

A Review on Chewable Tablet

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ABSTRACT:

Chewable dosage forms such as tablets, soft pills and chewing gum "chew-in squares" are a long part of the arsenal of pharmaceutical professionals. They must be broken in the middle of the teeth and chewed before administration. Priorities for solid dosage forms proposed for swallowing include good bioavailability, patient improved consistency of treatment, possible use to replace the use of solid dosage forms when rapid onset of action is required and improved patient acceptance. For example, in children or patients when they cannot swallow. These dosage forms are large in size and consequently difficult to swallow, and chewable tablets are chewed early in the swallow in the cheek cavity. The ideal characteristics of a chewable tablet are easy to chew, palatable (flavor masked or moderately flavored), and of appropriate size and shape. The continued need to develop chewable tablets, as patients are unaware and unfit with current delivery systems, limits the size of the tranquilizer tissue business and drug use, resulting in a large amount of disease. It has management costs. Excipients have unique considerations that must be given to the materials that make up the basis of chewable tablet formulations. Major excipients in chewable tablets include flavor sweeteners. enhancers and Tablets are manufactured by wet granulation process or direct compression. They consist gradually of active ingredients that are added to the tablet formulation to improve the ingestion properties of these forms. Chewable tablets are evaluated by chemical and physical evaluation methods. Physical methods appearance, include hardness, brittleness, disintegration, and dissolution, while chemical methods include drug content, dosage uniformity, in vitro and in vivo testing.

KEYWORDS: Chewable tablets, Children, Dysphagia, Flavoring Agent, Sweetening Agent, Compressibility Property.

I. INTRODUCTION¹⁻⁵:

A chewable tablet that must be crushed and chewed between the teeth before ingestion.

These tablets are given to children who have difficulty swallowing and adults who have difficulty swallowing. These tablets are designed to disintegrate smoothly in the mouth with or without chewing at a moderate rate. It is characterized by leaving any discomfort. Successful not development of a tablet formulation requires careful selection of ingredients to create a robust solid dosage form. Selection of appropriate excipients to perform specific functions in tablet formulations. B. Corrosion or lubrication can be critical to achieving acceptable manufacturing performance. Both natural and synthetic sweeteners are types of functional Excipients commonly used in the formulation of chewable tablets to mask unpleasant tastes and facilitate administration to children. Ideally, when chewed, it breaks down in the mouth, releasing the ingredients so there is no long lag time required for the tablet to disintegrate before being absorbed from the stomach. Chewable tablets are often used when the drug is intended to act locally rather than systemically. Chewable tablets are palatable and can be chewed and swallowed with little or no water. Chewable tablets are generally manufactured either by a wet granulation process or by direct compression. Micronized and submicron forms of therapeutically physiologically active substances and are increasingly being incorporated into tablet formulations to take advantage of the improved absorption properties of these forms. They are also used in the administration of antacids and carminative. Mannitol is widely used as an excipient in chewable tablets due to its nonhygroscopic properties for moisture-sensitive drugs. As we know, dysphagia (dysphagia) occurs in all age groups, but especially in the elderly and when swallowing conventional tablets and capsules. Elderly and pediatric patients who may not have direct access to water, and those who travel are most in need of easy-to-swallow dosage forms such as chewable tablets. The chewable tablet composition consists of a gum core that may or may not be coated. The core consists of an



insoluble gum base such as fillers, waxes, antioxidants, sweeteners and flavors.

Ideal Characteristics Of Chewable Tablets⁶:

- 1. Easy to chew.
- 2. Palatable (flavorful or worthy of flavor)
- 3. Appropriate size and shape
- 4. Instant disintegration to promote dissolution
- 5. All clear dosage forms are the same

6. Easy to swallow even for people who have difficulty swallowing regular tablets and capsules (about once a time)

7. Reduce the risk of drug-induced esophagitis. This occurs when the tablet becomes trapped in the esophagus and dissolves while still in contact with the delicate lining of the esophagus.

