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A COMPREHENSIVE REVIEW ON CHEWABLE TABLETS

Agilan V.*[1], S. Kokila[2] and Mr. S. Shyam Sudarsan S.[3]

[1*,3]M. Pharm, Department of Pharmaceutics. School of Pharmacy, Sathyabama Institute of Science and Technology. Chennai, Tamil Nadu- 600119.

[2]Assistant Professor, School of Pharmacy. Sathyabama Institute of Science and Technology. Chennai, Tamil Nadu- 600119.

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***Corresponding Author**
Agilan V.
M. Pharm, Department of Pharmaceutics. School of Pharmacy, Sathyabama Institute of Science and Technology. Chennai, Tamil Nadu- 600119.

ABSTRACT

Chewable tablets which are needed to be broken and masticated in between the teeth before ingestion. These tablets are given to the children who have difficulty in swallowing and to the grown-ups who dislike swallowing. These tablets are intended to disintegrate easily in the mouth at a moderate rate either with or without factual chewing, characteristically chewable tablets have a smooth texture upon decomposition, are affable tasting and leave no bitter or unwelcome taste. senior and paediatric cases and travelling cases who may not have ready access to water are most need of easy swallowing lozenge forms like chewable tablets. The composition of chewable tablet consists of goo core, which may or may not be carpeted. The core is composed of an undoable goo base like paddings, waxes, antioxidants, sweeteners, flavouring agents. The chance of goo base varies from 30-60 depending upon the base used and its parcels. A flavouring agent is included to make it more palatable. colourful factors involved in the expression of chewable tablets. The major expression factors are inflow, lubrication, decomposition, organoleptic parcels, compressibility, comity and stability, which are common to regular (swallowed) and chewable tablets; still, organoleptic parcels of the active medicine substances are primary concern then. A deviser may use one or further approaches to arrive at a combination of formula and process that affect in product with good organoleptic parcels. Such a substance must have respectable inflow, compressibility and stability characteristics.

KEYWORDS: chewable tablet, gum core, antioxidant, compressibility etc.

1. INTRODUCTION

Chewable tablets which are needed to be broken and masticated in between the teeth before ingestion. These tablets are given to the children who have difficulty in swallowing and to the grown-ups who dislike swallowing. These tablets are intended to disintegrate easily in mouth at a moderate rate either with or without factual chewing, characteristically chewable tablets have a smooth texture upon decomposition, are affable tasting and leave no bitter or unwelcome taste. Successful tablet expression development involves the careful selection of constituents in order to manufacture a robust solid lozenge form. Choosing the applicable excipient to perform a specific function in a tablet expression similar as decomposition or lubrication can be critical to achieving respectable manufacturing performance. Sweeteners, both naturally being and synthetic are one type of functional excipient generally used in chewable tablet phrasings to mask the unwelcome tastes and grease paediatric dosing. immaculately upon biting, they're broken down in the mouth and release their constituents in the process and thus, don’t have important pause time as needed for the decomposition of tablets before immersion from stomach. Chewable tablet is frequently employed when the active component is intended to act in a localized manner rather than systemically. Chewable tablet is one that's palatable and may be masticated and ingested with little or no water. Manufacturing of chewable tablet is generally done using either wet granulation process or direct contraction. Decreasingly, micronized and submicron forms of therapeutically and physiologically active substances are incorporated into tablet expression to take advantage of the enhanced immersion characteristics of these forms. They're also used in the administration of antacids and carminatives. Mannitol is extensively used as an excipient in chewable tablet for its non-hygroscopic nature for humidity sensitive medicines. As we know difficulty in swallowing Dysphasia) is common among all age groups, especially in senior and in also seen of swallowing of conventional tablets and capsules. senior and paediatric cases and travelling cases who may not have ready access to water are most need of easy swallowing lozenge forms like chewable tablets. The composition of chewable tablet consists of goo core, which may or may not be carpeted. The core is composed of an undoable goo base like paddings, waxes, antioxidants, sweeteners, flavouring agents. The chance of goo base varies from 30- 60 depending upon the base used and its parcels. A flavouring agent is included to make it more palatable.

