

A Review on: Design, Development and Evaluation of Mouth Dissolving Tablet

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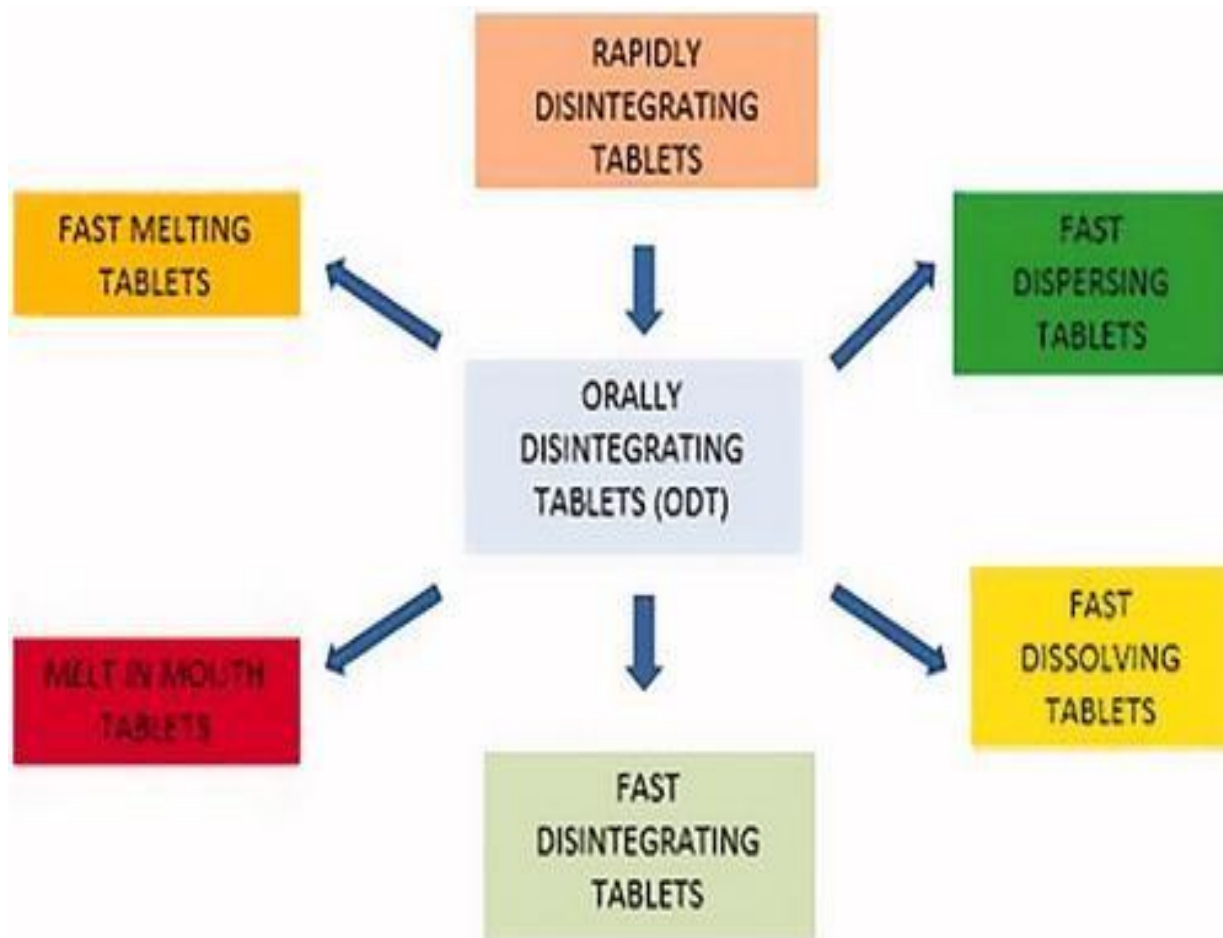
ABSTRACT

The benefits of orally disintegrating tablet are outlined in this article along with important considerations for MDT evaluation, such as bioequivalence, obstacles, and limitations. Finally, the current and future of MDTs are discussed. ODT demand has been continuously increasing, and the pharmaceutical industry is witnessing a sharp increase in this domain. These pills dissolve or break down in the tongue without requiring additional water. When ODTs are applied to the tongue, they instantly breakdown, releasing the medication, which then dissolves or diffuses in saliva. As the saliva travels down to the stomach, certain medications are absorbed from the mouth, throat, and esophagus. Well-known dose forms that are sold in the market are mouth dissolving pills. Over the last 10 years, there has been a rise in the need for MDTs (mouth disintegrating tablets), especially among pediatric, geriatric, and patients with swallowing difficulties. The development of fast-disintegrating drug delivery systems involves a number of techniques, including lyophilization, tablet molding, sublimation, spray drying, mass extrusion, direct compression, and the use of super-disintegrates. Quality control tests are also necessary to ensure that the desired characteristics and challenges are met.

