IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 1, May 2024

Chewable Tablet

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Abstract: *Chewable tablets are oral dosage forms that are intended to be chewedbefore swallowing. They are designed to be easily broken down in the mouth, usually flavoured to improve taste, and are convenient for patients who difficulty swallowing traditional tablets or capsules. Chewable dosage forms, such as tablets, lozenges, pills, gums, etc., before administration, they need to be broken and bitten in the middle of the teeth. Chewable tablet is given to children who struggle with swallowing and adults who are prefer not to swallow, these tablets address both demographics needs. Chewable tablets are meant to smoothly disintegrate in the mouth at a moderate pace, whether chewed or not. Patients in the geriatric and paediatric demographics, as well as those who are traveling and may lack immediate access to water, greatly benefit from easily swallowable dosage forms such as chewable tablets. They typically feature a smooth texture upon disintegration, are enjoyable to taste, and do not leave behind any bitter or unpleasant aftertaste. The main formulations factors common to chewable tablets include flow, lubrication, disintegration, compressibility, compatibility, and stability. The chewable composition includes a gum core, which may or may not be coated, comprising an insoluble gum base along with fillers, waxes, binders, sweeteners, and flavouring agents. The addition of flavouring agents enhances its palatability. Formulating chewable tablets involves various factors. This article discusses about chewable tablet, advantages and disadvantages of chewable tablet..*

Keywords: chewable tablet, disintegration compressibility, dissolution, bioavailability, Pharmacokinetics.

I. INTRODUCTION

Chewable tablets, necessary to break and chewed between the teeth prior to ingestion, that are provided to children struggling with swallowing and to adult's dislike to swallowing [1]. Since, pharmaceutical companies are now redirecting their efforts towards developing the new dosage forms for existing drugs. These forms aim to enhance the safety and efficacy while decreasing dosing frequency and producing more cost-effective alternatives. The oral route is favoured due to its adaptability the dosage forms design and patient adherence. While various administration routes are existed for drug delivery. The oral remains a prefer method of administration for most therapeutic agents intended to induce systemic effects. This preference is due to its numerous advantages and the greater patient compliance it offers c compared tomany alternative routes. Chewable tablets, necessary to break and chewed between the teeth prior to ingestion, that are provided to children struggling with swallowing and to adult's dislike to swallowing [1,3]. Since, pharmaceutical companies are now redirecting their efforts towards developing new dosage forms for existing drugs. These forms aim to enhance the safety and efficacy while decreasing dosing frequency and producing more cost-effective alternatives. The oral route is favoured due to its adaptability in dosage form design and patient adherence. While various administration routes are existed for drug delivery. The oral route remains the preferred method of administration for most therapeutic agents intended to induce systemic effects. This preference is due to its numerous advantages and the greater patient complains it offers compared to many alternative routes [2,4,5]. Upon disintegration chewable tablets usually possess a smooth texture, pleasant taste, and leave no bitter aftertaste. The tablet comprises the active pharmaceutical ingredient (activedrug) along with various excipientswhich are biologically inert substances serving to enhance therapeutic effects or necessary for tablet construction. Binders, such as methyl cellulose or gelatine bind ingredients tighter for tablet formation. Fillers or diluents, lactose, sorbitol, act as bulking agents proving materials for accurate tablet formation. Disintegrates, like starch or cellulose, facilitate tablet breakdown in gastrointestinal tract, assuring API dissolution. Occasionally, super disintegrantsexpedite tablet disintegration lubricants like magnesium stearate or polyethylene glycol reduce friction during compression and injection process. Additional ingredients like

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colouring agents, flavouring agents and coating agents also be included. Formulation is developed using small quantities n laboratory in laboratory device known as powder compaction stimulatorto validate manufacturing process and gather information.

