

A COMPREHENSIVE REVIEW ON FORMULATION AND EVALUATION OF CHEWABLE TABLET

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ABSTRACT

Chewable tablets are a specialized oral solid dosage form designed to be chewed in the mouth prior to swallowing, offering an effective alternative to conventional tablets. They are particularly advantageous for pediatric, geriatric, and dysphagic patients who experience difficulty in swallowing intact dosage forms. The primary objective of chewable tablet formulation is to enhance patient compliance by improving palatability, ease of administration, and overall acceptability. These tablets are formulated to disintegrate smoothly upon chewing, enabling faster drug release and, in some cases, improved bioavailability. The development of chewable tablets involves the careful selection of excipients such as directly compressible diluents (e.g., mannitol), sweeteners (natural or artificial), flavoring agents, and lubricants to mask the unpleasant taste of active pharmaceutical ingredients and provide a pleasant mouthfeel. The mechanical properties of the tablet, including hardness and low friability, are critical to ensure stability during handling, packaging, and transportation, while still allowing easy chewability. Preformulation and formulation strategies play a vital role in achieving uniform drug distribution, optimal compressibility, and stability. Various manufacturing techniques such as direct compression and wet granulation are commonly employed. Post-compression evaluation parameters including weight variation, hardness, friability, disintegration time, content uniformity, and in vitro drug release studies are essential to assess the quality, safety, and efficacy of the formulation. In conclusion, chewable tablets represent a promising and patient-centric drug delivery system that combines convenience, improved taste masking, and reliable therapeutic performance, making them an important dosage form in modern pharmaceutical development.

KEYWORDS: Chewable tablets, Oral drug delivery, Patient compliance, Taste masking.

INTRODUCTION

Introduction to chewable tablets: Oral route is most preferred route of administration due to its ease of administration, Patient compliance, Patient acceptance, accurate dosing and its cost effectiveness. The research on oral dosage forms is currently focused on improving the palatability and easy of administration especially in case of children and elderly patients.^[1] Chewable tablets which are needed to be broken masticated in between the teeth before ingestion. These tablets are given to the children who have difficulty swallowing and to the grown-ups who dislike swallowing. These tablets are intended to disintegrate easily in mouth at a moderate rate either with or without factual chewing characteristically chewable tablets have a smooth texture upon decomposition, are affable tasting and leave no bitter or unwelcome taste.

These tablets are given to the children who have difficulty in swallowing and to the adults who dislikes swallowing. Chewable tablets have emerge as a promising alternative to address these limitations, offering improved patient acceptability, faster drug absorption enhance therapeutic efficacy. Chewable tablets are allowing for pre- gastric absorption and improved dissolution of active pharmaceutical ingredients. 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.^[3]

Micronized and submicron forms of therapeutically and physiologically active substances increasingly being incorporated into tablet formulations to take advantage of the improved absorption properties of these forms. They are also used in the administration of antacids and carminative. Mannitol is widely used as an excipient in chewable tablets due to its non-hygroscopic properties for moisture-sensitive drugs. Successful development of a tablet formulation requires careful selection of ingredients to create a robust solid dosage form. Selection of appropriate excipients to perform specific functions in tablet formulations. Both natural and synthetic sweeteners are types of functional Excipients commonly used in the formulation of chewable tablets to mask unpleasant tastes and facilitate administration to children.



Fig: Chewable Tablets.

Ideal Characteristics of chewable tablets

1. Easy to chew
2. Appropriate size & shape.
3. Dosage form that do not require water
4. Easy to take on the go.
5. Convenient to take, anywhere & at any time.

6. Palatable
7. Improve consistency.
8. Tasty and comes in a variety of flavors.
9. Are simple & helpful to take.
10. Reduce risk of drug induced esophagitis.
11. Are provided as a single dose so no estimating is required.
12. Easy to swallow even for people who have difficulty swallowing regular tablets & capsules.

Advantages

1. Better absorption characteristics.
2. Patient convenience.
3. Improved understanding acknowledged through lovely taste.
4. Child friendly version.
5. Improves bioavailability by spoilage.
6. Stimulates to saliva in mouth.
7. Enhancing bioavailability by coming about because of expanded ingestion rate, because of its disintegration or being bitten in the mouth into the dissolution.
8. Suitable for bedridden people, disabled people, travelers, busy peoples etc. who do not have water every time.