Keyword: - MDT, Orally disintegrating tablet, evaluation test, dilution , disintegrants

1. Introduction:

Due to its simplicity of self-administration, compact design, and ease of manufacture, the tablet is the most commonly utilized dosage form currently in use. However, ingesting traditional tablets can be challenging for elderly, young, and mentally ill patients, which results in low patient compliance. Scientists have created a novel drug delivery method called mouth dissolving/disintegrating tablets (MDTs) to address these issues. [1] These MDTs should dissolve or disintegrate in less than three minutes, per European Pharmacopoeia. Patients with swallowing issues and those who are bedridden would benefit more from this formulation. Because of the advantages of MDTs—immediate onset of action, enhanced bioavailability, good stability, and improved patient compliance—these tablets are now widely used as the preferred dose form in the market. [3] An advantage of oral disintegrating tablets is that they are particularly beneficial for the elderly and pediatric those who have difficulty swallowing conventional tablets and capsules. [4] They are an excellent substitute for bedridden patients and travelers because they don't require water for administration. Psychotic patients are unable to conceal them in their mouths since they immediately disappear when placed there. Because the current formulation's line has been extended, these drugs not only improve patient compliance but also generate significant profits for the makers. [6] In terms of clinical practice, doctors most commonly prescribe non-steroidal anti-inflammatory medications (NSAIDs) for inflammatory illnesses. one of the NSAIDs that is most frequently recommended to treat a variety of inflammatory diseases, including low back pain, rheumatoid arthritis, tonsillitis, pharyngitis, and stomatitis. Since nimesulide is highly hydrophobic and little soluble in water, it has low bioavailability when taken as traditional tablets. Nimesulide's dissolving properties have been improved by the use of complexation and co-solvency procedures. [9]

1.1 TYPES OF MDT:**Ideal Properties of MDT:**

- Have no need for water when taken orally.
- Have a mouth feel that is attractive.
- Possess a flavor disguising property that is acceptable.
- Be less pliable and more firm.
- After administration, leave little to no residue in the mouth.
- Show minimal susceptibility to external factors such as humidity and temperature.
- Permit the production of tablets using standard processing and packaging tools.

1.2 Advantages and Disadvantages**Advantages:**

- 1) Administration those who decline to swallow, including pediatric, geriatric, and psychiatric patients; these patients include the elderly, bedridden, patients suffering from renal failure, and patients with no ability to swallow.
- 2) Increased bioavailability and faster absorption can be attained via pre-gastric medication absorption from the mouth, throat, and esophagus as saliva flows down.
- 3) By avoiding physical blockage during oral administration of conventional formulations the risk of choking or suffocation is minimized, improving safety.

- 4) Easy to administer and patient-compliant for people with disabilities or bed rest, as well as for busy individuals on the go who don't always have access to water.
- 5) Easy administration and precise dosage in comparison to liquids.
- 6) Quick medication absorption and dissolution, which could result in a quick start of action.
- 7) Pre-gastric absorption can lead to increased bioavailability and, because of lower dosages, better therapeutic outcomes by minimizing side effects.

DISADVANTAGES:

- 1) In most cases, the tablets' mechanical strength is inadequate. Thus, handling needs to be done carefully.
- 2) Drugs with relatively larger doses are difficult to formulate into MDTs example like antibiotics ciprofloxacin with adult dose tablet containing about 500mg of the tablet.
- 3) The tablets may leave your mouth feeling gritty or with an unpleasant taste, if not formulated properly.
- 4) Patients who concurrently take anticholinergic medications perhaps not the most suitable candidates for MDT. Similarly, Patients who experience reduced salivation leading to dry mouth may not be suitable candidates for these tablet formulations. ^[1,3]

1.3 Desired characteristics and challenges for developing rapid disintegration of medication administration systems:

- 1) Time required for disintegration
- 2) MDTs should disintegrate/dissolve/disperse or melting mouth without the need of water in very short duration of time, possibly within 60 seconds.
- 3) Taste of the active ingredient
- 4) As most drugs are unpalatable, rapid disintegration of medication administration systems usually contain the medicament in taste masked form. Delivery systems dissolve or disintegrate in patient's mouth, thus releasing the active ingredients which come in contact with the taste buds and hence, taste masking of the drugs becomes critical to patient compliance.
- 5) Fast dissolving tablets are either compressed into tablets with extremely low porosity or composed of very porous or soft-molded matrix to enable them to dissolve in the mouth. compressive force, which results in brittle and/or friable tablets that are challenging to handle and frequently call for specific peel-off blister packaging.
- 6) Hygroscopic nature: Several fast-disintegrating drug delivery dosage forms are hygroscopic and can not maintain physical integrity under normal condition from humidity which calls for specialized product packaging.
- 7) Mouth feel: Mouth feel is critical, and patients should receive a product that feels pleasant. Any large particles from the disintegrating tablet that are insoluble or slowly soluble in saliva would lead to an unpleasant gritty feeling. This can be overcome by keeping the majority of the particles below less than the detectable size threshold. Sometimes, even if the taste is the only thing changed, a product's mouth feel perception can be enhanced by specific flavors, giving the impression that it is less gritty. You can add effervescence to help with disintegration to aid disintegration and improve mouth feel by reducing the "dryness" of a product ^[4].

