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# Exploring the Versality of Chewable Tablets: A Comprehensive Analysis

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**Abstract:**

Chewable dosage forms, such as tablets, soft pills, gums, and chewable squares, are essential components in a pharmacist's toolkit. They are designed to be broken and bitten between the teeth before administration, offering a solution for children struggling with swallowing and adults who find swallowing unpleasant. Chewable tablets are formulated to smoothly disintegrate in the mouth, either through chewing or without, characterized by a pleasant taste and a smooth texture upon disintegration, without any bitter or unpleasant aftertaste. These dosage forms are particularly valuable for geriatric and pediatric patients, as well as for individuals on the move who may not have immediate access to water. The formulation of chewable tablets involves critical factors such as flow, lubrication, disintegration, organoleptic properties, compressibility, compatibility, and stability. While these factors are shared with regularly swallowed tablets, the focus on the sensory aspects of the active drug substances, known as organoleptic properties, becomes a primary concern in chewable formulations. Formulators employ various approaches to achieve an optimal combination of formula and process, prioritizing the development of a product with favorable organoleptic properties. This emphasis on taste and texture makes chewable tablets a valuable option for enhancing medication adherence, particularly in populations facing challenges related to swallowing. In summary, chewable dosage forms play a vital role in addressing the diverse needs of patients, offering a user-friendly alternative for various age groups and situations.

This comprehensive review paper explores the diverse landscape of chewable tablets, presenting a thorough examination of their advantages, disadvantages, ideal characteristics, formulation constituents, preparation techniques, and key evaluating various methods employed in the development of chewable tablets. Furthermore, it investigates the key pre-compression parameters such as Moisture content, angle of repose, Carr's index etc, along with post-compression parameters including hardness, friability, thickness, disintegration, and dissolution etc.

**Keywords:** Tablet, Chewable tablet, Dosage form, Formulation techniques, Evaluations

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## Introduction:

The oral route is the most widely used method for drug administration due to its dosage form versatility and patient adherence. Its preference is attributed to easy dosing, patient acceptance, precise medication quantities, cost-effective manufacturing, and prolonged product stability. Conventional drug delivery systems employ various methods such as tablets, capsules, pills, and liquids as carriers. Solid formulations, in particular, offer non-sterile condition requirements, making manufacturing less costly. This versatility and economic advantage contribute to their prevalence in drug delivery systems, providing effective, patient-friendly means of administering medication.[1]

The oral solid dosage form, particularly tablets, stands out as the most common method of drug delivery due to widespread acceptance and usage compared to capsules. Tablets are favored for reasons such as cost-effectiveness, resistance to temperature variations, ease of handling, packaging, and identification, as well as manufacturing

efficiency. With a history dating back over 150 years since their invention by Thomas Brockedon, tablets have maintained their popularity. The pharmaceutical industry shoulders the responsibility of ensuring tablets exhibit consistent quality across batches, possessing the necessary strength to endure packing, storage, and handling stresses. Additionally, tablets must disintegrate reliably and release drugs in a reproducible manner within the gastrointestinal tract, emphasizing the importance of precision in the manufacturing process to meet the desired therapeutic outcomes.[2]

**Dosage form:**

In pharmaceutical terms, a drug is any chemical entity designed for therapeutic purposes. Since drugs cannot be consumed in their pure state, they are formulated into specific dosage forms for effective administration into the body. Dosage forms represent pharmaceutical products as marketed for use, comprising a combination of active drug components and non-reusable materials that do not fall under the categories of ingredients or packaging. The oral route has gained prominence in the pharmaceutical field due to its advantages, including convenient administration, suitability for solid formulations, and enhanced patient compliance. This emphasis reflects the practical and beneficial aspects of utilizing the oral route for drug delivery.[3]

**Classification of dosage forms:**

Dosage forms are classified on the basis of following ways shown in figure 1:

- On the basis of physical state – solid, liquid, semi-solid, and gas.
- On the basis of route of administration – oral, rectal, transdermal, parenteral, intrarespiratory, intranasal, urethral, vaginal, intraocular, sublingual.
- On the basis of site of application – skin, eye, tooth, hand, foot, nasal, hair.
- On the basis of uses – internal and external.[4]

**Tablets:**

In accordance with the Indian Pharmacopoeia, pharmaceutical tablets are considered unit dosage forms. These solid, flat, or biconvex dishes are formed by compressing drugs, either alone or in combination, with or without additional substances known as excipients. Tablets are defined as compressed solid dosage forms containing medicinal substances, and their characteristics, including shapes, sizes, and weights, depend on the quantity of medicinal components and the intended method of administration. This standardized definition ensures consistency and quality in the production and administration of tablet medications in pharmaceutical practice.

