

“Mouth Dissolving Tablet: A Comprehensive Review On Formulation, Evaluation, And Advancements”

Dnyaneshwar s. Jadhav*, Dr. Sonia Singh, Prof. Pallavi Kaple, prof. shreeya Belwalkar

Department of Pharmaceutics, Alard college of pharmacy Hinjewadi Pune Maharashtra.

ABSTRACT :

Tablets and capsules are prone to dysphagia, leading to non-compliance and inefficient therapy. To avoid difficulties associated with conventional Mouth dissolving tablets are the preferred dosage form for paediatrics, geriatrics, and traveling patients due to its hardness, consistent dose, and ease of administration. The MDTs were designed to have high hardness, integrity, and rapid disintegration without water. Fast dissolving Tablets dissolve easily in saliva, eliminating the need for water. Fast-dissolving pills dissolve quickly in saliva, taking only a few seconds. Fast-disintegrating tablets contain chemicals that speed up tablet disintegration in the oral cavity, taking up to a minute to fully dissolve. This tablet type allows for oral delivery of a substantial dose without the need for water. Tablets dissolve quickly in saliva, typically within 60 seconds.

Keywords: Mouth dissolving tablet, Disintegration, Patented technologies, Marketed MDTs

Introduction:

The oral route remains the preferred method for administering therapeutic agents due to its accuracy, low cost, self-medication, non-invasive nature, and ease of administration, resulting in high patient compliance¹. Traditional tablets and capsules may be inconvenient for some geriatric patients due to physiological and neurological changes associated with aging, such as difficulty swallowing/dysphagia, hand tremors, deterioration in vision, hearing, memory, risk of choking, and changes in taste and smell. Solid dose forms can be difficult to administer to certain patient populations, including youngsters, the mentally impaired, bedridden individuals, and those who are recalcitrant. The FDA defines FDT formulation as "a solid dosage form containing medicinal substances that disintegrates rapidly, usually within seconds, when placed on the tongue."advancements in technology have resulted in development of viable dosage alternatives popularly known as orally disintegrating tablets (ODTs)¹⁻².During the past decade, the FDT (fast dissolving tablet) technology, which makes tablets dissolve or disintegrate in the mouth without additional water intake, has drawn a great deal of attention. The technology is also referred to as fast disintegrating tablet, fast dispersing tablet, rapid dissolve tablet, rapidmelt tablet, quick disintegrating tablet, and orally disintegrating tablet. The FDT formulation is defined by the Food and Drug Administration (FDA) as “a solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue”. The tablets disintegrate into smaller granules or melt in the mouth from a hard solid structure to a gel like structure, allowing easy swallowing by the patients. The duration for these tablets ranges from a few seconds to almost a minute²⁻

³. FDTs require specific features due to their quick disintegration, which differs from traditional tablet administration. They should dissolve or disintegrate in the mouth, preferably without or with minimal water, as the disintegration fluid is the patient's saliva. Disintegrating the pill into a soft paste or liquid suspension allows for easy swallowing and a pleasant mouthfeel. "Fast dissolution" or "fast disintegration" refers to the disintegration of a tablet within a minute²⁻³.

The significance of ODTs ⁴⁻⁵

ODTs provide advantages of both solid and liquid dose forms, with unique features such as:

- Unit solid dosage forms offer correct dosing, mobility, and chemical stability, making them appropriate for pediatric and geriatric patients.
- Enhanced bioavailability: Drugs absorb better through the mouth, pharynx, and esophagus.
- Rapid action: Tablets breakdown quickly, allowing for immediate absorption in the oral cavity.
- Patient compliance: No need for water when swallowing the dosage form. This is especially useful for those traveling without immediate access to water.
- Convenient administration: Ideal for elderly, pediatric, mentally impaired, and bedridden patients with swallowing difficulties.
- Obstruction-free swallowing eliminates the risk of suffocating in the airways, improving safety and compliance.
- Improved palatability for pediatric patients by concealing the bitter taste of the medicine.
- Simple packing: No specific packaging needed. It can be packaged in push-through blisters.
- Business Avenue: Create new business opportunities through product diversification, line extension, uniqueness, and lifecycle management.
- Cost-effective: Conventional processing and packaging equipment allows for low-cost tablet manufacture.

Ideal Properties of MDTs: ⁴

They should melt or disintegrate in the mouth in seconds, requiring no water to swallow.

Be compatible with flavor masking.

Be portable without fragility concerns.

Maintain a pleasant mouth feel.

Leave minimal or no residue in the mouth following oral administration.

Have little sensitivity to external conditions like temperature and humidity.

Use low-cost conventional processing and packaging equipment for tablet manufacturing.

Challenges in Formulating Fast Dissolving Tablets: ⁵⁻¹⁹

Palatability

FDTs are commonly used to conceal the taste of undesirable medications. After administration, the product dissolves in the patient's oral cavity, releasing active chemicals that interact with taste buds. Hence, taste-masking of medications becomes crucial for patient compliance.

Mechanical Strength

To disintegrate in the oral cavity, FDTs are made of porous and soft-molded matrices or compressed into tablets with low compression force. This makes the tablets friable and/or brittle, difficult to handle, and often requires specialized peel-off blister packing, which can be costly. Only Wow tab and Durasolv technologies can create tablets with sufficient hardness and durability to allow.

