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Review Article

Review On Efficacy of Chewable Tablets in Improving Oral Drug Delivery

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ABSTRACT

Chewable tablets have gained significant attention as an effective dosage form for enhancing oral drug delivery. They offer several advantages over conventional tablets, including ease of administration, improved patient compliance, and enhanced drug bioavailability. Their rapid disintegration in the oral cavity facilitates pre-gastric absorption, potentially reducing first-pass metabolism for certain drugs. Additionally, advancements in formulation technologies, such as taste-masking, excipient selection, and controlled-release mechanisms, have further improved their efficacy and therapeutic potential. This review provides a comprehensive analysis of the role of chewable tablets in modern drug delivery systems, discussing their formulation strategies, pharmacokinetic implications, clinical applications, and challenges in development. The findings highlight the growing importance of chewable tablets in optimizing drug therapy, particularly for pediatric, geriatric, and dysphagic patients.

INTRODUCTION

Oral drug delivery is the most preferred and widely used route for drug administration due to its ease of use, patient compliance, and cost-effectiveness. However, conventional oral dosage forms, such as tablets and capsules, often pose challenges such as swallowing difficulties, delayed onset of action, and reduced bioavailability due to first-pass metabolism. Chewable tablets have emerged as a promising alternative to address these limitations, offering improved patient acceptability, faster drug absorption, and enhanced therapeutic efficacy. Chewable tablets are designed to be broken down in the mouth before swallowing, allowing for pre-gastric absorption and improved dissolution of active pharmaceutical ingredients (APIs). These tablets are particularly beneficial for pediatric and geriatric patients, as well as individuals with dysphagia, a condition that affects the ability to swallow solid dosage forms. Studies suggest that chewable tablets enhance drug bioavailability by bypassing the first-pass

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metabolism to some extent and improving the dissolution rate of poorly water-soluble drugs Furthermore, they offer a palatable alternative by incorporating flavours and sweeteners, making medication adherence easier for patients The efficacy of chewable tablets in improving oral drug delivery depends on several factors, including formulation strategies, excipients used, and the physicochemical properties of the drug. Recent advancements in pharmaceutical technologies have enabled the development of chewable formulations with optimized disintegration, taste-masking, and stability properties Despite these advantages, challenges such as maintaining drug stability, preventing degradation, and ensuring uniformity in drug content must be addressed to maximize the therapeutic benefits of chewable tablets.

Advantages Of Chewable Tablets
1. Improves bioavailability by avoiding spoilage.
2. Pleasant taste and product differentiation have improved patient acceptance, especially in pediatrics.
3. Suitable for bedridden people, disabled people, travelers, busy people, etc. who do not have water every time.
4. Increased patient comfort; no water required to swallow.
5. For physiological and psychological reasons, children by early childhood usually have difficulty swallowing tablets and capsules. In such cases, chewable tablets are preferred due to their superior patient acceptability (palatableness) and stability
6. The size of the dosage form is difficult to swallow. In such cases, chewable tablets are suitable. The efficacy of the therapeutic is enhanced by the size re duction that occurs while chewing the tablet prior to swallowing.
7. It serves as an ideal drug delivery method for aphasia patients as it reduces the risk of aspiration.
8. Enables effective taste masking along with pleasant mouth feel.
9. Stimulate the flow of saliva in the mouth.
10. Can be used as an alternative to liquid dosage forms when fast acting is required.

Disadvantages of Chewable Tablets
1. Medicines that have a very bad taste cannot be prescribed as chewable tablets.
2. Chewing chewable tablets for a long time can lead to facial muscle soreness
3. Proper packaging is essential to keep the product safe and stable.
4. If not properly formulated, it may leave an unpleasant taste in the mouth.
5. Sweeteners like sorbitol can cause diarrhea and sucrose can cause tooth decay.
6. Chewable tablets require proper packaging for stable drug safety and stability
7. The presence of flavorings can cause ulcers in the mouth. Since it has no mechanical strength, care must be taken when handling it.