Figure 1. Chewable tablet

Advantages: -

Primary aim of chewable tablets is to offer a suitable unit dosage format for medication. Facilitating easy administration to individual such as children and elderly who can struggle with swallowing whole tablets possess several advantages are as follows:

1) Enhanced patient acceptance, particularly among paediatric patients, is achieved through a pleasant taste.
2) Patient convenience is assured as tablet require no water for swallowing.
3) It is feasible to employ them as replacement for liquid dosage forms in a situation requiring rapid onset of action.
4) Drug absorption occur at rapidly.
5) In some cases where dosage form is large and challenging to swallow, chewable tablets provide advantages over it.
6) Enhance bioavailability is achieved by passing disintegration leading increased dissolution.
7) Being unit dosage formed they exhibit excellent dose precision and minimal content variability.
8) By using a coating masking y objectionable odour and better taste is achieved.

Disadvantages of chewable tablets: -

1) Excessive fragrance in chewable tablets can lead to stomatitis.
2) Multiple excipients employed in chewable tablet to given tablet characteristic and bulk; however, certain excipients, such as sorbitol, pose risk to the body, inducing diarrhoea and flatulence.
3) Due to lower mechanical strength, careful handling required during packaging and transportation chewable tablets.
4) In production of chewable tablets, bitter substances are strictly avoided.
5) Extended chewing of chewable tablets results in discomfort in facial muscles.

Need/requirement for the development of chewable tablet: -

1) Oral dosage forms, such as chewable tablets, transition to another solid dosage form.
2) The persistence of the need to develop chewable tablets stems from patients' poor acceptance and adherence to current delivery systems, constraining the market size for pharmaceutical companies and their drug applications, along with the high cost of managing the disease.

General excipients used in the formulation of chewable tablets: -

The primary determinants of acceptability in formulating chewable tablets are taste, with appearance playing secondary role. Thus, it is crucial to select and utilize components that influence these properties appropriately. While ensuring purity, safety, efficacy, and stability remain paramount, the formulator should not overlook other pharmaceutical and

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biomedical considerations. Factors such as moisture content and absorption particle size distribution, blending and loading potential, as well as flow and compressibility, demand equal attention an must be addressed by the formulation/process development pharmacist. However, in case of chewable tablets, additional considerations such assweetness, chewiness, mouth feel, and taste must also be taken this account.

Some of the excipients are as follows: -

1) bulking agent / Diluent: -

bulking agent serve to augment the volume of chewable tablet formulations, ensuring that the finalproduct achieves adequate weight and bulk when combined with the medicinal components. This facilitates easier handling and production processes [6].

2) Mannitol: -

Frequently utilized as a diluent, mannitol proves to being appealing bulking agent for tablets when the taste of chewable tablets gains significance. Its utilization stems from its negative heat, sweetness, and “mouthfeel” attributes in solution, making it a commonchoice as diluent in chewable tablet formulations. Additionally, due to its lower water content, mannitol finds widespread use in formulations sensitive o moisture.

3) Sorbitol: -

Manifesting as an odourless, white, or nearly opaque crystalline powder with hygroscopic properties, sorbitol serves as polyol. Employed as a Diluents in tablets, it finds application in both wet granulation and direct compression manufacturing processes.

4) Dextrose: -

Within tablet formulations, dextrose functions as a diluent. This colourless substance, known as glucose, lacks odour and possess a sweet taste. Employed as most granules, dextrose serves as both a diluent and binder.

5) Lactose: -

Referred to as milk sugar, lactose is derived from milk, constituting a disaccharide. Obtained from the residual liquid post cheese and casein production. Lactose servesas prevalent diluent in tablet manufacturing. Widely acknowledged as an excipient for tablet formation, it holds a significant role.

6) Flavouring agent: -

Regarding consumer acceptance, taste emerge as the pivotal factor in evaluating chewable tablets. Taste comprises mouthfeels, sweetness, and flavour perceptions. n\mouth feel hinges on the heat of solution of soluble components, the smoothness of the combination during chewing, and tablet hardness. Flavouring agent play a crucial role in enhancing the taste of chewable tablets. Commonly, spices are employed to impart a pleasant favour and often fragrance to these tablet [7]. Thee flavouring agents are obtainable in various physical forms from numerous specialized suppliers, including water-miscible solutions, oil bases, emulsion, drypowder, spray-dried beadles, and dry absorbents [8].