Hygroscopicity

Orally disintegrating dose forms are prone to hygroscopicity, causing them to lose physical integrity under typical temperature and humidity levels. Humidity protection requires appropriate product packaging.

The amount of drug

The deployment of FDT technology is limited by the amount of medicine that may be included in each unit dose. For lyophilized dosage forms, the drug dose should be less than 400 mg for insoluble medications and 60 mg for soluble pharmaceuticals. Formulating fast-dissolving oral films or wafers presents a significant challenge in this parameter.

Aqueous solubility.

Water-soluble pharmaceuticals create eutectic mixtures, resulting in freezing-point depression and a glassy solid that may collapse upon drying due to loss of supporting structure during sublimation. This poses formulation issues. Matrix-forming excipients like mannitol can avoid collapse by causing crystallinity and stiffness in amorphous composite materials.

Size of the tablet

The size of a pill determines how easily it may be administered. tablets smaller than 8 mm are easier to swallow, whereas larger ones are easier to handle. Creating a tablet size that is both portable and user-friendly is challenging.

Formulation of MDTs : ⁵⁻⁸

Drug:

The ideal qualities of a medicine for oral dissolving and pre-gastric absorption from MDTs are:

- No bitter taste
- Low dose (less than 20 mg)
- Small to medium molecular weight

Soluble in saliva and permeable to oral mucosal tissue.

Bulking materials:

Bulking components play an important role in fast-melting tablet formulations. The material serves as a diluent, filler, and cost reducer. Bulking agents improve textural properties and enhance disintegration in the mouth. Additionally, they diminish the concentration of active ingredients in the composition. For this delivery technique, sugar-based bulking agents such mannitol, polydextrose, lactitol, DCL (direct compressible lactose), and starch hydrolysate are advised for increased effectiveness.

Emulsifying agents :

Emulsifying agents are essential excipients in fast-melting tablets, facilitating rapid breakdown and drug release without chewing, swallowing, or drinking water. Adding emulsifying agents can stabilize immiscible mixes and improve bioavailability. Fast-tablet formulation requires a variety of emulsifiers, such as alkyl sulfates, propylene glycol esters, lecithin, and sucrose esters. These compounds can be added to the final composition at a concentration ranging from 0.05 to 15% by weight.

Lubricants :

Lubricants are optional excipients that can improve tablet palatability following disintegration in the mouth. Lubricants reduce grittiness and help transfer drugs from the mouth to the stomach.

Flavors and sweeteners : make items more appealing to patients by disguising unpleasant tastes. These substances help mitigate the bitterness and unpleasant taste of some active compounds.

Superdisintegrants are excipients added to tablets or capsules to break apart compacted material when exposed to fluids.

Name of disintegrant	Brand name	Concentration (%)	Mechanism of action
Sodium Starch Glycolate	Explotab, Primogel	2-8%	Swelling
Micro crystalline cellulose	Avicel, Celex	2-15%	Water wicking
Cross linked povidone	Cross povidone	2-5%	Swelling, Water wicking
Low substituted hydroxy propyl cellulose	LH-11, LH-12 (Grades)	1-5%	Sweling
Crosscarmellose sodium	Ac-Di-Sol	1-3%Direct compression 2-4% wet granulation	Wicking and swelling
Pregelatinized starch	Starch 1500	1-20%	Swelling

Table1 : Enlists various existing super-disintegrants and also their mechanism of action

Selecting super disintegrants

When selecting superdisintegrants, keep in mind that they can impact mouth feel, tablet hardness, and friability, in addition to affecting disintegration rate. To pick suitable super disintegrants for a specific formulation, consider the following desirable factors:

- Tablets disintegrate quickly when exposed to saliva in the oral cavity.
- Be small enough to yield fewer friable tablets.
- Provide patients with a good mouth feel. Smaller particle sizes are desirable for patient compliance.
- Good flow increases overall blend characteristics.

Freeze-drying or Lyophilization ⁸⁻¹⁰

The freeze-drying procedure removes water from the product after freezing. Zydis technology (ZT) is a patented approach that has been used for pharmaceuticals such as famotidine, loperamide, piroxicam, oxazepam, lorazepam, domperidone, brompheniramine, olanzapine, ondansetron, and rizatriptan. This method has resulted in the production of 13 marketable items. MDT products available in the US include Claritin Reditab, Dimetapp Quick Dissolve, Feldene Melt, Maxalt-MLT, Pepcid RPD, Zofran ODT, and Zyprexa Zydis. Zydis formulations are available globally for oxazepam, lorazepam, loperamide, and enalapril. ZT uses a unique freeze-drying technique to provide completed dose units that differ from traditional oral systems.

The process involves the following steps:

Stage 1 involves preparing an aqueous medication solution or suspension and dosing it precisely into pre-formed blisters. The blister is an important part of the product package since it shapes the tablet.

In Stage 2, the filled blisters undergo a cryogenic freezing process to control the size of the ice crystals. This creates a porous matrix that allows for quick disintegration of the tablets. The frozen units are transferred to massive freeze dryers for sublimation, which removes the majority of moisture from the tablets.

Stage 3 involves sealing open blisters with a heat-seal method to protect the product from environmental factors.

