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HIGHLIGHTING CONCEPT OF FAST DISSOLVING TABLETS: A REVIEW

Surabhi Sinha[1], Vedant Kumar Prajapati[2]*, Vivek Kumar Patel[3]

[1]M. Pharma, Saraswati Higher Education and Technical College of Pharmacy Gahani Varansi – 221202.

[2]Assistant Professor, Department of Pharmaceutics, Saraswati Higher Education & Technical College of Pharmacy Gahani Varansi – 221202.

[3]Assistant Professor, Department of Pharmaceutics, Saraswati Higher Education & Technical College of Pharmacy Gahani Varansi – 221202.

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***Corresponding Author**
Vedant Kumar Prajapati
Assistant Professor, Department of Pharmaceutics, Saraswati Higher Education & Technical College of Pharmacy Gahani Varansi - 221202.

ABSTRACT

Despite its drawbacks, oral drug delivery continues to be the favoured method of drug delivery. Fast dissolving tablets have gained widespread recognition as an unique drug delivery mechanism for the treatment of a variety of ailments because they dissolve in the mouth without the need for extra water, allowing for convenient administration of active pharmaceutical ingredients. FDTs overcome the drawbacks of traditional dose forms, particularly dysphagia (swallowing difficulty) in juvenile and geriatric patients. FDT formulations offer the benefits of both traditional tablet and liquid dose forms. Spray drying, cotton candy process, sublimation, melt granulation, direct compression freezes drying/lyophilization, phase transition process, mass extrusion, and other technologies based on spray drying, cotton candy process, sublimation, melt granulation, direct compression freezes drying/lyophilization, phase transition process, mass extrusion, and other technologies have been developed for the manufacture of FDTs. This article provides a quick overview of the key benefits, desirable qualities, disintegration process, and development techniques for fast-dissolving tablets.

KEYWORDS: Oral, Drug, Delivery, Techniques, Mechanism.

INTRODUCTION

The basic demand and need of today is to formulate medications into a presentable shape. The dosage form is a type of drug delivery device that is used to administer a drug to a living person. Tablets, syrups, suspensions, suppositories, injections, transdermal patches, and injections are all examples of dosage forms with diverse drug delivery mechanisms. These traditional and current dose forms each have their own set of benefits and drawbacks. As a result, in the present situation, the pharmacist faces a significant barrier in developing an ideal drug delivery system. To achieve the desired effect, the drug should be delivered to the site of action at a rate and concentration that achieves the most therapeutic impact with the least amount of side effects. A thorough investigation of the physicochemical principles that govern a specific formulation of a drug should be subjected for the development of a suitable dosage form.[1]

Swallowing difficulties are frequent in senior patients due to fear of choking, hand tremors, dysphasia, and in young people due to underdeveloped muscular and neurological systems, as well as in schizophrenia patients, resulting in poor patient compliance. Swallowing difficulties affect about one-third of the population (mostly children and the elderly), resulting in poor adherence to oral tablet drug therapy and lower overall therapeutic effectiveness. As a result, tablets that dissolve or disintegrate quickly in the oral cavity have gotten a lot of attention. Fast dissolving tablet (FDT) is defined by the United States Food and Drug Administration (USFDA) as "a solid dosage form containing a medical drug or active component that disintegrates rapidly, usually within a matter of seconds, when put upon the tongue."[2]

These dosage forms can also be used when a local action in the mouth is desired, such as treating toothaches and oral ulcers.[3] Because the tablet disintegrates in the mouth, pregastric absorption from the mouth, pharynx, and oesophagus can improve the therapeutic efficacy of the drug. By bypassing first-pass hepatic processing, the drug's bioavailability is greatly increased compared to that of traditional tablets. Orally disintegrating tablets, orodispersible tablets, quick disintegrating tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapimelts are all terms used to describe FDTs.[4]

