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REVIEW ON: FAST DISSOLVE TABLET

Gaurav C. Saupure[1], Niranjan B. Girase [2], Dipak H. Ishi [2], Aniket V. Borse[2]

[1]Associate Professor, [1]Dept.Of Pharmaceutics, N.T.V.S's Institute Of Pharmacy Nandurbar Tal & Dist Nandurbar-425412, Maharashtra, India

[2]Student, N.T.V.S's Institute Of Pharmacy Nandurbar Tal & Dist Nandurbar-425412,Maharashtra, India

ABSTRACT:

Fast dissolving tablets (FDTs), also known as orally disintegrating tablets (ODTs), are a pharmaceutical dosage form designed to dissolve or disintegrate rapidly in the mouth without the need for water. This unique formulation is beneficial for individuals with difficulty swallowing conventional tablets or for those with busy lifestyles. FDTs are made using superdisintegrants, which promote the rapid breakdown of the tablet in the oral cavity, allowing the active pharmaceutical ingredient (API) to be absorbed quickly into the bloodstream. The preparation of FDTs involves techniques like lyophilization, direct compression, and spray drying. The applications of FDTs include both systemic and local treatments for conditions such as nausea, pain management, and chronic diseases, offering improved patient compliance and therapeutic efficacy. FDTs or orally disintegrating tablets provide an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. FDTs formulations contain super disintegrants to enhance the disintegration rate of a tablet in the buccal cavity. FDTs have merits such as easy portability and manufacturing, accurate dosing, good chemical and physical stability and an ideal alternative for geriatric and pediatric patients. FDTs have disintegrated fastly, absorb quickly so, in vitro drug release time enhance and this property of drugs (dosage form) improved bioavailability.

KEYWORDS:

Fast dissolving tablets, orally disintegrating tablets, superdisintegrants, drug delivery, patient compliance, pharmaceutical dosage forms, lyophilization, direct compression, oral cavity, active pharmaceutical ingredient.

INTRODUCTION:

Formulation of drugs into a presentable form is the basicrequirement and need of today. The dosage form is a mean of drugdelivery system, used for the application of the drug to a living body.Various type of dosage forms are available such as tablets, syrups,suspensions, suppositories, injections, transdermal and patcheshaving a different type of drug delivery mechanisms. Theseclassical/ modern dosage forms have some advantages anddisadvantages. Therefore, the development of an ideal drug deliverysystem isa big challenge to the pharmacist in the presence scenario.In order to get thedesired effect, the drug should be delivered to itssite of action at such rate and concentration to achieve the maximumtherapeutic effect and minimumadverse effect. For the developmentof a suitable dosage form a thorough study about thephysicochemical principles that governs a specific formulation of adrug should be subjected.[1]

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular becauseof ease of
administration, accurate dosage, self-medication, painavoidance and most importantly the patient compliance. The mostpopularsolid dosage forms are being tablets and capsules; oneimportant drawback of this dosage forms for some patients is thedifficulty to swallow. Drinking water plays an important role in theswallowing of oral dosage forms. Often times people experienceinconvenience in swallowing conventional dosage forms such astablet when water is not available, in the case of the motion sickness(kinetosis) and sudden episodes of coughing during the commoncold, allergic condition andbronchitis. For these reason, tablets thatcan rapidly dissolve or disintegrate in the oral cavity have attracteda great deal of attention.[2]

The problem of swallowing is a common phenomenon in a geriatricpatient due to fear of choking, hand tremors, dysphasia and in youngindividuals due tounderdeveloped muscular and nervous systemsand in schizophrenic patients which leads to poor patientcompliance. Approximately one-third of the population (mainlypaediatric and geriatric) has swallowing difficulties, resulting inpoor compliance with oral tablet drug therapy which leads toreducedoverall therapy effectiveness. For these reason, tablets thatcan rapidly dissolve or disintegrate in the oral cavity have attracteda great deal of attention.[3]

United States Food and Drug Administration (USFDA) definedfast dissolving tablet (FDT) as “a solid dosage form containing amedicinal substance or active ingredient which disintegraterapidly usually within a matter of seconds when placed upon thetongue”.[3]

Fast dissolving drug delivery systems were first developed in thelate 1970s as an alternative to conventional dosage forms for thepediatric and geriatric patient. These tablets are designed todissolve or disintegrate rapidly in the saliva generally less than 60seconds.[4]To fulfill these medical needs, pharmaceuticaltechnologists have developed a novel oral dosage forms known asorally disintegrating (dispersible) tablets (ODTs) or Fastdisintegrating (dissolving) tablets (FDTs) or mouth melting tablets(MMTs) or mouth dissolving tablets(MDTs), immediate releasetablets which disintegrate rapidly in saliva, usually in a matter ofseconds,without the need to take water.

