic effectiveness [1,2].

To overcome these limitations, novel oral drug delivery systems such as mouth dissolving tablets (MDTs) have been developed. MDTs are designed to disintegrate rapidly in the oral cavity without the need for water, thereby improving patient convenience and ensuring faster onset of action. These formulations allow drug release in the saliva, which may lead to partial absorption in the oral cavity and enhanced bioavailability [2,3].

The development of MDTs has gained significant attention in recent years due to their ability to combine the advantages of both solid and liquid dosage forms. They provide the stability of solid formulations along with the rapid onset of action typically associated with liquid dosage forms. The efficiency of MDTs largely depends on the selection of suitable excipients, particularly superdisintegrants, which facilitate rapid tablet breakdown upon contact with saliva [3].

In addition to formulation aspects, the physicochemical properties of the drug also play a crucial role in the development of MDTs. Drugs with poor aqueous solubility and slow dissolution rates, such as Telmisartan, require formulation strategies that enhance their dissolution and bioavailability. Incorporation of such drugs into MDT formulations can significantly improve their therapeutic performance [4].

1.1 CONCEPT OF MOUTH DISSOLVING TABLETS

Mouth dissolving tablets are solid dosage forms that disintegrate or dissolve quickly in the oral cavity, usually within a few seconds to a minute, without the need for water. These tablets are designed to release

the drug rapidly, ensuring quick onset of action and improved patient compliance.

1.1.1 Advantages of Mouth Dissolving Tablets

MDTs offer several advantages over conventional dosage forms:

- **Improved patient compliance:** Suitable for paediatric and geriatric patients
- **Rapid onset of action:** Faster drug release and absorption
- **No need for water:** Convenient for on-the-go administration
- **Enhanced bioavailability:** Due to pre-gastric absorption
- **Reduced risk of choking**

1.1.2 Limitation of Conventional Tablets

Conventional tablets have several drawbacks:

- Difficulty in swallowing (dysphagia)
- Slower disintegration and dissolution
- Delayed onset of action
- Reduced bioavailability due to first-pass metabolism

These limitations emphasize the need for advanced formulations like MDTs [2].

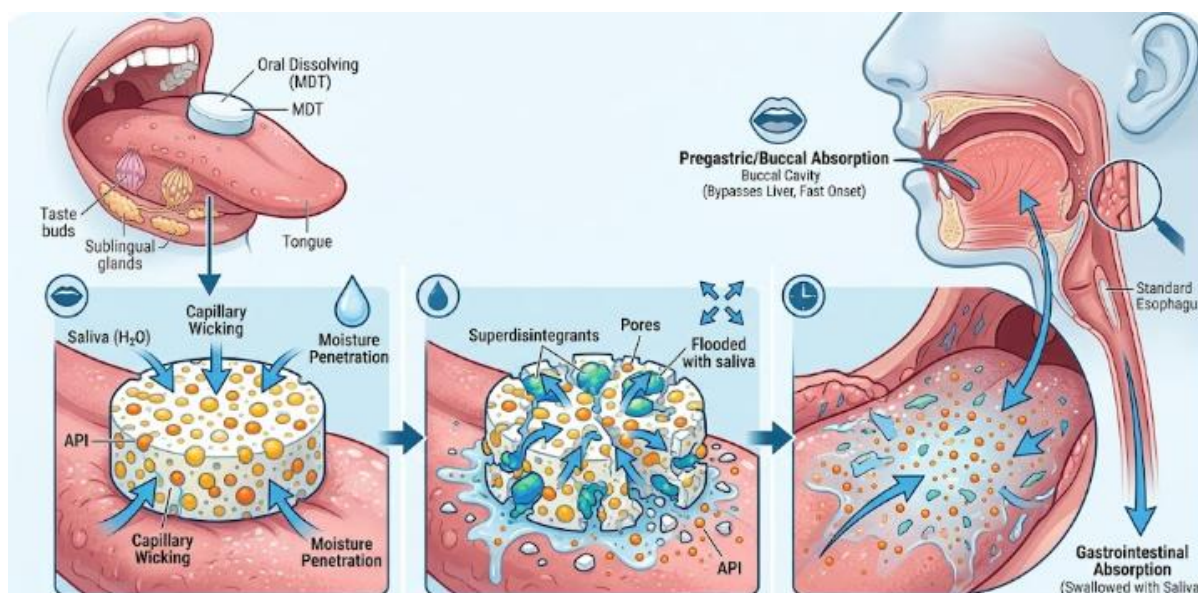


Fig1.1 Concept of Mouth Dissolving Tablet

1.2 TELMISARTAN

Telmisartan is an angiotensin II receptor blocker (ARB) used for the management of hypertension. It helps in lowering blood pressure by preventing vasoconstriction and reducing fluid retention, thereby improving cardiovascular function [4].

