Journal of Chemical and Pharmaceutical Sciences

Journal of Chemical and Pharmaceutical Sciences-JCHPS (2024) 17 (1): 28-44
Online ISSN: Online 2349-8552, Print ISSN: 0974-2115
Review Article | Pharmaceutical Sciences | MCI Approved | Peer-Reviewed | Referred | OA Journal |

A Review on Chewable Tablet and its Granulation Techniques

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Received: 29 Nov 2023 / Accepted: 8 Dec 2023 / Published online: 10 Jan 2024

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Abstract:

Tablets that are designed to be chewed between teeth need to be broken before being consumed. These tablets are given to kids who have trouble swallowing as well as to people who enjoy swallowing. These pills are meant to dissolve in the mouth easily and fast, with or without chewing. Chewable tablets usually dissolve smoothly, taste delicious, and don't leave behind any unpleasant or bitter aftertaste. Tablets that are designed to be chewed between teeth need to be broken before being consumed. These tablets are given to kids who have trouble swallowing as well as to people who enjoy swallowing. These pills are meant to dissolve in the mouth easily and fast, with or without chewing. Chewable tablets usually dissolve smoothly, taste delicious, and don't leave behind any unpleasant or bitter aftertaste. Tablets that are designed to be chewed between teeth need to be broken before being consumed. These tablets are given to kids who have trouble swallowing as well as to people who enjoy swallowing. These pills are meant to dissolve in the mouth easily and fast, with or without chewing. Chewable tablets usually dissolve smoothly, taste delicious, and don't leave behind any unpleasant or bitter aftertaste.

KEYWORDS:

Solid oral dosage forms, granulation techniques, chewable tablets, and excipients

INDRODUCTION

The most common way to administer medication is orally. The oral route is preferred over other methods of medicine delivery because of its flexible dose form formulation and high patient compliance. The oral route is appealing due to its ease of administration, patient acceptance, accurate dosage, cost-effective production procedure, and generally longer product shelf life. Many traditional drug delivery techniques employ liquids, pills, capsules, and other drug carriers as the drug delivery vehicle. Of these, solid formulations are less expensive to make as they don't have to be prepared in a sterile environment. When chewed, they should ideally dissolve in the mouth and release their constituent ingredients. This shortens the period before stomach absorption that the pill has to dissolve. Chewable pills are often employed when the active ingredient is intended to operate locally rather than systemically. A chewable tablet that tastes good can be taken with little or no water once it has been chewed. Chewable pills are generally made by wet granulation or direct compression. In order to benefit from the elevated the incorporation of therapeutically and physiologically active chemicals in micronized and submicron forms in tablet formulation is becoming more common, owing to absorption properties. [2] Patients who are bedridden, busy workers, or

travellers—especially those without access to water—are more likely to face this problem than paediatric and elderly adults. Chewable pills are guaranteed to taste good thanks to a sweetener. The food industry uses a wide variety of sweeteners, whether they are chemical, semi-natural, or natural. Every sweetener has advantages and disadvantages. For example, sugar has problems. Chewable tablets are a common dosage form for veterinary, nutraceutical, and pharmaceutical active substances. Chewable tablets are those that are meant to be broken down by chewing in order to aid in the release of the active ingredient. As a dosage form, chewable tablets are superior to regular tablets in terms of manufacturing, dosing accuracy, mobility, and long-term durability. Furthermore, because the drug is initially broken down into particles in the tongue, chewable pills facilitate simpler swallowing. Sugar cane or sugar beets are the natural sources of sugar. Chewable tablets are a common dose form for delivering active substances in pharmaceutical, nutraceutical, and veterinary products. They provide energy and are rapidly absorbed. Chewable tablets are those that are meant to be broken down by chewing in order to aid in the release of the active ingredient. As a dosage form, chewable tablets are superior to regular tablets in terms of manufacturing, dosing accuracy, mobility, and long-term durability. Furthermore, because the material is initially broken down into particles in the tongue, chewable pills facilitate simpler swallowing. [5]

CHEWABLE TABLETS' BEST FEATURES

1. Easy to chew
2. Delicious (tasty or deserving of flavor)
3. Being the ideal proportions
4. Quick dissolution to encourage quick disintegration
5. This holds true for all dose forms that are clear.
6. Easy to take (approximately once a time), especially for people who have trouble swallowing regular tablets and capsules
7. Reduce the likelihood of esophagitis brought on by drugs.
8. This occurs when the tablet dissolves while still in contact with the thin lining of the oesophagus after becoming lodged there.
9. Delectable and offered in several Flavors
10. Easy to use and convenient 10. There is no need for a prescription; just one dose is given.
11. Boost stability
12. Water-free dosage formulations that are available are
13. Waterless dosage forms are easy to travel and comfortable to carry anywhere, anytime [6].