1.1 Advantages of Chewable Tablets

Chewable tablets are generally nibbled in the mouth former to swallowing and aren't anticipated to swallow complete. Main purpose of chewable tablet is to give proper unit capsule form of medicine which can easily be administered to children or to the elderly who have difficulty in swallowing a tablet complete. Chewable tablet have some specific advantages.

- Further bioavailability through bypassing corruption (that increase dissolution.)
- Advanced case acceptance (especially paediatric) through affable taste.
- Case convenience; need no water for swallowing.
- Possible to use as a cover for liquid capsule forms where rapid-fire- fire onset of action is demanded.
- Absorption of drug is hastily.
- Product otherness through marketing prospective.
- The large size of the capsule form is delicate to swallow. In analogous cases chewable tablet offers advantages over it.
- Effectiveness of remedial agent is bettered by the reduction in size that occurs during mastication of tablet before swallowing.

1.2 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 common 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 mechanical strength, so careful handling is required.
- They require proper packaging for safety and stabilization of stable drugs.

2. GENERAL FORMULATION FACTORS

Various factors involved in the expression of chewable tablets. The major expression factors are flux, lubrication, corruption, organoleptic parcels, compressibility, harmony and stability, which are common to regular (swallowed) and chewable tablets; still, organoleptic parcels of the active drug substances are primary concern also. A formulator may use one or farther

approaches to arrive at a combination of formula and process that affect in product with good organoleptic parcels. Such a substance must have respectable flux, compressibility and stability characteristics.

2.1 Taste and Flavours

Physiologically, taste is a sensitive response performing from a chemical stimulation of the taste kiddies on the lingo. There are four introductory types of taste; salty, sour, sweet and bitter. Salty or sour tastes are derived from substances suitable of ionizing in the result. multitudinous organic medicinal mixes stimulate a bitter response indeed though they may not be suitable of ionizing in an arid medium. utmost saccharides, disaccharides, some aldehydes and numerous alcohols give a sweet taste. Substance unfits of producing a sensitive stimulation of the kiddies is known as tasteless.

2.2 Aroma

Pleasant smells are generally appertained to as aromas. For illustration, a well formulated, orange- flavoured chewable tablet should have a characteristic sweet and sour taste and aroma of fresh orange.

2.3 Mouth- sense

This term is related to the type of sensation or touch that a tablet yield in the mouth upon smelling. As analogous, it has nothing to do with chemical stimulation of olfactory jitters or taste kiddies. still, for an expression to be successful, the overall effect in the mouth is important. In general, gritty (e.g., calcium carbonates) or sticky texture is undesirable, whereas soothing and cooling sensation (e.g., mannitol) with smooth texture is preferred.

2.4 After goods

The most common after effect of multitudinous mixes is after taste. For illustration, some irons leave a “clay” after taste; saccharin in high amounts tends to leave a bitter after taste. Another common after effect is a deadening sensation of a portion of the whole face of the lingo and mouth. Bitter antihistamines like pyribenzamine hydrochloride and promethazine hydrochloride are typical of this class drugs.

3. ASSESSMENT OF THE PROBLEMS REGARDING FORMULATION

Wherever feasible and practical, the first step in the formulation of chewable tablet is to obtain a complete profile of the active drug. This usually leads to the most efficient

formulation of a stable and quality product as the drug usually dictates the choice of fillers, carriers, sweeteners, flavour compounds and other product modifiers. The drug profile ideally should contain information on the following**.**

3.1 Physical Properties

- Colour
- Odour
- Taste, after-taste and mouth-feel
- Physical form: crystal, powder, amorphous solid, oily liquid, etc.
- Melting temperature
- Polymorphism
- Moisture content
- Aqueous solubility
- Active drug stability
- Compressibility

3.2 Chemical Properties

- Chemical structure and chemical class
- Major reactions
- Major incompatible compounds
- Drug dose

This active drug profile would eliminate potentially incompatible excipients, flavours and leading the use of excipients that would best compliment the drug physically, chemically and organoleptically. The choice of excipients and other product modifiers would involve balancing their cost with their functionality. The use of low-caloric and non sugar based excipients may represent a marketing advantage, especially with consumers concerned about caloric intake and dental caries.