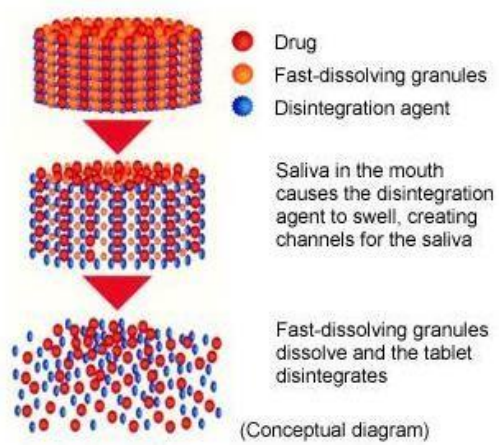

Figure 1: Conceptual Diagram of Fast dissolving Tablet.

Mouth-dissolving tablets, melt-in-mouth tablets, Orodispersible tablets, rapimelts, porous tablets, and quick dissolving tablets are examples of fast dissolving tablets. Without the need of water, fast dissolving tablets dissolve or disintegrate in the oral cavity. The bitter taste of the active ingredient must be disguised in most fast-dissolving tablets. The masked active component, combined with the soluble and insoluble excipients, is then ingested by the patient's saliva. It has been determined that quicker dissolving, absorption (just the unionised form of drug) and start of action are all beneficial. As saliva goes down into the stomach, some medications are absorbed from the mouth cavity, throat, and oesophagus. As a result, the drug's bioavailability is much higher than that of traditional tablets. The time it takes for fast dissolving tablets to dissolve is usually less than one minute.[5]

The Requirement for Development of FDTs

Patient factors[6]

Patients (especially children and the elderly) who are unable to swallow standard tablets and capsules with an 8-ounce glass of water should use fast dissolving dose forms. Among them are:

- Patients who have difficulty in swallowing or chewing solid dosage forms
- Patients incompliance due to fear of choking
- Very elderly patients of depression who may not be able to swallow solid dosage forms
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- An eight-year-old patient with allergies desires a more convenient dosage form than antihistamine syrup
- A middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2- blocker

- A schizophrenic patient who has difficulty swallowing or chewing solid dosage forms
- A patient with persistent nausea, who may be journey, or has little or no access to water.

Effectiveness factor[7]

Pre-gastric absorption of the drug is caused by its dispersion in saliva in the mouth cavity. Many medications are absorbed in the buccal, pharyngeal, and stomach regions. Any pre-gastric absorption avoids hepatic metabolism in the first pass, which increases bioavailability. Furthermore, safety profiles for medications that produce high amounts of hazardous metabolites through first-pass hepatic and gastric metabolism, as well as pharmaceuticals with a significant fraction of absorption in the oral cavity and pre-gastric regions of the GIT, may be improved.

Manufacturing and marketing factors[8]

Pharmaceutical companies frequently produce a given drug molecule in a new and improved dosage form when a medicine's patent life approaches its end. A novel dosage form enables a producer to extend market exclusivity, distinctive product differentiation, value-added product line expansion, and patent protection while providing a more convenient dosage form to its patient population. This increases revenue while simultaneously focusing on underrepresented and under-treated patient groups. In response to a generic challenge filed in the United States by Ranbaxy, Eisai Inc. developed Aricept FDT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and the United States in 2005. In response to seventeen generic registrations of simvastatin applied for in Japan in 2004, Merck's Japanese unit released Lipola M (simvastatin ODT), a line extension of their blockbuster, Zocor®, a cholesterol-lowering drug. Marketers create a stronger brand, which improves the company's reputation.