Lyoc

Lyoc technology freeze-drys an aqueous solution, suspension, or emulsion containing an API and excipients. Lyoc's high porosity leads to faster disintegration than compacted tablets. The Lyoc manufacturing process yields a stable product without the use of additives, preservatives, or gelatin. This procedure is ecologically benign and cost-effective as it does not use organic solvents. Lyoc technology supports CIMA flavor masking, customizable release, high dosage, and fixed-dose combo solutions.

Quicksolv⁹⁻¹⁰

is a porous solid form created by freezing an aqueous dispersion/solution of the drug matrix and drying it with sufficient alcohol to remove the water (solvent extraction).

Advantages

This process produces tablets with fast melting and low disintegration time, providing a pleasant mouthfeel.

Disadvantages

Lyophilization is a common technique, however it can be costly and time-consuming. Furthermore, the product obtained is unstable and brittle, making standard packing ineffective.

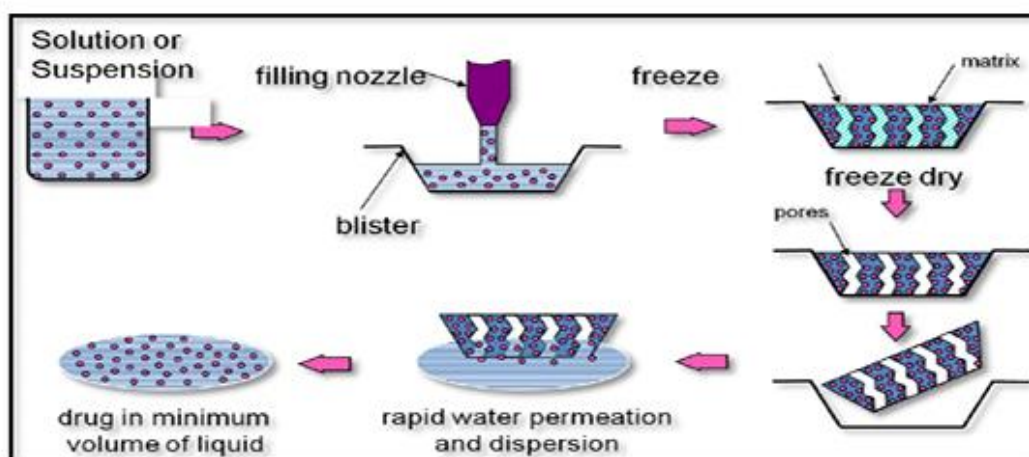


Fig1. Lyophilization Technology. Patented technology based on this process is Zydis technology

Tablet Moulding⁹⁻¹¹

Moulded tablets include water-soluble components that dissolve quickly and fully. Here are the many tablet moulding techniques:

Compression Moulding Process

The production technique comprises moistening the powder blend with a hydroalcoholic solvent and pressing it into mould plates to create a wetted mass (compression moulding). The solvent is removed through air drying, which is analogous to the production of tablet triturates. These tablets are less compact than compressed tablets and have a porous structure that accelerates dissolving.

Heat-Moulding Process

Heat-moulding involves establishing a molten mass with a distributed medicament. This procedure involves using agar solution as a binder, blister packaging, and a mould to create tablets. To make the

blister packaging, mix a suspension of medication, agar, and sugar. Pour the suspension into the blister, harden the agar solution at room temperature, and dry at 30°C under vacuum.

Molding using lyophilization Vacuum Evaporation

The process involves pouring a slurry or paste of the drug excipient into a desired mould, freezing it to form a solidified matrix, and vacuum drying it at a temperature between its collapse and equilibrium freezing temperatures. This produces a partially collapsed matrix. Unlike lyophilization, this approach involves evaporating free unbound solvent from a solid via the liquid phase to a gas under controlled conditions, rather than sublimation.

Direct Compression (DC)^{9–11}

DC is the most cost-effective tablet manufacturing technique for MDTs due to its ease of use with conventional machinery and the availability of excipients with improved flow, compressibility, and disintegration properties, including effervescent agents and sugar-based excipients.

Sr.No	Ideal requirements	Advantages	Limitations
1	Flowability	Cost effective production	Segregation
2	Compressibility	Better stability of API	Variation in functionality
3	Dilution Potential	Faster dissolution	Low dilution potential
4	Reworkability	Less wear and tear of punches	Reworkability
5	Stability	Simple validation	Poor compressibility of API
6	Controlled Particle Size	Low microbial contamination	Lubricant sensitivity

Table 2: Ideal Requirements, Advantages and Limitations of Direct Compression

Disintegrants

Disintegrants play a significant role in the rate of disintegration and dissolution in MDT products based on the DC method. The introduction of water-soluble excipients and effervescent agents further enhances this effect. The use of superdisintegrants has boosted the appeal of this technology. Tablet Optimizing disintegration time involves focusing on disintegrant concentrations. Tablet disintegration time decreases as disintegrant concentration decreases below a certain level. Above the critical concentration of disintegrant, disintegration time remains constant or decreases insignificantly. Flashtab is a DC-based technique that uses coated medication crystals, microgranules, and disintegrants. This method utilizes two forms of disintegrants: a high-swelling agent (e.g., modified cellulose) and a low-swelling agent (e.g., starch). Bi et al. and Watanbe produced MDTs using microcrystalline cellulose (MCC) and low substituted hydroxypropyl cellulose (HPC) at varying ratios (8:2 to 9:1)

Effervescent agents

The patented Orasolv technology (OT) is based on the disintegration process of CO₂, which is commonly employed in developing over-the-counter medicines. The product includes microparticles and is mildly effervescent. Saliva activates the effervescent ingredient, causing the tablet to dissolve. The OT was used to produce six commercialized medications, including four Triaminic Softchew formulations, Tempra FirsTabs, and Remeron Sol Tab.