THE CONSISTENT ADVANTAGES OF CHEWABLE TABLETS

1. Patient safety is number one.
2. Outstanding capacity for absorption.
3. Chewing food in the mouth promotes putrefaction, solubility, or absorption, all of which increase bioavailability.

4. The delight of comprehension and validation. Kid-friendly version.
5. The large size of the dose form makes it difficult for some people to swallow, particularly adults and children who object. In this case, chewable tablets offer more possibilities.
6. The therapeutically active substance is more effective when broken down and lowered in size in the mouth before being swallowed.
7. Easily available for taking care of oneself.
8. It is possible to obtain both a pleasing mouthfeel and an efficient taste concealing.
9. Improved bioavailability by avoiding disintegration and possibly increasing dissolution
10. Improving patient comfort by eliminating the need for water to be swallowed (chewable pills can be taken anywhere, even without access to water).
11. Potential use in place of liquid dose forms when a quick start of action is preferred. Enhanced patient acceptance thanks to the product's unique flavour and appealing appearance, particularly in kids.

CHEWABLE TEXTURE BENEFITS

1) No bitter substances are used in the production of chewable pills.
2) Chewable tablets that smell too strong can cause ulcers.
3) Chewable tablets are made with a number of excipients, some of which are detrimental to the body, in order to give them greater weight and improved attributes. For example, sorbitol induces indigestion and diarrhoea.
4) Pain in the muscles of the face following prolonged chewing of chewable tablets.
5) Because chewable pills are hygroscopic, they should be properly wrapped and stored in a dry environment.
6) Chewable tablets have a low mechanical quality, thus they should be packaged and carried carefully.
7) Shows brittle, fizzling granules. [7]

ORAL SOLID DOSAGE FORMATS

Since the 19th century, oral solid dosage forms like as tablets and hard gelatin capsules have been the most widely used type of dosage form. The patient is accustomed to and willing to follow the oral delivery method. For the manufacturer, solid oral dosage forms provide numerous advantages: cheap cost of technology; they are among the most stable drug delivery systems; they are compact; and they may be customised in appearance to build brand identification. [8]

Ingredients or components used in the manufacturing of chewable tablets. Inactive pharmaceutical compounds, which are those kept in storage throughout manufacture or found in excipients, are essential to the creation of pharmacological dosage forms, in addition to active pharmaceutical components or prodrugs. Examples of inactive pharmaceutical ingredients include:

1) Enhanced bioavailability and solubility of pharmaceutical components and excipients
2) More stability in the dose formulation of medications

3) Permit adaptable attachment in order to preserve perfect synchronization or polymorphic organization.
4) Maintain the osmotic pressure and pH of the liquid formulations.
5) Serves as a binding agent, diluent, aerosol propellant, emulsifier, and antioxidant.
6) Steer clear of separation and aggregation
7) Trigger an immunological reaction in response to the drug
8) To transport medications in quantity. [9]

1.Diluent or Bulking Agent

Chewable tablet formulations are made with more volume because to these components. When mixed with the medicinal component, the finished product has sufficient weight and mass to facilitate handling and manufacture.

2.Mannitol

Mannitol was a commonly used diluent. It is a popular agent for bulking tablets.The moment when chewable pill flavor becomes significant. In essence, the materials are pure, crystalline, non-hygroscopic, free-flowing, and dormant granules. Because of its negative heat, sweetness, and "mouthfeel," the solution is commonly employed as a diluent in the manufacturing of chewable tablet formulations.

Mannitol is used as a food ingredient and is estimated to be about 70% sweeter than sucrose. Mannitol in powder form performs well in wet granulation when paired with another binder. accessible in a granular format for direct printing procedures. Mannitol is not hygroscopic by nature. Mannitol with a low water content is typically used in formulations for moisture-sensitive products. Mannitol's powdery sweetness, mouthfeel, and non-hygroscopicity make it an extremely hospitable medium for the production of chewable pills.

3.Sorbitol

Sorbitol is a polyol that is odorless, white or almost clear, crystalline, and hygroscopic. Sorbitol is used as a diluent in tablets that are produced by direct compression or wet granulation. It is reasonably priced in Sorb Tab (ICI Americas) and Crystalline Tablet Type (Pfizer Chemical) forms for direct printing. Sorbitol is commonly added to precious chewable tablet formulations to provide a tempting, sweet flavor and provide a cooling effect. An isomer is. Sorbitol is getting more hygroscopic as opposed to mannitol.

4.Dextrose

Tablet formulations use dextrose as a diluent. Glucose is a colorless substance. They smell good and taste good. Dextrose is produced when starch is hydrolyzed by enzymes or acids. Starches hydrolyze, including starches derived from maize. Dextrose, in the form of wet granules, is used as a binder and diluent. For example, the most common form of dextrose used for binders and diluents in direct printing is in the form of chewable tablets. Glucose is around 70% sweeter than sucrose. There are versions that are anhydrous and monohydrate available. Lactose is also compared to a pill diluent. The tablets used to produce glucose monohydrate are prone to clumping immediately after printing and require further lubrication.