Disadvantages

1. Bitter tasting drugs are not used for formulation of chewable tablets.
2. Chewing of chewable tablets for long time can lead to facial muscle soreness.
3. Chewable tablets require proper packaging for stable drug safety and stability.
4. The use of more quantity of flavor enhancing agent in chewable tablet may cause ulcer in the oral cavity.
5. The number of chewable tablets is hygroscopic in nature, so they are kept in dry place with correct packaging.
6. Sweeteners like sorbitol can cause diarrhea and sucrose can cause tooth decay.
7. If not properly formulated, it may leave an unpleasant taste in the mouth.

Need for Development of Chewable Tablet

- **Improved patient compliance:** Ideal for pediatric, geriatric, and dysphagic patients who have difficulty swallowing conventional tablets.
- **Ease of administration:** Can be taken without water, making them convenient for on-the-go use.
- **Faster onset of action:** Chewing breaks the tablet into smaller particles, increasing surface area and enhancing drug dissolution.
- **Better palatability:** Taste-masking techniques and flavors improve patient acceptance, especially for bitter drugs.
- **Flexible formulation:** Allows incorporation of sweeteners, flavors, and directly compressible excipients.
- **Reduced risk of choking:** Safer compared to swallowing intact tablets.
- **Improved bioavailability (in some cases):** Pre-dispersed drug may enhance absorption.^[3,8]

Materials or excipients used in chewable

Chewable tablets are designed to be chewed in the mouth before swallowing, requiring a unique combination of excipients to ensure palatability, mechanical strength, rapid disintegration, and patient acceptability. Each excipient category plays a specific functional role in formulation.

1. Diluent/ Chewable base
2. Disintegrant
3. Binder
4. Anti-capping agent
5. Sweetner
6. Tastes masking agent
7. Gliadant
8. Lubricant
9. Colourant

1. Diluent (Chewable Base)

Diluents constitute the major portion of chewable tablets and are essential for providing bulk, improving compressibility, and ensuring a pleasant mouthfeel. Since chewable tablets are intended to be chewed, the choice of diluent significantly affects patient acceptability. Commonly used diluents include mannitol, sorbitol, sucrose, and lactose. Among these, mannitol is most preferred due to its non- hygroscopic nature, sweet taste, and cooling sensation, which enhances the overall organoleptic properties of the formulation.

2. Disintegrant

Disintegrants are incorporated to facilitate the breakdown of the tablet into smaller particles after chewing, thereby promoting rapid drug release and dissolution. They act primarily through mechanisms such as swelling and wicking, which enhance water uptake into the tablet matrix. Common disintegrants used in chewable tablets include crospovidone, croscarmellose sodium, and sodium starch glycolate. Although chewing aids disintegration, the presence of disintegrants ensures complete and efficient drug release.

3. Binder

Binders are added to impart mechanical strength and cohesion to the tablet by promoting adhesion between powder particles. They ensure that the tablet maintains its integrity during handling, packaging, and transportation. Commonly used binders include polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), and starch. However, excessive use of binders can result in harder tablets, which may negatively affect chewability and disintegration.

4. Anti-capping Agent

Anti-capping agents are used to prevent the separation of the top or bottom portion of a tablet, a defect known as capping, which typically occurs due to air entrapment or improper compression. These agents improve the cohesiveness and compressibility of the formulation. Microcrystalline cellulose and pre- gelatinized starch are commonly employed for this purpose. Proper formulation design and optimization of compression parameters also play a significant role in minimizing capping.

5. Sweeteners

Sweeteners are critical in chewable tablet formulations as they enhance palatability and improve patient compliance, especially in pediatric and geriatric populations. They may be natural, such as sucrose and glucose, or artificial, such as aspartame and saccharin sodium. Sugar alcohols like mannitol and xylitol are also widely used due to their low cariogenic potential and pleasant taste. The selection of sweeteners depends on factors such as stability, sweetness intensity, and compatibility with other formulation components.

6. Taste Masking Agents

Taste masking agents are employed to reduce or eliminate the unpleasant taste of active pharmaceutical ingredients. This is particularly important in chewable tablets, as the drug comes into direct contact with taste buds. Taste masking can be achieved through the use of flavors, sweeteners, coating techniques, or complexation methods. Commonly used flavoring agents include peppermint, orange, and strawberry, which help in improving the overall sensory experience.