Sugar-Based Excipients

To make MDTs by DC, sugar-based excipients such as dextrose, fructose, and isomalt can be used. Lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol have excellent water solubility and sweetness, providing taste masking and a pleasant mouthfeel. Mizumoto et al. differentiated sugar-based excipients into two categories based on their moldability and dissolving rate.

Type I saccharides, such as lactose and mannitol, have limited moldability but rapid dissolving rates.

Type II saccharides, such as maltose and maltitol, have high mouldability but low dissolving rate.

Mouldability refers to a compound's ability to compress and disintegrate. This does not refer to creating a mold through melting or solvent-wetting. Granulating Type I saccharide with a Type II saccharide solution improves its mouldability. WOWTAB technology uses fluidized bed granulation to surface-treat Type I and Type II saccharides. This process was used to produce Benadryl Fast melt pills. A tablet formulation with acceptable hardness and quick dissolution rate is created by combining two types of saccharides.

Cotton Candy Process^{3, 11, 12}

The FLASHDOSE® MDDDS uses Shearform™ technology and Ceform TITM technology to reduce the bitter taste of the medication. Shearform technology is used to create "floss," a matrix composed of excipients or pharmaceuticals. Floss, similar to cotton candy fibers, is formed of sucrose, dextrose, lactose, and fructose at temperatures ranging from 180-266 °F. Other polysaccharides, such as polymaltodextrins and polydextrose, can produce fibers at temperatures 30-40% lower than sucrose. This alteration allows for safe integration of thermolabile medicines into the formulation.

Spray-Drying^{3,12}

Allen et al. employed spray-drying to produce MDTs. The formulations used hydrolyzed and unhydrolyzed gelatin to support the matrix, mannitol for bulking, and sodium starch glycolate/croscarmellose as a disintegrant. Adding citric acid or sodium bicarbonate improved disintegration and dissolving. The suspension of excipients was spray-dried to create a porous powder that was compacted into tablets. This method produced tablets that decomposed in less than 20 seconds in aqueous media.

Steps involved in Spray Drying Technology

1. Preparation of aqueous composition of support matrix + bulking agent + volatilizing agent + disintegrants + Buffering agent
2. Aqueous composition introduced as droplets in a spray dryer
3. Heated to predetermined temperature causing evaporation of substantially all of aqueous medium and volatilizing agent from droplets
4. Dried particulate support matrix
5. Addition of active ingredient & other tablets excipients
6. Compressed into tablets
7. Rapidly dissolving tablets

Sublimation^{13,19}

Sublimation has been utilized to create MDTs with high porosity. To create a porous matrix, volatile chemicals and excipients are compressed into tablets, then sublimated. High-volatile solid substances such as ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylene tetramine, naphthalene, phthalic anhydride, urea, and urethane have been employed for this purpose.

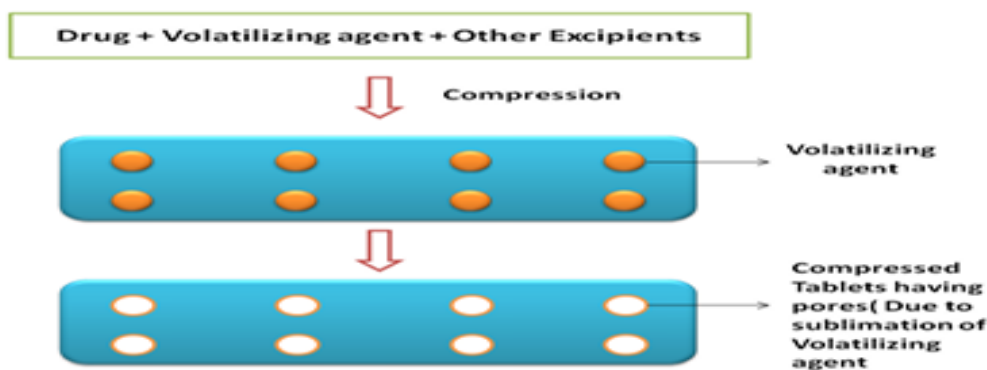


Figure2 : Sublimation technique. Evaporation of volatile agent results in formation of porous tablets thereby causing fast disintegration

Mass-Extrusion¹⁷

This approach softens the active blend with water-soluble polyethylene using an extruder or syringe. The resulting cylindrical extrude is then cut into even segments using a hot blade, forming tablets. This procedure can help hide the flavor of bitter medication granules.

Nanonization¹⁷

Nanomelt technology reduces medication particles to nanosize through patented wet-milling techniques. The drug nanocrystals are stabilized against agglomeration through surface adsorption with stabilizers, which are then integrated into MDTs. This approach is especially beneficial for medications with low water solubility. This technology offers several benefits, including faster disintegration of nanoparticles, increased absorption and bioavailability, cost-effective manufacturing, durable packaging, and a wide range of doses (up to 200 mg per unit).