8. Tasty and comes in a variety of flavors

9. Easy to take and useful

10. Offered as a single dose, no quote required.

11. Improve consistency

12. Dosage forms that do not require water are:

- Easy to carry on the go

- Convenient to carry anywhere anytime.

ADVANTAGES OF CHEWABLE TABLETS⁷:

1) Patient comfort.

2) Better absorption properties.

3) Increased bioavailability caused by chewing in the mouth with increased absorption, putrefaction, or dissolution.

4) Improvement of understanding and affirmation by sweetness.

5) Version for children.

6) The large size of the dosage form makes it difficult to swallow, especially for children and adults who refuse to swallow. In this case, chewable tablets offer more settings.

7) Efficacy of the therapeutically active agent is enhanced by chewing in the mouth to reduce its size to avoid disintegration prior to swallowing.

DISADVANTAGES OF CHEWABLE TABLETS:

1) No bitter chemicals are used in the formulation of chewable tablets.

2) Using too much fragrance in chewable tablets may cause Stomatitis.

3) Chewable tablets use many excipients to add tablet bulk and enhanced properties, some excipients are unsafe for the body. For example, Sorbitol causes diarrhea and gas.

4) Chewing chewable tablets for a long time causes pain in facial muscles.

5) Chewable tablets are hygroscopic and should be properly packaged and stored in a dry place.

6) Chewable tablets are of poor mechanical quality and should be handled with care during packaging and transport.

7) Shows brittle effervescent granules.

MATERIALS OR EXCIPIENTS USUALLY UTILIZED IN THE ADVANCEMENT OF CHEWABLE TABLETS^[8-10]:

Pharmaceutically inactive substances, other than active pharmacological ingredients or prodrugs, stored in the assembly process or included in the actual pharmaceutical product. Excipients play an important role in the manufacture of pharmaceutical dosage forms such as:

1) Improved bioavailability and solubility of drug substances and excipients

2) Improved drug stability in dose structure

3) Allow dynamic attachment to maintain optimal polymorphic structure or coordination

4) Stabilize the osmotic pressure and pH of liquid formulations

5) Acts to provide antioxidant benefits, emulsifying properties, aerosol propellants, binding properties, and disintegrants.

6) Prevention of separation and agglomeration

- 7) provide an immunogenic response to the drug
- 8) To deliver pharmaceutical bulk.

1. Bulking agent/Diluent :

They are included in chewable tablet formulations to increase tablet volume. When mixed with the drug substance, the final product is of sufficient weight and size to facilitate handling and manufacturing.

2. Mannitol

Mannitol was regularly used diluent. It is an attractive bulking agent for tablets. At a point where the taste of chewable tablets becomes an important factor. The materials are essentially dormant, non-hygroscopic, pure, crystalline, odorless or free-flowing granules. Due to the negative heat, sweetness, and "mouthfeel" of the solution, it is commonly used as a diluent in the manufacture of chewable tablet formulations. Mannitol is also considered a flavor enhancer and is said to be about 70% sweeter than sucrose.

Mannitol in powder form is suitable for wet granulation in a mixture with an auxiliary binder. Available in a granular structure for direct printing processes. Mannitol is not inherently hygroscopic. Mannitol has a low water content and is commonly used in moisture sensitive



formulations. Mannitol, along with what is known for its powdery sweetness, mouthfeel, and nonhygroscopicity, represents a highly favorable environment for the formulation of chewable tablets.

3.Sorbitol

Sorbitol is a polyol that exists as an odorless, white or virtually hazy, crystalline, hygroscopic powder. Sorbitol is used as a diluent for tablets manufactured by wet granulation or direct compression. For direct printing, it is economically available as SorbTab (ICI Americas) and Crystalline Tablet Type (Pfizer Chemical).

Sorbitol is regularly made into precious chewable tablet formulations to create an alluring, sweet taste and provide a cooling sensation. Is an isomer. In contrast to mannitol, sorbitol is increasingly hygroscopic.