7. Glidant

Glidants are added to improve the flow properties of powder blends during tablet manufacturing. They reduce interparticle friction and ensure uniform die filling, which is essential for maintaining consistent tablet weight and content uniformity. Common glidants include talc and colloidal silicon dioxide. Their proper use is important for achieving efficient and reproducible manufacturing processes.

8. Lubricant

Lubricants are used to reduce friction between the tablet material and the surfaces of the compression equipment, thereby facilitating smooth tablet ejection and preventing sticking. Magnesium stearate and stearic acid are the most commonly used lubricants. However, excessive use of lubricants may adversely affect tablet hardness and drug dissolution, and therefore must be used in optimal concentrations.

9. Colouring Agents

Colouring agents are incorporated to enhance the visual appeal of chewable tablets and aid in product identification and differentiation. They improve patient acceptability and compliance, especially in pediatric formulations. Commonly used colourants include synthetic dyes such as FD&C colors, iron oxides, and natural colorants. The selection of colouring agents must ensure stability and compatibility with other formulation components.

Tablet Manufacturing Method

- I. Direct Compression Method
- II. Dry granulation
- III. Wet granulation

I. Direct Compression Method

Direct compression is a simple and widely used method for tablet manufacturing in which powdered drug and excipients are directly compressed into tablets without any prior granulation step. In this method, the physical properties of the raw materials are not significantly altered, making it a fast and cost-effective process. Initially, direct compression was limited to a few crystalline drugs that naturally possessed good flowability and compressibility. However, with the development of advanced excipients such as directly compressible fillers and binders, this method is now applicable to a

broader range of drugs. For successful tablet formation, the powder blend must exhibit uniform mixing, adequate flow properties, and good compressibility. Excipients such as diluents, binders, and lubricants play a crucial role in ensuring proper tablet hardness, uniform weight, and mechanical strength.

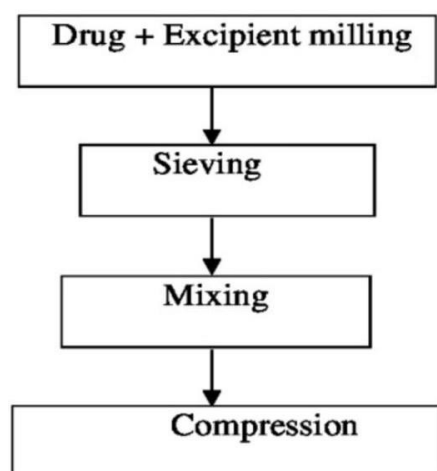


Fig: Direct compression.

II. Dry granulation

Dry granulation is a tablet manufacturing technique used for drugs that are sensitive to moisture and heat, as it does not require the use of liquid binders. In this method, powder particles are aggregated into granules by applying mechanical force, thereby improving flowability and compressibility. Dry granulation can be carried out by two main approaches: slugging and roller compaction.

In the slugging method, the powder blend consisting of drug, fillers, and binders is first compressed into large compacts or slugs using a tablet press. These slugs are then milled, crushed, and sieved to produce granules of uniform size. After this, disintegrants and lubricants are added, followed by final compression into tablets. Although effective, this method is relatively time-consuming and involves multiple processing steps.

In contrast, roller compaction is a more efficient and widely used method. In this process, the powder is fed between two counter-rotating rollers where it is compacted into sheets or flakes under pressure. These flakes are then milled and sieved to produce granules of desired size. The resulting granules exhibit good flow properties, high compressibility, and enable rapid disintegration, making them suitable for tablet formulation.

Dry granulation is applicable to a wide range of materials, including compressible pharmaceutical drugs, excipients, inorganic substances, and dried herbal materials. It is also suitable for the formulation of immediate-release as well as modified (delayed) release dosage forms. Key advantages of this method include shorter processing time (especially in roller compaction) and the production of granules with a more uniform particle size distribution compared to the slugging (slug–deslug) method. This uniformity contributes to improved content uniformity, consistent tablet weight, and enhanced overall product quality.