Fast Dissolving Films¹⁹

This innovative approach to MDDDS offers a more convenient way to take prescriptions and supplements. This technique involves creating a non-aqueous solution with a water-soluble film-forming polymer (e.g., pullulan, carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxyl ethylcellulose, hydroxyl propyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol, sodium alginate), drug, and taste masking ingredients. The solution is then evaporated to form a film. To treat bitter drugs, resin adsorbate or coated microparticles might be added to the film. When placed in the mouth, this film quickly dissolves and releases the medicine as a solution or suspension. This technique offers paper thin films (less than 2X2 inches) that dissolve in 5 minutes.

EVALUATION PARAMETERS:^{13,14,15,20,21}

Weight variation test: Randomly selected 20 tablets were taken and their individual weights & the average weight of 20 tablets were determined. The deviation of each individual tablet from the average weight was calculated and compared with the standard values given in Pharmacopoeia.

The % weight variation of each individual tablet from the average weight is calculated by the given formula

% *WeightVariation* =

$$\frac{\text{Individual weight of each tablet} - \text{Average weight of 20 tablets}}{\text{Average weight of 20 tablets}} \times 100$$

Hardness test:

Hardness of the tablets was measured by using hardness testers like Monsanto hardness tester, Pfizer hardness tester etc. The pressure required to break the tablets is measured as a function of hardness (kg/cm²). The values obtained must meet the standard value.

Friability:

Friability is to measure the extent of tablet breakage during physical stress conditions like Packing, transportation etc. A sample of randomly selected 6 tablets was evaluated for friability using Roche friabilator at 25 rpm for 4 minutes. The % weight loss is calculated by measuring the total weight of 6 tablets before and after operation. Formula for calculating the % weight loss is given below

$$\% \text{ Weight loss} = \frac{\text{Total weight of tablet before} - \text{Total weight of tablets after}}{\text{Total weight of tablets}} \times 100$$

Wetting Time:

Significant characteristics for mouth dissolving tablets are wetting time and water absorption ratio. To calculate tablet wetting time, use the following procedure. A circularly cut piece of filter paper was placed in a tiny petri dish filled with a water-soluble dye solution. The tablet was placed on paper to determine the time required for complete wettability Bi Y. et al. utilized a tissue paper folded twice and placed in a

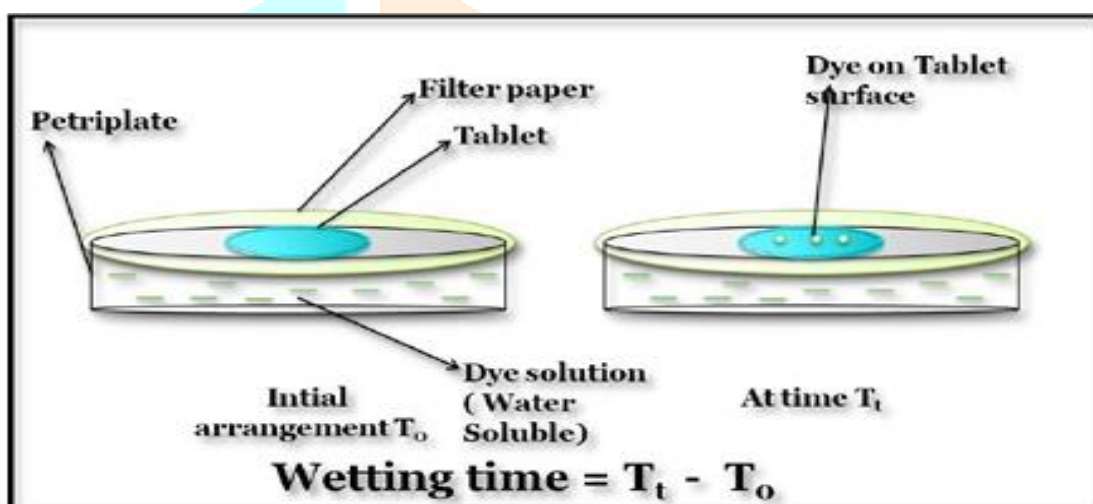


Figure: Wetting time of Mouth dissolving tablet.

Water absorption ratio:

Similar to the procedure followed in determination of wetting time However, here the initial weight and the final weight (after complete wetting) of tablet were calculated and the water absorption ratio was calculated by given formula:

$$= \frac{W_a - W_b}{W_b} \times 100$$

Where,

R is water absorption ratio,

W_a and W_b are weight of the tablet before and after wetting respectively

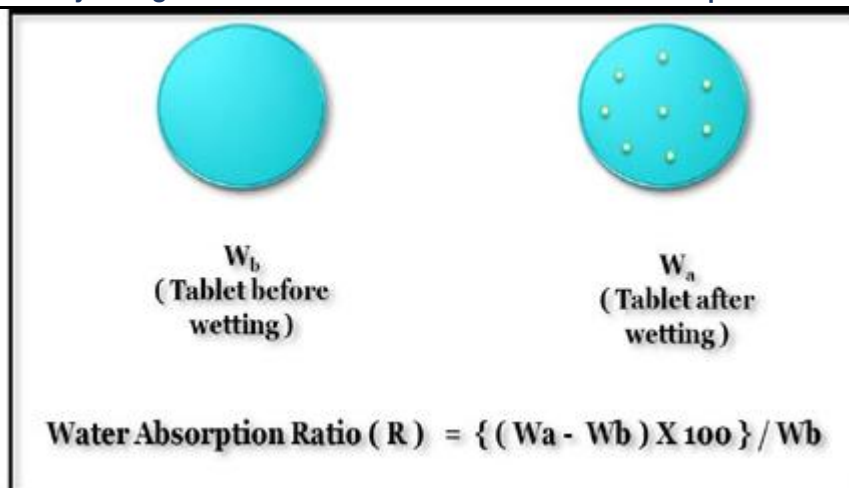


Figure : Calculation of water absorption ratio for MDTs.