4. NEED FOR THE DEVELOPMENT OF CHEWABLE TABLET

The need for non-invasive delivery systems persists due to cases' poor acceptance of, and compliance with, being delivery administrations, limited request size for medicine companies and medicine uses, coupled with high cost of complaint operation.

4.1 Case Related Factors

Roughly one- third of the cases need quick remedial action of medicine, performing in poor compliance with conventional the medicine remedy which leads to reduced overall remedy effectiveness. A new lozenge form, the immediate release tablets has been developed which offers the combined advantages of ease of dosing and convenience of dosing. These tablets are designed to release the cures with an enhanced rate. Chewable lozenge forms are particularly suitable for cases, who for one reason or the other; find it inconvenient to swallow traditional tablets and capsules with an 8- oz glass of water.

- Veritably senior cases who may not be suitable to swallow a diurnal cure of antidepressant.
- An eight- time old with disinclinations who desires a more accessible lozenge form than antihistamine saccharinity.

4.2 Effectiveness Factors

Increased bioavailability and briskly onset of action are a major claim of these phrasings. Any pre-gastric immersion avoids first pass metabolism and can be a great advantage in medicines that suffer a great deal of hepatic metabolism. likewise, safety biographies may be bettered for medicines that produce significant quantities of poisonous metabolites intermediated by first- pass liver metabolism and gastric metabolism.

4.3 Manufacturing and Marketing Affiliated Factors

Developing new medicine delivery technologies and exercising them in product development is critical for medicinal diligence to survive, anyhow of their size. As a medicine nears the end of its patent life, it's common for pharmaceutical manufacturers to develop a given medicine reality in a new and bettered lozenge form. A new lozenge form allows a manufacturer to extend request exclusivity, unique product isolation, value added product line extension and extend patent protection, while offering its patient population a more accessible lozenge form. This leads to increased profit, while also targeting underserved and under- treated case populations.

5. PHYSIOLOGY OF TASTE

Taste sensation can be expressed as a feeling by an individual when commodity is given into mouth in order to ascertain the whole element. There are generally four novitiate of taste

- Sweet and salty, mainly at the tip of lingo

- Sour, at the side of lingo
- Bitter, at the reverse of the lingo

Generally mortal lingo contains 50- 100 number onion shapes structures called taste kiddies. Chemical from foods or orally ingested cures are dissolved by saliva via taste pores. They either interact with face proteins known as taste receptors or ion- channels. These relations beget electrical changes within the taste cells that spark them to shoot chemical signal translate into neurotransmitters to the brain. swab and sour responses are of channel type responses, while sweet and bitter are face protein responses. Electrical responses, that shoot the signal to the brain, are result of varying attention of changed particles or ions within the taste cell. These cells generally retain negative charge. Tastants alter this taste by using varying means to increase the attention of positive ions within taste cell. This depolarization cause taste cells to release neurotransmitters, promoting neurons connected to the taste kiddies to shoot electrical dispatches to the brain. In the case of bitter taste drug by binding to G- protein coupled receptors on the face of the taste cell, prompts the protein subunit of birth, beta and the gamma to resolve and spark enzyme. This enzyme also converts precursor within the cell into “alternate runner ”. The alternate runner causes the release of calcium ions from endoplasmic reticulum of the taste cell. The performing figure- up of calcium ion cells lead to depolarization and neurotransmitter release. The signals give a sense which is interpreted as bitter taste. Effective blocking of taste receptors can be fulfilled by either coating the face severance or contending with the channel themselves to reduce the effect of bitter instigations firing.

5.1 Taste Masking

Taste masking is defined as a reduction of undesirable taste that would differently live. Taste masking can be achieved using taste masking agents, specific flavours and sweeteners. Sweeteners are essential to complete the experience and produce a affable taste of the product. This is one of the major limiting factors in the expression of oral capsule forms having unpleasant taste. Flavour masking and processing approaches are two primary styles to overcome this problem. Flavour masking generally include addition of flavour, sweetener, lipid and acids.