5.Dairy

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Lactose is also known as milk sugar. Lactose is a disaccharide present in milk. The liquid that remains in milk after making cheese and casein is called lactose. Lactose is commonly used as a diluent in tableting. It is a common excipient in tablet manufacturing. Because lactose is less sweet than glucose, it has a minimal role in chewable pills. Lactose is around 20% sweeter than sugar. This deficiency necessitates the use of a pseudo-sweetener that can counteract the blandness of lactose. Chewable pills are not appropriate for those who are lactose intolerant.

6.Sucrose

The sugar business commonly uses sucrose as a foil in wet granulation technique for tablets, as well as a sweetener and diluent. Compacted simple sucrose crystals have never worked; nonetheless, various modified sucrose has been employed in direct pressure regimens. Tab (2% each of 95% sucrose, 4% converted sugars, and 0.1–0.0 from starch and magnesium stearate) and (90–93% sucrose + 7–10 percent modified sugars). The direct compression tableting method uses binders and diluents that are all based on sucrose for chewable tablets. Steer clear of Especially use of artificial sweeteners is advised. Using sucrose as a bulking agent raises additional problems. Not less sugar, but sucrose dissolves easily. It gets darker over time. In addition, it has a texture like cake when left to stand and is hygroscopic.

7.Enhancer of flavor

Flavors and other excipients for chewable tablets are essential. Spices are often used to give amazing flavors, improvements, and fragrances to chewable pills. Beads that have been spray-dried are present together with the oils as solids. Flavors are usually added during the oil process because these ingredients are moisture-sensitive and tend to evaporate quickly when heated, as happens while drying wet granules. The low post-aging stability of aqueous (water-soluble) flavors has prevented them from being extensively studied. Consistency in flavor is weakened by oxidative reactions. Dried acacia is typically used in conjunction with spray to emulsify oils. Dried flavors are easier to work with and last longer than oils. After the oil settles in the lubrication pan, it is usually sprayed into the granules after being diluted with alcohol.

A list of additional strains and flavourings follows the table of typical benchmark taste variations.

The Group of Flavors for Tasting Types

- Berries, grapes, maple, sweet vanilla, and fruits
- Cherry, root beer, strawberry, anise, and raspberries are sour (acidic).
- Nutty, buttery, spiced, citrus, butterscotch, and blended with a hint of salt
- Butterscotch, fruits, and a hint of spice
- Bitter grapefruit, coffee, liquorice, fennel, peach, cherry, and
- mint
- Metallic Grape, Burgundy, Lemon-Lime

Flavor's	Group for Tasting Types

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Sweet	Vanilla, fruits, maple, stone fruits, berries, grape
Sour (Acidic)	Raspberry, anise, cherry, root beer, cherry, strawberry
Salty	Mixed citrus, maple, butterscotch, nutty, buttery, spice, mixed fruits, butterscotch, and a touch of spice
Bitter	Wine, fennel, peach, cherry, coffee, liquorice, grapefruit, and mint
Metallic	Lemon-lime, grape, burgundy,

Table 1: Tasting Types Group

8.Sweeteners and ingredients that enhance flavour

have a major part in the excipients of chewable tablets. Sweeteners are often added to chewable tablets when the normally used carriers, such as lactose, sucrose, mannitol, and dextrose, are unable to entirely mask the taste of the active component or the constituents of the active ingredient. Product formulators should employ artificial sweeteners in these cases to boost the overall variety of sweetness. due to the possibility that artificial sweeteners accidentally cause cancer. Saccharin and cyclamate, for instance. Pharmaceutical formulators' primary objective is to produce tablet goods without this kind of information. The earliest and most fundamental kind of taste-masking is the taste-masking approach, which uses chewable pills and liquid suggestions. However, this method is not very effective, especially when working with strong and very water-soluble medications. To make flavor-masking strategies more effective, fake tastes and sugars are sometimes combined with other methods.

Materials	**Relative Sweetness**
Aspartame	200
Glycyrrhiya	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

Table 2: Estimated Comparative Sweetness of Various Sweeteners

9.Take Away

Sometimes known as aspartame. NutraSweet, an artificial sweetener, is a non-drug solution. It's even sweeter than sucrose. Compared to regular sugar, aspartame has a larger margin. Aspartame should also be avoided in drinks, teas, and espresso. It occasionally improves the citrus's flavour. Aspartame is reasonably stable at pH 4 and has good dry strength at room temperature, even at 50% relative humidity. Aspartame is not often used in diets because it discolours when tartaric acid and ascorbic acid are present. Often found in tablets that are chewable. Aspartame ranging from 3 to 8 mg is present in chewable pills.

