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# Novel Formulation Techniques of Mouth Dissolving Tablets: A Review

**Shubham Vijay Desai*[1], Sanket Mukund Gandhi[1], Vijay Arjun Jagtap[1], Varsha Gajanan Rane[1] and Maseera Kazi**
**Department of Pharmaceutics, Yashwantrao Bhonsale College of Pharmacy, Sawantwadi, Sindhudurg, Maharashtra, India.**

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***Corresponding Author Email:** ceuticsybcp@gmail.com

## Abstract
The purpose of writing this assessment on mouth dissolving tablets was to compile the recent literature with special focus on increased absorption and pharmacokinetic profiles and a faster onset of therapeutic result. Mouth dissolving in the mouth allows some APIs to be absorbed from the rumor is, tubular cavity and passageway, avoiding gastric absorption to some extent. This review includes a definition, benefits, needs or requirements for MDTs, notable features of MDTs, limitations, challenges in designing MDTs, and marketed formulations of mouth dissolving tablets etc. The administration of drug through oral routes has better acceptability about 50-60% of drugs are administered through oral route. Amongst them the solid dosage forms are extensively used due to the acceptance in administration, accurateness in dosage forms, advantages of self-medication, escaping of pain, and last but not the least the high patient compliance. Tablets as well as capsules are the most popular solid dosage form which is given through the oral route. Excluding for swallowing it doesn't have any important disadvantages. The water is vital during this swallowing of drug. Some people face problems in swallowing the drug or dosage form. Mouth dissolving or orally disintegrate tablets are introduced to avoid such difficulties that have an advantage that it doesn't need any water and there is no requirement for swallowing of this tablet as it is dissolved or disintegrate in the saliva.

**Keywords**
Mouth dissolving Tablets, Orally Disintegrating Tablets, Superdisintegrants.

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## 1. INTRODUCTION[1]
Tablet formulations are preferred mainly because of their low factory price, packaging, transportation and increased stability, while pure formulations are the main requirement and need today. A dosage form is a means of a drug delivery system used to deliver a drug to a living organism. Various types are available that are tablets, syrups and also suspension, suppositories, injectable, and transdermal patches with different drug delivery mechanisms. To achieve the looked-for result, the medication must be delivered to the workplace in certain quantities and concentrations to achieve maximum therapeutic effect and minimum side effects. Tablets for oral dissolution are mainly made in two ways using Superdisintegrants and another method is to maximize the pore structure of tablets by lyophilization and vacuum drying. For all methods, direct compression is preferred because it is reliable, fast, and economical. Solid dosage forms are very

popular because easy administration, accurate dosing, self-medication, pain Avoidance and most importantly patient compliance. Most common solid dosage forms are tablets and capsules; an important disadvantage of this dosage method for some patients are difficulty in swallowing.

Drug distribution systems (DDS) are a key strategy for increasing marketplaces/suggestions, extending product life cycles also providing opportunities. Because of its convenience of consumption, pain avoidance, variety, and maximum prominently, patient obedience, oral administration is the most favored path for systemic effects. Moreover, solid oral dosage delivery systems there is no requirement of sterile conditions, they are less expensive to production. Due to Patient compliance, high-accuracy dosing, and manufacturing effectiveness make tablets the solid dosage form of choice. The Mouth dissolving Tablets (MDT) are widely used and accepted drug delivery method for patients who have trouble swallowing, such as the geriatric. The majority of fast-dissolving delivery system films must include masking the active ingredient's taste this masked active ingredient or component is formerly swallowed by the patient's saliva along with the soluble and insoluble excipients these are also identified as Regiments, porous tablets, melt-in-mouth tablets, oro-dispersible, quick-to-dissolve, or rapid-to-dissolve. Researchers have explored a variability of technologies meant for the formulation of mouth dissolving tablets, such as freeze-drying, tablet moulding, direct compression method, spray drying, and sublimation technology, to maximize the pore structure of the tablet matrix.

**1.1 Definition of Fast Disintegrating Tablet[2]**

"It is a solid dosage form having therapeutic substances, which disintegrates quickly within a matter of seconds, once placed under the tongue as per Food and Drug Administration of drug.

MDT must disperse in fewer than three minutes, as per European Pharmacopoeia,

"Fast dissolving Tablet" tablet that to be put in oral cavity where it disperses rapidly before swallowing.