4.Dextrose

Dextrose is used as a diluent in tablet formulations. Glucose is a colorless substance. They are odorless and have a sweet taste. Dextrose is obtained by enzymatic or acid hydrolysis of starch. Hydrolysis of starches, including maize or maize starch. Dextrose is used as moist granules as a diluent and binder. For example, dextrose, used in direct printing diluents and binders, is primarily used in chewable tablets. The sweetness of glucose is about 70% that of sucrose. Available in monohydrate and anhydrous structures. It also contrasts with lactose as a tablet diluent. Glucose monohydrate manufacturing tablets require more lubricant and tend to clump in the first few hours after printing.

5.Lactose

Lactose is also called milk sugar. Lactose is a disaccharide obtained from milk. Lactose is the remaining liquid in milk after making cheese and casein. Lactose is commonly used as a diluent in tableting. It is a commonly used excipient for tablet formation. Since lactose has less sweetness, the role of lactose in chewable tablets is small. Lactose is about 20% sweeter than sugar. This deficiency requires the addition of a pseudo-sweetener with sufficient strength to overcome the lactose dullness. Chewable tablets containing lactose are unacceptable for lactose-sensitive patients.

6.Sucrose

Sucrose is commonly used in tablets as a sweetener, a diluent by sugar marketing, and as a foil in wet granulation technology. Simple compacted sucrose crystals have never been successful, but various modified sucrose have been incorporated into direct pressure regimens. (90-93% sucrose + 7-10% modified sugars), and NuTab (2% each of 95% sucrose, 4% converted sugars, and 0.1-0.0). from cornstarch and magnesium stearate). All sucrose-based diluents and binders are applied in the direct compression tableting process for chewable tablets. In particular, counterfeit sweeteners should be avoided. As a bulking agent, sucrose has more drawbacks. Sucrose is soluble, not reduced sugar. It gets darker over time. It is also hygroscopic and tends to form a texture cake on standing.

7. Flavouring agent

Flavors are important excipients in chewable tablets. Spices are commonly used to add a nice flavor to, enhance, and often scent, chewable tablets. They are included as spray-dried beads and oils are included as solids. Flavors are usually included in the oil step as these materials are moisture sensitive and tend to evaporate rapidly when heated, for example during drying of wet granules. Water-soluble (aqueous) flavors have received little attention due to their low post-aging stability. Oxidative reactions reduce the consistency of taste. Oils are typically emulsified with dry acacia and spray.Dried flavors are easier to maintain and last longer than oils. The oil is generally diluted with alcohol and sprayed into granules as it falls into the lubrication pan. Various strains and flavors are listed below the table of common benchmark flavor types.

| Flavours | Group for Tasting Types | |
|--------------|---|--|
| Sweet | Vanilla, fruits, maple, stone fruits, berries, grape | |
| Sour(Acidic) | Raspberry, anise, cherry, root beer, cherry, strawberry | |
| Salty | Mixed citrus, butterscotch, maple, nutty, buttery, spice, | |
| | mixed fruits, butterscotch | |
| Bitter | Coffee, cherry, Liquorice, grapefruit, wine fennel, | |
| | peach, mint | |
| Metallic | Grape, burgundy, lemon-lime | |

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| Alkaline | Chocolate, Mint, cream, vanilla |
|----------|---------------------------------|

8. Sweeteners or taste enhancing agents:

Sweeteners are important excipients in chewable tablets. Sweeteners are commonly included in chewable tablets when the commonly used carriers such as lactose, sucrose, mannitol and dextrose do not completely mask the taste of the active substance or active substance ingredients. In such cases, product formulators should use artificial sweeteners to improve overall sweetness variation. Because of the accidental carcinogenicity of artificial sweeteners. B.ex. cyclamate and saccharin. Pharmaceutical formulators are primarily striving to build tablet products without such expertise. The taste-masking method is the first and simplest method of taste-masking, especially by pediatric definition, chewable tablets, and liquid indications. However, this method is not very effective, especially for potent and highly water-soluble drugs. Most often, counterfeit sugars and flavors are used in combination with other flavor-masking methods to improve the effectiveness of these strategies.