10.Glycyrrhizin

A substance derived from licorice that has a late-night sweetness. Glycyrrhizin is also known as manganese sweetener. These functional properties indicate that you can reduce aftertaste while increasing sweetness levels by using it as an extra sweetener. Taste more licorice-like in general.

11.Saccharin

Manufacturers of chewable tablets usually use saccharin as a sweetener. Saccharin, which is 500 times sweeter than sucrose, has been approved by the Food and Drug Administration (FDA). The main negative effect of saccharin is an unpleasant taste perception delay. A small amount (1%) of sodium chloride is dispensed to ease the unwanted situation. Saccharin-related post-season impressions are undoubtedly present in about 20% of the population. As the sweetness level increases, saccharin's overall sweetness decreases. For example, when saccharine total or core is enhanced, the degree of roughness increases.

12.Pigments

Colorants are frequently used in chewable tablet formulations for the following reasons:

1) An improved application that attracts users

2) The best method for differentiating between proof and separation

The 1938 Food Drug and Cosmetic Act divided coal tar colors into three categories. Only FD and C tints and D and C tints are used in the production of chewable pills. When used for remote application, the third classification (External D and C) is safe; however, it should not be used in situations where ingestion is anticipated because of potential oral hazards.

METHODS FOR MAKING TABLETS AND GRANULATION TECHNIQUES

The method of direct compression

Direct compression is the simplest method and offers the advantages of common technology, low manufacturing costs, and extensively used techniques. less processing steps and readily available excipients. When compared to alternative methods, the direct compression approach can accommodate higher dosages and even surpass the tablet's final weight. Disintegrates, effervescent agents, and solubilized excipients are used in tablet formulations to regulate the tablet's disintegration property. The speed at which a fast-dissolving tablet manufactured by direct compression dissolves depends on the use of super disintegrates. For the pill to disintegrate and have a pleasant mouth feel, the

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proper super disintegrates must be chosen. The direct compression method works well for producing tablets that dissolve quickly since sugar-based excipients and high-quality super disintegrants are widely accessible [11].

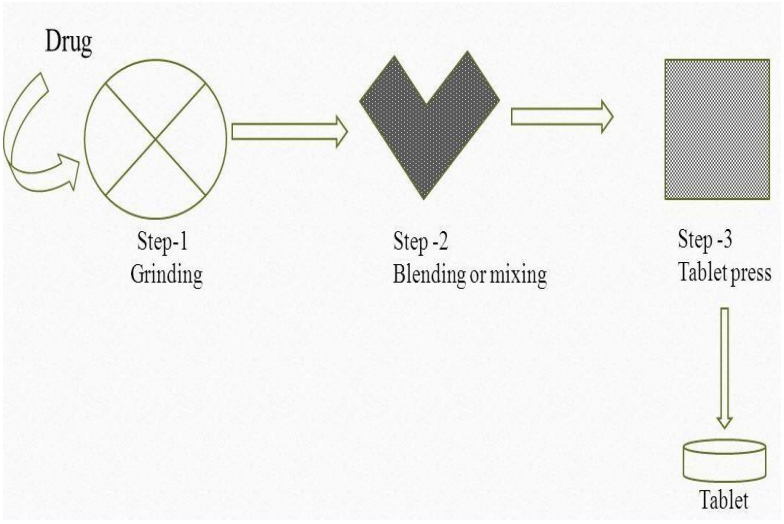

Fig. 1: Direct Compression Technique

a) Completely disintegrates

Depending on which super disintegrants are added and how they are chosen, fast-dissolving tablets prepared with the direct compression method dissolve and dissolve in different ways. Effervescent agents and water-soluble excipients are additional excipients that aid in improving the dissolution of fast-dissolving tablets [11].

IMPOSSIBLE ADJUVANT PERFECT SITUATIONS

The immediately compressible adjuvant ought to have unrestricted flow. Flowability is required for high-speed rotary tablet machines in order to guarantee a rapid and steady flow of powder during die filling. With a repeatability of +5%, the required amount of powder blend should be introduced into the die cavities during the short dwell time (milliseconds). Many common manufacturing problems, including uneven blending, excessive or insufficient dosage, and imprecise filling, can be attributed to improper powder flow. Effective tableting requires compressibility, or the mass's capacity to hold its compressed shape after the compression force is withdrawn. A limited quantity of excipients may be

Instantly compressed without any elastic rebound. The instantly compressible diluent should have strong compressibility because compaction pressure and volume are related. [12]

Dilution potential is the amount of an active component that, when combined with a given directly compressible excipient, can be sufficiently compressed into tablets. A immediately compressible adjuvant should have a high dilution potential because the final dosage form should weigh as little as possible. The dilution potential is influenced by the compressibility of the active pharmaceutical component. Reworking an adjuvant that is immediately compressible should not affect its flow or compressibility. Upon recompression, the adjuvant should exhibit satisfactory tableting properties. The adjuvant needs to keep its initial physical and chemical characteristics. The

instantly compressible adjuvant must not age with any physical or chemical changes and must be stable against air, moisture, and heat. Particles in an instantly compressible adjuvant ought to match the size of the active ingredients in the formulation.