Ideal Characteristics of Chewable Tablets
1. Easy to chew.
2. Palatable (flavorful or worthy of flavor)
3. Appropriate size and shape
4. Instant disintegration to promote dissolution
5. All clear dosage forms are the same

6. Easy to swallow even for people who have difficulty swallowing regular tablets and capsules (about once a time)
7. Reduce the risk of drug-induced esophagitis. This occurs when the tablet becomes trapped in the esophagus and dissolves while still in contact with the delicate lining of the esophagus.
8. Tasty and comes in a variety of flavors
9. Easy to take and useful
10. Offered as a single dose, no quote required.
11. Improve consistency
12. Dosage forms that do not require water are: - Easy to carry on the go - Convenient to carry anywhere anytime.

Formulation factors

Various factors such as flow, lubrication, disintegration, organoleptic properties, compressibility, compatibility and stability play a role. Tablets must have acceptable flow ability, compressibility and stability.

Taste and flavor: The product should have an acceptable sweetness and aroma. Physiologically, taste is a sensory response resulting from chemical stimulation of the taste buds on the tongue. The four basic tastes are salty, sour, sweet and bitter. The term flavor usually refers to a specific sense that combines taste and smell. For example, sugar has a sweet taste but no aro ma, whereas honey has a sweet taste and a distinctive odor.

Mouth feels: This term is related to the type of sensation or touch that a tablet produces in the mouth upon chewing. However, for a formulation to be effective, the overall effect in the mouth is important. In general, grit ty (e.g., calcium carbonates) or gummy texture is objectionable, whereas soothing and cooling sensation (e.g., mannitol) with smooth texture is preferred.

Compressibility: When formulating chewable tablets, the powder blend or granules should have the desired flow properties to obtain the final product. Powders/granules should have an optimum compression index to obtain the highest quality final product.

Compatibility: The active pharmaceutical ingredient must be compatible with the excipients in the chewable tablet formulation and compatible with compression. Taste masking: To achieve patient acceptability and compliance, taste-masking methods are applied to mask the bitter or unpleasant taste of active pharmaceutical ingredients/drugs. Oral administration of bitter or unpleasant drugs is often the greatest obstacle for patients mainly for pediatrics and geriatrics. Taste-masking effectiveness is often a key factor in enabling specialized dosage forms such as disintegrating tablets, orally disintegrating films and chewable tablets. The mechanism of taste-masking methods often relies on two main approaches. The first is to add sweeteners, flavors and effervescent agents to overcome the unpleasant taste, and the second is to prevent the interaction of bitter/unpleasant drugs with the taste buds.

The following techniques are used for taste masking:

- Coating by wet granulation
- Microencapsulation
- Solid dispersion
- Inclusion complexes
- Ion exchange
- Spray congealing and spray coating
- Formation of various derivatives or salts
- Use of amino acids and protein hydrolysates
- Molecular complexes
- Melt extrusion
- pH adjustment
- Development of liposomes

- Viscosity adjustment
- Prodrug approach

Excipients used for preparation of chewable tablets

The pharmaceutical industry is constantly striving to meet the therapeutic needs of patients and apart from active ingredients inert excipients play an important role in formulation development. Excipients are substances other than pharmacologically active drugs or prodrugs that are incorporated in the manufacturing process or included in the finished pharmaceut ical dosage form

Diluent: A diluent is a type of filler used to fill the tablet volume when the tablet is not sufficient to fill the volume.

Examples-

- **Mannitol** – Preferred due to its sweet taste, cooling effect, and non-cariogenic properties. **Sorbitol, Xylitol** – Used in sugar-free formulations with sweetness and a smooth mouthfeel.
- **Lactose** – Provides good compressibility but may cause intolerance issues.
- **Microcrystalline Cellulose (MCC)** – Improves tablet structure and mouthfeel.

Binder: Provides cohesion to powdered materials and can be added both dry and wet to form granules

Examples-

- Hydroxypropyl Methylcellulose (HPMC)
- Polyvinylpyrrolidone (PVP)
- Starch & Pregelatinized Starch

Sweeteners: The sweetness profile is adjusted by adding the desired sweetener. Sweeteners are added to improve the palatability of the formulation, especially for chewable tablets.