| Relative Sweetness |
|--------------------|
| |
| 200 |
| 50 |
| 500 |
| 1.7 |
| 0.2 |
| 0.5-0.7 |
| 0.5-0.6 |
| 1 |
| 30-50 |
| 0.7 |
| 0.3 |
| |

Aspartame :

Also known as aspartame. NutraSweet is a non-drug artificial sweetener. It is many times sweeter than sucrose. Aspartame's margin is more pronounced than regular sugar. Aspartame is also recommended for use in desserts, drinks, teas and espresso hours.It sometimes enhances the citrus flavor. Aspartame is generally stable at pH 4, but exhibits good dry strength at room temperature and 50% relative humidity. Aspartame is not usually used in the diet very often because it causes discoloration in the presence of tartaric acid and ascorbic acid.Common use in chewable tablets. Aspartame is used in chewable tablets of 3-8 mg per tablet.



Glycyrrhizin :

Glycyrrhizin is a daughter of licorice and has a long-lasting late sweetness. Glycyrrhizin is also known as a manganese sweetener. These functional properties point to its use as a supplemental sweetener to improve sweetness levels while reducing aftertaste. Tend to have more licorice flavor.

Saccharin :

Saccharin is commonly used as a sweetener in chewable tablets. Saccharin has been approved by the Food and Drug Administration (FDA) to be 500 times sweeter than sucrose. The main disadvantage of saccharin is an unpleasant delay in the impression of taste. The unfavorable situation is eliminated by presenting a small amount (1%) of sodium chloride. Saccharin-related post-season impressions are clearly prominent in about 20% of the population. As the sweetness level increases, the overall sweetness of saccharin decreases. For example, saccharine total or core is improved and the degree of roughness is increased.

Colorants

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

1) Improved application with taste for buyers

2) Easiest distinction between proof and separation The Food Drug and Cosmetic Act of 1938 established three classes of coal tar tints. Of these, only FD and C tints and D and C tints are used in the manufacture of chewable tablets. The third designation (External D and C) does not apply for use where ingestion is anticipated due to oral hazards, but is safe for use where remote application is intended it is believed.

TABLETSMANUFACTURINGMETHODSAND GRANULATION TECHNIQUES[11,12]:

Chewable tablets are commonly prepared by:

- 1. Direct compression methods
- 2. Dry granulation methods
- 3. Wet granulation methods

Granulation, a method of atomic expansion by agglomeration techniques, is generally one of the largest unit exercises in the era of pharmaceutical dosage structures such as tablets and capsules. Nevertheless, framed granules impose greater demands on content consistency and Physico-chemical properties such as granule size, mass thickness, porosity, hardness, moisture content, and compressibility, thus granulating the has various difficulties. Along with the physical and formulation strength of the drug. There are two types of granulation methods: the wet granulation method, which always uses a liquid, and the dry granulation method, which does not require a liquid.

1. Direct Compression:

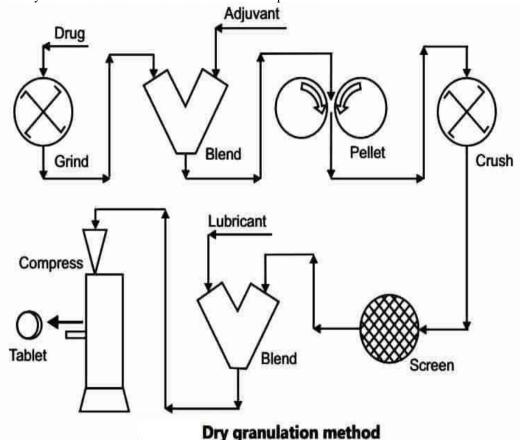
Direct printing, as the name suggests, is a method of directly compressing tablets from divided materials without adjusting the physical properties of the materials themselves. Until now, direct compression as a tablet manufacturing strategy was thought to be a small group of crystalline synthetic compounds with all the physical properties necessary to develop a superior tablet. lubricating powder) and pressure. To achieve high quality tablets by this method, dynamic fixation and excipients (builders, binders, lubricants, etc.) must support uniform mixing, large mass thickness, and excellent flow properties.