1.2.1 Mechanism of Action

Telmisartan exerts its antihypertensive effect by selectively blocking angiotensin II type 1 (AT₁) receptors, which are primarily responsible for mediating the actions of angiotensin II. Normally,

angiotensin II causes vasoconstriction, aldosterone secretion, and sodium and water retention, leading to an increase in blood pressure.

By inhibiting AT₁ receptors, Telmisartan prevents these effects, resulting in vasodilation of blood vessels, reduced peripheral resistance, and decreased blood pressure. It also reduces aldosterone release, thereby limiting fluid retention and contributing to further blood pressure control^[4].

Additionally, Telmisartan does not inhibit angiotensin-converting enzyme (ACE), so it does not interfere with bradykinin metabolism. This reduces the risk of side effects such as dry cough, which are commonly associated with ACE inhibitors. Overall, its targeted mechanism ensures effective and sustained antihypertensive action.

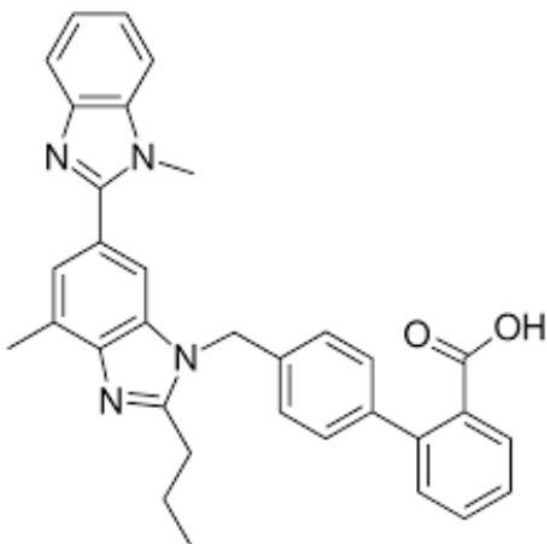


Fig.1.2 Chemical Structure of Telmisartan

1.2.2 Limitations of Telmisartan

- Poor aqueous solubility
- Slow dissolution rate
- Low oral bioavailability

These limitations make Telmisartan a suitable candidate for formulation as mouth dissolving tablets to enhance its therapeutic performance.

1.2.3 Biopharmaceutical Considerations

Telmisartan belongs to Biopharmaceutics Classification System (BCS) Class II, characterized by low solubility and high permeability. Due to its poor solubility, the rate of dissolution becomes the limiting step in drug absorption, which can result in variable bioavailability. Therefore, formulation approaches such as mouth dissolving tablets can

significantly improve its dissolution rate and enhance overall drug absorption^[4].

1.3 ROLE OF SUPERDISINTEGRANTS

Superdisintegrants are key excipients used in the formulation of mouth dissolving tablets (MDTs) to ensure rapid disintegration of the tablet when it comes in contact with saliva. Their primary function is to break the tablet into smaller fragments quickly, thereby increasing the surface area available for dissolution and enhancing drug release^[3].

The efficiency of MDTs largely depends on the type, concentration, and mechanism of action of the superdisintegrant used. An ideal superdisintegrant should possess properties such as high swelling capacity, good hydration ability, compatibility with other excipients, and rapid action at low concentrations^[6].

1.3.1 Mechanism of Superdisintegration

Superdisintegrants facilitate tablet disintegration through different mechanisms:

- Swelling: Absorption of water leads to expansion, causing the tablet to break apart
- Wicking (Capillary action): Draws water into the tablet matrix, leading to rupture
- Deformation recovery: Particles regain original shape after compression, aiding breakup
- Repulsive forces: Electrostatic repulsion between particles helps disintegration

Among these, swelling and wicking are the most common mechanisms involved in MDTs^[3].

1.3.2 Types of Superdisintegrants

Superdisintegrants are broadly classified into:

(a) Synthetic Superdisintegrants

- Crospovidone
- Sodium starch glycolate
- Croscarmellose sodium

These are widely used due to their high efficiency and predictable performance.

(b) Natural Superdisintegrants

- Guar gum
- Chitosan
- Plant-based starches

Natural superdisintegrants are gaining popularity due to their biocompatibility, low toxicity, eco-friendly nature, and cost-effectiveness^[6].

