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Review Article

Chewable Tablets: A Comprehensive Review

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A B S T R A C T

Tablets that can be chewed between the teeth must be broken before consumption. These tablets are provided to individuals who like swallowing and to youngsters who have difficulty swallowing. These tablets are designed to dissolve smoothly and quickly in the mouth, either with or without chewing. Typically, chewable tablets have a smooth texture when they dissolve, have a fruity flavour, and leave no bitter or unpleasant taste. Tablets that can be chewed between the teeth must be broken before consumption. These tablets are provided to individuals who like swallowing and to youngsters who have difficulty swallowing. These tablets are designed to dissolve smoothly and quickly in the mouth, either with or without chewing. Typically, chewable tablets have a smooth texture when they dissolve, have a fruity Flavour, and leave no bitter or unpleasant taste. Tablets that can be chewed between the teeth must be broken before consumption. These tablets are provided to individuals who like swallowing and to youngsters who have difficulty swallowing. These tablets are designed to dissolve smoothly and quickly in the mouth, either with or without chewing. Typically, chewable tablets have a smooth texture when they dissolve, have a fruity flavour, and leave no bitter or unpleasant taste.

Keywords: Chewable Tablets, Granulation Techniques. Solid Oral Dosage Forms, Excipients

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INTRODUCTION

Chewable tablets which are required to be broken and chewed in between the teeth before ingestion. These tablets are given to the children who have difficulty in swallowing and to the adults who dislike swallowing [1]. These tablets are intended to disintegrate smoothly in mouth at a moderate rate either with or without actual chewing, characteristically chewable tablets have a smooth texture upon disintegration, are pleasant tasting and leave no bitter or unpleasant taste. Successful tablet formulation development involves the careful selection of ingredients in order to manufacture a robust solid dosage form. Choosing the appropriate excipient to perform a specific function in a tablet formulation such as disintegration or lubrication can be critical to achieving acceptable manufacturing performance. Sweeteners, both naturally occurring and synthetic are one type of functional excipient commonly used in chewable tablet formulations to mask the unpleasant tastes and facilitate pediatric dosing [2,3].Ideally upon chewing, they are broken down in the mouth and release their ingredients in the process and therefore, do not have much lag time as required for the disintegration of tablets before absorption from stomach.

The chewable tablets biting beginnings in the mouth, the tablet is crushed or squashed into mouth with the littler particles from where increment dissolution and ensuing better availability occurs to impact the ideal pharmacologic or patient give beginning of activity. The expanded bioavailability from chewable tablets coming about because of expanded absorption characteristics because of its dissolution or being bitten in the mouth forms littler molecule, for example, expanded surface zone of molecule into GI tract in solution or granule structure is the significant bit of leeway over ordinary strong tablets or capsules which are ingested predominantly after breaking down and dissolution [4]. Chewable tablets are frequently used when it is expected that the active ingredient will act in a therapeutically localized rather than a systemic way.

Chewable tablet is one that is tasteful and could be bitten and ingested with water that is practically small in need. The procedure of chewable tablet is for the most part commonly done by utilizing either granulation or direct pressure. The wet granulation is mostly used to increase flow of granules and improved compressibility characteristics of granules. The direct compression is carryout the active material sensitive to moisture and heat. Progressively consolidating chewable tablet formulation, micronized and submicron types of restorative and physiologically dynamic substances exploit the improved intake qualities of this structure[5].Alternatively, the chewable tablet is used in arranging agents or carminatives for stomach settling. For its non-hygroscopic nature, mannitol is generally used as an excipient in chewable tablet dosage forms for dampness touchy medications.