Recent market studies indicate that more than half of the patientpopulation prefers FDTs to other dosage forms. Mouth dissolvingtablets are formulated mainly by two techniques first use of superdisintegrants like Croscarmellose sodium, sodium starch glycolateand crospovidone.Another method is maximising pore structure ofthe tablets by freeze drying and vacuum drying.
In all methods,direct compression is preferred because of its effortlessness, quickprocedure and cost-effectiveness.[1]

The bioavailability of some drugs may be increased due toabsorption of drugs in oral cavity and also due to pregastricabsorption of saliva containingdispersed drugs that pass down intothe stomach. Moreover, the amount of drug that is subjected to firstpass metabolism is reduced as compared to standard tablets.[4]

REQUIREMENTS OF FAST DISSOLVING TABLETS:

A fast-dissolving tablet (FDT), also known as orally disintegrating tablets (ODTs), is a pharmaceutical formulation designed to disintegrate and dissolve rapidly in the mouth, typically within 30 seconds to a minute, without the need for water. These tablets are particularly beneficial for patients who have difficulty swallowing conventional tablets or for those who require quick drug onset.

1. Formulation Composition:

Active Pharmaceutical Ingredient (API): The drug must be highly soluble and stable, ensuring its quick release and absorption in the body.

Excipients: The excipients used must facilitate fast dissolution. Key excipients include:

Superdisintegrants
(e.g., sodium starch glycolate, croscarmellose sodium, crospovidone): These promote rapid breakup of the tablet.

Binders
(e.g., hydroxypropyl cellulose, polyvinylpyrrolidone): To ensure the tablet maintains integrity before dissolution.

Filler or diluents
(e.g., mannitol, sorbitol): They help achieve the required tablet size while aiding in mouthfeel.

Lubricants
(e.g., magnesium stearate) to prevent sticking during manufacturing.

Sweeteners and flavoring agents: To improve the taste, especially if the active ingredient has a bitter taste.

2. Tablet Design:

Porous Structure: Tablets should have a porous structure to enhance dissolution and mouthfeel. Techniques like freeze drying (lyophilization), molding, or spray drying are commonly used to create a porous matrix.

Rapid Disintegration: The tablet must break down quickly upon contact with saliva. The inclusion of superdisintegrants and the selection of a proper manufacturing process are essential.

Low Density: A lower tablet density can enhance the dissolution rate, making it light and easy to break apart in the mouth.

Taste Masking: For APIs that have a bitter or unpleasant taste, effective taste-masking agents (like cyclodextrins or coating) are essential.

3. Manufacturing Process:

Direct Compression: This process involves the compression of ingredients without the use of solvents or other processing steps. It is commonly used in FDTs due to its simplicity and cost-effectiveness.

Spray Drying or Freeze Drying: These methods can be used to create porous structures or to produce fine drug particles, enhancing the solubility and dissolution rate.

Molding: Tablets may be prepared by molding rather than traditional compression to ensure a fast-dissolving matrix.

4. Performance Testing:

Disintegration Test: The tablet must disintegrate rapidly in the mouth, typically within 30 seconds to a minute.

Dissolution Profile: A fast dissolution profile is crucial for the drug to be absorbed quickly. In-vitro dissolution tests, such as the USP apparatus, are used to evaluate this characteristic.

Stability: The tablet must maintain its integrity and potency over its shelf life.