1.3.3 Factors Affecting Superdisintegrant Performance

The performance of superdisintegrants depends on several formulation variables:

- Concentration used in formulation
- Compression force during tablet preparation
- Type of excipients present
- Particle size and distribution

Optimizing these factors is essential to achieve rapid and efficient disintegration.

1.3.4 Importance in MDT Formulation

Superdisintegrants are crucial for:

- Reducing disintegration time
- Enhancing drug dissolution rate
- Improving bioavailability
- Ensuring rapid onset of action

Thus, the selection of an appropriate superdisintegrant is a critical step in the successful development of MDTs.

1.4 Guar Gum as Natural Superdisintegrant

Guar gum is a natural polysaccharide obtained from the seeds of *Cyamopsis tetragonoloba*. It is widely used in pharmaceutical formulations due to its excellent swelling, thickening, and water-absorbing properties. In recent years, guar gum has gained significant attention as a natural superdisintegrant in the formulation of mouth dissolving tablets (MDTs), offering a safe and eco-friendly alternative to synthetic agents [6].

The increasing demand for natural excipients in pharmaceutical formulations is driven by their biocompatibility, low toxicity, biodegradability, and cost-effectiveness. Guar gum fulfills these requirements and demonstrates efficient performance in enhancing tablet disintegration and drug release [7].

1.4.1 Physicochemical Properties

Guar gum possesses several properties that make it suitable for use as a superdisintegrant:

- High swelling index
- Excellent water absorption capacity
- Good binding and disintegrating ability
- Non-toxic and biocompatible nature

These characteristics contribute to its effectiveness in promoting rapid tablet disintegration.

1.4.2 Mechanism of Action

Guar gum primarily acts through the swelling mechanism. Upon contact with saliva, it rapidly absorbs water and swells, generating internal pressure within the tablet matrix. This leads to the breakup of the tablet into smaller fragments, thereby enhancing drug dissolution and release.

In addition to swelling, guar gum may also facilitate wicking action, allowing faster penetration of saliva

into the tablet, which further accelerates disintegration [7].

1.4.3 Advantages of Guar Gum

- Natural and biodegradable
- Safe and non-irritant
- Cost-effective and easily available
- Suitable for large-scale production
- Provides efficient disintegration at low concentrations

These advantages make guar gum a promising candidate for MDT formulations.

1.4.4 Limitations

Despite its benefits, guar gum has some limitations:

- Variation in quality due to natural origin
- Potential microbial contamination
- Sensitivity to environmental conditions (humidity, temperature)

Proper processing and storage conditions are required to overcome these challenges.

1.4.5 Role in MDT Formulation

In MDTs, guar gum significantly contributes to:

- Reducing disintegration time
- Enhancing drug dissolution rate
- Improving overall tablet performance

Its ability to provide rapid and effective disintegration makes it particularly suitable for drugs like Telmisartan, which require improved dissolution for better bioavailability.

II. FORMULATION OF MOUTH DISSOLVING TABLETS

2.1 METHODS OF PREPARATION

2.1.2 Wet Granulation Method

Wet granulation is a widely used method in tablet formulation where powders are converted into granules using a binder solution. In this process, Telmisartan and excipients are mixed thoroughly and then moistened with a suitable binder solution such as polyvinylpyrrolidone (PVP). The wet mass is passed through a sieve to form granules, which are then dried and compressed into tablets.

This method improves flow properties, compressibility, and content uniformity, making it suitable for drugs with poor flow characteristics. However, it involves multiple steps and exposure to moisture, which may not be suitable for moisture-sensitive drugs. Additionally, the process is time-consuming compared to direct compression [8].

2.1.3 Freeze Drying (Lyophilization) Method

Freeze drying is a sophisticated technique used to produce highly porous mouth dissolving tablets. In this method, the drug and excipients are dissolved or dispersed in a suitable solvent, followed by freezing at low temperatures. The frozen mass is then subjected to sublimation under vacuum, where the solvent is removed, leaving behind a porous structure.

The resulting tablets exhibit extremely rapid disintegration and dissolution due to their high porosity. However, the major limitations of this method include high cost, complex processing, and low mechanical strength, making the tablets fragile and difficult to handle [11].

2.1.4 Sublimation Method

The sublimation method involves the incorporation of volatile substances such as camphor, menthol, or ammonium bicarbonate into the tablet formulation. After compression, these substances are removed by sublimation, leaving behind a porous matrix.

This porous structure enhances the penetration of saliva into the tablet, resulting in faster disintegration and improved drug release. Although effective, this method requires careful control of processing conditions and may affect tablet stability if not properly optimized [11].