Difference between initial and final weights of tablet

is noted Water absorption

Disintegration time:

Disintegration time for randomly selected 6 tablets was measured using disintegration test apparatus. The average time required for disintegration was calculated and compared with standards

Invitro dissolution studies:

Randomly selected 6 tablets Drug release tests were conducted utilizing a USP dissolving device, 900 ml of dissolution medium, and a temperature of $37 \pm 0.5^\circ\text{C}$. 5 ml of sample was collected every 5 minutes for 30 minutes and replaced with 5 ml of new buffer solution. The samples were filtered and diluted before being analyzed with a UV spectrophotometer or HPLC instrument. The results were compared to standard values.

Taste or mouth feel Healthy human participants evaluated the tablet's taste and mouthfeel. One pill was examined for its mouthfeel. A panel of 5 people evaluated mouth feel using the time intensity approach. A sample of 40 mg was held in the mouth for ten minutes.

Stability studies:

Various stability studies like accelerated stability study, intermediate and long term stability studies were done during preformulation. The sample was subjected to higher temperature or humidity or both, to know their impact on the stability of mouth dissolving tablet.

Uniformity of dispersion:

Two randomly selected tablets were kept in 100 ml water and stirred for two minutes. The dispersion was passed through 22 meshes. The tablets were considered to pass the test if no residue remains on the screen.

Drugs to be promising in corporate in Mouth dissolving tablets 16,17,18,19 There are no particular limitations as long as it is a substance which is used as a pharmaceutical active ingredient.

Analgesics and Anti-inflammatory Agents:

Aloxiprin, Auranofin, Azapropazone, Diflunisal, Etodolac, Fenbufen, Fenoprofen Calcim, Flurbiprofen, Ibuprofen, Benorylate, Indomethacin, Ketoprofen, Meclofenamic Acid, Mefenamic Acid, Nabumetone, Naproxen, Oxaprozin, Oxyphenbutazone, Phenylbutazone, Piroxicam, Sulindac.

Anthelmintics :

Albendazole, Bephenium Hydroxynaphthoate, Cambendazole, Dichlorophen, Ivermectin, Mebendazole, Oxarnniquine, Oxfendazole, Oxantel Embonate, Praziquantel, Pyrantel Embonate, Thiabendazole.

Anti-Arrhythmic Agents:

Amiodarone, Disopyramide, Flecainide Acetate, Quinidine Sulphate,

Anti-bacterial Agents:

Benethamine Penicillin, Cinoxacin, Ciprofloxacin, Clarithromycin, Clofazimine, Cloxacillin, Demeclocycline, Doxycycline, Erythromycin, Ethionamide, Imipenem, Nalidixic Acid, Nitrofurantoin, Rifampicin, Spiramycin, Sulphabenzamide, Sulphadoxine, Sulphamerazine, Sulphacetamide, Sulphadiazine, Sulphafurazole, Sulphamethoxazole, Tetracycline, Trimethoprim.

Anti-Fungal Agents:

Sulphapyridine, Amphotericin, Butoconazole Nitrate, Clotrimazole, Econazole Nitrate, Fluconazole, Flucytosine, Griseofulvin, Itraconazole, Ketoconazole, Miconazole, Natamycin, Nystatin, Sulconazole Nitrate, Terbinafine, Terconazole, Tioconazole, Undecenoic Acid.

Anti-Gout Agents:

Allopurinol, Probenecid, Sulphinpyrazone.

Anti-Hypertensive Agents:

Amlodipine, Carvedilol, Benidipine, Darodipine, Dilitazem, Diazoxide, Felodipine, Guanabenz Acetate, Indoramin, Isradipine, Minoxidil, Nicardipine, Nifedipine, Nimodipine, Phenoxybenzamine, Prazosin, Reserpine, Terazosin.

Anti-Malarials:

Amodiaquine, Chloroquine, Chlorproguanil, Halofantrine, Mefloquine, Proguanil, Pyrimethamine, Quinine Sulphate. Anti-Migraine Agents: Dihydroergotamine Mesylate, Ergotamine Tartrate, Methysergide Maleate, Pizotifen Maleate, Sumatriptan Succinate.

Anti-Neoplastic Agents and Immunosuppressants:

Aminoglutethimide, Amsacrine, Azathioprine, Busulphan, Chlorambucil, Cyclosporin, Dacarbazine, Estramustine, Etoposide, Lomustine, Melphalan, Mercaptopurine, Methotrexate, Mitomycin, Mitotane, Mitozantrone, Procarbazine, Tamoxifen Citrate, Testolactone.

Anti-Thyroid Agents:

Carbimazole, Propylthiouracil.

