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A REVIEW ON MOUTH DISSOLVING TABLET

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ABSTRACT:

Scientists have long been drawn to the creation of elaborate oral medicine delivery systems as a strategy to increase patient compliance. Mouth dissolving drug delivery systems (MDDDS) have grown to be one of them. Standing in the market by resolving earlier administrative issues and helping to prolong the life of the patent. The distinctive feature of MDDDS is that they dissolve and release the medication as soon as they come into contact with saliva, eliminating the need for water during administration. As a result, these dosage forms have attracted a particular patient demographic to the market, including dysphagic, bedridden, mental, elderly, and paediatric patients. Recently, a number of methods have been created to enhance the fragile dosage forms' ability to disintegrate without losing their integrity. The available technologies and advancements are the main topics of this article. Made thus far in the subject of making tablets that dissolve in the mouth. In addition to the traditional fabrication techniques, this review discusses in depth a number of novel patented technologies, including Zydis, Lyoc, Quicksolv, Orasolv, Durasolv, Flashtab, Oraquick, Wowtab, and Ziplet, along with its benefits and drawbacks.

KEY WORDS: Mouth dissolving tablet (MDTs), super disintegrants, taste masking, lyophillization, direct compression

INTRODUCTION :

Many patient populations, including the elderly, kids, intellectually challenged, recalcitrant, or sick, have trouble swallowing. Typical dosage forms, such as pills. Like a lack of water, allergic reactions, and coughing fits will make it harder to swallow regular tablets[1]. The creation of quickly evaporating and dissolving tablet dosage forms for oral administration can address these issues. Because they dissolve in saliva and do not require water for swallowing, they are easy to administer. After intake, the dose form is quickly dissolved by saliva. Following swallowing of the saliva containing the dissolved or scattered medication, the medicine is absorbed as usual. As saliva travels from the mouth, throat, and oesophagus into the stomach, some medications are taken up by the body. In these situations, medication bioavailability is

much higher than that seen with traditional dose forms[2]. Some medications' bioavailability may be boosted by oral cavity absorption as well as by pregastric absorption. Drugs that are distributed in saliva that enter the stomach. Additionally, less medication undergoes first pass metabolism in comparison to regular tablets[3].

Despite significant improvements in medication delivery, the oral route continues to be the best method for administering medicinal Agents because to the low cost of treatment, simplicity of administration, accuracy of dosage, self-medication, ability to reduce pain, and adaptability, which results in high levels of patient compliance. The two most often used dosage forms are tablets and capsules[4]. But "Dysphagia," or trouble swallowing, is a significant disadvantage of such dose formulations. Nearly everyone is said to be affected disorder 35% of the populace as a whole. The following conditions are linked to this disorder:

1. Parkinsonism

2. motion sickness

3. Being unconscious

4. Senior citizens

5. Youngsters

6. People mental disabilities

7. The absence of water[5].

Greater patient compliance has been attained Massive demand. As a result, the demand for such technology is growing tremendously. It takes a lot of money, effort, and time to build a chemical entity. Therefore, efforts are being concentrated on creating new drug delivery methods for already available medications that have improved efficacy and bioavailability, thereby lowering the dose and frequency of dosing to reduce adverse effects.

IDEAL PROPERTIES OF MDTs [5,6] :

• They should melt or disintegrate in the mouth in a matter of seconds and not require water to be swallowed.

• Permit heavy drug loading.

• well with other excipients and flavour masking agents.

• good in the mouth.

• oral delivery, leave little to no leftovers in the mouth.

• Should be strong enough to survive the demands of manufacture and handling after manufacturing.

• They show little susceptibility to environmental factors like temperature and humidity.

• flexible to current processing and packaging equipment.

• it possible to produce tablets at minimal cost using standard manufacturing and packaging machinery.

ADVANTAGES OF MDTs [7-12] :

• There is no need for water when taking the tablet.

• simple to administer to Patients who are young, old, and intellectually challenged.

• More precise dosing than with liquids.

• Drug absorption and dissolution occur quickly, resulting in an immediate commencement of action.

• Drug bioavailability is increased because some medications are absorbed through saliva entering the stomach from the mouth, pharynx, and oesophagus.

• More convenient for administration and transportation than liquid medications

• Reduced first pass metabolism results in enhanced bioavailability, which lowers doses and side effects.

