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Review Article

Chewable Tablets as a Patient-Friendly Drug Delivery System: A Comprehensive Review

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ABSTRACT

Chewable tablets are solid dosage forms that disintegrate slowly when chewed or allowed to dissolve in the mouth for local action. Chewable tablets are especially useful in tablet formulations for children and geriatrics. They offer several advantages over conventional tablets, including improved patient compliance, ease of administration, and enhanced drug bioavailability. The ideal characteristics of a chewable tablet are easy to chew, palatable (masked flavor and taste), and of appropriate size and shape. The Major excipients used in chewable tablets include flavor enhancers and sweeteners and these tablets are Manufactured by Wet granulation, Dry granulation or Direct compression methods. The Evaluation tests for chewable tablets includes chemical and physical methods. Physical methods include appearance, hardness, Friability, disintegration, and dissolution, while chemical methods include assay of drug content, dosage uniformity, in vitro and in vivo testing.

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. Common oral drug delivery forms include tablets, capsules, and liquids. [1,2] However, few patients experience difficulty in swallowing of Oral dosage forms. [3] Hence, they are not very convenient. Moreover, the Unpleasant taste of some drugs leads to poor patient compliance [4]. The research on Oral dosage forms is currently focused on improving the palatability and ease of administration especially in case of children and elderly patients. In such cases, fast disintegrating, chewable, sustained release, sublingual and colon targeted tablets serve as good options of the oral tablets. Among these, chewable tablets are the best as they improve the compliance in pediatric as well as in geriatric patients [5].

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Fig 1: Chewable Tablets

Chewable tablets are a widely used dosage form for the delivery of pharmaceutical, nutraceutical, and veterinary active substances. Chewable tablets disintegrate slowly when chewed or allowed to dissolve in the mouth for local action. Chewable tablets are especially useful in tablet formulations for children and geriatrics. [6] Chewable tablets are intended to be chewed in the mouth prior to swallowing and are not intended to be swallowed intact. They facilitate swallowing as the product is initially broken down into particles in the oral cavity The purpose of the chewable tablet is to provide unit dosage form of medication which can be easily administered to infants and children or to the elderly, who may have difficulty in swallowing a tablet intact.[2] These tablets can be consumed with minimal or no water, making them convenient for patients who are bedridden, busy, traveling, or lack access to water, such as children and the elderly. The production of chewable tablets typically involves wet granulation or direct compression, incorporating micronized and submicron forms of active ingredients to enhance absorption [7,8,9].

Ideal Characteristics of Chewable Tablets: Chewable tablets possess a variety of characteristics that make them an appealing choice for Drug delivery.

The ideal features include:[10]

Fig 2: Ideal features

Advantages of Chewable Tablets: [11] Chewable tablets are generally chewed in the mouth prior to swallowing and are not expected to swallow intact. Main purpose of chewable tablet is to provide proper unit dosage form of medication which can easily be administered to children or to the elderly who have difficulty in swallowing a tablet intact.

Chewable tablet has some specific advantages:

Fig 3: Advantages of Chewable Tablets

Disadvantages of Chewable Tablets: [8] There are, of course some limitations to the use of chewable tablets having bad tasting drugs and extremely high dosage level.

Some common disadvantages of chewable tablet are:

Fig 4: Disadvantages of Chewable Tablets

General Formulation Factors: (12) The major formulation factors for Chewable tablets preparation are flow, lubrication, disintegration, organoleptic properties, compressibility, compatibility and stability concerns, these are also common to regular (swallowed) and chewable tablets. The most important here are the organoleptic properties of the active drug substances which are of primary concern.

T**aste and Flavors:** Physiologically, taste is a sensory response resulting from a chemical stimulation of the taste buds on the tongue. There are four basic types of taste;

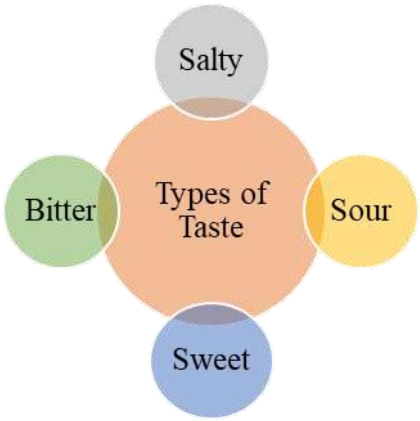


Fig 5: Types of Taste

Salty or sour tastes are derived from substances capable of ionizing in the solution. Many organic medicinal compounds have a bitter response even though they may not be capable of ionizing in an aqueous medium. Most saccharides, disaccharides, some aldehydes and few alcohols give a sweet taste. The substance which doesn't of produce a sensory stimulation to the buds is known as tasteless. For example, sugar has a sweet taste, but no flavor, whereas honey has a sweet taste and a characteristics smell.

Aroma: Pleasant smells are generally referred as aromas. For example, a well formulated, cherry-flavored chewable tablet should have a characteristic sweet taste and aroma of a cherry.