Nutritional Agents:

Betacarotene, Vitamin A, Vitamin B 2, Vitamin D, Vitamin E, Vitamin K. Opioid Analgesics: Codeine, Dextropropoxyphene, Dihydrocodeine, Meptazinol, Methadone, Morphine, Nalbuphine, Pentazocine.

Oral Vaccines:

Diamorphine, Vaccines designed to prevent or reduce the symptoms of diseases of which the following is a Representative Influenza, Tuberculosis, Meningitis, Hepatitis, Whooping Cough, Polio, Tetanus, Diphtheria, Malaria, Cholera, Herpes, Typhoid, HIV, Aids, Measles, Lyme Disease, Travellers Diarrhea, Hepatitis A, B And C, Otitis Media, Dengue Fever, Rabies, Parainfluenza, Rubella, Yellow Fever, Dysentery, Legionnaires Disease, Toxoplasmosis, Q-Fever, Haemorrhagic Fever, Argentina Haemorrhagic Fever, Caries, Chagas Disease, Urinary Tract Infection Caused By E.Coli, Pneumococcal Disease, Mumps, File://H:\Gits Mdt\Fast Dissolving Tablet The Future Of Compaction And Chikungunya.

Proteins, Peptides and Recombinant Drugs:

Insulin (Hexameric/Dimeric/Monomeric Glucagon, Growth Hormone (Somatotropin), Polypeptides or Their Derivatives, (Preferably With A Molecular Weight from 1000 To 300,000), Calcitonins And Synthetic Modifications Forms), Thereof, Enkephalins, Interferons (Especially Alpha-2 Inter Feron For Treatment Of Common Colds).

Sex Hormones:

Clomiphene Citrate, Danazol, Ethinyloestradiol, Medroxyprogesterone Acetate, Mestranol, Methyltestosterone, Norethisterone, Norgestrel, Oestradiol, Conjugated Oestrogens, Progesterone, Stibioestrol, Testosterone, Tibolone.

CONCLUSION:

For over a decade, manufacturers have focused on FDTs due to their potential advantages over traditional dose forms, including enhanced patient compliance, convenience, bioavailability, and rapid beginning of action. FDT formulations derived from some of these technologies Have enough strength. Mechanical disintegration or dissolving in the mouth without water. New oral products with increased features are expected to emerge quickly in this market area. Swallowing difficulties affect one-third of the population, particularly the elderly and children. This leads to poor compliance with oral tablet drug therapy, resulting in diminished therapy effectiveness. These tablets dissolve or disintegrate quickly in saliva, typically within 5-50 seconds. Developing a fast-dissolving tablet opens up the possibility of expanding the product range in the market. This dose form is suitable for a variety of pharmaceuticals, including neuroleptics, cardiovascular treatments, analgesics, antihistamines, and erectile dysfunction medications. Pharmaceutical producers often develop new and improved dosage forms for drugs nearing the end of their patent life. A novel dosage form extends a manufacturer's market exclusivity and provides a more convenient dosing schedule for patients.

REFERENCES

1. Kaur et al., Mouth dissolving tablets: A novel approach to drug delivery, International Journal of Current Pharmaceutical Research, 2011; 3:1-7.
2. Seong Hoon Jeong, Kinam Park., Material properties for making fast dissolving tablets by a compression method. Journal of Materials Chemistry; 2008; 18: 3527–3535.
3. McLaughlin Rosie, Banbury Susan, Crowley Kieran., Orally Disintegrating Tablets The Effect of Recent FDA Guidance on ODT Technologies and Applications, Pharmaceutical Technology: Sep. (2009)
4. D. Shukla et al., Mouth Dissolving Tablets I: An Overview of Formulation Technology, Scientia Pharmaceutica. 2009; 76; 309-326.
5. Hirani et al., Orally Disintegrating Tablets: A Review, Tropical Journal of Pharmaceutical Research, April 2009; 8 (2): 163
6. Rish RK et al., A review on fast dissolving tablets techniques. The Pharma Review 2004; 2: 32.
7. Kuchekar BS, Atul, Badhan C, Mahajan HS., Mouth dissolving tablets: A novel drug delivery system., PharmaTimes 2003; 35: 7-9.
8. Bhaskaran S, Narmada GV. Rapid dissolving tablets a novel dosage form. Indian Pharmacist 2002; 1: 9–12.
9. H. Seager., Drug-delivery Products and the Zydis Fast-dissolving Dosage Form., J. Pharm. Pharmacol. 1998; 50: 375-382.
10. Vummaneni. V et. al., Mouth Dissolving Tablets: A Review, American Journal of Pharmatech Research; 2012; 2(3).
11. D Bhowmik et al., Fast Dissolving Tablet: An Overview, Journal of Chemical and Pharmaceutical Research, 2009; 1(1): 163-177