• drug loading is permitted

• there is no chance of suffocating from physical obstruction when ingested, improving safety.

CRITERIA OF MDTs[13]:

The tablets must meet the following requirements:

• needing water to swallow, but dissolving or breaking down in the mouth at period of time.

• well with flavour muffling.

• transportable without posing a fragility risk.

• little to no aftertaste in the mouth following oral use.

• a low sensitivity to environmental factors like humidity and temperature.

• Permit inexpensive production of the tablet using standard processing and packaging machinery.

• Ease of administration to patients who are unable to swallow, such as the elderly, stroke victims, patients who are bedridden, and patients who have renal failure.

• The medicine will dissolve and absorb quickly, leading to an immediate start of action.

• as saliva descends into the stomach, some medications are absorbed from the mouth, pharynx, and oesophagus.

• Pregastric absorption can lead to increased bioavailability and lower dosages, which can improved clinical effectiveness by minimising side effects.

• By avoiding physical obstructions during oral administration of the standard formulation, the risk of choking or suffocation is reduced, improving safety.

• New commercial opportunities like life cycle management, patent extensions, and product differentiation and promotion.

• Helpful in situations requiring an ultra-rapid initiation of action, such as motion sickness, acute allergy attacks, or coughing.

• Improved bioavailability, especially for hydrophobic and insoluble medicines, as a result of quick, these tablets have a longer shelf life.

• the medicine is still in a solid dose form until it is ingested, preventing breakdown and dissolution. So it combines the stability benefits of solid dose forms with the bioavailability benefits of liquid dosage forms.

FORMULATION OF MDTs [14-17]:

Drug :

A drug's fundamental bodily absorption characteristics In oral and pregastric absorption, MDTs have the following characteristics:

• without an unpleasant taste

• lower than 20 mg dose

• Modest to Small Molecular Weight

• Excellent oral mucosal tissue penetration and solubility.

Bulking elements:

Bulking ingredients play a big role in the creation of fast-melting tablets. The substance provides diluent, filler, and cost-cutting properties. Bulking substances enhance the Additionally, adding bulk lowers the concentration of the active ingredient in the composition. Textural characteristics that improve disintegration in the mouth. For increased aqueous solubility and good sensory perception, more sugar-based bulking agents are advised for this delivery system, such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose), and starch hydrolystate. Bulking agents are incorporated into the final composition in amounts ranging from 10% to 90% by weight.

Emulsifying agent:

Emulsifying agents are crucial excipients in the formulation of fast-melting tablets because they provide quick drug release without chewing. Sipping water or swallowing. Additionally, adding emulsifying agents helps to stabilise immiscible mixes and improve bioavailability. Alkyl sulphates, propylene glycol esters, lecithin, sucrose esters, and a variety of other emulsifiers are all advised for use in the formulation of fast-acting tablets. These substances can be added in amounts ranging from 0.05 percent to roughly 15 percent by weight of the finished mixture.

Lubricants:

Lubricants, though not necessary excipients, can also help to improve the taste of these tablets when they dissolve in the mouth. Lubricants take away grit and helps the body's system for delivering drugs from the mouth to the stomach.

Flavours and sweeteners :

The products are made more edible and attractive for patients by adding flavours and taste-masking chemicals. These substances are added to help combat bitterness and several of the active substances have unpleasant tastes.

Superdisintegrant :

A disintegrant is an excipient that is added to a tablet or capsule mixture to help the compacted material break up when it is placed in a fluid environment.

Table 1: lists numerous currently used superdisintegrants along with their mode of action

Disintegrant name	**Mechanism of action**	**Brand name**	**Concentration in percentage**
Micro crystalline cellulose	Water wicking	Avicel , Celex	2-15%
Povidone with cross link	Water wicking and swelling	Cross povidone	2-5%
Crosscarmellose sodium	Wicking and swelling	Ac-Di-Sol	1-3%
Pregelatinized starch	Swelling	Starch 1500	1-20%

MECHANISM OF SUPERDISINTEGRANTS [18,19]:

1. **Swelling:**

Swelling is arguably the most commonly acknowledged general mode of action for tablet disintegration. High porosity tablets exhibit poor Breakdown brought by insufficient rising force. On the other hand, the tablet with poor porosity experiences enough swelling force. It is important to remember that when the packing percentage is very high, liquid cannot enter the tablet and the rate of disintegration is again slowed down.