Flavours	Group for testing types
Sweet	Vanilla, fruits, maple, berries
Sour	Raspberry, cherry, root beer, strawberry
Salty	Butterscotch, nutty, buttery, spice,
Bitter	Coffee, cherry, liquorice, peach, mint
Metallic	Grape, lemon-line
Alkaline	Chocolate, cream, vanilla v

Table No. 1: flavour groups and its taste and types

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7) Sweeteners or taste enhancing agents: -

Sweeteners play a crucial role as excipients in chewable tablets. Their inclusion is primarily necessary when commonly used carriers like lactose, sucrose, mannitol, and dextrose fail to completely mask the taste of the API or components. In such instances, formulators resort to artificial sweeteners to enhance overall sweetness levels [9]. The taste-masking technique represents the initial and most straight forward approach, particularly in paediatric formulations, chewable tablet and liquid preparations.

Materials	Relative sources
Aspartame	200
Glycerrhiya	50
Saccharine	500
Fructose	1.7
Lactose	0.2
Mannitol	0.5-0.7
Sorbitol	0.5-0.6
Sucrose	1
Cyclamates	30-50
Dextrose	0.7
Maltose	0.3

Table no.2: sweetening agent and their relative sweetness level

8) Colorants: -

Chewable tablet formulations frequently incorporate colorants for the subsequent purposes:

1.Elevating consumers perception of superior application.

2.Facilitating the straight forward product identification and differentiation

The 1938 food, drug and cosmetics Act established three categories of coal tar dyes, yet only FD and colours are utilized in chewable tablets, while D and C shades are utilized in their products[10]. The third category (External D and C) is deemed safefor external application but is deemed unsuitable for ingestible products due to oral risks.

Methods and techniques for manufacturing tablets and granulation: -

Chewable tablets are typically prepared through the following methods: -

1.Direct compression

2.Dry granulation

3.Wet granulation

1) Direct compression

In the direct compression method, pills are formed by combining components using a pill press, without altering any ingredients. This method is not commonly used due to the presence of active medicinal ingredients in many tables, which may not exhibit suitable consistency for direct compression. Previously, direct compression was primarily applied to a small subset of a crystalline synthetic compounds processing the requisite physical properties for producing high quality tablets [11].

Advantages of direct compression: -

-cost-effectiveness

-reduced stability issues

-optimal dissolution profile

-simplified validation process

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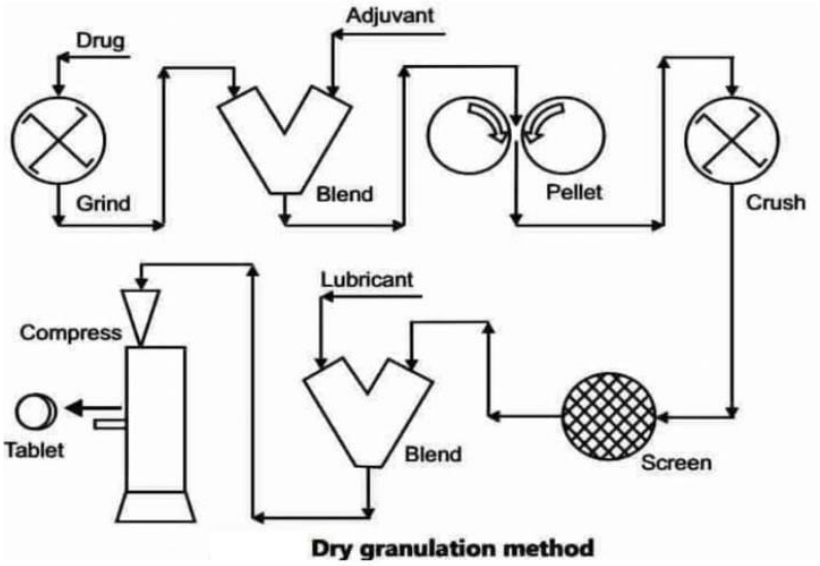
2) Dry granulation: -

A novel approach to semi-automated granule production is introduced, applicable to all solid dosage pharmaceutical. This method, replacing traditional solid dosage form development and manufacturing technologies, offers expediated development and enhanced quality [12]. Dry granulation, achieved through either roller compaction or slugging, involves compacting dry powder, granulating it into uniform particles, a shaping various form. Resulting granule are porous, highly compressible, allowing for rapid dissolution and customizable release times.