- **Natural Sweeteners**: Sucrose, glucose, fructose.
- **Artificial Sweeteners**: Aspartame, saccharin, sucralose, stevia.
- **Sugar Alcohols**: Xylitol, sorbitol (provide sweetness and reduce the risk of dental caries)

Table 1: Sweetening agents and their relative sweetness levels

Materials	Relative Sweeteness
Aspartame	200
Glycyrrhiza	50
Saccharin	500
Fructose(laevulose)	1.7
Lactose	0.2
Mannitol	0.5-0.7
Sorbitol	0.5-0.6
Sucrose	1
Cyclamates	30-50
Dextrose(glucose)	0.7
Maltose	0.3

Lubricants: Lubricants prevent ingredients from agglomerating and stick ing to the tablet press

Examples-

- Talcum Powder
- Magnesium Stearate
- Stearic Acid

These are used to facilitate powder flow by reducing friction and agglomeration between particles. Lubricants are basically used in combination with lubricants. These include fumed silica, talc, magnesium carbonate, and more.

Flavor : Flavor is an important excipient in chewable tablets. Flavors are used to impart a pleasant taste and can be used in combination with sweeteners to mask the off-taste of the active ingredient and improve the accept ability of the formulation. Flavors are used based on their intended characteristics and requirements

Table 2: Flavor groups and its taste types

Flavors	Group for testing
Sweet	Vanilla, fruits, maple, stone fruits, berries, grape
Sour (Acidic)	Raspberry, anise, cherry, root beer, cherry, straw berry

Salty	Mixed citrus, butterscotch, maple, nutty, buttery, spice, mixed fruits, butterscotch
Bitter	Coffee, cherry, Liquorice, grapefruit, wine fennel, peach, mint
Metallic	Grape, burgundy, lemon-lime
Alkaline	Chocolate, Mint, cream, vanilla

Colors: Colorants are used to enhance the appearance and organoleptic profile of dosage forms.. FD and C, D and C colors are used. The form of colorant used in the manufacture of chewable tablets depends on the manufacturing process. Coloring agents are commonly used in chewable tablets manufactured by wet granulation process.

Manufacturing

For chewable tablets, manufacturing means proper incorporation of the colouring agent, maintenance of correct moisture content, and achievement of proper tablet hardness. All of these are the routine responsibility of the manufacturer in the department once the parameters have been established during development. The process development and scale up considerations be thoroughly studied in order to ensure the establishment of proper specifications. If colour is added as a lake for direct compression blend, then the blending operation consists of the addition of coloured powder to white granules. So, coloured powder will uniformly coat the white granules. However, during compression, the granules release fresh white material to the surface, resulting in white spots on a coloured background or “speckling”.

Methods of Manufacturing

The Chewable tablets were prepared by using the following methods:

1. Non aqueous Granulation/Dry granulation
2. Aqueous Granulation/Wet granulation
3. Direct compression

1. Dry granulation: This is a new method for semi-automatic production of granules. This method is applicable to all fixed-dose drugs. Dry granulation, also known as pre-compression or double-compression, is a size-en larging process that has been considered to improve the flow and compression properties of powders that are not suitable for compression. In this process the powder mixture is compacted by applying force. This generally increases the size significantly. Dry granulation is typically used to produce tablets where formulation ingredients are prone to flow problems. Manu facture of tablets by the dry granulation process eliminates many unit operations, but includes milling, weighing, mixing, beating, dry sieving, lubricating, and compressing granules into tablets. Dry granulation refers to the process of granulating without the use of liquids. Forming granules using the dry granulation process is generally accomplished by either impact techniques or roller compaction. Slugging involves compacting primary powder particles into large flat pallets using a tablet press, or more commonly a large, heavy-duty rotary press. The resulting compact is then ground using conventional grinding equipment. The ground slag was then passed through a screen of desired mesh size for sizing. After adding lubricant granules, it is finally compressed into tablets. Roller compaction is a relatively simple, efficient and inexpensive form of dry granulation. In this process, the compounding ingredients are passed between two counter-rotating rollers where they are compressed and bonded into a layer of solid mass. The compact is then further ground, sorted, lubricated and compressed into tablets (Figure 1) . Various steps in volved in dry granulation. These are:

- Weighing of ingredients

- Mixing
- Compression of powder into slugs (Pre-compression)
- Milling and sieving
- Mixing with disintegrant and lubricant
- Compression of granules into tablets

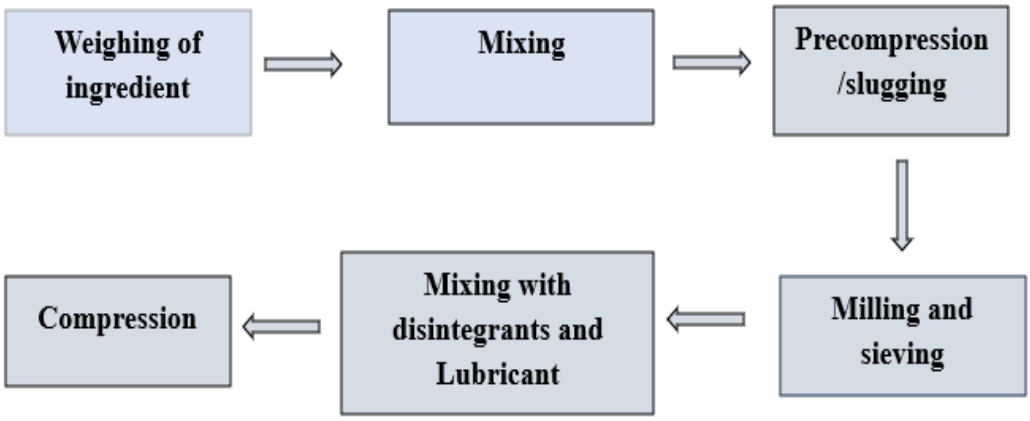

Figure 1: Dry granulation steps

Advantages of Dry granulation method:

- Suitable for moisture-sensitive drugs
- Avoids the need for heat exposure
- Reduces processing time compared to wet granulation

2. Wet granulation

Wet granulation: Wet granulation is the most commonly used granulation method. It uses a suitable non-toxic and volatile granulating fluid such as water, isopropanol or ethanol to agglomerate fine powder particles or into larger, stronger and relatively permanent structures called granules. It's a sizing process. The granulation solution can be used alone or as a solvent with a binder or granulating agent. The choice of granulation fluid is highly dependent on the properties of the material being granulated.

This involves four key mechanism steps:

- Wetting and Nucleation
- Coalescence
- Consolidation
- Attrition or breakage

Mechanism in wet granulation: Steps involved in the wet granulation method for tablet production are:

- Weighing and mixing of ingredients (excluding lubricants)
- Preparation of damp mass by the addition of binder solution
- Screening of damp mass into granules and drying
- Sizing of granules by dry screening
- Lubrication of granules
- Compression of granules into tablets

Advantages Of Wet Granulation Method :

- Improves the uniformity of content
- Enhances compressibility and flow properties
- Reduces dust formation

3. Dry granulation

The dry granulation process is used to form granules without using a liquid solution. This type of process is recommended for products, which are sensitive to moister and heat. Forming granules without moisture requires compacting and densifying the powders

Advantages Dry granulation method :

- Fastest and most cost-effective method
- Requires fewer processing steps
- Minimizes exposure to heat and moisture

Recent Advancements in Granulation Technology for Chewable Tablets

Granulation plays a crucial role in the manufacturing of chewable tablets, as it improves flowability, compressibility, and uniformity of the

final product. Recent advancements in granulation technology have focused on improving process efficiency, reducing energy consumption, and enhancing the quality of chewable tablets. The latest innovations in granulation techniques include:

1. Twin-Screw Granulation (TSG)

Twin-screw granulation is an advanced continuous granulation process that offers better control over granule properties and allows for rapid processing. It is an improvement over conventional wet granulation methods.