**Synonyms**

Mouth dissolving tablet, Melt-in-mouth tablet, Rapimelts, Porous Tablet, Quick dissolving tablet, orodispersible etc.

**1.2 Fast Disintegrating Drug Delivery System [3]**

In this consideration, studies of absorption, distribution, metabolism and excretion were carried out. After absorption, the drug reaches a therapeutic level and therefore causes a pharmacological effect, so the speed and duration of absorption are important. In conventional dosage forms, there is a delay in disintegration and thus dissolution, whereas FDT disintegrates rapidly and dissolves rapidly in the oral cavity due to the breakdown of FDT in the mouth, absorption starts from the mouth to the pharynx and from the pharynx to the esophagus.

Disintegrating tablets have increased in demand over the last decade and this field has become a rapidly growing area of the pharmaceutical industry.

**AN IDEAL MOUTH DISSOLVING TABLETS SHOULD BE**

1. Oral administration requires no water, yet these melt, disperse, and break in the mouth (buccal cavity) in a matter of seconds.
2. Feel pleasant in the mouth.
3. Have a suitable taste altering property.
4. be rigid and less fragile.
5. After administration, leave tiny or no residue in the buccal cavity.
6. Exhibit low sensitivity to environmental \ conditions (temperature and humidity).
7. Allow the manufacturing of tablets with conventional processing and packaging equipment.

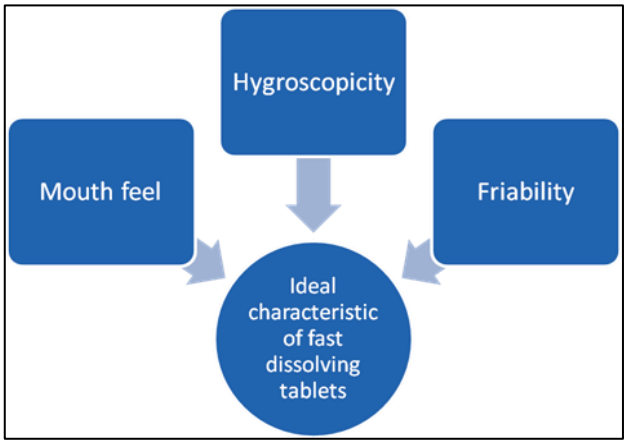


**Fig 1: Ideal Characteristic MDT**

**1.3 Advantages of Fast Disintegrating Tablets** [4]

- Ease of administration to patients who refuse to swallow a tablet.
- No need of water to swallow the dosage form.
- Quick dissolution and absorption of drug.
- Accessibility of administration and precise dosing as associated to liquids dosage.
- Good mouth feel property helps to change the basic view of medication as "unpleasant medication", particularly for paediatric patients.
- No need of drinking agent such as water to swallow tablets.
- FDT can be easily administered to paediatric patients, geriatric patients, and patients with mental disorders.
- Accurate dosage as compared to liquid.
- Dissolution and absorption of the drug is rapid, which offers a rapid onset of action.
- The bioavailability of drugs is increased because some drugs are absorbed from the mouth, pharynx and oesophagus via saliva flowing through the stomach.
- Advantages over liquid medication in terms of administration and transportation.
- First pass metabolism is reduced thus offering increased bioavailability and therefore reduced dosage and side effects.
- Offering enhance safety.

**1.4 Disadvantages of Fast Disintegrating Tablets**[5, 6, 7]

- They are fragile and brittle.
- It needs special package for protection during storage and transportation
- The main disadvantage of FDT is related to the mechanical strength of the tablet.
- FDT is a highly porous and soft matrix, that why tablets with low compression.
- Drugs that taste bad are difficult to formulate by FDT.
- Dry mouth due to reduced saliva production may not be a good candidate for this tablet formulation.
- Rate of absorption from the saliva solution and overall bioavailability.
- Drug and dosage form stability

**MECHANISM:** [8]

A drug's bioavailability is determined by its absorption, which is influenced by the drug's solubility in gastrointestinal fluid and permeability across the gastrointestinal membrane. A drug's solubility is mostly determined by its physiochemical characteristics. Disintegration of the tablet has a significant impact on the proportion of medication breakdown. Disintegrates are an important excipient in tablet formulation; they are always added to tablets to cause breakup when they come into contact with aqueous fluid. The disintegration process, which involves the desegregation of constituent particles before drug dissolution, is known as disintegration, and disintegrates are excipients that cause this process.