Tablets hold the primary position among prescribed medications due to their widespread use and versatile applications. Their popularity is attributed to several factors, notably ease of administration, uniform dosing, extended stability under diverse storage conditions, and efficient large-scale production. Tablets offer a convenient and familiar method for patients to take medication, ensuring consistent dosage delivery. They encompass various formulations, catering to different therapeutic needs, such as immediate or sustained release, chewable or dissolvable options. This diverse range of tablet types addresses patient preferences and medical requirements, making them a preferred choice for healthcare providers and patients alike.[5]

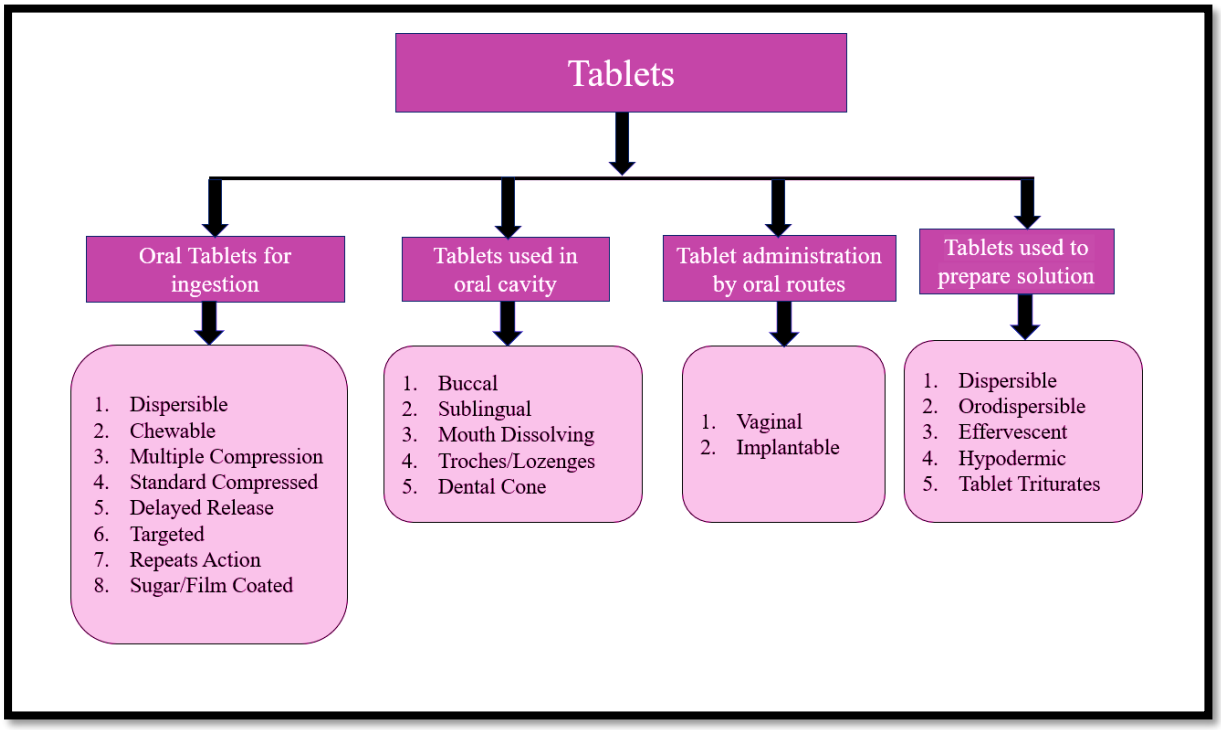


**Table.1:** Classification of Tablets

The formulation of various tablet types serves several purposes, aiming to create a delivery system that is both simple and cost-effective to manufacture, convenient for patients, and streamlined for regulatory approval. Tablets are classified based on their route of administration and the type of drug delivery system they represent within that route. Here's an overview:

1. **Oral Tablets for Ingestion:**[6]
    a. Standard Compressed Tablets
    b. Multiple Compressed Tablets
        - Compression Coated Tablets
        - Layered Tablets
        - Inlay Tablets
    c. Modified Release Tablets
    d. Delayed Action Tablets
    e. Targeted Action Tablets
        - Floating Tablets
        - Colon Targeting Tablets
    f. Chewable Tablets
    g. Dispersible Tablets

**2. Tablets Used in the Oral Cavity:**
    a. Lozenges and Troches
    b. Sublingual Tablets
    c. Buccal Tablets
    d. Dental Cones
    e. Mouth Dissolving Tablets

**3. Tablets Administered by Other Routes:**
    a. Vaginal Tablets
    b. Implants

**4. Tablets Used to Prepare Solutions:**
    a. Effervescent Tablets
    b. Hypodermic Tablets
    c. Soluble Tablets

**Ideal Characteristics of Tablets:**

The primary goal in designing and manufacturing compressed tablets is to ensure the accurate delivery of the appropriate drug amount in the correct form, at the right time and location, while preserving its chemical integrity. Key considerations include:

1. The tablet should exhibit an elegant appearance, devoid of defects.
2. It must possess the strength to withstand mechanical shocks encountered during production, packaging, and shipping.
3. The release of the medicinal agent in the body should occur predictably and reproducibly.
4. Uniformity in weight and drug content is essential.
5. Size and shape influence the tablet's passage through the gastrointestinal tract.
6. Physical and chemical stability is crucial to prevent alterations in the active ingredient over time.

**Advantages of Tablets:**

1. Tablets are unit dosage forms that have the most capabilities of any oral dosage form in terms of dose accuracy and content flexibility.
2. They are the simplest and least expensive to package and strip.
3. It is inexpensive.
4. It is lighter and more compact.
5. Possessing the highest chemical and microbiological stability of any oral dose form.
6. Suitable for mass production.
7. It is easy to swallow and has a low tendency to hang up.
8. The coating process can disguise unpleasant odors and harsh tastes.
9. Enteric coating allows for long-term product release.
10. Simple to use.

**Disadvantages of Tablets:**

1. Challenging for children and unconscious patients to swallow.
2. Certain drugs, due to their amorphous nature or low density, may resist compression into dense compacts.
3. Drugs with poor wetting, slow dissolution, and optimal absorption in the upper gastrointestinal tract (GIT) may pose challenges in formulating tablets while ensuring full drug bioavailability.
4. Bitter-tasting or malodorous drugs, as well as those sensitive to oxygen, may necessitate encapsulation or coating, with capsules potentially offering a more effective and cost-efficient solution.
5. Some solid drugs, such as aspirin, may cause irritation to the gastrointestinal mucosa.
6. Potential bioavailability issues may arise from slow disintegration and dissolution. [7]

**Chewable Tablets:**

Chewable tablets are a pharmaceutical dosage form designed to be broken and chewed between the teeth before swallowing. They are especially beneficial for individuals, particularly children, who face challenges in swallowing traditional pills or for adults with difficulty swallowing. These tablets are formulated to dissolve slowly in the mouth, whether they are chewed or allowed to naturally dissolve, and typically offer a smooth texture upon dissolving. Known for their pleasant taste and absence of bitter or unpleasant aftertaste, chewable tablets provide a more appealing option for individuals who find the act of swallowing challenging.[8]

**Mechanism of Chewable Tablets:**

Chewable tablets operate through a mechanism focused on easy breaking and chewing, rapid disintegration, and smooth dissolution in the oral cavity. Formulated to overcome bitterness, they use taste-masking techniques. Active ingredients are efficiently absorbed through the oral mucosa or transported to the stomach, ensuring therapeutic effectiveness. This user-friendly format enhances patient compliance, making it particularly suitable

for individuals who face challenges swallowing traditional pills, such as children or those with difficulty swallowing. The mechanism combines formulation strategies to optimize drug delivery, providing a convenient and palatable medication experience for a diverse range of users.