2.2 EXCIPIENTS USED IN MDT FORMULATION

Excipients play a crucial role in determining the performance, stability, and acceptability of mouth dissolving tablets. Each excipient is selected based on its specific function in the formulation.

2.2.1 Superdisintegrant

Superdisintegrants are the most critical components in MDTs. Guar gum, used as a natural superdisintegrant, enhances tablet disintegration by rapidly absorbing water and swelling.

Its effectiveness depends on concentration and distribution within the tablet matrix. Proper optimization ensures rapid disintegration without compromising tablet strength [6,7].

2.2.2 Diluents

Diluents are used to increase the bulk of the tablet and improve compressibility. Commonly used diluents include:

- Microcrystalline cellulose (MCC)
- Lactose
- Mannitol

Mannitol is particularly preferred in MDTs due to its pleasant mouthfeel and cooling sensation, which enhances patient acceptability. Diluents also contribute to tablet hardness and uniformity [8].

2.2.3 Binders

Binders provide cohesion to the powder blend, ensuring that the tablet remains intact after compression. Examples include:

- Polyvinylpyrrolidone (PVP)
- Starch paste

An optimal amount of binder is required because excessive binding may delay disintegration, while insufficient binding may lead to poor mechanical strength [12].

2.2.4 Lubricants and Glidants

Lubricants such as magnesium stearate reduce friction during tablet compression and prevent sticking to the punches. Glidants like talc improve the flow properties of the powder blend.

Proper use of these excipients ensures smooth manufacturing and uniform tablet weight. However, excessive lubricant can create a hydrophobic layer, which may delay disintegration [12].

2.2.5 Flavouring and Sweetening Agents

Since MDTs dissolve in the oral cavity, taste masking is essential. Sweeteners such as aspartame and mannitol are used to mask the bitterness of Telmisartan.

Flavouring agents like peppermint or orange enhance the overall palatability and patient acceptance. These agents play a significant role in improving compliance, especially in paediatric and geriatric patients.

Selection of Drug (Telmisartan)

↓

Selection of Excipients

↓

Superdisintegrant → Guar Gum

Diluents → MCC / Lactose / Mannitol

Binders → PVP / Starch

Lubricants → Magnesium stearate

Glidants → Talc

Sweeteners & Flavors

↓

Choice of Method of Preparation

↓

1. Wet Granulation

↓

Mix drug + excipients

Add binder solution (PVP)

Form wet mass → Sieve

Dry granules

Compress into tablets

2. Freeze Drying (Lyophilization)

↓

Dissolve/disperse drug + excipients

Freeze at low temperature

Sublimation under vacuum

Formation of porous tablets

3. Sublimation Method



Add volatile (camphor/menthol)

Compress tablets

Remove volatile (sublimation)

Porous structure formed

Tablet Compression



Formulation Considerations



Disintegration Time (30–60 sec)

Mechanical Strength (Hardness/Friability)

Compatibility (FTIR, DSC)