**METHODS FOR FORMULATING MOUTH DISSOLVING TABLETS:** [9, 10]

Various methods have been described for the preparation of Mouth dissolving tablets or Oro-dispersible tablets.

**1. Freeze-Drying or Lyophilization:**

Freeze drying is the method of removing water from a frozen product. This method provides a porous amorphous material that dissolves quickly. This section describes a typical approach for making ODT using this technique. The active drug is distributed or dissolved in an aqueous carrier/polymer solution. The mixture is prepared by weight and poured into the prefabricated blister packs' walls. To freeze the drug solution or dispersion, the trays containing the blister packs are run through a liquid nitrogen freezing tunnel. The frozen blister packs are then placed in refrigerators to continue to freeze-dry. The aluminum foil backing is placed using a blister-sealing machine after it has been freeze-dried. Finally, the aluminum foil backing is put on a blister-sealing machine after it has been freeze-dried. The blisters are finally packaged and dispatched. Improved absorption and bioavailability have been proven using the freeze-drying process. The main disadvantages of the lyophilization technology are its cost and time, along with its fragility, which makes traditional packaging inappropriate for these items and its poor stability under stress.

**2. Tablet Molding:**

There are two types of tablet moulding technique: solvent technique and heat technique. The solvent process entails moisturizing the powder mixture by a hydro alcoholic solvent, then compressing it in moulded plates at low pressures to form a moistened mass (compression molding). After that, the solvent is removed by air drying. This method produces tablets that are less dense than compressed tablets and have a spongy structure that speeds up dissolution. The heat moulding procedure entails making a solution containing a medication, agar, and sugar (e.g. mannitol or lactose), putting it into blister packaging wells, solidifying the agar at ambient temperature to create a jelly, and drying it at 30o C under vacuum. The mechanical strength of moulded tablets is an issue that needs to be addressed. Binding agents, which improve the tablet's mechanical strength. Need to be taken into account.

This technology also has a difficulty with taste masking. Spray coagulating a molten combination of hydrogenated cottonseed oil, lecithin, polyethylene glycol, sodium carbonate and an active component into a lactose-based tablet triturate form produced the taste-masked drug particles. The moulding approach produces tablets that are easier to scale up for industrial manufacture than the lyophilization technique.

**3. Sublimation:**

Acceptable to create a porous matrix, volatile chemicals are included in the formulation, which is then sublimated. Ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane, and ophthalmic anhydride are examples of very volatile substances that can be compacted with other excipients into a tablet. Sublimation is used to remove the volatile substance, leaving behind a porous matrix. Tablets made with this method have been reported to dissolve in 10-20 seconds. As pore generating agents, even solvents like cyclohexane and benzene can be utilized.