12. Bhupendra G Prajapati et al., A Review on Recent patents on Fast Dissolving Drug Delivery System, International Journal of PharmTech Research.2009,1(3)
13. Jagani et.al.,Fast Dissolving Tablets: Present and Future Prospectus., Journal of Advances in Pharmacy and Healthcare Research.,2011; 2(1):57-70.
14. Gupta Kumar Alok, Mittal Anuj and Prof.Jha.K.K.,Fast Dissolving Tablet- A Review., The Pharma Innovation., 2012; 1(1):1-8.
15. V.Dinesh kumar et al., A comprehensive review on fast dissolving tablet technology., Journal of Applied Pharmaceutical Science 01 (05); 2011: 50-58
16. D Bhowmik et al., Fast dissolving tablet: A review on revolution of novel drug delivery system and new market opportunities, Scholars Research Library; 2009, 1 (2) 262-276
17. Sharma.S.et al., Pharmainfo.net, 2008; 6(5). Available at: <http://www.pharmainfo.net/reviews>.
- 18) Rakesh Pahwa et al., Orally Disintegrating Tablets - Friendly to Pediatrics and Geriatrics, Archives of Applied Science Research, 2 (2): 35-48.
18. Abdul Sayeed et al., Mouth dissolving tablets: An Overview., International Journal of Research in Pharmaceutical and Biomedical Sciences, 2011; 2(3): 959-970.
19. Debjit Bhowmik et al., Fast dissolving tablet: A review on revolution of novel drug delivery system and new market opportunities, Der Pharmacia Lettre, 2009; 1 (2) 262-276.
20. Deepak et al.,Fast disintegrating tablets: A new era in novel drug delivery system and new market opportunities., Journal of Drug Delivery & Therapeutics 2012; 2(3): 74-86 Modasiya MK, Lala LL, Prajapati BG, Patel VM,Shah DA, Design and characterization of Fast Dissolving Tablets of Piroxicam, Indian J. Pharm.Tech. Res.,2009; 1 (2): 353.
2. Sahoo S, Mishra B, Biswal PK, Panda Omprakash, Mahapatra K Santosh, Jana K Goutam, Fast Dissolving Tablet: As A Potential Drug Delivery System, Drug Inv. Today, 2010; 2 (2).
22. Kaur et al., Mouth dissolving tablets: A novel approach to drug delivery, International Journal of Current Pharmaceutical Research, 20011; 3:1-7.
23. Nayak U.K., Patra S.K., Rout P.K., Patro B.K. and Nayak B.S., (2008)., Development and optimization of promethazine theoclate Mouth dissolving tablets; The Indian pharmacist., 65- 68.
24. Prajapati G.B., Patel S.B., (2010)., Formulation,Evaluation and Optimization of Orally Disintegrating Tablet of Piroxicam; International Journal Research., 1893-1899. of PharmTech
25. Mohan A. and Ghosh S.K., (2010)., Fast Dissolving Tablets: Past, Present and Future; Indian drug 47(6).,5-11.
26. Mishra D.N., Bindal M., Singh S.K and Kumar S.G.V: Rapidly disintegrating oral tablets of meloxicam. Indian Drugs. 2005, 42 (10), 685 687.
27. Kumari S., Visht S., Sharma P.K., Yadav R.K., (2010)., Fast dissolving Drug delivery system : Review Article;Journal of Pharmacy Research 3(6).,1444-1449.
28. C. Kumaresan., (2008)., Orally Disintegrating Tablet -Mouth dissolving, Sweet Taste, And Target Release Profile; Pharmaceutical review Vol-6.
29. Solanki A.B., Parikh J.R., Parikh R.H., (2007).,Formulation and Optimization of Piroxicam Proniosomes by 3-Factor, 3-Level Box-Behnken Design; AAPS PharmSciTech. 8(4).
30. Bhupendra G Prajapatiet al., A Review on Recent patents on Fast Dissolving Drug Delivery System, Int. J. Pharm. Tech. Res.,2009;1(3):790-798.
31. Patel S.S., Pate M.S., Patel N.M., (2009)., Flowability testing of directly compressible excipients accordind to british pharmacopoeia; Journal of Pharmaceutical Research Vol. 8. 66 -69.
32. D. Bhowmik et al., (2009)., Fast Dissolving Tablet: An Overview; Journal of Chemical and Pharmaceutical Research.,163-177.
33. Deepak et al.,Fast disintegrating tablets: A new era in novel drug delivery system and new market opportunities., Journal of Drug Delivery & Therapeutics 2012; 2(3): 74-86.
34. Shaikh S et al., (2010)., Formulation and evaluation of orodispersible tablets of piroxicam.,IJPI's Journal of Pharmaceutics and Cosmetology., 2-8.
35. Panigrahi R., Behera S.,(2010)., A Review On Fast Dissolving Tablets., WebmedCentral Quality and patient safety WMC00809., 1-15.

36. Mahaveer Pr. Khinchi., (2010)., Orally disintegrating tablets: A future prospectus., Int J Pharm Sci Bio., 71-79.
37. Ganesh Kumar Gudas., Formulation and evaluation of fast dissolving tablets of Chlorpromazine HCl, J. Pharm. Sci. Tech., 2010; 1: 99-102.
38. Indian Pharmacopoeia, Controller of Publications, New Delhi, 4th edition, Volume 2, pp735-736; 1996.
39. M. Nagar, A.V. Yadav, Cinnarazine orodispersible tablets: a chitosan based fast mouth dissolving technology, Int. J. Pharm. Tech. Res. 1 (4) (2009) 1079–1091.
40. Abdul Sayeed et al., Mouth dissolving tablets: An Overview., International Journal of Research in Pharmaceutical and Biomedical Sciences, 2011; 2(3): 959-970.

