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# A COMPREHENSIVE REVIEW OF FORMULATION METHODS OF CHEWABLE TABLET- A NOVEL APPROACH

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**Keywords:**

CDI (chewable difficulty index), Novel methods, 3D-printing, Fluid bed granulation, Compression coating

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**ABSTRACT:** Chewable tablets are produced using various manufacturing processes, each with its own unique characteristics and advantages. The most common method includes wet granulation, dry granulation, direct compression, extrusion, melt granulation, fluid bed granulation, compression coating, 3D printing. Each process offers distinct benefits, such as improve tablet strength better taste masking and increased manufacturing efficiency. The choice of process depends upon the specific formulation, desired tablet characteristic and production scale**.** Chewable tablets are designed to be easily broken down in the mouth, but their texture and hardness can vary significantly, affecting patient acceptability and compliance. The CDI is a reliable and valid tool for evaluating the chewability of chewable tablets. It can be used by manufacturers to optimize tablet formulation and design, and by regulatory agencies to set standards for chewable tablet quality.

**INTRODUCTION:** A chewable Tablet is a type of tablet that is designed to be chewed and swallowed, rather than swallowed whole. They are often used for medications, supplements or vitamins that need to be taken regularly. Chewable tablets are typically made with a soft and liable material that can be easily broken down by the teeth, making them easy to chew and swallow [2, 3, 5].

**Advantages [2, 3]:** Easy to swallow: Chewable tablets are designed to be chewed and swallowed, making them a great option for people who have difficulty swallowing traditional tablets or capsules.

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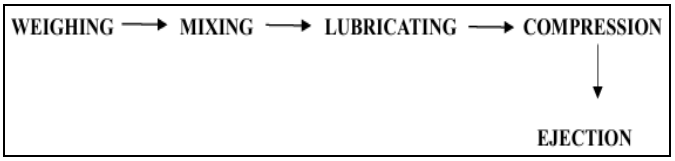
**Disadvantages [3, 2]:** Uncontrolled release: Chewable tablets can release the active ingredients too quickly, potentially leading to a rapid spike in levels, which may not be desirable.

**Formulation Methods used in Chewable Tablet:**
**Compression:**

1. Direct compression
2. Wet granulation
3. Dry granulation
4. Hot melt extrusion
5. Fluid bed granulation
6. Spray drying
7. 3 D printing
8. Compression coating
9. Encapsulation

**Direct Compression [1, 2]:** A simple and cost-effective method, where powders are directly compress

**Steps:**




**Advantages [1, 2]:**
**Flexibility:** Can be used for various tablet sizes and shapes.

**Easy Scale-up:** Simple to scale up from small to large batches.

**Disadvantages [1, 2]:**
**Moisture Sensitivity:** Materials sensitive to moisture may not be suitable.

**Material limitations:** Only suitable for materials with good flow and compression properties.

**Wet Granulation [1, 2]:** Wet granulation involves mixing powder ingredients with a liquid (binder such as water or a solvent) to create a uniform, moistened mixture. The mixture is then passed through a screen or forced through an extruder to create small, uniform granules.

**Steps:**
**Weighing:** Accurately weight the powder ingredients according to the formula.

**Mixing:** blend the powder together in a uniform mixture

**Granulating Fluid Preparation:** Prepare the granulating fluid (e.g., water, or binder solution).

**Wet Mixing:** add the granulating fluid to the powder mixture and mix until a uniform, moisture mixture form

**Granulation:** Pass the mixture through a granulator (e.g., sieve, extruder) to form granules.

**Wet Screening:** screen the granules to ensure uniform size and texture.

**Drying:** Dry the granules in a dryer (e.g., tray, fluid bed) to remove excess moisture.

**Sizing:** Size the dried granules to ensure uniformity.

**Lubrication:** Add lubricants (e.g., magnesium stearate) to the granules to prevent sticking.

**Compression:** Compress the granules into chewable tablets using a tablet press.

**Advantages [1, 2]:**

**Improved Flow Properties:** Wet granulation enhances the flowability of powders, making them easier to handle and process.

**Uniformity:** Ensures uniform distribution of ingredients and particle size, leading to consistent tablets.

**Disadvantages [1, 2]:**

**Time-Consuming:** Wet granulation is a more time-consuming process.

**Equipment Requirements:** Requires specialized equipment, such as mixers, granulators and dryers.

**Dry Granulation [1, 2, 3, 15]:** Dry granulation is a pharmaceutical manufacturing process used to convert powders into granules without using solvents or moisture.

**Steps:**
**Weighing and Mixing:** Weigh accurate amounts of active pharmaceutical ingredients (API's) and excipients. Mix powders to ensure uniform distribution.