2. Techniques used in the preparation of mouth disintegrating drug delivery systems:

- ❖ Freeze-drying (Lyophilization technologies)
- ❖ Tablet molding method
- ❖ Sublimation method
- ❖ Spray drying method
- ❖ Melt granulation
- ❖ Direct compression method

Freeze- drying (lyophilization)Method:

MDT formulation uses the porous product formation that occurs during the freeze-drying process. The process of lyophilization involves extracting the solvent from a drug solution or frozen suspension including additives that form the medication's structure. The drug's glossy, amorphous structure is imparted by freeze-drying it combined with additives, making the product extremely porous and lightweight. When the resulting pill is placed on the tongue, it dissolves quickly and releases the medication since the freeze-dried unit melts rapidly. Nonetheless, the lyophilized MDTs exhibit low humidity, low mechanical strength, and poor stability at higher temperatures. [3]

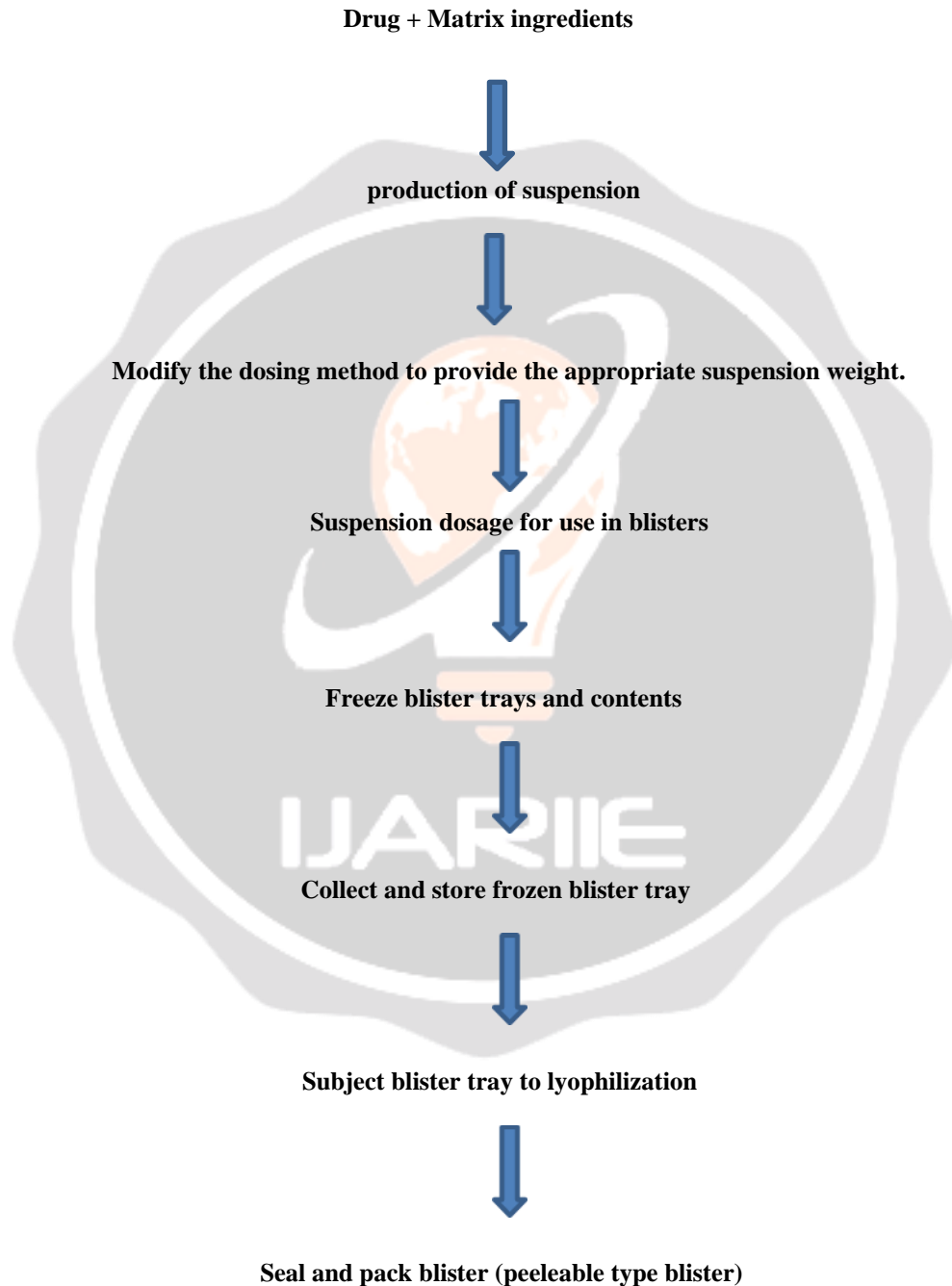


Figure: Steps involved in freeze drying technology

Tablet Molding method:

Using this approach, water-soluble materials are used to make molded tablets, which dissolve quickly and completely. A hydroalcoholic solvent is used to wet the powder blend before it is molded into tablets at a pressure that is lower than that of traditional tablet compression. After that, the solvent is eliminated by air-drying. Compared to compressed tablets, molded tablets are far less portable. These are more soluble because of their porous nature.