Current Technologies for Preparation of Fast Dissolving Tablets

The tablet's rapid dissolving property is due to a rapid uptake of water into the tablet matrix, resulting in rapid disintegration. As a result, maximising the porosity structure of the tablet matrix, incorporating the suitable disintegrating agent, and using highly water-soluble excipients in the formulation are the primary approaches for developing rapid dissolving tablets. The following are some of the technologies that have been employed to make rapid dissolving tablets[9]:

- **Method of Direct Compression**

This is one of the most often utilised methods for creating fast-acting dosage forms. Tablets are made directly by compressing a mixture of drug and excipients without any prior treatment in this method. The inclusion of superdisintegrants and water soluble excipients is the basic premise. This technique entails the use of superdisintegrants in the correct concentration to induce rapid disintegration while maintaining a pleasant mouth feel. The compressed mixture must have appropriate flow characteristics. Few medications can be directly compressed into high-quality tablets. The use of an effective concentration of superdisintegrant can shorten the time it takes for a tablet to disintegrate. Due to the absence of a binder and the low moisture content of the manufactured tablets, it is considered the ideal method for preparing orally disintegrating dosage forms. This method has a number of advantages, including ease of application, the use of standard equipment and readily available excipients, a minimum number of processing stages, and cost effectiveness.[10]

- **Freeze Drying**

The process of removing the solvent from a frozen drug solution or suspension including structure-forming excipients is known as freeze drying or lyophilization. The porous nature of freeze-dried or lyophilized tablets causes them to crumble and dissolve quickly when they come into contact with saliva. To bring the material below its eutectic point, it is first frozen. The moisture content of the drug product is reduced to roughly 4% w/w during primary drying. The bound moisture is then reduced to the desired volume by subsequent drying. Bulking agent and, in some cases, drug acquire a glossy amorphous form as a result of lyophilization, which improves solubility. One of the key advantages of this method is that the freeze-dried dosage form has less stability issues during its shelf life when stored in a dried state. This method is mostly used for heat-sensitive pharmaceuticals, also known as thermolabile compounds.[11]

- **Spray Drying**

This method uses a particulate support matrix, which is made by spray drying an aqueous composition containing the support matrix and other ingredients to produce highly porous and fine powders that dissolve quickly. This method was used by Allen et al to create FDTs. Bulking agents like mannitol and lactose were used, as well as a superdisintegrant such sodium starch glycolate, croscarmellose sodium, and acidic and alkaline substances. This spray dried powder demonstrated quick breakdown and increased dissolving when crushed

into tablets.[12]

➢ Sublimation

The presence of a porous structure in the tablet matrix is critical for quick disintegration for fast dissolving tablets. Because of the low porosity of the matrix, traditional compressed tablets containing highly water-soluble chemicals frequently dissolve quickly. As a result, volatile components are employed to create porous matrix, which are then subjected to a sublimation process. This method employs inert, high-volatility substances such as ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylenetetramine, naphthalene, phthalic anhydride, urea, and urethene, among others. Sublimation has been utilised to create high- porosity, fast-dissolving tablets. In this technique, a porous matrix is created by compressing volatile chemicals and other excipients into tablets, which are then exposed to a sublimation process, as shown in Figure 2. Pore forming agents can also be utilised with solvents like cyclohexane and benzene. This method was used to create fast-dissolving tablets with a porous structure and excellent mechanical strength.[13]