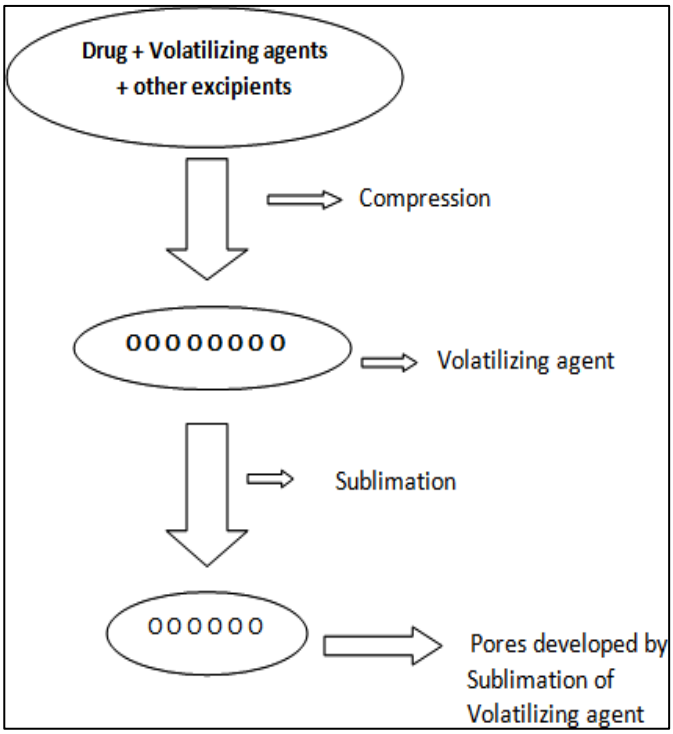


**Fig 2: Sublimation**

**4. Nanonization:**

A newly established Nano-melt technology includes reduction in the particle size of drug to nanosize by crushing the drug using a proprietary wet-milling technique. The nanocrystals of the drug are steadied against accumulation by surface adsorption on designated stabilizers, which are then combined into MDTs. This method is particularly beneficial for poorly water-soluble drugs. Other compensations of this technology comprise fast disintegration/ dissolution of nanoparticles leading to increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).

**5. Direct Compression:**

The Direct compression is the simplest and most cost-effective method of tablet production. Without any prior treatment, tablets are compressed directly from a mixture of medication and excipients in this procedure. The compressed mixture must have appropriate flow characteristics. This method can now be useful to preparation of ODT because of the availability of better-quality excipients especially Superdisintegrants and sugar-based excipients.

**Process of Direct Compression**

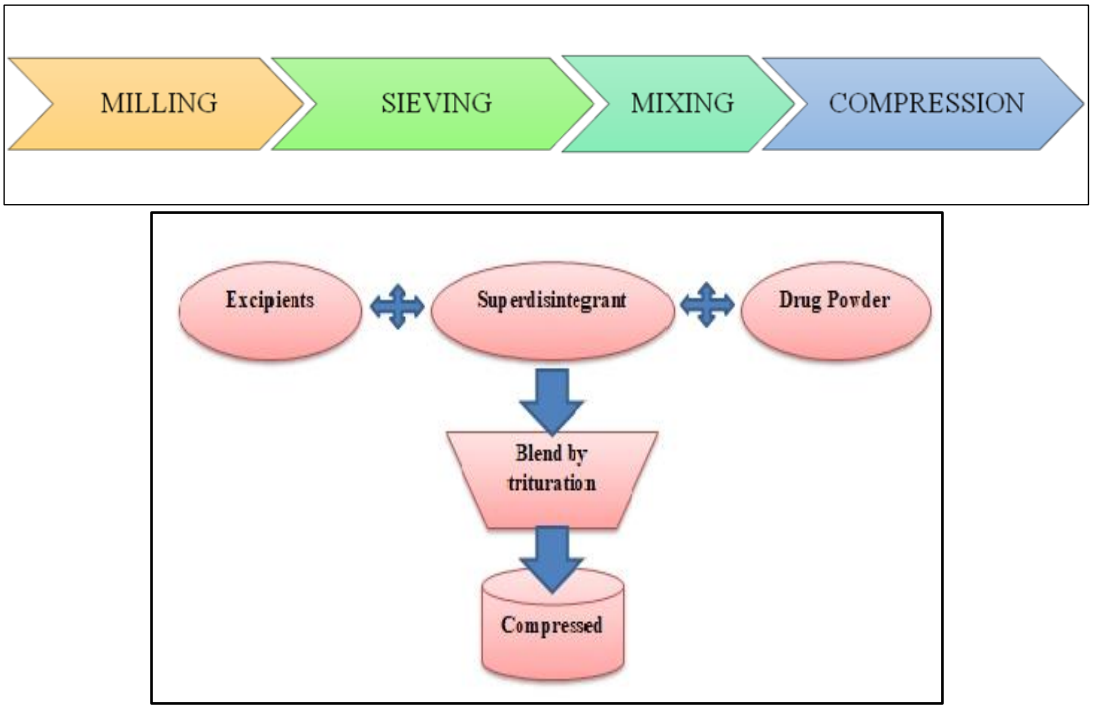


**Fig 2: Direct Compression**

**A) Superdisintegrants:**

The inclusion of Superdisintegrants alters the pace of disintegration time and thus the dissolution in several orally disintegrating tablet technologies based on direct compression. Other formulation elements, such as water-soluble excipients and effervescent agents, speed the disintegration process even more. The success of a mouth dissolving tablet depends on the tablet's ability to dissolve quickly, which is achieved by developing super disintegrates. In this section, we'll look at some of the most significant examples of Superdisintegrants.