Role of Guar Gum



Rapid swelling

Faster disintegration

Improved dissolution

Enhanced bioavailability

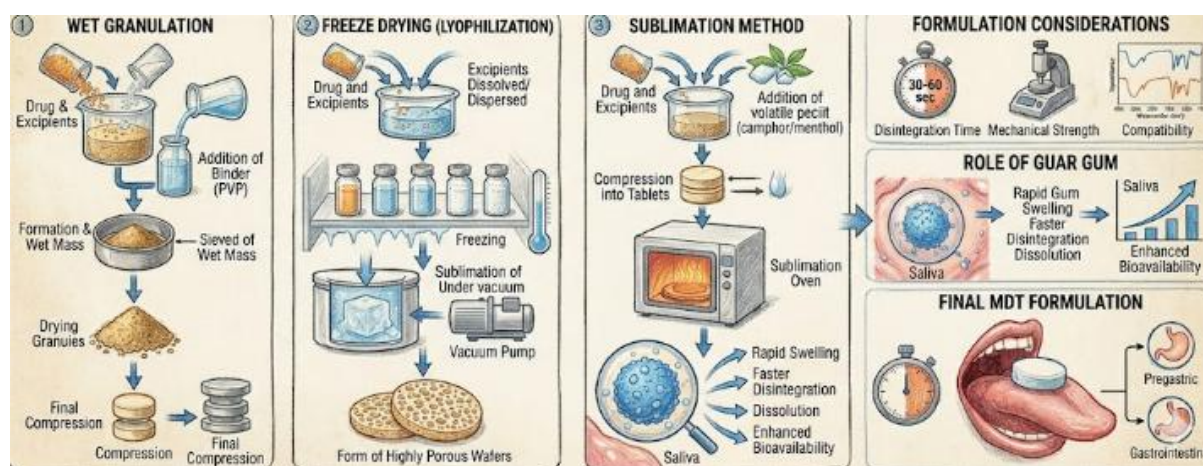


Fig.2.1 Method of Preparation of Mouth Dissolving Tablets

2.3 FORMULATION CONSIDERATIONS

2.3.1 Disintegration Time

Disintegration time is one of the most critical parameters for MDTs. The tablet should ideally disintegrate within 30–60 seconds upon contact with saliva.

Rapid disintegration ensures faster drug release and absorption, which is essential for achieving quick therapeutic action. The type and concentration of superdisintegrant significantly influence this parameter [8].

2.3.2 Mechanical Strength

Mechanical strength refers to the ability of the tablet to withstand handling, packaging, and transportation. It is usually assessed by hardness and friability tests. A balance must be maintained between mechanical strength and rapid disintegration, as higher compression force may increase hardness but delay disintegration. Therefore, optimization is necessary to achieve both properties effectively [12].

2.3.4 Compatibility of Excipients

Drug-excipient compatibility is essential to ensure the stability and effectiveness of the formulation. Incompatibility may lead to:

- Drug degradation

- Reduced efficacy
- Changes in physical properties

Techniques such as FTIR and DSC are commonly used to study compatibility. Ensuring compatibility helps maintain the quality, safety, and shelf-life of the MDT formulation [12].

2.4 ROLE OF GUAR GUM IN FORMULATION

Guar gum plays a significant role in the formulation of mouth dissolving tablets by acting as an efficient natural superdisintegrant. Its high swelling capacity allows rapid uptake of saliva, leading to quick tablet disintegration.

In addition to its disintegrating action, guar gum also contributes to tablet integrity and uniformity. It improves the overall performance of the formulation by enhancing:

- Disintegration rate
- Drug dissolution
- Bioavailability

Moreover, being a natural polymer, guar gum offers advantages such as biocompatibility, safety, and cost-effectiveness, making it a suitable alternative to synthetic superdisintegrants. Its use aligns with the

growing demand for eco-friendly and patient-friendly pharmaceutical excipients ^{16,71}.

III. EVALUATION OF MOUTH DISSOLVING TABLETS

3.1 PRE-COMPRESSION PARAMETERS

Pre-compression evaluation is essential to ensure that the powder blend possesses adequate flowability and compressibility for tablet manufacturing. These parameters directly influence uniform die filling, weight variation, and overall tablet quality.

3.1.1 Bulk Density

Bulk density refers to the mass of powder divided by the bulk volume it occupies before tapping. It provides an understanding of the packing behaviour of the powder particles. A lower bulk density indicates a more porous powder, while a higher value suggests closer packing of particles. This parameter plays a crucial role in determining the amount of powder that can be filled into the die cavity during compression. Proper bulk density ensures uniformity in tablet weight and consistency in drug content across batches ¹³¹.

3.1.2 Tapped Density

Tapped density is measured after mechanically tapping a measuring cylinder containing the powder until a constant volume is achieved. It reflects the ability of the powder to settle and rearrange under external forces. The difference between bulk density and tapped density provides insight into the compressibility of the powder blend. A significant difference indicates poor flow and high compressibility, which may require formulation adjustments. This parameter is also used to calculate Carr's index and Hausner ratio ¹³¹.

3.1.3 Angle of Repose

Angle of repose is a measure of the flowability of powder and is determined by allowing the powder to flow through a funnel to form a conical heap. The angle formed between the surface of the heap and the horizontal plane indicates the flow characteristics. A smaller angle (<30°) suggests excellent flow properties, whereas a larger angle (>40°) indicates poor flow. Good flowability is essential for uniform die filling and consistent tablet production, especially in direct compression methods ¹³¹.

3.1.4 Carr's Index and Hausner Ratio

Carr's index and Hausner ratio are derived parameters used to evaluate the compressibility and flow behaviour of powders. Carr's index is calculated based on the difference between bulk and tapped densities, while Hausner ratio is the ratio of tapped density to bulk density. Lower values of Carr's index (below 15%) and Hausner ratio (below 1.25) indicate

good flow properties. These parameters are critical in predicting the suitability of the powder blend for tablet compression and ensuring uniformity in the final product ¹³¹.