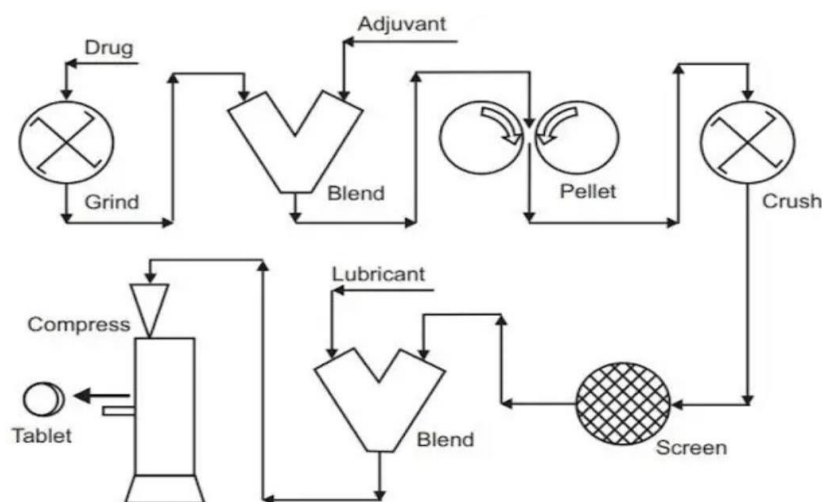


Fig: Dry Granulation.

III. Wet granulation

Wet granulation is a widely used tablet manufacturing technique that enhances the flowability and compressibility of powder blends, making it suitable for compression into tablets. This method involves the use of a non-toxic granulating fluid to agglomerate fine powder particles into larger, dense, and free-flowing granules. It is particularly useful for formulations that exhibit poor flow properties, low bulk density, inadequate compressibility, or lack of binding characteristics, making them unsuitable for direct compression or dry granulation.

In wet granulation, the active pharmaceutical ingredient (API) is mixed with excipients and then wetted using a granulating liquid, which may contain a binder. The wet mass formed is then processed into granules. This technique can be performed using two main approaches. The first is the conventional method, where the powder blend is moistened, passed through a sieve to form granules, and then dried using heat before final sizing. The second method involves the use of a fluid bed processor, in which particles are fluidized, and the granulating liquid is sprayed onto them. The particles are simultaneously agglomerated and dried, resulting in uniform granule formation in a single step.

Depending on the nature of the formulation, either aqueous (water-based) or non-aqueous (organic solvent-based) granulating fluids may be used. Fluid bed granulation is often preferred due to its efficiency, uniformity, and reduced processing time, making it a safer and more economical option in many cases.

Despite its advantages, wet granulation has certain limitations. It is a relatively expensive process due to the need for specialized equipment and multiple processing steps. Additionally, there may be material loss during various stages such as transfer, drying, and milling. However, due to its ability to produce granules with excellent flow and compressibility, wet granulation remains one of the most commonly used methods in pharmaceutical tablet manufacturing.

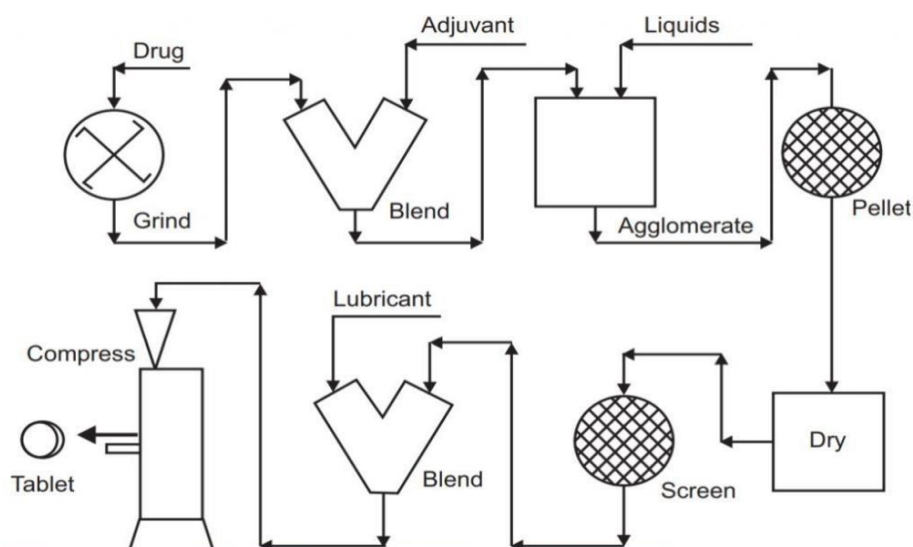


Fig: Wet granulation.