2. **Wicking (Porosity and capillary action):**

The initial stage of disintegration is always capillary action. When the tablet is placed in an appropriate aqueous solution, the medium permeates the air removed from the tablet and replaced with water, which weakens the intermolecular link and causes the tablet to crumble into tiny pieces. The hydrophilicity of

the medicine or excipient and the tableting circumstances affect how much water is absorbed by the tablet. In order to disintegrate by forming a hydrophilic network surrounding the drug particles, these forms of disintegrants require maintenance of porous structure and low interfacial tension aqueous fluid.

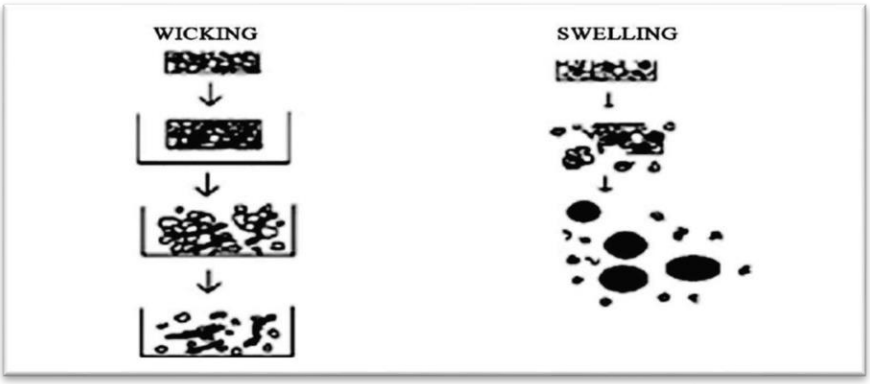


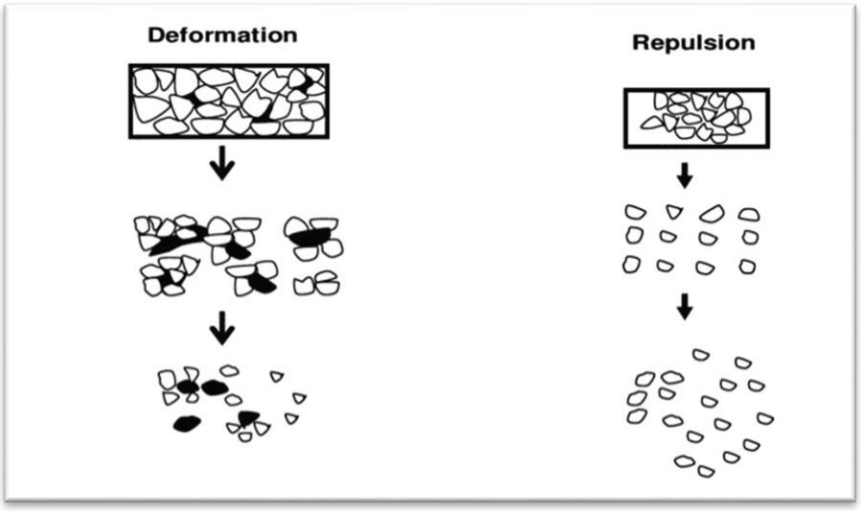
Fig 1: Disintegration of tablet by Wicking and swelling

3. Particle repulsive force/ Due to disintegrating particle:

Another disintegration process makes an attempt to explain why a tablet manufactured with 'nonswellable' disintegrants swells. Using Guyot- Hermann's Based on the discovery that nonswelling particles also contribute to tablet disintegration, a particle repulsion theory was presented. The mechanism of disintegration is the electric repulsive interactions between particles, and water is necessary for it. Researchers discovered that wicking comes second to repulsion**.**

4. Due to deformation:

Disintegrated particles deform during tablet compression, returning to their original



Particle swells to precompression. Drawn water into pores

Fig 2: Disintegration by deformation and repulsion.

shapes when they are released. Come into contact with water or aqueous media. Occasionally, when granules underwent significant deformation during compression, the starch's ability to swell was

enhanced. The tablet breaks up as a result of the distorted Particles' growth in size. Only lately has research on this potential starch mechanism started.