Ideal characteristics of chewable tablets

1. Simple to bite.
2. Palatable (taste-covered or of worthy taste)
3. Appropriate size and shape
4. Able to break down promptly to encourage dissolution
5. Like all easy to understand dosage forms
6. Are simple to swallow (once bit), in any event, for the individuals who experience challenges swallowing ordinary tablets and capsules
7. Reduce the risk of esophagitis instigated by medication which happens when a tablet is trapped in the esophagus and dissolve while staying in contact with the touchy esophagus lining
8. Taste lovely and arrive in a scope of flavors
9. Are simple and helpful to take
10. Are provided as a single dose so no estimating is required
11. Improve consistence[4]

Advantages of chewable tablets:[6,7]

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:

- Better bioavailability through bypassing disintegration (that increase dissolution).
- Improved patient acceptance (especially Pediatric)through pleasant taste.
- Patient convenience; need no water for swallowing.
- Possible to use as a substitute for liquid dosage forms where rapid onset of action is needed.
- Absorption of drug is faster.
- Product distinctiveness through marketing prospective.
- The large size of the dosage form is difficult to swallow. In such cases chewable tablet offers advantages over it.
- Effectiveness of therapeutic agent is improved by the reduction in size that occurs during mastication of tablet before swallowing.

Disadvantages of chewable tablets:

There are, of course some limitations to the use of chewable tablets having bad tasting drugs and extremely high dosage level. Some disadvantages of chewable tablet are:

- It contains sorbitol which causes diarrhoea and flatulence.
- Flavouring agents present in chewable tablet may causes ulcer in oral cavity.
- Prolonged chewing of chewable tablet results in pain in facial muscles.
- They are hygroscopic in nature, so must kept in dry place.
- They show the fragile, effervescence granules property.
- Since these tablets have insufficient mechanicalstrength, so careful handling is required.
- They require proper packaging for safety and stabilization of stable drugs.

MATERIALS OR EXCIPIENTS USUALLY UTILIZED IN THE ADVANCEMENT OF CHEWABLE TABLETS [8,2]

The pharmaceutical inactive substances other than the active pharmacological ingredients or prodrug which are remember for the assembling procedure or are contained in a current pharmaceutical product. Excipients assume a significant utilitarian role in creating pharmaceutical dosage forms, including:

1. Enhancing bioavailability & solubility of API and excipients
2. Increasing the steadiness of active substance in dose structures
3. Help dynamic fixings keeps up best polymorphic structures or adaptations
4. Stabilize there osmolarity and pH of the liquid formulations
5. Acts to provide anti-oxidants effects, emulsifying characteristics, aerosol propellants, binding properties, and disintegrations.
6. To Prevent separation and aggregation
7. Provide immunogenic responses of active ingredients
8. To provide bulk of the drug

Bulking agent/Diluent:

These are included a chewable tablet formulation to expand the volume of the tablet. When blending in with the medication substance, the final product is given satisfactory weight and size to help with dealing with and creation. Diluents generally utilized in chewable tablets include:

Mannitol:

Mannitol regularly utilized diluent. It is an alluring filler in tablets. At the point where the flavor of a chewable tablet is a significant factor. The material is pure and crystalline, scentless or free-streaming granules that is basically dormant and non-hygroscopic. Because of its negative warmth of solution, sweetness, and ' mouth sound, ' it is usually used as diluent in the assembly of chewable tablet formulations. Mannitol likewise goes about as taste improving specialist,

and is said to be about 70% as sweet as sucrose. The mannitol in powder form is reasonable for wet granulation in mix with an auxiliary binder. For direct pressure process is accessible in granular structure. Mannitol is non-hygroscopic in nature. Mannitol contains low dampness these are generally utilized in dampness delicate drug formulation. mannitol is joined with those identified with sweetness, mouth-feel and non-hygroscopic nature of the powder, represent to noteworthy favorable circumstances for the formulation of chewable tablets.

Sorbitol:

Sorbitol is a polyol that happens as a scentless, white or practically boring, crystalline, hygroscopic powder. sorbitol is utilized as a diluent in tablet plans arranged by either wet granulation technique or direct pressure. For direct pressure, it is accessible economically as SorbTab (ICI Americas) and Crystalline Tablet Type (Pfizer Chemical)Sorbitol is regularly valuable in chewable tablets formulation produce to its charming, sweet taste and give cooling sensation. It is a marginally sweeter and impressively increasingly hygroscopic isomer of mannitol. Sorbitol is progressively hygroscopic as contrast with the mannitol.