2. Dry Granulation:

Dry granulation can be achieved by roller compaction or slugging. The dry powder is passed through an agitator compactor and granulated into a uniform molecular size for use in frames on various surfaces. The granules produced by this strategy are permeable, highly compressible, capable of rapid disintegration and tunable ejection times. This method is ideal for moisture-sensitive pharmaceuticals. For particles that are sensitive to external factors such as temperature, moisture can generated by the dry-blending process. he Manufacturers can choose atoms with specific molecular sizes and readily compressible excipient grades as needed. Slug-DeSlug uses tablet presses to shift, mix (drugs + fillers + binders), slug, mill, size, mix (disintegrants), final mix (lubricants) and compaction. The snails are prepared using a compactor, crushed and sieved using some mills equipped with suitable sieves, and mixed with a lubricant using a mixer. The weakness of this technique is that it is a tedious process with many obvious processing advantages. Compaction is similar to the slag-de-slag process and is performed using a roller compactor. The powder is conveyed by a wooden auger onto rollers that roll up the container to fill the compaction zone with powder. Compaction takes place between rollers to create flakes. Agglomerates are sieved using the correct sieve size or processed into granules. The granules are then mixed with lubricant using a mixer. Compression is used to produce directly



compressible excipients, pharmaceuticals, pharmaceutical formulations, and granules of inorganic materials, dried herbal materials, immediate/delayed release formulations. Advantages include shorter process times and more consistent molecular size distribution of granules as opposed to granules provided by the Slag de Slag process.

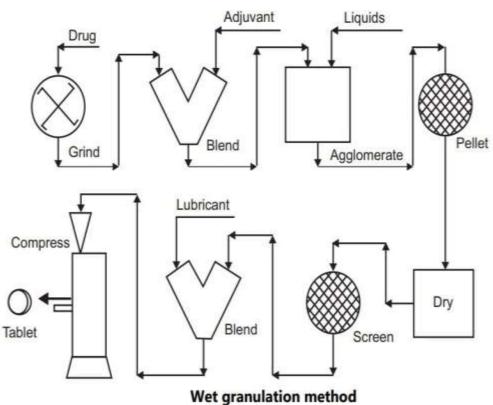


3. Wet Granulation:

Wet granulation technology improves the flowability and compressibility of the mixture for compression. This is the key reason why wet granulation was chosen in this study. It uses non-toxic granulation fluids suitable and mechanical development compared to dry granulation to agglomerate or combine fine powder particles into larger, solid, moderately unchanged structures called granules. It is a size-enlarging process that becomes Atoms that require wet granulation are those that are not suitable for the dry granulation process. That is, high proportions, low flowability, low bulk density, no binding properties, etc. Wet granulation is a commonly used process of producing granules by wet

massaging active pharmaceutical ingredients and granulating liquids with or without adhesive elements. Wet granulation is done in two different ways. One technique is to moisten the powder or powder mixture, sieve it to the expected mesh size, and use dry heat to produce granules of the ideal size. The second type used a fluid bed processor that sets, vigorously disperses and suspends the particles while liquid excipients are sprayed onto the particles and dried. Depending on the atomic influence, liquid (water) or non-aqueous (natural) solvents are used in the granulation process. Fluid methods are considered safer and more economical. The main drawbacks of wet granulation are that it is an expensive process and material is lost at various stages of production.