Mouth-feel: This term is related to the type of sensation or touch that a tablet produces in the mouth upon chewing. In general, gritty (e.g., calcium carbonates) or gummy texture is undesirable, whereas soothing and cooling sensation (e.g., mannitol) with smooth texture is preferred.

After Effects: Some irons leave a "rusty" after taste. For example: Saccharin when added in high amounts leaves a bitter after taste. Another common after effect is a numbing sensation of a portion of the whole surface of the tongue and mouth. Bitter antihistamines like pyribenzamine hydrochloride and promethazine hydrochloride are typical of this class drugs.

Taste Masking: [13,14] Taste masking is defined as a reduction of undesirable taste that would otherwise exist. Taste masking can be achieved using taste masking agents, specific flavors and sweeteners. Sweeteners are essential to complete the experience and produce a pleasant taste of the product. This is one of the major limiting factors in the formulation of oral dosage forms having unpleasant taste. Flavor masking and processing approaches are two primary methods to overcome this problem. Flavor masking generally includes addition of flavor, sweetener, lipid and acids.

Techniques for Taste Masking: [13,14] Before formulation some common problems encountered: undesirable taste, bad mouth-feel. The desired product should prevent or minimize stimulation of the taste buds, contain a suitable flavor and sweetener and achieve good mouth feel and compressibility.

The following techniques are used to solve these problems

- Coating by Wet granulation
- Microencapsulation
- Solid dispersions
- Adsorbate Formulation techniques (Solvent method)
- Ion Exchange
- Spray congealing and spray coating
- Formation of different salts or derivatives
- Use of amino acids and protein hydrolysates
- Inclusion complexes
- Molecular complexes

Need for the Development of Chewable Tablet

The need for the development of Chewable tablets depends upon the following factors:

- **Patient Related Factors**: The immediate release tablets offer the combined advantages of ease and convenience of dosing. These tablets are designed to release the medicaments with an enhanced rate.

- Chewable dosage forms are particularly suitable for patients,

  - Very elderly patients who may not be able to swallow a daily dose of antidepressants
  - An eight-year-old with allergies who desires a more convenient dosage form than antihistamine syrup.
  - A bedridden patient who has problem in swallowing the dosage form.

- **Effectiveness Factors:** Increased bioavailability and faster onset of action are the major effectiveness factors. Any pre-gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism.

- **Manufacturing and Marketing Related Factors:** Developing new drug delivery technologies and utilizing them in product development is critical for pharmaceutical industries to survive, regardless of their size. As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation, value added product line extension and extend patent protection, while offering its patient population a more convenient dosage form. This leads to increased revenue, while also targeting underserved and under-treated patient populations.

Excipients used in manufacturing of chewable tablets: [15,16]

1. **Bulking Agents:** They are added to increase the bulk of the Tablet. When mixed along with API they give appropriate weight and size making it easier to compress and produce the tablets.

2. **Mannitol:** It is a commonly used diluent for bulking of chewable tablets. The materials are non-hygroscopic, pure, crystalline, odorless or free-flowing and dormant. imparts a mild cooling sensation due to its negative heat of solution. Mannitol in powder form is suitable for wet granulation along with an auxiliary binder.

3. **Sorbitol:** Sorbitol is a an odorless, white or hazy, crystalline, hygroscopic powder exists as a polyol. It is an isomer of Mannitol and is more Hygroscopic. Sorbitol is used as a diluent in manufacturing of tablets by wet granulation or direct compression. SorbTab (ICI Americas) and Crystalline Tablet Type (Pfizer Chemical) are available for Direct Compression process.

4. **Dextrose:** Dextrose is odorless substance obtained by enzymatic or acid hydrolysis of starch such as maize or maize starch. It is approximately about 70% sweeter than that of sucrose. and is available in both anhydrous (but hygroscopic in nature) and monohydrated forms. Tablet manufactured with dextrose monohydrate requires more amount of lubricant and prone to solidify during initial hours after compression.

5. **Lactose:** It is also known as milk sugar. It is a disaccharide obtained from milk. Lactose is also one of the commonly used as diluent for tablet preparation. Lactose is about 20% sweeter than sugar. Hence it has a very little role in the formulation of chewable tablets. The appropriate pseudo sweetener is required to adjust the sweetness. People with lactose intolerance must should avoid chewable tablets.

6. **Sucrose:** It is commonly used as sweetener and also as a diluent. Modified sucrose have been incorporated into direct compression They are:
- Di-Pac (97% sucrose + 3% changed dextrins),
- Sugartab (90 to 93% sucrose + 7 to 10% modified sugar) and
- NuTab (95% sucrose, 4% modified sugar, and 0.1 to 0.2% every one of corn starch and magnesium stearate)

   Disadvantages: Sucrose is soluble and not a reduced sugar. sucrose gets darker over time and is also hygroscopic which tends to form a textured cake on standing.

7. **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

8. **Flavoring agent:** These excipients are added to often add the flavor, enhance the scent of chewable tablets. These are of various types i.e. water-miscible solutions, oil bases, emulsions, spray-dried beads, dry powders and dry adsorbates.