Particles in an instantly compressible adjuvant ought to match the size of the active ingredients in the formulation [12].

The advantages of direct compression [13]

1. Simple process to speed up production while lowering the cost of labor, equipment, and facility investments.
2. Lowering the cost of testing, evaluating equipment, and production process expenses.
3. Increase batch consistency because there are fewer steps in the production process.
4. Reduce cross-contamination and product losses.
5. Over the course of the preservation period, the rate of drug release varies less.
6. Increase the stability of the product.
7. Lessening of the substance's deterioration, encompassing active components that are susceptible to moisture or solvents as well as those that are quickly destroyed by heat.
8) Due to API particles coming into direct contact with the breakdown fluid instead of granules, tablets created by direct compression dissolve quite quickly.
9) The absence of water during granulation lowers the likelihood of microbial growth in tablets produced by direct compression.
10) This is very important because the official compendium now requires dissolving criteria for most solid dosage forms.

THE LIMITATIONS OF DIRECT COMPRESSION

1. Direct Compression:

Direct compression is more likely to result in segregation because of the difference in densities between the excipients and the API. The dry state of the material may generate static electricity and lead to segregation during mixing. Weight variance and content homogeneity problems could arise from this. Directly compressible excipients are produced via patented spray drying, fluid bed drying, roller drying, or co-crystallization. The end effect is that the products cost more than the equivalent raw materials. Since most directly compressible materials can only carry 30–40% of poorly compressible active compounds, such as acetaminophen, a tablet containing 500 mg of acetaminophen would need to weigh more than 1300 mg. Swallowing the larger tablets could be difficult. All spray-dried instantly compressible adjuvants show poor reworkability because the excipient particles' original spherical form is lost during the tablet-making process. Direct compression of API with poor flow characteristics and/or low bulk density is difficult. Since filler (such starch 1500) rarely fractures or shears during compression, lubricants have a greater detrimental effect on the filler. The hydrophobic and softening effects of alkaline stearates can be controlled by cutting the mixing time down to as little as 2 to 5 minutes. [13]

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2) Dry granulation technique

When compressed, cohesive particles that are smaller than a few microns in size often agglomerate. With dry granulation, larger granules can be produced under pressure without the use of binders by extruding, tumbling, and fluidizing powders. Pneumatic or mechanical pressing methods are available. Roll compaction is the common mechanical pressing method that was covered in an earlier chapter. Using a special pneumatic method that required releasing air from a pressurized chamber into a chamber that had previously been evacuated and housed the powders, superfine silica anhydride and diatomaceous earth were granulated. Their results indicate that this method can be applied to powders whose bulk volume can be compressed by air to a greater than 40% extent. Fine particles are "extruded" by being scoured using a perforated plate or filter. Even though this granulation technique is out of date, some organizations continue to use it since it is simple and quick. However, automating such equipment is difficult. Another difficulty is that the product granules' rod-like shape and narrow size distribution restrict the amount of flowability that can be improved.

The practice of tumble boarding dates back over 60 years. evaluated the capacity of the tumbling container to clump small ZnO particles. According to their claims, after 40000–635000 spins, steady-state granules may be created at 110 rpm. A model for granule growth was created and the Spherization behavior was studied for 12 hours using WC-10%Co powders with a diameter of 1-2 micrometres. However, industrial manufacturing cannot use such extended granulation durations. Additionally, it is difficult to produce spherical and tiny granules since tumbling is useless for creating granules smaller than 1 mm.

Even while the process of "fluidizing" fine cohesive particles is recognized to produce agglomerates, it is a difficult one. The impartial report on the agglomerating by Sugihara and Bearns was released in 1966 as far as the authors are aware of. Sugihara studied fluidization using small particles with a diameter of 0.9–35~m. According to his research, the measured minimum fluidization velocity increased with decreasing particle diameter, in contrast to the Urn of primary particles calculated from the Kozeny-Carman equation. [14]