| MARKETED PREPARATION OF CHEWABL | E TABLET ^[13-47] : |
|---------------------------------|--------------------------------------|
|---------------------------------|--------------------------------------|

| Brand Name | Active Constituent | Category | Indication | MFG. By |
|----------------------------|--|-----------------------------|--|---|
| Claritin[13-15] | Loratidin | Antihistamine | Running nose, sneezing, | Bayer |
| Montair[16-19] | Montelukast | Antiasthmatic | Sneezing, Asthama Attack | Cipla Ltd. |
| Lamictal[20] | Lamotrigine | Anticonvulsant | Seizure | Glaxosmithkline |
| Mylanta Gas Minis [21] | Simethicone | Gastrointestinal Agent | Relieve Flatulence | McNeil Consumer Pharmaceutical Company |
| Danacid | Magnesium Trisilicate | Antacid | Heart Burn , Acid Indigestion | Dana Pharmaceutical Ltd. |
| Lipitor[22-27] | Atorvastatin | Antihyperlipidemic Agent | Hypertension | Pfizer |
| Natecal D3 | Calcium, cholecalciferol | As a vitamin | Calcium Dificiency | Chiesi Ltd. |
| Imodium Advanced[28-32] | Loperamide Hydrochloride , Simethicone | Antidiarroaheal | Dirrohea, Irritable Bowel Syndrome[IBS] | McNeil Consumer Pharmaceutical Company |
| Alzol[33-36] | Albendazol | Anthelmentic | Parasitic Worm Infection | Rene Industries Ltd. |



| Tylenol[38-39] | Paracetamol | Analgesic , | Fever & Pain | McNeil |
|------------------|------------------|----------------------------|-------------------------------|---------------------------|
| Tylenoi[38-39] | Faracetainor | Antipyretic , | rever & rain | Consumer |
| | | Anapyrette | | Pharmaceutical |
| | | | | Company |
| Epanutin | Phenytoin | Anti Convulsants | Seizure | Pfizer |
| Infatabs[40-43] | Thenytom | 7 mili Convulsants | Seizure | 1 11201 |
| Limcee[44-47] | Ascorbic acid | As a Vitamin | Immuno Stimulant | Abbott |
| | | | | pharmaceutical |
| | | | | Ltd. |
| Fosrenol [48] | Lanthanum | Phosphate Binder | Lower High Phosphate Level | Shire US Inc. |
| Equalactin[49] | Polycarbophil | Laxative | Constipation | Numark |
| | | | | Laboratories |
| Draminate[50,51] | Dimenhydrinate | Anticholinergic | Motion Sickness | RPG |
| | | Antiemetics | | Lifesciences Ltd |
| Travel- | Meclizine | Anticholinergic | Dizziness | Travel-Ease Ltd. |
| Ease[52,53] | | Antiemetics | | |
| Tegretol[54,55] | Carbamazepine | Anticonvulsants | Seizure | Novartis India |
| | | | | Ltd. |
| Motrin[56,57] | Ibuprofen | Non-Steriodal | Arthritis | Johnson & |
| | | | | Johnson. |
| Methylin[58,59] | Methylphenidate | CNS Stimulant | Narcolepsy | SpecGx LLC |
| | | | | Webster Groves |
| Vyvanse[60-61] | Lisdexamfetamine | CNS Stimulant | Binge Eating Disorder | Shire LLC. |
| Zyrtec[62,63] | Cetrizine | Antihistamines | Hives | Dr. Reddy's |
| | | | | Laboratories |
| Lactaid[64,65] | Lactase | Digestive Enzyme | Break Down Dairy | McNeil |
| | | | Product | Nutritionals |
| Amoxil[66,67] | Amoxicillin | Aminopenicillins | Bacterial Infections | Zydus |
| | | | | Healthcare |
| | | | | Limited. |
| Augmentin[68- | Amoxicillin and | Beta-Lactamase | Bacterial Infections | Glaxo |
| 69] | Clavulanate | Inhibitors | | Smithkline |
| | | | | Pharmaceutical |
| | ~ ~ . | ard a i | | Ltd. |
| Suprax[70,71] | Cefixime | 3 rd Generation | Bacterial Infections | Elder |
| | | Cephalosporin | | Pharmaceutical |
| 1 | C 1 | | CODD | Ltd. |
| Availnex | Carbocysteine | Anti-Asthmatic | COPD | Hall Bioscience |
| Dem al 4[70,72] | Formatidia | | Castra as an 1 as a s 1 | Corporation. |
| Pepcid[72,73] | Famotidine | H2 Antagonist | Gastroesophageal | Nicholas Diramal India |
| | | | Reflux | Piramal India |
| I uride[74 75] | Sodium Fluoride | Minerals & | Cavities | Ltd. Bios Lab Pvt. |
| Luride[74,75] | Soutuin Fluoride | Electrolyes | Cavities | Ltd. |
| Milk of | Magnesium | Antacids & | Constipation & Heart | Deys Medical |
| Magnesia 01 | Hydroxide | Laxative | Burn | Pvt. Ltd. |
| NataChew[76- | Prenatal Vitamin | Iron Products& | Aid wiith Diet of | Eckson Labs |
| 79] | | Vitamin | Pregnancy | LENSUII LAUS |
| Bismarex[80-81] | Bismuth | Antidiarrheal | Diarrhea | Rexall Drug |
| Dismatex[00-01] | Subsalicylate | | | Comapany Ltd. |
| Prosteon[82] | Mineral & | Mineral & Vitamin | Growth | Albion |
| 1105000[02] | Vitamin | | Siowiii | Laboratories |
| | , ituiliili | l | 1 | Laboratoritos |