MANUFACTURING TECHNIQUES OF MDTs :

Now a days different newer manufacturing technologies are used for MDTs are as follow :

- Freeze drying/Lyophilization
- Molding
- Sublimation
- Spray Drying
- Direct Compression
- Mass Extrusion
- Nanonization
- Cotton Candy Process
- Fast Dissolving Films

Lyophilization:

After the product has been frozen during the freeze-drying process, the water is sublimed from it. This method serves as the foundation for the Zydis, Quicksolv, and Lyoc technologies that are utilised to create MDTs. Lyophilization was employed by Jaccard and Leyder to create an oral formulation. It enhanced the bioavailability of various medications, including spironolactone and trolendomycin, in addition to dissolving quickly [20]. Corveleyn and Remon used hydrochlorothiazide as a model medication to examine various formulation and process characteristics[21,22].

Using a trademarked method called Zydis technology (ZT), medications such loperamide, piroxicam, oxazepam, lorazepam, domeperidone, brompheniramine, olanzepine, ondansetron, and rizatriptan are some examples of medications. There are currently thirteen goods on the market that were produced utilising this technology. Claritin Reditab, Dimetapp Quick Dissolve, Feldene Melt, Maxalt- MLT, Pepcid RPD, Zofran ODT, and Zyprexa Zydis are among the MDT products that are offered in the United States. Zydis formulations for oxazepam, lorazepam, loperamide, and enalapril are also offered on the global market. ZT makes completed dose units using a special freeze-drying method that are very different from traditional oral systems.

The following are the steps in the process:

Stage 1- a large batch of an aqueous pharmaceutical mixture or solution and carefully dosing it into pre-Formed blisters. The blister is essential to the whole product package because it is the one that actually moulds the tablet.

Stage 2- order to control the final sizes of the ice crystals and ensure that the tablets have a porous matrix to support their speedy disintegration property of the process entails subjecting the filled blisters to a specially

designed cryogenic freezing operation. These frozen units are transferred after being frozen, and the sublimation procedure removes the majority of the remaining moisture from the tablets.

Stage 3- Using a heat-seal procedure to close the open blisters will provide product stability and defence against changing environmental factors.

Lyoc An aqueous solution, suspension, or emulsion comprising an API plus excipients is "freeze-dried" using lyoc technology. Due to Lyoc's high level of porosity, shorter slower rates of disintegration than compacted pills. A stable product is created during the Lyoc manufacturing process without the addition of additives, preservatives, or gelatins. Because it doesn't use organic solvents, this procedure is both economical and environmentally beneficial. CIMA taste-masking techniques, tailored release, high dosage, and fixed-dose combo solutions are all compatible with Lyoc technology[23,24,25].

Quicksolv is a porous solid form created by freezing an aqueous dispersion or solution of a drug-containing matrix, which is subsequently dried by draining the water utilising Excessive drinking (solvent extraction). Only medications that are insoluble in the extraction solvent can be employed in the final form, which degrades swiftly but is only effective at low drug concentrations. The optimum pharmacological properties needed for this approach include relatively low water solubility, small particle size 50 m, and good water stability in suspension[24,25].

Advantages: The main benefit of employing this method is that the tablets made using it disintegrate very slowly and have excellent mouthfeel as a result of the quick melting action.

Disadvantages: Lyophilization has some drawbacks, including the fact that it is a rather expensive and time-consuming procedure despite being a pretty normal one. Additionally, the resultant product is brittle and poorly stable, making standard packaging inappropriate.