Dextrose:

The dextrose is use in tablet formulation as diluent. Dextrose are colourless materials. These have no odour and have sweet taste. Dextrose is obtained by enzymatic or acid hydrolysis of starch. The hydrolysis of starch that incorporate maize or corn starch. Dextrose is utilized as wet granulation as diluent and binder. The dextrose utilized in direct pressure diluent and binder, for example, fundamentally utilized in chewable tablets. Sweetness level of dextrose is roughly 70% of sucrose. It is accessible in monohydrate and unhydrous structure. It is are likewise contrasted as a tablet diluent with lactose. The creation tablet with dextrose monohydrate requires more lubricant and tend to solidify during initial hardly any hours after pressure.

Lactose:

Lactose is otherwise called milk sugar. Lactose is a disaccharide monetarily created from the cows' milk. Lactose is residual fluid of the milk following ches and casein creation. Lactose is commonly used as diluent for tablet formation. It is the commonly used excipients in formation of tablets. The role of lactose in chewable tablets is a small because is a low sweetness. Roughly lactose sweetness is 20% as compared to sugar. This lack requiring the including the counterfeit sweetener of adequate strength to beat lactose's dullness. Lactose utilized chewable tablets are unacceptable for those patients have a lactose narrow minded

Sucrose:

Sucrose is normally utilized in tablets both as a sweetener, diluent, usually through marketing sugar, and folio in wet granulations techniques. The straightforwardly compress sucrose crystals have never been effective yet different altered sucroses have been brought into the direct pressure plan. These incorporate Di-Pac (97% sucrose + 3% changed dextrins), Sugartab (90 to 93% sucrose + 7 to 10% modify sugar) and NuTab (95% sucrose, 4% transform sugar, and 0.1 to 0.2% every one of corn starch and magnesium stearate). The entirety of the sucrose-based diluent and binding agent discover application in direct pressure tablet methods for chewable tablets, especially the counterfeit sweetening agent are to be stayed away from. Sucrose has more impediments as a filler. Sucrose isn't a decreasing sugar however with soluble materials. It is goes to dark colored with time. It is likewise hygroscopic and tends structure cake on standing.

Flavouring agent:

Flavouring agent are key excipients of chewable tablets. Seasoning operator are generally used to give lovely taste and enhance and frequently scent to chewable tablets. They are included solids as spray dried beadlets and oils. Flavouring agent are typically including the oil step, in light of the fact that this material touchy to the dampness and these materials propensity to volatilize quickly when warmed, for example, during drying of wet granules. water-soluble(aqueous) flavors have discovered little acknowledgment because of their lesser stability after maturing. The oxidation reaction reduces the flavor consistency, usually oils are emulsified with dried acacia and spray. Dry flavors are simple to take care of, and are steadier than oils on a regular basis. Oils are generally diluted in alcohol and sprayed into the granulation as they fall into a tub of lubrication. Different sorts and gathering of flavors for general benchmark taste types are appeared underneath table.

Table 1: Group for Tasting Types [11]

Flavour	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

Sweeteners or taste enhancing agents:

Sweeteners are key excipients of chewable tablets. Sweeteners is included basically in chewable tablets when the normally utilized bearers, for example, lactose, sucrose, mannitol, and dextrose don't totally veil the taste of the active medication substance or segments. These cases, the item formulation researcher should frequently utilize artificial

sweetening enhancers to improve the general sweetness sway. Since the chance cancer-causing nature of the artificial sweeteners, for example, ex. Cyclamates and saccharin. Pharmaceutical formulators are for the most part endeavor to structure their tablet items without such specialists.Taste covering method is the premier and the most straightforward methodology for taste veiling, particularly on account of pediatric definitions, chewable tablets, and fluid details. However, this methodology isn't extremely effective for exceptionally severe and profoundly water solvent medications. Counterfeit sugars and flavors are for the most part being utilized alongside other taste-veiling methods to improve the effectiveness of these strategies.[9]