**Compaction:** Feed powder mixture into a roller compactor or slug grinder. Apply pressure to compact powders into dense sheets or slugs. Control compaction force, speed and gap to achieve desired density.

**Milling:** Break down compacted sheets or slugs into smaller granules. Use mills (e.g., hammer, pin or oscillating mills) to achieve desired granule size.

**Sifting or Screening:** Separate granules by size to ensure uniformity. Remove fines and oversized particles.

**Blend Uniformity:** Blend granules to ensure uniform distribution of API's and excipients.

Verify blend uniformity through sampling and analysis.

**Tablet Compression:** Feed granules into a tablet press.

**Advantages [15]:**
**No Solvent Residue:** Dry granulation eliminates solvent-related issues.

**Moisture-Sensitive Materials:** Suitable for moisture-sensitive or thermolabile materials.

**Disadvantages [15]:**
**High Compression Force:** Requires high compression force, potentially causing tablet defects.

**Limited Binder usage:** Restricts binder selection and usage.

**Hot Melt Extrusion 6, 12:** Melt Extrusion is a revolutionary manufacturing process that transforms chewable tablets into a seamless blend of art and science. By combining active ingredients, excipients and binders into a uniform molten mixture, this technique creates a consistent and controlled release of flavors, textures, and nutrients.

**Steps:**
**Mix and Match:** Combine active ingredients, excipients, and waxes in a specific order.

**Heat it up:** Melt the mixture in an extruder, like a giant mixer, until it forms a uniform goo.

**Shape it:** Force the goo through a die to create a long, thin rope-like shape.

**Cool down:** Let the rope cool and harden.

**Chop Chop:** Cut the rope into small pieces, called extrudates.

**Mill time:** Grind the extrudates into a fine powder.

**Mix and mingle:** Blend the powder with other excipients, like flavours and colours.

**Compress:** Squish the mixture into a chewable tablet shape using a tablet press.

**Quality check:** Inspect the tablets for texture, taste and appearance.

**Advantages [14]:**

1. Fast and inexpensive process.
2. Reproducible process.
3. Customizable to many dosage forms.

**Disadvantages [14]:**

1. Formulation of large size capsules.
2. High start-up coast.

**Fluid Bed Granulation 4:** Fluid bed granulation is a process used in pharmaceutical manufacturing to create granules from powder materials.

In the context of chewable tablets, fluid bed granulation is particularly useful for several reasons such as; uniformity, flowability, densification, moisture control, taste masking, stability.

**Steps:**
**Pre-mixing:** Active pharmaceutical ingredients (API's), excipients and binders are mixed together in a uniform blend.

**Fluidization:** The pre-mix is loaded into a fluid bed granulator, where a steam of air is passed through the mixture, creating a fluidized state.

**Spraying:** A binding agent (e.g., water or solvent) is sprayed onto the fluidized mixture, creating droplets that stick together to form granules.

**Granulation:** The fluidized mixture is continuously mixed and sprayed with the binding agent, growing the granules to the desired size.

**Drying:** The fluid bed is used to dry the grains using hot air, removing moisture.

**Sizing:** The dried granules are sieved or milled to achieve a uniform size distribution.

**Blending:** Additional excipients (e.g., lubricants, flavourings) are blended with the granules.

**Compression:** The tablet technique is used to compress the finished blend into chewable tablet.

**Quality Control:** The tablets are inspected for weight, hardness, and other quality attributes.

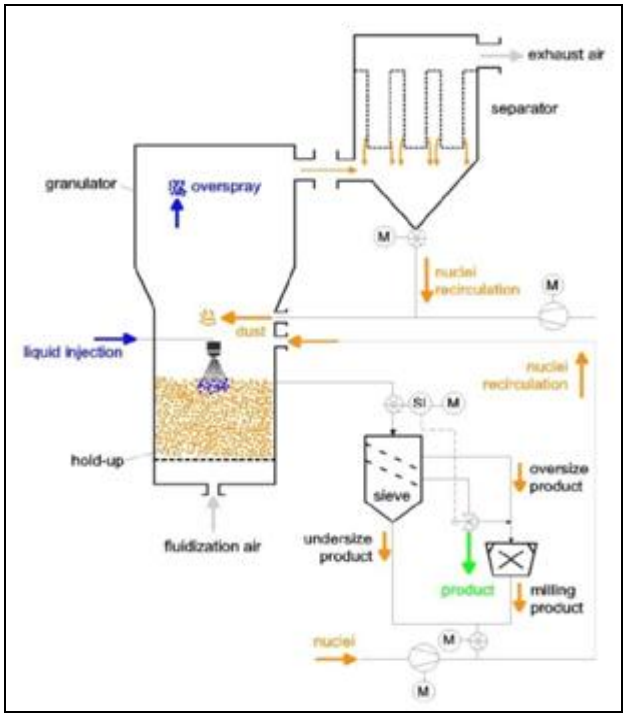



**FIG. 1: FLUID BED DRYER**

**Advantages [15]:** It facilitates the drying of thermostable substance. Since many things happened in static beds, the chance of soluble material migrating is eliminated by the free momentum of each individual particle.