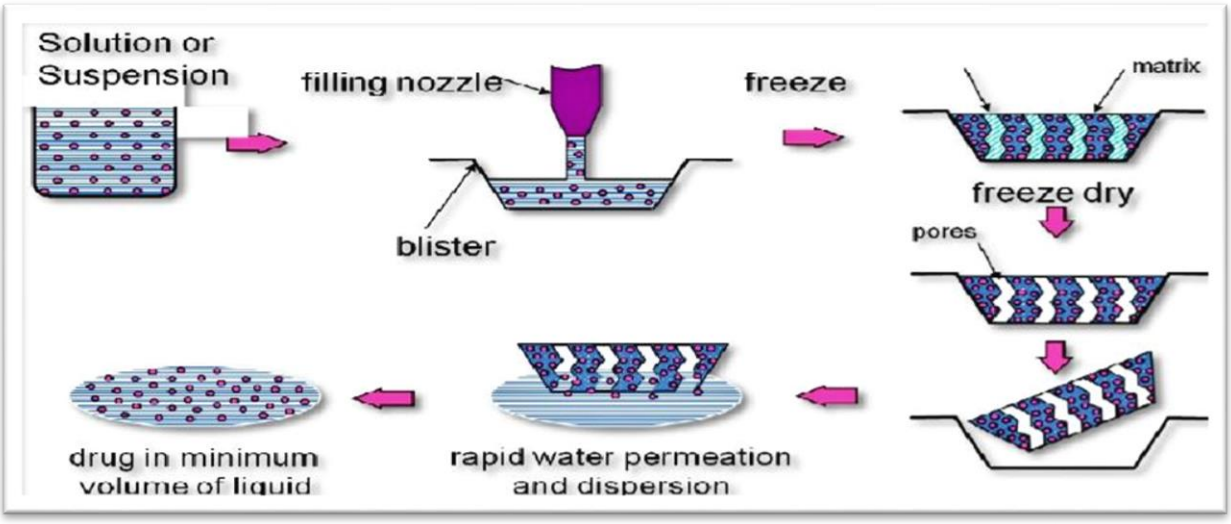


Fig 3 :The technology of Lyophilization. Based on this procedure is the Zydis technology, which has a patent.

Molding:

The two different moulding techniques are the solvent method and the heat method. The solvent approach entails wetting the powder mixture with a Using hydro-alcoholic solvent, formed plates are compressed at low pressures to create a wetted mass (compression molding). The solvent is removed through air drying. The so-produced tablets have a porous structure that speeds up dissolution and are less compact than compacted tablets. During the heat moulding procedure, a suspension containing a medication, agar, and sugar is created (e.g. mannitol or lactose). This suspension is poured into the blister packing wells, where agar is then allowed to solidify into a jelly at room temperature before being vacuum-dried at 30°C.The biggest issue with these moulded tablets is their mechanical strength, which is something that binding agents can help with. The taste-masking medication particles were created by congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol, and an active component into a lactose-based tablet triturate form. The moulding approach produces tablets more easily scaled up for industrial scale manufacturing than the lyophillization method does[26].

Sublimation:

In this method, inert volatile chemicals including urea, urethane, naphthalene, camphor, and others are added to other excipients and The tabletization of the combination. Tablets disintegrate when they come into contact with saliva because pores in the tablet's structure