3.2 POST-COMPRESSION PARAMETERS

Post-compression evaluation ensures that the tablets meet the required standards of mechanical strength, uniformity, and performance.

3.2.1 Hardness

Tablet hardness measures the force required to break a tablet and indicates its mechanical strength. It is an important parameter to ensure that the tablets can withstand handling, packaging, and transportation without breaking. However, for mouth dissolving tablets, excessive hardness can delay disintegration, which is undesirable. Therefore, an optimal balance must be maintained between hardness and disintegration time to achieve both durability and rapid action ¹⁹¹.

3.2.2 Friability

Friability testing evaluates the resistance of tablets to abrasion and mechanical stress. It is performed using a friabilator, where tablets are subjected to repeated tumbling. The percentage weight loss after the test should generally be less than 1%, indicating acceptable mechanical strength. High friability may lead to tablet breakage during handling, which affects product quality and patient acceptability ¹⁹¹.

3.2.3 Weight Variation

Weight variation test ensures that each tablet contains a uniform amount of formulation. This is critical for maintaining dose accuracy and therapeutic efficacy. Tablets are individually weighed, and the variation is compared with pharmacopeial limits. Uniform weight indicates proper mixing and consistent die filling during compression.

3.2.4 Thickness

Tablet thickness is measured using a vernier calliper and helps ensure uniformity in tablet size and appearance. Consistent thickness reflects uniform compression force and proper formulation. It also plays a role in packaging and overall product aesthetics.

3.2.5 Drug Content Uniformity

Drug content uniformity ensures that the active pharmaceutical ingredient is evenly distributed in all tablets. It is determined by dissolving a tablet in a suitable solvent and analysing it using spectrophotometric methods. Uniform drug content is essential for ensuring consistent therapeutic outcomes and maintaining product quality ¹⁷¹.

3.2.6 Disintegration Time

Disintegration time is one of the most critical parameters for MDTs. It measures the time required for the tablet to break down into smaller particles in the presence of saliva. Ideally, MDTs should disintegrate within 30–60 seconds. The presence of superdisintegrants like guar gum plays a key role in achieving rapid disintegration by swelling and breaking the tablet matrix [16].

3.2.7 Wetting Time

Wetting time indicates how quickly the tablet absorbs moisture when placed in contact with a liquid medium. It is an indirect measure of the disintegration process. A shorter wetting time suggests faster penetration of saliva into the tablet, leading to rapid disintegration. This parameter is particularly important for evaluating the effectiveness of superdisintegrants.

3.2.8 Water Absorption Ratio

Water absorption ratio measures the amount of water absorbed by the tablet, which directly influences swelling and disintegration. Higher water absorption indicates better swelling capacity of the superdisintegrant, resulting in faster tablet breakup. This parameter helps in understanding the efficiency of the formulation in promoting rapid drug release.

3.3 IN-VITRO DISSOLUTION STUDY

In-vitro dissolution studies are conducted to evaluate the rate and extent of drug release from the tablet. These studies are typically performed using a USP dissolution apparatus under controlled conditions. For drugs like Telmisartan, which have poor solubility, enhanced dissolution is crucial for improving bioavailability. MDTs are expected to release the drug rapidly, ensuring quicker therapeutic action. Dissolution data also help in predicting in-vivo performance and ensuring consistency between batches [10,19].

3.4 STABILITY STUDIES

Stability studies are carried out to determine the effect of environmental conditions such as temperature and humidity on the formulation over time. Tablets are stored under accelerated and real-time conditions, and parameters such as drug content, disintegration time, hardness, and physical appearance are evaluated at regular intervals. These studies help in determining the shelf life and ensuring that the formulation remains stable, safe, and effective throughout its storage period [20].

IV. ADVANTAGES OF MOUTH DISSOLVING TABLETS

Mouth dissolving tablets (MDTs) have emerged as an advanced drug delivery system that overcomes many limitations associated with conventional oral dosage forms. Their unique property of rapid disintegration in the oral cavity without the need for water makes them highly advantageous in modern therapeutics. The benefits of MDTs are not only limited to improved drug delivery but also extend to enhanced patient compliance and overall treatment effectiveness.

4.1.1 Improved Patient Compliance

One of the most significant advantages of MDTs is their ability to improve patient compliance, especially among populations that face difficulty in swallowing conventional tablets, such as paediatric, geriatric, and bedridden patients. Dysphagia is a common issue in these groups, which often leads to non-adherence to medication. MDTs eliminate the need for swallowing intact tablets, as they disintegrate quickly in the mouth, making administration easy and comfortable. This convenience encourages patients to follow prescribed treatment regimens more consistently, ultimately improving therapeutic outcomes [11].