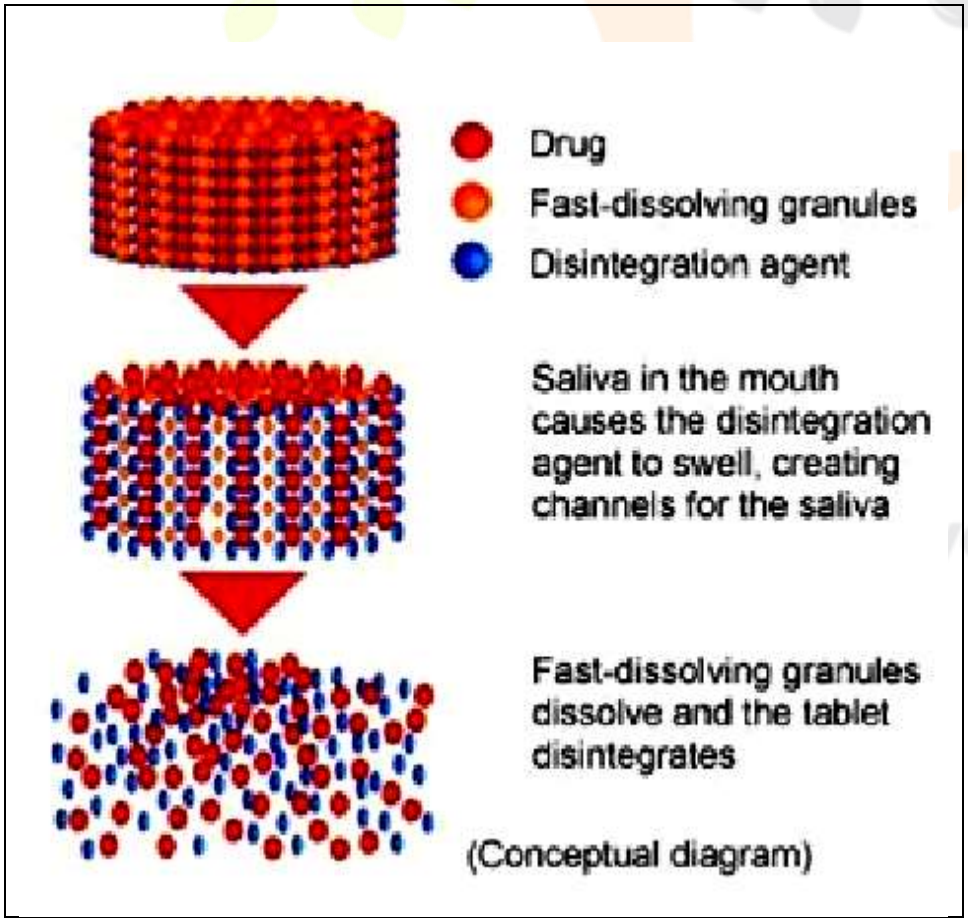
Taste Evaluation: The tablet should not only dissolve quickly but also have an acceptable taste, especially for pediatric or geriatric populations.

5. Regulatory Requirements:
The development of FDTs must comply with guidelines from regulatory agencies like the FDA or EMA. These guidelines provide standards for the formulation, manufacturing process, and testing required for approval.

Stability and bioavailability data should be provided to demonstrate the efficacy and safety of the product. [5,6,7]

MECHANISM:

Bioavailability of a drug depends inabsorption of the drug, which is affected by solubility of the drug in gastrointestinal fluid and permeability of the drug across gastrointestinal membrane. Thesolubility of a drug mainly depends on physiochemicalproperties of the drug. The rate of drug dissolution is greatly influenced by disintegration of the tablet.Disintegrants are important excipient of the tablet formulation, they are always added to tablet to induce breakup of tablet when they are comes in contact with aqueous fluid and this process of desegregation of constituent particles before the drug dissolution occurs, is known as disintegration process and excipients which induce this process are known asdisintegrants.
The objectives behind addition of disintegrants are to increase surface area of the tablet fragments and to overcome cohesive forces that keep particales together.[8]



(fig.1

ADVANTAGES:

Fast dissolving tablets (FDTs), also known as orally disintegrating tablets (ODTs), offer several advantages, particularly in the context of patient compliance, convenience, and drug delivery. Here are the key benefits:

1. Improved Patient Compliance: Fast dissolving tablets are easy to administer, especially for individuals who have difficulty swallowing conventional tablets or capsules (e.g., elderly patients, children, or those with dysphagia). FDTs dissolve quickly on the tongue without the need for water, making them convenient and accessible.

2. Rapid Onset of Action: These tablets dissolve quickly in the mouth, leading to faster absorption of the drug in the gastrointestinal tract. This can be particularly advantageous when a rapid onset of therapeutic action is required, such as in the case of acute pain, nausea, or migraine treatment.

3. Enhanced Bioavailability: FDTs often provide improved bioavailability for certain drugs. Since the drug starts to dissolve in the mouth and is partially absorbed through the mucosal membranes, it may bypass first-pass metabolism, enhancing the amount of active drug that reaches the bloodstream.

4. Convenience: As no water is required for ingestion, FDTs are particularly useful for people on the go or those who are unable to drink fluids at the time of medication administration. This is especially beneficial in emergency situations or for travelers.

5. Masking of Unpleasant Taste: Many active pharmaceutical ingredients (APIs) have a bitter taste, which can be a barrier to patient adherence. FDTs can incorporate flavoring agents or taste-masking technologies that help to improve the palatability of the tablet.

6. Versatility in Drug Formulation: FDTs can be designed to suit various types of drugs, including those that are poorly soluble, highly potent, or require a controlled-release profile. This versatility makes them a suitable option for a wide range of therapeutic applications.