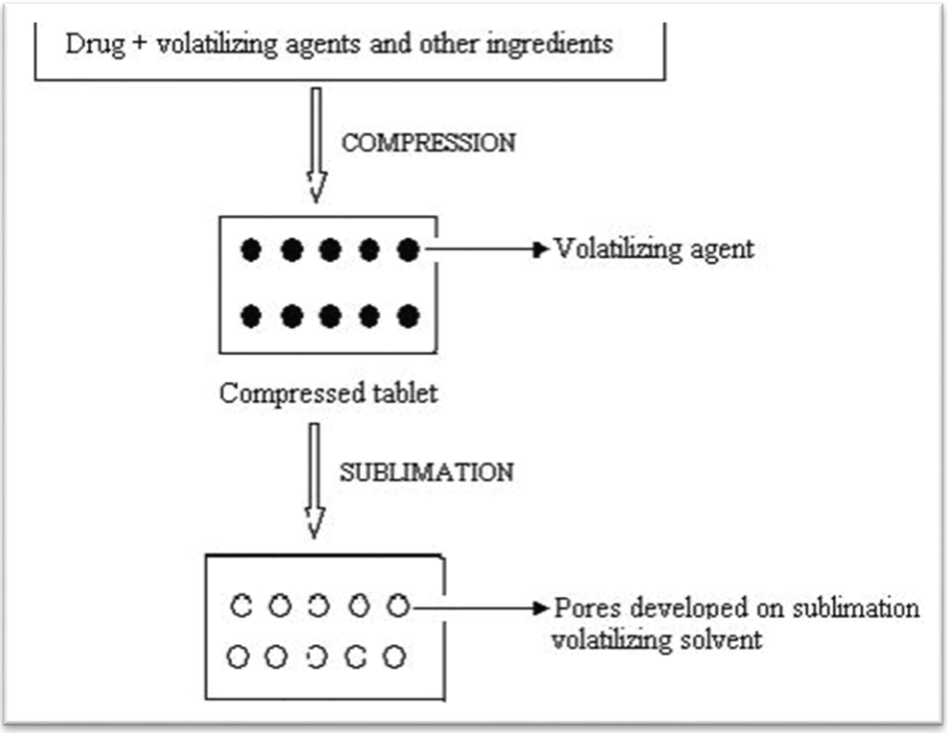


Fig 4: Schematic of the MDT Preparation Method Using Sublimation

caused by the removal of volatile substance via sublimation. Additionally, a number of solvents, including benzene and cyclohexane, can be utilised as pore-forming agents. By using this technique, mouth-dissolving tablets with a highly porous structure and good mechanical strength have been created[27,28].

Spray drying[29,30].

Spray-drying has been employed by Allen et al. To create MDTs. The compositions used both hydrolyzed and unhydrolyzed gelatin as a matrix support substance, Using sodium starch glycolate/croscarmellose as a disintegrant and mannitol as a bulking agent. By incorporating an acid (like citric acid) or an alkali, dissolution and disintegration were increased even further (e.g., sodium bicarbonate).Spray-drying the excipient suspension produced a porous powder that was then crushed into tablets. This approach produced tablets that decomposed in an aqueous solution in under 20 seconds.

Direct compression(DC) [24,25,31]:

Since MDTs can be made using standard tablet manufacturing, DC is the most straightforward and economical tablet manufacturing method available. Due to the availability of tabletting excipients with improved flow, compressibility, and disintegration properties—particularly tablet disintegrants, effervescent agents, and sugar-based excipients—as well as to packing equipment.

Sr.no.	Ideal requirements	Benefits	Limitations
1	Flowability	Affordable production	Segregation
2	Controlled particle size	Minimal microbiological contaminants	Sensitive to lubricant
3	Stability	Easy verification	API has poor compressibility
4	Reworkability	Punches suffer less damage and wear	Reworkability
5	Compressibility	Better API stability	Varying levels of functionality
6	Potential for dilution	More rapid dissolution	Low potential for diluting

Table 2: Ideal requirements, benefits and limitations of direct compression.

Mass extrusion：

Utilizing a solvent mixture of methanol and water soluble polyethylene glycol, this method softens the active blend. This mellowed a cylindrical extrusion is produced after bulk is forced through an extruder or syringe; it is then sliced into even pieces using a hot blade to create tablets. This technique can be used to coat bitter medication granules to disguise their flavour[32].

Nanonization [33].

Through the use of a patented wet-milling procedure, a recently developed technology called Nanomelt reduces drug particle size to nanoscale. The surface adsorption on particular stabilisers prevents the

agglomeration of drug nanocrystals, which are then integrated into MDTs. For medications that are weakly water soluble, this method is extremely beneficial. Other benefits of this technology include quick nanoparticle disintegration or dissolution, which increases absorption and, as a result, higher bioavailability and dose reduction, a cost-effective manufacturing process, and conventional packaging due to its exceptional durability and wide range of doses (up to 200 mg of drug per unit).

Cotton candy process:

The FLASHDOSE® is an MDDDS created using ShearformTM technology in conjunction with Ceform TITM technology to get rid of the medicine's bitter taste [34,35]. A matrix known as Shearform is created using the Shearform technology. “Floss" prepared from a mixture of excipients, either by itself or in combination with medications. Typically formed of saccharides such sucrose, dextrose, lactose, and fructose at temperatures between 180 and 266 °F, floss is a fibrous substance resembling cotton-candy fibres[36]. Other polysaccharides, like polymaltodextrins and polydextrose, can, however, be converted into fibres at temperatures 30–40% lower than sucrose. This change enables the formulation to safely incorporate thermolabile medicines[37].Due to the quick solubilization of sugars in the presence of saliva, the tablets produced using this procedure have a very porous character and have a very pleasant mouthfeel. The production the method can be broken down into the four parts shown below.