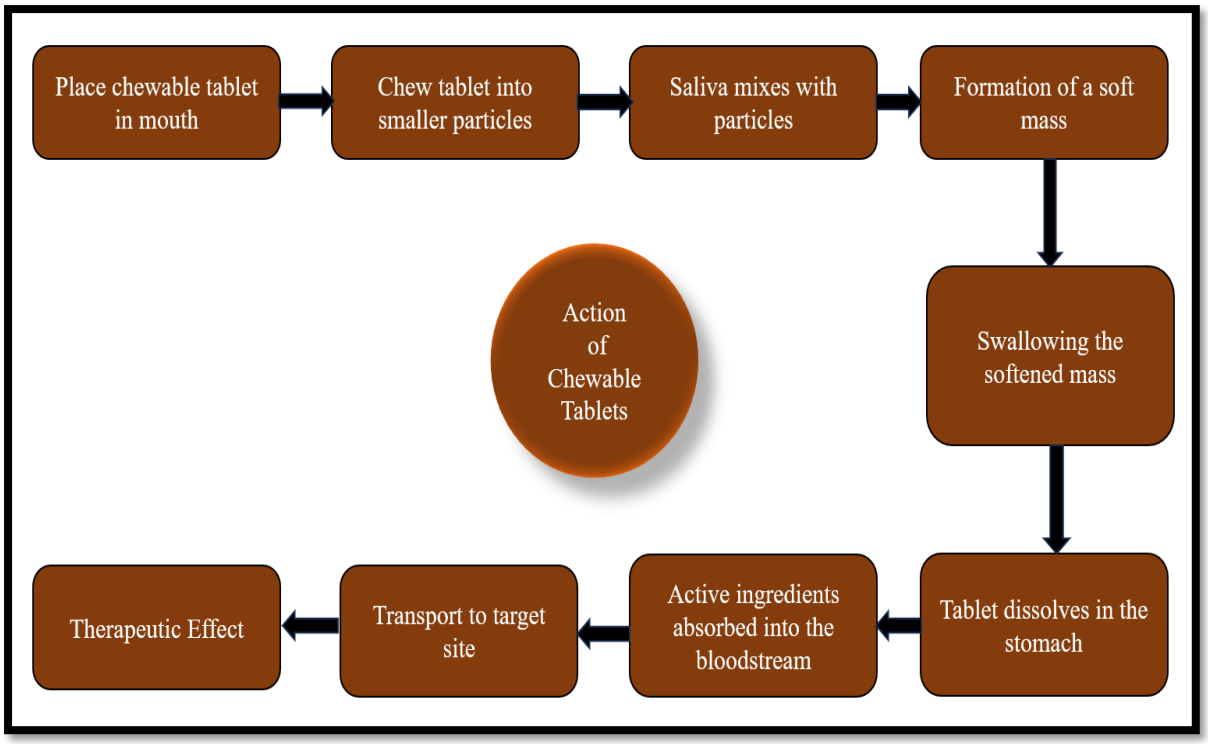


**Fig.2: Action of Chewable Tablets**

**Ideal Characteristics of Chewable Tablets**:

1. Simple to chew.
2. Pleasant in taste or deserving of flavor.
3. Swift disintegration for quick dissolution.
4. Effortless to ingest, especially suitable for individuals experiencing challenges in swallowing standard tablets and capsules.
5. Enjoyable taste, available in various flavors.

**Advantages of Chewable Tablets:**

1. Provides a child-friendly and convenient version for easier administration.
2. Demonstrates superior absorption properties, optimizing the assimilation of medicinal compounds.
3. Enhances bioavailability by accelerating the ingestion rate, whether through swift disintegration or chewing in the mouth.
4. Overcomes challenges associated with swallowing larger forms, particularly advantageous for individuals averse to traditional methods.
5. Amplifies the therapeutic effectiveness of active agents by reducing size through mouth-chewing, eliminating the need for disintegration before swallowing.
6. Ensures better patient compliance, especially for those with difficulties in ingesting conventional forms.
7. Offers a diverse range of flavors, contributing to a more pleasant medication experience.
8. Facilitates quicker onset of action, thanks to the rapid dissolution in the oral cavity.
9. Reduces the likelihood of choking or discomfort during administration, promoting a safer medication intake.
10. Ideal for individuals with taste sensitivity, as the chewable format helps mask any undesirable flavors associated with the active ingredients.