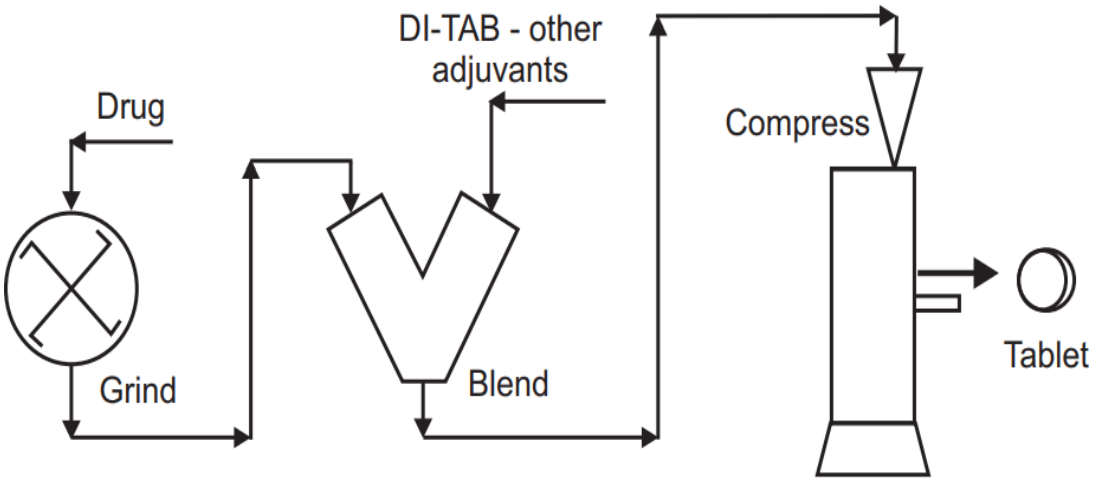

Fig. 2: Method of dry granulation

Restrictions

1) A challenging procedure.

2) Not suitable for every substance.

3) Lag in algorithms. [15]

Advantages of dry compression

1) Prevents exposure to moisture and drying out.

2) Limited processing phases.

3) Deacreation results in less capping or splitting.

4) For substances that are prone to dampness.

5) For thermally sensitive materials.

6) For substances that are prone to dampness.

Negative aspects

1) Slug formation calls for a specialized, robust tablet press.

2) It prevents the homogeneous dispersion of color that can be achieved through wet granulation, in which the dye and binder liquid can be combined.

3) There is a greater chance of contamination because the method usually generates more dust than wet granulation.[16]

3.Wet Granulation Process

A. The procedures followed in wet granulation

a. Mixing the drugs and excipients together
b. First, create a binder solution. To generate a wet mass, step two involves mixing the powder mixture and binder solution.
c. utilizing a suitable sieve to coarsely screen damp bulk material with a mesh size of 6 to 12.
d. moist particles as they dry.
e. Granules that are dry are screened using a suitable sieve (14–20 # mesh).
f. mixing screened grains with disintegrates, gliders, and lubricants. [17]
g. Distinctive wet granulation methods
h. Shearing-Spheronization process
i. Granulation in a Fluid Bed,
j. Elevated Shear Blending Granulation
k. Dry granulation and spray drying.

Weighing, mixing, granulating, screening the wet mass, drying, dry screening, lubricating, and finally compression are the fundamental processes in the process. Nevertheless, it is challenging to replicate consistent granulation from

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one lot to the next because each of these processes has a time constraint. The main flaw in the technique. The active ingredients, diluents, and disintegrants have all been well-combined. A twin-shell blender or a ribbon blender can be used for large-scale mixing. The combined material is then run through a screen that has a mesh thin enough to break up or eliminate any lumps. Stir the powder and gradually add the binding agent solution until the mixture resembles wet snow or brown sugar. For this, the pharmaceutical industry may use a Sigma blade mixer or a Twin-shell blender. The moist bulk is then forced through a six- or eight-mesh screen. Larger quantities can be processed using one of several comminating mills made for wet screening, although smaller amounts can be screened by hand. The Fitzpatrick grinding mill is the preferred instrument. The resultant granular material is dried in a fluid bed drier or hot air oven on trays. It may take up to 12 hours for the oven to dry. Particles can cluster and agglomerate during drying, so a dry screening step is usually required after drying. Tablet granulation can also be easily prepared using the air suspension coating process. Using this method, inert material particles or suspended active medication are sprayed with a granulating material solution in a vertical column. Particle size constantly increases leading to the production of granules.

Incorporating a soluble die into the granulating fluid enables wet granulation to produce uniform tablets. Wet granulation is most effective when making tablets for potent drugs that are taken in very tiny doses. Wet granulation technique is garnering a lot of interest because the direct compression method is not the best approach for many active substances that are in large dosages or in fine powder form. [18]