Sublimation method

The secret to MDTs disintegrating quickly is an extremely porous structure in the tablet matrix. The poor porosity of typical tablets prevents them from disintegrating quickly, even though they contain highly water-soluble chemicals. Volatile materials that sublime from the produced tablet, such camphor, can be utilized in the tableting process to improve porosity 33. created MDTs with the use of camphor, a subliming agent extracted from compressed tablets made with mannitol and camphor combined. Following preparation of the tablets, camphor was sublimated for 30 minutes at 80°C in a vacuum.

Spray drying method

One method for creating fine, very porous powders is spray drying. The pharmaceutical sector always uses spray-dryers to create extremely porous powders. Fast dissolving pills have been produced using this method, according to Allen et al.'s research. Spray drying is a useful technique for making tablets that dissolve quickly. This method is based on a spray-dried particle support matrix that is combined with other ingredients to create an aqueous composition that is both extremely porous and finely powdered. The active component is then combined with this and compacted into a tablet. The spray-dried tablet, which was fast dissolving, destroyed in 20 seconds.

Melt granulation

By using PEG-6-stearate, a hydrophilic waxy binder (super polystate), MDTs may be made using this approach. Super polystate is a waxy material that melts between 33 and 37 degrees Celsius and has a hydrophilic-lipophilic balance of 9. In addition to serving as a binder and strengthening the tablets' physical resistance, it also facilitates the tablets' disintegration by melting quickly in the mouth and immediately solubilizing, leaving no trace. Super polystate was added to MDT formulations using the melt granulation process, which forms granules from the material's molten state.

Direct compression methods

This technology makes it simple to construct MDTs since it requires fewer processing stages, has lower manufacturing costs, and can handle higher dosages without compromising tablet final weight, which can easily surpass that of other production methods. Directly compressed tablet disintegration and dissolving are dependent on the individual or combined actions of the disintegrant, effervescent agents, and water soluble excipients. Tablet hardness and size have a significant impact on disintegrant efficacy. Low hardness, low physical resistance, and medium or small tablet sizes can all be used to improve disintegration qualities. In order to ensure rapid dissolution and maximal dissolution, it is crucial to select an appropriate and ideal disintegrant concentration. To enhance the dissolution or disintegration qualities, effervescent agents or water-soluble excipients might be added. Fast disintegration is possible with super disintegrants

2.1 Patented Technologies for Fast Dissolving Tablets:

Zydis Technology:

Zydis formulation is a special type of freeze-dried tablet where the medication is trapped or completely dissolved in the quickly disintegrating carrier material matrix. The freeze-dried structure of zydis units dissolves instantly in the mouth and doesn't need water to facilitate swallowing. The zydis matrix is made up of numerous components in order to accomplish several goals. Polymers such as gelatin, dextran, or alginates are added to provide strength and resilience during handling. These combine to create a strong, glossy, amorphous structure. Saccharides like sorbitol or mannitol are added to achieve crystallinity, beauty, and hardness. Different types of gums are employed to avoid the sedimentation of dispersed medicine, while water is used in the manufacturing process to ensure the manufacture of porous units to achieve quick disintegration.

Preparation of aqueous composition of support matrix + bulking agent + volatizing agent + disintegrates + buffering agent