Key Features:

- Continuous manufacturing, reducing batch-to-batch variations
- Enhanced control over granule size and porosity
- Reduced processing time and solvent usage

2. Melt Granulation

Melt granulation is a solvent-free alternative to wet granulation that uses lipid-based binders, reducing the need for drying and solvent removal. This method is particularly beneficial for chewable tablets with flavoring agents.

Key Features:

- No need for water or solvents, making it ideal for moisture-sensitive drugs
- Faster processing and lower energy consumption
- Improved taste-masking for chewable formulations

3. Foam Granulation

Foam granulation is an innovative wet granulation method that replaces liquid spray systems with foamed binders, leading to improved uniformity and reduced binder consumption.

4. Roller Compaction with Modified Rollers

Recent advancements in dry granulation include roller compaction with modified roller designs, allowing for better control of granule properties and density.

Key Features:

- Improved compaction efficiency with reduced fines formation
- Better control over granule size and hardness
- Enhanced scalability for continuous manufacturing

5. 3D Printing for Granulation and Tablet Formation

3D printing is an emerging technology that allows for precise control over drug release and dosage forms. It has been explored for chewable tablets to enhance patient compliance, especially for pediatric and geriatric populations.

Key Features:

- Enables on-demand manufacturing of chewable tablets
- Precise control over porosity, drug release, and taste-masking
- Reduces material wastage compared to traditional granulation methods

Evaluation of chewable tablets

Evaluation of chewable tablets includes various physical and chemical par ameters .These are: Physical evaluation: It involve

- Tablet physical appearance and organoleptic characteristics
- Friability
- Hardness
- Weight variation
- Disintegration
- Dissolution

Chemical evaluation: It involves

- Assay
- Drug content uniformity
- In vitro and in vivo evaluation

Physical appearance and organoleptic characteristics: The general appearance, visual identity and overall elegance of all tablets are essential for consumer acceptance. Chewable tablets are evaluated for sensory characteristics such as size, shape, color, odor and taste. For chewable tablets, taste is an important factor in

patient acceptance. Flavors can be attributed to APIs and additives, especially flavorings and sweeteners. One can control the size and state of the tablet by controlling its dimensions. Size and thick ness should be consistent from tablet to tablet and batch to batch. Tablet diameter and thickness can be estimated with vernier calliper. Hardness: Hardness testing is performed to measure the force required to break a tablet on a particular plane. Tablets should be hard enough to with stand the rigors of manufacturing, packaging, transportation, and distribution, but not so hard as to cause chewing problems. It can be measured and expressed in units. An index relating tablet hardness to tablet breaking load was developed to produce a number that can be used to compare the chewability of chewable tablets (Agarwal SP and Khanna R, 2000). Tablet hardness is determined using a hardness analyzer that measures the force required to break a tablet (Figure 2)

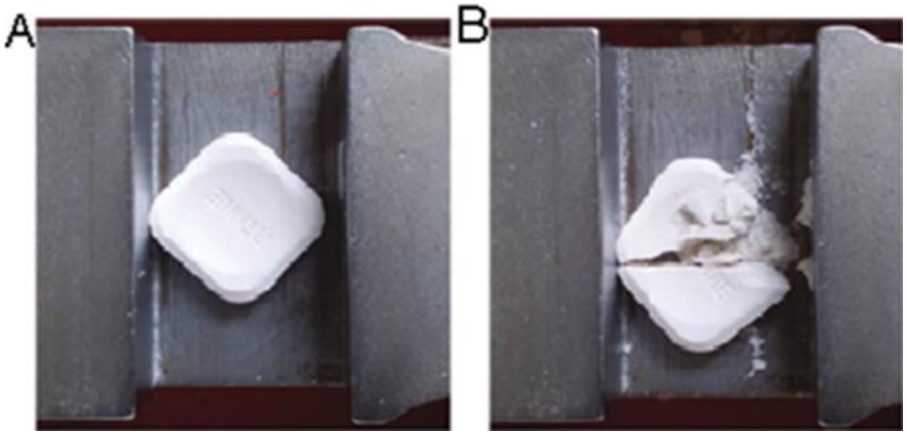

Figure 2: Tablet configuration for breaking force measurement, (A): Tablet before applying the pressure; (B): Tablet after the test (Agar wal SP and Khanna R, 2000)