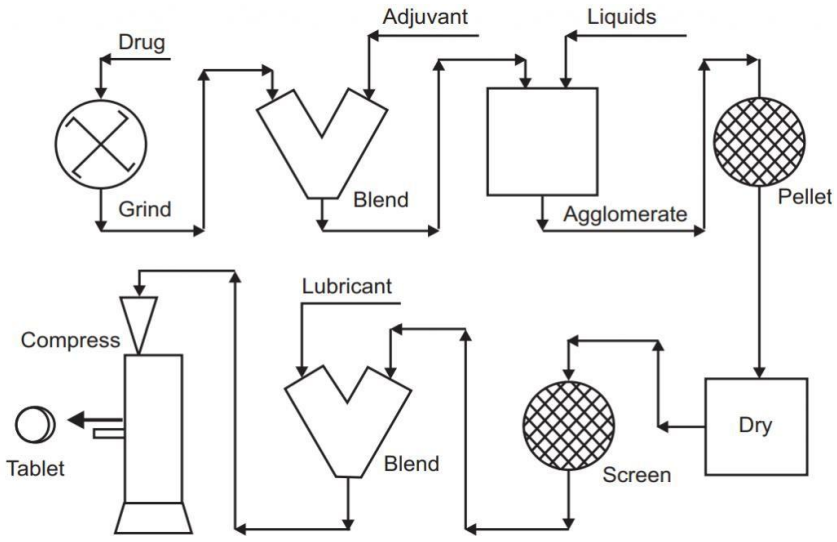

Fig 3: Method of Wet Granulation

Advantages

1) Permits powder handling by machine without sacrificing the quality of the blend.

2) The powder's sphericity and particle size are raised to enhance its flow properties.

3) Strengthens and increases the uniformity of the powder density.

4) Decreases trapping of air

5) Promotes cohesiveness and strengthens cohesiveness during and after compaction.

6) Lowers the quantity of dust and cross contamination.

7) Makes it possible to add a liquid phase to powders.

STANDARDS FOR EATING TABLET EVALUATION

Chewable pill creation requires careful consideration of several evaluation criteria.

They are offered in the following manner:

Organoleptic evaluation is being conducted.

Throughout the process of creating a chewable pill, this evaluation takes place multiple times. Below is a list of them:

1. Drug evaluation involves the material's characterization and comparison, either in absolute terms or with a recognized reference standard.
2. Evaluation of coated drugs: This entails contrasting coated and pure medications as well as taking different coating techniques into account.
3. Evaluation of the unflavored base formulation: This includes contrasting different cars, the proportion of cars, or other aspects of the formulation when the medication is coated.

ANALYSIS OF CHEMICALS

Among them are the following:

1.Analysis of drug content

2.uniformity in the dosage

3.Evaluation both in vitro and in vivo

THE FOLLOWING ARE INCLUDED IN THE PHYSICAL ASSESSMENT:

1.The tablet's appearance

2.Hardness

3.Friability

4.Breakdown. [19]

General appearance, thickness, and diameter:

Size and form:

The tablet's size and form must be precise and customizable in compliance with the part specifications. You can keep an eye on and manage the dimensions of your tablet. The utility is responsible for managing the printing procedure.

Color and Odor:

Many prescription tablets use shading to make evidence easier to identify and to function as a useful consumer reference. However, it must remain consistent among tablets, between batches, and across individual tablets. The fragrance of tablet clusters is an indicator of stability issues. Nutrients have a particular fragrance. Tablet thickness, which is determined to the nearest micron, is the most important dimension feature found by this method, which has

a substantial impact on the patient's acceptance of chewable tablets. There are several methods to stack 5 or 10 tablets on the retaining plate, and their combined thickness and flavor can be adjusted. Estimates using caliper scales are feasible. A standard deviation of no more than 5% should be seen in tablet thickness. The thickness of pills is also affected by their packaging.

Hardness

To find out how hard tablets are, use this tablet hardness tester. An example of a Pfizer Schlesinger hardness tester is seen here. The Monsanto hardness tester consists of a cylinder with a compression spring inside and two defoggers. The lower unlogger strikes the tablet, so there's no need to read through. Lastly, until the tablet breaks (40–60 N), crank the cranked jerk while pressing the top decampere on the spring, unless differently instructed in each case. You can see the definitions and rationale for this file (Indicators of Trouble Chewing) in Appendix I of this Chronicle. While the article is being improved, padding and agglomeration are possible thanks to the chewing difficulty index data. The hardness of the pill determines the force required to split it. "Hardness" refers to a tablet's strength or characteristic. The degree of hardness was measured using a Monsanto hardness tester or analyser. kg/cm2 is the unit of measurement. [20]

Change in Weight:

The weight of 20 tablets is controlled by computing only the standard load and comparing each tablet's load to the norm, per the USP weight grade research. The projected weights from breed tests are given in percentages. As per the USP, a tablet is considered to pass the test if the average difference between any two of its component masses and the standard mass is not greater than one and if the standard mass is not exceeded by twice. (Starting Weight - Average Weight)/Average Weight multiplied by 100 is the formula used to compute weight change. A pill's weight shouldn't vary by more than 5% from the usual weight. [21]