**Advantages of Superdisintegrants**

- Effective in lower concentrations
- Compatible with commonly used therapeutically agents and excipients.
- Compressibility having less effect and flow ability.
- Remarkable tendency on wetting causing rapid disintegration
- Work similarly effective in hydrophilic and hydrophobic preparations.

**B) Sugar-Based Excipients**:

Another method for producing ODT by direct compression is to use sugar-based excipients. The usage of sugar-based excipients, particularly bulking agents such as dextrose, fructose, isomalt, maltilol, maltose, sorbitol, mannitol starch hydrolysate, polydextrose, and xylitol, which have high aqueous solubility and sweetness and hence offer masking of taste and a pleasant mouth feel.

**Selection of Excipients**

The property of the active ingredients in fast-disintegrating tablets is balanced by excipients.

**1. Bulk agents**[16]

Fast disintegrating tablets that accumulate in large quantities are essential. It improves physical properties, improves disintegration in the mouth and reduces the convergence of dynamic compounds in the composition. Specialists in the construction of these transport frames have to rely on added sugars such as polydextrose, Mannitol, lactate, DCL and starch hydrolysate for higher liquid solubility and good sensory perception. Above all, Mannitol has high solubility in liquids and excellent sensory perception. Fillers are also included in the range of 10 to 90% by weight of the final composition. The other ingredients may be listed in order of friability: crystalline polysaccharide > spray-dried lactose > beta lactose > alpha-lactose > alpha-lactose monohydrate > dicalcium phosphate dihydrate. Sugar-based excipients commonly used as special assembly carriers (such as dextrose, fructose, maltose, mannitol, sorbitol, hydrolysed starch, polydextrose and xylitol) exhibit high solubility and sweet taste in liquids, giving a sugar-situated

Excipients based on molding and dissolution cost. The saccharides of one form (lactose and Mannitol) showed low molding capacity but excessive dissolution rate. Enter a pair of saccharides (maltose and malitol) which exhibit high moldability but low dissolution rate.

**2 Lubricants**[17]

This will formulate the tablet more palatable once it dissolves in the mouth. Lubricants remove grittiness and edges. In drugs, the mechanism is transmitted from the mouth to the stomach. Some lubricants are stearic acid, magnesium stearate, zinc stearate, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulphate, colloidal silicon oxide.

**3 Flavors and sweetener**

When added to the product, the aroma and flavor-hiding active ingredients create a pleasant and pleasant taste for the patient. The addition of these ingredients has the benefit of overcoming the spiciness and inconsistent taste of some of the active ingredients. Every natural and synthetic fragrance is often used to enhance the organoleptic properties of FDT. Mint fragrance, aromatic fragrance oil, peppermint oil, clove oil, laurel oil, anise oil, eucalyptus oil, thyme oil, sour almond oil. Flavors include vanilla, citrus oil, fruit essence. Formulators can choose from a good variety of sweeteners, in addition to sugar, dextrose and fructose, as well as non-food sweeteners such as aspartame, sodium saccharin, sugar alcohol, and sucralose.

**4 Superdisintegrants**[18]

Tablet and capsule formulation, the super disintegrant are usually incorporated to enhance moisture perforation and dispersion of the dosage form matrix in the dissolution liquid. Superdisintegrants are usually used at low concentrations, usually 1-10% by weight by weight of the total unit dose. Ideally, these materials should cause the tablet to disintegrate not only into granules from which the tablet is fully compressed, but also into powder particles from which the granules are formulated. Commonly used super disintegrating agents are cross-linked polymers and cross-linked starch or microcrystalline cellulose, croscarmellose sodium (AcDi-Sol), crospovidone (CP), sodium starch glycolate (SSG), modified corn starch, pregelatinized starch, i.e., gelatinized starch. Carboxymethyl cellulose, calcium carboxymethyl cellulose. Sodium starch glycolate has a high fluidity of croscarmellose sodium. Crospovidone are naturally tough and very compact.