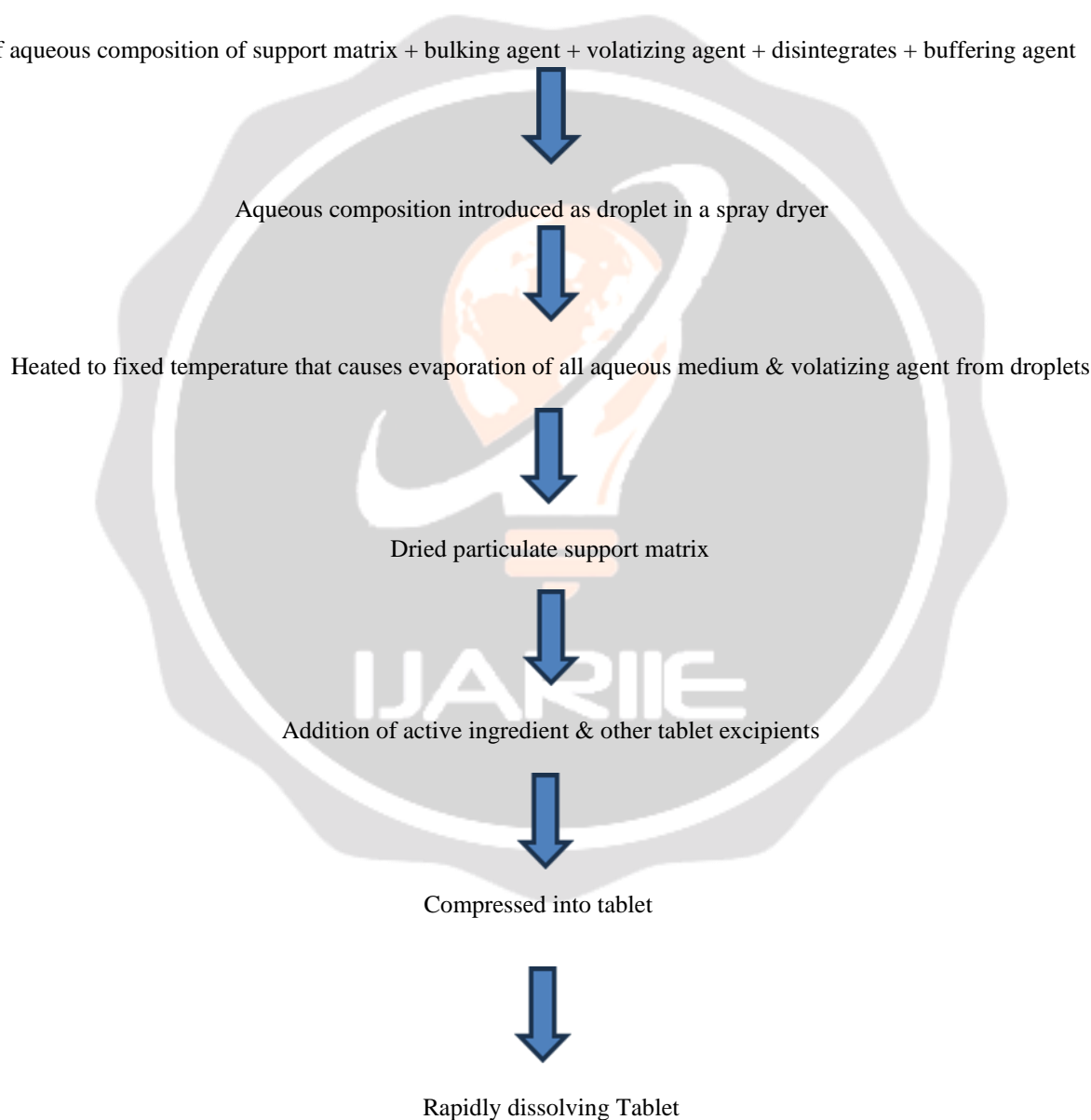


Figure: Steps Involved spray drying method

Flash tab Technology:

The Flash tab technology is patented by Prographarm Laboratories for tablet. The active component produced by this method is in the form of microcrystals. The traditional methods of coacervation, micro encapsulation, and extrusion spheronization can be applied to create drug microgranules. Every processing step made use of traditional tablet technology. [3]

Flash Dose Technology:

Fuisz has unique flash dosage technology. Nurofenmeltlet, a the company Biovail Corporation has introduced its first commercial product, a new formulation of ibuprofen in the form of melt-in-mouth tablets made with flash dosage technology. The "floss" in "flash dose" tablets is a self-binding shear form matrix. WOW, or "Without Water," prepares shear form matrices. To create a powerful tablet that melts quickly, a combination of low and high moldability saccharides is used in this procedure. Lactose, glucose, and mannitol are examples of low moldability saccharides that are combined with the active component, and maltose and oligosaccharides are examples of high moldability saccharides that are granulated.

Orasolv Technology:

Orasolv Technology has been created by CIMA labs. The active medication in this system is disguised by flavor. An effervescent disintegrating agent is also present. To reduce oral dissolution time, tablets are produced using a low compression force direct compression approach. The tablets are made using traditional blenders and tablet presses. The resultant tablets are friable and soft.

2.2 INGREDIENTS TO BE USED FOR FDTS:

This covers the excipients as well as the active component, or medicine. In FDTS, excipients counteract the actives' characteristics. Excipients play a crucial part in the composition of tablets that melt quickly. For faster melting qualities, the excipients should ideally be at a temperature of between 30 and 350 C.

Super Disintegrants Used in MDTs:

As days passes, demand for faster disintegrating formulation is increased. So, A pharmacist must create super disintegrants, or disintegrants that are more effective intra granularly, dissolve at lower concentrations, and have higher disintegration efficiency. This super disintegrants act by swelling and due to swelling pressure exerted in the outer direction or radial direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration. Various types of Super disintegrants used are as follows–

- 1) Crosspovidone
- 2) Micro crystalline cellulose
- 3) Sodium starch glycollate
- 4) Sodium carboxy methyl cellulose /Cross carmelose sodium
- 5) Cross carmellose sodium
- 6) Calcium carboxy methyl cellulose
- 7) Modified corn starch
- 8) Kyron^[4]

Ingredients and Technologies Used for Formulating MDT:

Drugs	Ingredients used	Technologies used	Disintegration time(sec)
Rizatriptan benzoate	Primogel, Ac-di-sol, Kollidon, Avicel PH102, Orocell, Talc, Aerosil and Magnesium stearate, Aspartame and Sucralose.	Direct compression	85
Capecitabine	Crospovidone, HPMC, Mannitol, MCC.	Direct compression	50
Granisetron HCL	Cyclodextrin, CCS, Magnesium stearate, Lactose, Mannitol.	Direct compression	17.1
Amlodipine Besilate	Avicel PH 101 or 301, Mannitol, Eudragit EPO.	Direct compression followed by sublimation	15-37.8
Aceclofenac	SSG, Mannitol, MCC.	Direct compression technique	12.2-27.5
Modafinil	CCS, MCC, Lactose, Pre-gelatinized starch.	Wet granulation	-
Resperidone	Mannitol, Aspartame, PEG 400 & 4000, MCC (Ph200), Gelucire 44/14.	Spray drying and compression	Below30
Clarithromycin or Cefixime	Carrageenan NF, Tricalcium phosphate, Avicel PH105, LSHPC, Sucrose stearate.	Extrusion spheronization	Lessthan60
Famotidine	Mannitol, PVPK 30, Dextran, Sucralose, Sugar, Lactose.	Freeze drying	2.6
Epinephrine bitartrate	Avicel PH-301, Crospovidone, Mannitol, LSHPC (LH11), Magnesium stearate.	Direct Compression	Lessthan10
Diclofenac,	Mannitol, Sodium CMC,Citric	Molding, decompression	-
Acetyl salicylic Acid	Acid in ethanol, EC, Aspartame.		
ADH	CCS, Sodium bicarbonate, Lactose	Granulation	-
Ibuprofen Indomethacin Naproxen Diclofenac	Crospovidone, SSG, Mannitol, MCC, Xanthangum, Silica, Magnesium stearate, Nasaccharine, Talc.	Direct Compression	8-15
Ondansetron	SSG, Polacrillin potassium, MCC, Colloidal SiO ₂ , Aspartame, Talc.	Direct Compression	10-15sec
Fexofenadine	Mannitol, Crospovidone, Precipitated silica, Magnesium stearate, sucralose	Direct Compression	15-20sec

Ascorbic acid, Cimetidine	Erythritol, D mannitol, MCC, Corn starch, Pregelatinized starch.	Molding, direct Compression	31-37
Topiramate	Mannitol, CCS, Hydroxypropyl- β cyclodextrin PEG 3350, Mannose, SiO ₂ , Lactose	Wet Granulation	-
Sildenafil	Crosspovidone, Aspartame, Mannitol.	Freeze drying	< 30
Olanzapine 0Donepezil	MCC, Mannitol, Sodium stearyl fumarate, Polacrillin potassium, Aspartame, Strawberry flavor.	Direct compression	< 30
Chlorpromazine HCl	Sodium starch glycolate, Crosopovidone, Croscarmellose, LHPC, Pregelatinised starch.	Direct compressio	Lessthan 60

SELECTION OF FDT DRUG CANDIDATES:

Several factors must be considered when selecting drug candidates for delivery as MDT dosage forms.

- The medications whose pharmacokinetic characteristics alter noticeably when the same dose is given in a traditional dosage form. such as buspirone, apomorphine, selegiline, etc.
- foods and beverages that have a high absorption rate within the oral cavity and in the pre-gastric GIT, as well as those that produce a significant amount of harmful metabolites during first-pass liver and stomach metabolism.
- Drugs having ability to diffuse and partition into the epithelium of the upper GIT and those able to permeate oral mucosal tissue are considered ideal for FDT formulations.
- Individuals who use anticholinergic medicines simultaneously might not be the greatest candidates for these prescriptions.
- Individuals suffering from Sjögren's syndrome or experiencing dry mouth as a result of reduced salivary flow might not be suitable candidates for FDT formulations..
- Drugs with a short half-life and frequent dosing.
- FDT has been created by pharmaceutical companies for a range of medication classes, including anti-epileptics, analgesics, anti-allergic, antiepileptic, anxiolytics, sedatives, hypnotics, diuretics, anti-bacterials, neuroleptics, and medications for erectile dysfunction.[3]
- Drugs which require controlled or sustained release are unsuitable candidates of fast dissolving oral dosage forms.
- medications with extremely strong flavors or those whose flavors are not acceptable due to the inability to disguise flavors

3. Evaluation of Mouth Dissolving Tablets

Tablet Tensile Strength-

A tablet hardness tester is used to determine the tablet tensile strength, which is the force needed to shatter a tablet by compressing it in a radial direction. The hardness tester's plunger is pushed down at a rate of 20 mm/min in order to gauge the tablets' hardness. Equation 1 can be utilized to compute the tensile strength for crushing (T):

$$T = 2F / \pi dt$$

Where,

F= crushing load,

d= diameter

t= thickness of the tablet.

Though, this is a widely used and accepted method for hardness testing, it is not applicable to very delicate tablets prepared by lyophilization technique where in the liquid suspension of drug and excipients is freeze dried in the blister pocket and the dried tablets are finally sealed in the blister. Special aluminum (alu) blisters with peel off blister covers are used as packaging material for these tablets. Flash dose tablets prepared by cotton candy process are also poor candidates for this test. This test is best suited for tablets prepared by direct compression and molding methods. However, the tensile strength of these tablets is always kept low which needs to be compromised to keep the disintegration time as minimum as possible.