**Disadvantages [15]:** It is crucial to electrically earth the drying process in order to prevent the development of electro static charges in many organic powders.

**Spray Drying [7]:** A cutting-edge technique for adding delicate components, such APIs and excipients, to chewable tablets is spray drying.

This process involves atomizing a liquid mixture containing the active ingredients into a hot gas stream, instantly evaporating the water and leaving behind a powder or dry particles after being combined with additional excipients, these particles are compacted into chewable tablet.

**Steps:**

**Pre-mixing:** Blend active ingredients, excipients and binders in a uniform mixture.

**Liquid Preparation:** Dissolve or suspend the pre-mix in a solvent (e.g., water or ethanol).

**Spray Drying:** Spray the liquid mixture into a hot air stream, instantly evaporating the solvent.

**Particle Formation:** The mixture forms small, uniform particles (powder or granules).

**Collection:** Collect the powder/granules in a chamber.

**Milling:** Mill the powder/granules to a uniform size, if needed.

**Lubrication:** Add lubricants (e.g., magnesium stearate) to the powder/granules.

**Compression:** Compress the powder/granules into chewable tablets using a tablet press.

**Quality Control:** Test the tablets for texture, taste, and performance.

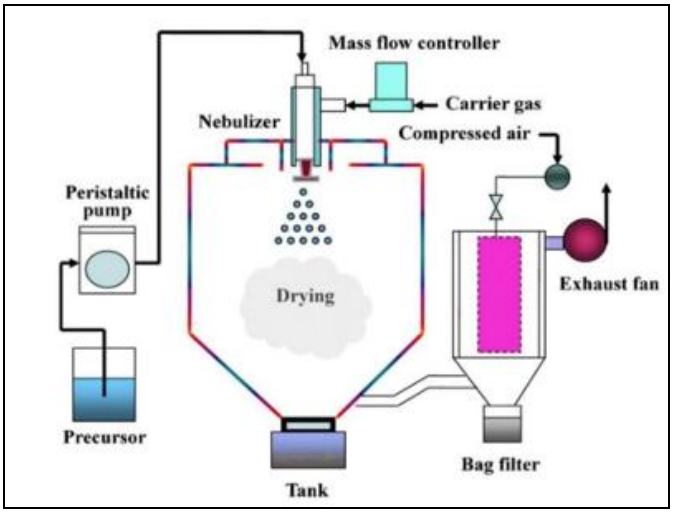



**FIG. 2: SPRAY DRYING**

**Advantages [11, 9, 15]:** It improves the better physical properties such as better flowability, compatibility or reduced hygroscopicity compared to individual compounds or their physical mixtures. Benefits of spray drying to improve direct compression properties of pharmaceutical excipients and API's. The product exhibits outstanding solubility, and the fine droplets that form offer a significant surface area for heat and mass exchanges.

**Disadvantages [15]:** It should be operate in under oxygen free environment. It is use full for encapsule (coating) of solid and liquid particles.

**3D Printing Method 8, 16:** In light of this, a unique manufacturing technique for creating personalized chewable dose forms has been proposed: three-dimensional 3D printing, specifically the semi-solid extrusion technologies.

This cutting-edge method provides flexibility for patient-specific dosages, excipients, and organoleptic properties all of which are essential for guaranteeing therapy efficacy, safety, and compliance.

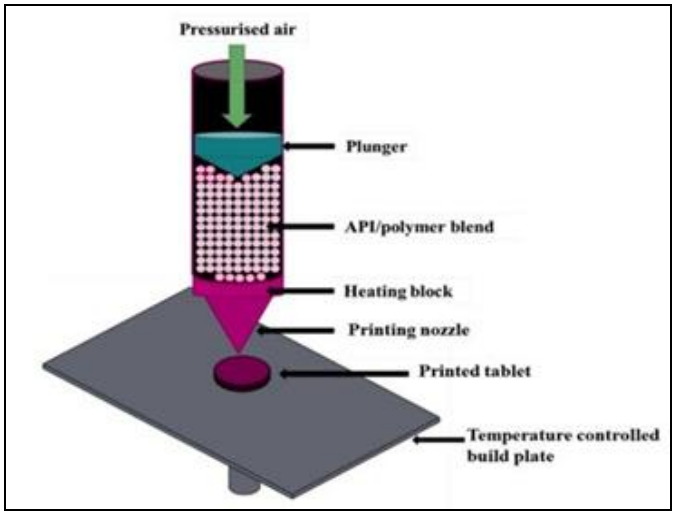



**FIG. 3: 3D PRINTING**

**Steps:**

**Design:** Create a digital blueprint of the tablet's shape, size and structure using computer- aided design (CAD) software.