5.2 Techniques for Taste

Masking Before formulation some common problems encountered: undesirable taste, bad mouth-feel. The desired product should prevent or minimize stimulation of the taste buds, contain a suitable flavour and sweetener and achieve good mouth feel and compressibility.

The following techniques are used to solve these problems.

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

6. GENERAL EXCIPIENTS USED IN THE FORMULATION OF CHEWABLE TABLETS

Special consideration, still, needs to be given to those accoutrements that form the base for chewable tablet expression. The adequacy in the expression of chewable tablets will be primarily determined by taste and to a lower degree, appearance. thus, applicable selection and use of factors that impact on these parcels are of extreme significance. Of course, the deviser must n't come as concerned with these parcels as to lose sight of other medicinal and biomedical considerations; the attendant product must be as pure, safe, efficient, and stable as any other. The wet granulation, dry granulation, direct contraction and direct contraction processes are as applicable to chewable tablets as to any other type of tablet. The concern similar as humidity content and uptake, flyspeck size distribution, blending and loading capabilities, inflow and compressibility is no less important, and must be addressed by the expression/ process development druggist as for any product. still, in the case of chewable, the new enterprises of agreeableness, chew- capability, mouth- sense and taste must also be considered. Major excipients, similar as paddings or direct contraction vehicle have the major part in the outgrowth of these enterprises; process, a lower(but clearly not minor) part. numerous of the sweeteners are generally used in the tablet expression are especially

applicable for use in chewable tablets due to their capability to give the necessary parcels of agreeableness and chew- capability. In general these all excipients fall under the sugar order, although a combination of mellow excipients with artificial sweeteners may give a satisfactory volition. Some common chewable tablet sweeteners are Brown sugar, Compressible sugar, Honey, Dextrose/ fructose, Lactose, Mannitol, Sorbitol. Many of them need farther explanation as follows.

6.1 Sweeteners

a). Dextrose: Dextrose is the sugar attained through the complete hydrolysis of bounce. Its agreeableness position is roughly 70 that of sucrose, and is available in both anhydrous (but hygroscopic in nature) and monohydrated form.

b). Lactose: Lactose is the monosaccharide that produced from whey, a derivate of the processing of rubbish. Although generally conceded as the most extensively used pharmaceutical excipient in the world. Its connection to chewable tablets is minor at best, due to its extremely low agreeableness position (15 sucrose). This insufficiency requires the addition of an artificial sweetener of sufficient energy to overcome lactose's hotness. For wet granulation operations, regular pharmaceutical grades (hydrous fine maquillages) are available. For direct contraction, an anhydrous greasepaint having good inflow and compressible characteristics is available as lactose.

c). Mannitol: Mannitol is a white, liquid polyol roughly 50 as sweet as sucrose. It's freely answerable in water and, when masticated or dissolved in the mouth, imparts a mild cooling sensation due to its negative heat of result. This combined with an exceptionally smooth thickness has made mannitol the excipient of choice for chewable tablet phrasings.

d). Sorbitol: Sorbitol is slightly sweeter and vastly further hygroscopic isomer of mannitol. For direct contraction, it's available commercially as Sorb- Tab and liquid Tablet Type.

Table 1.1: Approximate Relative Sweetness of different Sweeteners.

Materials	Relative sweetness
Aspartame	200
Saccharins	450
Glycyrrhizin	50
Sucrose	1
Sorbitol	0.5 - 0.6
Mannitol	0.5 – 0.7
Dextrose	0.7
Maltose	0.3
Fructose	1.7
Lactose	0.2

6.2 Flavouring Agents

The perspective of consumer acceptance, taste is nearly clearly the most important parameter of the evaluation of chewable tablets. Taste is a combination of the comprehensions of mouth- sense, agreeableness and flavour. Mouth- sense is affected by heat of result of the answerable factors, smoothness of the combination during chewing and hardness of the tablet. These factors are directly and nearly entirely related to the active component and major excipients. agreeableness, at an applicable position, is a necessary background to any flavour. The primary contributors to agreeableness in a chewable tablet are the medicine, natural sweeteners and artificial agreeableness enhance that may be incorporated in the expression. Flavouring agents are available in a variety of physical forms from a large number of suppliers specializing in these accoutrements. nearly all offer specialized support services, which will be addressed in the section on flavour expression. colourful forms available include water- miscible results, oil painting bases, mixes, dry maquillages, spot-dried beadlets, and dry adsorbates. A typical flavour having the capability of producing several hundred combinations for a given operation.