Table 2: Approximate Relative Sweetness of different Sweetener [15]

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

Aspartame:

Aspartame are likewise known NutraSweet is a non-medicate favoring artificial sweetening agent. It is around multiple times sweeter than sucrose. Aspartame span is more more noteworthy than common sugars. Aspartame is additionally endorsed for use in desserts, beverges, and moment of tea and espresso. It improves and expands times. citrus flavors. It is dry soundness is great at room temperature and relative mugginess is 50%, while aspartame arrangement it is generally steady at pH 4.Aspartame delivered dis-colouration in the present of tartaric and ascorbic acid, accordingly ordinarily lessen it use in formula. Its common use in chewable tablets. Aspartame are use inchewable tablets is 3 to 8 mg/tablet.

Glycyrrhizin:

Glycyrrhizin it is a Liquorice subsidiary with a lost-enduring extraordinary, late sweetness. Glycyrrhizin are also known as mangnasweet. These functional properties exhibit its use as an assistant sweetening agent to upgrading sweetness level while lessen lingering flavor. Glycyrrhizin run of the mill use levels is 0.005-0.1%, with increasing fixations having a tendency to loan a slight liquorice flavor.

Saccharin:

Saccharin is normally utilized sweetener in chewable tablets, saccharin is Food and Drug Administration FDA) affirmed, it is five hundred times sweetness than sucrose. The significant inconvenience of saccharin is unpleasant delayed flavor impression. The dis-favorable circumstances are kills by presenting the minor amount (1%) of sodium chloride. The saccharin deferred season impression are significantly noticeable to around 20% of the populace. The general sweetness of saccharin decline as the sweetness level is improved. for instance, the saccharin sum or center is improved, the degree of harshness trailing sensation increase.

Colorants:

Colorants is utilized in formulation of chewable tablets for some accompanying reasons:

1. To improve tasteful application to the purchaser
2. To most straightforward in item distinguishing proof and separation

The Food Drug and Cosmetic Act of 1938 made three classes of coal tar tints, of which just FD and C tones and D and C conceals are utilized in the production of chewable tablets. The third portrayal (External D and C) are not valid for use in things expected for ingestion because of their oral danger yet are viewed as safe for use in things applied remotely.

METHODS OF MANUFACTURING OF CHEWABLE TABLETS [10,16]

The Chewable tablets were prepared by using the following methods:

Non aqueous Granulation/Dry granulation

Aqueous Granulation/Wet granulation

Direct compression

Granulation:

Granulation is the process in which primary powder particles are made to adhere to form larger, multi- particles entities called granules. Pharmaceutically granules have size range between 0.2 to 4.0 mm. Granulation is used to improve flow and compressibility of powders and to prevent segregation of the blend components. Granulation is mainly done by using two techniques.

Dry granulation:

It is the novel method for semi-automatic production of granules. The method is applicable to any solid dosage pharmaceutical products. Dry granulation method replaces existing solid dosage form development and manufacturing technologies offering more rapid development and better quality. In this process, the powder mixture is compressed without the use of heat and solvent. Two methods are used for dry granulation. The more widely used is slugging where the powder is recompressed and the resulting tablet are milled to yield the granules.

Wet granulation:

Wet granulation is the most commonly used granulation method. This process involves wet massing of powder blend with a granulating liquid, wet sizing and drying. The granulating liquid contains a solvent which must be volatile so that it can be removed by drying and must be non-toxic in nature. Typical liquid includes water, ethanol and Isopropyl alcohol. In the traditional wet granulation method, the wet

mass is forced through a sieve to produce wet granules which are subsequently dried.