7. No Need for Special Storage Conditions: Unlike some liquid formulations or injectables, FDTs are stable at room temperature, which makes them easy to store and transport.[9,10,11]

LIMITATIONS OF FDTS:

• The major disadvantages of FDTs is related to the mechanical strength of tablets.
• FDT are very porous and soft molded metrics or compressed in a tablet withlow compression, which makes tablet friable and brittle which difficult to handle.
• Bad tastes drugs are difficult to formulate as FDT; special precaution should have to be taken before formulate such kind of drug.
• Several FDT are hygroscopic cannot maintain physical integrity under normal condition from humidity which requires specialized package.
• Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.
• Rate of absorption from the saliva solution and overall bioavailability.[12,13]

CHALLENGES TO DEVELOP FDTS:

1.Palatability:

As most drugs are unpalatable, FDTs usually contain the medicament in a taste-masked form. FDTs after administration, it disintegrates or dissolves in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds. Hence, taste-masking of the drugs becomes critical to patient compliance.[14,16]

2.Mechanical strength and disintegration time:
In order to allow FDTs to disintegrate in the oral cavity, they are made of either very porous and soft-molded matrix or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may add to the cost. [14,16]Only wow tab and durasolv technologies can produce tablets that are sufficiently hard and durable to allow them to be packaged in multi-dosebottles.[14]

3.Hygroscopicity:
Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions oftemperature and humidity [14,16]
Hence, they need protection from humidity which calls for specialized product packaging.

4.Amount of drug:
The application of technologies used for FDTs is limited by the amount of drug that can be incorporated into each unit dose. For lyophilized dosage forms, the drug dose must be less than 400 mg for insoluble drugs[14,16] and 60 mg for soluble drugs this parameter is particularly challenging when formulating a fast dissolving oral films or wafers. [14]

5.Aqueous solubility:
Water-soluble drugs pose various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process[14,15,16] Such collapse sometimes can be prevented by using various matrix-forming excipients such as mannitol that can induce crystallinity and hence, impart rigidity to the amorphous composite.[14]

6.Size of tablet:
The ease of administration of a tablet depends on its size. It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.[14,15]

7.Mouth feel:
FDTs should not disintegrate into larger particles in the oral cavity.
The particles generated after disintegration of the FDTs should be as small as possible. Moreover addition of flavours and cooling agents like menthol improve the mouth feel. [15]

8.Sensitivity to environmental conditions:
FDTs should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in FDTs are meant to dissolve in minimum quantity of water.[15]

THE NEED FOR DEVELOPMENT OF FDTS:

1.Patient factors:[17,18]
Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of water.

These include the following:
1.patients who have difficulty in swallowing or chewing solid dosage forms.
2.patients incompliance due to fear of choking.
3.very elderly patients of depression who may not be able to swallow the solid dosage forms.
4.an eight-year old patient with allergies desires a more convenient dosage form than antihistamine syrup.
5. a middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2- blocker.
6.a schizophrenic patient who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic.
7. a patient with persistent nausea, who may be journey, or has little or no access to water.

2.Effectiveness factor:
Dispersion in saliva in oral cavity causes pre-gastric absorption of drug which dissolves. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass hepatic metabolism which increase the bioavailability. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolitesmediated by first-pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and pre-gastric segments of GIT.

3.Manufacturing and marketing factors:
As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drugentity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity,
unique product differentiation, value-added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form. This leads to increased revenue, while also targeting underserved and under-treated patient populations. As examples, Eisai Inc. launched Aricept FDT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and
in the U.S. in 2005 in response to a generic challenge filed in the U.S. by
Ranbaxy. Merck's Japanese subsidiary launched Lipola M (simvastatin ODT), a line extension of its block-buster, Zocor®, a cholesterol-lowering drug, in
response to seventeen generic registrations of simvastatin applied for in Japan in 2004. Marketers build a better brand and in this way company's reputation can be improved.

CONCLUSION:

Fast dissolving tablets (FDTs) represent a significant advancement in pharmaceutical dosage forms, providing a practical solution for patients who have difficulty swallowing conventional tablets or capsules. The rapid disintegration and absorption of FDTs offer improved patient compliance, especially in pediatric, geriatric, and bedridden populations. These tablets, which dissolve quickly in the mouth without the need for water, can enhance the bioavailability of certain drugs, improving therapeutic outcomes. The formulation and development of FDTs rely on various technologies, including the use of superdisintegrants, lyophilization, and direct compression techniques, among others. While FDTs offer several benefits, challenges such as taste masking, stability, and the need for specialized manufacturing processes remain. Nevertheless, with continuous research and development, fast dissolving tablets are becoming an increasingly important and popular dosage form in the pharmaceutical industry, contributing to enhanced patient care and convenience.

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