**Material Preparation:** Mix and prepare the active pharmaceutical ingredients (APIs) with suitable excipients and binders to create a printable paste or filament.

**Loading:** Fill the 3D printer's reservoir or extruder with the prepared material.

**Layer Formation:** The printer deposits the material layer by layer, following the designed pattern, to build the tablet's structure.

**Fusion:** Apply heat, pressure, or solvent to fuse the layers together, ensuring tablet cohesion.

**Shaping:** The printer shapes the tablet to its final form, including any intricate designs or features.

**Drying:** Allow the tablet to dry completely, removing any excess moisture.

**Finishing:** Apply coatings, colours or other finishes as desired.

**Quality Control:** Inspect the printed tablets for quality, accuracy and consistency.

**Packaging:** Package the 3D-printed chewable tablets for distribution and use.

**Advantages [8]:** This technique is adaptable and can quickly customize the drug release profile, size, shape, and dosage of small batches of medications. One effective substitute technique for creating customized chewable tablets is 3D printing.

**Disavantages [8]:** It is suitable for certain kind of excipients and API'S only.

**Compression Coating [10]:** Compression coating is a pharmaceutical manufacturing process that involves applying a layer of material, usually a polymer or wax, to the surface of a chewable tablet using compression forces. This coating enhances This coating improves the tablet's the durability, controls the release of active substances, improves appearance, and covers up undesirable tastes or odorsor odors, controls the release of active ingredients, and improves durability.

**Preparation of Tablet Core:** Manufacture the chewable tablet core using a combination of active ingredients, excipients, and binders.

**Preparation of Coating Material:** Mix the coating material (e.g., polymer, wax) with other ingredients like: Plasticizers (e.g., Glycerine, triacetin) Pigments (e.g., colors) Flavorings (e.g., sweeteners, fruit flavors) other additives (e.g., anti-tacking agents, lubricants).

**Application of Coating Material:** Load the tablet cores into a tablet press or coating pan. Apply a controlled amount of coating material on to the tablet cores. Use a spraying or dusting technique to evenly distribute the coating material.

**Compression:** Use a tablet press to compress the coated tablet cores. Apply a controlled force (compression force) to ensure the coating adheres evenly and firmly to the tablet core.

**De-dusting:** Remove Excess coating material from the tablet surfaces using a de-dusting process (e.g. air jet, brush).

**Polishing (Optional):** Apply a small amount of wax (e.g., beeswax, carnauba wax) to the tablet surfaces. Use a polishing pan or tablet press to

distribute the wax evenly, enhancing the tablet's appearance.

**Inspection and Packaging:** Inspect the coated tablets for Uniformity of coating, Colour consistency, Absence of defects (ex., chipping, cracking). Package the coated tablets in suitable containers (e.g., bottles, blister packs).

**Advantages [13]:** It is possible to create tablets in a variety of shapes, including rectangular and triangle ones Effects resulting from subtherapeutic concentrations in plasma will be avoided Plasma levels remain stable throughout the treatment period and remain within the therapeutic window. Many tablets can be film coated in a short time.

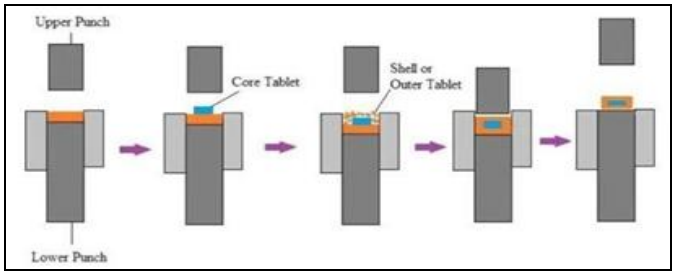



**FIG. 4: COMPRESSION COATING METHOD**

**Disadvantages [15]:** Due to its simplicity and low cost, it has not replaced film coating. Recent developments in coating materials, such as side-vented containers, have improved the performance of aqueous processes to such an extent that even aspirin tablets can be processed.