Direct compression:

Direct compression is the most popular choice because it provides the shortest, most effective and least complex way to produce tablets. This method is mainly used when a group of ingredients can be blended. This is more suitable for moisture and heat sensitive API's since it eliminates wetting and drying steps and increase the stability of active ingredient by reducing detrimental (harmful) effects. In this process, API mixed with the excipients and lubricant, followed by compression which makes the product easy to process.

CRITERIA FOR CHEWABLE TABLET ASSESSMENT

When creating chewable pills, a range of evaluation criteria must be considered. They are provided as follows:

Organoleptic assessment in progress:

This assessment happens at numerous points during the creation of a chewable tablet. They are listed below:

- Drug evaluation: Characterization and comparison of the material in an absolute amount or with a recognize reference standard are involved.
- Assessment of coated drugs: This involves comparing coated drugs to pure drugs and considering various coating treatments.
- Assessment of the unflavored base formulation: This involves comparing various vehicles, the percentage of vehicles, or other formulation factors when the drug is coated.

Chemical Analysis

Included are the following:

1. Drug content analysis
2. Uniformity of dosage
3. Assessment in vivo and in vitro

Physical Assessment

Included are the following:

1. The appearance of the tablet
2. Hardness
3. Friability
4. Dissolution.[11,20]

APPEARANCE IN GENERAL, DIAMETER, AND THICKNESS

Size and Shape:

In accordance with part specifications, tablet size and shape must be adjustable and accurate. Dimensionally, you may monitor and control the size and condition of your tablet. The tool is in charge of controlling the printing process.

Colour and Odour:

To facilitate identifiable evidence and to serve as a good consumer reference, many pharmaceutical tablets use shading. Yet, it needs to be constant throughout batches, between tablets, and inside a single tablet. Tablet clusters' smell serves as a sign of stability problems. The smell of nutrients is distinctive. The patient's acceptance of chewable tablets is significantly influenced the most significant dimensions characteristic identified by this method is tablet thickness, which is calculated to the closest micron. 5 or 10 tablets can be arranged in a variety of ways on the retaining plate, and their combined thickness taste. Caliper scale estimates are possible. Tablet thickness should be kept to a standard deviation of 5% or less. The packaging of tablets also has an impact on thickness.

Hardness:

Use this tablet hardness tester to determine the hardness of tablets. This is an illustration of a Schlesinger hardness tester from Pfizer. The Monsanto hardness tester comprises of two defoggers and a cylinder with a compression spring inside. There is no need to read through because the lower unlogger hits the tablet. Finally, unless otherwise specified in each instance, crank the cranked jerk while pressing the top decampere on the spring until the tablet breaks (40-60 N). In this Chronicle's Appendix I, you may find the definitions and justification for this file (Indicators of Trouble Chewing). Chewing difficulty index data and permits the possibility of padding and agglomeration while the article is being improved. The force needed to split pills depend on the hardness. The term "hardness" describes the strength or quality of a tablet. A Monsanto hardness analyzer or tester was used to measure the degree of hardness. The units of measurement are kg/cm^2.[12]

Weight Variation:

According to the USP weight grade research, the weight of 20 tablets is managed by calculating only the standard load and comparing the load of each tablet to the norm. Breed test estimated weights are expressed as percentages, The USP states that a tablet passes the test if no more than two of its individual masses depart from the standard. mass by more than an average deviation and not more than twice the standard mass. Weight change is calculated as (beginning weight average weight)/average weight multiplied by 100. The weight of a single pill shouldn't deviate from the average weight by more than 5%.

Friability:

Testing for friability reveals whether tablets can become less expensive and prevent abrasion during handling duringshipping and packaging. during the use of Roche Friabilator. Weigh 10 tablets, put them in the friabilator, and spin. them for 4 minutes at 25 rpm. Afterwards the tablets were taken out, dusted, and tested again. The formula,

% Brittleness = [((starting weight - final weight)/initial weight]] 100, determines the rate at which tablets break.