Table 1: Flavors

Flavors	Group for Tasting Types
Sweet	Vanilla, fruits, maple, stone fruits, berries, grape

Sour (Acidic)	Raspberry, anise, cherry, root beer, cherry, strawberry
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

9. **Sweeteners and taste-improving substances:** [17] When the taste of API cannot be masked by normal carriers like sucrose, lactose, mannitol and dextrose. Other artificial sweeteners are to be employed.

Table 2: Excipients and their sweetness

Materials	Relative Sweetness
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

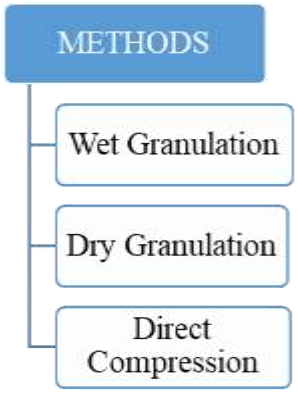
10. **Lubricants:** Lubricants prevent from agglomeration and sticking of ingredients to the tablet press by improving the flow and reducing the friction between particles. They are generally used along with Glidants.

Examples-

- Talcum Powder
- Magnesium Stearate
- Stearic Acid

11. **Colorants:** Colorants are used to improve the overall appearance and the organoleptic properties of the formulation. According to FD&C act 1938, There are Three classes of Coal tar colors. Only the first two classes are used for the manufacture of Chewable tablets. The third class is not suitable to be used in products that are ingested.

Methods for Manufacturing of Tablets: [18,19]



Wet Granulation: One of the most commonly used methods. It utilizes a Granulating fluid such as water, Isopropanol, ethanol to transform the fine powder into Larger, stronger agglomerates called as Granules. The Granulating fluid may be used alone or can be used as a solvent along with binder. In a Traditional Wet granulation practice, the wet mass is forces to pass through a sieve and the wet grains are dried later.

Wet granulation mainly involves 4 mechanisms:

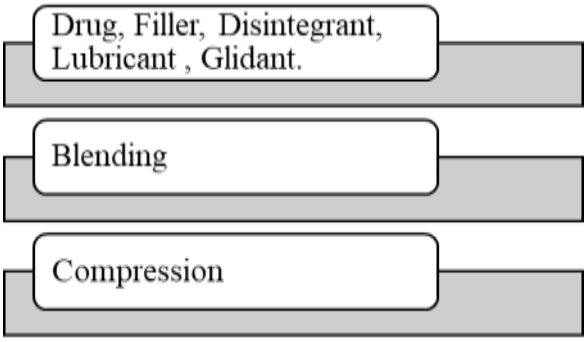
1. Wetting and Nucleation
2. Coalescence
3. Consolidation
4. Attrition or breakage

Dry Granulation: The Dry granulation doesn't use any liquid solution. It is most suitable for the moist and heat sensitive products. It involves a process of Compacting and densifying powders. It improves the flow characteristics of formulation ingredients. In this process the powder blend is compacted by applying force. Granules by using the dry granulation process are formed by either impact or roller compaction techniques. Slugging is a process which involves compacting powder particles primary into large flat pallets using a

tablet press or a heavy-duty rotary press. The resulting compact is then grounded and screened by using desired mesh size. After adding lubricant granules, it is finally compressed into tablets.

Roller compaction is relatively simpler and more efficient for dry granulation. In this process, the blend is passed in between two counter-rotating rollers where they compress the blend into a layer of solid mass. The compact is then further grounded, screened, lubricated and compressed into tablets.

Direct Compression: [20] The term direct compression is used to define the process by which tablets are compressed directly from powder blends of active ingredient and excipients, which flow uniformly in the dies & forms a film compact.



Recent Advancements in Granulation for Chewable Tablets

1. Twin-Screw Granulation (TSG)
2. Melt Granulation
3. Foam Granulation
4. Roller Compaction with Modified Rollers
5. 3D Printing for Granulation and Tablet Formation

Evaluation of Chewable Tablets [21,22]

Chemical Evaluation: It involves the following:

1. Assay of drug content
2. Dosage uniformity
3. In vitro and In vivo Evaluation

Physical Evaluation: It involves the following:

1. Tablet physical appearance
2. Hardness
3. Friability
4. Disintegration
5. Dissolution

Applications of chewable tablet: [12]

1. Local therapy: Chewable tablet can release drug at a controlled rate over an extended period of time thus providing a prolonged local effect**.** Example: Antacids (e.g., calcium carbonate, magnesium hydroxide) to provide relief from acid reflux and indigestion.

2. Pain: Chewable tablet provides quick relief from pain through its faster absorption. Example: Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) (e.g., ibuprofen, aspirin) for headaches, fever, and minor aches.

3. Systemic Therapy: Chewable tablet Used to deliver drugs systemically through GIT. Example: Anthelmintics (e.g., albendazole, mebendazole) for deworming therapy.

4. Smoking Cessation: Chewing gum formulations containing nicotine, lobeline and silver acetate have been clinically tested as smoking cessation aids.

5. Obesity: Several chewing gum formulations containing caffeine, guarana or chromium are available. Caffeine and guarana are centrally acting anorectic agents that increase the metabolic rate.

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