Friability: Tablet friability can be determined using the Roche friabilator. 10 tablets are weighed and placed in a friabilator rotating at 25 rpm for 4 minutes. Then remove the tablet, dust with powder and weigh again. Tab lets with less than 0.5%-1.0% weight loss are considered acceptable. Also, discard the tablet if capping occurs during the test. The percentage friability of the tablet is calculated by the formula Percentage friability= [(Initial weight-Final weight)/Initial weight] × 100 Weight variation: According to the United States Pharmacopeia (USP) weight variation study, the weight of 20 tablets is regulated by calculating the standard load and comparing the individual tablet load to normal (Ud din M, et al., 2016). Weight grade test values are given in percent. According to the USP, a tablet passes the test if no more than 2 tablets are outside the percentage limit and no tablets are outside the percentage limit by more than twice (Table 3).

Table 3: Weight variation limits for tablets

Average weight tablets (mg)	Maximum % difference limits
130 or less	± 10.0
130 to 324	± 7.50
More than 324	± 5.0

Weight variation=[(Initial weight-Average weight)/Average weight] × 100

Disintegration: Disintegration time is the time it takes for a tablet to break up into small particles. The presence of the right amount and type of dis integrant usually makes it easier for the patient to disintegrate the tablet quickly and chew it completely. In vitro disintegration testing should be performed on intact tablets in a suitable medium using USP disintegration apparatus and methods. Dissolution: Drug absorption from chewable tablets depends on the release of the drug substance from the intact or chewed tablet. In vitro dissolution testing of chewable tablets should follow the principles of conventional Immediate

Release (IR) tablet dissolution testing. During dissolution, the active pharmaceutical ingredient of a chewable tablet should leach sufficiently out of the tablet. For characterization of products under development, in vitro dissolution studies should be performed on intact tablets in at least four media which includes water, pH 1.2 aqueous media, pH 4.5 buffered aqueous media and a buffered aqueous medium at pH 6.8. Consistency of drug content: The drug content of all formulations is assessed by High Performance Liquid Chromatography (HPLC) technique. Powder 20 chewable tablets and accurately weigh 100 mg of powdered drug into a 50 ml volumetric flask. Add 5 ml of methanolic sulfuric acid and shake well. Bring the final volume to 50 ml with methanol. Then filter with filter paper (Whatman) No. 41. The first 10 ml are discarded. 5 ml of the clear filtrate is then pipetted into a 50 ml volumetric flask and made up to 50 ml with methanol. Inject 2 µl of standard solution and sample preparation separately onto the column. The flow rate is maintained at 2 mL/min and estimates are made at 254 nm. Chromatograms are recorded separately for both standard and sample preparations (Table 4).

Tablet 4: FDA chewable tablets guidance-critical quality considerations summary

Attributes	Recommendations
Tablet Hardness	Less than 12 kp, higher hardness values may be considered if justified (e.g., tablet rapidly softens or disintegrates after brief (<30s) exposure to stimulated saliva
Disintegration	Typically, the same specifications as immediate-release tablets; important to determine since some individuals may swallow tablets without chewing
Dissolution	Typically, the same specifications as immediate-release tablets. Does not apply to chewable modified release products
	In vitro dissolution testing should be conducted on intact chewable tablets since some individuals may swallow tablets without chewing
Others	Specific to the individual product (e.g., tablet with functionally coated particles should not be adversely affected by chewing)
	Tablet size, shape, thickness, friability, palatability
	Chewing difficulty index is discussed in the guidance: However limits are not provided

Applications of chewable tablet

Chewable tablets are widely used for different therapeutic purposes, offering advantages such as ease of administration, faster onset of action, and improved patient compliance. Below are the applications of chewable tablets along with relevant references:

1. Local Therapy

- Chewable tablets can deliver active ingredients directly to the oral cavity for local effects.