Drug Content determination:

The mechanical component of the USP collapse is made up of six glass tubes with PR tops that are 3 inches long and are held against a 10 mesh screen at the base of a container rack. le inserts one tablet into each cylinder and places the basket stand in the specified medium at 37 2 °C to determine the disintegration time. The down stays within an inch of the cup's bottom. The tablet-containing basket assembly is pushed up and down by ordinary motorized equipment at a frequency of 28-32 cycles per minute across a distance of 5-6 cm.[13]

In vitro dissolution studies:

Dissolution studies calculate the amount of time needed under various pH, volume, agitation, and temperature conditions for a specified proportion of the medication in a tablet to be removed. The look of the prescribed medication affects how well a drug is absorbed from chewable tablets, whether they are intact or chewable. Chewable tablet in vitro disintegration testing currently requires adherence to commercial IR tablet disintegration. testing standards. In vitro disintegration testing on whole tablets should be coordinated across all four media for product presentations that are currently in development. Use the USP Device 1 (basket), USP Device 2 (paddle), or USP Device 3 (piston cylinder) for in vitro drug administration. ML. of vehicle, 0.1N HCl. The filament rotated at a speed of 50 rpm while the dissolution medium temperature was held constant at 37 0.5 °C. At various intervals of 10, 20, and 30 minutes, samples were obtained and replaced by adding an equal volume of brand-new dissolving medium. Samples were properly diluted, and UV-Vis spectroscopy was used to assess the solution's absorption at wavelengths with maximum and minimum absorbance of roughly 308 nm and 350 nm, respectively [19].

Stability Analysis:

To record time-dependent changes that occur in partial dosage structures, investigations of dosing structure or dosing item stability are conducted. Strength tests can be time-based, animated, or they can evolve in a variety of ways. A problem's prospective quality alterations are foreseen through accelerated reliability testing. Tests for potency, disintegration speed, and in vitro dissolution were examined towards the conclusion of the term. Our stability programmer includes many checks like:

- Verification of the active medication content utilizing recognized stability indication assay techniques.
- Modifications to the physical characteristics of tablets, such as motting of tablets with shadows, colour of thetablet surface, crystallization of the active ingredient, and enhancement of odour
- Hygroscopic chemicals in tablets that absorb moisture become brittle, crumble, and become sticky when chewed. Tablets grow increasingly brittle as moisture is lost from them. The hardness of tablets could alsoget harder.
- Stability entails a framework that prevents the degradation of the polymers utilized in the taste-masking procedure to enable the presentation of dynamic medication particles. Grids and casings must to be sturdy andprovide flavor safety.
- Pigment Stability: Color tablets pigments should not bleed or shift over time. Testing for colour stability included techniques including tristimulus alignment with standards and introduction quality.[14,17]

APPLICATION OF CHEWABLE TABLET

- Local therapy: Chewable tablets can release an active chemical at a controlled rate over time, resulting in a sustained local effect.
- Pain: Effective treatment of small pains, headaches, cold pains, muscular aches, etc. requires quick absorption of therapeutic amounts of the active component.
- Chewable tablets may be useful for treating mild pain since buccal absorption causes a quick beginning of action and lowers the possibility of gastrointestinal adverse effects.
- Systemic Therapy: Chewable tablets are advantageous for systemic drug ingredient is absorbed through the buccal mucosa. Administration, particularly if the active
- Aids for Quitting Smoking: Formulations of chewing gum containing nicotine, lobeline, and silver acetate have been clinically studied as quit-smoking aids.
- Obesity: Chewing gum formulations with chromium, Guarani, or caffeine are readily available. The centrally stimulating anorectic drugs caffeine and Guarani have been shown to speed up metabolism.[15,18]

CONCLUSION

Chewable tablets are flexible dosage forms that combine the benefits of solid products and majorly focus in this granulation techniques. All techniques have Benefits and drawbacks. The choice of method mostly depends on the properties of each ingredient, on their ability to flow, expel, dissolve, and compress. Accurate granulation requires knowledge of each element in the procedure, of how they are combined, and of how they interact with one another.

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CONFLICT OF INTEREST

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