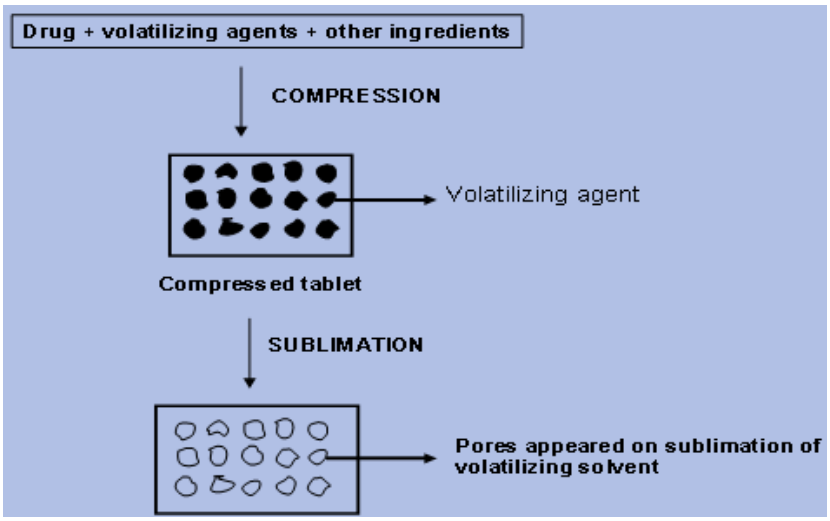

Figure 2: Diagrammatic representation of sublimation technique.

➢ Tablet Moulding

Moulded tablets are made to aid in the absorption of active substances through the mouth's mucosal linings. The components blend is moistened with a hydro alcoholic or aqueous solvent in this method. The mixture is formed into tablets using modest compression pressure. Water soluble chemicals are used in the moulding method to ensure that tablets dissolve completely and quickly. These tablets are less compact than compressed tablets and

have a porous structure that speeds up the dissolution process. There are several moulding techniques available, including compression moulding, heat moulding, and vacuum evaporation without lyophilization. The fact that the dispersion matrix is made up of water-soluble carbohydrates means that moulded tablets disintegrate more quickly and have a better taste. However, the fundamental downside of this method is that the moulded tablets have little mechanical strength, which means they may be eroded or broken during handling.[14]

- **Cotton Candy Production and Mass Extrusion**

Softening the active blend with a solvent mixture of water soluble polyethylene glycol and methanol, then extruding the softened bulk through an extruder or syringe to form a cylinder of the product into even segments using a heated blade to produce tablets. The dried cylinder can also be used to coat bitter taste drug grains and disguise their flavour. Cotton candy is made with a special spinning mechanism that creates a floss-like crystalline structure. The simultaneous action of flash melting and spinning results in the production of a matrix of polysaccharides or saccharides. To increase flow properties and compressibility, the matrix is partially recrystallized. This matrix is then processed and mixed with active components and excipients before being compressed into a fast-acting tablet. This method can handle bigger drug doses and has better mechanical strength. However, the utilisation of this technology is limited due to the high temperature of the process.[15]

Selection of FDT Drug Candidates

When choosing drug candidates for delivery as FDT dosage forms, several considerations must be taken into account.

- Drugs having markedly different pharmacokinetic characteristics as compared to the same dose given in a standard dosage form.[16] Examples include selegiline, apomorphine, and buspirone.
- Medications that produce a significant number of hazardous metabolites via first- pass hepatic and gastric metabolism, as well as drugs with a significant fraction of absorption in the oral cavity and pre-gastric GIT segments.
- Drugs that can diffuse and partition into the upper GIT epithelium (log P > 1, or preferred > 2), as well as those that can permeate oral mucosal tissue, are excellent for FDT formulations.
- Patients who are taking anticholinergic medications at the same time may not be the best candidates for these treatments.

- Patients with Sjögren's syndrome or dry mouth as a result of decreased saliva production may not be suitable for FDT formulations.
- Drugs with a short half-life and high dose frequency.
- Drugs with an extremely bitter or otherwise unpalatable taste due to a lack of taste masking.
- Fast dissolving oral dose forms are not appropriate for drugs that require controlled or sustained release.
- FDT has been developed by pharmaceutical companies for a variety of medications, including neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptics, anxiolytics, sedatives, hypnotics, diuretics, anti- parkinsonism agents, anti-bacterial agents, and erectile dysfunction treatments.[17]

Challenges To Develop FDTS

➢ **Palatability**

FDTs normally contain the medication in a taste-masked form, as most medications are unpleasant. FDTs disintegrate or dissolve in the patient's oral cavity after delivery, releasing the active components that come into contact with the taste buds. As a result, concealing the taste of the medications is crucial for patient compliance.[18]

➢ **Disintegration time and mechanical strength**

FDTs are made of either very porous and soft-molded matrix or compressed into tablets with very low compression force to allow them to disintegrate in the oral cavity. This makes the tablets friable and/or brittle, difficult to handle, and often necessitates specialised peel-off blister packing, which can add to the cost. Only the wow tab and durasolv technologies are capable of producing tablets that are hard and robust enough to be put in multi-dose bottles.