**Mechanism of superdisintegrant**[19]

The adequacy of solid dosage forms is increased with the use of Superdisintegrants. This can be achieved through various mechanisms. The mechanism by which tablets are broken into small pieces to form a homogeneous suspension is based on:

- **Swelling**

Although the influx of water may be a necessary disintegration initiative, flatulence is probably the most common mechanism of action for tablet disintegration. Matched with a suitable medium, the explosive particles swell when returned and a swelling force develops which causes the matrix to dissolve. High consistency tablets show poor degradation due to lack of sufficient swelling power. Instead, the swelling power is applied inside the tablet with a low consistency. It should be noted that with a very high pressing section, the liquid cannot penetrate the inside of the tablet and the decomposition is reversed again.

- **Porosity and surface tension (wicking)**

Effective explosives that do not expand exhibit their explosive effect through porosity and surface tension. The porosity of the tablet provides room for the liquid to penetrate the tablet. When we put the tablet in a suitable liquid medium, the medium penetrates into the tablet and replaces the air which is absorbed by the particles, which weakness the intermolecular bonds and breaks the tablet into fine particles. The hydrophilicity of the active substance/excipient determines the water absorption per tablet. The hydrophilic network around the active ingredient particles aids degradation. Particle Repelling Power of the disintegration system explains that the disintegrant "does not swell" causing the tablet to swell. The molecular avoidance hypothesis asserts that non-swelling molecules lead to further degradation of the tablet. Its main component is the electric repulsion between particles.

- **Deformation**

During tablet compression the crushed particles are deformed, and when these distorted particles are existing for contact with liquid or water, they return to their traditional structure. The pressure increases the starch's ability to swell, causing the enlargement of the particles to destroy initiating the tablet to disintegrate.

**Method of Incorporation of Superdisintegrants**[19]

**During granulation**

In this, the superdisintegrant is mixed through other powders and granulated.

This is how the super disintegrant is incorporated into the granules.

**Extra granules or before pressing**

In this, the superdisintegrants is mixed with the finished granules Compression.

**Combination of superdisintegrants at intra and extra granulation steps**

Part of the superdisintegrants is added to the Intragranular and part to the extra Details. This method gives better results than the Type 1 and Type 2 methods.

**Role of Superdisintegrant in Fast Disintegrating Tablets**

A superdisintegrant is a substance added to a tablet that promotes the disintegration of the tablet into smaller fragments in the aqueous medium there in by increasing the available surface area and promoting faster drug release. They stimulate moistness permeation and tablet matrix dispersion. Tablet disintegration has received significant consideration as an important step in achieving rapid drug release. Superdisintegrants are usually used in small amounts in solid dosage forms, usually 1-10% by weight, depend upon entire dose.

**5 Surface active agents**

Sodium dodecyl sulfate, sodium lauryl sulphate, polyoxy ethylene Sorbitan fatty acid esters (Tweens), sorbitan fatty acid esters (Spans), polyoxy ethylene stearates

**6 Binder**

Polyvinyl pyrrolidone (PVP), polyvinyl alcohol (PVA), (HPMC).

**7 Color**

Sunset yellow, Amaranth etc.

**6. Cotton Candy Process**

The FLASHDOSE® is an MDDDS made with ShearformTM technology in the United States. Collaboration with Ceform TITM technology obliterate the medicine's unpleasant flavor, The Shearform method is used in a variety of applications. The process of creating a 'floss' matrix made up of a number of different excipients either alone or with the usage of medications the floss is a fibrous material. A substance that resembles cotton candy fibers, Saccharides, such by means of sucrose, are extensively used. Temperatures of dextrose, lactose, and fructose ranging from 180 to 266 degrees Fahrenheit. Additional polysaccharides, such as polymaltodextrins and polydextrose, can be converted into fibres at temperatures 30–40% lower than sucrose. This change allows thermolabile medicines to be securely merged into the formulation. Due to the rapid solubilization of sugars in the occurrence of saliva, the tablets produced by this method are highly permeable in nature and have a very pleasing mouth feel. The manufacturing process can be fragmented down into four parts, as shown below.

a) Floss Blend
b) Floss Processing
c) Floss Cutting and Conditioning
d) Compression and blending

**7. Mass Extrusion**

Softening the active mixture with a solvent blend of water-soluble polyethylene glycol and methanol, then extruding the softened material through an extruder or needle to produce a cylinder-shaped extrude, which is then cut into even sections by a hot blade to form tablets. This technique can also be used to coat bitter medication granules in order to disguise their taste.