Flavour Selection and Formulation

Originally, the essential taste of the active medicine must be estimated to determine its probable donation to the expression and a final decision must be made relative to expression factors that would impact on both the pharmaceutical parcels and organoleptic characteristics of the tablet. Throughout in expression development, these considerations must be maintained and ultimately optimized. The thing must be a birth expression having respectable parcels similar as hardness, frangibility, and dissolution, while furnishing a suitable mouth-sense and agreeableness background for flavouring. Having succeeded in the medication of one or further unflavoured bases, the development druggist should next prepare several introductory flavoured preferences samples. These should be designed to constrict the flavour focus to one or further groups of flavour preferred by decision makers within the company.

Table 1.2: Flavour groups for general Baseline taste types.

Sweet	Grape, berries, honey, vanilla
Sour (acidic)	Citrus, liquorice, strawberry, cherry
Salty	Buttery, spice, mixed citrus, mixed fruit
Bitter	Liquorice, wine, mint, nut, fennel, grapefruit

6.3 Colour Integration

The final aspect of taste psychology requires that the flavour and colour match. A mismatch may detract from consumer acceptance.

Colourants

Colourants are used in the manufacture of chewable tablets for the following reasons To increase aesthetic appeal to the consumer To mask non steady colour of raw paraphernalia To round and match the flavour used in the expression To prop in product identification and insulation The Food drug and cosmetic Act of 1938 created three orders of the colourants of which only first two are applicable to the manufacture of chewable tablets. These are mooted as follows FD & C colours These are colourants that are authentic for use in foods, drugs and cosmetics. D&C colours These are colourings and colours considered safe for use in drugs and cosmetics when in contact with mucous membranes or when ingested. External D&C These colourants, due to their oral poison, are n't authentic for use in products intended for ingestion but are considered safe for use in products applied externally. colourings and lakes are two main form of colourants used in the manufacture of chewable tablets depending on whether the process of manufacture is by wet granulation or direct compression.

Dyes

These are chemical conflation that exhibits their colouring power or tinctorial strength when dissolved in a soap. They are generally 80 to 93(rarely 94 to 99) pure colourant material. colorings are answerable in propylene glycol and glycerine.

Lakes

Lakes have been defined by the FDA as the “aluminium hearties of FD&C water answerable colorings extended on a substratum of alumina. Lakes prepared by extending the calcium hearties of FD&C colorings are also permitted. Lakes also must be certified by FDA.

7. MANUFACTURING

For chewable tablets, manufacturing means proper objectification of the colouring agent, conservation of correct humidity content, and achievement of proper tablet hardness. All of these are the routine responsibility of the manufacturer in the department once the parameters have been established during development. The process development and gauge up considerations be completely studied in order to insure the establishment of proper specifications. If colour is added as a lake for direct contraction mix, also the blending

operation consists of the addition of coloured greasepaint to white grains. So, coloured greasepaint will slightly cover the white grains. still, during contraction, the grains release fresh white material to the face, performing in white spots on a coloured background or "speckling".

7.1 Methods of Manufacturing

The Chewable tablets were prepared by using the following methods:

1. Non aqueous Granulation/Dry granulation
2. Aqueous Granulation/Wet granulation
3. Direct compression

Granulation

Granulation is the process in which primary greasepaint patches are made to cleave to form larger, multi-particles realities called grains. Pharmaceutically grains have size range between 0.2 to 4.0 mm. Granulation is used to ameliorate inflow and compressibility of maquillages and to help isolation of the mix factors. Granulation is substantially done by using two ways.