➢ **Hygroscopicity**

Several orally disintegrating dosage forms are hygroscopic, which means they can't keep their physical integrity under typical temperature and humidity settings. As a result, they require humidity protection, which necessitates the use of specialist product packaging.[19]

➢ **Amount of drug**

The amount of drug that can be included into each unit dose limits the application of FDT technologies. The drug dose must be less than 400 mg for insoluble pharmaceuticals and 60 mg for soluble drugs in lyophilized dosage forms. When creating fast-dissolving oral films or

wafers, this characteristic is particularly difficult to control.[20]

➢ **Tablet Dimensions**

The size of a tablet determines how easy it is to administer. The easiest size of pill to swallow is 7-8 mm, whereas the easiest size to handle is one larger than 8 mm, according to research. As a result, finding a tablet size that is both easy to take and easy to hold is tough.

➢ **Mouth feel**

FDTs with a mouth feel should not break down into larger particles in the oral cavity. The particles produced after the FDTs disintegrate should be as tiny as feasible. Furthermore, flavourings and cooling ingredients such as menthol increase the tongue feel.[21]

➢ **Sensitivity to environmental conditions**

Because most of the materials used in FDTs are designed to dissolve in a small amount of water, they should be somewhat insensitive to environmental variables such as humidity and temperature.

Advantages of Fast Dissolving Tablets

The advantages of these dosage forms are constantly and rapidly being recognised in both the pharmaceutical and academic industries. FDTs offer the benefits of both solid and liquid dosage forms, as well as a number of additional features[22]:

- Because they are unit solid dosage forms, they offer the convenience of precise dosing, easy portability and production, good physical and chemical stability, and are an excellent choice for paediatric and geriatric patients.
- It is simple to administer to patients who are unable to swallow, such as the elderly, bedridden patients, paediatric, geriatric, mental, and renal failure patients.
- There is no possibility of the dose form becoming obstructed, which is advantageous for patients who are travelling and do not have access to water.
- When taken, these dose forms pose no risk of asphyxia owing to physical obstruction, resulting in increased patient compliance.
- No chewing is required in the case of these dose forms, and taste masking provides a better taste.
- The drug dissolves and absorbs quickly, resulting in a faster commencement of action and better therapeutic effects.
- Because first-pass metabolism is lowered, the dose size is reduced, as are the negative

effects.

- Pleasant tongue feel, especially for paediatric kids, due to the adoption of a flavour masking approach to hide the drug's unpleasant taste.
- Drug bioavailability is increased due to absorption through the mouth, pharynx, and oesophagus.
- In terms of administration and transportation, it is preferable to liquid medication.
- Tablets can be produced at a minimal cost using standard processing and packaging equipment.

CONCLUSION

The FDT concept was developed to address some of the issues that existed in traditional solid dosage forms, such as difficulties swallowing tablets in juvenile and geriatric patients, who make up a significant section of the world's population. Due to its rapid absorption from mouth to GIT as saliva passes, FDT may improve efficacy, bioavailability, rapid beginning of action, and patient compliance. When administered, a fast-dissolving tablet operates as a solid dose form when outside the body and as a solution when inside the body. Because of its rapid action, FDT may become the most accepted and prescribed dose form in the future (within minute). In today's hurried world, its unique advantages such as administration without water, anywhere, at any time, lead to better patient compliance. Given the numerous advantages of FDTs, most pharmaceutical companies create a variety of formulations in FDT form. The popularity of these dose forms will undoubtedly grow in the future as a result of rising patient demand.

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