Advantages: -

-reduced processing times and consistent particle size distribution compared to granules produced via the slug-de-slug process.



2. Dry granulation method [**Fig** 13]

3) Wet granulation: -

Utilizing wet granulation technology enhances the flow and compressibility of the mixture for compression by employing appropriate nontoxic granulation fluids and mechanical agitation [14]. Unlike dry granulation, wet granulation amalgamates fine powder particles into larger, solid, relatively unchanged structures known as granules. This processenlarges particle size and is ideal for materials unsuitable for dry granulation due to factors such as high proportions, poor flowability, low bulk density, and lack of binding properties. Wet granulation, a widely utilizes method, involves wet massing active pharmaceutical ingredients with granulating liquids, optionally incorporating binding agents.

Advantages of wet granulation method: -

1.Prevents segregation of components within a homogeneous powder.

2. achieves controlled release of dosage forms through the selection of appropriate binder solvents.

Factors for formulation: -

In the formulation of chewable tablet, multiple factors contribute to their composition. The characteristics of the active pharmaceutical ingredients hold paramount importance particularly regarding the organoleptic properties of both swallowed and chewable tablet [15].

1]Taste and flavour: -

Upon chemical stimulation of the taste receptors of the tongue, a sensory responseknown as taste occurs. The foundational taste encompassessalty,sour,sweet,and biter [16]. A substance is deemed tasteless if it fails to elicit any

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response from the sensory receptors in the taste buds. The term “flavour” delineates a distinct blend of taste and aromas.

For example: - honey

2]taste masking: -

the process of flavour masking entails the elimination of unpleased taste. This can be accomplished by employing taste-masking agents, particular aromas, andsweeteners to hide undesirable taste [17]. Flavour masking and processing technique serve as the main approaches to tackle these issues, frequently incorporating additions such as flavouringssweeteners, fats and acids to disguise tastes.

3] Aroma: -

The term “aromas” encompasses all pleasant fragrances collectively. For example, a well-crafted chewable orange tablet should possess the sweet-tart flavour and aroma reminiscent of a real orange.

4}Mouth feel: -

This term denotes the tactile sensation felt within the oral cavity while chewing the tablet [18].

Evaluation parameters for the chewable tablet: - [19,20]

When formulating chewable tablet, its essential to consider a variety of evaluation parameters, which are outlinesfollows: -

In process organoleptic evaluation: -

This evaluation occurs at various stages during the development of a chewable tablet, andthese stagesinclude: -

1) Evaluation of dug itself: -

It entails characterizing and comparing the substances either in absolute quantity or against a recognized reference standard.

2) Evaluation of coated tablet: -

Comparison is made against both the pure drug and various coating treatments.

3) Evaluation of unflavoured baseline formulation: -

It entails comparing different vehicles, proportions of vehicle s, or other formulation variable in the presence of coating drug.

4) Evaluation of flavoured baseline formulation: -

It includes comparing different flavoured formulations.

5) Evaluation of final selection and product acceptance: -

Test entails comparing between two formulations or competitive product.

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

1]Physical appearance: -

Size and shape: -

Controlling tablet size ad shape to adhere to specifications is essential. This is achieved during the compression process using the appropriate tooling [21,22].

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2] Hardness: -

To determine the hardness of tablets, utilize a tablet hardness tester such as Pfizer's Schenirer harness tester as an example he Monsanto hardness tester comprises acylinder with the compression spring positioned between two defoggers. The lower delogger contacts the tablet, eliminating the need for read-through. Next press he upper delogger against the spring by rotatingthe cocked lever until the tablets breaks(40-60N), unless otherwise specified. Refer to the guidelines and rationale provided in Appendix I of the chronicle under "indicators of Difficulty Chewing". This allows for padding / agglomeration possibilities and facilitates the transmission of chewing difficulty index data for rtvcle enhancement. Hardness represents the force required to fracture the tablets, reflecting their strength or quality. Hardness is evaluated using a Monsanto hardness analyser or tester, with results expressed in kg/cm2[23].