**Encapsulation Method [9, 7, 5]:** Encapsulation of chewable tablets is a pharmaceutical manufacturing process where a chewable tablet core is enclosed within a capsule shell, typically made of Gelatine, HPMC (hydroxypropyl methylcellulose), or starch-based materials. This process enhances the tablet's appearance, masks unpleasant tastes or odors and improves patient compliance.

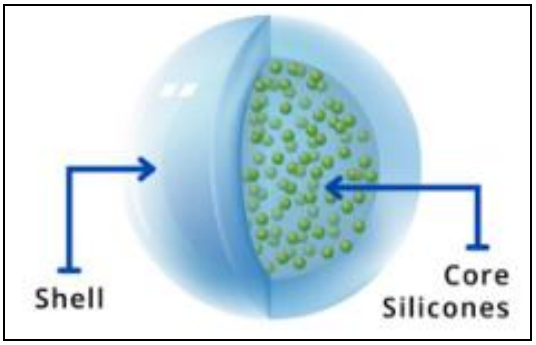



**FIG. 5: ENCAPSULATION**

**Steps:**

1. Dispensing of material according to order and accurate amount.
2. Then collect the entire material.
3. Binding agent was taken and dissolve in suitable solvent.
4. After that add the API with binding solution.
5. Continuously mixing & dry the solution in the tray dryer.
6. Dried material shifted with the help of 20 mesh.
7. Keep the sifted material separately.
8. Then add the lubricant and glidant in the sifted material.
9. Final tablet is compressed in tablet press.

**Advantages [11]:** The main benefits is handling of liable material because of the short time contact in dryer. Protect the molecule from the compound.

**Disadvantages [14]:** Difficult to control. Unwanted action. Thorough cleaning is required to remove monomers, organic solvents and surfactants.

**Chewing Difficulty Index for (FFRT) Flat Faced Round Tablet [8, 10]:** In chewable tablets, the hardness of the tablet is also an important factor in its suitability for the intended patient. The two most commonly used methods for measuring tablet strength are:

1. Diamond compression (Diamond tensile strength)
2. Flexural bending. (flexure tensile strength test)

Discover the relationship between two methods for calculating the cost of (CDI) Chewing difficulty index. Radial tensile strength ((σh)) is calculated using the following formula:

$$\sigma h = 2Fh/\pi DH \quad \text{……. Equation (1)}$$

Fh = Load required to break the tablet, D = Tablet diameter, H = Thickness of tablet.

Equation 2…… provides another way to calculate the transverse tensile strength due to bending.

$$\sigma f = 3FfL/(2D\,H^2) \text{……. Equation (2)}$$

Ff = tablet breaking force, L= constant distance between two lower supports.

The tensile strength value determined by the two methods (diameter and bending method) is proportional. Rearrange the equation. 4 gives the relationship between the forces Ff and Fh.

$$\sigma f = k\sigma h \text{ …. Equation (3)}$$

K = Proportionality constant, Subequation (1) & (2) in equation (3).

$$3FfL/2DH^2 = K\ 2Fn/\pi DH \text{ …… equation (4)}$$

Rearrangement equation (4) gives the relationship between the Ff and Fh.

$$(3\pi L/4K)Ff = FhH \text{ …….equation (5)}$$

Formula 5 defines the limits and relationships of the difficult digestion index (CDI). If the tensile strength is measured by the diameter pressure test.

$3\pi L/A$ = Experimental constant

K = proportionality constant between two tensile strength, Fh = the product of the load required to break the tablet, H = Tablet thickness, Both (Fh) and (H) measure the difficulty of chewing a tablet.

$$CDI = FhH$$

Bursting strength is a measure of the mechanical strength of tablets. The FDA guidance on chewable tablet recommends a breaking force upper limit of 12 kiloponds (kp).

CDI score: 2-3(out of 10)

Easy to chew, requires minimal forces & effort to break down.

**CONCLUSION:** Chewable tablet is designed for the dysphagia patients. The chewable Tablets also provide systemic and local effect. The comprehensive review serves as valuable resource for pharmaceutical research involved in the development of chewable tablet, ultimately to improve therapeutic action of patients and also have beneficial effect, aim to reduce the adverse effect rises from using excipients. In this review discussed about the chewable tablet along with their formulation methods and explained about various methodologies involved in formulation of chewable tablet. Additionally, clearly elaborate the novel methodologies used in the chewable formulation. The review discuss the CDI (chewable difficulty index) it plays important role in the evaluation process of chewable table

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**CONFLICT OF INTEREST:** The authors declare the there is no conflict of interest

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