Table 3: Tablet Friability Weight Variation Limitations

Sr.no	Average weight tablets(mg)	Maximum %difference limits
1	130 or less	10%
2	130 to 324	7.5%
3	More than 324	5.0%

Maximum percentage difference restrictions for Senior No. Average weight pills (mg)

1 less than 130 or 10%

2~130 to 324~7.5%

3. Over 324 5.0 percent

Friability testing determines whether tablets can be made less costly and can stop abrasions from occurring during handling, shipping, and packing. when utilizing the Roche Friabilator. Ten tablets should be weighed, placed in the flibrator, and spun at 25 rpm for four minutes. The tablets were then removed, cleaned, and tested once more. The

rate at which tablets break is calculated using the formula % Brittleness = [((beginning weight - final weight)/initial weight]] 100.

Determining the Drug Content:

Six three-inch-long glass tubes with open tops that are pressed up against a ten-mesh screen at the bottom of a container rack comprise the mechanical part of the USP collapse. To find the disintegration time, he puts one tablet into each cylinder and sets the basket stand in the designated medium at 37 2 °C. The down remains within one inch of the bottom of the cup. Using standard motorized equipment, the tablet-containing basket assembly is moved up and down over a distance of 5–6 cm at a frequency of 28–32 cycles per minute.[21]

Studies on *in vitro* dissolution:

Dissolution tests determine how long it will take for a given percentage of a tablet's drug to dissolve under different pH, volume, agitation, and temperature settings. Whether the pills are chewable or intact, the appearance of the prescription medication influences how efficiently it is absorbed. Currently, commercial IR tablet disintegration testing criteria must be followed when doing in vitro chewable tablet disintegration testing. For product presentations that are presently under development, coordination of in vitro disintegration tests on entire tablets across all four media is necessary. For in vitro drug administration, use USP Devices 1 (basket), 2 (paddle), or 3 (piston cylinder). ML of the car and 0.1N HCl. The dissolution medium temperature was maintained constant at 37 0.5 °C while the filament cycled at a speed of 50 rpm. Samples were taken at different intervals of 10, 20, and 30 minutes, and each time a fresh batch of dissolving medium was added in an equal volume. After the samples were appropriately diluted, the solution's absorption at wavelengths with maximum and minimum absorbances of approximately 308 nm and 350 nm, respectively, was evaluated using UV-Vis spectroscopy. [22]

Analysis of Stability:

Research on dosing structure or dosing item stability is done to document changes in partial dosage forms over time. Strength tests can change over time, be animated, or take on different forms. Accelerated reliability testing predicts potential quality changes related to a problem. Towards the end of the semester, tests for potency, disintegration speed, and in vitro dissolution were looked at. Our stability programmer performs numerous checks, such as:

1. Confirming the amount of active medication by using established stability indication assay methods.
2. Alterations to the physical properties of tablets, such as the addition of a stronger scent, the motting of shadows on the tablet surface, the color of the tablet, and the crystallization of the active ingredient
3. Hygroscopic compounds in tablets: When chewed, tablets that absorb moisture shatter, break, and turn sticky. When tablets lose moisture, they become more fragile. It is also possible for tablet hardness to increase.
4. For active drug particles to be presented, stability requires a structure that stops the polymers used in the taste-making process from degrading. Sturdy and flavor-safe grids and casings are essential.
5. Pigment Stability: Over time, the pigments in color tablets shouldn't bleed or move. Techniques for testing color stability included introduction quality and tristimulus alignment with standards [23].

THE USE OF CHEWABLE TABLETS

1. Local therapy: Chewable tablets have the ability to release an active ingredient gradually over time at a predetermined rate, producing a long-lasting local effect.
2. Pain: Rapid absorption of therapeutic doses of the active ingredient is necessary for the effective treatment of minor aches, headaches, cold sores, and muscle aches, among other conditions.
3. Chewable tablets have the potential to be helpful in the treatment of minor pain because of their rapid onset of action and reduced risk of gastrointestinal side effects due to buccal absorption.
4. Chewable tablets are useful for systemic medication delivery in systemic therapy, especially if the drug's active ingredient is absorbed through the buccal mucosa.
5. Aids for Quitting: Chewing gum formulations with lobeline, nicotine, and silver acetate have been clinically investigated as aids for quitting.
6. Obesity: Chewing gum formulations containing Guarani, caffeine, or chromium are easily obtainable. It has been demonstrated that anorectic medications with cerebral stimulation, such as Guarani and caffeine, accelerate metabolism. [24]

CONCLUSION

Chewable tablets are versatile dosage forms that primarily concentrate on granulation techniques while combining the advantages of solid goods. Every technique has advantages and disadvantages. The ability of each element to flow, eject, dissolve, and compress is a major factor in the method selection. Knowing each step of the process, how to combine them, and how they work together is necessary for accurate granulation.

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