3. Friability: -

Friability testing offers insights into the tablets' ability to resist abrasion and prevent breakage during handling, shipping, and packaging. Using a Roche Friabilator, 10 tablets are weighed, placed in the apparatus, and spun at 25 rpm for 4 minutes. Afterward, the tablets are removed, dusted, and retested [24].

The equation to determine the tablet's brittleness is:

% Brittleness = [(initial weight – final weight)/initial weight] × 100.

Disintegration: -

The USP collapse mechanical unit comprises six open-top glass tubes, each three inches long,secured against mesh screen at the bottom of a container rack. To assess degradation time, insert one tablet into each cylinder and position the basket rack in the designated medium at 37 ± 2 °C, ensuring the down remains within 1 inch of the bottom of the cup. A standard motorized device moves the basket assembly, containing the tablets, up and down over a distance of 5-6 cm at a frequency of 28-32 cycles per minute [25-27]

5] Dissolution: -

The dissolution test assesses the time required for a given percentage of medication in a tabletto release under specific conditions of pH, volume, agitation, and temperature. The absorption of drugs from chewable tablets relies on the release of the active ingredient(s) from the intact or chewed tablets. Therefore, in vitro dissolution testing of chewable tablets should adhere to the guidelines established for the dissolution testing of conventional immediate-release (IR) tablets.

For product characterization during development, in vitro dissolution testing should be conducted on intact tablets in at least four media, including water, liquid media at pH 1.2, buffered aqueous media at pH 4.5, and buffered aqueous media at pH 6.8, utilizingestablished dissolution methods employing equipment such as USP Apparatus 1 (basket), USP Apparatus 2 (paddle), or USP Apparatus 3 (reciprocating cylinder). In vitro drug release studies are performed using USP Apparatus 2 (paddle) with 900 ml of 0.1N HCl as the dissolution medium. The temperature of the dissolution medium is maintained at 37±0.5°C, and the rotation speed is set to 50 rpm. Samples are withdrawn at various time intervals of 10, 20, and 30 minutes and replaced with an equal volume of fresh dissolution medium. The samples are appropriately diluted, and the absorbance of the solution is determined using UV-visible spectroscopy at wavelengths of maximum and minimum absorbance, approximately 308 nm and 350 nm, respectively [28].

Uses of chewable tablets: - [29-31]

1.Local therapy involves the gradual release of an active substance from a chewable tablet over an extended duration.

2.For pain relief its crucial to achieve rapid absorption of therapeutic levels of the active ingredient. Chewable tablets are beneficial for treating mild pain because buccal absorption ensures a swift onset of action while reducing the risk of gastrointestinal side effects.

3.Chewable tablets can also aid in systemic drug delivery, particularly if the active ingredient is absorbed through the buccal mucosa.

4.tn the clinical trials, nicotine, lobeline, and silver acetate chewing gum formulations have been investigated as aids for smoking cessation.

5.In the context of obesity management, chewing gum formulations containing caffeine and chromium are available.

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Marketed formulations of chewable tablet: -

Brand name	Active Constituent	Category	indication	MFG. By
Claritin [32]	Loratadine	Antihistamine	Running nose, sneezing	Bayer
Montair[33]	Montelukast	Antiasthmatic	Sneezing , asthma attack	Cipla Ltd.
Lamictal[34]	Lamotrigine	Anticonvulsant	Seizure	GlaxoSmithKline
Mylanta Gas Minis[35]	simethicone	Gastrointestinal agent	Relieve flatulence	McNeil Consumer Pharmaceutical Company

II. CONCLUSION

Chewable tablets offer versality s a dosage form, blending the manufacturing and stability benefits of solid products with favourable organoleptic qualities and ease of administration the growing focus on patient -centric formulations in drug delivery opens up additional possibilities for utilizing chewable tablets, particularly in targeted population like paediatric and for specialized pharmaceutical products. Moreover, they find applications in various healthcare sectors such as nutritional products, nutraceuticals, and veterinary medicines.

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