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EVALUATION PARAMETER OF CHEWABLE TABLETS^[83-90]:

Chewable tablets are evaluated by chemical and physical evaluation methods:

Chemical Evaluation :

Chemical Evaluation that involves the following:

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

Physical Evaluation :

Physical Evaluation involve the following: 1. Tablet physical appearance or Organoleptic Characteristics

- 2. Friability
- 2. Friability 3. Hardness
- 3. Hardness
- 4. Disintegration
- 5. Dissolution

General Appearance, Diameter and Thickness : Size and Shape :

Tablet size and shape must be controllable and true to size, according to part specifications. You can check and manage the size and condition of your tablet dimensionally. During the printing process is controlled by the tool.

Colour and Odour :

Many pharmaceutical tablets use shading to facilitate recognizable evidence and are also suitable for customer reference. However, it must be consistent within a single tablet, between tablets, and between batches. Stability issues can be evidenced by the scent of tablet clusters. B. Nutrients have a branded odor. For chewable tablets, taste is an important factor in patient acceptance. Tablet thickness is the most important dimensional variable determined by this method, and tablet thickness is estimated to the nearest micron. In various ways, 5 or 10 tablets can be placed on the holding plate and their total thickness can be estimated on the caliper scale. Tablet thickness should be controlled within \pm 5% standard deviation. Thickness is also affected when packaging tablets.

Hardness:

To find out the hardness of tablets, use this test tablet hardness tester. This is an example of Pfizer's Schleuniger hardness tester. The Monsanto hardness tester consists of a cylinder with a compression spring placed between two deloggers. Lower unlogger touches the tablet, so no read-through is required. Then, unless determined in each case, press the upper declamper against the spring by turning the cocked jerk until the tablet breaks (40-60 N). See the boundaries and rationale for this file (Indicators of Difficulty Chewing) in Appendix I of this Chronicle. Allows padding/agglomeration possibilities and transmits chewing difficulty index data during article improvement. Hardness is the force required to separate tablets. A tablet's hardness refers to its strength or quality. Hardness was assessed using a Monsanto hardness analyzer or tester. Properties are sent in kg/cm2.

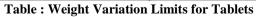
Weight variation:

As stated in the USP weight grade study, the weight of 20 tablets is controlled by calculating only the standard load and comparing the load of each tablet to normal. Breed test estimate weights are expressed as percentages. According to the USP, a tablet passes the test if no more than two of its individual masses deviate from the standard mass by more than an average deviation and not more than two times the standard mass.