**Disadvantages of Chewable Tablets:**

1. Inclusion of sorbitol can lead to diarrhea and flatulence.
2. Flavors in chewable tablets may induce oral cavity ulcers.
3. Extended chewing of these tablets can cause facial muscle pain.
4. Being hygroscopic, they should be stored in a dry environment.
5. They exhibit fragility and effervescence granules characteristics.
6. Due to limited mechanical strength, cautious handling is necessary.
7. Adequate packaging is essential for the safety and stability of the included drugs.[9]

**Formulation Constituents (Besides API) of Chewable Tablets:**

Tablet formulations typically consist of not only active pharmaceutical ingredients (APIs) but also

various inert materials known as excipients or additives. These excipients serve several purposes in the tablet formulation process, contributing to the stability, manufacturability, and efficacy of the final product. Different types of excipients include:

1. **Disintegrants:** Disintegrants facilitate tablet breakup upon contact with water in the gastrointestinal tract, ensuring effective drug release for absorption.
2. **Diluents:** Diluents are fillers used to increase the bulk of a tablet when the drug dosage alone is insufficient. They also enhance cohesion and facilitate the use of direct compression methods.
3. **Binders:** Binders are employed to form cohesive compacts, especially in directly compressed tablets. They help hold the tablet ingredients together.
4. **Lubricants:** Lubricants aim to prevent tablet materials from sticking to the surfaces of dies and punches during the compression process. They also reduce inter-particle friction and improve granulation flow.
5. **Glidants:** Glidants are added to promote the flow of granules or powder by reducing friction between particles. This enhances the overall flowability of the tablet material.
6. **Anti-adherents:** Anti-adherents are included in tablet formulations to prevent materials from sticking to the walls of the tablet press during manufacturing.
7. **Disintegrants**: Disintegrants are added to facilitate the breaking or disintegration of tablets when they come into contact with water in the gastrointestinal tract. This promotes drug release.
8. **Sweeteners:** Sweeteners in tablets, like sucrose or aspartame, enhance taste, especially in chewable forms. They mask the bitterness of drugs, improving palatability and patient compliance. Various sweeteners, such as xylitol or stevia, cater to different preferences and requirements.
9. **Coloring Agents:** Coloring agents serve multiple purposes, including masking the color of drugs, aiding in product identification, and enhancing the overall appearance of the tablet.
10. **Absorbents:** Absorbents are included in tablet formulations to handle substances with high water affinity. They prevent hygroscopic materials from making the blend wet and challenging to handle during manufacturing.
11. **Flavoring Agents:** Flavoring agents, particularly in the form of oils for chewable tablets, are added to improve the taste and palatability of the product.[10]

**Table 1. List of excipients used in chewable tablet formulations.[3]**

| S. No. | Excipients | Role | Synthetic | Natural |
|---|---|---|---|---|
| 1 | Disintegrants/ Super disintegrants | They facilitate tablet breaking when it comes in contact with water as well as in GIT. | Croscarmellose sodium, crospovidone, SSG, Starch etc. | Fenugreek seed mucilage, Chitin and Chitosan, Guar gum etc. |
| 2 | Binders | Impart cohesiveness to powdered materials. | Gelatin, glucose, lactose, MC, EC, HPMC, starch, povidone, sodium alginate, CMC, Acacia etc. | Rice starch, maize starch, potato starch etc. |
| 3 | Diluents | Make required bulk of tablet, improve cohesion, flow properties, compatibility, and stability. | Lactose, spray dried lactose, MCC, Mannitol, Sorbitol, Dibasic calcium phosphate etc. | Starches, hydrolyzed starches, and partially pre-gelatinized starches etc. |
| 4 | Lubricants | Prevent adhesion of tablet material to surface of dies and punches and reduce inter particulate friction. | Insoluble stearic acid, Magnesium stearate, talc, Paraffin, Sodium benzoate, PEG etc. | Aloe vera, Yogurt, Olive oil, and Virgin coconut oil. |
| 5 | Glidants | Improve flow characteristics of powder mixture. | Colloidal silicon dioxide, Talc etc. | Corn starch |
| 6 | Sweeteners | Produce a palatable dosage form. | Sucrose, Sucralose, Saccharin, Aspartame etc. | Honey, Dates, Coconut sugar etc. |
| 7 | Flavouring agents | Enhance palatability. | Peppermint, Vanilla, Orange, Banana, Mango, Cinnamon etc. | Caraway, Clove, Lemon, Spearmint, Rose etc. |