Friability:

When employing tablet friability equipment and rotating the tablet at 25 rpm for 4 minutes (100 rotations), the pharmacopoeial limit of the friability test is not more than 1%. To attain the shortest feasible disintegration time, a formulator must, however, preserve hardness at the lowest level while still achieving friability within this limit for MDT products. Again, lyophilized and flash dose tablets are exempt from this test; however, it is always advised for tablets made by direct compression and molding procedures to make sure they have sufficient mechanical strength to withstand abrasion during transportation and shelf life.

Moisture Uptake Study:

MDTs usually contain high concentration of hydrophilic excipients with the minimum possible hardness which together contribute to their increased susceptibility to moisture uptake. In order to maintain their physical integrity and surface texture, special attention is required during the storage and packaging of these dosage forms. Therefore, For MDTs, investigations on moisture absorption are highly advised.. Ten pills and calcium chloride can be tested by placing them in a desiccators that is kept at 37 °C for 24 hours to guarantee that the tablets are completely dry.. After that, the pills are weighed and kept at room temperature for two weeks while exposed to 75% RH. You can attain the necessary humidity by maintaining a saturated sodium chloride solution in the desiccators for a full day. The tablets are reweighed and the percentage increase in weight is recorded. If the moisture uptake tendency of a product is high, it requires special dehumidified area for manufacturing and packing. The materials with high moisture resistant properties should be used for packaging for e.g. alu strip pack, alu-alu blister or polyethylene sealing on blister. The use of appropriate quantity of desiccant in HDPE bottle packs with minimum head space is highly recommended to ensure stability of the product during its shelflife.

Measurement of Tablet Porosity:

The porosity of the tablets, which is a relative evaluation of the amount of water penetration in the formulation that causes their quick disintegration, may be measured with a mercury penetration porosimeter. This instrument is based on the capillary rise phenomenon wherein an excess pressure is required to cause a non-wetting liquid to climb up a narrow capillary. The pressure difference across the interface is given by the Washburn equation II, where the pressure drop is inversely related to the pore size (perpendicular radius).

$$\Delta P = - (2\gamma/r) \cos \theta$$

Where,

γ = is the surface tension of the liquid

r = is the perpendicular radius

θ = is the angle of contact between the liquid and the capillary walls.

Pore radius is calculated from eq II using experimental data obtained in the form of P. In this test, the contact angle between mercury and the tablet is kept at 140° and the surface tension at the interface of mercury and the tablet is 0.486 N/m. Pore sizes in the range of 0.06–360 μm , can be efficiently measured by this technique.

Wetting Time and Water Absorption Ratio:

A study on wetting time and water absorption ratio reported the use of a piece of double folded tissue paper placed in a Petri dish containing 6 ml of water. The time it took for a single pill to completely wet was recorded as the wetting time, and it was placed on this page. The wetted tablet was then weighed and the water absorption ratio, R, was determined according to equation.

$$R=100 (W_a-W_b)/W_b$$

Where,

W_b = the weights of tablet before water absorption

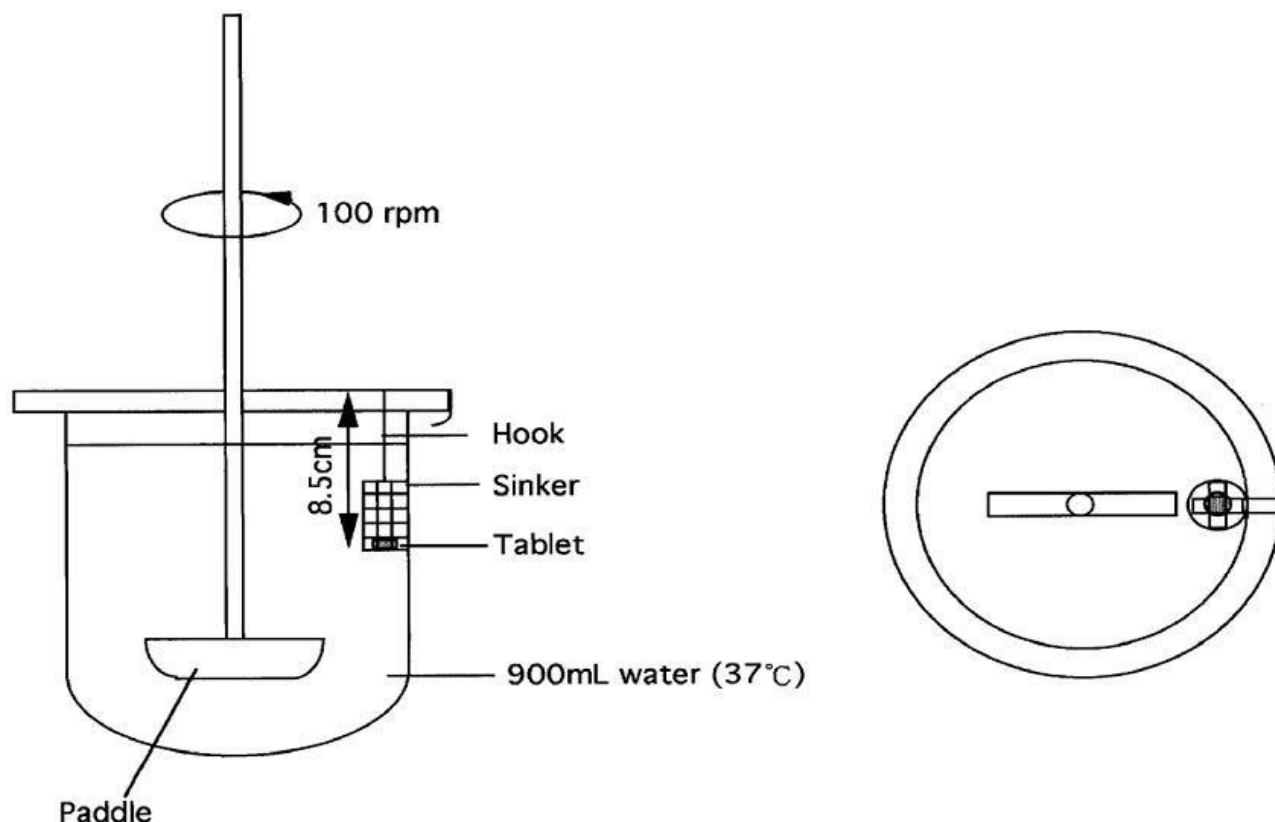
W_a = the weights of tablet after water absorption