4.1.2 Rapid Onset of Action

MDTs are designed to disintegrate and release the drug rapidly upon contact with saliva, leading to a faster onset of action compared to conventional tablets. The quick breakdown of the tablet increases the surface area available for dissolution, allowing the drug to become available for absorption more rapidly. In some cases, a portion of the drug may be absorbed directly through the oral mucosa, bypassing gastrointestinal transit time. This rapid drug availability is particularly beneficial in conditions where immediate therapeutic action is required [10].

4.1.3 Enhanced Bioavailability

Another important advantage of MDTs is their potential to improve bioavailability. Since the drug is released quickly and may undergo partial absorption in the oral cavity, it can bypass first-pass metabolism to some extent. This results in a higher fraction of the drug reaching systemic circulation in an active form. For poorly soluble drugs like Telmisartan, improved dissolution in MDT formulations further enhances drug absorption, thereby increasing overall bioavailability and therapeutic effectiveness [10].

4.1.4 Convenience of Administration

MDTs provide exceptional convenience as they can be administered without water, making them suitable for use in situations where access to water is limited.

This feature is particularly useful for patients who are traveling, working, or in emergency conditions. The ease of administration enhances patient independence and flexibility, contributing to better adherence and overall treatment satisfaction.

4.1.5 Improved Taste and Patient Acceptance

The incorporation of flavouring agents and sweeteners in MDT formulations significantly improves their palatability. Since these tablets dissolve in the oral cavity, taste plays a crucial role in patient acceptance. By masking the bitter taste of drugs such as Telmisartan, MDTs become more acceptable, especially for children and sensitive patients. Improved taste not only enhances the patient experience but also ensures consistent medication intake.

4.1.6 Reduced Risk of Choking

Conventional tablets may pose a risk of choking, particularly in elderly and paediatric patients. MDTs eliminate this risk by rapidly disintegrating in the mouth, thereby enhancing safety during administration. This feature makes MDTs a preferred choice in populations where swallowing difficulties are common.

4.1.7 Better Therapeutic Efficiency

Due to rapid disintegration, faster drug release, and improved bioavailability, MDTs often provide better therapeutic efficiency compared to traditional dosage forms. The quick onset of action ensures timely relief of symptoms, while consistent drug release maintains effective plasma concentration levels. This overall improvement in drug performance contributes to enhanced treatment outcomes and patient satisfaction.

V. CHALLENGES IN MOUTH DISSOLVING TABLETS

Although mouth dissolving tablets (MDTs) offer numerous advantages, their formulation and development involve several challenges that must be carefully addressed to ensure product quality, stability, and effectiveness. These challenges arise due to the need to balance rapid disintegration with adequate mechanical strength, along with ensuring patient acceptability and large-scale manufacturability.

5.1.1 Mechanical Strength and Fragility

One of the primary challenges in MDT formulation is maintaining sufficient mechanical strength while ensuring rapid disintegration. MDTs are designed to break down quickly in the oral cavity, which often results in a porous and less dense structure. This can make the tablets fragile and more prone to breakage

during handling, packaging, and transportation. Achieving an optimal balance between hardness and disintegration time is critical, as increasing compression force may improve strength but can negatively impact disintegration performance. Therefore, careful optimization of formulation components and compression parameters is required [12].

5.1.2 Taste Masking Difficulties

Since MDTs dissolve directly in the mouth, the taste of the drug becomes an important factor influencing patient acceptance. Many drugs, including Telmisartan, have a bitter or unpleasant taste that can lead to poor compliance if not properly masked. Effective taste masking techniques such as the use of sweeteners, Flavors, coating methods, or complexation strategies are necessary. However, incorporating these techniques without affecting the disintegration time or drug release profile presents a significant formulation challenge.

5.1.3 Stability Issues

MDTs are highly sensitive to environmental conditions, particularly humidity and temperature. Due to their porous nature and the presence of hygroscopic excipients, they tend to absorb moisture from the surroundings. This can lead to premature disintegration, reduced mechanical strength, and potential degradation of the drug. Maintaining stability throughout the product's shelf life requires proper formulation strategies, use of suitable packaging materials, and controlled storage conditions [12].

5.1.4 Manufacturing and Scale-Up Complexity

While methods such as direct compression are relatively simple, advanced techniques like freeze drying and sublimation involve complex processing steps and higher production costs. Scaling up these processes for industrial production can be challenging due to equipment requirements, process variability, and cost considerations. Ensuring uniformity and reproducibility during large-scale manufacturing is essential but often difficult to achieve without proper optimization.