**Techniques in preparation of Chewable Tables:**

Several methods are employed in the formulation of chewable tablets to ensure they meet the desired characteristics, such as palatability, ease of administration, and effective drug delivery. Here are some common techniques:

**1. Direct Compression:**

Direct compression is a straightforward and cost-effective method for tablet manufacturing, involving fewer processing steps than alternative methods. In this approach, tablets are compressed directly from a uniform powder mix of active ingredients and

excipients that can flow smoothly through dies to form a film compact. This simplicity makes direct compression an efficient and popular choice in pharmaceutical manufacturing. The method is particularly advantageous when the active ingredients and excipients exhibit good flow and compressibility properties, allowing for a streamlined process of tablet formation without the need for intermediate granulation steps. The direct compression process minimizes production costs, reduces manufacturing time, and is well-suited for drugs that are sensitive to heat or moisture, ensuring the preservation of their stability and efficacy.[11]

The production of tablets using the direct compression method involves a limited number of sequential steps:

- Pre-milling of Ingredients: This initial step includes the preparation of the active pharmaceutical ingredients (API) and other necessary components.
- Mixing of All Ingredients: The next stage involves the blending of the pre-milled ingredients, ensuring a homogeneous mixture.
- Compression: The final step entails the compression of the thoroughly mixed ingredients, forming tablets ready for subsequent processing or packaging.[11]

**2. Dry granulation:**

Dry granulation is a pharmaceutical manufacturing method employed to enhance the flow and compression characteristics of powders in tablet formulation, particularly beneficial for moisture or heat-sensitive materials. The process involves two primary techniques: slugging and roller compaction. In slugging, the powder blend undergoes initial compression into large tablets or slugs using a tablet press, followed by milling or crushing to produce granules. Roller compaction, on the other hand, utilizes counter-rotating rollers to compress the powder into a thin ribbon, subsequently broken into granules. Dry granulation offers advantages such as simplicity, cost-effectiveness, and avoidance of liquid binders, making it suitable for moisture-sensitive substances. However, it may generate dust in the slugging method, potentially leading to particle segregation, while roller compaction, although more complex, allows for continuous processing and better control over granule characteristics. The choice between these techniques depends on factors like particle size requirements, production scale, and the specific properties of the materials involved.[12]

**3. Wet granulation:**

Wet granulation is a fundamental pharmaceutical manufacturing process employed to enhance the characteristics of powder mixtures for tablet formulation. In this method, a liquid binder, often water or a solvent, is added to the powder blend, facilitating the formation of granules through particle agglomeration. The process typically involves weighing and mixing of raw materials, wet massing to create cohesive granules, screening or sizing to achieve uniformity, followed by drying to eliminate moisture. Dry screening may then be employed to attain the desired particle size distribution. Lubrication is often added to improve granule flow, and the final step involves compressing the granules into tablets using a tablet press. While wet granulation is effective in producing granules with favorable flow and compression properties, its drawbacks include additional processing steps and potential challenges with moisture-sensitive materials. Despite these considerations, it remains a widely utilized method in the pharmaceutical industry for achieving optimal tablet characteristics.[13]

**Evaluation parameters for chewable tablet:**

The formulation of chewable tablets requires careful consideration of various evaluation parameters to ensure the final product meets the desired standards for safety, efficacy, and patient acceptability. Key parameters to be mindful of during the formulation process include:

❖ **Pre-compression parameters:**

1. **Moisture Content:** The moisture content of the granulate batches is determined using a Halogen Moisture Analyzer. Samples are taken immediately after blending and after exposure to 65% relative humidity for 8 hours. One-gram samples are analyzed in the apparatus, and the procedure is repeated twice, with results expressed as the average of three determinations.
2. **Angle of Repose:** The angle of repose (θ) is determined using the funnel method. A funnel is secured at a fixed height above a graph paper, and the granulate is poured until the apex of the conical pile touches the funnel's tip. The angle of repose is calculated using the formula: $\theta = \tan^{-1}(h/r)$, where h is the height and r is the radius of the conical pile.
3. **Bulk Density:** Bulk density (ρb) is determined by pouring the granulate into a 10 ml graduated glass cylinder. Excess granulate is leveled off with a spatula, and the bulk density is calculated by dividing the weight of the granulate by the volume.
4. **Tapped Density:** Tapped density (ρt) is determined by tapping a graduated glass cylinder containing a known weight of granulates for a fixed time period. Tapped density is obtained by dividing the weight of granulate by the minimum volume of granulate after tapping.
5. **Carr's Index:** Carr's index (C) is used to predict compressibility and ease of flow. It

is calculated using the formula C = (ρt - ρb) / ρt * 100, where ρt is the tapped density and ρb is the bulk density. This index provides insights into the compressibility and flow characteristics of the granulate.[14]

6. **Hausner Ratio:** The Hausner ratio, an index indicating the ease of flow of powder or granulates, is calculated as the ratio of tapped density to bulk density (ρt/ρb). Values around 1.2 indicate good granulate flowability, while values greater than 1.6 suggest poor flowability and cohesive properties. [14,15,16]

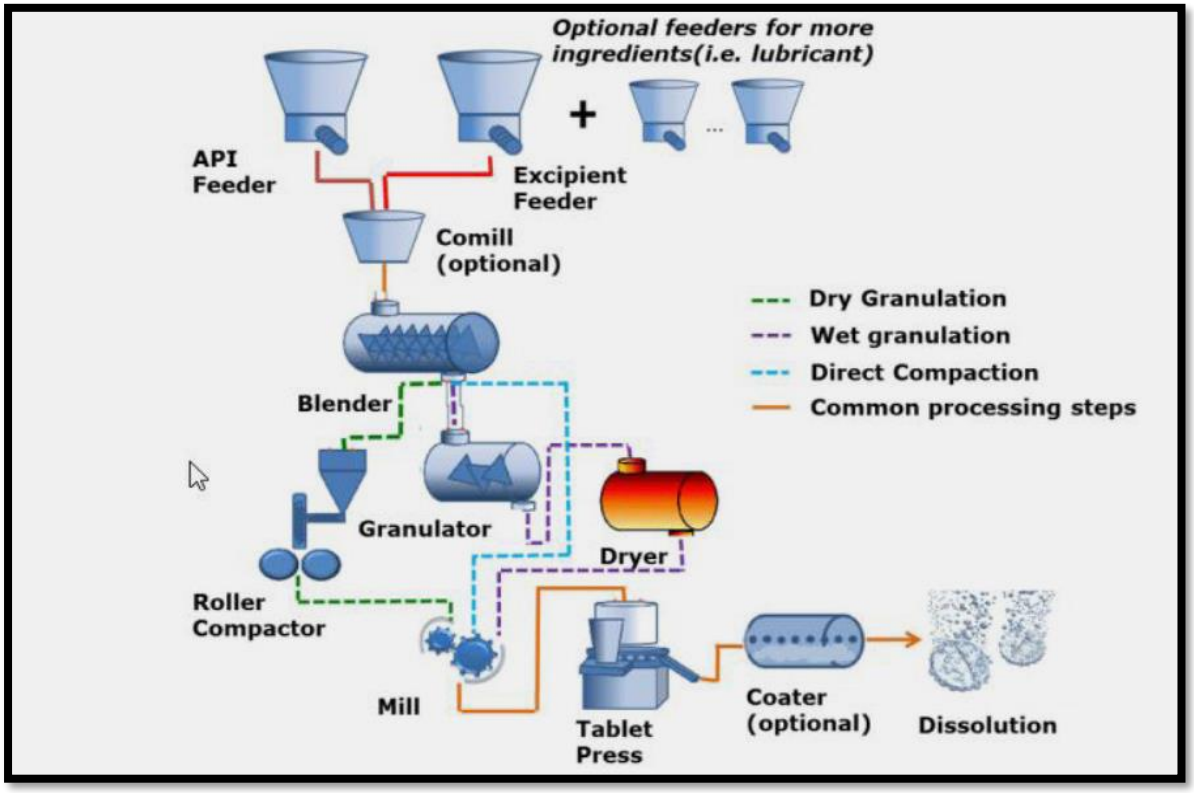


Fig. 3: Steps involved in direct compression method of tablet manufacturing

❖ **Post compression parameters:**

Post-compression parameters are critical aspects evaluated after the tablet compression process to ensure the quality, performance, and stability of the final product. These parameters provide insights into the characteristics of the tablets and help in assessing whether they meet the required specifications. Key post-compression parameters include:

1. **Appearance:** The appearance evaluation parameter in tablet manufacturing refers to the visual characteristics of the tablet, encompassing its overall identity, elegance, shape, color, and surface textures.
2. **Tablet thickness:** Tablet thickness is determined using vernier calipers on a sample of 10 tablets. Measurements are taken at multiple points, and the mean thickness ± standard deviation is calculated, ensuring uniformity and adherence to pharmaceutical quality standards in millimeters (mm).
3. **Hardness:** Tablet hardness, indicating strength and resistance to capping or breakage, is measured using a Monsanto hardness tester. Ten randomly selected tablets from the batch undergo testing, with results expressed in kg/cm2, ensuring quality and durability assessment.
4. **Weight variation:** For weight variation in tablets, randomly select a sample, weigh each tablet, calculate the mean weight, and define an acceptable range. Assess percentage from the mean for each tablet to ensure uniformity and comply with quality standards.
5. **Friability Test:** Friability testing assesses tablet durability during packing and transit. Tablets are rotated in a drum with a baffle, simulating handling stress. Broken tablets are inspected, and the percentage of mass lost through chipping is calculated for quality control.
   It is calculated using the formula:
   Friability (%) = (Initial Weight− Final Weight / Initial Weight) × 100
6. **Wetting time:** Wetting time of a tablet is determined by placing it on a piece of tissue paper in a petri dish containing a specified volume of a wetting solution. The time taken for the tablet to become completely wetted is measured. Lower wetting time

indicates better water penetration and wettability of the tablet, often crucial for efficient disintegration and drug release.

7. **Disintegration test:** Content uniformity refers to the consistent distribution of the active ingredient in pharmaceutical dosage forms. Content uniformity testing utilizes a content or potency assay to assess the active material's content in various samples taken from different locations within a batch. UV analysis is then employed to determine drug content or uniformity, ensuring consistent quality across the entire batch.
8. **In-vitro drug release (Dissolution apparatus):** In vitro drug release assesses how a drug is released from its formulation in a simulated laboratory environment, replicating conditions outside the body. Common apparatus for this includes dissolution apparatus, where drug-containing products are placed in a dissolution medium, and samples are analyzed over time to understand the release profile.
9. **Stability study:** Stability in pharmaceuticals refers to a drug's ability to maintain its physical, chemical, therapeutic, and toxicological properties within specified limits during storage. Stability studies involve assessing characteristics like appearance, weight gain, thickness, and in vitro release under varying conditions. Results indicate the formulation's stability across different storage conditions, ensuring product integrity. [17,18,19]

**Some marketed formulations of chewable tablet:**
The Chewable Tablet has become one of the most popular dosage forms today, widely employed for delivering various active components. Numerous marketed products of chewable tablets are outlined in Table 2.

**Table.2: Some marketed formulations of chewable tablet:**

| S.NO. | Brand Name | Active Ingredients | Application |
|---|---|---|---|
| 1. | Tylenol | Acetaminophen | Analgesic |
| 2. | Montair | Montelukast | Asthma |
| 3. | Claritin | Loratadine | Antihistamine |
| 4. | Mylanta Gas | Simethicone | Gastric relief |

**Conclusion:**
In conclusion, chewable tablets offer a valuable and patient-friendly alternative in the realm of pharmaceutical formulations. Their unique design facilitates easy administration, particularly for individuals, including children, facing challenges with traditional pill swallowing. The rapid disintegration and pleasant taste contribute to an enhanced user experience, fostering better patient compliance. While there are considerations such as the need for careful handling, potential side effects, and proper storage conditions, the advantages, including improved bioavailability and diversified flavor options, outweigh the challenges. Overall, chewable tablets stand as a versatile and effective option, catering to a wide range of preferences and addressing specific needs in medication delivery.

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