Weight change = (starting weight - average weight)/average weight x 100

The weight of the same tablet should not differ from the normal weight by more than 5%.

| Sr. no. | Average weight tablets (mg) | Maximum % difference limits |
|---------|--------------------------------|-----------------------------|
| 1 | 130 or less | ± 10.0 |
| 2 | 130 to 324 | ± 7.50 |
| 3 | More than 324 | ± 5.0 |





Friability:

Friability testing provides information on the ability of tablets to become inexpensive and prevent abrasion during handling during shipping and packaging. When using Roche Friabilator. Weigh 10 tablets, place in flibrator and spin at 25 rpm for 4 minutes. The tablets were then removed, dusted and retested. The equation calculates the tablet crushing rate,

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

Disintegration Time :

The Mechanical unit of the USP collapse consists of six 3 inch long open top glass tubes held against a 10 mesh screen at the bottom of a container rack. To test the degradation time, place one tablet into each cylinder and place the basket rack in the specified medium at 37 ± 2 °C. The down stays within 1 inch of the bottom of the cup. A standard motorized device is used to move 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.

Drug Content determination :

The Mechanical unit of the USP collapse consists of six 3 inch long open top glass tubes held against a 10 mesh screen at the bottom of a container rack. To test the disintegration time, he puts one tablet into each cylinder and places the basket stand in the designated medium at 37 ± 2 °C. The down stays within 1 inch of the bottom of the cup. Using standard motorized equipment, the tablet-containing basket assembly is moved up and down a distance of 5-6 cm at a frequency of 28-32 cycles per minute.

In Vitro Dissolution Studies:

Dissolution studies estimate the time required for a specific percentage of drug in a tablet to be eliminated under conditions of pH, volume, agitation, and temperature. Absorption of drugs from chewable tablets, whether intact or chewable, depends on the appearance of the prescribed substance. Currently, in vitro disintegration testing of chewable tablets must follow commercial IR tablet disintegration testing guidelines.

For product presentations under development, in vitro disintegration testing of unbroken tablets should be coordinated in all four media. Perform in vitro drug delivery using USP Device 1 (basket), USP Device 2 (paddle), or USP Device 3 (piston cylinder) USP 2 (paddle) with 900 mL of 0.1N HCl as vehicle. The dissolution medium temperature was maintained at 37 ± 0.5 °C and the filament speed was 50 rpm. Samples were taken at various intervals of 10, 20 and 30 minutes and replaced by adding an equal volume of fresh dissolution medium. Samples were diluted appropriately and solution absorption was measured by UV-Vis spectroscopy at wavelengths of maximum and minimum absorbance of approximately 308 nm and 350 nm.

Stability Analysis:

Dosing structure or dosing item stability studies are performed to capture time-dependent changes that occur in partial dose structures. Strength tests are either time-based, animated, or progress under a wide range of conditions. Accelerated reliability testing is used to predict potential quality changes that may occur in a problem. Towards the end of the period, tests of potency, disintegration time, and in vitro dissolution tests were analyzed.

Various tests in our stability program include:

1. Assurance of active drug content using approved stability indicating assay methods.

2. Changes in physical properties of tablets -Mottling of tablets with shadows, coloration of tablet surface, crystallization of active ingredient on tablet surface, improvement of odor, etc.

3. Tablet hardness, friability, solubility, and in some cases changes in solubility, increased disintegration time.

4. Hygroscopic substances in tablets - Absorption of moisture by tablets leads to delicate tablets that disintegrate and sticky after chewing. When tablets lose moisture, they become brittle and this brittleness increases. In addition, tablet hardness may increase.

5. Stability involves a scaffold that the polymers used in the taste-masking process must not degrade, facilitating the presentation of dynamic drug particles. Casings and grids should also be stable and ensure taste safety.

6. Pigment Stability - Pigments in color tablets should not bleed or migrate over time. Colour stability testing included strategies such as tristimulus alignment with guidelines and introductory quality.

II. CONCLUSION:

Chewable tablets are versatile dosage forms that combine the manufacturability and stability advantages of solid products while offering beneficial Organoleptic and



Administration benefits. The increasing emphasis on patient-centered formulation in drug delivery has driven not only specific populations such as pediatrics and differentiated pharmaceuticals, but also other populations such as nutritional products, dietary supplements and veterinary drugs. The healthcare market also offers more opportunities to use Chewable Tablets.

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