5.1.5 Drug Loading Limitations

Another limitation of MDTs is their restricted drug loading capacity. Incorporating high doses of drugs can increase tablet size and negatively affect disintegration time and mouthfeel. This makes MDTs less suitable for drugs that require higher doses. Formulators must carefully balance drug concentration with excipient composition to maintain both efficacy and patient acceptability.

5.1.6 Specialized Packaging Requirements

Due to their fragile nature and sensitivity to moisture, MDTs require specialized packaging such as blister packs or moisture-resistant containers. These packaging systems increase the overall cost of the product and may require additional handling precautions. Proper packaging is essential to protect the tablets from environmental factors and mechanical damage during storage and transportation.

5.1.7 Patient-Related Factors

Variability in saliva volume and composition among patients can influence the disintegration and dissolution behaviour of MDTs. Conditions such as dry mouth (xerostomia) may delay tablet disintegration, affecting drug release and therapeutic response. Therefore, patient-related variability must be considered during formulation development.

VI. CONCLUSION

The development of mouth dissolving tablets (MDTs) of Telmisartan using guar gum as a natural superdisintegrant represents a promising advancement in oral drug delivery systems. Conventional dosage forms of Telmisartan often suffer from limitations such as poor solubility, slow dissolution, and reduced bioavailability, which can ultimately affect therapeutic outcomes. The MDT approach effectively addresses these issues by enhancing the rate of disintegration and improving drug release characteristics, thereby ensuring faster onset of action and improved patient compliance.

The incorporation of guar gum as a natural superdisintegrant plays a crucial role in achieving rapid tablet disintegration. Its excellent swelling and water absorption properties facilitate quick breakdown of the tablet matrix upon contact with saliva, leading to enhanced dissolution of Telmisartan. In addition to its functional benefits, guar gum offers advantages such as biocompatibility, safety, cost-effectiveness, and eco-friendly nature, making it a suitable alternative to synthetic superdisintegrants.

Furthermore, the formulation and evaluation studies demonstrate that MDTs can be successfully developed with optimal mechanical strength, rapid disintegration time, and efficient drug release profile. The use of appropriate excipients and formulation techniques ensures that the tablets maintain stability while delivering improved therapeutic performance. Evaluation parameters such as hardness, friability, disintegration time, and

dissolution studies confirm the effectiveness and reliability of the developed formulation.

Overall, MDTs of Telmisartan using guar gum provide a patient-friendly, efficient, and innovative dosage form that overcomes the limitations of conventional tablets. This approach not only enhances drug delivery but also improves treatment adherence and patient satisfaction, highlighting its potential for widespread pharmaceutical application.

VII. FUTURE PROSPECTS

The future of mouth dissolving tablets (MDTs) is highly promising, with continuous advancements in pharmaceutical technology and increasing demand for patient-centric drug delivery systems. The use of natural superdisintegrants such as guar gum is expected to gain further attention due to their safety, sustainability, and cost-effectiveness. Ongoing research is focused on identifying and optimizing new natural polymers that can provide enhanced disintegration efficiency and improved formulation performance.

One of the key future directions involves the integration of advanced formulation techniques such as nanotechnology and solid dispersion systems to further improve the solubility and bioavailability of poorly soluble drugs like Telmisartan. These approaches can enhance drug dissolution rates and provide more consistent therapeutic outcomes. Additionally, the development of multifunctional excipients that combine disintegrating, binding, and taste-masking properties may simplify formulation design and improve product efficiency.

Another important area of research is the improvement of taste masking technologies. Since MDTs dissolve in the oral cavity, ensuring pleasant taste and mouthfeel is essential for patient acceptance. Innovative techniques such as microencapsulation, inclusion complexation, and coating methods are being explored to effectively mask the bitterness of drugs without affecting disintegration and drug release.

From an industrial perspective, efforts are being directed toward optimizing manufacturing processes to enable large-scale production of MDTs with consistent quality. The use of cost-effective and scalable techniques like direct compression, along with improved packaging solutions, will play a crucial role in commercialization. Stability enhancement through advanced packaging and formulation strategies is also an important focus area to ensure longer shelf life and product reliability.

Moreover, MDTs have the potential to be widely applied in the delivery of various therapeutic

agents beyond antihypertensive drugs, including analgesics, anti-allergic drugs, and central nervous system agents. Their adaptability and patient-friendly nature make them suitable for a broad range of clinical applications.

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