Common examples include:

- **Antacids** (e.g., calcium carbonate, magnesium hydroxide) for relief from acid reflux and indigestion.
- **Oral hygiene agents** (e.g., chlorhexidine) to prevent plaque buildup and gum infections.
- **Lozenges and throat pain relief** formulations (e.g., benzocaine, menthol).

2. Pain Management

- Chewable tablets provide quick relief by allowing faster absorption in the oral cavity.

Common examples include:

- **Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)** (e.g., ibuprofen, aspirin) for headaches, fever, and minor aches.
- **Acetaminophen (Paracetamol)** chewable formulations for mild to moderate pain.

3. Systemic Therapy

- Used to deliver drugs systemically through gastrointestinal absorption.
- Common examples:
  - **Multivitamins and mineral supplements** (e.g., vitamin C, calcium, iron) for deficiencies.
  - **Anthelmintics** (e.g., albendazole, mebendazole) for deworming therapy.
  - **Antihistamines** (e.g., loratadine) for allergies.

4. Obesity Management

- Chewable formulations can enhance patient compliance in weight management treatments.

Common examples:

- **Orlistat chewable tablets** to reduce fat absorption.
- **Fiber-based chewable supplements** to promote satiety and reduce caloric intake.

Marketed products of chewable tablet

Chewable tablet is one of the most popular dosage forms available in market, used for delivering the active components. The available marketed products of chewable tablet are given below in Table 5

Table 5: Available marketed products of chewable tablets

Brand Name (Drug Name)	Category	Method Used	Method Used	Reference
Tums (Calcium Carbonate)	Antacid	Direct compression	Rapid relief from acid reflux & heartburn	Allen et al., 2013
Mylanta (Magnesium Hydroxide, Aluminum Hydroxide, Simethicone)	Antacid, Anti-gas	Wet granulation	Effective in acid indigestion & gas relief	Lachman et al., 1986
Tylenol Chewable (Acetaminophen)	Analgesic, Antipyretic	Direct compression	Quick pain relief & fever reduction	Patel & Patel, 2016
Advil Chewables (Ibuprofen)	NSAID (Pain relief)	Dry granulation	Rapid absorption & pain relief	USP Monograph
Claritin RediTabs (Loratadine)	Antihistamine	Orally disintegrating formulation	Fast allergy symptom relief	FDA Drug Database
Albendazole Chewable (Zentel)	Anthelmintic (Deworming)	Wet granulation	Effective in treating worm infections	WHO Guidelines, 2021
Orlistat Chewable (Alli)	Anti-obesity	Lipase inhibitor-based formulation	Reduces fat absorption in diet	Bray & Frühbeck, 2014
Calpol Chewable (Paracetamol)	Analgesic, Antipyretic	Direct compression	Provides fever & pain relief	BP Formulary
Supradyn Chewable (Multivitamins)	Nutritional Supplement	Effervescent-based formulation	Enhances absorption of vitamins & minerals	Merck Manual
Zyrtec Chewable (Cetirizine)	Antihistamine	Orally disintegrating technology	Rapid relief of allergic reactions	FDA Drug Approval

CONCLUSION

Chewable tablets play a crucial role in improving oral drug delivery by enhancing patient compliance, ensuring faster drug absorption, and providing a convenient dosage form for various therapeutic applications. Their ease of

administration makes them particularly beneficial for pediatric, geriatric, and dysphagic patients. Additionally, chewable formulations improve the bioavailability of drugs by allowing partial absorption through the oral mucosa, leading to a quicker onset of action. The efficacy of chewable tablets is well established in multiple therapeutic areas, including pain management, systemic therapy, gastrointestinal relief, and obesity treatment. Advances in formulation techniques, such as direct compression, wet granulation, and effervescent technology, have further improved the effectiveness of these tablets. However, challenges such as taste masking, stability, and uniformity in drug distribution need continuous optimization. Overall, chewable tablets provide a promising alternative to conventional solid oral dosage forms, offering improved therapeutic outcomes and better patient adherence. Further research and innovation in excipient selection, drug release mechanisms, and taste-masking technologies will continue to enhance their efficacy and expand their applications in modern pharmacotherapy.

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