**8. Phase Transition Process**

A mixture of low and high melting point sugar alcohols, in addition to a phase transition in the production process, are found to be necessary for creating MDTs without the use of specific equipment. MDT was made by compressing erythritol (melting point: 122 °C) and xylitol (melting point: 93 95 °C) powder and heating it for 15 minutes at 93 °C. The average pore size of the tablets was increased after heating, as was the tablet hardness. The crystal state of the lower melting point sugar alcohol had no effect on the increase in tablet rigidity with space heating and storage.

**PATENTED TECHNOLOGY FOR THE FORMULATION OF MDT**

The fast dissolution property of ODT is usually attributed to the rapid penetration of water into the tablet matrix, leading to its rapid disintegration. Several technologies have been developed based on different aspects of formulation and process, and the obtained dosage forms vary in several parameters such as mechanical strength, porosity, dosage, stability, taste, mouth feel, dissolution rate and overall bioavailability.

**1. Zydus Technology[11]**

The Zydus formula is a unique frozen tablet in which the drug is physically trapped or dissolved in a fast-dissolving carrier matrix. When the Zydus unit is placed in the mouth, the lyophilized structure disintegrates immediately, and no water is required for easy swallowing. The Zydus Matrix is made up of many materials designed to accomplish a variety of purposes. Polymers such as gelatin, dextran or alginate are included to provide strength and elasticity during handling. They form a shiny amorphous structure that gives strength.

**2. Orasolv Technology [12]**

Orasolv technology was developed by the CIMA laboratory. In this system, the active substance is masked by the taste. It also contains bubbly explosives. The tablets were prepared using a direct compression technique at low compressive strength to minimize oral dissolution time. For the manufacture of tablets, blenders and tablets are commonly used. Tablets produced are soft and brittle, packaged in a specially designated place.

**3. OraQuick** [13]

K.V.S.Pharmaceutical have a patent over this innovation. It uses Taste concealing microsphere innovation called as micromask, which Gives better mouth feel over taste covering options, huge mechanical strength, and fast breaking down/Disintegration of the item. Any sort of solvents is not used by Taste concealing interaction. Along these lines it prompts unrivaled and quick effective item.

**4. Pharmabust technology**[14]

Pharmabust innovation is being licensed by SPI pharma. The tablet Fabricated by this interaction includes a dry mix of a medication, flavors, and oil then, at that point, trailed by pressure into tablets which then Disintegrate inside 30-40 seconds. Tablets made by this System have adequate strength can be pressed in rankle pack and jugs

**5 Lyo (pharmalyoc)** [14]

Oil In water emulsion is get ready and set straight forwardly into rankle Holes followed by freeze – drying. Non-homogeneity during Freeze-drying is kept away from by consolidating latent filler to build the thickness at long last the sedimentation. A high extent of filler decreases the porosity of tablet because of which crumbling is brought down.

**6 Sheaform technology**[15]

The innovation depends on the arrangement of floss that is otherwise called, shear from framework, which is delivered by oppressing a feed stock containing a sugar transporter by streak heat handling. In this Cycle, the sugar is at the same time exposed to radial power and to a temperature angle, which raises the temperature of the mass to make an interior, stream condition, which allows part of it to move with deference of the mass.

## CONCLUSION

Fast dissolving tablets are novel dosage forms that were established and specifically designed to address some of the issues associated with traditional solid dosage forms, such as complications swallowing tablets in geriatric and pediatric patients. Fast dissolving tablets are envisioned to dissolve or disintegrate in the saliva in less than 60 seconds (range of 5-60 seconds). When associated to traditional oral dose forms, fast dissolving tablets offer higher patient compliance and acceptance, which may progress biopharmaceutical properties, bioavailability, effectiveness, suitability, and safety. Over the last era, the popularity of MDTs has increased. MDTs are desirable for psychotic patients, immobile patients, geriatric patients, pediatrics patients, patients who may not have access to water, and patients who are wandering. MDT formulations established by some of these conventional and patent technologies and MDTs have sufficient mechanical strength and fast disintegration/dissolution in the buccal cavity without the need of water. The newest technologies used in the formulation of MDTs enable more in effect dosage forms with fewer drawbacks and more advantages.

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