Evaluation Parameters

1. Physical evaluation

a) Organoleptic Properties

Organoleptic evaluation includes appearance, color, odor, taste, and texture, which are critical for patient compliance. Tablets should be uniform, smooth, and free from defects such as cracking, capping, and mottling.

b) Weight Variation

This test ensures dose uniformity by weighing individual tablets and comparing them with the average weight. The results must comply with pharmacopeial limits.

c) Thickness and Diameter

Measured using a vernier caliper, these parameters ensure uniformity in tablet size and proper packaging.

d) Hardness (Crushing Strength)

Hardness indicates the mechanical strength of tablets. Chewable tablets typically exhibit lower hardness ($\approx 3\text{--}6\text{ kg/cm}^2$) to allow easy chewing while maintaining sufficient integrity during handling.

e) Friability

Friability evaluates resistance to abrasion using a friabilator. A weight loss of less than 1% is generally considered acceptable.

f) Disintegration Behavior

Although chewable tablets are intended to be chewed, disintegration testing is performed to ensure that the tablet will break down appropriately if swallowed intact.

g) Palatability and Mouthfeel

Palatability is a critical quality attribute, assessed through taste masking efficiency, sweetness, flavor, and absence of grittiness. Sensory evaluation panels are often used.

2. Chemical Evaluation

a) Drug Content (Assay)

The amount of active pharmaceutical ingredient is determined using analytical techniques such as UV spectrophotometry or HPLC, typically within 95–105% of the labeled claim.

Method: Tablets are weighed, powdered, dissolved in a suitable solvent, filtered, and analyzed using UV spectrophotometry or HPLC.

b) Content Uniformity

This test ensures that individual tablets contain a consistent amount of drug, which is essential for dose accuracy.

c) Dissolution Studies

Dissolution testing evaluates the rate and extent of drug release in a specified medium, ensuring adequate bioavailability even if the tablet is not fully chewed.

Method: The tablet (chewed or intact) is placed in a dissolution apparatus (USP type II – paddle) containing suitable medium. Samples are withdrawn at specific intervals and analyzed using UV or HPLC. Acceptance: Typically $Q \geq 80\%$ drug release within 30–45 minutes (depends on formulation).

d) Stability Studies

Stability testing under ICH conditions (temperature and humidity) determines shelf life and ensures maintenance of physical integrity, potency, and palatability over time.

e) Moisture Content

Moisture analysis (e.g., Karl Fischer method) is important as excess moisture can affect tablet hardness, stability, and microbial growth.

f) pH Measurement

The pH of the dissolved tablet is assessed to ensure drug stability and acceptable taste.

Application of chewable tablet

1. **Pediatric drug delivery:** Palatable dosage form for children to improve compliance.
2. **Geriatric use:** Suitable for patients with dysphagia (difficulty in swallowing).
3. **Antacid formulations:** Provides rapid relief due to faster disintegration in the oral cavity.
4. **Nutraceuticals and dietary supplements:** Used for vitamins, minerals, and health supplements.
5. **Oral health products:** Fluoride tablets and dental care formulations.
6. **Systemic drug delivery:** Enables faster onset of action for certain drugs.
7. **Analgesics:** Pain-relieving medications in chewable form.
8. **Cold and cough preparations:** Easy-to-administer formulations.
9. **Antiemetic and motion sickness drugs:** Convenient administration without water.
10. **Prophylactic therapies:** Used for prevention of nutritional deficiencies and other conditions.

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. The efficacy of chewable tablets is well established in multiple therapeutic areas, including pain management, systemic therapy, gastrointestinal relief and obesity treatment. Chewable tablets are an effective and patient-friendly dosage form designed to improve compliance, especially in pediatric and geriatric populations. They eliminate the need for swallowing whole tablets and provide rapid disintegration in the oral cavity, enhancing convenience and ease of administration. The successful formulation of chewable tablets depends on the proper selection of excipients such as sweeteners, flavoring agents, and directly compressible diluents to ensure acceptable taste, texture, and mechanical strength. Evaluation parameters including hardness, friability, disintegration, and drug release confirm the quality and performance of the formulation. Overall, chewable tablets represent a promising oral drug delivery system with improved palatability, stability, and therapeutic efficacy.

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