Dry granulation

It's the new system for semi-automatic product of grains. The system is applicable to any solid lozenge medicinal products. Dry granulation system replaces being solid lozenge form development and manufacturing technologies offering more rapid-fire development and better quality. In this process, the greasepaint admixture is compressed without the use of heat and detergent. Two styles are used for dry granulation. The further extensively used is slugging where the greasepaint is recompressed and the performing tablet are mulled to yield the grains.

Wet granulation

Wet granulation is the most generally used granulation system. This process involves wet massing of greasepaint mix with a granulating liquid, wet sizing and drying. The granulating liquid contains a detergent which must be unpredictable so that it can be removed by drying and must benon-toxic in nature. Typical liquid include water, ethanol and Isopropyl alcohol. In the traditional wet granulation system the wet mass is forced through a sieve to produce wet grains which are latterly dried.

Direct Compression

Direct contraction is the most popular choice because it provides the shortest, most effective and least complex way to produce tablets. This system is substantially used when a group of constituents can be blended. This is more suitable for humidity and heat sensitive API's since it eliminates wetting down and drying way and increase the stability of active component by reducing mischievous (dangerous) goods. In this process, API mixed with the excipients and lubricant, followed by contraction which makes the product easy to reuse.

8. EVALUATION PARAMETERS FOR CHEWABLE TABLET

The variety of evaluation parameters must be kept in mind during the formulation of chewable tablets. These are given as follows.

8.1 In-process Organoleptic evaluation

This evaluation takes place at various stages in the development of a chewable tablet. These are as follows.

Evaluation of drug itself: Evaluation of medicine itself It involves characterization and comparison of the substance in an absolute quantum or against a known reference standard.

Evaluation of coated drug: Evaluation of carpeted medicine It involves comparison against the pure medicine as well as different coating treatment.

Evaluation of unflavoured baseline formulation: Evaluation of unflavoured birth expression It involves comparison among different vehicles, proportion of vehicles or other expression variables in presence of carpeted medicine.

Evaluation of flavoured baseline formulation: Evaluation of flavoured birth expression It involves comparison among different flavoured phrasings.

Evaluation of final selection and product acceptance test: Evaluation of final selection and product acceptance test It involves comparison between two phrasings or competitive product.

8.2 Chemical Evaluation

It involves the following.

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

8.3 Physical Evaluation

It involves the following.

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

9. APPLICATION OF CHEWABLE TABLETS

1. **Local therapy:** Chewable tablet can release an active substance at a controlled rate over an extended period of time providing a prolonged local effect.
2. **Pain:** Successful treatment of minor pains, headaches, pains of cold, muscular aches, etc. requires rapid absorption of therapeutic doses of the active substance. Chewable tablet as a drug delivery system could be beneficial in minor pain treatment, when buccal absorption results in fast onset of action and reduces the risk of gastrointestinal side effects.
3. **Systemic Therapy:** Chewable tablet provides benefits to systemic drug delivery, especially if the active substance is absorbed through the buccal mucosa.
4. **Smoking Cessation:** Chewing gum formulations containing nicotine, lobeline and silver acetate have been clinically tested as aids to smoking cessation.
5. **Obesity:** Several chewing gum formulations containing caffeine, guarana or chromium are available. Caffeine and guarana are central stimulating anorectic agents that have proved to increase the metabolic rate.

10. SOME MARKETED FORMULATIONS OF CHEWABLE TABLET

Today Chewable Tablet is one of the most popular dosage forms, used for delivering the many active components. Some marketed products of chewable tablet are given below in table.

Table 1.3: Marketed Formulations of Chewable Tablets.

S. No.	Brand Name	Active Ingredient	Application
1	Claritin	Loratadine	Anti histamine
2	Montair	Montelukast	Asthma
3	Lamictal	Lamotrigine	Seizures
4	Mylanta Gas	Simethicone	Gastric relief
5	Natecal D3	Natecal D3	Osteoporosis

6	Imodium Advanced	Loperamide Hydrochloride	Anti-diarrhoel
7	Alzol	Albendazole	Anthelmintic
8	Tylenol	Acetaminophen	Analgesic

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