Fineness of Dispersion:

For dispersible tablets, EP has established a qualitative test like this one. It is advised to do this test using fast oral disintegrating tablets (ODTs), rather than actual mouth dissolving tablets. It is an evaluation of the grit that results from the tablet breaking down into larger pieces. To conduct the test, submerge two tablets in 100 milliliters of water and mix gently until the pills dissolve completely. The formulation is stated to create a smooth dispersion if the whole dispersion passes through a sieve screen with a nominal mesh aperture of 710 μm and leaves no residue on the mesh.

Disintegration Time:

The literature provided an explanation of the techniques used to measure in-vivo disintegration time. However, because the disintegration time variation is usually only a few seconds, the findings of this kind of test usually show inadequate reproducibility and lack reliability. Furthermore, there are several ethical and volunteer safety concerns with the in-vivo disintegration test. Currently, the Pharmacopoeias-described disintegration test for traditional tablets is used to determine the disintegration time of MDTs. With traditional disintegration equipment, EP has set a maximum disintegration time of three minutes for MDTs. Nevertheless, the pharmacopoeias do not specify any specific equipment for the disintegration test of MDTs, and the currently used conventional method appears to be inadequate.



***Disintegration Test using Modified Dissolution Apparatus**

Dissolution Testing of Mouth Dissolving Tablets:

The conventional method of dissolution could be extended to in-vitro evaluation of MDT. The dissolution conditions for the reference listed drugs available in USP can be utilized for preliminary in-vitro studies to mimic better in-vivo conditions. In addition to the aforementioned, multimedia dissolving tests in different buffer solutions with varying pH values, such as pH 4.5 and 6.8 buffers and 0.1 N HCl, should be conducted to understand their in vivo performance and medicinal similarity. USP apparatus II (paddle) with a speed of 50 rpm seems to be most suitable and common choice with appropriate dissolution media volume to maintain sink condition. Typically, the dissolution of MDTs is very fast when using USP monograph conditions and therefore, under such conditions the dosage forms behave almost equally. Hence, slower paddle speeds may be employed to obtain a profile and better discrimination among various batches prepared during the developmental stage. In case of tablets getting close to or over 1 gm weight and containing relatively dense insoluble particles, there are the chances of heap formation at the bottom of the dissolution vessel. Under such a condition, although the tablet disintegrates completely, there is a significant reduction in the apparent dissolution rate. However, this issue can be resolved by using higher paddle speed of 75 rpm. The USP I (basket) apparatus may have application for certain MDTs which disintegrate into particles with floating tendency. However, tablet fragments or disintegrated tablet masses may become trapped on the inner top side of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles. In that case, a higher basket rotation speed of 100 rpm is recommended for quality assurance purpose while the formulation should be evaluated on the basis of a separate discriminatory disintegration test as listed above.^[6]

4. CONCLUSIONS

The acceptance of mouth dissolving tablets is rapidly increasing as it provides important advantages to the patients. The formulation techniques are very convenient as well as it requires a small amount of API to formulate it. As it disintegrates rapidly in the mouth, the absorption and bioavailability of those tablets rise rapidly. Hence it can improve the therapeutic effect in patients. MDTs can readily absorb through the buccal cavity or the mucosal membrane of the mouth. It is most suitable for children or elderly patients who have been suffering from swallowing problems. So, the future prospects of MDTs must be bright as patients demand increases.

5. ACKNOWLEDGEMENT

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