1.Floss blend :

The floss mix is created in this step by blending 80% sucrose, mannitol/dextrose, and 1% surfactant. The surfactant helps to retain the structural integrity of the floss strands by acting as a crystallisation enhancer. Additionally, it aids in the conversion of changing a portion of the mass of amorphous sugar into crystalline form and then transforming the remaining component of the mass into a fully crystallised structure. This procedure minimises migration out of the mixture by aiding in the retention of the dispersed medication in the matrix[38].

2.Floss processing:

The floss formation machine creates matrix from the carrier material using flash flow and flash heat techniques. The apparatus resembles the one used to make “cotton candy,” which consists of heating components and a rotating head. When using flash heat, the heat causes the carrier substance to flow inside. Then it exits the spinning head (2000-3600 rpm), which propels the floss with the help of centrifugal force and separates it into long, thin floss fibres that are often amorphous in form[39-41].

3.Floss chopping and conditioning :

In this process, fibres are broken down into smaller pieces in a high shear mixer-granulator. An ethanol treatment (1%) is used to partially crystallise the floss during conditioning, and the ethanol is then sprayed onto the floss and evaporated to impart the conditioning. Better cohesion and flow characteristics for the floss[36].

4.Blending and compression :

The medicine and other necessary excipients are then combined with the chopped and conditioned floss fibres before being compacted into tablets. A curing process is also used to increase the mechanical strength of the tablets, and it entails exposing the dose forms to heightened temperatures and humidity levels for 15 minutes (40 °C and 85% RH). This is anticipated to lead to the floss material crystallising, resulting in binding and bridging to strengthen the dosage form's structural integrity [42].

Fast dissolving film [43] :

It is a brand-new area of MDDDS that offers a very practical way to take prescription drugs and dietary supplements. This method involves creating a non-aqueous solution. Containing a drug and other taste-masking ingredients that are allowed to form a film after the solvent evaporates. Examples of such ingredients include pullulan, carboxy methylcellulose, hydroxypropyl methylcellulose, hydroxyl ethylcellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, and sodium alginate. A resin adsorbate or coated microparticle of a bitter medication may be incorporated into the film. When put in the mouth, this film quickly melts or dissolves, releasing the medication as a solution or suspension. Paper thin films of various sizes are among the properties of this system. Less than 2X2 inches, 5-second disintegration, immediate medication delivery, and flavouring aftertaste.

PATENTED MDTs WITH TASTE MASKING TECHNOLOGY:

A variety of patented taste-masking techniques have been used to create MDTs with palatable tastes. The dissolution-retarding excipient is coated on the medication as part of CIMA Labs' taste-masking method[44],Microencapsulation procedure using the coacervation-phase separation method[45,46],Drugs are coated with a sustained release agent using the Solutab technology, and then medication is blended with cyclodextrins[47], mannitol, and ultimately enteric polymer[48], are a few of the taste-masking techniques used in the production of MDTs. Another formulation in this group is OraQuick's MicroMask, which creates microspheres and has a better mouthfeel than other taste-masking substitutes. This procedure produces goods more quickly and effectively because it doesn't utilise solvents. OraQuick is suitable for heat-sensitive medications due to its comparatively low manufacturing heat. The more malleable matrix that surrounds the medication in the microencapsulated particles allows for greater mechanical strength to be applied while compressing the tablets without affecting their ability to disguise flavour. OraQuick states that in addition to having superior taste-masking capabilities, the MDT dissolves quickly (in secs) [49].Additionally, using this method, MDTs containing the unpleasant-tasting anticholinergic/antispasmodic medication hyoscyamine sulphate were created[50].In order to provide a very distinctive controlled release MDT product, AdvaTab technology combines Microcaps technology for taste masking and Diffuscap controlled release technology[51].

CONCLUSION :

Tablets that dissolve in the mouth have a number of pharmacological benefits, such as increased efficacy compared to traditional dose forms. For instance, compared to standard tablets and capsules, they offer greater drug bioavailability, improve absorption profiles, and require lower amounts of active ingredient to be effective. The technology described in this article demonstrates current advancements. Technology for development and processing supports the efforts to reach a sophisticated medicine delivery device. Oral contraceptives, elderly patients with good judgement, immobile patients, and people on the go who don't need to check their watering. Very pregastric locations can be reached by drugs administered to MDT'S.

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